Review Article

The electronic artificial urinary sphincter: ongoing innovation of a classic device—a narrative review

George E. Koch, Melissa R. Kaufman

Department of Urology, Vanderbilt University Medical Center, Nashville, TN, USA

Contributions: (I) Conception and design: MR Kaufman; (II) Administrative support: GE Koch; (III) Provision of study materials or patients: Both authors; (IV) Collection and assembly of data: Both authors; (V) Data analysis and interpretation: Both authors; (VI) Manuscript writing: Both authors; (VII) Final approval of manuscript: Both authors.

Correspondence to: George E. Koch, MD. Department of Urology, Vanderbilt University Medical Center, 1211 Medical Center Dr, Nashville, TN 37215, USA. Email: George.e.koch@vumc.org.

Background and Objective: While the modern artificial urinary sphincter (AUS) has benefited from incremental innovation, which has improved both device efficacy and complication rates, the foundational technology in use in Boston Scientific's AMS800 can be traced back to the fundamental hydraulic tenets of the AS721. Research and development in adaptive technology and electronic integration stand to further improve AUS outcomes.

Methods: The Medline online retrieval system was queried using the MeSH terms "artificial urinary sphincter", "electronic", "complications", "history", and "development" in various combinations. Publications were reviewed if applicable, and their reference lists were used to collect additional articles as needed. Final article inclusion was based on senior author discretion.

Key Content and Findings: The AMS800 AUS is the gold standard for male stress incontinence implants. A 2015 consensus conference set out the goals for sphincter device development in the coming decades. A future ideal sphincter would adjust cuff pressure dynamically as well as function with minimal manipulation, or even via electronic control. Multiple new devices are in various states of development. During the next decade, artificial urinary sphincter technology is likely to include multiple Food and Drug Administration (FDA)-approved devices with varying features aimed at satisfying the 2015 consensus conference goal for an "ideal" AUS.

Conclusions: The future of stress incontinence therapy lies in both continued innovation for the AUS, as well as advances in regenerative medicine. Electronic and adaptive developments in AUS technology will increase device safety, efficacy, and longevity while improving the user and caregiver experience. For some, regenerative medicine may even make AUS technology obsolete.

Keywords: Electronic artificial urinary sphincter (electronic AUS); male stress urinary incontinence (male SUI); adaptive pressure regulation; app-based interface

Submitted Dec 24, 2022. Accepted for publication Jun 16, 2023. Published online Jun 30, 2023.
doi: 10.21037/tau-22-858
View this article at: https://dx.doi.org/10.21037/tau-22-858

Introduction

Efforts to augment sphincter function to ameliorate stress urinary incontinence (SUI) likely predate our first official record of an occlusive periurethral cuff described by Foley in 1947 (1). The contemporary iteration of the artificial urinary sphincter (AUS), the AS721, was first implanted in 1973, interestingly in a female myelomeningocele patient (2). The AS721 was the first commercially available implantable sphincter to create circumferential pressure around the urethra or bladder neck designed to restrict incontinence secondary to sphincter deficiency. The

Table 1 Search strategy summary

Items	Specification
Date of search	Multiple searches were conducted from 8/12/22 to 2023
Databases and other sources searched	Medline online retrieval system
Search terms used	"Artificial urinary sphincter" "electronic" "complications" "history" "development"
Timeframe	1940 to 2023
Exclusion criteria	Excluded non-English studies
Selection process	Dr. Kaufman and Dr. Koch conducted two independent searches and combined the results
Any additional considerations, if applicable	References lists of any relevant articles were also used to compile potential sources for this article

technology was born in intense collaboration between urology, neurology, and engineering. This basic mechanism, involving a cuff, a reservoir, an inflation pump, and a deflation pump, evolved out of decades of substantial effort on bulbourethral compression balloons and the application of silicone elastomers originally developed for the space program (3,4). The AUS has endured through time as the gold standard treatment for male SUI.

While several contemporary innovations in AUS technology have improved both device efficacy and complication rates, the basic technology in use in Boston Scientific's AMS800 can be traced back to the fundamental hydraulic tenets of the AS721 (5). Even the components of the AMS800 differ only in the replacement of the AS721's deflation pump with the AMS800's pressure-regulating balloon (PRB). When the scrotal pump of the AMS800, which lies in series between the cuff and the PRB, is cycled, it pumps fluid into the PRB against its native pressure gradient, thereby drawing fluid out of the urethral cuff. The PRB then passively empties fluid back into the urethral cuff via the scrotal pump as it returns to its resting pressure (6). Research and development in adaptive technology and electronic integration to automate some of the AMS800's manual mechanisms stand to further improve AUS outcomes and widen its surgical indications in the coming decades. Finally, novel regenerative therapies aim to eventually replace the AUS through the repair and replacement of damaged native urinary sphincter musculature. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-858/rc).

Methods

The Medline online retrieval system was queried using the MeSH terms "artificial urinary sphincter", "electronic", "complications", "history", and "development" in various combinations to identify articles for this narrative review. Publications were reviewed if applicable, and their reference lists were used to collect additional articles as needed. Final article inclusion was based on senior author discretion. Articles not primarily written in English or with an available translation were excluded. A search strategy summary can be found in *Table 1*.

Goals of AUS innovation

The fundamental aspects of the AUS have endured through the decades, enhancing the quality of life for a vast number of patients. Given the efficacy and durability of the foundational design, contemporary AUS innovation has expanded to include further improving the user experience and increasing the eligible patient population. As such, some thoughtful discourse was promoted by the AUS Consensus Group outlining potential features of an "ideal" AUS to include:

(I) Easy manipulation and deactivation;
(II) Modifiable urethral cuff pressure following implantation;
(III) Adaptive cuff pressure;
(IV) Simple, robust design;
(V) Minimally-invasive implantation;
(VI) Cost-effective (7).

One of the essential components the committee outlined

for the "ideal" AUS included improved ease of manipulation for both patients and caregivers. Currently, patients and caregivers cycle and deactivate an implanted AUS through manual subcutaneous pump manipulation, which can be limited by both poor or deteriorating dexterity or cognitive function (8). This is often difficult due to the mobility of the pump under lax scrotal skin. It can be painful if not cycled gently and can be both physically challenging and embarrassing for less experienced caregivers. AUS control via an electronic remote or smartphone application would reduce the burden of decreased patient dexterity or cognitive function.

Remote AUS control would also open the door for a more customizable device. The current sphincter allows for cuff pressure adjustment at the time of implantation through multiple options for the resting cuff pressure, mediated by the PRB. However, postoperatively, the urethral cuff will always reflect the static pressure generated by the chosen PRB when not actively being cycled or deactivated. Remote control of the device with an electronic interface may allow for the utilization of both timed/scheduled cuff-pressure mediation as well as activity-responsive cuff pressures. Allowing patient control over timed deactivation, or even a "low pressure" mode would give the urethra a release from the tonal pressure of the current AUS without sacrificing incontinence outcomes as the patient would be able to time the decreased cuff pressure during periods of supine rest. Adaptive cuff pressure adjustments would work in reverse, sensing increased intraabdominal pressures and temporarily increasing the AUS cuff pressure to reduce leakage in times of high exertion. Although data regarding the benefits of selective deactivation or adaptive cuff pressures are early and inconclusive, the concept of selective deactivation and adaptive cuff pressures may theoretically improve device survival without a decrease in efficacy (9). Both of the features were cited by the panel as necessary in the "ideal" AUS.

Focus on improving mechanical longevity has been another area of focus in AUS innovation. Although the current AMS800 enjoys incredible durability for a decades-old design, the short-term complication rate of AUS implantation is reportedly as high as 21% based on surgical approach. Most complications are associated with known intraoperative or postoperative events such as hematoma formation and wound infection (10). Linder *et al* demonstrated in an AUS cohort with a median follow-up of 4.1 years, that the most frequently reported long-term complication was mechanical failure in 14.8% of patients (11). While less common, device infections and erosions (8.2%) and sub-cuff urethral atrophy (8.2%) often present in follow-up as recurrent incontinence. Although infections, erosions, and atrophy can be treated with device removal and replacement, long-term lower urinary tract dysfunction secondary to erosions and infections can persist and even potentiate end-stage-bladder in rare cases (12).

While historical reports indicate that all-cause rates of revision increase by 5% for every year the device has been implanted, Deruyver *et al* recently described a revision-free device survival rate of 62% at 5 years (13). In a 2015 meta-analysis, the average revision rate was increased by almost 20% (19.8% to 37.3%) for patients with a history of prior radiation, but more recent studies report the difference in device survival rates to be much smaller, albeit still significant (14,15). These improvements in more contemporary cohorts may be secondary to improved surgical technique (e.g., "no-touch technique") or device improvements (e.g., Inhibizone coating).

Given the high patient satisfaction rate for the AUS, patients commonly opt for device revision in the setting of mechanical failures or complications (16). Reports comparing outcomes of primary AUS implantation versus revisions have demonstrated that although device survival may decrease for revisions (61% *vs.* 74% at 5 years), patient satisfaction remains exceptionally high (17). The AUS Consensus Conference suggested efforts to decrease mechanical dysfunction may include one-piece, pre-filled devices to limit discrepancies in techniques as well as exploration of non-hydraulic mechanisms of action.

Minimally invasive surgical approaches have become the norm for many aspects of Urology, including Reconstructive Urology. Because most perioperative complications are thought to stem from technical surgical errors, technical adaptations to reduce human error may also be at the forefront of AUS innovation (10). Endeavoring to advance robotic procedures for bladder neck placement, thereby decreasing skin incisions for perineal placement was brought to the forefront by the committee.

Finally, in the era of cost containment in medicine, the promotion of devices with the least economic burden to the health system should be considered (7). Widespread adoption of such technologies will then be feasible from a global perspective, allowing service to many marginalized populations with limited access to innovation. In addition to these market factors, variations in government regulations have allowed innovative devices to emerge in select markets, making vigilance for prosthetic surgeons and their patients regarding outcomes even more pronounced (18).

Table 2 Contemporary artificial urinary device developments

Company/device	Novel/unique features	Potential advantages
Boston scientific: AMS800	Personal device integration for bluetooth control	Long-standing data on device reliability from which to add electronic integration
Montreal AUSs	Pump systems can be retrofitted onto the AMS800	Long-standing data on device reliability from which to add electronic integration
	Dual manual and electronic control options	Failsafe in the event of electronic malfunction
	Adaptive pressure regulation	May allow for periods of urethral rest
	Rechargeable battery	
UroMems	Wireless control	Device control not limited by dexterity
	Adaptive pressure regulation	May allow for periods of urethral rest
ARTUS	Adaptive pressure regulation	May allow for periods of urethral rest
GASS	All-in-one components	Simplifies implantation by decreasing component connections
Dualis Artificial Sphincter	Wireless control	Device control not limited by dexterity
	Adaptive pressure regulation	May allow for periods of urethral rest
	Second "safety" pump	Failsafe in the event of electronic malfunction
FlowSecure	Stress relief balloon	Simplified mechanism for adaptive pressure regulation
	Fluid adjustment port	Allows for in-office tonal pressure adjustment
	All-in-one components	Simplifies implantation by decreasing component connections

AUS, artificial urinary sphincter; GASS, German artificial sphincter system.

Contemporary developments

A staggering array of possibilities exist to enhance the current occlusive artificial sphincter prosthesis. An exceptional and comprehensive evaluation of the engineering design parameters for the spectrum of commercially available unconventional activation technologies is presented by Marziale *et al* with select devices and additional emerging technologies outlined in the following section (19).

While the experience with the innovative devices outlined below in human subjects is limited, it promises the potential of exciting new advancements in AUS technology. Should the improved AUS features deliver on their potential, the ability of the cuff to sense pressure exerted upon the urethra and the freedom of implanters to modify the fluid volume in-office may enhance both the efficacy and mechanical longevity of the device. With patient-centered developments in remote activation of the pump via a wireless interface on the horizon, patient adoption and ease of utilization will undoubtedly expand. However, the added complexities of electronic integration with developing AUS technology may increase the risks of complications or new types of electromechanical malfunction. Contemporary developments in AUS technology are outlined below and in *Table 2*.

Montreal AUS

Capitalizing on technological innovations such as Bluetooth communication, novel designs for the classic hydraulic mechanical sphincter with regard to remote control alternatives were pioneered by the Montreal group in 2017 (20). Three distinct options for modifications of the control system of the current AUS were explored, preserving the occlusive cuff and PRB. In these designs, in lieu of the system that transmits pressure, the balloon serves only as a fluid reservoir. In sophisticated *in vitro* and *ex vivo* model systems, the authors pioneered pump systems that would be compatible to retrofit onto the current AUS800. The first concept (termed AUS #1) was designed to replace the pump with a unidirectional, magnetically controlled pump. A

piezoelectric micropump and hydraulic resistor are mounted in parallel with a primary lithium battery designed to last for 16 years with an average of 7 micturition cycles per day. The sphincter is operated by advancing a small neodymium magnet to the switch and is confirmed with sound. Several prior magnetically actuated devices have been proposed; however, such technologies may be limited by the ease of utilization, efficacy, and lack of MRI compatibility (21).

A second iteration was proposed with the manual pump in parallel for dual safety parameters allowing both manual and electromagnetic deactivation (20). Designated AUS #2, this device integrates a Bluetooth communicating microcontroller to actuate a latched microvalve. The rechargeable lithium battery for this unit is designed for a 41-day life span between charges. This system is additionally designed to be mounted in parallel with the traditional scrotal pump. The third system, AUS #3, is both remote-controlled and adaptive to alterations in transmitted pressure. (20) The device incorporates continuous pressure regulation, wireless communication, and a wireless power delivery system based on an inductive power standard. A centrifugal pump and latched solenoid microvalve deliver capacity via Bluetooth integration for fast pump cycling via the reservoir of fluid housed in the PRB. The rechargeable lithium battery associated with AUS #3 has a theoretical lifespan of 10 months between charges. Each of these devices was tested and determined to display appropriate functionality and pressure transmission with *in vitro* and an *ex vivo* pig bladder model. All three iterations of the AUS control pumps were able to sustain appropriate occlusive cuff pressures and are a powerful platform for further innovation to retrofit onto the contemporary AMS800 pump and PRB.

UroMems

Exciting progress is evolving regarding the UroMems artificial urinary sphincter (eAUS, UroActive™), a novel implantable with a wireless control component. In addition to allowing remote operation, the system is a genuine active implantable, employing a technology termed myo-electrical mechanical system (MEMS) to accommodate transmitted urethral pressures dependent on patient activity. Preclinical data was presented in an animal model with 14 implants (22). The control unit for the device, which is composed of a reservoir, automatic pump, and electronic components, was placed in a right-sided submuscular location. Outside of a solitary infection, no device-related complications were noted with function noted for all implants.

Adjunct data on urodynamic parameters in human cadavers compared the UroMems device to the AMS800 (23). Mean urethral closure pressures in this model accommodated ranges covered by the entire suite of PRBs for the AMS800, demonstrating wide latitude in the ability to set and modify the occlusive pressure of the UroMems sphincter to tailor for an individual patient.

The prospective open-label feasibility trial designed to enroll 6 adult males and assess safety and efficacy was opened in the fall of 2022 with multiple sites in France. (First-in-human Study to Assess the UrOMems Artificial Urinary sPHincter In the treAtment of Stress Incontinence, ClinicalTrials.gov Identifier: NCT05547672).

ARTUS

With the concept of electronically modulated intermittent urethral compression, the ARTUS™ (Affluent Medical SA, Aix-en-Provence, France) device has undergone pre-clinical testing, including cadaver implantation in both genders (24-26). The adaptive cuff responds to changes in abdominal pressure and is manipulated with an external remote control. The modular system is based on the development of shape-memory alloys (SMA) which are capable of shape alterations based on temperatures. The sphincter consists of multiple wires placed along the urethra which exert variable and periodic compression to allow areas of rest and theoretically diminish complications associated with chronic pressure-related changes resulting in ischemia and allow tailoring to patient requirements accomplished via physician programming at follow-up (27). The first feasibility trial of the device included 3 female patients with temporary bladder neck implants which completed enrollment in 2018. (Feasibility of ARTUS MONO Artificial Urinary Sphincter Implant in Women, ClinicalTrials.gov Identifier: NCT03703843). Affluent Medical is embarking upon a complex clinical trial for bulbar urethral implantation for regulatory approval with current sites in Spain and Czechia, although records at the time of this writing indicated the study is not yet recruiting. [ClinicalTrials.gov Identifier: NCT04827199, Safety and Clinical Performance Study of the ARTUS® AUS (DRY)]. Of note, this final device is not MRI-compatible, which may limit utility in certain populations.

German artificial sphincter system (GASS)

Multiple iterations of a teleautomatic prosthesis for both

urinary and fecal indications have been pioneered as the GASS (28). The device pump is driven by piezoelectric crystals which can be induced to change physical form, thereby activating the hydraulic mechanism, based on the application of an electrical stimulus via the battery. This integrated, modular, electronically actuated device has an admirable range of potential applications and is currently being developed first for fecal stress incontinence. The current iteration, GASS III, incorporates all the components, the micropump, regulator, microprocessor, batteries, and telemetric control components, into a single casing (29). The advantage of this "all-in-one" implant lies in the ease of implantation surgery which involves no tubing or component connections, decreasing the opportunity for intraoperative complications and subsequent mechanical failure (30). Pilot *in vitro* studies are encouraging and translation of the engineering feats to patient application is eagerly anticipated.

Dualis artificial sphincter

In cooperation with the Fraunhofer Research Institution for modular solid-state technologies (EMFT), Dualis Medtech (Seefeld, Germany) has been endeavoring for a decade to develop an electronic pump for the AUS. Based on the company's proprietary wireless energy and data transfer technologies, the device has promise for automatic pressure adjustments. Published data regarding the device is not currently available, but the patent application granted in 2018 (patent number: 10154892) indicates that in addition to the electrical pump, a second emergency pump is incorporated as a safety measure.

FlowSecure AUS

Although not an electronically actuated device, the FlowSecure AUS does offer pressure-sensing technology which may serve as a platform for other technologies. The FlowSecure AUS relies on a similar apparatus to Boston Scientifics AMS800 save for a second PRB ("Stress relief balloon) lying in series with the rest of the hydraulic system. This second balloon is placed pre-peritoneally and transmits transient increases in intraabdominal pressure, reflected due to its proximity to the peritoneal space, to the AUS cuff. The FlowSecure device is also designed for in-office fluid adjustments to tailor to specific patient continence severity and boasts an "all-in-one" design that requires no tubing connections during placement (31). Unfortunately despite multiple potential improvements over the AMS800, data on the efficacy and durability of FlowSecure devices is lacking without a report within the last 10 years.

Boston scientific

The current AMS800 device is manufactured by Boston Scientific who acquired the technology upon the dissolution of American Medical Systems. Although there is sparse information publicly available regarding their electronic AUS program, the company reports they have made significant investments to develop the technology, and working prototypes of the eAUS have been manufactured and tested (personal communication). Notably, baseline information regarding the efficacy and safety of the current iteration of the device is fundamental to allowing innovation in the current regulatory environment. As such, a large-scale clinical trial has just completed enrollment, potentially in anticipation of setting parameters appropriate for eAUS trials and eventual approval in the United States [Artificial Urinary Sphincter Clinical Outcomes (AUSCO) ClinicalTrials.gov Identifier: NCT04088331].

Future considerations

From a design perspective, future innovations may implement materials and technologies that more accurately replicate the function of the native urinary sphincter. Contemporary research and development have been generally focused on alternative methods of device activation to take advantage of novel electronic pressure sensing, pumps, and actuators which can be coupled with wireless technology. Additionally, numerous energy innovations will likely drive future development. Recent innovations include the development of a phantom model demonstrating a unidirectional communication path for an active implantable AUS that is responsive to human signals such as discrete pressure on the abdominal wall for activation (32).

Regenerative technology

The newest frontier of therapy for SUI centers on regenerative medicine with cell-based therapies. Stem cell therapies have the potential to restore the external sphincter (striated muscle) and internal sphincter (smooth muscle), as well as the neuromuscular synapse and blood supply (33).

Stem cells are the foundation of cell-based strategies and

are categorized as either embryonic or adult stem cells (34). As there is continued scientific and ethical debate regarding the use of pluripotent embryonic stem cells, current cell-based therapies proposed for SUI utilize somatic multipotent stem cells derived from various adult tissue types. These cells are terminally differentiated and serve as progenitor cells for the renewal of local tissues *in situ*. Several different cell types have been considered in SUI management in both animal and human studies, including bone marrow mesenchymal stem cells, adipose-derived stem cells, umbilical cord blood stem cells, autologous total nucleated cells, and muscle-derived cells (35).

Contemporary clinical trials for urinary incontinence involve the injection of stem cells into the striated urethral sphincter with the goal of regeneration of the natural continence mechanism. As opposed to our current treatment options for SUI which manage the symptoms, the aim of cell-based therapies is to truly reverse the primary pathophysiology of intrinsic sphincter deficiency (ISD) thereby treating the cause of SUI.

Most research and clinical trials regarding regenerative cell-based therapy for SUI have focused on autologous muscle-derived cells for urethral sphincter regeneration (AMDC-USR). Autologous muscle-derived cells are harvested from skeletal muscle and delivered back into the external urethral sphincter after *ex vivo* expansion with the goal of regenerating the muscle, thereby restoring function and continence. Although the technology is nearing commercial application for female stress incontinence, AMDC-USR for male SUI following prostatectomy is currently undergoing preliminary investigation (clinicaltrials.gov: NCT02291432) (36,37).

Conclusions

The future of male SUI therapy includes technological advancements that will expand the eligibility for AUS implantation as well as increase device safety, efficacy, and longevity. For some, regenerative medicine may even make AUS technology obsolete. Such savvy technologic enhancements will inevitably deliver a positive impact on men with SUI and continue to substantially improve quality of life for decades to come.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editor (Eric Chung) for the series "50 Years Anniversary of the Modern Artificial Urinary Sphincter" published in Translational Andrology and Urology. The article has undergone external peer review.

Reporting Checklist: The authors have completed the Narrative Review reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-22-858/rc

Peer Review File: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-858/prf

Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-22-858/coif). The series "50 Years Anniversary of the Modern Artificial Urinary Sphincter" was commissioned by the editorial office without any funding or sponsorship. MRK receives honoraria from Boston Scientific to teach at resident and fellow educational course, but this did not support this review article in any way. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Cite this article as: Koch GE, Kaufman MR. The electronic artificial urinary sphincter: ongoing innovation of a classic device—a narrative review. Transl Androl Urol 2023. doi: 10.21037/tau-22-858

