Review Article

Narrative patent review of penile clamp, artificial urinary sphincter, and sling innovation in the management of male stress urinary incontinence

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Background and Objective: Stress urinary incontinence (SUI) is the involuntary loss of urine affecting 1–3% of the male population. To manage leakage, patients may try a plethora of penile clamps. and may even consider artificial urinary sphincters (AUS) or sling implantation. We aimed to synthesize the evolution of the modern clamp, AUS, and sling through a comprehensive patent search.

Methods: Patents were found through the databases of United States Patent and Trademark Office (USPTO), GooglePatents, and the World Intellectual Property Office Patentscope, covering patents published through January 6, 2024.

Key Content and Findings: We found 30 different patents (10 clamps, 13 AUS, and 7 slings), including the patents pertaining to the functionalities and design of five commercially available penile clamps, the American Medical System 800 (AMS 800), the InVance, AdVance, AdVance XP, and Virtue Slings. The clamps, spanning back to 1938 with Bard Cunningham's clamp, have undergone significant refinements. For example, inventors such as Edson S. Outwin and Juan F. V. Wiesner, have modified the location of the primary pressure point. Accessibility has also improved with inventors, such as Gerald French and John W. Timmons, fastening the clamps with Velcro®, as opposed to the screw and ratchet catch closing mechanism, as in Cunningham's clamp. Similarly, the AUS has greatly evolved since Foley's 1947 "Artificial Sphincter and Method", which was the primary AUS precedent to Mark Polyak's AUS invention, which covered the essential elements and functionalities, such as the incorporation of a balloon reservoir, for the AMS 800. In addressing AUS limitations, inventors such as David W. Anderson and Louisa Thomas have created non-hydraulic AUSs. Likewise, the male sling has seen an evolution in the method of securement, from the use of fixed bone anchors in the InVance sling to the transobturator route used in the AdVance XP, avoiding bone complications. Additionally, innovation in sling adjustment of urethral compression allows for adjustable urethral elevation and distal compression respectively. Recent patents have claimed technological integration for clamps, AUS, and slings, especially concerning automation.

Conclusions: Overall, patents have built upon the limitations of previous devices. However, there is still a need to innovate for increased clamp comfort and reduced reoperation rates for the AUS and sling.

Keywords: Male stress urinary incontinence (male SUI); penile clamp; artificial urinary sphincter (AUS); slings; male incontinence management

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Introduction

Background

Stress urinary incontinence (SUI) is the involuntary loss of urine due to physical activity, such as sneezing and coughing, which affects around 1–3% of the male population (1). One of the more common irreversible causes of SUI is having undergone varied treatments for prostate cancer, benign prostatic hyperplasia or following benign prostate enlargement due to bladder outlet obstruction (2,3). Other secondary causes of male SUI include iatrogenic injuries and neurological disorders (2). For patients with SUI, the American Urological Association (AUA) first recommends a medical evaluation including a physical exam and possible ancillary testing to match each individual to an appropriate treatment (4). Per the AUA, conservative therapies include lifestyle changes such as weight loss and pelvic floor rehabilitation exercises (4). The severity of SUI can be evaluated using adult briefs (diapers, pads), which absorb patients' leakage and can therefore help doctors monitor responses to conservative treatments. However, if these therapies do not manage leakage effectively for extended periods of time, patients are referred to a urologist for further assessment. Recommendations at that point may include occlusive penile clamps or surgical treatment options-the most common being the artificial urinary sphincter (AUS) or surgical sling placement (4).

In addition to the profound impact on quality of life and mental health, SUI management incurs a financial burden. The cost of diapers is not covered by Medicare, although there are some options to help relieve some of the financial burden such as a Medicaid waiver program and diaper banks (5). There are financial costs associated with medical evaluation and the currently available treatments as well. Physical therapy has inconsistent insurance reimbursement (6), and there is a cottage industry of penile clamps and containment devices, which are not covered by insurance. Typically, the cost of an AUS, the gold standard surgical treatment, is between 10,000 to 25,000 USD (5). Sling placement can also cost as much as $5,000 for the procedure alone (5).

Highlight box

Key findings
- We identified 30 different patents—10 pertaining to clamps, 13 to artificial urinary sphincters (AUS), and 7 to slings—for males in managing stress urinary incontinence.
- Five clamps are commercially available and Mark Polyak's 1989 "Artificial Sphincter" pertains to the American Medical System 800 (AMS 800).
- Clamp innovation has refined the method of closing the device and where the primary pressure point is with the aim to improve accessibility and comfort.
- AUS innovation since 1938 has seen modifications in the modern equivalent of a pressure-regulating balloon and the variability of conduits with the aim to improve accessibility.
- Clamp and AUS patents have filed claims for wireless automation.
- Slings have evolved anchorage and urethral compression methods. Innovation to include hydraulic pressure mechanisms, similar to the AMS 800, can be seen in some slings.

What is known and what is new?
- Patients try a plethora of clamps as part of their first-line treatment and if they are candidates, may opt for the AMS 800 or sling surgery options.
- No paper has conducted a patent review of penile clamps, AUS, and slings to synthesize the evolution of these devices and gauge where these devices are going to be innovated for the future.

What is the implication, and what should change now?
- Penile clamps, AUS, and slings have evolved greatly, but there remains a need for innovation. Currently, inventors are looking how to integrate cutting-edge technologies in these devices to improve patient outcomes.

Rationale and knowledge gap

Given the clear influence of incontinence on patients' health and finances, there have been attempts to innovate solutions that are better at decreasing leakage, more comfortable, and more cost-effective, such as reducing failure and dissatisfaction for SUI patients. Most patients will try a plethora of clamps as part of their first line treatment to SUI (7). Furthermore, The AUS remains the most popular surgical solution for incontinence and the development of the modern artificial sphincter is a remarkable engineering achievement, despite its flaws (8). As the sling is also a recommended treatment, we also aimed to synthesize its evolution, especially with many different variations (4). There have been no previous studies conducted on the

Table 1 The search strategy summary

Items	Specification
Date of search	January 6, 2024
Databases and other sources searched	United States Patent and Trademark Office (USPTO), GooglePatents, and the World Intellectual Property Office Patentscope
Search terms used	Stress urinary incontinence NOT drugs NOT pharmaceuticals NOT female NOT vaginal NOT prevention AND device AND leakage
Timeframe	Until January 6, 2024
Inclusion and exclusion criteria	Publicly available and English. Female SUI and pharmacological solutions were excluded
Selection process	Titles and full-text patents were screened by two independent reviewers (A.J.S. and A.S.S.), and any disagreements were resolved by consulting a third author (E.Y.W.). Full patents were then analyzed by two reviewers (A.J.S. and A.S.S.)
Any additional considerations, if applicable	Senior author supplemented us with one filed, but not published patent. And some patents were found from references within patents we found in our search

SUI, stress urinary incontinence.

patent evolution of penile clamps, AUS, and male sub urethral slings published.

Objective

This study thus aimed to aggregate the previous, current, and future technological solutions in the penile clamp, AUS, and male urethral sling categories for male SUI. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-24-115/rc).

Methods

We aimed to synthesize the evolution of penile clamps, AUS and sling through a comprehensive patent search to gauge the areas these devices have improved upon, but also possible future directions (*Table 1*). We used the databases of the United States Patent and Trademark Office (USPTO), GooglePatents, and the World Intellectual Property Office Patentscope, covering patents published through January 6, 2024. We queried the terms "stress urinary incontinence NOT drugs NOT pharmaceuticals NOT female NOT vaginal NOT prevention AND device AND leakage" in looking for patents related to SUI treatment devices. Titles and full-text patents were screened by two independent reviewers (A.J.S. and A.S.S.), and any disagreements were resolved by consulting a third author (E.Y.W.). Full patents were then analyzed by two reviewers (A.J.S. and A.S.S.). Additional relevant patents were discovered through references of "prior art" in patents or via senior author review (A.J.C.) who had access to a not publicly assessable provisional patent treating SUI that had been filed. Given the nature of this review, the study was deemed Institutional Review Board (IRB) exempt.

Results

We found 30 patents: 10 clamps, 13 AUS's, and 7 slings (*Figure 1*). The clamps spanned from 1938 with Bard Cunningham's clamp to the 2021 Pacey Cuff (Figure S1). Of these ten clamps, five are still commercially available. Initial conception of the AUS began in 1947 with Frederic E. B. Foley's "Artificial Sphincter and Method" and its limitations were built upon by inventors such as Robert E. Buuck, Robert E. Trick and John Burton (Figure S1). Mark Polyak's "Artificial Sphincter Device", patented in 1989, covers the functionalities and methods of constriction of the American Medical System 800 (AMS 800), the most widely used AUS (9). Due to the high failure rates of the AMS 800, inventors have continued to modify the hydraulic AUS and even invent more mechanical AUS. Regarding slings, the evolution of male urethral slings, began in 1960 with John L. Berry's (10) fix-anchored non-adjustable sling and has since evolved to Coloplast Corp.'s Virtue (Minneapolis, USA) hybrid quadratic sling or Arnal and Siegal's 2005 sling, which incorporates hydraulic elements, similar to the AMS 800. These changes aim to reduce reoperation rates. In chronological order, and connecting to modern SUI treatment options, we will describe the evolution of penile clamps, AUS's, and slings as dictated by the 30 different

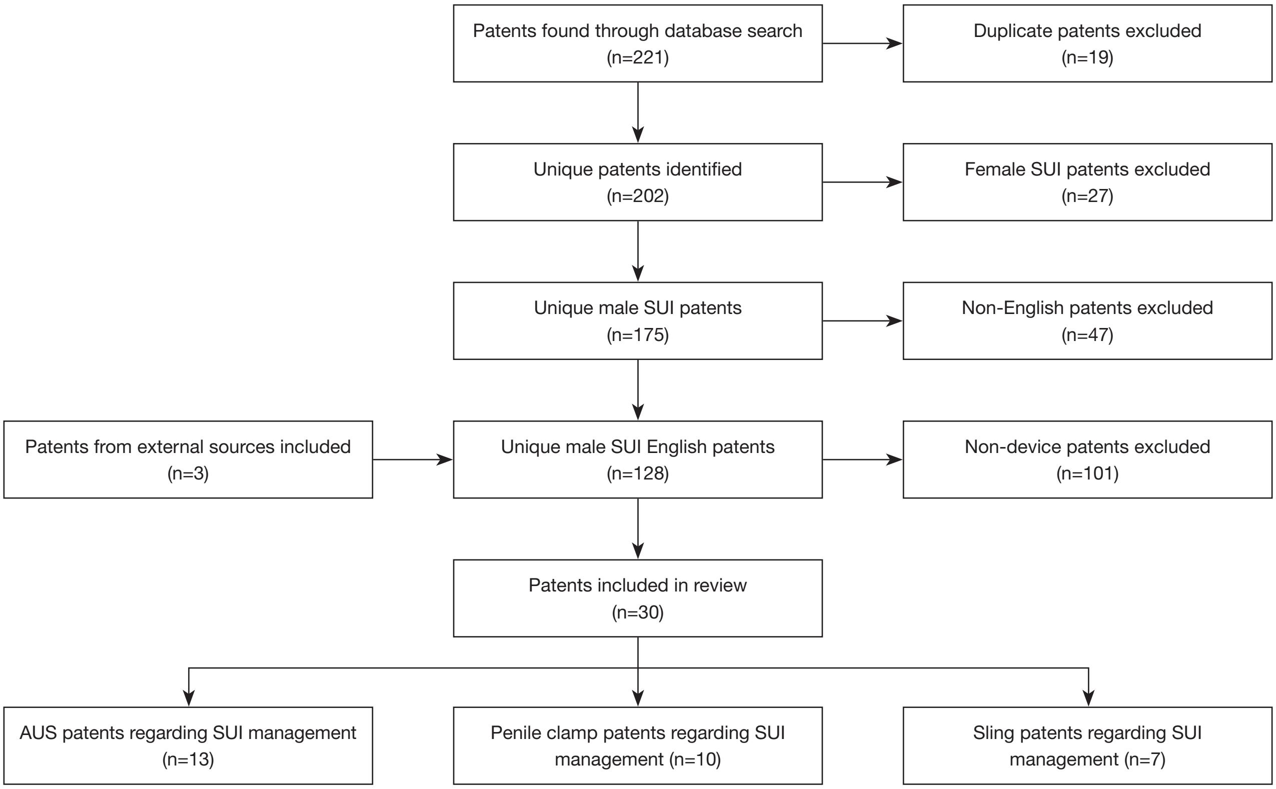

Figure 1 Schematic of patent search conducted for male stress urinary incontinence management devices. Two hundred and twenty-one patents were identified from patent databases and were filtered out for any patents that were duplicates, regarding female stress urinary incontinence, or if not in English. We then screened out any non-device related treatments and added three more patents to review, which were noted from author knowledge (A.J.C.). Thirty total patents with thirteen pertaining to artificial urinary sphincter, ten pertaining to clamp innovations, and seven pertaining to slings were included in this review. AUS, artificial urinary sphincters; SUI, stress urinary incontinence.

patents we found.

Evolution of penile clamps

Bard Catalog of Urological Instruments in 1938 discussed the invention of the Cunningham clamp (*Figure 2A*) (11). The Cunningham clamp has two foam pads that apply pressure to the urethra and penile shaft from opposing sides (11,12). It has a ratchet catch to adjust pressure in five different settings and is commercially available for patients in three different sizes.

While the Cunningham clamp is the earliest penile clamp innovation, it was not patented. Our patent search resulted in ten different clamps, with the first US patented penile clamp being in 1963 (12). The first officially patented penile clamp from our search was filed by Edson S. Outwin in 1963 (*Figure 2B*). Although he did not cite this specifically as a solution for SUI, inventing it for those with "paralyzed bladders", it is precedent for many of the SUI clamps currently used and patented (13). Tourniquets had been proposed as being able to stop urinary leakage, but, as Outwin describes in his patent, these tourniquets were not able to apply enough pressure to the urethra, but even applied too much pressure to the corpus cavernosum, causing artificial erections (13). Another concern in designing a clamp device was in catering size and shape to different patient morphologies, and thus Outwin's clamp consists of two "pad" parts where the first pad is directly adjacent to the urethra and then one is opposed (13). The pads are held in place by a flexible material strip that wraps around the shaft and is secured in place by Velcro® (13).

In 1964, Jay A. Bialick filed for an "Incontinence Clamp device" which sought to improve upon the Cunningham and Outwin clamps (*Figure 2C*) (14). He aimed to create a penile device that, like its precedents, applied pressure to the urethra on opposing sides but included a jack screw

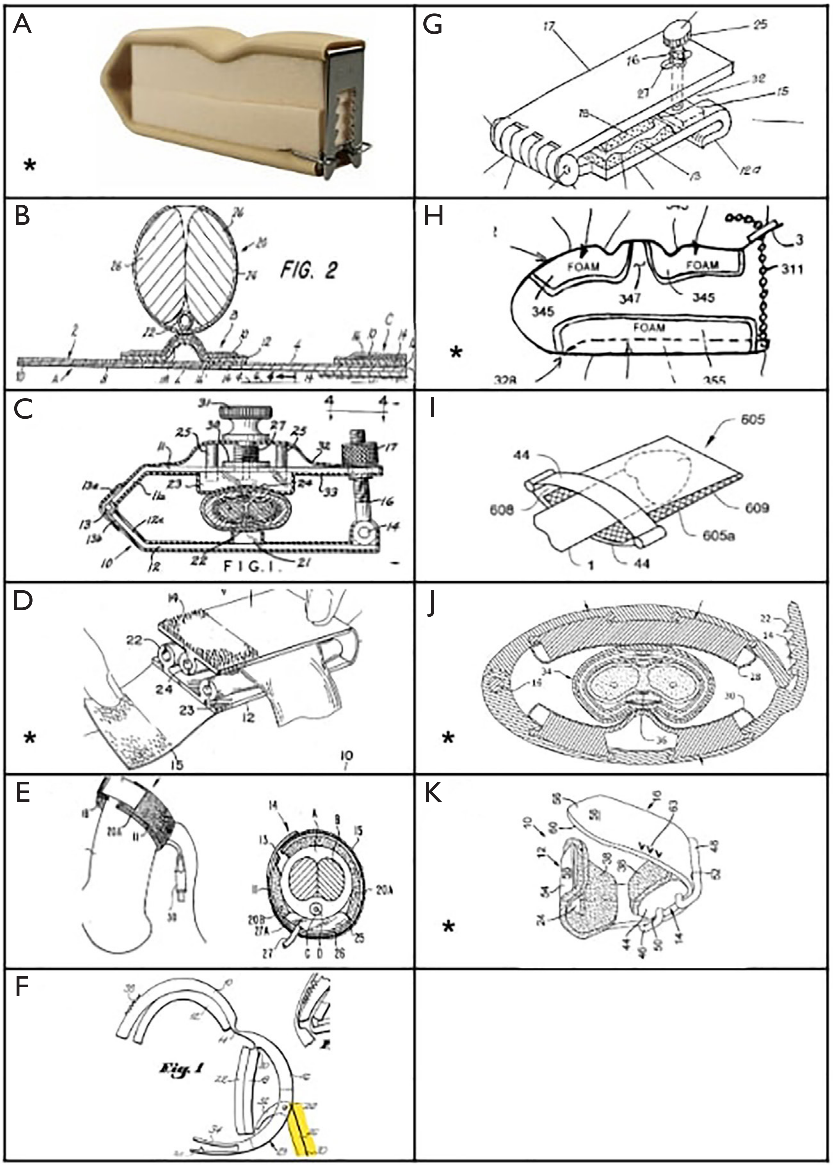

Figure 2 Evolution and design variations of penile clamps for male stress urinary incontinence management. The matrix depicts the progression of penile clamps developed for the management of male stress urinary incontinence from 1938 to 2021. *, indicates commercial availability of the device. The notations in the device images are sourced from the patent and are not indicative of any findings. (A) Bard Cunningham clamp (1938): penis is inserted between the foam pads with pressure applied from a metallic ratchet catch perpendicular to the direction of urine flow. Commercially available. (B) Outwin's Male Incontinence Clamp (1963): clamp portrayed in open position with the penis placed directly above the primary compression point. Not commercially available. (C) Bialick's Incontinence Clamp Device (1965): clamp portrayed in a closed position with a jack screw applying pressure to the penis perpendicular to the direction of urine flow. Not commercially available. (D) Baumrucker Incontinence Device (1975): clamp folds closed with three primary pressure points applied to the sides and underside of the penis, secured by Velcro® strap. Commercially available. (E) French External Strap Incontinence Control Device (1987): clamp portrayed in the closed position, applying a uniform circumferential compression to the penis via a magnetic urethral valve. Not commercially available. (F) Timmons External Incontinency Device (1990): clamp portrayed in the open position, designed to apply pressure to the urethra using a rotating lever highlighted in yellow. Not commercially available. (G) Chadwick Clamp (1995): clamp portrayed with a screw-fastened hinge mechanism applying pressure to the penis perpendicular to direction of urine flow. Not commercially available. (H) Squeezer Klip™ (2002): clamp portrayed in the closed position with three pressure points, designed with gap in top foam pads to avoid pressure on arteries and veins of penis shaft. Commercially available. (I) Anderson and Timm Penile Compression Device (2007): device portrayed in closed position with absorbent pads and indented circular compression. Not commercially available. (J) Wiesner Incontinence Clamp (2020): clamp portrayed in the closed position with silicone pads and one primary contact point on the urethra. Commercially available. (K) Pacey Cuff Ultra (2021): clamp portrayed in the open position with an adjustable strap to direct pressure to the urethra. Commercially available.

and thumb note mechanism instead of the ratchet catch to improve comfort (14). This device did not include any sort of foam or sponge rubber, unlike the Outwin and Cunningham clamps did in the pads, as this foam or sponge material flattens over time and is hard to clean (14).

Baumrucker in 1975 created a clamp with three pressure points, creating an S shape when clamped down, that would be better for patients with lower hand dexterity or disabilities than the Bialick clamp (*Figure 2D*) (15). Their S shape design disclosed applying pressure in opposing sides of the penis but with two pressure points on one side and one on the other (15). They also claimed this would reduce adverse side effects such as necrosis and, as with the Outwin clamp, used Velcro® for both accessibility and comfort (15). In working to design a device that is even more intuitive for patients, and requires even less fine motor skills, Gerald French in 1987 filed for the "External Strap Incontinence Control Device" (*Figure 2E*) (16). This clamp uses a magnetic urethral valve to manually clamp shut. However, during urination, if there is sufficient pressure applied by the urethra, the clamp can then open.

Similarly, following this trend of moving towards design, John W. Timmons in 1990 filed for his "External Incontinency Device" (*Figure 2F*) (17). Timmons' design included a rotating lever that could be rotated 30 degrees from the clamping to non-clamping positions, allowing urination without removing the device (17). As with the Cunningham clamp, Timmons included a ratchet design, but he also incorporated a pinch guard (17).

Six years later, Dale A. Chadwick filed his version of the clamp in trying to improve upon previous clamps (*Figure 2G*) (18). Namely, he wanted to find a new way to fasten the clamp other than a ratchet recess clamp or Velcro®, as in the Outwin clamp, as this material is susceptible to wear down over time with lint interference (18). However, unlike the Bialick design, he wanted the device to be applicable with only one hand for easier urinal usage (18). Thus, using nonporous materials to allow easy cleaning, he created a screw-fastened hinged clamshell clamp (18). The screw has a spring for quicker release, making urination easier (18).

In 2002, Singer and Cochrane filed their patent for the Squeezer Klip™, which followed the Baumrucker clamp in having three pressure points (*Figure 2H*) (19). However, they modified the Baumrucker clamp so that they avoid applying pressure on the superficial dorsal vein, deep dorsal vein, lateral superficial veins, and dorsal arteries and veins of the penis shaft, in hopes to prevent discomfort (19). They claim that their device can reduce leakage by 1–6% of total urine output, again, through applying pressure to the urethra (19). To fasten, the user adjusts a threaded adjustment knob, which can be harder for arthritic males or patients with overall low hand dexterity (20).

Anderson and Timm patented a clamp in 2007 and their novelty came in the inclusion of an absorbent component to hold excess leakage and a distinct overall clamp shape (*Figure 2I*) (20). Their clamp is circular but has one indented part which primarily applies pressure to only the urethra portion of one side of the shaft (20).

The Wiesner Incontinence Clamp was patented in 2020 by Juan F. V. Wiesner (*Figure 2J*) (21). This clamp includes Polyvinylsiloxane pads, and as they explain in their patent, these can cause irritation to the skin and release oil that acts as a lubricant and causes the clamp to slip off. This clamp has an upper and lower clamp arm, and a ratchet catch hinge pivotally connects them with four settings (21). The upper arm has a curved concave inner surface with the goal to allow "correct blood circulation" and maximal comfort (21). The lower arm in the middle is curved convex to apply pressure to the urethra specifically (*Figure 2J*) (21,22). This clamp can be commercially obtained, and Wiesner claims it is the lightest and smallest clamp on the market (22).

In 2021, Pacey Medtech Ltd. (Vancouver, BC, Canada), invented a clamp that unlike many of its precedents, specifically the Cunningham clamp and Squeezer Klip, does not apply directly opposed pressure (*Figure 2K*) (23). It includes a single-use foam that can allow for size adjustment and a dorsal hood and urethral compressor which distribute pressure across the shaft (*Figure 2K*) (23). They also wanted a device that could be used during sexual activity and not constrict arterial blood flow. Their patent including sensors in their urethral compression pads and the dorsal hood to track pressure, which they said could be useful during the treatment recovery period after prostate resection. They also patented an embodiment of their clamp that would allow the user to remotely adjust the pressure or even make the sensors pulse oximeters or thermometers that can monitor oxygen saturation and/or temperature. They also claim that unlike many of the precedents, their device can be worn at all times without compromising vascular supply to the penis or increasing risk of necrosis. This device can be commercially purchased.

Evolution of modern hydraulic AUS

In 1947, Frederic E. B. Foley filed the "Artificial Sphincter and Method" (*Figure 3A*) patent targeted as a general

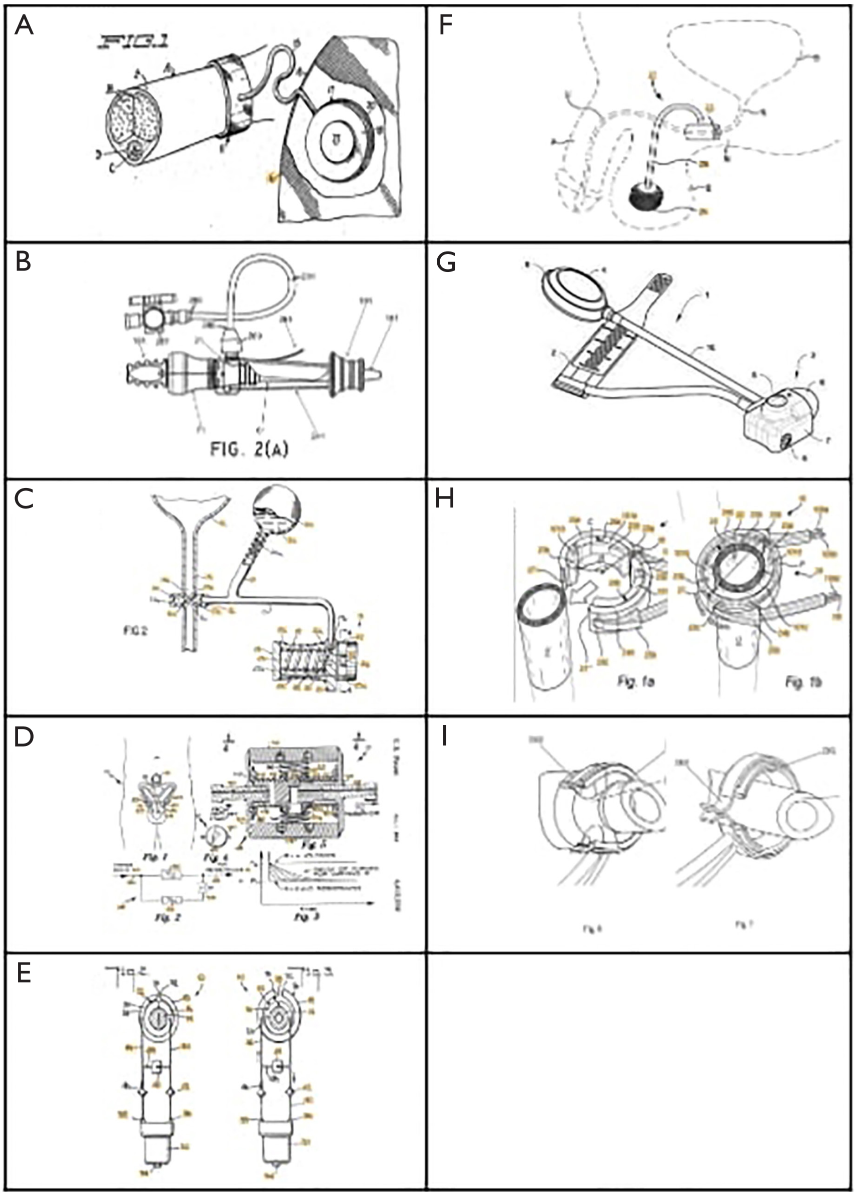

Figure 3 Evolution and design variations of hydraulic artificial urinary sphincters for male stress urinary incontinence management. The matrix depicts the progression of hydraulic artificial urinary sphincters developed for the management of male stress urinary incontinence from 1947 to 2023. None of the above are commercially available but have components included in the AMS 800. The notations in the device images are sourced from the patent and are not indicative of any findings. (A) Artificial Sphincter and Method, FEB. Foley (1947): fluid activated clamping ring applied to a penis with a control unit placed in the clothing pocket of the user. (B) Incontinence System and Methods of Implanting and Using Same, RE. Buuck (1975): implantable inflatable cuff unit placed on the urethra with an inner adjacent bulb that can be squeezed by the user to pump fluid from the reservoir to the cuff. (C) Apparatus for Reversibly Closing a Body Passage, RE. Trick (1983): similar implanted inflatable cuff unit around the urethra with a push-actuated button. (D) Dual-mode Valve Pressure Regulating System, J. Burton (1983): four-valve system with two stage unit to control output of fluid shown in body. (E) Artificial Sphincter Device, M. Polyak (1989): C-shaped reservoir ring with resistor and conduits portrayed in the closed (left) and opened (right) position. (F) Method of Treating Urinary Incontinence by Implanting a Reservoir Around a Urethra of the User, S. McClurg (2013–2019): artificial Urinary Sphincter with bulb-type reservoir component replaced with additional storage component in the cuff shown implanted with a conduit between the cuff and pump. (G) Hydraulic Urethral Occlusive Device, DW. Anderson (2016): occlusive cuff shown connected to a control mechanism via a conduit tube. (H) Implantable Device for Internal Urinary Control, P. Forsell (2021): operable hydraulic constriction element shown around the urethra in the unapplied (left) and applied (right) position. (I) Urinary Incontinence Automatic Control System Having Multi-Point Alternate Switching Function, S. Wu (2023): automatic control system with a constricting element shown around the urethra in the open (left) and closed (right) position.

artificial sphincter for "animal bodies" (24,25). Foley's invention was ineffective as it lacked a pressure-regulating mechanism or reservoir (24,25). His invention included an inflatable cuff, detachable pump to be stored in the patient's pants pocket, and a surgically inserted internal catheter. However, it was missing the modern equivalent of the balloon reservoir, which allows restriction of compression around the anterior urethra (24,25).

Robert E. Buuck was in 1975 motivated by the limitations of the clamps, notably the Cunningham clamp, and Foley's invention to invent "Incontinence System and Methods of Implanting and Using Same" (*Figure 3B*) (26). This was one of the first internal surgical device patents in the creation of the AMS 800, the most used AUS in the US (26). Buuck includes an inflatable cuff unit with both a rigid and a deformable wall. The relatively rigid wall would have threads that project out with end portions that connect around an excretory vessel in the body-in this case it would be around the urethra (26). The deformable wall can be controlled and would be against the vessel with a reservoir filled with fluid and inner adjacent bulbs that the user can squeeze to pump fluid between the cuff and reservoir (26).

In 1983, Robert E. Trick filed for "Apparatus for reversibly closing a body passage" and revised upon Buuck with push button actuation (*Figure 3C*) (27). However, it has a similar expandible reservoir for the pressurized fluid and with tubing attached to the cuff and reservoir, forming a "closed system" (27). Similarly, in 1983, John Burton built on Buuck's work and filed for "Dual-mode valve pressure regulating system", which was specifically meant for urinary incontinence (UI) (*Figure 3D*) (28). He replaced the four-valve system with a valve controlling output with a two-stage valve unit with a cracking valve and a holding valve (28). The holding pressure is described as the pressure to "maintain continence" while the cracking pressure is the threshold upon which damage to the bladder can occur (28). The flow resistor is in parallel with the cracking valve and in series with the holding valve and this acts as a buffer pressure zone (28). The cracking valve also allows for urination where fluid can rapidly enter the reservoir again (28).

In 1989, furthering hydraulic AUS progress, Mark Polyak filed for "Artificial Sphincter Device", which includes an inflatable cuff surrounded by a C-shaped reservoir ring (*Figure 3E*) (9). There is a resistor that controls the flow between the cuff and the reservoir and three different fluid transmission lines (conduits) (9). The important distinction between this AUS and many of its precedents is that it does not require a bulb reservoir, as those must be separately implanted, so this AUS device should have faster operation and recovery times (9,28). As the reservoir ring does not expand as much as reservoir bulbs, the use of the reservoir ring reduces the damage to the tissue surrounding the implant compared to other devices that use bulbs. A version of the device patented also includes a heating circuit within the ring. This patent covered the methods and functionalities of the AMS 800.

The AMS 800 is currently the gold standard AUS (8). However, there is a device failure rate of around 28.5%, with these patients requiring reoperation (8). Thus, there remains a need for additional innovation, fueling the following inventions. Failure of the pressure regulating balloon is often a cause of recurrent incontinence, and thus reoperation (8). As a result, from 2013 to 2019, Steven McClurg filed variations of "Method of treating urinary incontinence by implanting a reservoir around a urethra of the user" (*Figure 3F*) (29-32). In this AUS system, there is no pressure-regulated balloon (more officially called a bulb-type reservoir), and instead it has been replaced by an additional storage component in the cuff. This embodiment of the AUS, McClurg claims, can also be used in female patients if implanted in the labia instead of the scrotum, and the benefit of having this smaller AUS device is that it is "*easier to implant and offers a quicker recovery time from the implantation surgery*" (32). This embodiment includes a conduit between the cuff and pump, allowing suction to change the configuration of the cuff from the opened to closed positions.

In 2016, David W. Anderson filed for "Hydraulic Urethral Occlusive Device", which utilizes an occlusive cuff connected to a control mechanism via a conduit tube (*Figure 3G*) (33). One of their invention targets was to design an AUS that would be easier for patients to operate because in other models, there is a small lockout valve in the scrotum that was hard for some patients to operate (2). In the constricted, or occlusive, position, there is a preset tension applied to the flexible diaphragm with a constant force spring within the control mechanism (33).

Peter Forsell filed for "Implantable device for internal urinary control" in 2021 (*Figure 3H*) (34). The implant consists of at least one operable hydraulic constriction element, the inflation of which can be determined through a controller. The integration of the fluid conduit into the support elements allowed for less protruding parts, thus reducing the risk of damaging the urethra (34). The first and second urethra contracting elements comprise of two separate hydraulic constriction elements, while the third urethra contracting element consists of a cushioning element (34). Closure of the device cuff occurs with an external magnet (34). In one embodiment, the device is also capable of wireless automation (34).

The most recent AUS designs involve the incorporation of controllers that open and close the urethral opening. In 2023, Shuangchen Wu published a design that featured remote controlled opening and closing of the urethra with two 'C' shaped urethra blockers surrounded by a support ring (*Figure 3I*) (35). The intracorporal microcontroller electronically connects to an alarm system that emits a signal whenever any abnormalities are detected, with an option to connect to a Bluetooth and/or Wi-Fi module (35).

Overview of non-hydraulic AUS innovation

Although not as popular, there also exists non-hydraulic AUS such as Gerald Timm's 1998 "Vessel Occlusive Apparatus and Method", which was invented as hydraulics may not provide uniform pressure when inflated and can cause urethral erosion after extensive usage (*Figure 4A*) (36). His invention includes a partially elongated cuff around the urethra which can be implanted using minimally invasive methods and tightened with a pulley and coil method (36). The implant is around 100 grams and should require minimal dexterity to operate and may even be electromagnetically controlled (36). In 2000, David W. Anderson and Gerald W. Timm similarly patented a mechanical AUS which includes an intrinsic spring force around the urethra, applying pressure (*Figure 4B*) (37). A control mechanism can be manipulated to relieve pressure when the user wants to urinate. They claim only one surgical incision would be required to implement the device with no intra-operative assembly needed (37). They also note the cuff is narrower in this AUS iteration than in the hydraulic ones, so less tissue dissection is required and there is future possibility of automation (37).

A hybrid hydraulic and mechanical AUS was also invented by Christophe Gomez-Llorens in 2010 and is a surgical implant with an inflatable cuff element that inflates in response to fluid pressure (*Figure 4C*) (38). The cuff is connected to a pressurized tank that uses hydraulics to expand, connected to a catheter between the control unit and the inflatable unit (38). The control unit is connected to a hand-operated pump (38). This patent specifies advantageous use in "*artificial urinary sphincter for men or women*, *artificial anal sphincter*, *artificial pylorus or esophagus sphincter or to constitute a gastric band*" (38).

Another mechanical method of occluding the urethra is demonstrated in "Vessel Occlusive Apparatus and Method" published in 2011 by inventors David W. Anderson and Gerald W. Timm (*Figure 4D*) (39). Initial tension on the urethra or chosen vessel is applied through a tensioning suture and can be decompressed using the control mechanism (39). Additionally, it allows drug elution to prevent infection. and while the patent does not specify sphincters, it does generalize use of the device for any vessel (39).

The most recent mechanical clamp we found was filed for in 2022 by Thomas *et al.* titled "Shape Memory Alloy Urethral Continence Device" (*Figure 4E*) (40). This device can be surgically implanted through an incision under the scrotum and the novelty of this device comes from the shape memory alloy (40). This alloy is held in place by a resin sleeve and together, applies pressure around the urethra. This metal piece includes a power source that can apply a current through external wiring, though in some embodiments it could be wireless and activated by Bluetooth. This current will increase the temperature of the clamp, activating the shape changing metal and thus allow the pressure to be relieved and urination (40). The return to ambient body temperature returns the device to the clamped shape configuration, providing continence. This device follows the trend of the most recent AUS and clamp inventions of integrating technological claims.

Evolution of slings

Nonadjustable slings

In 1960, John L. Berry filed for his "Apparatus for Control of Urinary Incontinence", patenting the first male urethral sling (10) (*Figure 5A*). He describes surgically inserting a support muscular or fascial sling between the bulbocavernosus muscle and the urethra to apply pressure to the urethra (10). Using four strands of steel wire looped through each corner, the prosthesis is fixed in a surgically prepared pocket, permanently anchoring the prosthesis in position (10). Joseph J. Kaufman in 1972 described the "Kaufman I–III Procedures", a revision of the Berry procedure, in which he attempted to correct post-prostatectomy incontinence by providing upward compression on the bulb of the urethra via the crura of the penis (41).

Early sling-innovation can be characterized as fixed and non-adjustable, often requiring an additional procedure to make minor adjustments to the pressure exerted on the urethra to control unintentional voiding. These slings are anchored to

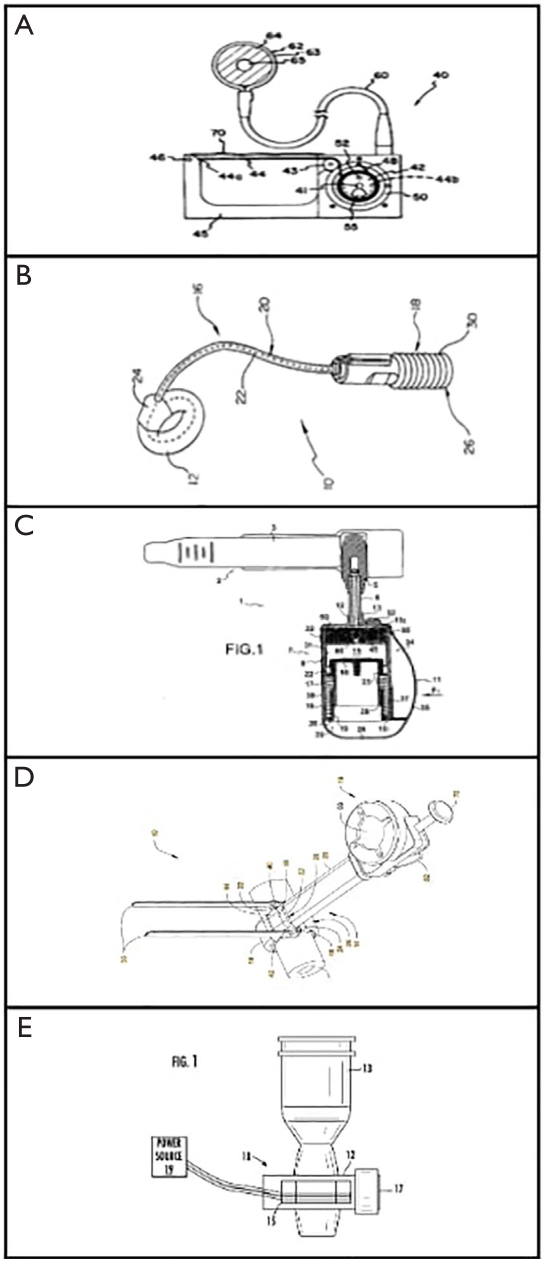

Figure 4 Evolution and design variations of non-hydraulic artificial urinary sphincters for male stress urinary incontinence management. The matrix depicts the progression of nonhydraulic artificial urinary sphincters developed for the management of male stress urinary incontinence from 1998 to 2023. None of the above are commercially available. The notations in the device images are sourced from the patent and are not indicative of any findings. (A) Vessel Occlusive Apparatus and Method, GW. Timm (1998): pulley and coil mechanism depicted used to tighten the urethra. (B) Vessel Occlusive Apparatus and Method, DW. Anderson and GW. Timm (2000): artificial urinary sphincter depicted with an intrinsic spring mechanism which applies pressure to the urethra. (C) Surgical Implant, In Particular Artificial Sphincter with Adjusted Pressure, C. Gomez-Llorens (2010): hybrid mechanical and hydraulic Artificial Urinary Sphincter shown with a pressurized tank that responds to fluid pressure to constrict the urethra. (D) Vessel Occlusive Apparatus and Method, DW. Anderson & GW. Timm (2011): system depicts a tensioning suture that can respond to a control system to decompress and compress accordingly. (E) Shape Memory Alloy Urethral Continence Device, L. Thomas *et al.* (2022): a shape memory alloy is connected to a power source that conforms in shape at varying temperatures when a current is applied, affecting the pressure applied to the urethra.

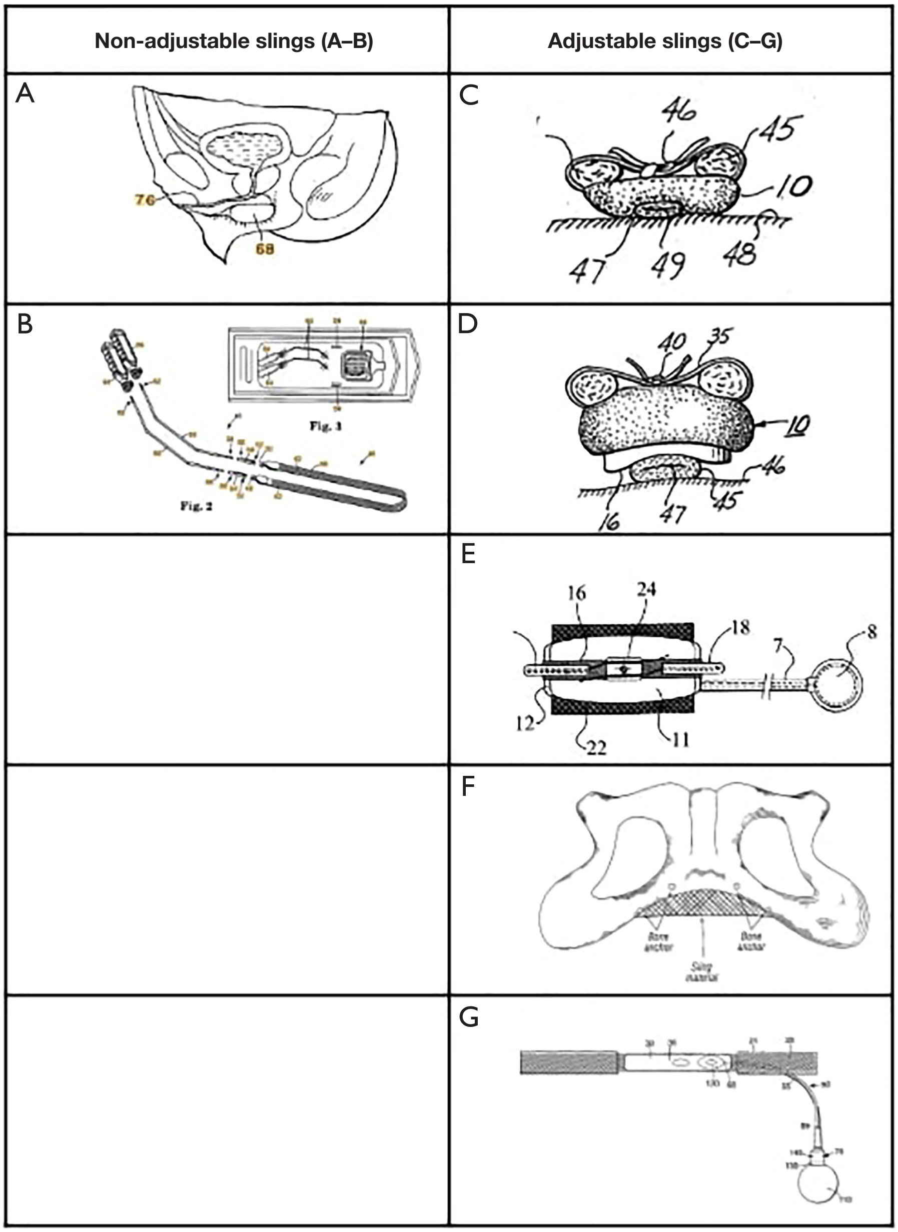

Figure 5 Evolution and design variations of non-adjustable and adjustable slings for male stress urinary incontinence management. The matrix depicts the progression of non-adjustable and adjustable male slings developed for the management of male stress urinary incontinence from 1960 to 2009. None of the above are commercially available. The notations in the device images are sourced from the patent and are not indicative of any findings. (A) Apparatus for Control of Urinary Incontinence, JL. Berry (1960): prosthesis shown positioned in a surgically created pocket between the bulbocavernosus muscle and urethra. (B) Transobturator Surgical Articles and Methods, KA. Anderson (2003): transobturator path needle guide depicted with corresponding sling kit. (C) Urethral Prosthesis, R. Schulte (1974): fluid-impervious gel capsule prosthesis shown closing the lumen of the urethra. (D) Compression Implant for Urinary Incontinence, MB. Fitzgerald (1977): cavity formed by cap, base and wall, filled with an adjustable amount of fluid shown applying pressure to the urethra. (E) Device for the Height-Adjustable Fixing and Support of Internal Anatomical Organs, JM. Gil-Vernet (2000): side view of adjustable sling with fastening of suspension threads depicted. (F) Method and Apparatus for Correction for Gynecological Pathologies Including Treatment of Female Cystocele, S. Raz (2003): view of sling location, bone-anchor fixation points and sling material used in accordance of this invention. (G) Male Urethral Prosthesis, K. Arnal & S. Siegal (2005): urethral prosthesis with inflatable pillow attached to substrate depicted.

the bones of the pelvis by the use of at least one bone screw. The use of bone-anchored male slings (BAMS) has progressed to the modern InVance Male Sling of American Medical Systems (AMS) in which the silicone-coated polyester sling is secured to the descending pubic ramus (42). However, BAMS have seen a decreased favorability due to risk of bone-infection and increased complication rates, even leading to the removal of the InVance sling from the market (43).

The introduction of transobturator slings securely provides support to the urethra without requiring bone-anchorage. In "Transobturator surgical articles and methods", Kimberly A. Anderson discusses a transobturator tissue path, in which the sling, via a guide needle, is passed through the obturator foramen, an opening in the pelvic bone (44) (*Figure 5B*). While this patent specifically discusses female SUI, this pathway has applications to male SUI (44). This approach minimizes the risk of bone-related complications and simplifies the surgical procedure when compared to BAMS (44). The AdVance sling of Boston Scientific (formerly AMS, Livonia, USA) is the modern progression of transobturator male slings, replaced on the market by the AdVance XP in 2010 (45). Like its precedents, the polypropylene mesh AdVance sling follows a transobturator surgical insertion route with the improved AdVance XP sling including additional directional chevron anchors for fixation (45).

As a hybrid of its transobturator and bulbourethral sling precedents, the Virtue sling was introduced by Coloplast Corp. in 2009 (43). This non-adjustable sling has two transobturator arms, two pre-pubic arms and a polypropylene mesh sling. The Virtue sling is able to provide elongated urethral compression using the two transobturator arms to provide ventral urethral elevation and the two pre-pubic arms to provide distal compression (43).

Adjustable slings

In 1974, Rudolf Schulte patented "Urethral Prosthesis" which was invented for both female and male patients with UI (46) (*Figure 5C*). It comprises of a fluid, flexible, and deformable capsule with a gel-filled or liquid-filled cavity therein, inspired by the AUS (46). A cover encapsulates the capsule and is connected to two flexible sling times that extend beyond the cover (46). Unlike the AUS though which wraps around the urethra, the deformable capsule will just press against the urethra (46).

Another iteration of a sling with a fluid component was patented three years later by Martin B. Fitzgerald in 1977 (47) (*Figure 5D*). His "Compression Implant for Urinary Incontinence" includes a cap with an external planar pressure face and a base with an external bearing face (47). There is also a wall that connects the cap and base (47). The cap, base, and wall form a cavity that can be filled with an adjustable amount of fluid (47). This was one of the first innovations with a method of adjusting the force against the urethra after implantation (47).

In 2000, Gil-Vernet reports a "Device for the height-adjustable fixing and support of internal anatomical organs" for "*adjusting the height of internal anatomical organs*", which although not invented specifically for SUI was a precedent in how to vary volumes in implants (48) (*Figure 5E*). Gil-Vernet's invention includes a chamber that allows for fluid volume to be varied with a capsule connected to it with a tube. There are threads around the capsule that attach to the organ that should be "adjusted in height" (48).

Similar to the how the AMS 800 can use hydraulics to exert pressure, Raz *et al.* invented a female UI sling, that can vary these volumes using hydraulics, which inspired future male sling innovations (49) (*Figure 5F*). Raz, in 2001, invented a hydraulic female sling to treat female cystocele. Raz *et al.* filed for a "hammock-like" sling that would be positioned between the descending rami of the pubic bone (49). As in the AMS 800, their sling includes an inflatable balloon device that passively compresses on the bulbar urethra to prevent leakage (49). The balloon's volume could be adjusted by the patient even after implantation (49).

Inspired by Raz, in 2003, Arnal and Siegal filed for "Male Urethral Prosthesis". This sling includes a "*substrate*, *an inflatable pillow attached to the substrate*, *a pressurized reservoir in fluid communication with the pillow and a restrictor*" (50) (*Figure 5G*). The pillow refers to a reservoir that can hold liquid or gas to exert pressure on the patient's bladder, preventing leakage (50). With this device, the inflatable pillow would be compressed causing the inflating agent (liquid or gas) to flow to the pressurized reservoir (50). With no compression, the inflating agent would return to the inflatable pillow (50). This sling also incorporates hydraulics to exert pressure on the bladder, like the AMS 800, but for male sling (50).

Discussion

In the past several decades, innovation in the landscape of treatment devices for male SUI has grown remarkably and this paper was the first patent review paper aiming to synthesize the evolution of male SUI management devices in the penile clamp, AUS, and sling categories.

As our understanding of the condition and patient-centered care further develops, new devices that attempt to overcome the multi-faceted challenges of SUI have been introduced, addressing where their precedents fell short. We thus found a clear trend of innovators designing based on previous innovation limitations. This review adopted a narrative approach to synthesize the historical and technological evolution of penile clamps, AUS, and slings. This approach allowed us to analyze the breadth and depth of advances over several decades, accommodating the flexible exploration of our findings from diverse patent and literature sources. Such evolution of devices can be seen in the penile clamp, from the progression of the 1938 Cunningham clamp which provided an undirected bilateral compression limit on the urethra and penile shaft to the more recent 2021 Pacey Cuff offering a more directed and distributed compression, even excluding the restriction of blood flow. Likewise, the AUS has seen similar progression from Foley's 1947 rudimentary external cuff/pump mechanism which lacked proper pressure regulation to the current gold standard surgically implanted, self-pressure-regulating AMS 800. The evolution of male urethral slings showcases a similar transformation from John L. Berry's fix-anchored non-adjustable sling to Coloplast Corp.'s Virtue hybrid quadratic sling, reducing the risk of bone-related complications through innovative securing techniques. These developments emphasize prioritization of user control, patient comfort, device efficacy, and longevity.

Despite the considerable progress in device research and design, the need for further innovation for ideal SUI treatment persists. Surgical management innovation can primarily be directed towards solution longevity and avoiding the need for revision surgery as seen in the failure rate of the AUS at 28% at 5 years, 46% at 10 years, 59% at 15 years, and 67% at 20 years (51). Additionally, the impacts of previous radiation treatment, a common adjunct to prostate cancer treatment, are a further detriment to device function and longevity (52). Similarly, sling failure rate is as high as 19.4% in general patients and in irradiated patients, as high as 50% (53). In regards to penile clamps, qualitative analysis of penile clamp reviews has shown that around 23% of patients negatively view the materials and comfort of the clamps currently on the market, continuing the need for clamp innovation (7). Also, as with all things in healthcare, accessibility of SUI management remains a critical concern as the financial burden imposed on SUI patients emphasizes the need for cost-effective solutions.

While the last century has seen the introduction and evolution of male SUI management devices, the integration of cutting-edge technologies in SUI management seems foreseeable in the coming years. Technology such as remote-sensing for leakage detection, adjustable self-actuating pressure mechanisms, and smart-device connectivity can provide additional user-control and keep the patient more informed of their device's condition. This integration can offer personalized treatment control, real-time monitoring, and improved patient outcomes. The ongoing refinement and development of SUI treatment devices will undoubtedly continue to improve the lives of men experiencing this condition, offering hope and improved care options in the years to come.

Limitations

Our narrative review process required extensive hand searching and database querying, a screening process subject to variability due to multiple reviewers and strategies. In our methods of database querying and excluding non-English patents for male SUI management, it is possible that relevant patents may have been unintentionally excluded. However, we were still able to evaluate the general trends in innovation and the patents pertaining to the functionalities and design of five commercially available penile clamps, the AMS 800, InVance Sling, AdVance Sling, AdVance XP Sling, and Virtue Sling. We also, for the inventions which did not make it to market, only had information from their respective patents. Thus, we could not determine why they did not make it to market.

Furthermore, the patents were narrative in addressing the previous limitations of predecessor inventions. Thus, this led to a narrative approach to our review, but was naturally informed by the narrative natures of the patents we reviewed.

Conclusions

Penile clamps the AUS, and slings remain the primary standard of treatment for male SUI, externally and internally respectively. Penile clamp innovation has persisted since the introduction of the Cunningham clamp in 1938, to the more recent Pacey Cuff in 2021. Primary areas of innovation in penile clamp devices can be seen in the location and distribution of pressure along the penis as well as the method of securing the clamp. Innovations of the AUS can be seen from Foley's 1947 cuff/pump mechanism to Polyak's 1989 rendition which has led to the current

AMS 800. Primary areas of innovation in AUS can be seen in modifying the pressure regulation mechanisms and the variability in the use of conduits. Since the adoption of the AMS 800, inventors have developed upon its failure-points and limitations. Primary areas of innovation in slings can be seen in modifying the means of adjustable urethral elevation and distal compression, as well as even beginning to integrate AUS's hydraulic elements. As with the AMS 800, inventors are aiming to targeting device failure and efficacy in their new inventions. Currently, five penile clamps included in our review are commercially available and one AUS and two slings are offered via surgical implantation. Recent and future innovations in male SUI management can be noted in the trend of integration with technology to allow as remote monitoring, self-regulation, and actuation. As seen in our evaluation of the different devices in male SUI management, there is a clear direction for innovation in the coming years to improve patient outcomes, accessibility, and comfort.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-24-115/coif). A.J.C. reports that he supplemented the patent search with one patent filed by him titled "Memory Shape Alloy". The other authors have no 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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