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INVITED REVIEW

Operational Andrology

# Future considerations in prosthetic urology

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Since their popularization, genitourinary prosthetics have remained a gold-standard therapy for the treatment of erectile dysfunction and stress urinary incontinence and in cases of testicular loss or dysfunction. They have also represented an area of significant innovation, which has contributed to excellent long-term outcomes. Given this history, the objective of the current review was to provide a 5–10-year outlook on anticipated trends and developments in the field of genitourinary prosthetics. To accomplish this objective, a PubMed and patent search was performed of topics relating to penile and testicular prostheses and urinary sphincters. In regard to penile prostheses, findings demonstrated several new concepts including temperature-sensitive alloys, automated pumps, devices designed specifically for neophalluses, and improved malleable designs. With artificial urinary sphincters, new concepts include the ability to add or remove fluid from an existing system, two-piece systems, and new mechanisms to occlude the urethra. For testicular prosthetics, future implementations may not only better replicate the feel of a biological testicle but also add endocrinological functions. Beyond device innovation, the future of prosthetics is also one of expanding geographic boundaries, which necessitates variable cost modeling and regulatory considerations. Surgical trends are also changing, with a greater emphasis on nonnarcotic, postoperative pain control, outpatient surgeries, and adjunctive techniques to lengthen the penis and address concomitant stress incontinence, among others. Concomitant with device and surgical changes, future considerations also include a greater need for education and training, particularly given the rapid expansion of sexual medicine into developing nations.

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## INTRODUCTION

Prosthetics have been available in some form dating to at least the 1500s, when hollowed out wooden splints were used to straighten the penis (likely for use with urination).<sup>1</sup> However, it is only in recent times when synthetic devices have been created to more closely mimic andrological functions. Beginning in the 1950s, an acrylic splint was first introduced to achieve erectile rigidity, with multiple improvements subsequently reported and novel surgical approaches and materials employed.<sup>2</sup> A significant advancement occurred in 1973, when Scott and colleagues reported both on an implanted inflatable penile prosthesis (IPP) and on an artificial urinary sphincter (AUS).<sup>3,4</sup> These advances resulted in the popularization and eventual mainstreaming of these procedures to a point where they remain the gold-standard therapy for refractory erectile dysfunction (ED) and male stress incontinence today. In contrast to the well-established history of penile and urinary prosthetics, much less is known about the origins and timelines of testicular prostheses, with surgical reports dating at least to the 1970s.<sup>5</sup>

Genitourinary prostheses also have a long history of excellent outcomes, including low complication rates and high patient satisfaction in contemporary series. Particularly in the case of IPPs, significant advancements in design and antimicrobial properties have reduced infection rates to the 2% range and improved mechanical reliability with an estimated 10-year survival rate of >80%.<sup>6</sup> Given the excellent track record to date, the question becomes, “what does the future hold for genitourinary prosthetics?” More specifically, what device improvements are expected, which surgical innovations are

trending, and what are international and financial considerations that are driving the overall development cycle? To address these questions, a PubMed search was performed using the terms penile prosthesis, urinary sphincter, and testicular prosthesis, with an emphasis placed on articles published since 2014. In addition, recent patent applications were also reviewed and summarized where available. The review will be outlined to discuss advancements and notable findings with penile, urinary, and testicular prostheses, followed by a discussion of recent surgical trends and patterns, and finally a discussion on ongoing needs and considerations. Regarding the topics addressed, there is no universally agreed upon definition of what constitutes a genitourinary prosthetic. For the sake of the current review, this was defined as a surgically placed, self-contained unit that replaces or restores genitourinary function and does not consist solely of a suture or mesh-like material. Urinary slings, mesh, patch grafts, and suture techniques were, therefore, all outside of the current scope. In addition, given the large number of implants currently available, the focus of the review was predominantly on novel devices or concepts, with some discussion of existing devices included to provide context and perspective.

## PROSTHETICS

### *Penile prostheses*

Penile prostheses have historically represented one of the largest areas of innovation within the andrological space. Notable landmark dates included the introduction of the antibacterial InhibiZone in

2001 (American Medical Systems, now Boston Scientific [BSCI], Marlborough, Massachusetts, USA) and hydrophilic coatings in 2002 (Mentor, now Coloplast, Humlebaek, Denmark), followed by the Momentary Squeeze (BSCI, 2006) and One-Touch Release (Coloplast, 2008) enhancements. Other advancements included the Conceal reservoir (BSCI, 2011) and 0° tubing with contouring of the distal prosthetic tips (Coloplast, 2012).

More recently, the BSCI announced the release of the Tactra device, a malleable prosthesis that incorporates a nitinol core to enhance axial rigidity and prevent buckling with penetration. The device also includes two layers of silicone and rounded distal silicone tips to better reproduce a more natural feel. The device is further able to better maintain a 90° bend, enhancing the underlying concealability. In addition, BSCI has submitted several patents over the past few years, which one might speculate would indicate plans to enhance current pump functionality. Specifically, patent application #14/863,965 describes a subamplifier that is designed to augment manual pressure applied to the pump. Moreover, patents #10285815, #9522065, #9889010, and #9808343 describe an automated pump system that uses an external control to help wirelessly generate the power necessary to activate the pump mechanisms. These innovative concepts and designs may potentially address one of the most limiting aspects of 3-piece devices, which is the need for manual inflation and deflation of the device. This is a particularly relevant issue among men with scrotal sensitivity, abnormal scrotal anatomy, or those who are unable to reach or fully inflate the pump. Coloplast has also applied for patents relating to improvements with insertion of the prosthesis itself, including application #9980722, which describes a locking needle to be used with the Furlow insertion tool. Although the specific role for the invention remains undisclosed, it may relate to facilitating needle passage during implantation and preventing inadvertent injury of surrounding tissues or the prosthetic itself.

Another innovative prosthetic device design involves the use of a nickel-titanium alloy that morphs between flaccid and erect states with increasing temperature. To provide the necessary elevated temperature for device activation, a magnetic induction coil can be externally applied, with resultant deformation of the materials into a straightened (erect) state.<sup>7</sup> As the device cools, it subsequently returns to its bent (detumesced) and more malleable state. An *in vitro* mechanical assessment of the device demonstrated the ability to support 2.6 kg of axial load in the straightened (erect) state, which was superior to inflatable prostheses (1.4 kg) and inferior to other malleable devices (6.5 kg).<sup>8</sup> The device also was shown to have significant durability, with the ability to repeatedly cycle between states without any noticeable structural deterioration.

The device does have a few notable limitations (logistical and otherwise) that would hinder its clinical utility. The current blend of alloys requires an increase of 10°C–15°C (18°F–27°F) to achieve straightening. This would, thus, require elevating and maintaining the temperature of the device to roughly 53°C (130°F), which is technically challenging to achieve. In addition, although *in vitro* assessments did not demonstrate histological damage, it is unclear how local tissues would be impacted by sustained elevated temperatures as well as regional spikes in temperature. Also, the logistics of maintaining an induction field close enough to the device to achieve the desired effect requires development. Despite these limitations, the underlying concept and technology for this novel prosthesis are intriguing and warrant further investigation. This is particularly the case given the many advantages that such a prosthesis would offer, including improved durability, negation of manual pump inflation, simpler fabrication, improved/equivalent rigidity to other devices, likely reduced infection

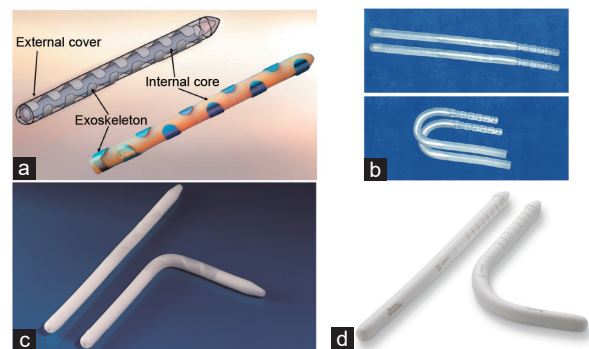
rate, simpler insertion, and obviation of reservoirs and associated complications, among others.

A newer introduction in the field of penile prosthetics is the Zephyr 475 (Zephyr Surgical Implants, Geneva, Switzerland). The device is currently not cleared by the US Food and Drug Administration (FDA), and only one study has reported outcomes to date. From a manufacturing standpoint, the Zephyr uses a 3-layer design with silicone and fabric which permits controlled girth expansion while purportedly limiting tunical herniation. In contrast to the BSCI and Coloplast devices, the Zephyr does not incorporate a one-touch release mechanism or antibiotic impregnation (directly or indirectly via coatings that uptake antibiotics), but is often less expensive than the more traditional 3-piece implants. The overall design is otherwise very similar to the BSCI and Coloplast devices, with two cylinders, pump, and a saline-filled reservoir. In a preliminary study of 28 men undergoing placement of the device (median follow-up of 35 months), 93% were revision free at most recent follow-up, and the overall satisfaction was 93%.<sup>9</sup> Another malleable prosthesis (ZSI 100) has also been introduced; however, no data on outcomes have been published to date. Given the preliminary nature of the data with Zephyr penile prosthetics in general, additional studies are required to assess how long-term outcomes compare to more established devices. **Figure 1** and **2** show images of the various malleable and inflatable penile prostheses.

An additional prosthetic worth mentioning is the Penuma silicone sleeve. Although Penuma does not function in a similar manner to the traditional penile prostheses and is not intended to augment erectile function, it is a surgically inserted prosthesis into the penis and is therefore appropriately classified in this section. The prosthesis consists of a sheet of silicone that is shaped as a 3/4 circumferential penile shaft and includes a Dacron mesh layer for silicone durability. The device has been registered with the FDA with an indication to use in the cosmetic correction of penile soft-tissue deformities. In a study of 400 men who underwent device implantation, the results demonstrated increased penile girth, self-confidence, and self-esteem (at 6–8 weeks postoperatively), with 81% of men reporting high or very high levels of satisfaction at a mean of 4 years postoperative.<sup>10</sup> Complications included seroma (5%), scarring (5%), and infection (3%), with no impacts on sexual function, erections, or ejaculation noted. Given its novelty, external validation and long-term outcomes are warranted.

#### Artificial urinary sphincters

Similar to IPPs, AUS devices have remained the gold-standard therapy for moderate-to-severe male stress urinary incontinence since their



**Figure 1:** Image demonstrating various existing and novel malleable penile prostheses. (a) Nickel-titanium alloy which deforms based on temperature changes; (b) Zephyr Surgical Implants, ZSI 100; (c) Coloplast Genesis; (d) Boston Scientific Tactra.

popularization. For several years, the only AUS available was the AMS 800, with long-term data demonstrating 57%–64% complication-free survival at 10 years and maintained functional improvements through at least 10 years.<sup>11,12</sup>

In 2005, the Zephyr ZSI 375 (Zephyr Surgical Implants) was released. In contrast to the AMS 800, the Zephyr device is a two-piece unit, with a pressure-regulating system integrated within the pump itself. The cuff and pump mechanism are otherwise relatively similar to the AMS 800. Very limited data are currently available on the Zephyr device. The results from the first study of 36 men reported social continence in 73% of men at 6 months and complications requiring removal in 11%.<sup>13</sup> Two subsequent studies ( $n = 63$  combined, median follow-up: 13.5–21 months) observed social continence in 58% of men, with complications relating to device defects in 6%–31%, infections in 0–15%, and an overall explantation rate of 24%–62%.<sup>14</sup>

More recently, a group from Montreal, Canada, reported outcomes of three modified AMS 800 devices.<sup>15</sup> All three incorporated an electronic pump to an unmodified pump and reservoir and were controlled with either an electromagnetic system or two versions of Bluetooth. *In vitro* functional outcomes demonstrated stable cuff pressures which provided a preliminary proof of concept. As with the potential IPP advancements, the introduction of a system that would not require manual pumping would represent a significant advancement in the technology. This would potentially increase the number of men who would be viable candidates for an AUS, would increase viable locations for surgical implantation (greater concealment), and could improve overall patient safety (autorelease options), among other benefits.

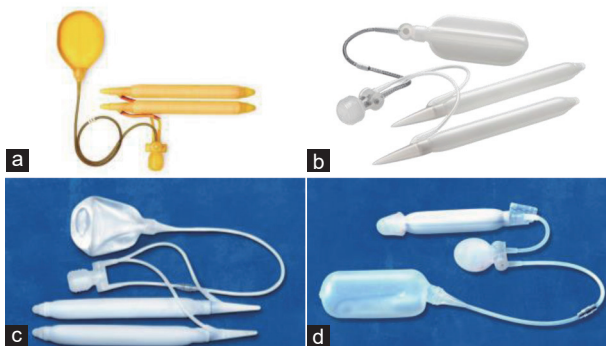
Another novel AUS system, the VICTO (single balloon; Promedon, Cordoba, Argentina) and VICTO-plus (double-balloon), was recently published in the *Central European Journal of Urology*.<sup>16</sup> Similar to the AMS 800, the system includes a cuff, pressure-regulating reservoir, and scrotal pump. However, it exhibits several notable differences/enhancements from the BSCI model, including the ability to add additional fluid percutaneously (pressure adjustment), 3.7 cm cuff option, more evenly distributed circumferential compression, dynamic pressure increases with Valsalva, and native configuration of an additional reservoir (VICTO-plus). The results of 25 men undergoing 15 VICTO and 10 VICTO-plus systems demonstrated improved continence with no complications requiring device explantation. However, it is notable that the findings are very preliminary, with only a few sentences on outcomes reported in the publication. **Figure 3** shows various AUS devices.

Although not as complex as the other devices mentioned, ProACT (men) and ACT (women; Uromedica, Plymouth, MN, USA) represent another implantable device that is designed to improve urinary incontinence. The system consists of a single inflatable balloon that is implanted bilaterally at the bladder neck or prostatic (or remnant) apex. The balloon is subsequently inflated at the time of surgery or later via a percutaneous approach using titanium ports in the scrotum or labia. In an initial evaluation of 117 consecutive men undergoing placement of ProACT devices, Hubner and colleagues reported that 67% of men were using one security pad or less after a mean of three adjustments.<sup>17</sup> A smaller study of 10 men postprostatectomy similarly demonstrated significant reductions in pad use (from 2.8 to 0.3 pads per day;  $P < 0.001$ ) and incontinence scores on standardized assessments.<sup>18</sup> To date, no direct head-to-head comparisons have been performed of the ProACT device and other methods of incontinence treatment.

It is likely that additional options will be available for the AUS device in the near future. In reviewing recent patents, there are multiple filings by Coloplast in the past several years. One notable contribution includes #15/153,737, which describes a urinary cuff and pump system wherein the fluid reservoir may reside in the cuff itself. As a two-piece system, this could potentially simplify the implantation of the device compared to other three-piece AUS devices. A second patent (#14/270,367) describes a novel method of urethral occlusion, wherein an iris-type “cuff” could be manually adjusted via the perineum to presumably increase the level of resistance achieved with the cuff itself. The most recent filing (#16/255,837) includes a novel cuff system that utilizes a backboard and a pair of endwalls to occlude the urethra. In addition to Coloplast, an additional patent was filed by several individuals in California (#15/076,973) and details a modified cuff system, whereby separate force members are able to shift between an open and closed state, resulting in direct compression rather than annular occlusion. The system is notable for the absence of internal fluid or the need for a pressure-regulating balloon. A follow-up patent by the same group (#16/159,280) provided additional details, wherein the device would be implanted on the inferior aspect of the bulbar urethra (in men) or on the superior side of the urethra (in women).

**Testicular prostheses**

Testicular prostheses represent a much simpler device compared to IPPs and AUSs and comprise a smaller market overall. These factors may help explain the relatively limited innovation which has occurred in this space compared to other prosthetics. Different prostheses are currently available internationally, including Torosa (Coloplast – only US FDA-



**Figure 2:** Image demonstrating existing inflatable penile prostheses. (a) Boston Scientific AMS 700; (b) Coloplast Titan One Touch Release; (c) Zephyr Surgical Implants ZSI 450; (d) Zephyr Surgical Implants ZSI FtM.



**Figure 3:** Image demonstrating existing artificial urinary sphincters. (a) Boston Scientific AMS 800; (b) Zephyr Surgical Implants ZSI 375; (c) Promedon VICTO; (d) Promedon VICTO-plus



approved device), Promedon (Endotherapeutics, Sydney, Australia), and Testi10 (Rigicon, Ronkonkoma, NY, USA), among others.

Outcomes of men undergoing testicular prostheses are excellent, although relatively few potential candidates ultimately undergo the procedures. A 2019 study of men with germ cell tumors who had undergone orchiectomy reported that 25% of men ultimately elected to receive a testicular prosthesis, although 42% indicated that they never recalled being offered a prosthesis by their practitioner.<sup>19</sup> Interestingly, although 90% of men were satisfied with the overall look of the prosthesis, only 59% were happy with the feel, suggesting room for further innovation. A second study confirmed high satisfaction rates (83%) and again highlighted that a large percentage of men felt that the device was too firm (44%).<sup>20</sup>

Although there have been relatively few novel concepts introduced in recent years, one notable innovation was reported by Chen and colleagues in 2017.<sup>21</sup> The authors described implantation of a dual-layer testicular prosthesis in rats that incorporated controlled-release testosterone undecanoate. The results showed equivalent testosterone levels in rats receiving the prostheses compared to those with the more traditional oral administration. Overall, the findings suggest a novel potential mechanism for testosterone supplementation; however, several key issues are outstanding, including the feasibility in humans, pharmacokinetics and dose delivery, duration of testosterone release, and changes that may occur with the prosthesis over time. **Figure 4** shows various testicular prostheses.

In reviewing patent applications for testicular prostheses, the most recent filing was in 2008 (by AMS – application #12/016,535) and describes an adjustable fill prosthetic that is otherwise similar to other implants. One notable mention from 2001 (#6620203) is a description of development of a bioengineered scaffold, upon which chondrocytes and Leydig cells could be applied, and wherein the interior may be filled with testosterone. However, given the time since filing without development and production, it is unclear if this latter device will ever become available for clinical use.

## CHANGES IN CLINICAL/SURGICAL PRACTICE

### *International distribution and cost considerations*

Although once limited to only a few countries, genitourinary prosthetics are rapidly becoming widely available. This “globalization” of the prosthetic market has led to strategic restructuring within prosthetic companies and has mandated a strategic emphasis on simpler and more cost-effective options. This is likely due to a lower “willingness to pay” threshold outside of wealthier nations, lack of government health-

care subsidization, and limited surgeon experience in placing more complex (e.g., three-piece IPP) prosthetics. The emphasis on lower cost alternatives has also led to a resurgence of publications reporting use of malleable penile prosthetics over IPPs, a trend which had not been seen in several decades. It is also evidenced by the first release of a completely redesigned penile prosthetic (Tactra) in nearly 20 years.

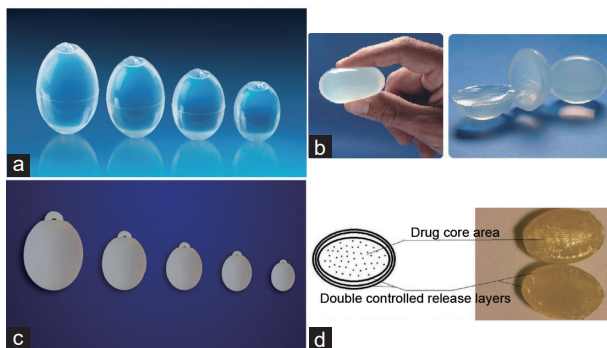
In addition to the impact of market factors, geographically variable governmental oversight and regulation has allowed innovative but relatively untested devices to rapidly emerge in select markets. The long-term impact of these lesser-established alternatives is unclear, although it is plausible that this would have a bipolar effect of yielding more rapid innovation while also leading to greater numbers of harms and complications. This may ultimately contribute to a growing trend of medical tourism for prosthetics, particularly given that many of the less well-established prosthetic companies may never choose to undergo the expensive testing required to enter the European and US markets. Physicians and patients will also need to be more keenly aware of inaccurate or deceptive marketing which may inappropriately extrapolate outcomes from the more established devices to those with few or no publications available. Without controls and oversight, these changes would be expected to lead to a new frontier, or “wild west” of sorts, with genitourinary prosthetics.

### *Clinical decision-making and surgical planning trends*

For the majority of cases, clinical decision-making patterns have remained unchanged over the past two to three decades. The one clear exception to this trend has been observed with penile prostheses. Particularly, since the introduction of phosphodiesterase-5 inhibitors (PDE5s) and intracavernosal injection therapies, penile prostheses were largely considered to be third-line options. However, the American Urological Association recently released an updated guideline on the management of ED and indicated, for the first time, that penile prostheses may be considered as first-line therapies.<sup>22</sup> It is unclear how this change in direction may impact the field of prosthetics in the short- and long-term, but it would be expected to increase the total number of prosthetic devices placed. In addition, the mean age for device placement may plausibly decrease over time, which may subsequently lead to a larger percentage of revision cases. It may also minorly impact health system finances, including insurance coverage and authorizations for coverage, particularly given that several PDE5s are generically available at the current time.

An additional trend which has been occurring with penile prostheses (not necessarily observed with AUS prostheses) is the switch from inpatient, hospital-based care to outpatient, surgical center or even office-based surgeries.<sup>23,24</sup> This shift is likely secondary to several factors, including improved patient/surgeon convenience, focus on cost-effective and value-based care, insurance mandates, changing reimbursement, and use of long-acting anesthetics, among others. The change may also be contributing to the popularization of alternative penile prosthetic approaches, such as the subcoronal technique, which is arguably less invasive and may be performed under lesser anesthetic requirements.<sup>25</sup> Aside from cost-effectiveness, there are currently no data to suggest superiority or inferiority of any surgical setting on short- or long-term outcomes.<sup>26</sup>

A third trend which has received significant attention in the US in the past several years is the limiting of orally administered narcotic medications. This has resulted largely from a rise in prescription drug addictions, with increasing emphasis placed on providers to limit the use and prescribing of oral narcotics. In response, several authors have published protocols that have reduced the need for narcotic



**Figure 4:** Image demonstrating existing and future concepts for testicular prostheses. (a) Coloplast Torosa; (b) Endotherapeutics Promedon; (c) Rigicon Testi10; (d) Dual-layer, drug-eluting testicular prosthesis.

medications using local anesthetics (short- and long-acting) and/or multimodal, nonnarcotic pain relievers.<sup>27,28</sup> Interestingly, in some cases, this has not only led to a lower number of narcotic prescriptions but also improved pain control and overall recovery.<sup>27</sup> Given the variable risks with nonnarcotic pain medications (particularly nonsteroidal anti-inflammatory drugs [NSAID] and similar therapies), larger data sets will be required to determine the overall cost-effectiveness and safety of nonnarcotic pain control approaches over time.

### **Surgical procedures**

In addition to ongoing improvements in prosthetic devices, surgical techniques are similarly, continuously evolving. Among the most notable recent trends in prosthetic surgery is the use of adjunctive techniques to enhance penile length. Techniques described include multiple slits (MUST) in the corpora, sliding technique, modified sliding technique, and circumferential grafting.<sup>29–32</sup> The fact that there are such a large number of variations of surgical techniques to lengthen the penis suggests both a strong desire for a legitimate lengthening procedure and the fact that the ideal technique has yet to be developed. Given the severity and devastating nature of penile necrosis that can occur with concomitant lengthening at the time of prosthesis placement, although infrequent, it is unlikely that the current round of adjunctive techniques will experience mainstream adoption. If, however, a modified technique can be developed that eliminates this complication, the likelihood for widespread use would increase. As a corollary, several surgeons have described other adjunctive techniques such as scrotoplasty, suspensory ligament release, and suprapubic lipectomy.<sup>33,34</sup> Although these procedures are much less prone to severe complications, the benefits are more debatable (actual or perceived), and they have not been routinely implemented by the majority of implanters. As such, for the near future, adjunctive penile lengthening techniques will likely remain selectively utilized and not routinely adopted.

Another recent concept with penile prosthesis surgery is the idea of corporal sparing, which emphasizes minimal corporal dilation prior to placement of cylinders.<sup>35</sup> The results from a randomized study evaluating this technique demonstrated greater spontaneous penile tumescence and improved girth when compared to the more traditional approach. Given these promising results, plausible mechanism, and ease of performance, corporal sparing has the possibility of becoming a new standard of care. Further investigations and external validation are warranted.

Two additional adjunctive techniques have been increasing in popularity in recent years and will likely continue to expand. The first is the use of mesh or other material at the time of penile prosthesis to address stress urinary incontinence (mini-Jupette).<sup>36</sup> Several factors contribute to its popularity, including the frequency of combined ED and stress urinary incontinence, increasing use of male slings to address incontinence, and the direct access to the urethra and corpora with a penoscrotal approach. Although it represents a promising therapy, the long-term viability may ultimately depend on insurance reimbursement. This is particularly relevant because insurance trends have been in the opposite direction, where combined prosthetic surgeries are not fully reimbursed (e.g., Medicare decision to not reimburse combined penile prostheses and AUS procedures). The second adjunctive technique is glanulopexy at the time of penile prosthesis implantation to treat glanular hypermobility/supersonic transporter deformity.<sup>37</sup> Given the potential impact of hypermobility on short- and long-term satisfaction and complications, and as it may be

performed rapidly and with minimal or no additional morbidity, it will likely be increasingly utilized with further time and training.

### **ONGOING NEEDS AND CONSIDERATIONS**

There are several ongoing needs in the field of genitourinary prosthetics. One such need is a prosthetic specifically designed for placement in a neophallus. To address this gap, Zephyr Surgical Implants has developed the ZSI 475FtM which utilizes an enlarged single cylinder and a silicone tip shaped like a glans. The device also incorporates a stainless-steel plate which facilitates fixation to the pubic bone. In addition, with an enlarged and blunted distal tip, the device potentially reduces the likelihood for cylinder erosion, a common issue in the tunica albuginea lacking neophallus. Preliminary data from twenty patients (mean follow-up of 9 months) demonstrated 10% device malfunctions and 5% infections requiring explantation.<sup>38</sup> Of the 14 men who responded to a satisfaction questionnaire, 86% were able to have penetrative intercourse, and 93% were satisfied with the prosthesis. Other inflatable devices are also commonly used with neophalluses, including the use of grafting materials to reduce erosion; however, there remain significant gaps with all currently available prosthetics.<sup>39</sup>

A second gap that exists with the current-generation devices is a need for an automatic pump. Arguably, one of the most common complaints among men with IPPs is difficulty with inflating and deflating the device. This is particularly relevant because IPPs are often used in older men or in men with severe obesity that precludes being able to easily access and function the pump. Similarly, difficulty in functioning an AUS pump precludes some men from receiving the implant, while urinary retention secondary to not cycling the pump (e.g., dementia) is occasionally a safety issue in some populations. Although it is unclear if any company has direct plans to address this need, as previously noted, the BSCI has filed several patents over the past few years, which suggests that they may be developing this much-needed feature.

Beyond improvements in the devices themselves, another key need in the field of prosthetics is improved education and training. To address this issue, The International Society of Sexual Medicine (ISSM) is investing in two key initiatives, namely the ISSM Online University and outreach programs to deliver cadaveric-training courses to regional societies. In addition, regional sexual medicine affiliates are also increasingly working in cooperation with device manufacturers to provide greater access to experienced implanters and didactic curriculum. Despite these attempts, several key hurdles remain, including slow regulatory approval processes, lack of device availability, cost-limitations precluding access to select prosthetics, and rapid expansion where the needs and desires outpace training. In addition, as placement of genitourinary prosthetics does not require any specific certification, outcomes are often dependent on the experience and skill of the surgeon, rather than due to characteristics of the implant itself. This is in contrast to other surgeries where robotic or laser certification are required prior to performing select procedures. This lack of standardization of quality may slow the broader acceptance of genitourinary prosthetics, as patients and referring providers may be influenced by examples of suboptimal outcomes.

### **SUMMARY AND CONCLUSION**

Genitourinary prosthetics, as a class, represent a highly successful therapeutic option for the management of ED, stress incontinence, or to enhance testicular or penile esthetics. Given their excellent outcomes and ongoing innovation, they will likely continue to have a significant role for the foreseeable future. The pace of innovation is quickening

in recent years and is predominantly limited by cost and regulatory considerations, rather than by the technologies themselves. Coinciding with these device changes, surgical practice is similarly adapting and innovating to deliver improved outcomes while minimizing morbidity. Despite these innovations, several needs are ongoing, including a need for cost-effective options, devices suited for neophalluses, and automatic pump systems. Similarly, the rapid expansion of prosthetics worldwide requires improved mechanisms to deliver education and training to an ever-expanding base of implanters, particularly among developing nations. With each of these considerations in mind, the upcoming decades will likely represent an exciting time for the field of genitourinary prosthetics.

## AUTHOR CONTRIBUTIONS

LT performed literature and patent review, drafted, and finalized the manuscript. The author read and approved the final manuscript.

## COMPETING INTERESTS

The author declared no competing interests.

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