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SURGERY

Longitudinal and Horizontal Load Testing of Inflatable Penile Implant Cylinders of Two Manufacturers: An Ex Vivo Demonstration of Inflated Rigidity

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ABSTRACT

Introduction: Since the inception of the inflatable penile prosthesis, a new era has been ushered in for the management of erectile dysfunction. Despite multiple innovations to improve function and reliability, there are no current data comparing the biomechanical properties of these devices.

Aim: To compare the resistance of the Coloplast Titan (Minneapolis, MN, USA) with that of the AMS 700 LGX (Minnetonka, MN, USA) penile prosthesis cylinders to longitudinal (penetration) and horizontal (gravity) forces.

Methods: We compared two cylinder sizes from each company: the Coloplast Titan (18 and 22 cm) and the AMS 700 LGX (18 and 21 cm). To evaluate axial rigidity, which simulates forces during penetration, we performed a longitudinal load compression test to determine the load required to cause the cylinder to kink. To test horizontal rigidity, which simulates the horizontal forces exerted by gravity, we performed a modified cantilever test and measured the degrees of bend for each device. All devices were tested at 10, 15, and 20 PSI to simulate in vivo pressures.

Main Outcome Measures: The main outcome measurement for the longitudinal load test (penetration) was the force required for the inflated cylinder to bend, thereby affecting its rigidity. The main outcome for the horizontal rigidity test (gravity) was the angle of displacement, in which a smaller angle represents a more horizontally rigid device.

Results: Longitudinal column testing (penetration) demonstrated that less force was required for the AMS device to kink compared with the Coloplast implant across all three fill pressures tested. The Coloplast Titan also had a smaller angle of displacement at the modified cantilever test (gravity) compared with the AMS implant across all fill pressures.

Conclusion: The Coloplast Titan demonstrated greater resistance to longitudinal (penetration) and horizontal (gravity) forces in this study. The AMS device was very sensitive to fill pressures. In contrast, the Coloplast Titan's ability to resist these forces was less dependent on the device fill pressure.

Key Words: Erectile Dysfunction; Material Properties; Prosthesis

INTRODUCTION

The inflatable penile prosthesis (IPP) is the gold standard for surgical management of erectile dysfunction that is refractory to medical therapy. Patients and their partners have reported exceptionally high satisfaction rates.[1] Since the development of the IPP in the 1970s, several innovations have been made to enhance function, reliability, and cosmesis.[2–4] Currently, Coloplast (Minneapolis, MN, USA) and American Medical

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Systems (AMS; Minnetonka, MN, USA) are the two major manufacturers of IPPs in the United States.

During the past several decades, several important changes have been made to IPP devices, including the introduction of the lockout valve,[5] antibiotic coatings,[6,7] and flat reservoirs.[8] Although clinical trials have evaluated many of these improvements, there has been little biomechanical research to validate the mechanical attributes or marketing claims of each company.

Mechanically, the implants differ in that the Coloplast Titan is marketed as expanding circumferentially, whereas the AMS 700 LGX is advertised as expanding in length and girth.[2,9,10] The most recent study evaluating the biomechanical properties of the IPP was published in 1993 by Pescatori and Goldstein.[11] This gap in research underscores the surprising lack of data available for an otherwise commonly used device.

Although the Coloplast and AMS devices have many similarities, there are sparse data to support which device is advantageous and in what scenario a surgeon should choose one manufacturer over the other. There is no evidence that the devices produced by the two manufacturers are so similar that this decision is merely the "surgeon's preference." In our men's health clinic, we anecdotally found that some patients were dissatisfied with the rigidity of their device for penetration after being trained on proper use. We also noted that some men without any prior evidence of Peyronie's disease had some penile curvature after prolonged use. Moreover, we heard from many men that their phallus hung in a more dependent position after placement of the IPP. These complaints led us to wonder whether there were differences in the mechanical capabilities of the two devices causing these complaints and whether we could demonstrate the differences in the laboratory.

Given the anecdotal discrepancy in rigidity, penile dependence, and curvature that we observed in the clinic, we performed a blinded biomechanical study to compare the two sizes of Coloplast Titan with the AMS 700 LGX. Our goal was to report objective end points to highlight the inherent differences between the two devices. The penile implant is designed to emulate an erection in the form of a hydraulic pump. We set out to test two functions of the implants during intercourse, which are penetration (longitudinal column rigidity) and horizontal lie of the penis (horizontal rigidity). A visible cylinder kink denoted mechanical device failure during longitudinal column rigidity testing. To evaluate turgidity, we measured horizontal rigidity, which simulated resistance to bending with gravity.

METHODS

We compared four IPP models in blinded fashion: the Coloplast Titan (18 and 22 cm) and the AMS 700 LGX (18 and 21 cm). Testing was performed at the Rice University Materials Science and Nano-Engineering Department (Houston, TX, USA). The individuals performing the testing were blinded to manufacturer and had no prior experience testing such a device. All tests were performed in the presence of the lead author who is an andrology fellowship-trained urologist with experience placing the two brands of implant.

Each implant's system was tested apart from its fluid reservoir for ease of testing. The cylinder-pump assembly was inflated with 0.9% normal saline to various fill pressures using a 60-mL syringe as surrogate reservoir. The cylinders were pressurized into an intact column by pumping. Each pump delivered approximately 7 mL of saline solution per pump action (based on manufacturer specifications) until the selected test pressures were reached. Before pressurizing, a "tee" was placed in line between the pump and the implant cylinder. The pumping action produced pressure readings on the pressure gauge placed on the tee. When a desired pressure was reached, a hemostat was used to clamp off the cylinder so the tee could be removed. Because we noted differences in volumes required to completely fill each cylinder, we used devices pressures as a constant to compare device column failure. Then, a hemostat was used to clamp off the tube to maintain the desired pressure after the pressure was achieved. We compared each device at an inflation pressure of 10, 15, and 20 PSI (68.9, 103.4, and 137.9 kPa). The cylinder's length and diameter were measured before being placed in the test fixtures once they were pressurized. Because patients might not fill the device to maximum inflation owing to preference or physical inability, we tested each implant at various levels of inflation to simulate clinical usage. All testing was documented and preserved on video.

Longitudinal Column Load Testing (to Simulate Penetration)

To simulate penetration, we performed a longitudinal column load test. We designated compromised column strength as a visible kink in the cylinder. The cylinders were compressed along their longitudinal axes and were fastened into the machine with custom-machined metal holders. The testing machine compressed the implants longitudinally at an automated setting of 1 inch/min (2.54 cm/min). Each cylinder was tested individually using the ADMET eXpert 7600 Single Column Testing Machine (ADMET, Inc, Norwood, MA, USA). Sensors recorded the length of compression sustained until the implant kinked and recorded the load of pressure throughout compression to the device. Compromise of rigidity was identified as a visual kink in the device cylinder created by the compression. This kink also could be observed on the load-curve generated by the ADMET eXpert 7600. Then, the data were recorded and plotted for compression length and load sustained. Each implant was tested individually because it was not possible on our platform to test side by side. We tested the two cylinders from each manufacturer to minimize intra-cylindrical variation within a device. We defined maximum load as the force required to generate a kink in the cylinder, which was determined visually and by a sudden decrease in load pressure during testing.

Table 1. Length and diameter of devices at different fill pressures (0, 10, 15, and 20 PSI)

Device	AMS 700 LGX				Coloplast Titan			
Size (cm)	18 (1)	18 (2)	21 (1)	21 (2)	18 (1)	18 (2)	22 (1)	22 (2)
Length (cm)								
Pressure, PSI (kPa)								
0	18.0	18.0	21.0	20.9	18.2	18.2	22.1	22.1
10 (68.9)	19.2	19.1	22.7	23.4	18.2	18.2	22.2	22.1
15 (103.4)	21.0	20.7	23.7	24.2	18.4	18.4	22.2	22.2
20 (137.9)	21.2	21.0	24.0	24.9	18.4	18.5	22.7	22.8
Diameter (cm)								
Pressure, PSI (kPa)								
10 (68.9)	1.6	1.6	1.6	1.6	1.8	1.8	1.7	1.8
15 (103.4)	1.7	1.8	1.7	1.8	1.9	1.9	1.8	1.8
20 (137.9)	1.7	1.8	1.7	1.8	2.2	2.2	1.8	1.9
Volume per cylinder (mL)								
Pressure per two cylinder system, PSI (kPa)								
10 (68.9)	42	—	68	—	50	—	76	—
15 (103.4)	62	—	84	—	57	—	87	—
20 (137.9)	68	—	90	—	70	—	111	—

Cantilever Testing (Horizontal Penile Lie)

To replicate resistance to bending with gravity or penile lie, we examined horizontal rigidity. We looked at change in device angle in a loaded and an unloaded setting in the form of a cantilever test. The cantilever test is modeled after the ASTM D747-10 (ASTM International, West Conshohocken, PA, USA). The inflated cylinders were hung horizontally and were fastened into a custom-machined metal holder secured on a horizontal surface. Horizontal bend was measured with the device unloaded and with a weight of 20 g applied 76 mm from the base of the implant to simulate a bending load (loaded). The deflection angle and deflection were recorded. We tested each implant at various levels of inflation to simulate clinical usage of the prosthetic devices when patients might not fill the device to maximum inflation owing to preference or physical inability. We compared each device at an inflation pressure of 10, 15, and 20 PSI. Although each implant was tested individually owing to limitations of the testing platform, we tested the two cylinders from each implant to minimize intra-cylindrical variation within a device. The two cylinders for each implant were tested.

RESULTS

Two sizes of implantable cylinder-pump assemblies from two IPP manufacturers were tested for their ability to withstand longitudinal column loads (penetration) at various pressures. The length and diameter of each device were measured before longitudinal column testing (penetration) at various fill pressures (0, 10, 15, and 20 PSI; Table 1). Measurement confirmed the stated sizes of the AMS (18 and 21 cm) and Coloplast (18 and 22 cm) devices at 0 PSI. The two AMS cylinders increased in length but not in diameter with increasing fill pressure. In contrast, the Coloplast implants exhibited a minimal increase in length with increasing fill pressures. Only the 18-cm Coloplast Titan had an increase in diameter with filling. Fill volumes of each device were similar between the 18-cm cylinders at each fill pressure (42—70 mL). The AMS 21-cm device and the Coloplast 22-cm device had larger fill volumes (50—70 mL and 76—111 cm, respectively; Table 1).

Using single longitudinal column compression load to mimic penetration, we evaluated the minimum longitudinal load required for device kinking (Figure 1). The AMS devices kinked at a lower load at all three fill pressures than the Coloplast devices. Although all devices kinked at greater longitudinal loads at increasing fill pressures, the AMS devices appeared to be more sensitive to fill pressure, whereas the Coloplast devices could tolerate similar load pressures across all three fill volumes (Figure 2). The 18-cm Coloplast Titan device withstood the greatest longitudinal load force of any device measured. We also recorded the location of device kinking during longitudinal load forces. The AMS devices kinked more proximally than the Coloplast devices, which kinked just behind the silicone tip (Figure 3).

To evaluate resistance to gravitational forces, we examined horizontal rigidity using a cantilever test across all three fill pressures (Figure 4). A smaller angle of displacement represents a greater resistance to gravity. At maximal fill pressures, the AMS and Coloplast devices had similar horizontal rigidity. However, the AMS devices tended to displace farther at lower fill volume, whereas the Coloplast devices achieved near-maximal rigidity at the lowest fill pressure tested (Table 2 and Figure 5).

DISCUSSION

The penile implant is a prosthetic device designed to emulate an erection. To mechanically replicate the cylinder rigidity

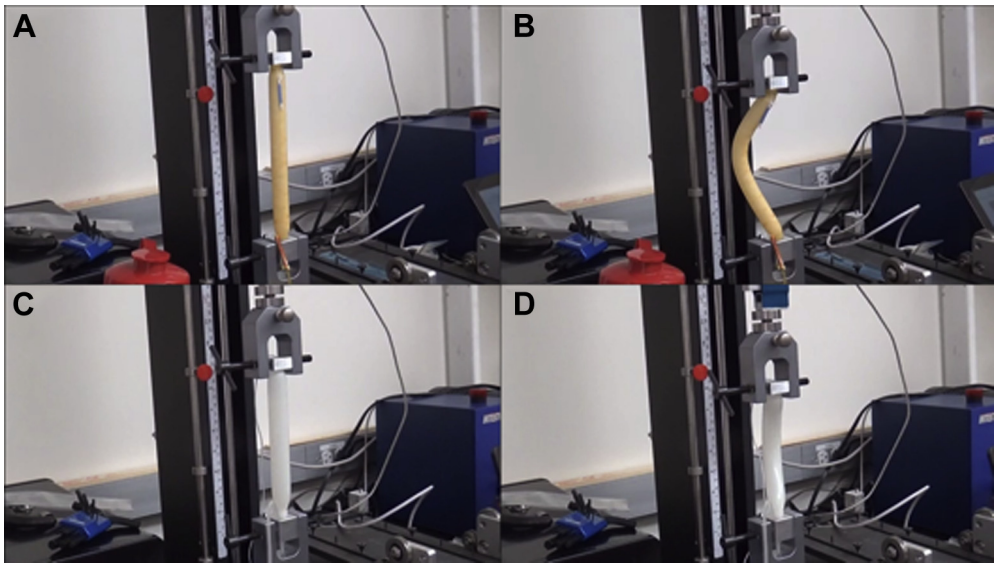

Figure 1. ADMET eXpert 7600 Single Column Testing Machine load testing of the 21-cm AMS 700 LGX (A—B) and the 22-cm Coloplast Titan (C—D). Figure 1 is available in color at www.jsm.jsexmed.org.

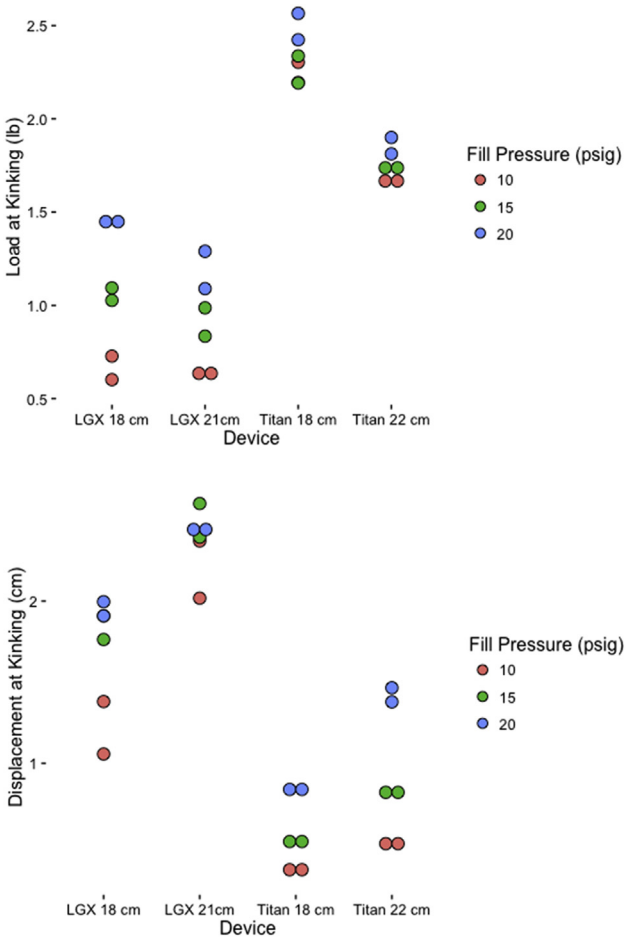

Figure 2. Maximum load of compression achieved at device failure and location of failure at different fill pressures. The lowest column load required to achieve kinking is reported for each cylinder represented by an individual dot. Figure 2 is available in color at www.jsm.jsexmed.org.

during penetration, we performed a longitudinal column load test. We defined device compromise as a visible kink in the cylinder. We reported the differences in longitudinal loads required to generate a kink in four commonly used IPP devices.

To evaluate patient claims of penile curvature over time, we tested horizontal rigidity of the cylinder by hanging a weight on the partially and fully inflated cylinder. At full rigidity in our testing (20 PSI), all cylinders performed admirably at smaller volumes (ie, pressure), although the AMS cylinders curved in response to the cantilever test.

The longitudinal compression and horizontal rigidity tests showed that the Coloplast Titan was more resistant to longitudinal and horizontal forces especially at lower pressures (fill volumes). Importantly, the Coloplast Titan was less sensitive to changes in fill pressures, which could represent superior real-world performance because individual use varies for fill volume and pressure achieved by the patient.

The results of this study highlight important differences between the two devices. The AMS 700 LGX implants became longer with increasing pressures, with the 21-cm implant having the most change in cylinder length of 3.9 cm at a maximum pressure of 20 PSI. The 18-cm AMS LGX had a length change second to that of its longer counterpart at 3.1 cm at 20 PSI. The Coloplast cylinders might have had a minimal increase in length, although more replicates would be required to appropriately document this change. However, the Coloplast cylinders had changes in length only at higher pressure loads.

During longitudinal pressure loading of the AMS 700 LGX devices, there was a large variability in load pressures required to generate device kinking. Kink load for the two AMS devices had a range of device load failure from 0.7 lb at 10 PSI to 1.1 to 1.5 lb at 20 PSI. The Coloplast products required greater and lesser

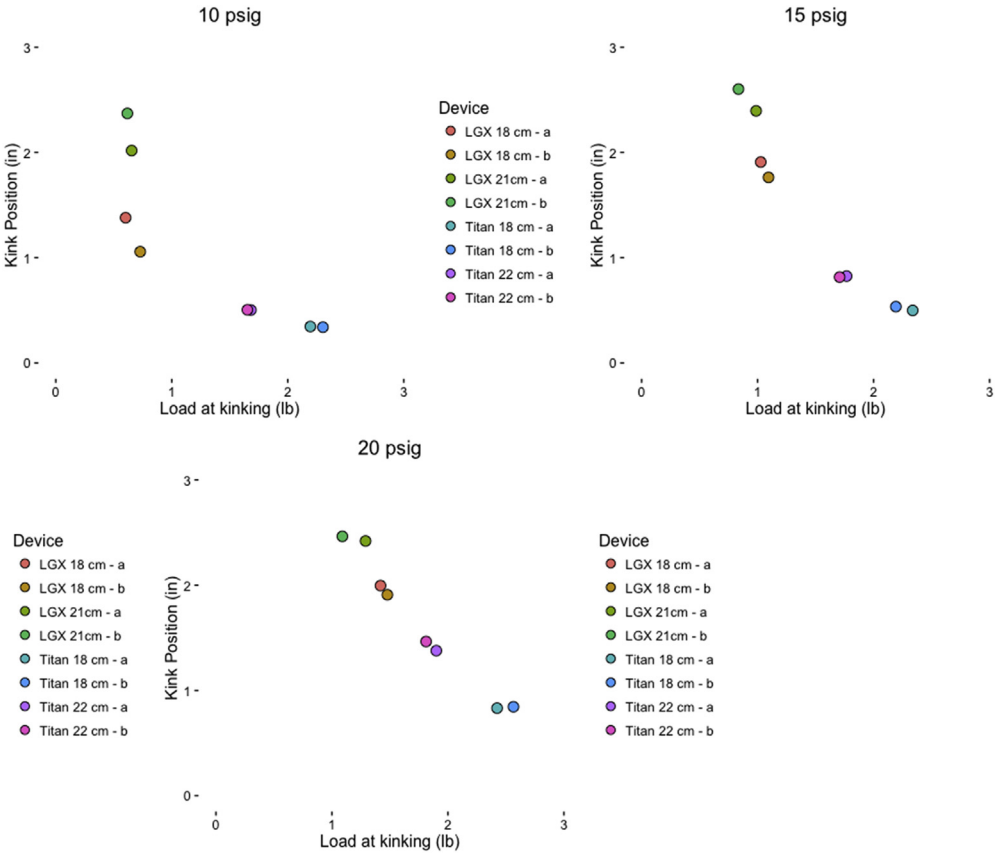

Figure 3. Load and location of device failure at 10, 15, and 20 PSI. Figure 3 is available in color at www.jsm.jsexmed.org.

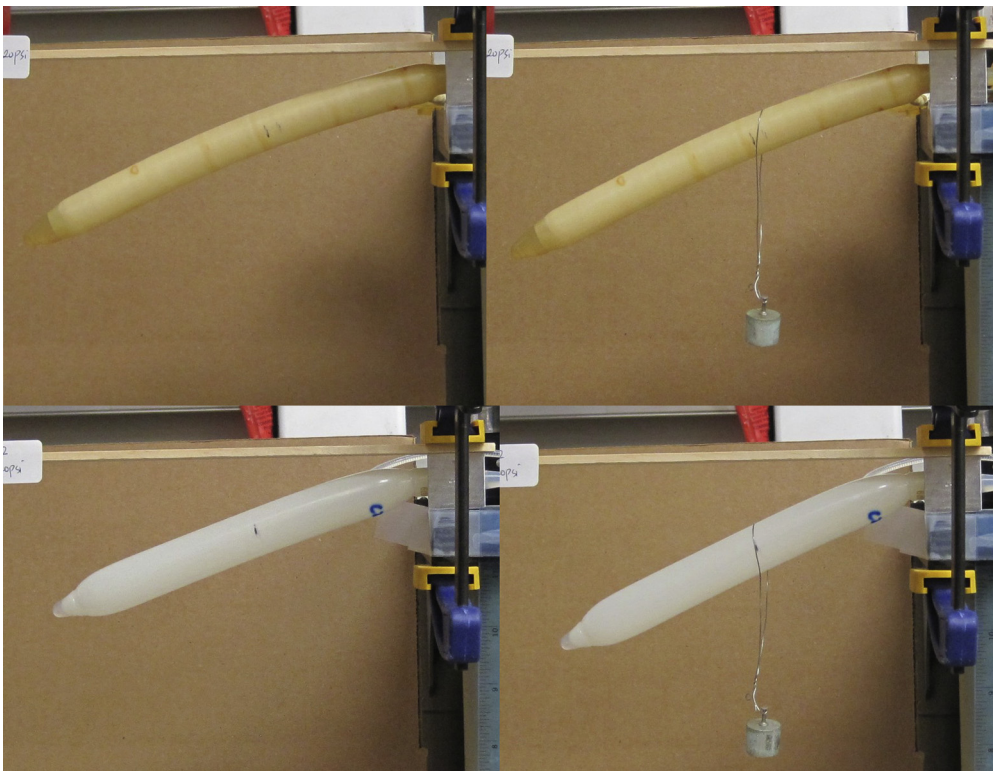

Figure 4. Unloaded and loaded cantilever testing of the 18-cm AMS 700 LGX and 18-cm Coloplast Titan. Figure 4 is available in color at www.jsm.jsexmed.org.

Table 2. Displacement during unloaded and loaded modified cantilever testing at 10, 15, and 20 PSIG

Device	Boston Scientific 700 LGX				Coloplast Titan			
Size (cm)	18 (1)	18 (2)	21 (1)	21 (2)	18 (1)	18 (2)	22 (1)	22 (2)
Unloaded angle (°)								
Pressure, PSI (kPa)								
10 (68.9)	22.0	23.8	34.3	39.5	6.2	4.6	12.6	13.5
15 (103.4)	20.7	20.4	21.2	26.9	7.7	6.1	13.9	15.3
20 (137.9)	15.7	15.4	15.9	19.4	8.9	7.8	16.8	17.6
Loaded angle (°)								
Pressure, PSI (kPa)								
10 (68.9)	31.6	32.9	36.9	41.5	12.3	10.9	17.9	19.1
15 (103.4)	25.4	25.0	23.7	30.2	12.7	12.4	18.6	19.3
20 (137.9)	19.7	19.1	17.9	21.4	13.6	12.7	21.2	22.9

variable pressures to generate kinking, with pressures ranging from 1.7 lb (22 cm) to 2.2 lb (18 cm; Figure 2).

Our study highlights that there are inherent differences in each of the IPP devices that should be considered for each patient. Traditionally, implants have been chosen based on surgeon preference after evaluation of the stated properties of each device by the manufacturer. The AMS 700 LGX expanded mostly in the longitudinal direction and less so circumferentially and was very dependent on pressures with a lower kink load than its counterpart. In vivo testing will be required to determine whether these differences can be used to more appropriately assign devices to the correct patient populations. The AMS device could be troublesome for patients who have corporal fibrosis because this device appears to be less resilient to external forces. However, the AMS 700 LGX might be optimal for the man who is primarily concerned with penile length. We hypothesize that at lower pressures and volumes, the Titan might be superior for the patient who has severe corporal fibrosis because it had a high kink load and smaller angles at the cantilever test. During the loaded and unloaded cantilever tests, the Titan was less pressure dependent compared with the AMS 700 LGX and did not have cylinder displacement angles that were nearly as large. The Titan might be a superior product for men who need greater axial loading during penetration and for men who are concerned with their phallus hanging lower after implant placement.

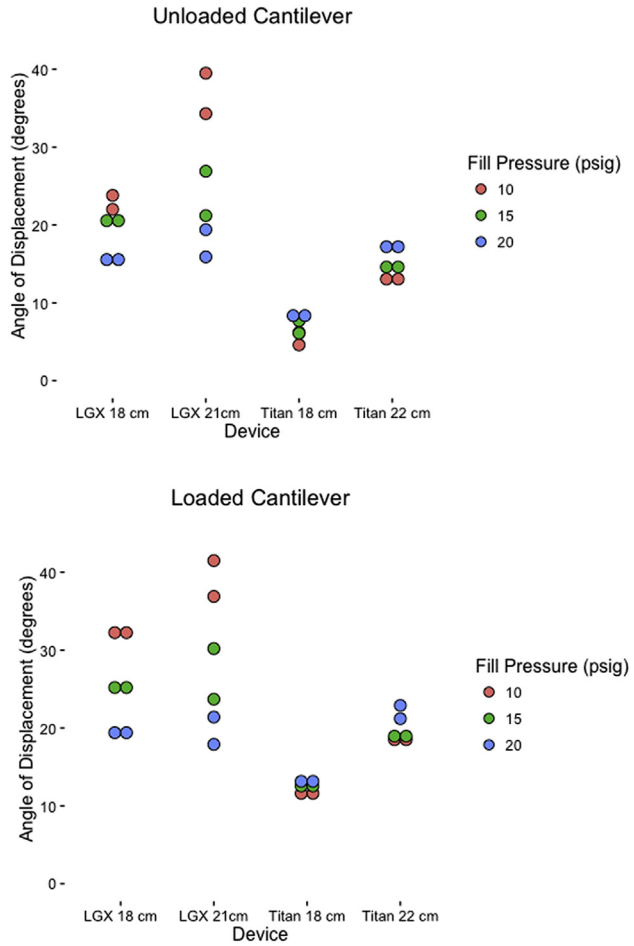

Figure 5. Angle of displacement of unloaded and loaded AMS and Coloplast devices. Figure 5 is available in color at www.jsm.jsexmed.org.

For longitudinal compression, the Titan's Bioflex material appeared to be more resilient ex vivo. Admittedly, the compression load required to compress each device might be greater than what many patients experience during sexual intercourse. Nevertheless, our data suggest that patients who might not be motivated or capable of filling the device to larger volumes might benefit from a Coloplast device because these were less dependent on filling pressures to maintain longitudinal rigidity. Patients who have partners who require increased pressure to achieve penetration also might benefit from the increased longitudinal strength of the Coloplast devices, especially at lower pressures.

This study has several key strengths and limitations that must be addressed. We analyzed each cylinder individually as opposed to the entire device because we believed this setup would allow for clear end points with less variability. These tests were performed ex vivo, which does not account for the anatomic factors that can enhance or negate the differences in device

performance. Additional anatomic constraints imposed by the tunica albuginea are likely to change the dynamics of these devices. Future work on the variation and biomechanical properties of the tunica albuginea and surrounding tissues will be important in developing a device that leverages our understanding about these structures.[12] Our study also was limited by the number of devices per manufacturer and the number of devices tested. This study was funded by the principal author and not funded by industry. Laboratory time and the biomechanical engineering were purchased from Rice University. The implants were purchased at a discount from the manufacturers or third-party vendors. These cost constraints limited the number of pump-cylinder assemblies purchased from the manufacturers. It also created the scenario that only the 18-cm cylinder was the same length from the two manufacturers. It also would have been ideal to test the AMS CX cylinders and other cylinder sizes of the devices. The AMS CX is likely to have greater rigidity than the AMS 700 LGX, which would have provided a more similar comparison between the two manufacturers' devices. We hope that the publication of our initial findings with a limited number of cylinder sizes will stimulate a more extensive study.

We chose to test each device at 10, 15, and 20 PSI because we judged these pressures represented similar rigidity experienced in vivo. However, these pressures required supraphysiologic fill volumes. We hypothesize that additional in vivo dynamics, including the added rigidity and support provided by the tunica albuginea, might allow the device to achieve similar fill pressures at lower fill volumes.

Our results suggest that differences in longitudinal load response during penetration are due more likely to differences in manufacturer design and materials than to the size of the device. This study is strengthened by the methodology used to measure the response to longitudinal and horizontal loads. The testers were blinded to manufacturers during testing and had no prior experience with penile prostheses, which limited their ability to identify which manufacturer produced which device. The biomechanical testing was performed on a validated platform that provided accurate and precise data.

These data support that inherent differences exist between IPPs that surgeons must consider when treating erectile dysfunction. We plan to perform additional biomechanical testing ex vivo and in vivo to further characterize the strengths of each device to help guide surgeons as to which patients might benefit from each prosthetic device.

CONCLUSIONS

This is the first biomechanical comparison of the AMS 700 LGX with the Coloplast Titan. Inherent differences exist between the two IPP devices in their ability to resist longitudinal and horizontal forces. The Coloplast Titan was superior to the AMS 700 LGX in resisting longitudinal and horizontal forces in this study. The AMS implant's performance was more dependent on fill pressures, suggesting the potential for greater variability in patient experience.

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Conflicts of Interest: Steven Wilson is a consultant for Coloplast, Neotract, AMS, Sontec, and Abeon. Rafael E. Carrion is a consultant for Coloplast and Endo. Tariq S. Hakky is a consultant for Coloplast. The other authors report no conflicts of interest.

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