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REVIEW

The Role of the Artificial Urinary Sphincter in Female Incontinence in 2023: A Literature Update

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Abstract

Purpose of Review This article provides a brief outline of stress urinary incontinence (SUI) treatments and the use of artificial urinary sphincters for the treatment of female incontinence, drawing from research published over the past decade. Through a review of the contemporary data, we hope to learn more about the efficacy of the artificial urinary sphincter (AUS), success and failure rates, durability, contraindications and comparative advantages over other treatment methods.

Recent Findings The use of the AUS has become a more popular treatment choice for SUI, with a significant increase in device implantation over the last decade. Technological advancements have allowed the insertion of the device to become more successful and less invasive, leading to greater patient satisfaction overall.

Summary There is an increasing trend towards the use of female AUS, with alternative techniques being employed to assist in complex patients with multiple previous surgeries. There is a growing database of evidence supporting its use however longer-term studies are needed.

Keywords Female artificial urinary sphincter · Continence surgery · Stress urinary incontinence · Functional urology

Introduction

Stress urinary incontinence (SUI) describes the involuntary release of urine related to an increase in intrabdominal pressure. The mechanisms of SUI include an insufficient bladder neck, urethral hypermobility, and intrinsic sphincter deficiency (ISD). SUI can cause marked morbidity with significant social and psychological impact. While medical assessment of severity is made by quantifying the volume and frequency of leakage, patients were found to determine the severity of their SUI using a much broader set of criteria, ranging from personal bodily experiences to the extent of disruption to their social activities and everyday routines [1].

The 2023 AUA/SUFU Updates to Surgical Treatment of Female Stress Urinary Incontinence guidelines recommend the following surgical treatment options for SUI in women: bulking agents, mid-urethral slings, autologous fascia pubovaginal slings and Burch colposuspension. The artificial urinary sphincter may be considered in severe cases of intrinsic sphincter deficiency as a second or third line treatment, especially when there is concomitant detrusor underactivity because the other options listed above may be relatively contraindicated due to risk of urinary retention unless the patient can self-catheterise. Other anti-incontinence

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procedures include urinary diversion such as the ileal conduit or continent diversions, however these are more major operations [2••].

This article provides a brief outline of SUI treatments by way of background and context, then focuses on the current literature on the use of artificial urinary sphincters for the treatment of female incontinence, drawing from research published over the past decade. Through a review of the contemporary data, we hope to learn more about the efficacy of the AUS, success and failure rates, durability, contraindications and comparative advantages over other treatment methods.

Historical Use of the Device

The first surgical treatment of SUI using synthetic material was described in 1965, with subsequent development of techniques utilising mid urethral tape and tension-free vaginal tape gaining popularity as an alternative to colposuspension with equivalent efficacy without the need for laparotomy [3]. The use of polypropylene mesh became controversial in the last decade due to high rates of post operative complications such as mesh erosion, infection, painful intercourse, urinary retention and voiding dysfunction [4]. As such, native tissue slings using rectus fascia or fascia lata, are gaining popularity again.

Urethral bulking agent injections, which are overall reported as safe with associated minor post operative complications such as dysuria, haematuria and pain usually resolving within 48 h. Agents such as Bulkamid® have a reported 70% success rate at 5 years in one study and 42% at 8 years in a second study with no need for follow up procedures. However, there is still limited long-term high-level evidence available [2••, 5].

The artificial urinary sphincter (AUS) is used to treat patients with severe SUI secondary to ISD or refractory SUI after previous anti-incontinence procedures. The device was first reported in the literature in 1973 for neurogenic patients, where five cases, four female and one male, were reported showing significant improvement in continence, improvement in flow rate post operatively with minimal abdominal straining [6]. Despite the original developments of the device being preferentially used in female patients, the AMS-800 device is now more commonly used in males, with pubovaginal slings or bulking agents more commonly used in females [7•].

Methodology

A comprehensive search of the academic literature was carried out with the assistance of PubMed and Medline (Ovid). We reviewed the literature from the past 10 years to present this literature update. Keywords used for the search included "female artificial urinary sphincter", "female artificial sphincter", "female urinary incontinence" and "AMS 800".

Literature Review

Modern Use of the Device

The use of AUS as a treatment for SUI is increasing in both males and females. According to the 2023 AMS 800 consensus statement by Chung et al., female AUS insertion is still considered an uncommon procedure, however, is recommended in female patients with urodynamically proven detrusor underactivity and concomitant ISD. Use of the device is contraindicated in patients with previous pelvic radiation therapy, active urosepsis or cellulitis [8••].

Peyronnet et al. described total use of the device increasing by 8.8% from 2012 to 2017. From 2015 in the female population however there was an increase in the number of implants by 28.9% [7•].

Barakat et al. published a systematic review to assess the results and complications of female AUS and concluded that implantation of AUS in women with SUI is an effective treatment option for patients who have failed first line therapies [9]. A meta-analysis performed by Reus et al. showed a "no pad rate" that ranged between 42 and 86% across all studies included, with a post-surgical adverse event rate reported between 2 and 54%. The wide range of outcome heterogeneity is due to variations in surgical technique, the indiscriminate inclusion of neurogenic and non-neurogenic patients, and a high percentage of AUS patients having one or more previous operation for incontinence [10].

A 2023 study conducted in France compared the long-term device survival of the AMS 800 in men and women. 107 women were compared to 316 men, who had all undergone AUS insertion for non-neurogenic SUI in a single centre between 2000 and 2013. During a median follow up of 5.1 years it was seen that 13.9% of men and 11.2% of women required explantation, and 26.9% of men and 26.1% of women required revision surgery. In the first six months of implantation, there were zero women requiring revision surgery, compared to 13 men. As demonstrated by this study, the AUS had better long-term survival in women, recognising that results may have been affected by varied surgical approach [11].

Phe et al. conducted a long-term study on female patients with SUI treated with an AUS between 1984 and 2011. A cohort of 26 patients were reviewed retrospectively. Of the patients, 23 underwent open device insertion and 3 underwent laparoscopic insertion, with 24 pumps inserted in the right labia. 58% of patients had previously undergone surgical intervention for SUI including Burch colposuspension,

retropubic tension free vaginal tape and one prior augmentation cystoplasty. A median follow up of 7.5 years saw 57.7% (15/26) of patients still using the original device, with revision surgery occurring in 35.2% (9/26). At the time of final follow up 71.4% of patients were continent, requiring no pads. This study may be adversely affected by the length of his treatment period as modern advancements and surgical techniques may result in better outcomes in newer studies [12].

A systematic review and meta-analysis were performed in 2022, looking at 308 articles with an aim to determine the complication rate of AUS, exclusively in female patients with SUI, which resulted from ISD. The most common complications included atrophy, necrosis, erosion, infection, mechanical failure, reconstructive surgery and leak. These complications were subdivided per the surgical implantation method of open and minimally invasive. The study determined that the minimally invasive approach significantly decreased the incidence of mechanical failure (0.53% vs 8.22%) and the need for reconstructive surgery (3.72% vs 14.2%), however significantly increased the risk of infection (6.38% vs 3.2%). All revisions were due to the mechanical failure of the pump, the balloon, the cuff or the connections [13].

Surgical Techniques

In terms of surgical approach, the implantation can be performed open, transvaginally, laparoscopic, and robot-assisted, placing the cuff around the bladder neck, pressure regulated balloon (PRB) in the lower abdomen, and pump in the labia majora. The 2023 consensus by Chung et al. recommend a retropubic approach to allow adequate AUS cuff placement at the bladder neck with a 14fr or 16fr foley catheter to facilitate urethra palpation, particularly in patients with a history of pelvic trauma, diabetes or previous urethral surgery. Intraoperative cystoscopy is also encouraged to be a routine part of the procedure to ensure no urethral injury, however a peri-catheter leak test may be used as an alternative if necessary [8••]. The main steps of the robotic approach are illustrated in Figs. 1, 2, 3 and 4 (Figures courtesy of Dr. Vincent Tse).

Peyronnet et al. performed the first multicentre retrospective review in 2019 of 49 female patients who underwent robotic AUS implantation between 2012 and 2017. The outcomes of this study revealed a 16.3% complication rate but only 4.1% were Clavien-Dindo grade 3 or higher. There was a 2.1% erosion rate, with 6.1% of patients needing revision. 81.6% of patients were fully continent, 12.2% had improved continence and 6.1% had unchanged continence. The same study compared the robotic approach and outcomes in male and female patients; 149 patients were included, 91 male and 58 female. There was a significantly shorter operating time for male patients (137.4 min vs 179.4 min) with comparable complication rates (20.8% vs 27.6%), however the female group was found to have remarkably higher rates of complete continence at 3 months, with zero pads used in 76.4% of females and 42.3% of males [14•].

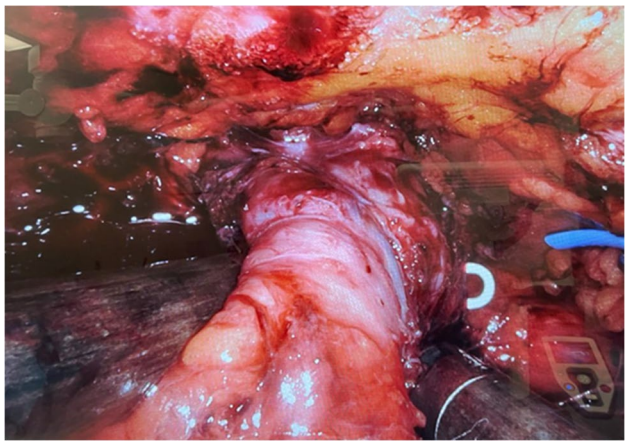

Fig. 1 Dissection of the plane between the vagina and bladder neck, during a robotic approach from an anterior aspect (all images courtesy of Dr. V. Tse)

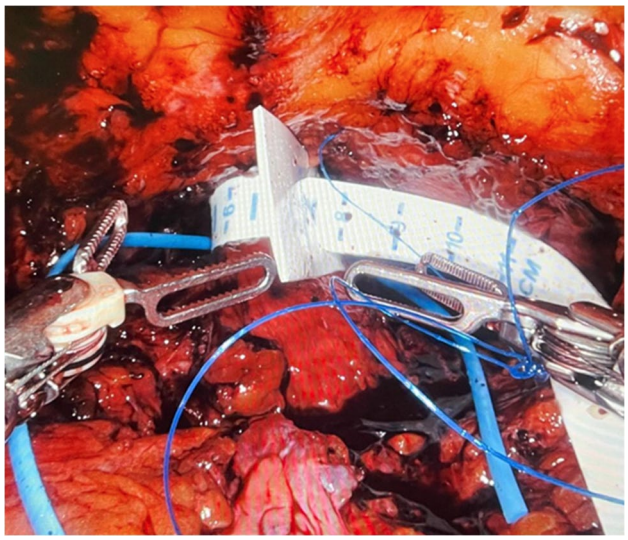

Fig. 2 Sizer used to determine the bladder neck cuff size, which often ranges between 6.5–7.5cm

Gondrand-Tellier et al. used a posterior approach to minimise blind dissection and thus the risk of bladder or vaginal injury. The single surgeon study included 8 patients who underwent robot assisted AUS insertion between 2017 and 2018. Of the cohort, 62.5% had previously undergone pelvic surgery for SUI or vaginal prolapse. The approach resulted in no bladder or vaginal injuries. This study is limited by a small cohort, which may not provide an accurate cross section of

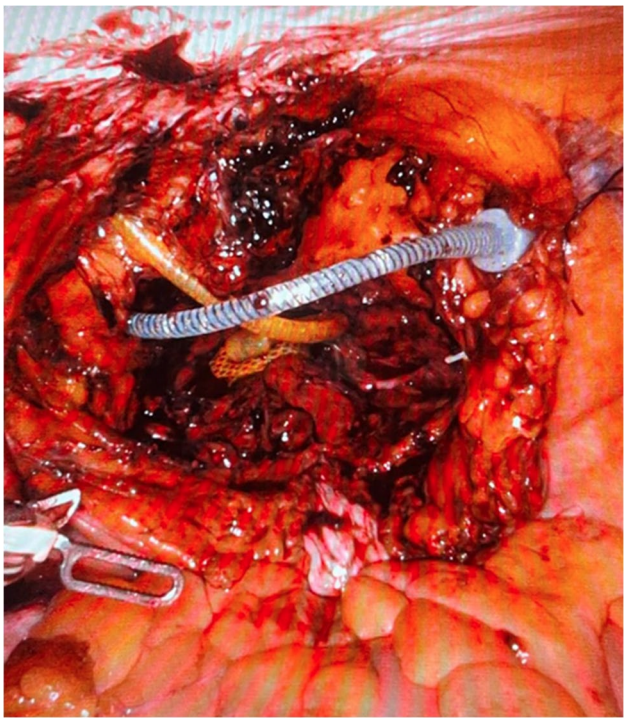

Fig. 3 Cuff secured and pressure regulating balloon placed and covered with intraperitoneal fat that have been secured

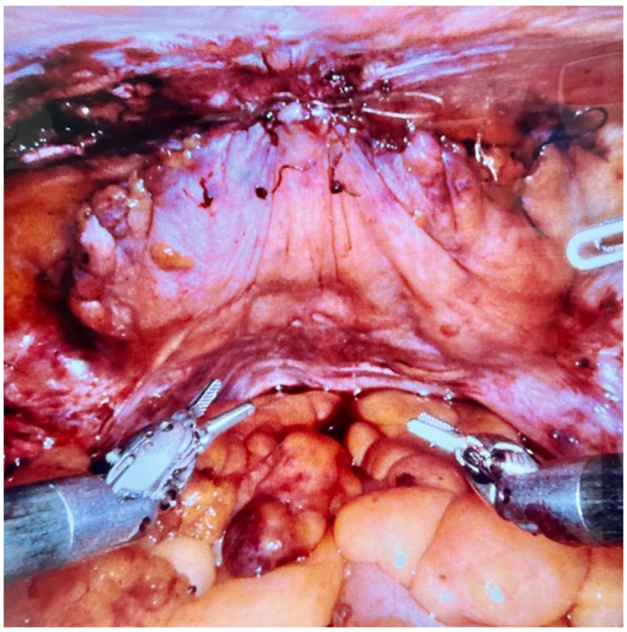

Fig. 4 Extraperitonealisation of the device at the end of the robotic procedure

patients who may undergo this procedure [15]. To compare a larger cohort, Orchoa Vargas et al. utilised this technique on 40 patients from 2017 to 2022, noting the challenge of ensuring adequate vesicovaginal dissection low enough to place the cuff. 87.5% of patients were able to be completed using this technique, with 2 patients needing conversion to open, and 3 patients needing modifications to surgical approach. 97.5% of patients had previous SUI surgery. There were bladder injuries sustained in 23% of cases, vaginal injury in 14% of cases and bladder neck injury in 3.5% of cases. 5.7% of the devices were removed and 5.7% of patients needed revision surgery. There was a continence rate of 94% [16].

Haudebert et al. presented a case report at EAU 2023 about a robotic extraperitoneal approach in a female patient with spina bifida and a surgical history of a supra-trigonal cystectomy and augmentation cystoplasty in 1996. She had additionally had a history of an enteric fistula secondary to an oophorectomy and had previously had a pubovaginal sling inserted to treat her SUI which had no longer remained effective to maintain continence. This approach was successful and the patient was fully continent at the 6 month follow up [17]. While this is evidence of a successful implantation technique in a single complicated patient, there has only been a relatively short follow up period within which failure and longer term complications can occur.

Other surgical techniques utilised include a laparoscopic approach with a posterior dissection used in 49 female patients, the majority of which had spinal cord injuries. There was a bladder injury rate of 18.4%, a 10.8% explantation rate and a 84% rate of improved or complete continence which is comparable to robotic methods [18].

Contraindications

The AUS is contraindicated in patients with recurrent UTI's, anatomical abnormalities such as urethral diverticulae or recurrent stricture disease, poor bladder compliance, acontractile detrusor or patients with reduced manual dexterity or cognitive dysfunction. Recurrent renal or bladder stone disease and vesicouretric reflux are relative contraindications to the device, and prior radiation therapy has been associated with high rates of intraoperative on post-operative complications in some studies [19].

With respect to women of child-bearing age, it is important to note that they are at greater risk of cuff erosion during vaginal delivery. Deactivation during labor and delivery is necessary, along with recommendations against future pregnancy, opting for elective caesarean section, and deactivation of the device during the final trimester in order to minimize the risk of erosion [20].

Conclusion

There is an increasing trend towards the use of female AUS, with alternative techniques being employed to assist in complex patients with multiple previous anti-incontinence

surgeries, especially when there is concomitant detrusor underactivity. Although the continence rates in most studies are very acceptable in this difficult patient group, there is still no definitive guideline regarding the use of this potentially beneficial option to these patients. As the dissection between the anterior vaginal wall and bladder neck is often technically challenging due to previous surgeries, the use of the AUS earlier in the surgical pathway is worthy of further study and investigation. Longer term follow-up studies are needed but it is hopeful that the future may see the AUS becoming a more frequently utilised option in the treatment paradigm of female SUI.

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Declarations

Competing Interests AC(2) is a proctor for Boston Scientific, Coloplast and Medtronic. AC(2) is an advisory board member for Coloplast. The other authors declare no competing interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

Ethical Approval Not Applicable.

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References

Papers of particular interest, published recently, have been highlighted as: • Of importance •• Of major importance

1. Lynch R, Toozs-Hobson P, Duckett J, Tincello D, Cohn S. Making a decision about surgery for female urinary incontinence: a qualitative study of women's views. Int Urogynecol J. 2021;32(1):127–33.
2.•• Kobashi Kathleen C, Vasavada S, Bloschichak A, Hermanson L, Kaczmarek J, Kim Sennett K, et al. Updates to Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline (2023). J Urol. 2023;209(6):1091–8. **This is the most recent SIU guideline for the treatment of stress urinary incontinence in females. It is of major importance when considering treatment options in this field.**
3. Izett M, Kupelian A, Vashisht A. Safety and efficacy of non-absorbable mesh in contemporary gynaecological surgery. Gynecol Surg. 2018;15(1):20.
4. Barski D, Otto T, Gerullis H. Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair. Surg Technol Int. 2014;24:217–24.
5. Hoe V, Haller B, Yao HH, O'Connell HE. Urethral bulking agents for the treatment of stress urinary incontinence in women: A systematic review. Neurourol Urodyn. 2021;40(6):1349–88.
6. Brantley Scott F, Bradley WE, Timm GW. Treatment of urinary incontinence by implantable prosthetic sphincter. Urology. 1973;1(3):252–9.
7.• Peyronnet B, Hascoet J, Scailteux LM, Game X, Cornu JN. The Changing Face of Artificial Urinary Sphincter Use in France: The Future is Female. Eur Urol Focus. 2020;6(6):1248–50. **Articles focusing on the future of AUS appeared less frequently in my literature review, which made this an important article in my review.**
8.•• Chung E, Liao L, Kim JH, Wang Z, Kitta T, Lin AT, et al. The Asia-Pacific AMS800 artificial urinary sphincter consensus statement. Int J Urol. 2023;30(2):128–38. **This article is the Asia-Pacific consensus statement on AUS use, and is of very significant importance to the urologists use of the device in all patients. Inclusion of both of these articles was essential to the understanding of device options and treatment modalities.**
9. Barakat B, Franke K, Hijazi S, Schakaki S, Gauger U, Hasselhof V, et al. A systematic review and meta-analysis of clinical and functional outcomes of artificial urinary sphincter implantation in women with stress urinary incontinence. Arab J Urol. 2020;18(2):78–87.
10. Reus CR, Phé V, Dechartres A, Grilo NR, Chartier-Kastler EJ, Mozer PC. Performance and safety of the Artificial Urinary Sphincter (AMS 800) for non-neurogenic women with urinary incontinence secondary to intrinsic sphincter deficiency: A systematic review. Eur Urol Focus. 2020;6(2):327–38.
11. Cotte J, Dechartres A, Mozer P, Poinard F, Chartier-Kastler E, Beaugerie A. Long-term device survival after a first implantation of AMS800 for stress urinary incontinence: Comparison between men and women. Neurourol Urodyn. 2023;42(1):80–9.
12. Phe V, Leon P, Granger B, Denys P, Bitker MO, Mozer P, et al. Stress urinary incontinence in female neurological patients: long-term functional outcomes after artificial urinary sphincter (AMS 800(TM)) implantation. Neurourol Urodyn. 2017;36(3):764–9.
13. Shokri P, Kharaz L, Talebian N, Borumandnia N, Ziaee SAM, Shakhssalim N. A systematic review and meta-analysis of complications of artificial urinary sphincters in female patients with urinary incontinence due to internal sphincter insufficiency. BMC Urol. 2023;23(1):97.
14.• Peyronnet B, Capon G, Belas O, Manunta A, Allenet C, Hascoet J, et al. Robot-assisted AMS-800 artificial urinary sphincter bladder neck implantation in female patients with stress urinary incontinence. Eur Urol. 2019;75(1):169–75. **This article carefully addressed the surgical morbidity with a significant patient base, across 10 surgeons, allowing a thorough scope of considerations to be made.**

15. Gondran-Tellier B, Boissier R, Baboudjian M, Rouy M, Gaillet S, Lechevallier E, et al. Robot-assisted implantation of an artificial urinary sphincter, the AMS-800, via a posterior approach to the bladder neck in women with intrinsic sphincter deficiency. BJU Int. 2019;124(6):1077–80.
16. Vargas CO, Broudeur L, Le Normand L, Karam G, Rigaud J, Perrouin-Verbe M. Robot-assisted female artificial urinary sphincter (AUS) implantation by posterior approach with endoscopy monitoring. Eur Urol. 2023;83:S2016. https://doi.org/10.1016/S0302-2838(23)01444-6
17. Haudebert C, Richard C, Hascoet J, Peyronnet B. Robotic extraperitonal artificial urinary sphincter implantation in female patients. Eur Urol. 2023;83:S2015. https://doi.org/10.1016/S0302-2838(23)01443-4
18. Schroeder A, Munier P, Saussine C, Tricard T. Outcomes of laparoscopic artificial urinary sphincter in women with stress urinary incontinence: mid-term evaluation. World J Urol. 2021;39(8):3057–62.
19. Islah M, Cho SY, Son H. The current role of the artificial urinary sphincter in male and female urinary incontinence. World J Mens Health. 2013;31(1):21–30.
20. Chung E. Artificial urinary sphincter surgery in the special populations: neurological, revision, concurrent penile prosthesis and female stress urinary incontinence groups. Asian J Androl. 2020;22(1):45–50.

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