Current Use of the Artificial Urinary Sphincter in Adult Females

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Abstract

Purpose of Review The aim of the present report was to review the recent evidences regarding the use of artificial urinary sphincter (AUS) in adult females.

Recent Findings While the excellent functional outcomes of AUS in female patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) have been reported for decades, its use has remained confidential in most countries likely due to its challenging implantation and inherent morbidity. Over the past few years, laparoscopic and, more recently, robotic techniques of AUS implantation in female patients have been described with promising perioperative outcomes. As a result, the use of AUS has increased in several countries. The indications are mostly recurrent or persistent SUI after previous anti-incontinence procedures and neurogenic SUI. Owing to its unique potential to restore continence while maintaining low outlet resistance during the voiding phase, AUS may be of special interest in female patients with detrusor underactivity. High level of evidence data from trials which are underway, along with developments in robotic surgery and technological refinements of the device, may well, almost 50 years after its introduction, give to the AUS its momentum as a major contributor in the female SUI armamentarium.

Summary While the use of AUS in female patients has been restricted to some countries and a few high-volume centers, it has started spreading again over the past few years, thanks to the rise of minimally invasive approaches which facilitate its implantation, and this is yielding promising outcomes.

Keywords (MeSH) Urinary sphincter, artificial · Female · Urinary incontinence, stress · Robotics

Introduction

Stress urinary incontinence (SUI) is a highly prevalent symptom in women which occurrence increases with age [1]. The

negative impact of SUI on the quality of life (qol) is the main reason for patients to seek surgical treatment [2] and is largely influenced by incontinence severity and prior anti-incontinence procedures [3]. While the impact of the current

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mesh controversy on future SUI surgical treatment algorithms remains uncertain, synthetic midurethral sling (MUS) are still widely regarded as the gold standard treatment for most women with SUI [4••] especially those with urethral hypermobility [4••, 5]. The surgical management is less consensual in female patients with a SUI related to intrinsic sphincter deficiency (ISD), i.e., patients who have failed previous anti-incontinence surgical procedures or patients with neurogenic SUI [6]. Although fascial pubovaginal slings (FPVS), bulking agents, and repeat MUS are the favored options in most countries [7, 8], some use the artificial urinary sphincter (AUS) AMS 800 (Boston Scientific™; Inc. USA) in these scenarios [9]. The aim of the present manuscript was to provide an overview on the current use of AUS in adult females.

Methods

A literature search was conducted in January 2020 using the MedLine and Embase databases, screening for randomized controlled trials (RCTs), prospective and retrospective series, and reviews on female AUS. The search strategy involved a free text protocol with the following keywords (“artificial urinary sphincter” or “artificial sphincter”) AND (“female” or “women”) that were used alone or in combination. Only articles published in English and deemed relevant were included in this review.

The Origins

Nowadays, the AUS is predominantly used in male patients with post-prostatectomy incontinence [10]. Yet, most people ignore this, but the American Medical System AUS was initially designed mostly for women [11]. Indeed, the first clinical experiences with AUS date back from the early 1970s [11, 12], before the spread of radical prostatectomy and therefore in an era with a very low prevalence of male SUI, mainly restricted to neurogenic patients. In the first reports published, the AUS cuff was implanted at the bladder neck level using an abdominal approach [11]. Several small sample size series were then reported in the 1980s and 1990s, mostly from North American institutions without real take off in the use of AUS in female patients. Some of these series reported the use of a vaginal approach which was promptly abandoned by a vast majority of surgeons, likely due to poor outcomes although it could not be asserted because very scarce series were published [13••]. In the mid-1990s, female AUS was not approved by the US Food and Drug Administration (FDA) and from then was almost abandoned by US urologists [10]. Over the past two decades, female AUS was used mostly in Europe, especially in France and in some tertiary referral centers in the UK, Belgium, the Netherlands, and Germany [14] using an

open approach with a recent rise of minimally invasive approaches which helped to overcome the technical complexity of AUS implantation and to lower its morbidity [13••, 15••].

Consideration on Indications

Stress urinary incontinence (SUI) is common in women and increases with age with a reported prevalence of up to 30–60% in elderly women [16]. Over the past two decades, the use of synthetic midurethral slings (MUS) has become the gold standard surgical treatment of SUI in female patients [4••, 16]. Beyond the current mesh controversy that is challenging this paradigm in numerous parts of the world [17], one should note that MUS fail in about 15% of women with SUI [18] and long-term recurrence of SUI as high as 68.3% have been reported [19]. Female patients with a lack of urethral mobility [9, 20] and, to a lesser extent, those with low urethral closure pressure have an increased risk of persistent SUI after MUS, as high as 75% [9, 21].

The mechanism causing SUI in these patients is often termed intrinsic sphincter deficiency (ISD) and refers to the incomplete coaptation of the urethral lumen due to decreased outlet resistance as opposed to SUI related to urethral hypermobility referring to lack of urethral support [1, 9]. There is no universally accepted definition of SUI due to ISD [1, 9]. The ISD definition used in France is a combination of clinical and urodynamic criteria, the former being the key determinant: demonstrable SUI on cough stress test with lack of urethral mobility, negative Marshall/Bonney test (i.e., still leaking on cough stress test despite urethral support), and a low maximum urethral closure pressure [9]. Fixed urethra is the core feature of this definition which makes the indication of female AUS highly dependent on clinical judgment and expertise as standardized measurements of urethral mobility such as the Q-tip test or urethral ultrasound have not been widely adopted for various reasons [22, 23]. However, visual urethral mobility evaluation, when performed by experienced clinicians, has been reported to strongly correlate with the Q-tip test [24]. Other clinical criteria such as failure of a first anti-incontinence procedure, high SUI scores, constant leakage for any daily activity, and leakage with abdominal straining may reinforce the clinical suspicion of ISD [9]. In female patients with SUI due to ISD, as defined above, AUS is recommended as the gold standard treatment in the French guidelines [9]. In daily practice, SUI due to ISD most commonly occurs in two different populations: female patients with neurogenic stress urinary incontinence (usually due to spinal cord injury (SCI), spina bifida, cauda equina syndrome or pelvic trauma), or patients who failed previous anti-incontinence surgical procedures [15••]. However, there are considerable discrepancies in the role and use of AUS in female patients from one country to another and the situation in France has for long

been pretty unique with a much wider use than in any other country in the world [25, 26••].

Beyond the excellent functional outcomes reported in the literature (see below), the main theoretical advantage of AUS over other surgical options for female SUI due to ISD is that it would be the only anti-incontinence procedure with the ability to restore both normal storage and voiding function by increasing the outlet resistance at rest when the cuff is closed but maintaining low outlet resistance during the voiding phase with the cuff being opened [13••]. Despite the fact that urodynamic data are lacking to demonstrate this hypothesis, the mechanisms of action of all the other anti-incontinence procedures traditionally used in female patients with SUI due to ISD (i.e., bulking agents, fascial slings, adjustable MUS) have been shown to rely on bladder outlet obstruction [27]. AUS could then be of particular interest in the subgroup of female patients with SUI and coexistent detrusor underactivity.

With regard to the neurogenic SUI population, a few long-term series have suggested satisfactory functional outcomes with relatively limited rates of erosion and infection [28••, 29]. However, AUS in neurologic patients may have two significant drawbacks. Firstly, myelomeningocele and SCI are younger patient populations and AUS implantation would expose these patients to multiple reoperations for surgical revision over their lifetime. Secondly, the AUS asset of being hypothetically non-obstructive is of no interest in this self-catheterizing population, with, conversely, a possibly increased risk of urinary tract erosion due to clean-intermittent catheterization and an increased risk of exposition due to the neurological perineal impairment and wheelchair use [30].

The total absence of comparative data in the literature between AUS and fascial sling or any other anti-incontinence procedures makes it impossible to draw robust conclusions as to where AUS might be placed in the surgical armamentarium for recurrent/persistent SUI and neurogenic SUI in female patients and more globally to build an evidenced-based therapeutic algorithm in these patients' population [31, 32].

Current Role of Female AUS According to National and International Guidelines

According to the European Association of Urology guidelines, AUS should be implanted only as a last resort procedure and only in expert centers, the panel recommending consideration of synthetic sling, colposuspension, and autologous sling as first options in these patients and to inform them of the high risk of complications; mechanical failure, or need for explantation (level of evidence 3, grade of recommendations: weak) [33]. The International Consultation on Incontinence (ICI) of the International Continence Society (ICS) recommends use of AUS only in highly selected individuals, usually

those with recurrent SUI and only with appropriate counseling regarding the likely need for revision over time and the lack of long-term RCT data (grade C recommendation) [34]. The NICE guidelines recommend against AUS as an option to manage female SUI unless previous surgery have failed [35]. A counterargument to placing female AUS very late in the armamentarium would be that the risk of surgical complications may increase proportionally to the number of previous anti-incontinence procedures [36••]. Because AUS in female patients is not approved by the Food and Drugs Administration (FDA), it is not mentioned as an option in the American Urological Association (AUA) guidelines on SUI [37] and its use has been very limited in the United States of America (USA) over the past years [10]. In contrast with all these international guidelines, the French national guidelines recommend AUS as the gold standard treatment of female patients with ISD-related SUI [9]. The indications of AUS in female patients in various national and international guidelines and in high-volume implanting centers are summarized in Table 1.

Preoperative Work-Up

The preoperative work-up usually performed before female robotic AUS implantation is summarized in Table 2. It includes a thorough medical history, paying special attention to history of previous anti-incontinence surgery, and more globally of previous pelvic surgery. Many of the female AUS patients have undergone previous midurethral slings and the question of excision of the tape before scheduling the AUS implantation should always be raised, especially in those with voiding dysfunction or other mesh-related complications. History of pelvic radiation therapy should also be sought because it has been proven to increase the risk of AUS erosion in female patients in open series [36] and is traditionally regarded as a contraindication to AUS implantation in female patients. During the clinical interview, subclinical cognitive dysfunction should be sought, especially in elderly women as it may hinder device handling [13••]. Physical examination should investigate whether the patient will be able to easily manipulate the device, especially in women, making sure they can grab their labia majora which can be challenging in obese patients. A pencil test may be useful to assess patients' cognitive function and manual dexterity. The principle of the pencil test is to ask the patient to plug in and remove a pen cap. Physical examination will also strive to demonstrate SUI using a cough stress test in the lithotomy position. In female patients, the urethral mobility should be assessed and an Ulmsten test may be performed, evaluating whether SUI is corrected when supporting the mid urethra. When urine leakage is not demonstrated with the patient lying, having the patient cough while standing may help unmask

Table 1 Indications of female artificial urinary sphincter in current guidelines

	Indications of female artificial urinary sphincter	Grade of recommendations/level of evidence
European Association of Urology (EAU) [32]	Complicated stress urinary incontinence, as a last resort option, only in expert centers	Level of evidence: 3/grade of recommendations: weak
International Consultation on Incontinence (ICI/ICS) [33]	In highly selected individuals, usually those with recurrent SUI	Grade of recommendations: C
American Urological Association (AUA) [36]	Not mentioned	NA
National Institute for Health and Care Excellence (NICE) [34]	Only in case of failed previous surgeries	NR
French Association of Urology (AFU) [9]	Gold standard treatment for SUI due to ISD, especially if lack of urethral mobility	NR
Canadian guidelines of Urology [37]	One of the options if ISD is the primary cause of SUI	Grade of recommendations: B
High-volume implanting centers in Europe	Recurrent or persistent SUI after one or multiple previous anti-incontinence procedures Neurogenic SUI	NR

ISD intrinsic sphincter deficiency

SUI stress urinary incontinence

NR not reported

NA not applicable

SUI. Pelvic organ prolapse is also sought and, when present, can lead to offer concomitant sacrocolpopexy [15•]. In case vulvovaginal atrophy is noted, topical estrogen therapy preoperatively can be prescribed aiming to minimize the risk of intraoperative vaginal injury although there is currently no

Table 2 Usual preoperative work-up prior to AUS implantation

Female AUS preoperative work-up
Thorough medical history
Physical examination
Pencil test
Questionnaires (e.g., ICIQ-SF, UDI)
Uroflowmetry and post-void residual (except in self-catheterizing neurogenic patients)
Urethrocystoscopy
Urodynamics

data to support this idea. Validated self-administered questionnaires are done to further explore and gauge lower urinary tract symptoms (LUTS) as well as their impact on patients' quality of life. A free uroflowmetry and post-void residual (PVR) can be useful to rule out voiding dysfunction which could prompt to perform midurethral slings excision/urethrolisis before scheduling the AUS implantation. A urethrocystoscopy is also part of the systematic preoperative work-up to rule out midurethral sling perforation and bladder stone. Finally, urodynamics is routinely done preoperatively and of particular importance in neurological patients to detect detrusor overactivity (DO) or poor compliance bladder that could worsen and result in upper urinary tract deterioration post-operatively. In non-neurogenic patients with constant leakage, defunctionalized bladder can mimic DO and poor compliance and is, therefore, rarely changing the indication [38]. Urodynamics could also be useful to measure maximum urethral closure pressure and/or Valsalva leak point pressure which reductions reinforce the suspicion of ISD [1, 9]. Videourodynamics might have the added value over standard urodynamic to assess the bladder neck and urethra mobility thanks to the fluoroscopic images [1, 9].

Traditional Open Surgical Technique

The principle of female AUS implantation is to insert the exact same three components AMS-800 device that is used in male patients placing the cuff around the bladder neck, the pressure-regulating balloon (PRB) in the subperitoneal space, and the pump in the labia majora. Although the vaginal approach has been used initially in the 1980s, it has been largely abandoned in favor of an abdominal approach. Antibiotic prophylaxis is given and a 14 Fr indwelling catheter is inserted. In the traditional open approach technique, the bladder is dropped down from the abdominal wall and the Retzius space is dissected downwards until the endopelvic fascia is identified on both sides of the bladder neck [36•]. The surgeon then places one finger in one of the vaginal fornices pushing upward and laterally to put the vaginal wall on tension and facilitate the identification of the vesicovaginal plane, historically called the bald plane (because white, shiny and smooth looking like a bald head), by dissecting on the tip of the finger with cold scissor [36•]. Once the vesicovaginal plane has been found, the surgeon dissects the posterior part of the bladder neck with the scissor along his finger. The same maneuver is done on the other side of the bladder neck, and the two dissected spaces are joined together to place the measuring tape all around the bladder neck. The cuff is then inserted as well as the balloon (a 61–70 cmH₂O PRB is favored by most teams) [13•], and the pump is placed in the labia majora creating a subcutaneous space from the abdominal incision.

The Rise of Minimally Invasive Surgical Approaches

The challenge of AUS implantation in females lies in the dissection of the bladder neck. As stated by Scott, one of the fathers of AUS, this surgery is difficult because there is no natural plane between the urethra and vagina [39] and the bladder neck is located deep in the pelvis. The open approach has been predominant for AUS implantation in female patients for decades, yielding deceiving perioperative outcomes in most series with up to 43.8% of intraoperative bladder neck injury, up to 25% of intraoperative vaginal injury, and up to 45.3% rate of explantation [13•]. This relatively high morbidity has led surgeons to explore other approaches aiming to minimize the technical difficulty of AUS implantation. In the late 2000s, laparoscopic AUS implantation in female patients was described with encouraging outcomes in experienced hands [40, 41]. More recently, several series have reported the use of a robotic approach for female AUS implantation, which may combine minimally invasiveness and lower technical complexity compared to the laparoscopic route, thanks to the enhanced dexterity with the endowrist technology allowing multiple dimensions mobility of the instruments, the magnified 3D image, the physiologic tremor filtering, and motion scaling of the surgical robot [15•, 42•, 43•, 44–47, 48•]. In addition to technically facilitating the implantation per se, laparoscopic and even more robotic approaches offer significant educational advantages, thanks to the perfect vision trainees can get and tools such as dual console and simulators. The studies reporting on robotic AUS implantation in female patients are presented in Table 3. In a

preliminary series of six cases, Fournier et al. reported promising outcomes with no explantation/erosion and 83.3% of patients fully continent post-operatively [42•]. The technique used largely duplicated the surgical steps of the traditional open technique, using the same “anterior” robotic technique, with a paramount role of the assistant finger pushing the vaginal fornix to expose the vesicovaginal plane allowing direct vision throughout the bladder neck dissection (Fig. 1), Peyronnet et al. later reported their eight first robotic cases and observed a significantly decreased postoperative complications rate compared to their open cohort (25% vs. 75%; $p = 0.02$) with a reduced length of hospital stay (3.8 vs. 9.3 days; $p = 0.09$) [43•]. The excellent outcomes of this technique were further confirmed in a multicenter series of 49 cases with a minimum 12 months follow-up. In this complex patients’ population with 85.7% having a history of previous anti-incontinence surgery, the authors reported only one explantation (2%) with 81.6% of patients fully continent after a median follow-up of 18.5 months [15•]. An international multicenter experience of 123 patients implanted in 14 institutions from four European countries using this technique was to be presented as a conference abstract this year, confirming these findings with only four explantations for erosion after a median follow-up of 13 months (3.3%) [45]. A Canadian team reported a first case using a similar “anterior” robotic technique in 2019 [47]. Using a slightly different technique, without the help of the assistant’s finger and with the cuff placed more distally towards the mid urethra, Biardeau et al. reported 9 cases with less favorable outcomes, especially 22.2% of erosions, highlighting the need of standardized surgical steps in addition to the robotic approach to decrease female AUS

Table 3 Series of robot-assisted artificial urinary sphincter implantation in women

Study	Number of patients	Bladder neck injury (%)	Vaginal injury (%)	Mean length of stay (days)	Post-operative complications (%)	Major (Clavien $\geq$ 3) complications (%)	Mean follow-up (months)	Explantation* (%)	Revision* (%)
Fournier G 2014 [42•]	6	0%	0%	6	16.7%	0%	14.3	0%	0%
Biardeau X 2015 [44]	9 ¹	22.2%	22.2%	4.9	33.3%	22.2%	18.9	22.2%	0%
Peyronnet B 2016 [43•]	8	25%	12.5%	3.5	25%	12.5%	5	12.5%	0%
Peyronnet B 2019 [15•]	49	10.2%	6.1%	4	18.3%	4.1%	18.5	2%	6.1%
Kourbanhoussen K 2019 [46]	10	40%	0%	4.1	20%	10%	22	0%	20%
Gondran-Tellier 2020 [47]	8	0%	0%	NR	37.5%	0%	12	0%	0%
Peyronnet B 2020 [45]	123	9.8%	6.5%	3.5	18%	3.3%	13	4.1%	5.5%

¹ Only AUS implantations are presented (the two revisions were excluded)

implantation surgical morbidity [44]. More recently, Gondran-Tellier et al. described an alternative robotic technique of AUS implantation in female patients, with a posterior approach of the bladder neck involving a full dissection of the vesico-vaginal plane starting at the vaginal dome with the aim of facilitating the vision of the posterior dissection of the bladder neck at the cost of a more extensive dissection [48•]. They reported no intraoperative bladder neck or vaginal injury and no erosion after a median follow-up of 12 months [48•]. A Spanish team recently described the use of the same “posterior” technique with a laparoscopic approach [49]. Interestingly, an association between the development of these minimally invasive implantation techniques and an increase in the use of female AUS has been noted in France (+28.9% from 205 to 2017) suggesting that the technical facilitation of AUS implantation, thanks to these newer approaches, may favor the adoption of female AUS by urologists [26•].

Existing Evidence

Although female AUS implantation has been described almost five decades ago, the evidence supporting its use is relatively limited [13•]. Especially, no randomized controlled trial (RCT) nor prospective series on AUS implantation in female patients has been published so far [13•]. In the current evidence-based medicine era, this may have hindered its adoption by the urological community [13•]. However, this may clearly not be regarded as the only factor explaining this relatively limited use given that there is a similar lack of high level of evidence studies supporting the use of male AUS

(only one underpowered poorly designed RCT) [50, 51]. Under the auspices of the ICS, an international group of experts recently performed a systematic review of the female AUS literature following the PRISMA statement and Cochrane Handbook recommendations [13•]. They found 17 case series, mostly retrospective, reporting on 6 to 344 female AUS patients. The vast majority of patients had undergone at least one anti-incontinence surgical procedure prior to AUS implantation (69.1% to 100%). Neurogenic SUI accounted for 0% to 50% of indications [13•]. One study reported on vaginal AUS implantation, 11 on open AUS implantation, two on laparoscopic AUS implantation, two on robot-assisted AUS implantation, and one compared open and robot-assisted implantations. The intraoperative bladder neck injury rate ranged from 5.8% to 43.8%, from 0 to 16.7%, and from 0 to 25% in open, laparoscopic, and robot-assisted series, respectively. The intraoperative vaginal injury rates ranged from 0 to 25% with the open approach, from 2% to 16.7% with the laparoscopic approach and from 0% to 25% with the robot-assisted approach. Interestingly, among open series, the two largest studies reported the lowest rates of intraoperative bladder neck and/or vaginal injury [13•]. The mean length of stay was rarely reported, but when it was, it tended to be shorter in the laparoscopic (2 to 7 days) and robot-assisted (3.5 to 6 days) cohorts than in the open cohorts (9.3 to 14.1 days). The postoperative complications rates varied widely and ranged from 16.7% to 33.3% in robotic series and from 4.1% to 75% in open series. After mean follow-up periods ranging from 5 to 204 months, the complete, social, and improved continence rates ranged from 61.1% to 100%, from 71% to 100% and from 81.3% to 100%, respectively.

Fig. 1 Assistant finger pushing into the right vaginal fornix upward and laterally towards the ipsilateral shoulder therefore creating a hernia into the endopelvic fascia and exposing progressively the vesicovaginal plane

The rates of explantation, erosion, and mechanical failure varied from 0% to 45.3%, 0% to 22.2%, and 0% to 44.1%, respectively [13•]. Seven series, all reporting on open AUS implantations, had a mean follow-up over 5 years (range: 72.3 to 204 months) [13•]. At the latest follow-up in these series, 61.1% to 85.6% of patients reported being fully continent [13•].

Perspectives

AMS-800 AUS is the only mechanical device that can mimic the function of biological urinary sphincter by increasing the outlet resistance during the storage phase while maintaining low outlet resistance during the voiding phase when the cuff is opened. While it has proven to be safe and effective, AMS-800 AUS is not without limitations. One of the most significant is the need to activate the pump to void which can be an important barrier to AUS use in female patients with up to 14.9% failing to manipulate the pump [13•]. A handful of electromechanical artificial sphincters have been developed over the past decade, but none has gone from bench to bedside [52–54]. The main advantages of electromechanical AUS are that they would be remotely controlled, allowing the labia majora pump to be omitted, and that they may allow to adjust the pressure exerted on the urethra, hypothetically reducing the risk of erosion and revision due to damage to the bladder neck tissue. Several teams and industrial companies are currently working on electromechanical AUS prototypes which should be used in clinical research studies in the near future.

With the steadily increasing popularity of robotic approaches for AUS implantation in female patients, technological advances in the field of robotic surgery may also be an added value to female AUS developments especially with systems such as the Da Vinci Single port platform which may facilitate even more AUS implantation owing to the improved ergonomics [55].

Finally, lack of high level of evidence studies is a drawback of female AUS use which should be overcome in upcoming years with two large prospective studies currently ongoing and recruiting: the SUACT trial ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02490917) identifier: NCT02490917), a RCT comparing adjustable continence therapy periurethral balloons to AUS in female patients with SUI due to ISD, and the VENUS study, a prospective cohort study on female AUS involving 25 centers throughout Europe and conducted by the EAU Research Foundation.

Conclusion

Owing to its excellent functional outcomes, long history, and unique potential to restore continence while maintaining low

outlet resistance during the voiding phase, AMS-800 AUS can be a valuable option to treat female patients with SUI due to ISD. While its use has been restricted to some countries and a few high-volume centers, it has started spreading again over the past few years, thanks to the rise of minimally invasive approaches which facilitate its implantation, and this is yielding promising outcomes. High level of evidence data from trials which are underway, along with developments in robotic surgery and technological refinements of the device, may well, almost 50 years after its introduction, give the AUS momentum as a major contributor in the female SUI armamentarium.

Compliance with Ethical Standards

Conflicts of Interest Dr. Peyronnet is a consultant for Allergan, Medtronic, Astellas, Pierre Fabre and reports personal fees from Boston Scientific, outside the submitted work.

Dr. Thiruchelvam reports personal fees from Boston Scientific, during the conduct of the study; personal fees from Teleflex, personal fees from Coloplast, personal fees from Galvani, outside the submitted work.

Dr. Greenwell reports personal fees from Boston scientific, other from Astellas, other from Axonics, other from Contura, other from ferring, other from June Medical, other from Laborie, other from Medtronic, outside the submitted work.

Dr. Van Koeveringe reports personal fees from Boston Scientific, outside the submitted work.

Dr. Gray reports personal fees from Boston scientific, grants from Bioness, personal fees from Axonics, from Contura, outside the submitted work.

Dr. Fournier reports personal fees from Boston Scientific, outside the submitted work.

Dr. Capon reports personal fees from Boston Scientific, outside the submitted work.

Dr. Van der Aa reports personal fees from Boston Scientific, other from Cousin, personal fees from Promedon, outside the submitted work.

Dr. López-Fando reports personal fees from Astellas Pharma SA, personal fees from Neomedic, personal fees from Boston Scientific, personal fees from Wellspect, personal fees from Coloplast, outside the submitted work.

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- Of importance
- Of major importance

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