Review Article

Prosthetics in urology: Current status and future directions

Abhilash Cheriyan*

Department of Urology, Christian Medical College and Hospital, Vellore, Tamil Nadu, India
*E-mail: abhilashcheriyan@gmail.com

ABSTRACT

The field of genitourinary prosthetics has evolved rapidly to become the standard of care for conditions such as incontinence and refractory erectile dysfunction. Its scope has expanded to encompass newer indications such as Peyronie's disease and gender-affirming surgeries. This review, based on the Urological Society of India's Best Essay Award 2022, aims to elaborate on the advances in the field of urological prosthetics in the past 20 years as well as to provide an insight into ongoing research and what one can expect to see in the next decade, particularly in the area of penile and testicular prosthetics as well as treatment of incontinence. A PubMed and patent search was performed to achieve these objectives. Future considerations include improving acceptance, reliability, making them more accessible for developing countries and improving training and education to improve outcomes.

INTRODUCTION

The word prosthesis is derived from the Greek words-*pro* and *tithenai* in the 16th century (which mean "in addition" and "to place," respectively). A prosthesis is an artificial device that substitutes a defective or an absent body part *and* attempts to restore its structure and function. From the accounts of prosthetic limbs used by Queen Vishpala in the Rig Veda and the books of Greek Historian Herodotus,[1] the field of prosthetics has evolved beyond orthopedics and trauma to various other medical fields, including urology.

Increase in longevity due to advancements in medical care has made optimal management of conditions such as incontinence and erectile dysfunction (ED) vital for maintaining a normal quality of life. The scope of prosthetics in urology includes penile prostheses (PP), artificial urinary sphincters (AUS), slings, and testicular prostheses (TP), as shown in Figure 1.

The objective of this review is to describe the current role of prosthetics, recent advances, and future trends in the field of urological prosthetics. This review is based on the Urological Society of India's Best Essay for 2022.

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METHODS

A PubMed search was performed for English language articles using the search terms-"urological prosthesis," "penile prosthetics," "urinary sphincters," "testicular prosthesis," and "slings." After screening the available abstracts, relevant full-text articles that addressed the search terms were selected for this review. A Google patent search was also performed to identify newer concepts and patents filed since 2010 related AUS and, penile and TP.

CURRENT STATUS OF PROSTHETICS IN UROLOGY

Penile prosthesis

History of penile implants

While Ambroise Pare is credited with making the first penile implant in the 16th century, the first documented use

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for ED was by Nikolaj Bogoraz, a Russian surgeon, who in 1936 fashioned an implant using a rib cartilage.[2] However, the modern era of PP was marked by the introduction of an inflatable penile prosthesis (IPP) in 1972 by Scott *et al.*[3] A few years later, a semirigid rod prosthesis by Small and Carrion was marketed.[4] Subsequent modifications to Scott's inflatable prosthesis led to the AMS 700 in 1983. PP for the treatment of ED have the highest patient and partner satisfaction rates.[5] Although there was a dip in PP sales in 1998 when sildenafil was approved by the Food and Drug Administration (FDA), sales eventually improved once it was evident that conservative therapy was not universally effective.[6,7] Applications have now expanded to Peyronie's disease and gender-affirming surgeries.

Types of penile implants

Two types of PP are available – hydraulic (2 or 3-piece) and semi-rigid implants. The main manufacturers for the penile implant are Coloplast (Minneapolis, MA) and Boston Scientific (Marlborough, MA) in the USA. Data from these manufacturers indicate that around 85% of all penile implant surgeries worldwide are performed within the United States with IPPs accounting for over 80% of these implants.[8,9] In contrast, cheaper semi-rigid implants are more popular in Asia.

Semi-rigid implants

Semi-rigid implants consist of malleable rods made of a core (spiral wire or silicone), an outer jacket, and a provision for rear tip extenders to adjust the size of the implant. The AMS 600 Spectra and the Coloplast Genesis, the two most popular devices, reported patient and partner satisfaction rates comparable to IPP.[10] The AMS Spectra was replaced by the AMS Tactra in 2019, which has a dual-layer silicone exterior with a nitinol core, resulting in better axial rigidity.

Some of the popular malleable implants are the Rigi10 by Rigicon (USA), Zephyr ZSI 100 (Switzerland), Shah implant (India), Silimed penile prosthesis (Brazil), and the Promedon tube prosthesis (Argentina). The Shah implant, first reported in a patient who underwent total phallic reconstruction, is an affordable alternative in developing countries like India. The soft tip and a malleable hinge reduce the risk of erosions, while the addition of a removable sleeve makes it versatile and cost-efficient.[11]

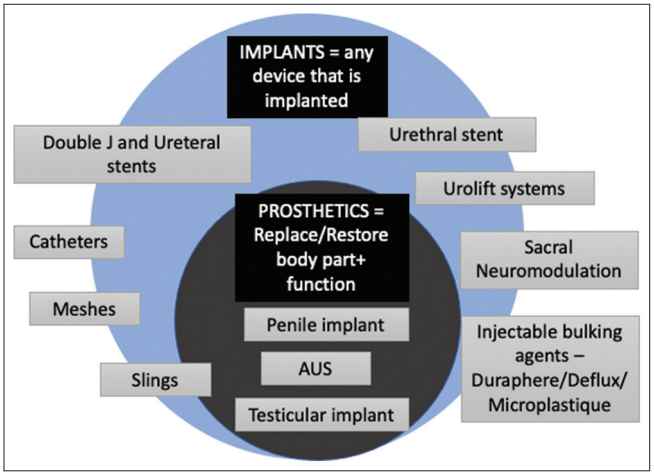

Figure 1: Scope of prosthetics in urology

Inflatable penile prosthesis

IPPs have a more natural appearance in the flaccid and erect state. A three-piece prosthesis has a scrotal pump, a reservoir that is typically placed in the Retzius space or submuscular space below the rectus, and two inflatable cylinders. The AMS 700 series and the Coloplast Titan series are the only three-piece inflatable implants approved for use in the United States (US). Ambicor, the most popular two-piece IPP, is an upgraded version of the now-discontinued AMS Dynaflex (a one-piece IPP). Although axial rigidity is inferior to the three-piece IPP, reliability and patient satisfaction are over 90%.[12] Ambicor can be considered in patients who desire an IPP, but a reservoir cannot be placed due to prior surgeries.

One of the major concerns with penile implant surgeries are the reoperation rates. Data of 14969 men who underwent IPP insertion with a median follow-up of 95 months showed an overall reoperation rate of 6.4%.[13] Both Coloplast and AMS have incorporated various modifications over the past two decades to reduce complications and improve the durability and ease of use of both malleable and IPP which have been incorporated in newer models [Figure 2]. Current IPPs are durable and enable a good quality of life even at a 20-year follow-up.[14]

The introduction of antibiotic and hydrophilic coated implants has reduced the infection rates to 0.3%–2.7% from around 3%–5% in the early 2000s.[15] "No touch" techniques have further reduced infection rates to as low as 0.46%.[16] Some of the recent advances are summarized in Table 1.[17-21]

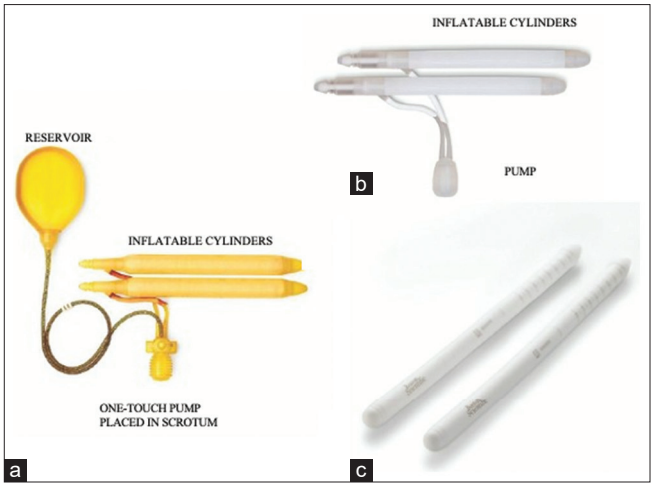

Figure 2: Few of the penile prostheses currently available in the market. (a) AMS 700™ with Inhibizone coating, (b) Ambicor two-piece implant, (c) Tactra malleable implant. (Images are used with written permission from Boston Scientific Corporation)

Table 1: Recent advances in penile prosthetics

Advances	Year/model	Salient features	Result/comments
Coating			
Parylene micro coating	2000/AMS CX 700	Improved lubrication, reduced friction, and wear	Reduced mechanical failures from 10.8% to 2.5%
InhibiZone	2001/AMS 700	Rifampin+Minocycline precoated implants – Orange color	Reduced infection rates to <1% in primary and from 10% to 2.45% in revision cases
Hydrophilic coating	2002/Titan, Genesis	Dip in an antibiotic solution of surgeon's choice before implant; coating retains it	Reduced infection rates
Cylinder			
Improved 3-layer	1990s/AMS	Inner silicone, middle Dacron/lycra, and outer silicone. The middle layer aided in expansion	Reduced mechanical failure, such as cylinder aneurysm
LGX	2006	Length-Girth expansion	
Narrow base	2017/Narrow base Titan AMS CXM	Useful when corporal dilation is limited	
Nitinol core in Tactra	2019/AMS Tactra	Nitinol Core, outer layer made of silicone	Additional axial rigidity
Rounded distal tip	2012	Better cosmesis	
Rear tip extenders	Snap-fit AMS 1998 Twist on/Coloplast NarrowRTE/2013Coloplast	Easier to attach and remove during revision/explant	
Pumps			
Lock-out valve	2001	Prevent auto inflation	Reduce mechanical failure
One-touch pumps	2004/AMS Tactile 2008/Coloplast	Ease of localization for inflation/deflation	Improved ease and convenience
MS pump (momentary squeeze)	2006/AMS	Single press pumps with faster deflation, no need to keep pressing	Improved ease and convenience
One-touch release pump	2013/Coloplast OTR		
Reservoirs			
Flat reservoirs	2010 Cloverleaf (Coloplast) Conceal (AMS)	Better concealment, less space required	For ectopic placement, prior surgeries
Tubing			
Optimized tubing length	2017/AMS	Improve pump positioning	Reduced mechanical failure, tube kinking
0° tubing angle	2012/Coloplast	Used for a narrow base prosthesis to reduce tube wear due to improper corporotomy	

AMS=American Medical Systems, OTR=One-Touch Release

Artificial urinary sphincter

Male stress urinary incontinence (SUI) is a relatively rare condition in community-dwelling men, with a prevalence of 3.78% in those aged 45–65 years of age.[22] The most common cause for male SUI is postprostatectomy incontinence (PPUI) and the incidence is 4% to 39%[23,24] which is a major factor affecting the quality of life.

The earliest description of an "Artificial sphincter" was by Foley in 1947, when he devised a pneumatic clamp for men with nocturnal enuresis.[25] The AUS in its current form (AMS 800™), was a result of various upgrades to the one described in 1972 by Scott *et al*.[26] In 1977, Furlow introduced the concept of primary deactivation of the cuff to prevent erosions.[27] Further developments and upgrades were directed toward reducing cuff pressures and improving mechanical reliability. The AMS 800 is the only AUS device that has both FDA and CE approval for severe UI. It is a highly durable, safe, and effective option based on published reports.

AMS 800

This three-piece device consists of an inflatable cuff with different sizes, a hydraulic pump to activate the pump, and a pressure-regulating balloon (PRB). Squeezing the pump draws the fluid from the cuff into the PRB, allowing the person to void.

Even though AMS 800 is considered the gold standard for PPUI, a systematic review showed that complications such as mechanical failure (6.2%), urethral atrophy (7.9%), and infection and erosion (8.5%) result in reintervention rates as high as 26%.[28]

The important drawbacks of AMS 800 that need to be addressed are (i) constant urethral cuff pressure that can compromise the vascularity of the urethra, (ii) multiple components that increase the chance of mechanical failure and infections, (iii) affordability, and (iv) the need for manual dexterity. Newer devices such as Zephyr 375, Victo, and Victo + are promising, but long-term outcomes are awaited. Table 2 shows the artificial sphincters currently available for clinical use.[29-31]

Male slings

Bulbourethral slings were initially designed to provide a less invasive alternative to AUS. Many patients prefer a sling to AUS as it does not have mechanical components and one does not need to rely on cognitive ability. The slings currently in use are summarized in Table 3.[32-40]

Table 2: Artificial sphincters currently available for clinical use

Device	Manufacturer	Device	Features/benefits over AMS 800	Results
AMS 800	Boston Scientific, Both CE, and FDA approved Expensive	Three-piece	InhibiZone coating, kink-resistant tubing, narrow-backed cuff	Continence 75%–80% at 10 years Erosion/infection 2% at 10 years Revision 10%–15% at 10 years
Victo and Victo+ (Previously FlowSecure)	Promedon, Argentina	Single unit, preconnected Occluding cuff, PRB, scrotal pump	Victo+has an additional stress release balloon Preconnected components Self-sealing port in the scrotal pump.	At the median follow-up of 15 months, 94% continence and 76% dry. No major complications
Zephyr ZSI 375	Zephyr, Switzerland	Single unit, two parts. Adjustable cuff and pump unit (pressure regulating tank with pump) within the scrotum	Adjustable cuff fits all. In situ pressure adjustment through a pressure regulating tank. No reservoir -> reduced surgical morbidity	Improved continence in 88% at 4 years. Revision or explant in 24%.
Periurethral constrictor device	Silimed, Brazil, No FDA/CE approval	Used initially in children with neurogenic bladder. No need to manipulate	Affordable Adjustable constrictor cuff connected to a hydraulic self-sealing valve Constant periurethral pressure – patients have to void against it	High erosion rates - 63% Malfunction - 20%

FDA=Food and Drug Administration, PRB=Pressure-regulating balloon, CE=Conformité Européenne

Table 3: Summary of slings available for treatment of male urinary incontinence

Device and manufacturer	Type	Features	Results	Comments
Advance (2006) and AdVance XP (2010) (BSCI)	Fixed polypropylene mesh	TOT method; relocates the urethra	80% improvement in incontinence @ 5 years	Most commonly performed
Virtue sling 2012 (Coloplast)	Fixed quadratic microporous polypropylene	Transobturator and prepubic arms - Relocation of the urethra and urethral compression	Variable reports; 68% failure to 79.2% success has been reported	No long-term results
I-stop TOMS (CL medical) 2012	Fixed polypropylene mesh	TOT method, relocates the urethra	Social continence (0–1 pad) at 1 year in 77%, but reduced to 22% at 5 years	
Argus (Promedon)	Adjustable Silicone foam cushion and silicon arms	Retropubic method	52-79% were dry at 27 months. 12% had urethral stricture, up to 15.8% explant rate	Improvement incontinence not sustained on longer follow up
Argus T (Promedon)	Adjustable	TOT - components similar to argus	Median follow-up of 22 months - Improvement or cure in up to 86.2%. 42.9% required adjustment/revision	Outcomes poorer in severe UI
Remeex Male (Neomedic). Later Remeex II - upgrade	Adjustable	Retropubic method. monofilament polypropylene	64.7% were dry at 32 months	Initially described in women
ATOMS (A.M.I)	Adjustable Silicone inflatable cushion with microporous monofilament polypropylene mesh arms	TOT. Currently, 3rd generation. Adjustment via instilling fluid through scrotal port	Overall success of 90%. Median adjustments of 3 at 31 months. 20% explant - mainly in older generations	

TOT=Transobturator, UI=Urinary incontinence

Adjustable balloon device – ProACT

The ProACT system consists of two silicone balloons with titanium ports accessible through the scrotum, implanted using minimally invasive methods. Continence is achieved by adjusting the balloon which in turn adjusts the urethral resistance. In a recent meta-analysis, 81.9% of patients showed improvement in continence, and pad usage reduced from 4 to 1.1 pads/day.[41]

Female slings

Contemporary minimally invasive options for surgical management of female SUI include autologous fascia pubovaginal slings (AF-PVS) and various synthetic mid-urethral slings (transvaginal tape [TVT], transobturator tape–in and out), and mini slings. Retropubic TVT is safe and effective even on long-term follow-up.[42] Overall adverse events are low for mid-urethral slings irrespective of the route used.[43] AF-PVS is currently used as a second-line option for failed mid-urethral slings. AUS is theoretically the best option for intrinsic sphincter deficiency, however, better studies are required to establish its definitive role in the treatment of female SUI.

Testicular prosthesis

The first testicular implant was made of vittalium (an alloy of cobalt, chromium, and molybdenum).[44] Although it helped with the psychological aspects of testicular loss, the metallic feel was unpleasant. Focus had then shifted to the development of natural feel implants. The next 10 years saw the use of various materials such as polymethylacrylate, glass spheres, and Dacron, but these options did not gain popularity. Silicone gel-filled implants were introduced in the 1970s were widely used until 1992, when the FDA temporarily halted the use of all silicon prostheses, based on adverse effects reported with silicone-gel-filled breast implants.[45,46]

Currently, Coloplast Torosa, a saline-filled implant, is the only FDA-approved testicular prosthesis in the USA and has the highest acceptance worldwide. It is a saline-filled TP, available in various sizes, which aims to restore the natural appearance and feel. It also has a suture tab to secure the device at the desired position within the scrotum and an inflation port to adjust the firmness. Other manufacturers include the Rigicon (USA), Promedon (Argentina), and Uromed (Germany). These implants are made of silicone outer shell containing either saline, silicone gel, or solid elastomer.

Although TP implantation is safe and recipients of testicular implants report satisfaction rates of 73%–100% and subjective improvement of body image in over 50%, there appears to be a disconnect between its use and its potential.[47-49] A testicular prosthesis is not offered in 35%–50% of patients,[50,51] and this number is likely to be higher in developing countries.

The feeling of shame or loss of masculinity was particularly high in those who were never offered a TP as compared to patients who were offered and rejected.[52] Among those who were unsatisfied with TP, the TP firmness, implant size, and positioning too high in the scrotum are the main factors.[53]

UNMET NEEDS AND ONGOING PROJECTS

Milestones in the evolution of prosthetic technology are summarized in Figure 3. There are various ongoing investigations to improve prosthetic technology and one of the most prominent themes is automation while ensuring optimal performance, cost, and reliability.

Penile prosthetics

An area of interest is the automation of the penile prosthesis, enabling the patient to control the device remotely. AMS has obtained various patents for this device and this may be available soon. One of these devices has a piezo-electric pump activated by a magnetic field. A vibrating penile implant to improve partner satisfaction has also been evaluated but the longevity of battery-powered devices without needing replacement is of concern.

Although various implant coatings have reduced infection rates, revision of an infected implant and tackling biofilms has remained problematic. A calcium-sulphate cast with tobramycin and vancomycin has been described as a temporary placeholder for the management of infected penile implants to preserve penile length and corporal space.[53] Ultrasound-targeted microbubble destruction for the treatment of biofilms in titanium implants has been attempted in orthopedics. The addition of the human beta-defensin-3 peptide seems to augment its action against Staphylococcus biofilms.[54] It remains to be seen whether similar technology is effective against biofilms in silicone prostheses. Alternatively, while it may not be possible to prevent biofilms, a novel approach to facilitating bio-film formation by nonpathogenic bacteria is intriguing.[55]

As technology and material science evolves, doing away with reservoirs and hydraulic technology which make it cumbersome and allow scope for malfunction is a direction worth investigating. One such potential technology is the shape-memory alloy, which can be activated by magnetic induction, which will be discussed later.

Artificial urinary sphincters

Similar to PP, automation, reduced need for dexterity, and improving reliability are the need of the hour. The Politano-Sayet-Sutherland device is fluid-free and can be controlled with a handheld remote, allowing postimplant adjustments and remote telemonitoring.[56] Another novel idea is a small electronic pump that can be remotely operated using Bluetooth technolog, y retro-compatible with AMS 800.[57] The magnetic artificial sphincter is a prototype that uses an external magnet to manipulate an internal magnet housed within the scrotum, which controls the urethral compression cuff.[58]

The high rates of urethral erosions may be inherent to the constant urethral compression and novel proof-of-concept devices, such as the emAUS and ARTUS, have tried to address this. These electromechanical devices apply sequential alternating or "piano mode" compression to the urethra to avoid damage to urethral vascularity and early reports are encouraging.[59,60] An automatic sphincter system that dynamically adapts to changes in the intravesical pressures is also being studied.[61]

On examining recently filed patents online, a two-piece system by Coloplast (#15/153,737) where fluid is stored within the cuff, and an AUS with sensors to provide a second closure pressure (#WO2019169277A1) based on dynamic input seem promising. Other notable innovations in the cuff technology include an iris-diaphragm-like cuff (#ES14171954.2T) and a novel system that has a

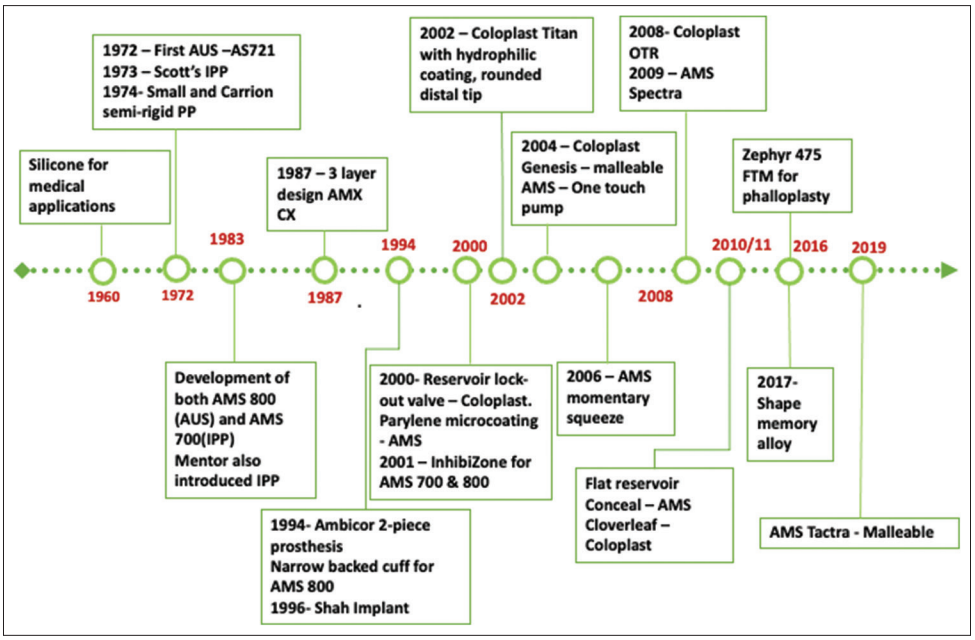

Figure 3: Important milestones in the evolution of urological prostheses

backboard and a pair of end-walls (#16/255,837) by Coloplast.

Testicular prosthesis

Compared to AUS and PP, the scope of innovations is much smaller since it is a simpler device. One of the novel ideas in this field is the testosterone-eluting double-layer silicon TP.[62] This silicon prosthesis with controlled release of testosterone undecanoate was effective and safe in castrated rats.

Gender-affirming surgery

Female-to-male gender-affirming surgeries are increasing in frequency and pose unique challenges. Various implants, both hydraulic and semi-rigid have been used such as AMS700CS, Ambicor, Coloplast Genesis, and Titan. However, one of the major concerns is higher rates of complications in the transgender population with malposition and erosions in as many as 22.7%.[63] The Zephyr ZSI 475 FTM was designed specifically for phalloplasty, and the outcomes were recently published. It has a rounded distal tip mimicking the glans and a steel plate to anchor the implant to the pubis. Although the design has theoretical benefits, well-planned trials will be required to make any conclusions about the outcomes and patient satisfaction. A testicular prosthesis may be placed at the same sitting as the phalloplasty or in a delayed manner. Recent reports favor delayed implantation of smaller and lighter TP.[64]

APPLICATION OF NEWER TECHNOLOGY

Shape memory alloys and nanotechnology

A shape-memory alloy (SMA) is based on the property of certain alloys to change crystal structure at characteristic temperatures. A nickel–titanium alloy implant changes its configuration on the application of heat within an acceptable physiological range either via surface probe or magnetic induction. Early *in vitro* results of this SMA implant show axial rigidity comparable to that of IPP. In the inactive state, they mimic the flaccid state, unlike other malleable implants. Although it is in the early stages of research, it has the potential to be an affordable and reliable alternative to IPP with fewer parts and easier activation, and potentially lower mechanical failure rates.[65]

SMA wires have been used in AUS prototypes where SMA wires are programmed to occlude the urethra in "piano mode." Although promising, concerns about thermal insulation, the need for a high-power battery, and the time lag for activation need to be addressed. Few of these concerns may be addressed by artificial muscle sphincters made of nanostructures based on electrically activated polymers.[66]

Role of 3D printing

3D printing technology to study cadaver penis shapes to improve the shape of existing PP, or even to provide personalized implants is no longer a flight of fancy. Applications of 3D printing being investigated include customized SMA penile prosthesis and well as 3D printed scaffolds seeded with stem cells to develop bioengineered vascularized corpora.[67,68] 3D printing can be used to engineer native tissue-like meta-materials for natural feeling testicular prosthetics.[69] Such implants do not require silicone or liquid infills.

3D printing has been utilized to replicate male pelvic structures including their relative tissue densities using polyvinyl alcohol. These are cost-effective compared to

cadaver models and can be used to train a low-volume surgeon or a resident in PP and AUS surgeries.[70,71]

Regenerative medicine and tissue engineering

The safety of stem cell therapies, especially in oncological patients such as those with PPUI and ED is a concern due to the risk of latent carcinogenesis and tumor recurrence. The cost and invasiveness of harvesting bone-marrow-derived mesenchymal stem cells, which is the gold standard for adult stems cells is also prohibitive. *In vivo* stem cell implantation has a very low survival rate as they upregulate MHC-II expression. The use of cell implantable 3D biological scaffolds is believed to allow precise delivery as well as a favorable environment for the stem cells.[72] Despite these limitations, better understanding, and advancements in material science, the scope is limitless. For instance, various trials have been registered in an attempt to regenerate the urethral sphincter and to salvage the function of erectile tissue.[73] Another group demonstrated the potential of biodegradable synthetic polymers to serve as scaffolds for autologous chondrocytes, which can be used for autologous PP.[74]

Potential hurdles

Although the pace of prosthetic research has increased in the last decade, prosthetic research is protracted and expensive and often many of the smaller manufacturers may not have the financial strength to steer their innovations from bench to bedside. For instance, only AMS and Coloplast have approved three-piece inflatable implants in the US which is the largest market for penile implants. This remains a real-life hurdle for many of the inventions. Due to the above reasons, costs are unlikely to reduce unless volumes or competition between manufacturers increases significantly.

Strict and expensive regulatory procedures in the US and Europe are a double-edged sword. While lesser established prosthetic companies are unable to afford the rigorous testing required for regulatory clearances in the US and European markets, they are being utilized in other countries without published long-term outcomes or safety profiles. Therefore, regulatory reforms are required to make it standardized and less cumbersome while ensuring patients' safety.

Unlike fields like oncology, there are no standard guidelines or certifications for a surgeon practicing prosthetic urology and it may be important to liaison with device manufacturers to improve accessibility and training.

CONCLUSIONS

Although the basic concepts behind current urological prostheses are decades old, recent advances have made them reliable and safe. While novel retro-compatible devices may enable better automation, the focus needs to be on newer technologies such as SMA that will also reduce the number of components and improve reliability, affordability, and ease of implantation. Nanotechnology and advances in material science may completely change the landscape in the coming decades. However, practical hurdles such as affordability, wider distribution, and acceptance are yet to be addressed.

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