Biomedical engineering and erectile restoration: design considerations for urologic prosthetics

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For patients with moderate-to-severe erectile dysfunction, implantable penile prostheses continue to be a viable treatment. Medical device developers apply design controls during the development cycle to ensure that a product performs as intended in the final use environment. This process relies heavily on the principles of systems engineering and documents every facet of performance, unmet need, and risk. To better understand design philosophy, it is important to frame benchmarked performance outcomes in the context of the ideal state. Careful consideration of erectile anatomy and physiology, including flaccid state, transitional phases, and full tumescence, informs penile prosthesis design philosophy and provides the foundation for product advancement.

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INTRODUCTION

For patients with moderate-to-severe erectile dysfunction, implantable penile prostheses continue to offer reliable performance in an inflatable or a malleable configuration. Product design and development considerations will be reviewed, including discussion of key penile prosthesis performance parameters governing device behavior in the flaccid, transitional, and tumescent states.

DESIGN CONTROL FOUNDATION

While an exhaustive discussion of best practices and procedures for medical device design and development are not critical for this discussion, it is important to understand that medical device developers apply design controls to device development to ensure that device systems perform as intended in the final use environment. This process relies heavily on the principles of systems engineering and documents every facet of performance, unmet need, and risk (including foreseeable misuse). This body of information is woven into a lattice of interconnected requirements that frame and constrain the final embodiment, manufacture, and postmarket surveillance of a device system. Industry partners skilled in the discipline of systems engineering are critical for ultimate patient outcomes and satisfaction with device solutions.

ERECTILE RESTORATION DESIGN PHILOSOPHY

The marriage of engineering and medicine has advanced the standard of care across many specialties. Medical device engineers are often faced with the challenge of restoring physiological or anatomic function of incredibly complex and dependable biologic systems. This combination of complexity and durability appears at odds. How many mechanical systems function continuously for years without interruption or preventive maintenance?

When approaching a given organ system, it is first critical to deconstruct physiologic mechanisms of action and principles of operation into a discrete and measurable set of performance criteria. Biological systems are incredible in their complexity, reliability, and durability and are not always fully understood by traditional engineers or scientists. For systems serving as functional analogs, it is important to understand the key principles of operation of the biologic system.

To the casual observer, standard prosthetic urology therapies for erectile restoration appear to be decoupled from the elegant functionality of native anatomy. To better understand urologic prosthetic design philosophy, it is important to frame benchmarked performance outcomes in the context of the ideal state. Careful consideration should be given to key elements of erectile physiology, including the flaccid state, the transitional phase, and the erect state.

FLACCID STATE CONSIDERATIONS

Restorative systems should maintain or augment resting fullness and length in the flaccid state, while addressing additional secondary performance parameters. In the flaccid state, the glans and penile shaft maintain a certain density and elastomeric behavior upon palpation and compression. Key design criteria focus on limiting detectability of the system. Designers should be mindful of a few questions when considering the flaccid state. Does the phallus look normal? Does it feel normal? Does it sound normal? Does it meet the patient's expectations? Is it satisfactorily concealable? Does it meet the partner's expectations? Will the system survive the continual manipulations of postural change and normal patient activity throughout the day? Does the system predictably remain in the flaccid state?

Voice of customer activities reinforces patients' desire for discretion when considering a restorative therapy for a disease state carrying the societal and emotional sensitivities of erectile dysfunction. A mark of an effective device solution is when the patient forgets the involvement of the mechanical system all together and is taken in by life and can return to spontaneity. The design challenge is to bring a
patient as close to this experience as possible. Significant factors that can break the illusion of natural behavior and complete restoration in the flaccid phase of operation are related to palpability. What does the device feel like? At first glance, one might think that a patient really does not want to feel anything. That perception is perhaps close to truth, but may reflect an overly simplistic view. The patient may have difficulty in describing what a phallus should feel like during physical manipulation or palpation, but in all probability their position is relatively straightforward.

“It should feel like it felt before.”

Given this basic truth, the designer should seek to understand the baseline condition of palpability. Consideration should be given to compressibility, elastomeric behavior, and consistency of modulus from one phallic region to another. Is the palpability of the glans different than before? If so, in what ways? The flaccid state design intent of any device solution is to preserve resting fullness and girth, while delivering elastomeric behaviors, density, and mass that is as indiscernible from the natural anatomy as possible.

Designers should be mindful of characteristics that break the illusion of restoration. In the case of implantable penile prostheses, this can be a challenge. While malleable devices facilitate simple and immediate intromission, thus accomplishing a primary objective of the therapy, they may fall short of the patient’s desired palpability. The newest malleable devices have taken great steps to advance the performance of malleable systems, but still fall short of some inflatable penile prostheses (IPPs) when it comes to palpable detectability.

Inflatable penile prosthesis performance is far preferable in this regard, but certain design pitfalls must still be mitigated. Regions of transition from low elastic modulus to slightly higher elastic modulus structures are detectable by the patient and should be limited by targeting consistent device compressibility across all segments of the device along with gradual transitions in durometer that behave less as step functions and more like smooth curves. IPPs have the advantage of facilitating a resting flaccid angle anywhere along the major length of the device shaft. The transitional zone, where the device folds over to provide the desired flaccid angle, presents certain design challenges. Bending an IPP cylinder is analogous to the experience of folding over a garden hose to momentarily arrest the flow of water. If the designer has given due consideration to the composition of the cylinder wall to accommodate the very small radii resulting from the kinked tube and the apparent stress risers in the cylinder wall resulting from these acute angles, there should be no impact on overall device integrity or long-term device survival, function, or reliability. However, a bent/ kinked segment may produce rigid and distinctly palpable corners through the dermal layer that could be undesirable and distract from the perception of complete restoration. Through material selection and design configuration, the small radii and rigidity of this segment should be attenuated, making this transitional segment no more palpable than any other aspect of the cylinder shaft while at rest.

An often overlooked, but relevant element of penile prosthesis concealability involves the audible artifacts that can occur when the device is indirectly palpated or otherwise inadvertently manipulated due to typical and routine postural changes. This is analogous to the crinkling of a snack bag in a quiet room. Under typical conditions, this effect may not be detectable, but in a quiet room, when discretion is paramount, this otherwise minor noise could be noticeable to the patient or partner. Designers should strive to avoid unintentional auditory signaling of prosthetic use under these conditions. Material selection and design configuration can ensure that manipulation of the system in the flaccid state remains undetectable.

Designers anticipate that the device will spend most of the time in a deflated or flaccid position. The resting or flaccid state creates unique stresses on both the device and surrounding anatomic tissue that must be anticipated and accommodated by the designer. For penile prostheses, the flaccid orientation is typically associated with an extreme bend angle. This can create elevated loads between apposed surfaces as well as small radii within the creases of cylinder wall. Material folds may increase stress with the potential for fatigue and fold wear. To further exacerbate the situation, the flaccid state is associated with low to medium varying amplitude oscillatory motion throughout the day as well as compressive loads from a variety of orientations. These conditions can propagate material compromise and associated downstream device functional failure if not appropriately mitigated by the design. In addition, consideration should also be given to the anticipated compression from undergarments and other clothing. The flaccid condition should not induce undue prosthetic pressure or patient discomfort on any aspect of the penile glans or shaft.

Flaccid state reliability can be distilled into some basic tenants: “Device integrity should be maintained in the flaccid state.” “The device should remain flaccid in the flaccid state.”

In the case of inflatable devices, designers typically distill these observations into the fault trees associated with fluid loss and autoinflation. While fluid loss is commonly associated with compromised physical integrity of an inflatable system, auto-cylinder inflation occurs when a stable or momentary pressure differential exists between the fluid reservoir and the cylinder interior that is insufficiently maintained by the associated pump valve mechanisms. If unchecked, the system drives toward equilibrium, resulting in net transfer of fluid into the cylinders and axial alignment of the cylinder column. Designers have developed effective “lock-out” features intended to isolate and preserve the reservoir pressure head resulting from its vertical position and the myriad of intra-abdominal pressure events associated with postural change and diaphragmatic incursion.

In a typical IPP, subsystem connections are provided by tubing with monofilament-reinforced walls that provide excellent burst and kink resistance. This tubing has been designed to maintain physical integrity and tubing patency across foreseeable implant use cases. Strain reliefs are incorporated into transitional components to mitigate stress risers that would otherwise be present when tubing connects to a higher modulus component of an associated IPP subsystem. The AMS 700™ with MS Pump™ Penile Prosthesis (Figure 1) (Boston Scientific, Marlborough, MA, USA), reservoir adapter, pump valve block, and cylinder rear tip all contain features at the tubing/subsystem interface to avoid excess bending and flow path obstruction when tubing is under tension.

Fluid-filled IPP systems require a steady supply of working volume to ensure accessibility of the entire performance envelope of a given system. For class leading IPPs, larger cylinders require more volume for full tumescence than do smaller cylinders. Traditional spherical fluid reservoirs represent the lowest device surface area for a given fluid capacity, but other reservoir configurations are available to accommodate clinician preference.

**TRANSITIONAL PHASE CONSIDERATIONS**

The transitional phase (the transition between flaccid and fully tumescent states) of the erectile cycle presents an interesting challenge for the designer. Inflatable prosthesis pump designs represent elegant approaches to fluid transfer, but result in an inherently unnatural aspect of the prosthetic patient experience. Manual, hydraulic penile prosthetic pumps of today represent the best available erectile
dysfunction solution for the appropriate patient, but they do not replicate the natural and spontaneous erectile response. Design intent for the inflatable penile prosthesis pump focuses on ease of use for the patient and reliability. Ease of use involves consideration of human factors including cognitive engagement, comfort, dexterity, hand strength, and effort.

For the IPP designer, a primary objective of the transitional phase is to limit a patient’s awareness of the mechanical nature of the restorative system. It is easy for engineers to be consumed by the physics of fluid dynamics and mechanics, but patients tend to look at the situation with a certain clarity:

- “The system should inflate when desired/on demand.”
- “The system should not inflate when not desired.”
- “The system should deflate when desired/on demand.”
- “The system should not deflate spontaneously.”

With this in mind, IPP designers focus on device system required effort and reliability to improve patient experience with the pump subsystem. Designers seek to understand the nature of patient engagement with the device and deconstruct this into measurable performance parameters, with consideration given to use and foreseeable misuse. If the goal of the IPP system is to be an unnoticed partner in the erectile cycle, these performance conditions must be understood. Disciplined developers follow a systematic approach to gathering and establishing design requirements, supported by patient performance parameter studies with extensive simulation of parameter combinations. Among other things, consideration should be given to shape, texture, effort, and user dexterity. Designers need to know how patients interface with the pump. Will they use a two-handed or one-handed technique with key pinch, tip pinch, or palmar squeeze technique? Pump functional features should be easy to identify and actuate. Texture of the pump surface should balance immobilization of the pump during manipulation with patient comfort. To understand permissible limits of these features, the magnitude, bearing area, and orientation of compressive loads must be understood.

**Boston Scientific AMS 700™ with MS Pump™ penile prosthesis operation**

The AMS 700™ with MS Pump™ is regarded for its “Momentary Squeeze” deflation mechanism (Figure 2) and is an example of a currently available penile prosthesis pump in wide use.

During an inflation cycle, the initial AMS 700™ with MS Pump™ bulb squeeze moves the poppet valve to its far-sealing position (Figure 3). The resulting pressure opens the cylinder check valve while stabilizing the poppet valve at its far-sealing position (to prevent fluid flow into the reservoir when the pump bulb is squeezed). A certain ejection fraction of pump bulb volume is transferred into the cylinders with each pump bulb squeeze. After each release, the pump bulb rebounds to create a vacuum for refilling. This vacuum draws the reservoir check valve away from its far-sealing position, where it resides in between the far- and intermediate-sealing positions. When the poppet is in this position, it allows fluid flow from the reservoir and subsequent pump bulb refill. During inflation, cylinder pressure closes the cylinder check valve to prevent deflation.

For deflation, a 2–4-s squeeze of the deflation button moves the poppet valve between the sealing annulus and skirt and unseats the cylinder check valve, thereby permitting flow along two potential paths to facilitate the momentary squeeze deflation behavior. The first pathway is pressurized cylinder fluid flow along and over the (unsealed) cylinder check valve and poppet valve. This first pathway remains open while the deflation button is pressed. Spring action pushes the poppet valve into the annulus to seal off the first pathway, when the deflation button is released. Provided the deflation button was held for 2–4 s, fluid will continue to flow along a longer pathway in the MS Pump™ to deflate the cylinders, after the deflation button is released. Resistance to autoinflation is established by the poppet valve and skirt. A ball check valve closes off the secondary fluid pathway, arresting flow from a pressurized reservoir.

When activating the pump for cylinder inflation as described, output pressure created from pump bulb compression pushes the
poppet valve past the sealing ring. The product has been designed to accommodate a wide range of pulse pressure amplitude and duration consistent with the capabilities of the demographic range of prospective patients. Under certain circumstances, some patients may apply pump bulb compressions at the extreme low end of the spectrum with incomplete or slow pump bulb squeezes. If insufficient pressure is generated, the poppet valve (Figure 3) may not fully displace past the valve block sealing ring, thereby arresting fluid flow from the reservoir to the pump bulb.

Silicone components of the MS Pump™ provide many performance advantages, but remain elastomers and are subject to elastic deformation under elevated load. Aspects of the elastomeric behavior support high levels of performance seen with currently available pumps, but if a pump is operated well outside its intended performance envelope, it is possible for perceived use difficulties to arise. Elastomeric compliance permits a certain degree of physical distortion and ensures that check valves seal appropriately while accommodating the typical movements of postural change. If a patient applies unusually light squeeze forces, the pulse pressure profile may not adequately support displacement of the poppet. This could present a scenario where the poppet valve does not deploy into its free-floating position (Figure 4), resulting in arrested flow from the reservoir and a collapsed pump bulb.

In this situation, it may become necessary to gently distort the valve block to induce leakage from the reservoir past the sealed poppet and into the pump bulb to fully restore the pump bulb volume. The same effect is possible if a patient compresses the MS Pump™ deflation button while simultaneously squeezing the pump bulb. Under certain circumstances, this manipulation may be enough to produce bypass flow past the poppet valve and associated attenuation of the pump bulb squeeze pulse pressure. The simplest approach for patient management is to explain why a “firm, quick” squeeze is the preferred technique for initial squeeze and associated pump activation. If patients simultaneously compress both the deflation button and the pump bulb, sealing surfaces can become distorted and poppet valve components are not free to move as designed. When instructing patients in MS Pump™ use, it is worth clarifying that the deflation button is to be pressed for deflation only and that the pump bulb is to be squeezed during inflation only. Any other type of interaction is asking the device to perform in deflation only and that the pump bulb is to be squeezed during inflation only. Any other type of interaction is asking the device to perform in a manner other than as designed.

One might ask, “Why not make the required initial squeeze force lower?” While this is certainly possible from a design perspective, designers must balance the desire to accommodate the extreme lower boundary of the patient grip strength spectrum with the need to avoid inadvertent pump bulb compression from postural change or typical daily movements. If pump requirements do not properly constrain the lower bound of pump bulb compression, incremental cylinder inflation from small-volume transfer over time could lead to autoinflation and potentially unwanted circumstances for a prospective patient.

TUMESCENT STATE CONSIDERATIONS

In the inflated state, designers focus attention on creating the perception of complete restoration of natural physiologic performance for both the patient and potential partner. This presents some unique challenges, but the basic approach is to deconstruct these grossly observable characteristics into discrete/measurable performance parameters. The device system should look and feel normal to the patient. To model natural tumescence, a device system should target natural palpability and rigidity. Again, consider compressibility, elastomeric behavior, and consistency of modulus from one phallic region to another. Glans support continues to be an opportunity for IPP designers, and every effort should be made to arm the clinician with as much information as possible to ensure correct sizing and distal IPP cylinder tip placement. A restorative system should preserve fullness, hardness, and rigidity, while delivering elastomeric behaviors, density, and mass that is indistinguishable from natural anatomy.

Continuing a theme from the flaccid state discussion, the system should remain silent during the inflated state. Consideration should be given to the relative compressibility of adjacent structures under axial or lateral load and every effort made to avoid relative motion between prosthetic structural elements that can create auditory signals, indicating the presence of a mechanical system.

To preserve long-term reliability, it is important to understand the impact of prosthetic cylinder placement on the physical integrity of natural anatomical structures. The very act of placing an IPP cylinder destroys much of the erectile structural elements that facilitate the dynamic behavior of natural anatomy. While typical tunica is a strong biomaterial, it is important to consider the hoop stress in an expanded corporal body following device placement and build intrinsic integrity into the IPP cylinder. Designers are cautious about relying on tunica as a key structural element, essential for functional performance of the device/tissue composite. From patient to patient, this tissue may be unreliable in terms of its contribution to overall system integrity. Given disparate patient factors and histories, designers should mitigate undue stress transfer to unreinforced tunical structural elements (consider the destruction of intracavernous pillars and the intracavernous fibrous framework of normal corporal bodies). Designers may desire to build in constraint that regulates expansion for cylinder subsystems operating above typical physiologic corporal inflation pressure. Consideration should be given to tissue flaws that may permit localized stress to propagate new or previous tunical injury (surgical or other injury). To further avoid tissue stress in the distal corpora, designers also consider the relationship between IPP girth expansion and associated separation between the center axis of adjoining cylinders during an IPP inflation cycle. Given that final cylinder inflated girth has a direct impact on the lateral separation between the apex of each cylinder front tip in an implanted pair, designers should be mindful of the contribution of cylinder girth expansion to lateral tunical pressure in the distal corpora.

Figure 4: Fluid flow during pump bulb refilling. (a) Cross-section view of pump showing components of interest. (b) Fluid flow when poppet valve has been fully activated. Pump bulb will refill normally. (c) Fluid flow when reservoir poppet valve has not been activated or is partially activated. Pump bulb will not refill as designed resulting in a collapsed pump bulb.
WHAT IS NEXT?
The coming years present incredible opportunity for the prosthetic implanter and patient. Industry is driving technology development that blurs the demarcation between mechanical systems and native anatomy. Minimizing patient engagement with restorative device systems continues to be a primary innovation target. The overarching design philosophy for erectile restoration systems is to be an invisible and spontaneous partner for the patient, allowing the patient to live life with the perception of complete restoration of native functionality. Until users no longer think about the process and simply live in the moment, there is an opportunity for continued innovation and truly transformative device solutions.

COMPETING INTERESTS
Jonathan J Lund is an engineer employed by Boston Scientific.

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