Asian Journal of Andrology (2020) 22, 154–157
www.asiaandro.com; www.ajandrology.com

Open Access

INVITED REVIEW

Operational Andrology

Artificial urinary sphincter: current status and future directions

Culley C Carson

Urge urinary incontinence (UUI) is one of the most troublesome complications of surgery of the prostate whether for malignancy or benign conditions. For many decades, there have been attempts to reduce the morbidity of this outcome with variable results. Since its development in the 1970s, the artificial urinary sphincter (AUS) has been the "gold standard" for treatment of the most severe cases of UUI. Other attempts including injectable bulking agents, previous sphincter designs, and slings have been developed, but largely abandoned because of poor long-term efficacy and significant complications. The AUS has had several sentinel redesigns since its first introduction to reduce erosion and infection and increase efficacy. None of these changes in the basic AUS design have occurred in the past three decades, and the AUS remains the same despite newer technology and materials that could improve its function and safety. Recently, newer compressive devices and slings to reposition the bladder neck for men with mild-to-moderate UUI have been developed with success in select patients. Similarly, the AUS has had applied antibiotic coating to all portions except the pressure-regulating balloon (PRB) to reduce infection risk. The basic AUS design, however, has not changed. With newer electronic technology, the concept of the electronic AUS or eAUS has been proposed and several possible iterations of this eAUS have been reported. While the eAUS is as yet not available, its development continues and a prototype device may be available soon. Possible design options are discussed in this review.

Asian Journal of Andrology (2020) **22**, 154–157; doi: 10.4103/aja.aja_5_20; published online: 25 February 2020

Keywords: artificial sphincter; bladder sling; prostate; sphincter; urinary incontinence

INTRODUCTION

The treatment of postprostatectomy incontinence (PPI) continues to be a challenge for urologists and their patients after prostate surgery. While PPI occurs after treatment for benign prostatic enlargement (BPE), the most troublesome and life-altering PPI is the stress urinary incontinence (SUI) sustained by men after radical prostatectomy and other treatments for prostatic malignancies.[1–3] The development of artificial urinary sphincter (AUS) in the 1970s revolutionized the treatment of these men with PPI. While the AUS remains the gold standard for the treatment of these men, little change or redesign of the basic AUS has taken place in the past three decades.[4]

Approximately 90 000 radical prostatectomies are performed annually in the US, of which more than 70 000 are performed robotically. Of those prostatectomies, more than 70% are performed by surgeons who do fewer than 100 radical prostatectomy cases annually. There is a steep learning curve for this complex procedure and outcomes are often dependent on the experience and skill of the operating surgeon. The SUI following these procedures is reported with various prevalence as a result of reports from high-volume centers that do not always represent the global prevalence. Reports in the worldwide literature include prevalence of <5% to almost 70%.[5] With these significant numbers of men suffering from SUI, treatment of many men is either not offered or is delayed unnecessarily. The consensus statement of the International Continence Society published in 2015 stated that men should be offered treatment for their SUI if the incontinence continues for >6 months and that men with adequate manual dexterity should be offered the AUS if appropriate. Further delay beyond 6 months will not salvage patients that have incontinence after radical retropuybic prostatectomy (RRP).[6]

While the AUS remains the "gold standard" for the treatment of SUI after RRP, there are other options available for these men. Indeed, a decade ago, there were few other effective options beyond the AUS. Injections of bulking agents were used as minimally invasive options for these men, but were associated with long-term failure and need for many repeat treatments. Indeed, Kim *et al*.[7] reported that >60% of men required multiple treatments and fewer than 40% had durable improvement in their SUI. More recently, urethral slings have been introduced to provide an option for men with mild-to-moderate SUI as an alternative to AUS which has more mechanical risks. These slings were initially designed to provide urethral compression and some were designed to offer the ability to increase the volume of the compressive device after implantation to improve recurrent SUI. Older attempts at this concept using the Kaufman 3 procedure usually result in long-term failures, and this compressive device was largely abandoned.[8] More recently, the adjustable transobturator male system (ATOMS®, A.M.I., Feldkirch, Austria) device has been implanted for all degrees of post-RRP SUI with reported good long-term results.[9] The ATOMS device is an adjustable male sling placed via the transobturator approach and is marketed by the Agency for Medical Innovations GmbH, Feldkirch, Austria. It is constructed with a central integrated cushion attached to a mesh tape and is placed over the bulbar urethra through

Department of Urology, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599, USA.
Correspondence: Dr. CC Carson (culley_carson@med.unc.edu)
Received: 09 January 2020; Accepted: 17 January 2020

a perineal incision. There is an access port positioned in the scrotum to allow perioperative filling and postoperative adjustment of cushion volume. Outcome data are limited to <3 years, but use in both initial implants and as revision for failed slings or AUS have been promising.[10,11] Other slings have been designed to reposition the proximal urethra and bladder neck to provide posterior urethral elongation and repositioning and increasing the mucosal seal in the sphincter area. These devices, best used in men with mild-to-moderate SUI, are primarily the AdVance and AdVance XP urethral slings (Boston Scientific, Malden, MA, USA). The sling design incorporates a tape of polypropylene mesh that is placed beneath the membranous urethra after resection of the central tendon and secured through the obturator foramen.[12] The recently approved AdVance XP is available in both the US and Europe and has been modified to include a longer tape length, anchors on the tape arms with a protection sheath over these anchors, and a redesigned placement tool. Recent publications with 3 years of follow-up have documented a 66% dry rate and a further 23.4% improvement rate.[13] Pusateri *et al.*,[14] however, have shown a decreasing use of the AdVance sling in favor of the AUS.The Virtue Sling (Coloplast, Minneapolis, MN, USA) is another sling that has a combination of repositioning and compressive arms with a larger template than the AdVance sling. The Virtue Quadratic Male Sling is a four-arm polypropylene mesh sling with two transobturator arms and two prepubic arms. This sling was designed to provide both urethral elevation and prepubic compression for enhanced continence restoration.[15,16] Ferro *et al.*[16] followed 29 men for 36 months after the Virtue sling and found significant improvement as measured by both pad weights and patient-reported outcomes.

ARTIFICIAL URINARY SPHINCTER

While there were attempts at designing artificial sphincters before the 1970s, the design and publication of the first hydraulic artificial urinary sphincter was credited to the publication in 1973 of the devices known as the AS721 by Scott *et al.*[17] This collaboration between a urologist, a neurologist, and an engineer has revolutionized the treatment of men with SUI after RRP and TURP. The original device consisted of a two-piece reservoir, inflatable cuff, two pumps, and resistors for inflation and deflation. The material for construction of the device was a silicone elastomer developed for the space program in the 1960s.[18] The original concept was for the device to be inflated by the patient to their needs for retarding leakage. Originally, the implantation procedure was to place the inflatable cuff around the bladder neck as most men needing these devices had SUI from TURP and the bladder neck was intact and accessible. The AS721 was implanted for approximately 3 years and redesigned as a result of mechanical problems and erosions. The redesigns continued into the 1980s when Furlow *et al.*[19] reported the concept of primary deactivation to reduce erosions. Deactivation was leaving the cuff empty with no compression of the urethra for 6 weeks to permit the surgical area and urethra to heal and revascularize before applying pressure through the AUS cuff. The success of deactivation led to redesign and introduction of the AMS 800, which changed the concept of inflation and allowed postoperative activation without further surgery. This new concept combined the previously available sized inflatable cuffs with a pressure-regulating balloon that used a defined pressure to occlude the urethra, a pump with a deactivation mechanism functioned through the scrotal skin. As a result, the mechanical malfunction and erosion rates declined to <5%.[20] Subsequent major design changes were few after the AMS 800 was introduced in 1982. Infection in these devices continued to be a concern although the AUS reported fewer infection-related complications than the inflatable penile prosthesis (IPP). Using the concept from the IPP to reduce infection, the AUS was treated with inhibizone, a combination of rifampin and minocycline.[21] While there are robust data confirming the reduction of infection with the IPP, the few studies that have reviewed the efficacy of inhibizone in AUS have failed to show a significant effect.[22,23] One issue is the inability to treat the pressure-regulating balloon with inhibizone (**Figure 1**).[22] The outcomes of the AMS 800, however, are excellent and have been reported as producing >80% dry significant patient satisfaction and good long-term survivals. In a recent single-center study, Viers *et al.*[24] reviewed the outcomes of 278 patients after both primary and secondary AMS 800 implantation with a median follow-up of 8.3 years. Continence rates were reported as 56% and 55%, respectively, but reported a decrease in continence rates and satisfaction as measured by the quality of life (QOL) in patients followed for >10 years.[24] Because most single-center series are small, a meta-analysis of published studies was published by Chen *et al.*[25] Their analysis showed cure rates of 56% with a statistically significant reduction in pad usage of 4.56–2.93 pads per day ($P < 0.001$). While the studies examined had significant variability in reporting, the conclusions of the meta-analysis were that the AUS was effective in the long-term treatment of PPI.

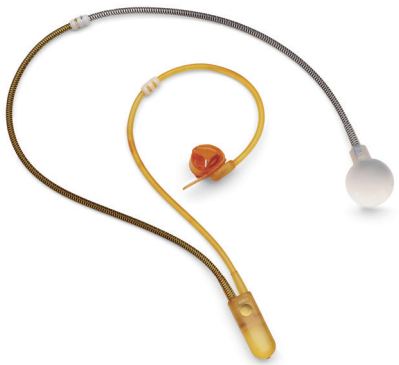

Figure 1: Boston Scientific AMS 800 Artificial Urinary Sphincter with inhibizone coating of all parts except the pressure-regulating balloon.

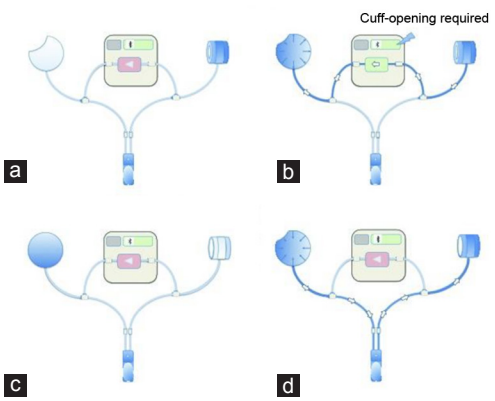

Figure 2: Current possible designs for remote-controlled electronic artificial urinary sphincters.[35] (**a**) "Closed" state: the cuff is inflated and the pump is unpowered; the pressure is equilibrated between the pressure-regulating balloon and the cuff, allowing to maintain a constant predetermined OCP as long as necessary. (**b**) Cuff deflation: as soon as a Bluetooth connection is established, the microcontroller activates the pump; the fluid is then transferred from the cuff to the balloon; the AUS#2 returns to an "open" status. (**c**) "Open state": the cuff is deflated and the pump is unpowered. (**d**) Cuff inflation: as soon as decided via the control interface, the fluid progressively flows back to the cuff in 2–3 min thanks to the hydraulic resistor, returning to a "closed" status. Images are reproduced with pemission from *Canadian Urological Association Journal*.

Because the AUS has not been modified or updated significantly for more than two decades, Boston Scientific and other manufacturers are introducing newer concepts for the artificial urinary sphincter. Many of these modifications remain in development and are proprietary; data reported in the published literature will be discussed for a peek at the future of the treatment of PPI.

Over the past several years, the Zephyr artificial sphincter device (Zephyr ZSI 375; Zephyr Surgical Implants, Geneva, Switzerland) has been investigated and results have been recently reported. This preconnected device needs no remote reservoir balloon and consists of an adjustable inflatable cuff. The cuff is one size and can be adjusted for continence after a healing period postoperatively.[26,27] Llorens and Pottek[28] reported medium-term results and reported on 106 patients with a mean age of 72 years and followed up for 24 months. They found a 91.8% success rate with 83.6% of patients dry. There were 4 infections, 19 erosions, and a total of 24 patients required explantation. There were three mechanical malfunctions caused by intraoperative sphincter cuff damage. Ostrowski *et al*.[27] reported on fifty patients followed for a median of 21.04 months. There were 12 explantations (9 erosions, 3 mechanical malfunctions, and 0 infections). Outcomes were 0–1 pads per day 29/50 (58%), and there was improvement to 50% of preoperative pads per day 15/50 (30%) and failure in 6/50 (12%). Ripert and Pierrevelcin[29] reviewed the urodynamics of the Zephyr and compared with the AMS 800. The urodynamics were similar in both groups, with both voiding flow rates and cuff pressures similar although the cuff pressure in the AMS 800 was somewhat higher. This device is not currently approved for use in the US, and long-term data on the effectiveness and reliability are lacking, but the data available show some promise for the Zephyr ZSI 375.

Another new artificial urinary sphincter undergoing development with recently reported clinical results is the VICTO, and VICTO+ from Promodon (Cordoba, Argentina) is a modification of the former sphincter called the FlowSecure. The VICTO adjustable, prefilled AUS that has an inflatable urethral cuff, a pressure-regulating balloon, and a scrotal pump has an injection port for percutaneous adjustment after implantation. The VICTO+ has an additional "stress" balloon in the preperitoneal area designed to permit pressure changes in the cuff with abdominal pressure peeks. Few long-term clinical data are available. Weibl *et al*.[30] recently reported short-term follow-up of 25 patients (15 VICTO and 10 VICTO+) followed up for a year. The reported data had no patients with erosions, infections, or explantations, and all were reported as dry or improved. Specific data for these patients including number of volume adjustments are not as yet reported.

A new concept of AUS is the ARTUS (Affluent Medical, Paris, France) artificial urinary sphincter. This electromechanical device consists of an adjustable urethral cuff adjusted by incontinence severity. Voiding is by pressing the main button on an actuator remote control handled externally. At patient follow-ups, cuff closure can be adjusted to achieve continence. Adjustments are through the remote device and are performed by the physician. The first clinical trial was approved in the Czech Republic in February 2018. A cadaver study was reported by Ludwig *et al*.[31] in 2015.

Another new design of the classic hydraulic AUS model BR-SL-AS-904 was recently reported from Brazil.[32] This modified AUS has a pressure transmission system with a reservoir placed in the abdominal cavity with connection with the inflatable urethral cuff. Any increase in pressure on this reservoir is transmitted through the hydraulic system to the urethral cuff, allowing increased pressure and preserved continence during stress-related increases in abdominal pressure. The authors have reported on 15 patients followed up for >1 year. Continence rates and patient satisfaction were excellent. There were no infections, and 27.2% of the devices were removed for mechanical complications with a 4% urethral erosion rate.

Several other devices have been described in early clinical or engineering trials without subsequent large trials or regulatory approval.[4,33] Chung,[34] in an engineering review stated, "Emerging novel therapies such as a nanotechnology driven device and stem cell therapy are attractive, but are not commercially available or have no proven long-term outcome. Until the emergence of a better engineered urinary device and/or further achievement in stem cell therapy or tissue engineering, significant challenges remain in the quest for an ideal urinary continence therapy."

Much of the current research and development is focused on changes in the activation and regulation mechanism. The occlusive cuffs while varying in their design are quite similar. The original hydraulic mechanism for activation and opening has changed little since the 1980s. With newer engineering developments for electronics and remote control, activation mechanisms can be designed to meet the needs of individual patients. If a patient needs more pressure for a specific activity as in heavy lifting or straining, the electronic actuator could be programmed to meet that need. Recent developments in lithium battery technology with batteries rated to last up to 16 years, *i.e*., battery-operated actuators, can be expected to function long term with scheduled battery exchange once per decade. Using these concepts, Biardeau *et al*.[35-37] proposed three options for an electronic control system for the AMS 800 AUS. The three designs preserve the cuff design and the pressure-regulating balloon (PRB), but instead of providing the pressure for cuff function, the PRB acts only as a fluid reservoir (**Figure 2**). The electronic actuators are controlled remotely. In their first concept, the electronic actuator is in parallel with the manual pump and the manual pump can be used to deactivate the device postoperatively or be present for emergency cuff inflation when the external activator is unavailable. The control device contains a piezoelectric micropump with a hydraulic resistor mounted in parallel. The sphincter is operated by placing a neodymium magnet close to the implanted control unit. AUS#2 is similar in design to AUS#1, but in place of the magnet to open the cuff, Bluetooth technology is used to control the cuff. This permits external programming of the cuff pressure and timing during the day of pressure differences and allowance for increased pressure during physical stress. The manual hydraulic pump is maintained as in AUS#1. AUS#3 removes the manual pump and replaces it with a remotely controlled pumping system. This allows for real-time occlusion closure pressure (OCP) adjustment with wireless remote communication for continuous pressure regulation. The pumps and activating mechanisms are currently available as reported by the authors. The *in vitro* and *in vivo* testing of these devices is promising, and clinical trials remain to demonstrate their safety and comparative efficacy. While there is more foreign body implanted and the implanting procedures may be more time consuming, the promise of a more easily controlled cuff and the ability to program pressure changes for patient needs and urethral safety are promising.

CONCLUSION

The treatment of PPI continues to be a challenge, but control of SUI in these men leads to enhanced QOL and patient satisfaction. Currently, implantable urethral slings are available and effective for men with mild-to-moderate SUI. More difficult situations with postradiation SUI, severe SUI, and failure of less invasive options continue to require treatment with the gold standard AUS. As the AMS 800 AUS continues to be the industry standard but has not been significantly redesigned

for more than two decades, the addition of newer technologies from the 21st century will enhance the outcomes of these devices. The addition of newer concept surface treatment to further reduce infection risk is also a promise on the development horizon. As stated by Chung[34] in his summary of the state-of-the-art, progress in stem cell research and nanotechnology is likely to supplement or eventually replace these devices.

REFERENCES

1 Bessede T, Sooriakumaran P, Takenaka A, Tewari A. Neural supply of the male urethral sphincter: comprehensive anatomical review and implications for continence recovery after radical prostatectomy. *World J Urol* 2017; 35: 549–65.
2 Trofimenko V, Myers JB, Brant WO. Post-prostatectomy incontinence: how common and bothersome is it really? *Sex Med Rev* 2017; 5: 536–43.
3 Moon D, Murphy DG, Nguyen PL, Resnick MJ, Nam RK. Survival and complications following surgery and radiation for localized prostate cancer: an international collaborative review. *Eur Urol* 2018; 73: 11–20.
4 Yafi FA, Powers MK, Zurawin J, Hellstrom WJ. Contemporary review of artificial urinary sphincters for male stress urinary incontinence. *Sex Med Rev* 2016; 4: 157–66.
5 Kretschmer A, Nitti V. Surgical treatment of male postprostatectomy incontinence: current concepts. *Eur Urol Focus* 2017; 3: 364–76.
6 Biardeau X, Aharony S; AUS Consensus Group, Campeau L, Corcos J. Overview of the 2015 ICS Consensus Conference. *Neurourol Urodyn* 2016; 35: 437–43.
7 Kim PH, Pinheiro LC, Atoria CL, Eastham JA, Sandhu JS, *et al*. Trends in the use of incontinence procedures after radical prostatectomy: a population based analysis. *J Urol* 2013; 189: 602–8.
8 Graham SD Jr, Carson CC 3rd, Anderson EE. Long-term results with the Kaufman prosthesis. *J Urol* 1982; 128: 328–30.
9 Angulo JC, Esquinas C, Arance I, Rodríguez A, Pereira J, *et al*. Adjustable transobturator male system after failed surgical devices for male stress urinary incontinence: a feasibility study. *Urol Int* 2018; 101: 106–13.
10 Angulo JC, Cruz F, Esquinas C, Arance I, Manso M, *et al*. Treatment of male stress urinary incontinence with the adjustable transobturator male system: outcomes of a multi-center Iberian study. *Neurourol Urodyn* 2018; 37: 1458–66.
11 Rubin RS, Xavier KR, Rhee E. Virtue Quadratic Male Sling for stress incontinence-surgical guide for placement and delayed revision. *Transl Androl Urol* 2017; 4: 666–73.
12 Bauer RM, Grabbert MT, Klehr B, Gebhartl P, Gozzi C, *et al*. 36-month data for the AdVance XP® male sling: results of a prospective multicentre study. *BJU Int* 2017; 119: 626–30.
13 Collado A, Domínguez-Escrig J, Ortiz Rodríguez IM, Ramirez-Backhaus M, Rodríguez Torreblanca C, *et al*. Functional follow-up after Advance® and Advance XP® male sling surgery: assessment of predictive factors. *World J Urol* 2019; 37: 195–200.
14 Pusateri CR, Zuckerman JM. AdVance sling use decreasing relative to artificial urinary sphincters. *Can J Urol* 2017; 24: 9121–5.
15 Rubin RS, Xavier KR, Rhee E. Virtue Quadratic Male Sling for stress incontinence-surgical guide for placement and delayed revision. *Transl Androl Urol* 2017; 6: 666–73.
16 Ferro M, Bottero D, D'Elia C, Matei DV, Cioffi A, *et al*. Virtue male sling for post-prostatectomy stress incontinence: a prospective evaluation and mid-term outcomes. *BJU Int* 2017; 119: 482–8.
17 Scott FB, Bradley WE, Timm GW. Treatment of urinary incontinence by implantable prosthetic sphincter. *Urology* 1973; 1: 252–9.
18 Rouse DJ, Brown JN Jr, Whitten RP. Methodology for NASA technology transfer in medicine. *Med Instrum* 1981; 15: 234–6.
19 Furlow WL. Implantation of a new semiautomatic artificial genitourinary sphincter: experience with primary activation and deactivation in 47 patients. *J Urol* 1981; 126: 741–4.
20 Elliott DS, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. *J Urol* 1998; 159: 1206–8.
21 Carson CC 3rd. Efficacy of antibiotic impregnation of inflatable penile prostheses in decreasing infection in original implants. *J Urol* 2004; 171: 1611–4.
22 Hüsch T, Kretschmer A, Thomsen F, Kronlachner D, Kurosch M; Debates on Male Incontinence (DOMINO)-Project. Antibiotic coating of the artificial urinary sphincter (AMS 800): is it worthwhile? *Urology* 2017; 103: 179–84.
23 de Cógáin MR, Elliott DS. The impact of an antibiotic coating on the artificial urinary sphincter infection rate. *J Urol* 2013; 190: 113–7.
24 Viers BR, Linder BJ, Rivera ME, Rangel LJ, Ziegelmann MJ, *et al*. Long-term quality of life and functional outcomes among primary and secondary artificial urinary sphincter implantations in men with stress urinary incontinence. *J Urol* 2016; 196: 838–43.
25 Chen YC, Lin PH, Jou YY, Lin VC. Surgical treatment for urinary incontinence after prostatectomy: a meta-analysis and systematic review. *PLoS One* 2017; 12: e0130867.
26 Ostrowski I, Ciechan J, Sledz E, Dys W, Golabek T, *et al*. Four-year follow-up on a Zephyr Surgical Implants 375 artificial urinary sphincter for male urinary incontinence from one urological centre in Poland. *Cent European J Urol* 2018; 71: 320–5.
27 Ostrowski I, Blewniewski M, Neugart F, von Heyden B, Selvaggio O, *et al*. Multicentre experience with ZSI 375 artificial urinary sphincter for the treatment of stress urinary incontinence in men. *Urologia* 2017; 84: 148–52.
28 Llorens C, Pottek T. Urinary artificial sphincter ZSI 375 for treatment of stress urinary incontinence in men: 5 and 7 years follow-up report. *Urologia* 2017; 84: 263–6.
29 Ripert T, Pierrevelcin J. Comparative study of urodynamic tests after AMS 800 and ZSI 375 insertion. *Urologia* 2018; 85: 15–8.
30 Weibl P, Hoelzel R, Rutkowski M, Huebner W. VICTO and VICTO-plus – novel alternative for the management of postprostatectomy incontinence. Early perioperative and postoperative experience. *Cent EurJ Urol* 2018; 71: 248–9.
31 Ludwig TA, Reiss P, Wieland M, Becker A, Fisch M, *et al*. The ARTUS device: the first feasibility study in human cadavers. *Can J Urol* 2015; 22: 8100–4.
32 Lima SV, de Barros EG, Vilar FO, Pinto FC, Barros TD, *et al*. Artificial sphincter "BR – SL – AS 904" in the treatment of urinary incontinence after radical prostatectomy: efficacy, practicality and safety in a prospective and multicenter study. *Int Braz J Urol* 2018; 44: 1215–23.
33 Vakalopoulos I, Kampantais S, Laskaridis L, Chachopoulos V, Koptsis M, *et al*. New artificial urinary sphincter devices in the treatment of male iatrogenic incontinence. *Adv Urol* 2012; 2012: 439372.
34 Chung E. A state-of-the-art review on the evolution of urinary sphincter devices for the treatment of post-prostatectomy urinary incontinence: past, present and future innovations. *J Med Eng Technol* 2014; 38: 328–32.
35 Biardeau X, Hached S, Loutochin O, Campeau L, Sawan M, *et al*. Montreal electronic artificial urinary sphincters: our futuristic alternatives to the AMS800™. *Can Urol Assoc J* 2017; 11: E396–404.
36 Biardeau X, Aharony S; AUS Consensus Group, Campeau L, Corcos J. Artificial urinary sphincter: report of the 2015 Consensus Conference. *Neurourol Urodyn* 2016; 35 Suppl 2: S8–24.
37 Biardeau X, Aharony S; AUS Consensus Group, Campeau L, Corcos J. Artificial urinary sphincter: executive summary of the 2015 Consensus Conference. *Neurourol Urodyn* 2016; 35 Suppl 2: S5–7.