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INVITED REVIEW

Operational Andrology

Artificial urinary sphincter surgery in the special populations: neurological, revision, concurrent penile prosthesis and female stress urinary incontinence groups

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The artificial urinary sphincter (AUS) remains the standard of care in men with severe stress urinary incontinence (SUI) following prostate surgery and radiation. While the current AUS provides an effective, safe, and durable treatment option, it is not without its limitations and complications, especially with regard to its utility in some "high-risk" populations. This article provides a critical review of relevant publications pertaining to AUS surgery in specific high-risk groups such as men with spinal cord injury, revision cases, concurrent penile prosthesis implant, and female SUI. The discussion of each category includes a brief review of surgical challenge and a practical action-based set of recommendations. Our increased understandings of the pathophysiology of various SUI cases coupled with effective therapeutic strategies to enhance AUS surgery continue to improve clinical outcomes of many patients with SUI.
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Keywords: artificial urinary sphincter; female stress incontinence; penile prosthesis implant; revision surgery; spinal cord injury; urinary incontinence

INTRODUCTION

The artificial urinary sphincter (AUS) has been considered the standard of care for men with severe stress urinary incontinence (SUI) and/or radiotherapy-related SUI.[1,2] The hydraulically controlled AMS 800™ AUS (Boston Scientific, Minnetonka, MN, USA) remains the most commercially successful and effective sphincteric device since it was developed in 1972.[3] This ingenious urinary device consists of three components: a control pump placed in the scrotum, an inflatable cuff which is usually implanted around the proximal bulbar urethra, and a pressure-regulating balloon in the retropubic space, which serves dual functions, both a pressure regulator and a fluid reservoir. While long-term clinical outcomes, safety profile, and mechanical durability of the current model of the AMS 800 device are well documented, it is not without its limitations and complications such as prosthetic infection and mechanical failure rate.[4]

While the clinical use of AMS 800 AUS in a standard male patient with "uncomplicated" SUI history is well established, there are limited high-quality studies pertaining to AUS outcomes in the selected high-risk groups such as neurogenic bladder dysfunction, revision cases, men who require concurrent penile prosthesis implant for erectile dysfunction, and finally, in female SUI. This article explores the clinical outcomes of AUS in these special populations.

MATERIALS AND METHODS

A critical review of all relevant publications pertaining to AMS 800 AUS was conducted in PubMed and Embase databases, using keywords "urinary incontinence," "AMS 800," "artificial urinary sphincter," "neurogenic urinary incontinence," "revision," "female stress urinary incontinence," and "concurrent penile prosthesis implant." Full surgical descriptions related to AUS implant and/or revision surgery were excluded in this review. The discussion of each category of special populations also includes a brief review of surgical challenge and a practical action-based set of recommendations on surgical options (**Table 1**).

DISCUSSION

Neurologic SUI

Neurogenic bladder dysfunction due to spinal cord injury (SCI) can result in urinary incontinence, renal impairment, urinary tract infection, bladder or renal stones, and poor quality of life. Most patients will require careful bladder management to ensure a low-pressure bladder, complete bladder emptying, and adequate urinary continence with the use of anticholinergic medications and clean intermittent catheterization (CIC) as first-line therapy, prior to more invasive procedures such as neuromodulation or bladder augmentation. In many SCI patients with persistent urinary incontinence, the AUS provides an ideal continence therapy to address underlying intrinsic sphincter insufficiency, without resorting to urinary diversion. In contrast to the traditional placement of AUS cuff in the proximal bulbar urethra for the treatment of male SUI, the cuff is often placed at the bladder neck or periprostatic tissue to ensure a lower rate of

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Table 1: Special populations and recommended practical action-based strategies

Special populations	*Main issues to considered*	*Surgical strategies*	*References*
Neurogenic	Need for self-catheterization (higher risk of erosion with bulbar urethral cuff) Underlying bladder dysfunction Higher nonmechanical failure and revision rate Lower continence rate	Cuff placement at bladder neck Need for greater intraoperative and postoperative care	5–13
Revision (urethral atrophy)	Ischemic changes to previous cuff area More difficult surgical dissection Higher risk of infection and nonmechanical failure	Replace urethral cuff in a new location Downsizing the urethral cuff size Tandem or second urethral cuff Transcorporal cuff placement Revising pressure-regulating balloon to high pressure	14–25
Concurrent erectile dysfunction for penile prosthesis implant	Synchronous or staged (delayed) AUS and penile prosthesis implant More difficult surgery and cautious corporal dilatation near the urethral cuff Higher risk of infection Cost issue	Synchronous surgery Higher complication rates and the difficulty of manipulating the two scrotal pumping devices Staged or sequential (delayed) surgery Higher surgery attention to avoid damaging existing implant Additional surgical cost	26–37
Female stress urinary incontinence	Usually as salvage option in failed slings More difficult surgical dissection Higher risk of infection and nonmechanical failure	Preserving integrity of the vesicovaginal surgical plane during cuff placement at bladder neck Avoid future vaginal delivery (cuff erosion)	38–52

AUS: artificial urinary sphincter

cuff erosion from frequent urethral instrumentations. Furthermore, patients with SCI-related urinary incontinence should be counseled regarding higher risks of nonmechanical device failure and revision surgery and that their overall long-term continence rates may be poorer compared to the nonneurogenic group.

Chartier Kastler *et al.*[5] published a 10-year retrospective series on AUS in neurogenic male urinary incontinence and showed that 74% of the patients had no or moderate incontinence between CICs that spanned at least 4 h, at a mean 83-month follow-up period. The majority of these men had SCI and 39% of men with detrusor overactivity underwent concomitant bladder augmentation. Similarly, Guillot-Tantay *et al.*[6] reported the 5-, 10-, 15-, and 20-year explantation-free survival rates of 85.7%, 62.3%, 52.0%, and 39.0%, respectively, in SCI men who underwent AMS 800 implantation. The revision-free survival rates were 78.6% (at 5 years), 42.9% (at 10 years), 28.6% (at 15 years), and 7.1% (at 20 years). Approximately 50% of men were continent at recent follow-up visit (mean: 18.3 years). Three native devices were still in place, eight were revised (four of them were secondarily explanted), and three were explanted due to erosion or infection.

Comparing the clinical outcomes between AUS cuff placement at bulbar urethra and bladder neck, Khene *et al.*[7] found a trend favoring bladder neck over peribulbar cuff placement with median revision-free device survival at 14.3 and 11.7 years, respectively ($P = 0.73$), while the median explantation-free device survival was 24.5 and 18.5 years, respectively ($P = 0.08$). On multivariate analysis, CIC was the only predictor of AUS device failure.

In a study that directly compares the AUS implantation for neurogenic and nonneurogenic incontinence, Murphy *et al.*[8] found higher revision rates in the neurogenic group (11 out of 13 patients) and only three remained completely dry at a mean 6-year follow-up. In contrast, seven of 17 patients in the nonneurogenic group did not require revision, and eleven were completely dry. The nonmechanical failure rate of the AUS was significantly higher in the neurogenic group.

Gonzalez *et al.*[9] published a retrospective study on AUS and bladder augmentation surgery and reported no significant difference in clinical success between the timing of AUS placement and bladder augmentation. However, the two patients who had sphincter erosions had an injury of the augmented bladder during surgery or belonged to the simultaneous surgery group, highlighting the importance of adequate bowel preparation and maintenance of sterile urine during the AUS surgery. Using a modified surgical implant of a port instead of a pump, Bersch *et al.*[10] reported that this technique was effective and safe at the reported cure rate at 90% with a 35% revision rate after 8-year follow-up.

Robotic-assisted AUS implantation was reported in the early 2010s and Yates *et al.*[11] showed no complications in six SCI patients. However, longer-term safety and cost efficacy of this novel technique will need to be conducted to compare with traditional open surgical methods.

In the younger population, Ruiz *et al.*[12] found that patients with bladder exstrophy and many previous bladder procedures are more exposed to complications such as device erosion compared with patients with epispadias or anorectal malformation. In another series, Spiess *et al.*[13] reported that 19 out of 30 (63%) boys were completely dry, 6 (20%) were slightly wet, and 5 (17%) were incontinent, with the mean lifetime of all AUS devices at 4.7 years with no statistically significant difference in device survival between cuff placed at bladder neck or bulbar urethra (4.6 and 4.9 years, respectively). However, survival analysis revealed a sharp drop after 100 months with only 8.3% of the sphincters implanted lasting beyond this point. There were a total of 32 revisions performed in 17 patients constituting a 0.164 revision rate per patient-years.

Revision group secondary to urethral atrophy

A common cause of recurrent or delayed SUI following AUS implantation is tissue atrophy resulting in loss of circumferential urethral compression and luminal occlusion. In fact, tissue atrophy is probably the most common cause of nonmechanical failure and the most common cause for AUS revision. Patients who were initially continent with the device usually complain of gradually increasing urinary incontinence over months or even years and report having to squeeze the pump more often to deflate the cuff to void. Withdrawal urethral pressure profile can be conducted with the cuff in inflated and deflated modes to show the difference in luminal pressure while cystourethroscopic evaluation will show ischemic changes to the bulbar urethra and poor mucosal coaptation when the cuff is fully inflated.[14] Surgical options for AUS revision in urethral atrophy include replacement of the urethral cuff in a new location,[15] downsizing the urethral cuff size,[16] placement of a second (tandem) urethral cuff,[17] transcorporal cuff placement,[18] or revising the pressure-regulating balloon to a higher pressure.[19]

In a recent publication comparing primary versus AUS revision cases, Suh *et al.*[20] showed that nonmechanical failure (70.7%) was a dominant etiology of reoperation, and at longer-term follow-up, men with primary AUS performed better than those with AUS revision. While the immediate success rates of primary AUS without reoperation (pAUS) and AUS revision without secondary reoperation (rAUS) groups were 88.6% and 79.2% ($P = 0.352$), respectively, at a median follow-up of 45.1 (range: 9–126) months, the social continence rate was higher in patients with pAUS (92.1%) than with rAUS (62.5%) ($P = 0.001$).

In an *ex vivo* culture study, Ziegelmann *et al.*[21] reported that the two most common reasons for AUS revision were urethral atrophy ($n = 31$, 39%) and mechanical failure ($n = 49$, 52%). Excluding patients undergoing revision for infection or erosion, positive culture swabs were identified in 37/200 components (19%), including 25/86 cuffs (29%), 7/56 pumps (13%), and 5/58 reservoirs (9%), with the majority being skin organisms such as *Staphylococcus* species (57%), *Propionibacterium* (10%), and *Aerococcus* (5%). More than a third (39%) of patients had at least one positive component culture, and those patients were more likely to have a history of radiation (65% *vs* 33%, $P = 0.006$). Positive AUS component bacterial swab cultures were found in 39% of patients undergoing AUS revision in the absence of clinical infection. Those patients with positive cultures were more likely to have a history of pelvic radiation. These results suggest that bacterial colonization of organisms with low virulence may not lead to device infection.

In another large series, Raj *et al.*[22] showed nonmechanical failure accounted for the majority of AUS revision compared to mechanical failure. Of the 119 patients undergoing secondary implantation, 91 (76.5%) needed no additional surgical intervention, while 28 (23.5%) required a total of 40 surgical revisions for new mechanical (15 [37.5%]) and nonmechanical (25 [62.5%]) problems. Five-year durability outcomes for primary and secondary AUS implantation were comparable at 80% and 88%, respectively. This study confirmed that outcomes for secondary AUS reimplantation remained comparable to those of primary AUS implantation and that salvage surgery can still produce a good clinical outcome, even following multiple prior revisions and cuff erosion.

Linder *et al.*[23] compared the clinical outcomes between cuff downsize versus tandem cuff placement in AUS revision and concluded that there was no significant difference in the overall device survival in patients undergoing single cuff downsizing or tandem cuff placement during AUS revision for urethral atrophy. Of the 69 revision surgeries for urethral atrophy, 56 (82%) were tandem cuff placements, 12 (18%) were single cuff downsizings, and one was the relocation of a single cuff. Furthermore, there was no difference in 3-year overall device survival compared between the single cuff and tandem cuff revisions (60% *vs* 76%, $P = 0.94$). In another retrospective study, O'Connor *et al.*[24] reported a significantly higher rate of complete continence and improvement in the urinary continence score seen in men with double-cuff compared with single-cuff devices. Daily pad use decreased from 7.7 to 1.1 in patients treated with a single-cuff AUS and from 7.8 to 0.7 in patients with a double-cuff AUS ($P = 0.25$) and complete continence was reported in 3 (11%) of 28 men with single-cuff and 12 (43%) of 28 men with double-cuff sphincters ($P = 0.008$). Five complications were reported in the single-cuff recipients and four in the double-cuff patients. In a multicenter study, Eswara *et al.*[25] reported the outcomes after various revision of AUS strategies and found that tandem cuff placement was associated with a lower rate of incontinence failure ($P = 0.02$), whereas cuff repositioning was associated with a higher rate of incontinence failure ($P = 0.02$). An increased rate of mechanical failure was observed with cuff downsizing ($P = 0.01$).

Coexisting erectile dysfunction for concurrent penile prosthesis implant surgery

In patients who have both SUI and erectile dysfunction (ED), it may be necessary to counsel these men regarding synchronous or sequential (delayed) AUS and penile prosthesis implantation. Candidates for dual implants are usually patients who have failed conservative management for both conditions and wish to undergo a single surgery. The theoretical concerns of synchronous prostheses implant are potential higher complication rates and the difficulty of manipulating the two scrotal pumping devices in some patients especially in the early stage. On the other hand, a 2-stage procedure requires more attentive surgery in order to avoid damaging the components of the existing implant and possibly operating in less well-defined tissue planes. In either situation, patients need to be counseled on the pros and cons of dual versus staged implants and technical considerations for the device placement will vary depending on the sequence of device implant and the surgeon preferences. Most surgeons usually advocate the dissection and mobilization of the proximal bulbar first as inadvertent urethral injury would require abandoning or modifying the procedure without discarding any of the prostheses. Corporal dilatation must proceed cautiously in the proximal part of corpora near the cuff. At the level of the bulbar urethra, the corporal bodies have already diverged and therefore the likelihood of injuring the cuff or urethra is lower. Single-step dilatation may be a better option than sequential dilatation to avoid injuring the urethra.

The publication of trans-scrotal insertion of AUS implant[26] has led to synchronous dual implants performed through a single incision. If the implants are not placed synchronously, the AUS is usually placed first followed by penile prosthesis for the reasons cited above. In a sequential device implant, the greatest concern is accidental damage to the preexisting device and its tubing. Great care needs to be taken to avoid damaging the AUS cuff when subsequently placing the penile cylinders. Some authors proposed that malleable penile prosthesis is utilized in a sequential implant because of lesser components required and that the implant could be performed more distally on the corporal bodies and hence avoid encountering the AUS device. While it is expected that all implants should have ipsilateral tubing and reservoir placement, surgeons should exercise precaution such as reviewing previous surgical records or organizing preoperative imaging study to avoid intraoperative surprises and the placement of the second implant can be planned for the pump and reservoir at the contralateral side. The incision should be performed away from the existing device, with meticulous dissection and the use of cutting currents to avoid damage to any components of the first device.

Prosthetic infection is the most dreaded complication and generally occurs due to the inadvertent introduction of skin organisms at the time of surgery and early postoperative bacteremia. Shortening the operative time would seem a logical way of decreasing this incidence, but published literature on synchronous and sequential dual implants has not revealed any higher incidence of prosthetic infection, probably due to the low incidence of prosthesis infection. In the event of an infection, the concern is that it will spread to all components necessitating their removal and making revision surgery more technically challenging. In order to salvage an infected prosthesis, one needs to determine which prosthetic device is infected and whether it is possible to leave the components of the unaffected device intact. Bhalchandra *et al.*[27] argued that in this situation, provided that the infected device is

identified early, and if one acts promptly to locate the components affected, it is possible to salvage the components of the unaffected device. While device erosion without infection may make salvaging one of the devices possible, in the context of device infection, it is often difficult to ascertain which device is affected, confidently exclude the possibility of only one device being infected and therefore it would be safer to remove both devices. However, Wilson *et al.*[26] showed that it is possible to preserve one device when the other infected device was removed. The feasibility of salvage surgery was also conferred by Bryan *et al.*[28] where three patients who had simultaneous dual implant had their device successfully salvaged and one patient underwent two dual salvage procedures.

In a multi-institutional study on the dual implant, Kendirci *et al.*[29] reported no prosthetic infection postoperatively among the 22 men over a mean follow-up of 17 months following a single upper transverse scrotal approach. The overall revision rate was 14%, mostly due to complications associated with the AUS device such as cuff erosion. In a cost analysis study, Sellers *et al.*[30] showed that dual prosthetic implantation in a single-stage procedure significantly reduced the operative time (24.7%, $P < 0.05$) and was associated with approximately a $7000 cost savings compared with individual procedures, with no report of infective complications or device erosion over the 16 months of follow up. Rolle *et al.*[31] showed no difference in the pain score, postoperative hospital stays (2.5 days after the double-implant procedure and 2.4 days after AUS alone), and continence rate (65% *vs* 68%). Furthermore, when given options, all patients stated that they would have preferred synchronous surgery. Mancini *et al.*[32] also reported encouraging outcomes in patient satisfaction, ease of use, and functionality in the dual implantation group that are similar to those observed in the individual prosthesis group. In fact, most patients (94%) stated that they would recommend the dual implantation procedure to others and have the procedure done again.

In their series of 55 combined procedures compared to the single insertion of 336 inflatable penile prostheses and 279 artificial urinary sphincters over a 12-year period, Segal *et al.*[33] reported that men treated with combined implantation had a greater mean age and were at greater risk for prostate cancer diagnosis and treatment, and at lesser risk for Peyronie's disease than men who received an inflatable penile prosthesis alone (each $P < 0.05$). Although the operative time was significantly longer for the combined procedure than for the inflatable penile prosthesis alone and the AUS alone (mean: 218.1 *vs* 145.9 and 114.7 min, respectively, $P < 0.0001$), the rate of device infection, erosion, or malfunction was not increased in combined or staged procedures ($P > 0.05$).

Based on the SPARCS (New York State Department of Health Statewide Planning and Research Cooperative) database for men who underwent inflatable penile prosthesis and/or artificial urinary sphincter insertion between 2000 and 2014, Patel *et al.*[34] found that combined inflatable penile prosthesis and artificial urinary sphincter insertion portends a higher likelihood of inflatable penile prosthesis reoperation at 1 year (OR: 2.08, 95% CI: 1.32–3.27, $P < 0.01$) and 3 years (OR: 2.60, 95% CI: 1.69–3.99, $P < 0.01$), while the artificial urinary sphincter outcomes remain comparable.

The literature on patients who underwent dual implants after radiotherapy is limited. Kendirci *et al.*[29] reported that the only erosions following synchronous insertion of AUS and PP occurred in the irradiated patients postradical prostatectomy. The higher AUS revision rates in patients who received previous radiation were also confirmed by Martins and Boyd.[35] The poorer surgical outcomes in irradiated population are likely attributed to several factors such as poorer quality of urethral tissue, difficult surgical dissection with delayed recognition of urethral injury as well as improper cuff sizing, and higher rates of cuff atrophy. In a more complex patient cohort such as those with neobladders, Loh-Doyle *et al.*[36] concluded that an AUS and PPI can be performed without an increased risk of device-related complications when compared to a control group of nonneobladder patients. Furthermore, among the five prosthetic infection cases, the infection was confined to a single device and salvage surgery was feasible.

Dual implantation of AUS and penile prosthesis is feasible, safe, efficient, and cost-effective for the surgical treatment of PPI and ED. The decision to perform synchronous or delayed surgery for concurrent urinary and penile prosthetic implants is dependent on whether concurrent surgery increases the complication rate and is cost-effective in the longer term. Pertinent points to discuss with prospective patients interested in dual implants include counseling on the complexity of the surgery and potential complications and having enough manual dexterity to recycle either pump as required.[37] In a carefully selected group of patients, there is no doubt that most patients are satisfied with the outcomes and highly appreciative of the improvements in their quality of life. From the surgeon point of view, the dual implant of urinary and penile devices is technically challenging, and the surgeon should be competent at placing either device independently before contemplating dual implantation. Dual implantation of urinary and penile prostheses is feasible and safe provided that strict adherence to prosthetic surgical protocols are adhered to and has been shown to be cost-effective and highly efficacious to treat men with PPI and ED.

Female stress urinary incontinence

Synthetic sling surgery has gained widespread acceptance as the standard of care in female SUI, but recent negative press related to synthetic mesh has placed considerable concerns among surgeons and patients. In women with multiple continence surgeries, the placement of AUS potentially offers a better continence rate through circumferential compression and coaptation of the "scarred" urethra and remains a safe and effective salvage option in a carefully selected patient cohort.

The limited number of publications on the outcomes of urinary continence following placement of AUS in women is likely related to the complexity of AUS surgery and lack of awareness of AUS as an effective treatment option for female AUS. Among all surgical procedures for female SUI, AUS implantation is thought to have the highest long-term (>5 years) success rate in a recent web-based survey.[38] However, the responding international urologists and gynecologists also think that AUS implantation has the highest risk of complications and/or revisions. Unfortunately, at present, there is no randomized head-to-head trial between minimally invasive synthetic sling surgery and AUS.

The earliest publication on AUS implantation for women with SUI was by Scott,[39] who reported more than 90% of patients with socially acceptable continence and 66% of patients completely dry among the 139 female patients with variable ages and mixed etiologies of urinary incontinence when followed up to 6 years. Over the last three decades, published literature shows that AUS surgery is safe and clinically effective in properly selected women with genuine SUI.[40–46] In fact, the comparison of the clinical outcomes between AUS in men and women were not too dissimilar in terms of continence rate and patient satisfaction.[45]

Similar continence rates were also reported in women who received laparoscopic AUS implantation.[47,48] More recently, robotic-assisted AUS implantation has been shown to be equally effective and safe.[49,50] In a pilot study comparing robotic-assisted and open approaches, Peyronnet

et al.[51] reported that the change in surgical trend from an open approach (2008–2012) to a robot-assisted approach (2013–2014) was associated with a lower intraoperative complication rate (37.5% *vs* 62.5%; $P = 0.25$), decreased blood loss (17 ml *vs* 275 ml; $P = 0.22$), and shorter length of stay (3.5 *vs* 9.3 days; $P = 0.09$) in the robot-assisted group with comparable continence rates in both groups (75% *vs* 68.8%; $P = 0.75$).

Most published literature pertaining to AUS implantation in female patients has a shorter-term follow-up of <5 years. A longer-term follow-up study by Chung and Cartmill[46] showed that more than 80% of AUS devices remained functioning after 100 months and currently has the longest mean follow-up period of 13.5 years. It is difficult to deduce from most published literature with regard to the role of AUS as a salvage surgical option due to the indiscriminate reporting of the outcomes for patients with or without previous anti-incontinence surgeries; incomplete data collection; and the loose definition of continence rates whether it is pad free or with minimal usage of pads. Most published studies on AUS span over the different generations of AUS and advances in technology such as durable kink-proof tubing, lockout valve, as well as the pressure-regulating balloon may have increased the durability of the AUS device.[52]

In recent years, there has been a shift in the treatment paradigm for female stress urinary incontinence toward minimally invasive surgery. Currently, the placement of AUS in female patients is only performed in few major teaching centers. Despite the few existing indications for AUS in women, AUS can potentially be a suitable treatment option for females with SUI secondary to intrinsic sphincter deficiency. Perioperative injury remains the most significant risk factor for AUS explantation. Most studies stressed the importance of preserving the integrity of the vesicovaginal surgical plane as the key to successful implantation. In addition, women of child-bearing age should be warned of the danger of cuff erosion during vaginal delivery with advice ranging from no future pregnancy, elective caesarean delivery, and deactivation of the AUS in the final trimester, as recommended to minimize the risk of cuff erosion. Deactivation during labor and delivery is imperative.

With proper selection and strict adherence to surgical techniques, AUS is safe, highly effective, and demonstrated excellent long-term outcomes. Perhaps the role of AUS in distressed and socially restricted women with persistent SUI or recurrent urinary incontinence following anti-incontinence surgeries is underutilized and should be given due consideration.

CONCLUSION

Over the past four decades, advances in mechanical design, applications of new technology, and lessons learned from the past clinical experiences have made AMS 800 AUS the standard of care in men with SUI. While the current AMS 800 device provides an effective, safe, and durable therapeutic option, it is not without its limitations and complications, especially with regard to its utility in some of high-risk populations. Increased understanding of the pathophysiology of various SUI cases, coupled with effective strategies, further improves AUS clinical outcomes. However, the emergence of novel therapies such as a nanotechnology-driven device and stem cell therapy may one day circumvent traditional AUS surgery.

COMPETING INTERESTS

The author declared no competing interests.

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