

SURGERY

Biomechanical Comparison of Inflatable Penile Implants: A Cadaveric Pilot Study



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ABSTRACT

Background: Throughout the last decade there has been a growing interest in the biomechanical differences between inflatable penile prostheses (IPPs) and their significance with regard to the patient experience.

Aim: To present our findings assessing the biomechanical properties of IPPs with and without rear tip extenders (RTEs).

Methods: This is a biomechanical study of the 3 most commonly used IPPs (AMS CX, AMS LGX, and Coloplast Titan) as assessed by column compression, modified cantilever deflection, and 3-point bending methods. The IPPs were surgically placed into 3 fresh cadavers via an infrapubic technique by a single large-volume implanter. A biomechanical evaluation of the properties of each IPP inside the fibroelastic tunica albuginea was assessed in blinded testing, and analyses were based on industry standard methods for assessment.

Outcomes: Maximum axial load; kink formation; horizontal stiffness; and resistance to 3-point flexure testing were measured.

Results: At maximum inflation, all 3 implants had similar performance. Differences appear to be most affected by fill pressures. In fact, only the AMS LGX at less than maximum inflation (LTMI) was unable to consistently withstand the roughly 0.9 kg (2 lbs) of pressure for column load testing mimicking vaginal intromission. The Coloplast Titan showed slightly better rigidity than the AMS LGX and CX devices in horizontal load testing, and, with 3-point flexure testing, the CX showed the best rigidity in the shortest phallus (A). Overall, the Titan showed slightly better rigidity in the longest phallus (C) and the phallus with mild Peyronie's disease (B).

Clinical Translations: Penile implants with circumferential expansion had higher rigidity on biomechanical testing and should be considered in a patient's decision during selection of a penile implant.

Strengths and Limitations: Strengths include blinding of the biomechanical testing and analyses, surgical procedures performed by a highly experienced surgeon, and that this is the "closest to" in vivo evaluation (inside the tunica albuginea) of penile implant function and properties to date. Weaknesses are that this study was performed in cadavers and not in live patients. It also has a small sample size, including the use of only 3 cadavers, and there was no correlation of performance to patient satisfaction.

Conclusion: The results of this study support the conclusion that all devices are capable of functionally restoring erectile capacity. However, we observed that, in general, the 2 circumferentially expanding penile prosthesis showed greater resistance in biomechanical testing when compared with longitudinal and circumferential expanding devices. This should be considered as a guide during device selection for a patient undergoing penile prosthesis. **Wallen JJ, Barrera EV, Ge L, et al. Biomechanical Comparison of Inflatable Penile Implants: A Cadaveric Pilot Study. J Sex Med 2018;15:1034–1040.**

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Key Words: Inflatable Penile Implant; Erectile Dysfunction; Peyronie's Disease; Axial Rigidity; Biomechanical Function; Rear Tip Extender

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INTRODUCTION

The inflatable penile prosthesis (IPP) is currently the only surgical treatment for erectile dysfunction (ED) refractory to medical management. The 2 modern-day devices manufactured by American Medical Systems (AMS [now Boston Scientific]; Minnetonka, MN) and Coloplast (Minneapolis, MN) were introduced in the early 1980s. Currently, the AMS CX, AMS 700 LGX, and the Coloplast Titan devices are the most commonly placed devices globally. To date, device selection has largely been dependent on surgeon preference, familiarity, and training, with few objective criteria by which individual patients can base selection of implantation devices.

Almost 90 years after the advent of surgical techniques to manage ED, there is now an interest in understanding what drives patient and partner satisfaction, and to this end, new data on biomechanical properties of IPPs are beginning to emerge. As early as 1985, Karacan et al¹ described a minimum requirement when they reported that a rod that is unable to withstand a force less than 500 g (1.1 lbs) was unable to achieve vaginal intromission. Since then, further work by the Goldstein group reported on a population with an average 1 kg (2.2 lbs) of axial force required for intromission.² At the time of this publication, this group is unaware of any cadaveric or human data regarding the axial force required for anal intromission. Furthermore, Ansari et al³ measured in vivo axial rigidity in patients with postsurgical inflatable and semi-rigid penile prostheses and compared this with patient satisfaction. The volumes and pressures in inflatable devices in this study were not standardized, and the authors found that patients with lower axial rigidity were more likely to report lower satisfaction scores. However, all devices tested were able to achieve a mean axial rigidity score suitable for intromission and intercourse.

In 2016, Scovell et al⁴ described the biomechanical properties of the AMS 700 LGX and the Coloplast Titan IPP cylinders in an ex vivo setting. In this study, cylinder pressures were standardized, and column load (simulating penetration) and modified cantilever (vertical lie) testing were performed, with significant differences in the performance of the 2 devices. The Coloplast Titan device was able to withstand a larger column load across all the pressures and fill volumes tested, had a reduced angular displacement with gravitational forces, and was less sensitive to fill pressures as compared with the AMS LGX device. However, the LGX was better able to expand in a lengthwise manner with increasing fill pressures than the Titan. The study concluded that the AMS LGX may be better for a patient with a primary concern of maximizing penile length. However, they also concluded that the Titan may be a better implant for patients with corporal fibrosis, those with difficulty compressing the pump to manually reach high fill pressures, and those who have a partner who requires more force for intromission.⁴

Romo et al⁵ later published a similar evaluation of the ex vivo biomechanical properties of the AMS CX, AMS CXR, AMS 700

LGX, Coloplast Titan, and the Coloplast Titan Narrow. The results were similar to the Scovell study in that the AMS CXR, Titan, and the Titan Narrow performed in a cluster just above the AMS CX and AMS LGX in both tests. The authors reported a 50% greater force required to compress the 2 Coloplast devices, leading them to suggest that the Bioflex material may be the cause of this difference in strength between devices.⁵

The IPP is designed to produce an erection using a hydraulic pump. Mechanically, IPPs differ in that the AMS CX and the Coloplast Titan devices are marketed as expanding circumferentially, whereas the AMS LGX expands in both a lengthwise and circumferential manner. The previous studies of these differences in biomechanical properties have spurred a growing interest in the biomechanical differences between these IPPs and if these differences have clinical significance. We set out to examine whether the biomechanical differences observed in an ex vivo setting would translate when device performance was evaluated inside the fibroelastic tunica albuginea in a cadaver setting.

In this archetypal study, we performed an evaluation of the biomechanical properties of IPPs with and without rear tip extenders (RTEs) in cadavers. We examined 3 properties of the IPPs to simulate stresses during sexual intercourse: penetration (longitudinal column rigidity), horizontal lie of the penis (horizontal rigidity using a modified cantilever test), and bending stiffness (flexure testing via 3-point bend testing).

METHODS

Funding was obtained through Coloplast Corporation; 3 fresh human cadaver pelvises were obtained; and phallic length and girth were measured with a standard disposable ruler. Length was measured as the distance between symphysis pubis and the proximal coronal sulcus, and girth was measured at the base of the penis only. The cadaveric study was designed with cadavers to simulate the “closest to” in vivo setting we could attain. We wanted to see how the implants would function within their natural setting inside the tunica albuginea but understood that accrual may be quite difficult for a true in vivo study based on the nature of the biomechanical testing. We obtained via purchase, a single pair of 18-cm cylinders for each of the following implants: AMS CX, AMS 700 LGX, and Coloplast Titan. RTEs were added to each cylinder to optimally accommodate the length of the corporal bodies in each cadaver. Each cadaver was initially implanted with 1 of the 18-cm implants, and then the devices were systematically rotated throughout the cadavers. All of the cylinders had a T-connector placed into 1 of the cylinder exit tubes to ensure pressures remained constant within and between IPPs throughout testing (Figure 1). All IPPs were surgically placed into all 3 cadavers via an infrapubic approach by a high-volume surgeon before undergoing blinded biomechanical testing by engineers. Testing was repeated to check reproducibility, but repeated testing was limited to minimize cadaver damage. Testing

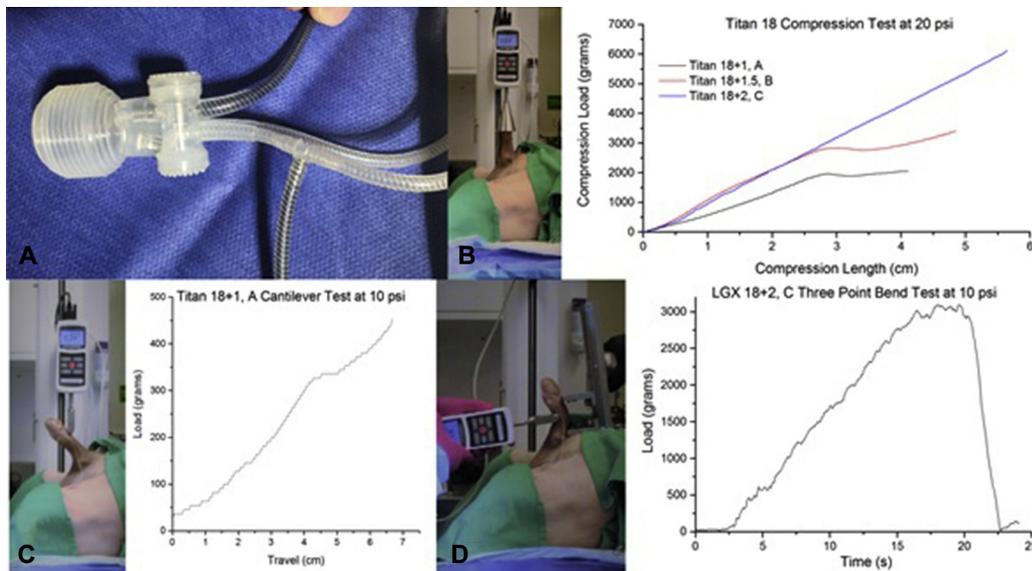


Figure 1. Test setup and example of data. Picture A (upper left hand) shows that a “T” connector was placed in the exit tubing to 1 of the cylinders to measure the fill pressure in the implant. Picture B (upper middle) shows longitudinal column load testing. Graph 1(upper right) shows deflections in the graph represent kinking with load. Picture C (lower left) shows horizontal rigidity testing via modified cantilever deflection. Graph 2 (bottom left) shows that the slope of the graph represents stiffness with applied load. Picture D (lower right) demonstrates flexure testing via 3-point bending. Graph 3 (lower right) shows the maximum load in the graph represents the bending flexure load. [Figure 1](http://www.jsm.jsexmed.org) is available in color online at www.jsm.jsexmed.org.

occurred over a 10-hour period, and the cadavers remained notably unchanged during testing. Specifically, no proximal or distal perforation of the tunica of any of our cadaver specimens was noted throughout the entirety of our testing. Corporotomies were closed in standard fashion with 2-0 PDS stay sutures and were kept to the minimum length for implant insertion, or roughly 1.5–2 cm. The corporal length of cadaver A was 19 cm and a 1.0-cm RTE was added to all of the implants inserted into this phallus. Cadavers B and C had a total corporal length of 19.5 cm and 20 cm, respectively, and a 1.5-cm and a 2.0-cm RTE, respectively, were added to these implants. Of note, cadaver B had a 20° distal dorsal Peyronie’s curve, which was noted at the time of artificial erection prior to insertion of the cylinders.

Engineers with expertise in mechanical engineering, nano-engineering, polymer engineering, materials science, chemistry, and mechanical testing performed our biomechanical studies and were blinded to which IPP was in use both during testing and during analyses. The testing pressures used were 517 mm Hg (10 psi) and 1,034 mm Hg (20 psi). We used 1034 mm Hg (20 PSI) to closely correlate with the 1,000 mm Hg needed for maximum inflation as described by Pescatori et al.⁶ The difference of 34 mm Hg is believed to be insignificant by our engineering team. To contrast this with a less-than-maximum inflation (LTMI) pressure that correlates to a patient with manual dexterity issues (any issue that would limit hand dexterity enough to limit the patient’s ability to squeeze the pump) or difficulty pumping the device to maximum inflation as a result of poor pump placement, we chose 517 mm Hg (10 PSI) as a second comparison inflation pressure. These pressures were previously used in our ex vivo study.⁴ Biomechanical properties of the IPPs were assessed using a

Mark 10 ESM303 Motorized Tension/Compression Test Stand and Mark 10 Series 5 Force Gauge in longitudinal (column compression), horizontal (modified cantilever deflection), and flexure (3-point bending) modes.

Tests were designed to compare to standardized column buckling, cantilever beam testing, and 3-point bend testing.^{7,8} Cantilever beam tests were performed at different settings to properly select which test would best compare to actual implant use. In ex vivo testing, the cantilever test assessed cantilever beam bending with a constant load applied.⁴ The modified cantilever tests in this study assessed pivoting around the base of the phallus or essentially the fulcrum of a straight cantilever beam.

Longitudinal Column Load Testing (to Simulate Penetration)

To simulate vaginal penetration, longitudinal column load testing was performed: 2 IPP cylinders simultaneously implanted in each cadaver were compressed along their longitudinal axis by a metal cone-shaped holder fastened into the force gauge ([Figure 1](#), Picture B). The testing machine compressed the implants longitudinally at an automated rate of 2.54 cm/min (1 in/min). This rate was chosen because it is close to the industry standards for polymers of 1% of specimen length per second and furthermore was the same rate used for our previous ex vivo study. Sensors recorded the compression displacement sustained and the applied load throughout compression. We designated column strength as a drop in compression load, which was the characteristic of kink formation in the previous ex vivo study, or by the maximum load value applied when no kink

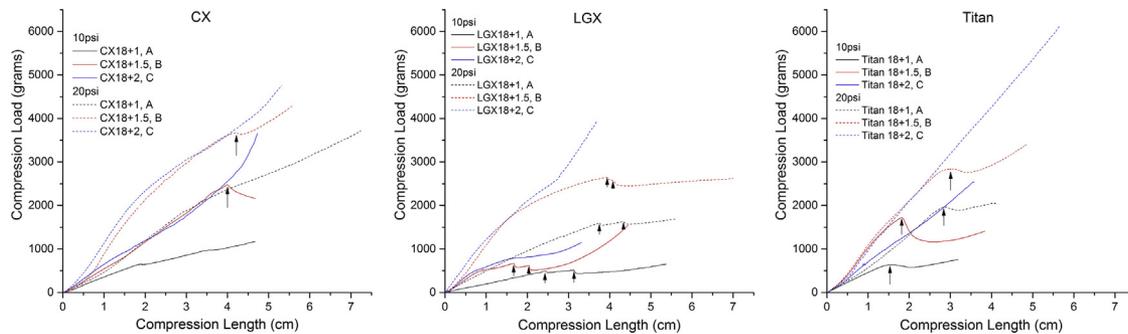


Figure 2. Compression Load Testing. Graph 1: CX (left), Graph 2: LGX (middle), and Graph 3: Titan (right). The legend in the upper left corner of each graph is representative of the pressure settings, length of cylinders in centimeters, and additional rear tip extender length in centimeters for each of the respective implant in the graphs. A drop in the load curve is representative of kinking of the cylinder(s). [Figure 2](http://www.jsm.jsexmed.org) is available in color online at www.jsm.jsexmed.org.

formation occurs. Stiffness was defined as the slope of load length of the compression curve at 1.27 cm (0.5 in) of compression. The load range was partially determined on the basis of the bowing of the penis to the point where the cone-shaped holder would not traumatize the penile skin.

Horizontal Stiffness via Modified Cantilever Deflection (Vertical Lie)

To replicate resistance to bending with gravity or penile lie, we assessed horizontal rigidity of IPPs after implantation. We examined change in load using a modified cantilever test in loaded and unloaded settings. The cantilever test is modeled after the ASTM D747-10 (ASTM International, West Conshohocken, PA).⁶ Please refer to [Figure 1](#), Picture C, for pictorial representation of testing setup, as well as a graphical example of the data tracings. Downward deflection of the implanted inflated cylinders was simulated by the testing machine at an automated setting of 2.54 cm/min.

Flexure Testing via 3-Point Bending (Aggressive Angulation)

To replicate resistance to bending, we examined IPP rigidity under maximum load using a 3-point bend test. The 3-point bend test is modeled after the ASTM D790-17 (ASTM International).⁷ Please refer to [Figure 1](#), Picture D, for pictorial representation of testing setup as well as a graphical example of the data tracings. The distance between supporting pins is 5.08 cm (2 in). A moveable loading pin (attached to the force gauge) pushes the penis to line up with the support pits of the 3-point bend device. This loading is applied manually.

RESULTS

Longitudinal Column Load Testing

The column load strengths of the CX, LGX, and Titan implant cylinders were tested after being implanted into the tunica albuginea in fresh human cadavers ([Figure 2](#)), with stiffness (slope of compression curve at 1.27-cm deviation) and maximum load before device failure (kink formation) being the 2

primary outcomes. Our stiffness measure was chosen as 1.27-cm compression length to evaluate the implants at the same point statistically before any implant kinked. The compression test simulates penetration where the implant and the penis are subject to compression load on the distal end after implantation inside a fixed location, the cadaver tunica albuginea. When the subject experiences a kink, it is considered a failure. All samples were expected to pass the penetration load.

The implant cylinders behaved differently at 1034 mm Hg and 517 mm Hg of pressure. The LGX at LTMI (517 mm Hg) was the weakest of the implants, with implants in all 3 cadavers undergoing kink formation or significant deviation in stiffness (horizontal slope) at or before 909.1 g (2.0 lbs) of force ([Figure 2](#), Graph 2). In fact, we observe a load drop (downward deflection) followed by a second load drop in the LGX at LTMI in cadavers A and B and again at a pressure of 1034 mm Hg in cadaver A ([Figure 2](#), Graph 2). These double-load drop phenomena signify either kinking of 1 cylinder and then the other at a greater pressure or simultaneous kinking of both cylinders and a second kink formation at the point of second load drop.

In comparison, the CX ([Figure 2](#), Graph 1) and Titan ([Figure 2](#), Graph 3) IPPs only failed to surpass the 909.1 g threshold in cadaver A (18 + 1 cm RTE) at LTMI. In cadaver B, the Coloplast Titan underwent a drop in load signifying kink formation at roughly 1,704.5 g (3.75 lbs), whereas the CX required a load of 2,386.4 g (5.25 lbs) prior to having a similar drop in load. Interestingly, at LTMI the AMS CX and Coloplast Titan were the stiffest of the implants tested. We also observed that for all implants, increasing the total length of RTEs (1 cm, 1.5 cm, to 2 cm) resulted in the phallus tolerating a higher maximum column load before significant deformation. This RTE-enhanced biomechanical performance will be seen in our other tests as well.

When we increased cylinder pressures to physiological levels of 1034 mm Hg and repeated the studies, the implants performed more similar. In comparison, the CX and Titan demonstrated less kinking and tolerated higher maximum loads. Based on these results, the CX appears to be a slightly stiffer device in certain cadavers, and the AMS CX and Coloplast Titan consistently

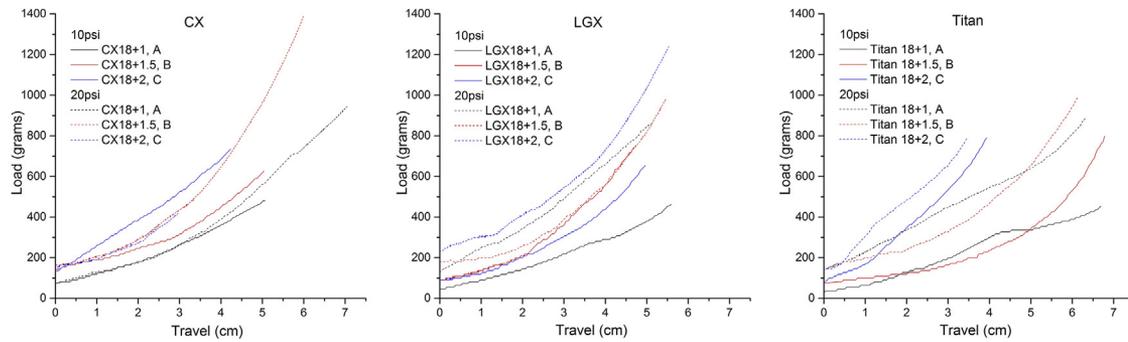


Figure 3. Horizontal stiffness via modified cantilever testing. Graph 1: CX (left), Graph 2: LGX (middle), and Graph 3: Titan (right). The legend (upper left corner) is representative of the pressure settings, length of cylinders, and additional rear tips for each of the respective implant models in the graphs. Figure 3 is available in color online at www.jsm.jsexmed.org.

outperformed the AMS LGX device. Note that although the CX appears to resist column compression more than the Titan in the shorter phallus, the Titan surpasses the CX in the longest and widest cadaver phallus (C).

Horizontal Stiffness via Modified Cantilever Deflection

Modified cantilever deflection is an assessment of quality of erection where a load is applied to bend the penis supported by only 1 pivot point. Figure 1C shows how the horizontal stiffness via modified cantilever deflection was tested using the CX, LGX, and Titan implant cylinders. The load vs deflection data for all 3 devices (in alphabetic order) in 3 cadavers is plotted in Figure 3. The Titan showed a stiffer response compared with the other 2 implants in horizontal stiffness, as represented by less deflection with increasing loads (Figure 3, Graphs 1, 2, and 3). All devices appear to perform better on this test with physiological inflation versus LTMI and also with increasing RTE size.

Flexure Testing via 3-Point Bending

The 3-point bending is an assessment of quality of erection that simulates when part of the penis is inserted in the vagina (or other orifice) and subject to a perpendicular bending load. Figure 1D shows how the 3-point bending test is conducted on cadavers. The outcome of this test for all 3 devices is plotted in Figure 4. The CX outperformed both the Titan and LGX in the shortest phallus (cadaver A). The Titan IPP showed higher loads compared with the CX and LGX in cadavers B and C. In the longest phallus, the Titan showed higher loads than the CX and LGX. Furthermore, the cadaver with a small percentage ($\sim 20^\circ$) of dorsal Peyronie's disease curve also showed higher loads with Titan cylinders implanted.

DISCUSSION

Ansari et al³ suggested that all IPP devices are able to achieve a mean axial rigidity score suitable for vaginal intromission and intercourse. Our results with column loading confirm most of these findings, although small differences were noted in device performance across the battery of tests. It is important to note that this

pilot study is significantly underpowered to prove statistical significance between devices. However, the AMS 700 LGX device seemed to be the most sensitive to changes in pressure, and at LTMI was the only 1 of the 3 devices consistently unable to exceed the pressure threshold for vaginal intromission. This is consistent with our previously published ex vivo data of the LGX performance being more sensitive to fill pressures.⁴ This makes some intuitive sense given that the LGX is the only length- and girth-expanding device and thus is affected more by the laws of physics and fluid dynamics. With maximum inflation pressures of the devices, however, all implants observed loads that allowed for penetration. Furthermore, we observed that all of the IPPs appear to have greater maximum loads as RTE length increases (in this study, up to 2 cm). This is contrary to expert opinion; these new data suggest that increasing the length of RTEs may improve a patient's ability to penetrate because a lack of RTEs on IPPs was associated with increased pressures resisting similar forces. This will have to be further studied to confirm what exactly the relationship is between RTEs and IPP performance.

Because we understand that sexual activity is a dynamic process, our study then examined the horizontal stiffness and vertical phallic lie to assess the ability of an erection to resist bending from horizontal forces and to remain in a physiologic position (ie, straight, upward slant) while erect. In our study, the Titan demonstrated slightly higher rigidity than the other 2 implants in these tests. We also observed increasing maximum horizontal stiffness with increasing length of RTE; however, the use of RTEs was associated with lower compression strengths at 1.27 cm of displacement. In step 3, we performed flexure testing via 3-point bending to simulate aggressive angulation during sexual activity, and the Titan again demonstrated slightly higher rigidity with increasing loads than the other 2 implants in 2 of 3 cadavers. It is in cadavers B and C that the Titan performed the best. Previous ex vivo data show that the Titan implants have greater radii, which may allow for greater resistance to pressures, and its increased ability to withstand a horizontal and flexure load may be advantageous in its performance in patients with not only longer phalluses, but also those with fibrosis or scarring (Table 1).^{4,5} These claims, however, would have to be further validated with studies specifically designed to examine these variables.

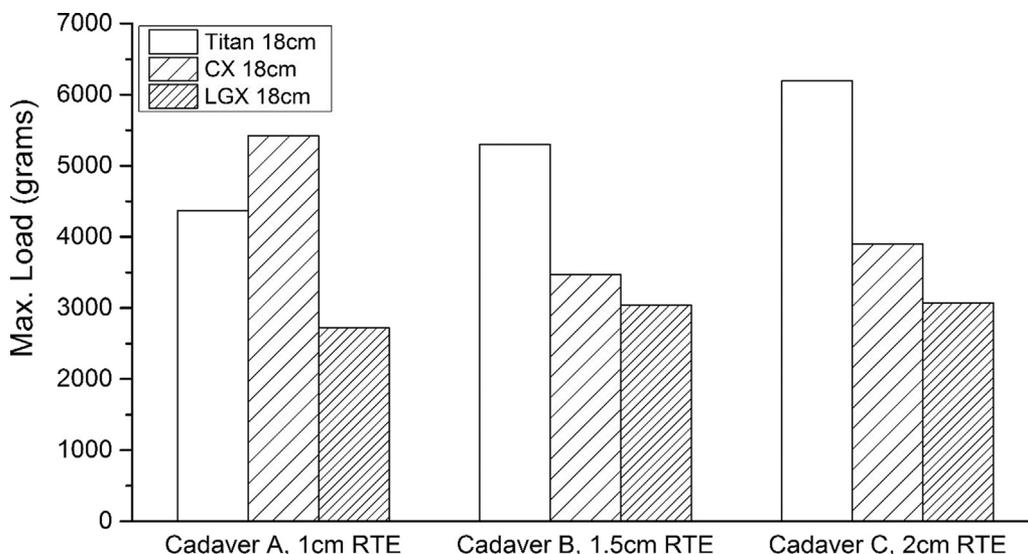


Figure 4. Flexure testing via 3-point bend. Graphic depiction of the pressure necessary to cause flexion as pictured in Figure 1, Graph 3. The Titan appeared to require the most force for flexion in the longest phallus (Cadaver C) and in the phallus with 20% dorsal Peyronie’s disease (Cadaver B). The CX required the most force for flexion in the shortest phallus (Cadaver A).

Although no algorithm for device selection prior to surgery exists, we can infer trends from our data and the literature. All IPPs are capable of vaginal intromission at standard filling pressures for each device. We do not know if this holds true for anal intromission because data on the resistance force required for anal intromission does not exist in the literature. If a patient has manual dexterity issues that limit his ability to inflate the device to maximum pressure, yet still desires an inflatable device, an AMS CX or Coloplast Titan device could be suggested in comparison with an AMS LGX on the basis of its sensitivity to filling pressures in our data and previous literature.⁴ Furthermore, based on this sensitivity, patients with difficult pump mechanisms or pump placement that inhibits their ability to pump to maximum inflation would likely have a more consistent experience with an AMS CX or Coloplast Titan device. It should be noted that there are differences in routine pump-mechanism function and also the volume with each pump that further confound this specific situation. We also did not test specifically fill volumes but standardized pressures instead based on previous IPP research done by Pescatori et al.⁶

There are several limitations to this study, including the cadaver numbers used (N = 3) and the fact that these implants were not placed in living tissues with patient-experience data recorded. We also examined filling pressures of only 1,034 (20 PSI) mm Hg and 517 mm Hg (10 PSI), which were chosen as closest to maximum inflation (20 PSI) and an arbitrary LTMI (10 PSI), respectively, because the settings on our machine were valued in PSI. We also alternated the order of which cadaver was tested with each implant, which could have possibly introduced a structural bias in our results. Because IPP devices were serially placed in each cadaver, this may change the biomechanical properties of the tunica albuginea and surrounding penile soft tissues. Another limitation is that we did not study the AMS CXR or Titan narrow devices, and furthermore that we only evaluated the 18-cm inflatable cylinders. Finally, we acknowledge that the study authors use a majority of Coloplast devices in their clinical practice, and this could certainly introduce bias.

This study is strengthened by the validated biomechanical method used to measure the response to longitudinal loads.

Table 1. Kink load and maximum load

Implant, Cadaver	517 mm Hg			1,034 mm Hg		
	First Kink (g)	Second Kink (g)	Maximum Load (g)	First Kink (g)	Second Kink (g)	Maximum Load (g)
CX 18+1, A	—	—	1,170	—	—	3,720
LGX 18+1, A	490	520	—	1,600	1,620	—
Titan 18+1, A	640	—	—	1,970	—	—
CX 18+1.5, B	2,490	—	—	3,670	—	—
LGX 18+1.5, B	670	620	—	2,650	2,580	—
Titan 18+1.5, B	1,710	—	—	2,830	—	—
CX 18+2, C	—	—	3,660	—	—	4,750
LGX 18+2, C	—	—	1,150	—	—	3,940
Titan 18+2, C	2,540	—	—	—	—	6,110

The 3 tests were designed to assess the biomechanical performance of IPPs in cadavers in relevance to their intended use in 3 very common loading situations encountered during sexual intercourse. The biomechanical testing was performed on a validated platform that provides accurate and precise data. Furthermore, as mentioned previously, the engineering investigators were blinded to which implant was in place during testing and their analyses, which limited their ability to identify which manufacturer produced the device and thus limited potential biases in the data. All of the implants used in this study were brand-new out of the box and had never been used before, and they were surgically placed by a high-volume experienced surgeon, which limited the potential for error in operative placement of the devices as a confounder in the differences seen in our data.

These data support the presence of some small inherent differences between IPPs that surgeons must consider when treating ED. We plan to perform additional biomechanical testing both *ex vivo* and as close to, or if possible, *in vivo* settings to further characterize the strengths of each device to help guide surgeons regarding which patients may benefit from each IPP device.

CONCLUSION

In this study, a biomechanical comparison of the AMS CX, AMS LGX, and the Coloplast Titan IPPs was conducted in a cadaveric setting. Although all IPPs at maximum inflation can meet the physical demands of sexual activity, there are some differences between devices. Further study is required to correlate these differences to clinical outcomes and patient satisfaction and to further evaluate the impact of total RTE length on device biomechanical function. Inherent differences exist between the 3 IPP devices with respect to their ability to resist both longitudinal and horizontal forces. The AMS LGX performance was more dependent on fill pressures, suggesting the potential for greater variability in patient experience. The structural differences observed by manufacturers in the biomimicry of the IPP correlate to differences seen in their performance observed in the cadavers. The results of this study support the conclusion that all devices are capable of functionally restoring erectile capacity. However, we observed that in general, the 2 circumferentially expanding IPPs showed greater resistance in biomechanical testing when compared with longitudinal- and circumferential-expanding devices. This should be considered as a guide during device selection for a patient undergoing penile prosthesis.

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Conflict of Interest: Drs Pastuszak, Carrion, Perito, and Hakky are all consultants for Coloplast Corporation. Drs Carrion and Perito consult for Boston Scientific (AMS). Drs Wallen, Barrera, and Ge report no conflicts of interest.

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