



Biomechanical Comparison of the Relationship between Variable Rear Tip Extender & Inflatable Penile Implant Cylinder Lengths with X-Ray Imaging: A Cadaveric Pilot Study

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Abstract

Objective: Here we present our findings assessing the biomechanical properties of IPPs with differing lengths of RTEs.

Materials and Methods: This is a biomechanical study of the interaction of penile implant cylinders and RTE as assessed by column compression and modified cantilever deflection. X-Ray (XR) photography was also used to identify the precise location of kink formation after failure. The IPPs were surgically placed into two fresh cadavers via a penoscrotal technique by a single large volume implanter. A biomechanical evaluation of the properties of the IPP and RTE inside the fibroelastic tunica albuginea was assessed in unblinded testing and analyses were based on industry standard methods for assessment.

Results: In the 20 and 24 cm phallus respectively, the maximum load before kink was shown to be highest with no RTEs. This is to say device failure was at lower force when more RTE were present versus when no RTE were present. We also see in the shorter phallus there is a higher overall resistance to kink formation, even with increasing RTE lengths. Results from the horizontal studies were mixed and no direct conclusions can be drawn.

Conclusions: Column load testing to the maximum load before kink formation increases sequentially with decreasing RTE. This suggests no RTE will translate to a higher load tolerance for patients when we consider the physiologic act of intromission. Our data also suggest that even with more RTE, shorter phalluses can resist higher loads. Surgeons should use this as a guide to maximize cylinder lengths when performing IPP surgery. Further research will be required to validate these findings.

Introduction

The inflatable penile prosthesis (IPP) is currently the only surgical treatment for erectile dysfunction (ED) refractory to medical management. The first IPP was introduced by F. Brantley Scott in 1973. This device helped to recreate a more physiologic surgical solution for ED, as prior options were mainly malleable rods that had problems such as erosion and lack of a more natural

detumescence state. Many improvements have been made since 1973 including lock out valves to prevent auto inflation (2000), kink resistant tubing (1986) to help prevent mechanical malfunction, and rear tip extenders (1983) were also added to add additional length to the prosthetic cylinders to allow the surgeon to more appropriately fill the corpora cavernosa length and prevent post-surgical length loss [1].

Recently there is a renewed interest in the biomechanical function of devices, how well they recreate normal physiology, and what factors influence patient satisfaction. Ansari et al. measured *in-vivo* axial rigidity and they found that post-surgical patients with lower axial rigidity were more likely to have lower satisfaction scores [2]. Previous studies by the Goldstein Group have shown that high intracavernosal pressures, large diameter short phalluses, and high cavernosal expandability increased penile buckling force resistance in normal physiologic function [3]. As early as 1985, Karacan et al. 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 while all rods able to withstand 1.5 kg (3.3 lbs) were successful [4]. There still remains no more extensive data than this rudimentary study on the physiologic axial force

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required for vaginal or anal intromission. Previous cadaveric studies suggest that at maximum inflation pressures all devices are capable of achieving intromission, however if patients are able to routinely reach these pressures in real life is unknown. Further, this study suggested a possible benefit of RTE (up to 2 cm) increasing the longitudinal column max load and horizontal stiffness [5].

In this archetypal study, we performed an evaluation of the biomechanical properties of variable RTE and IPP cylinder lengths in cadavers. We examined two main properties of the IPPs to simulate stresses during sexual intercourse: penetration (longitudinal column rigidity) and horizontal stiffness of the penis (horizontal rigidity using a modified cantilever test).

Material and Methods

Three (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. Only two (2) cadavers were used in final analysis as Cadaver 1 had significant Peyronie's Disease which would have further confounded our results and as such this was excluded. The cadaveric study was designed with cadavers to simulate the "closest to" *in-vivo* setting we could attain.

We allowed the cadavers to thaw and performed an artificial erection with saline and contrast and performed XR imaging of the corpora. We obtained via purchase, a single pair of Coloplast Titan cylinders for each of the following sizes: 16, 18, 20, 22, and 24 cm. We also performed testing on one of the 21 cm AMS 700 CX cylinders (with a 3 cm RTE) in the 24 cm phallus to have continuous data. The reason for this was we wanted to compare the 20 cm + 4 RTE and 22 cm + 2 RTE scenarios to the 21 cm + 3 RTE scenario to further evaluate the differences in rigidity with differing length of RTE. We did however understand the differences in devices could confound our results. Nevertheless, it like the Titan is a radially expanding penile implant. RTEs were added to each cylinder to optimally accommodate the length of the corporal bodies in each cadaver. The cylinders were filled with a 50 – 50 mixture of injectable saline and contrast to allow for better visualization for XR photography to determine kink location. Specifically, we were interested if failure occurred due to kink formation of the cylinders, RTEs, or both which was seen radiographically on XR.

Each cadaver was initially implanted with the correct cylinder size for corporal length with no RTE. Cadaver 2 was 24 cm and Cadaver 3 was 20 cm respectively. Then, in a stepwise fashion 2 cm and 4 cm RTE were added with appropriate decreases in Cylinder length. Finally, in Cadaver 2 the 21 cm + 3 RTE AMS 700 CX was tested. All of the cylinders had a T-connector placed into one of the cylinders exit tubes to ensure pressures remained constant throughout testing as we have previously described [5,6]. All IPPs were surgically placed into both cadavers via a penoscrotal approach by a high-volume surgeon prior to undergoing unblinded biomechanical testing by our engineering team. Testing was repeated to check reproducibility but repeated

testing was limited to minimize cadaver damage. Testing occurred over an 8-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 and this was confirmed with XR. 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 device pressure is regulated to 1034 mmHg (20 psi). We used 1034 mmHg (20 PSI) to closely correlate with the 1000 mmHg needed for maximum inflation as described by Pescatori et al.[7], The difference of 34 mmHg is considered to be insignificant. Biomechanical properties of the IPPs were assessed using a Mark 10 ESM303 Motorized Tension/Compression Test Stand and Mark 10 Series 5 Force Gauge for longitudinal column compression. Horizontal load testing, modified cantilever deflection was performed with manual instruments operated by our team of engineers. Tests were designed to compare to standardized column buckling and cantilever beam testing [8,9].

Longitudinal Column Load Testing (to Simulate Penetration)

To simulate intromission, longitudinal column load testing was performed (Figure 1). Two IPP cylinders with appropriate additional RTE simultaneously implanted in each cadaver were compressed along their longitudinal axis by a metal cone-shaped holder fastened into the force gauge. The testing machine compressed the implants longitudinally at an automated rate of 2.54 cm/min (1 inch/min) [5,6]. Sensors recorded the applied load throughout compression. We designated device failure as a drop-in compression load, which was the characteristic of kink formation as in our previous studies. The load range was partially determined based on the bowing of the penis to the point we would not traumatize the penis with the instruments. After failure was noted, the compression was stopped and XR photography was performed to evaluate for location of kink failure. Specifically, we noted if failure occurred in the cylinders, RTE or both.

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. This study performed with a hand-held force gauge. The tip of the gauge was applied 4 inches from base of penis. The direction of the bending force was always oriented perpendicular to shaft of the penis and pushed in a caudal direction. The measurements were the forces required to deviate the penis from its original lie with max inflation, approximately 90 degrees from a vertical line perpendicular to the axial skeleton (VPAS) until the penis was at an angle roughly 45 degrees, from VPAS (Figure 2).

X-Ray photography

XR photography was performed using GE Healthcare's OEC Elite CFD, a mobile C-arm offering both a 31cm and 21cm CMOS flat panel detector, which is designed to produce high image quality

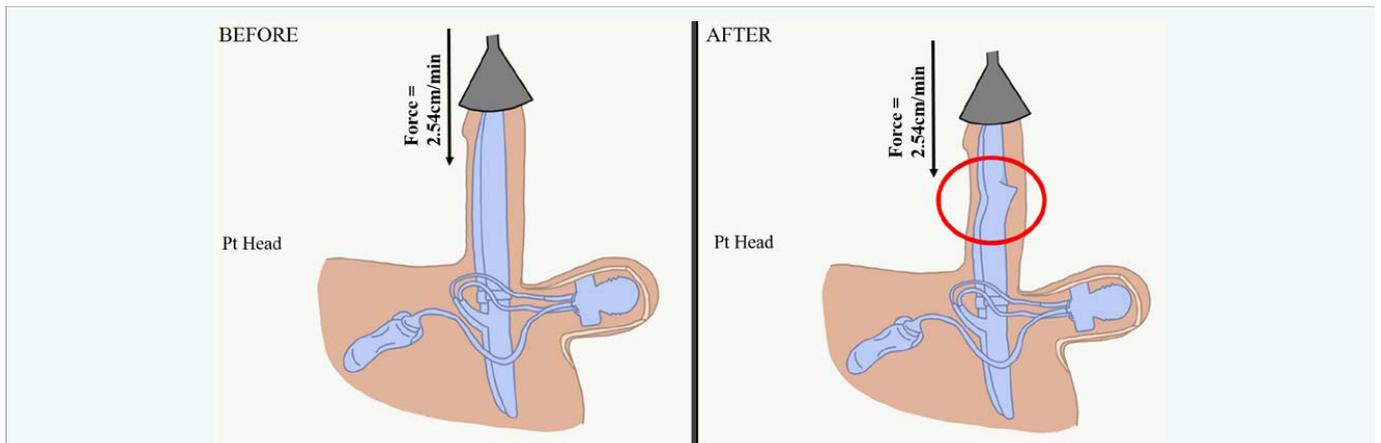


Figure 1 Illustration of the Vertical Column Load Testing. Initially the phallus is in a upright 90 degree angle from the Axial Skeleton and the Mark 10 machine applies a downward longitudinal force to the penis with the Glans penis being compressed by a cone shaped adapter. Failure is seen with kink formation in the cylinders of the IPP as highlighted in Red.

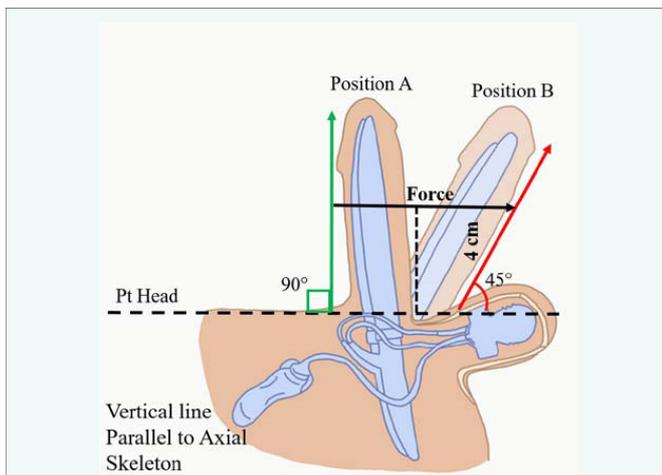


Figure 2 Illustration of Horizontal Stiffness Testing. Initially the Phallus lies approximately at a 45- degree angle from parallel along the Vertical Line Parallel to the Axial Skeleton (VPAS). With the manual applied force at a fixed distance of 4 cm from the base of the penis the phallus is moved from a position perpendicular to VPAS to 45 degrees from VPAS.

at a low dose. XR images were recorded before compression load was applied and after maximum column strength was reached where the characteristic drop in compression load indicates kink formation.

Results

Longitudinal Column Load Testing

The results from the column load testing appear to be consistent with conventional expert opinion which advocates for minimizing the number of RTE added to the IPP cylinders resulting in better device function. We find in Cadaver 2 the 24 cm Titan Implant cylinders with no RTE has the best column rigidity with a kink load failure of 6.52 lbs (Table 1). We can

also see that increasing the RTE with 2, 3, and 4 cm of RTE with respective decreases in implant cylinder length results in less ability to resist column buckling. In fact, we see kink load failures at 4.92, 3.3, and 2.46 lbs for the above increasing RTE lengths respectively (Table 1). The 20cm + 0 RTE cylinders were able to withstand 8.8 lbs prior to failure and ultimately the 18cm + 2 RTE and 16cm + 4 RTE testing scenarios were able to withstand 5.24 and 5.32 lbs respectively. When we look at the XR photography studies we find that with the +2 and +4 cm scenarios in Cadaver 2 we identify RTE failure as the etiology of kink load failure. This can be seen in Figures 3 and 4. The results in Cadaver 3 were somewhat less clear as there was cylinder buckling, simultaneous cylinder and RTE buckling, and finally cylinder buckling with possible RTE failure in the 0, 2, and 4 cm RTE scenarios. This can be seen in Figures 5-7.

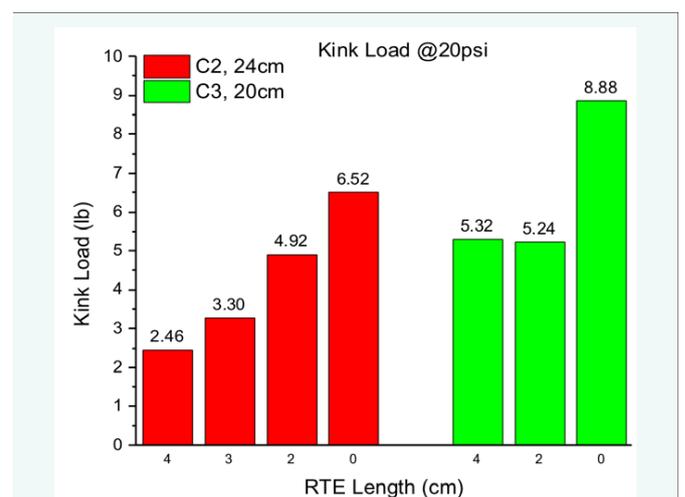


Table 1 Kink load plots from Cadaver 2 & 3 with alternating levels of 0, 2, and 4 CM of RTE. Cadaver 2 also had a 3 cm RTE scenario. The Y axis represents the maximum load in pounds each scenario can tolerate before kind load failure.

C2 (22+2)



Figure 3 Cadaver 2 22 cm + 2 RTE scenario XR Photography showing RTE Failure with preserved cylinder inflation.

C2 (20+4)

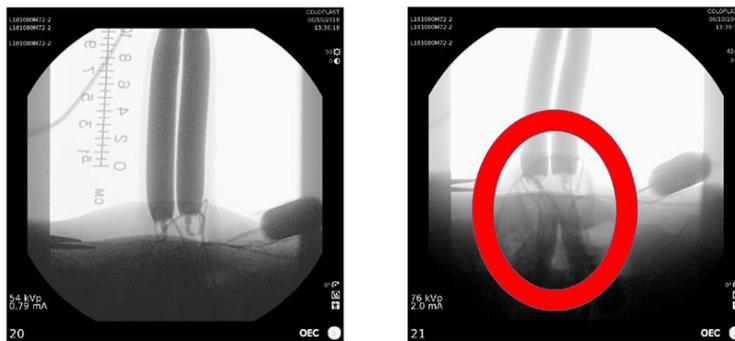


Figure 4 Cadaver 2 20 cm + 4 RTE scenario XR Photography showing RTE Failure with preserved cylinder inflation.

C3 (20+0)



Figure 5 Cadaver 3 20 cm + 0 RTE scenario XR Photography showing cylinder failure.

C3 (18+2)

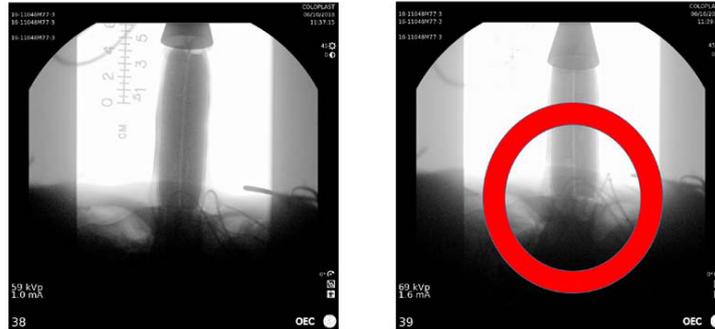


Figure 6 Cadaver 3 18 cm + 2 RTE scenario XR Photography showing combined cylinder and RTE failure.

C3 (16+4)

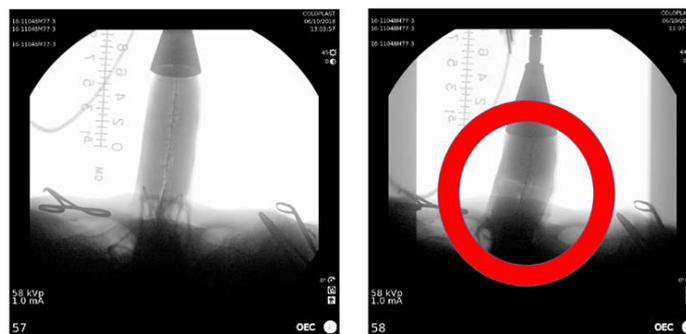


Figure 7 Cadaver 3 16 cm + 4 RTE scenario XR Photography showing cylinder failure and possible combined RTE failure as they are very difficult to visualize.

Horizontal Stiffness via Modified Cantilever deflection

Regarding the results from the horizontal stiffness testing, we don't see a clear trend in the data. We do however see that in general less than 2 cm of RTE resulted in higher loads tolerated by a slight margin. This can be seen in Table 2.

Discussion

It was reported in 2015 that greater than 90% of implanters were routinely using RTE in addition to IPP devices to more accurately fit the device to varying corporal lengths within the population and prevent post-surgical loss of penile length [10]. Conventional expert opinion has varied on whether the addition of RTE to an IPP cylinder positively or negatively impacted patient outcomes. Naturally two groups existed, those that thought that RTE were beneficial and advocate for routine use and those that proposed that maximizing IPP cylinder length and minimizing RTE was best for patient outcomes from rigidity and from an

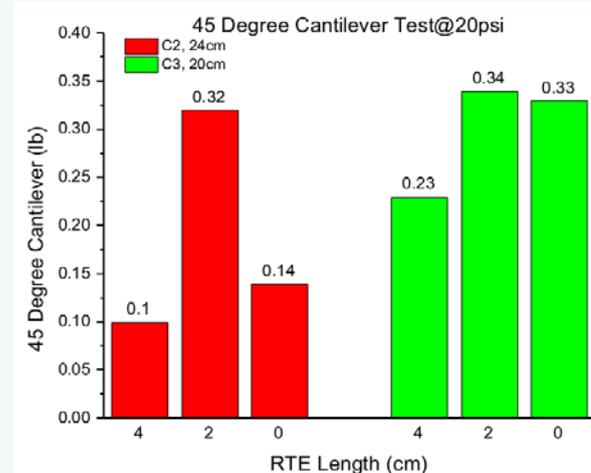


Table 2 Cadaver 2 & 3 performance in the 45 Degree Cantilever Test.



anti-infective standpoint as the AMS rear tips are not coated with antibiotics like the rest of the Inflatable IPP components. Previous literature that has attempted to define this is limited. No such *in-vivo* data exists to this group's knowledge, although a biomechanical study of implant cylinders alone in the *ex-vivo* setting certainly has been done [6,11].

One study by Eid et al., used a single simulated laboratory model of a 3-D printed human pelvis and studied various combinations (22-0, 20-2, 18-4) of IPP cylinders and RTE lengths to fit into a corporal length of 22 cm [12]. This study really only captured horizontal stiffness as they inflated devices to standard pressures and then measured horizontal deflection after application of a 200-gram weight from the tip of the implant. They found that with increasing lengths of RTE there was increased deflection suggesting decreased rigidity [12]. Previous cadaveric studies conversely suggested a possible benefit of RTE (up to 2 cm) increasing the maximum longitudinal column load and horizontal stiffness. In this study appropriately sized IPPs and RTEs were surgically placed inside the tunica albuginea of cadaver pelvis and sequentially tested with column loading, horizontal stiffness and resistance to 3-point bend testing. The results of this study observed that increasing column and horizontal load resistance was seen with increasing RTE size from 1cm, 1.5 cm, and 2 cm respectively [5].

Each IPP has buckling or pivot point where the kink forms. The pivot point is where the maximum pressure is exerted over the device, and in a physiologic erection this would be at the base of the corpora where it attaches to the pelvic bone. Increasing the length of RTEs shifts this pivot point distally on the phallus. We have shown that it is these shifts in the pivot point towards the pelvic bone distally away from the crus of the corpora decreased the maximum load before failure and increased penile implant cylinder and RTE instability. This instability is due to the fact that there is air inside the RTE connecting to the penile implant. We describe this connection as the "cup holder" effect due to the mechanism that the RTE attaches to the end of the cylinder. We suggest that this instability at the base of the IPP should be avoided when possible, by avoiding the use of RTE. Specifically; in Cadaver 2 of this recent study we see the +2 and +4 cm RTE testing scenarios show the RTE as the source of the biomechanical failure and not the cylinders. It is the increasing length of the RTEs creating instability by moving this pivot point forward. We also noted with the stacking of RTE we saw instability with movement of the stacked RTE during compression, which could translate to disconnection of the RTE.

Regarding the results from the horizontal stiffness testing, there is no clear trend in the bending force vs RTE length. For safety reasons, we did not obtain X-ray images during our horizontal stiffness testing. We speculate that a major source of the mixed result come from bending rigidity of different parts of the implant such as the RTE, solid end of the cylinder and the liquid filled portion of the implant. An alternative source could be the weight of liquid inside the IPPs pulling the shaft downward when penis is at 45-degree. The lack of a trend in the data with the cantilever test perhaps is a combination small differences in actual starting angle (prior studies have shown that large

phalluses sit lower), i.e. not all phalluses stand at 90 degrees, change in fulcrum with modifying RTE length, and change in location of pressure allocation as the angle changes given it's a fixed 4 cm from the pubis rather than pressure administered at the tip. However, we see that in general less than 2 cm of RTE resulted in higher loads tolerated by a slight margin.

This study is strengthened by the validated biomechanical methodology used to measure the response to longitudinal loads. The tests were designed to assess the biomechanical performance of IPPs and RTEs in their natural environment inside the tunica albuginea in relevance to their intended use in the most common loading situations encountered during sexual intercourse. The biomechanical testing was performed on a validated platform that provides accurate and precise data. The engineering investigators were unblinded in this study which is unlikely to have, but could potentially have, introduced bias given that the majority of the testing was performed with Coloplast Titan cylinders, and one AMS CX device and the only comparison was differing sizes of RTE and cylinder lengths. 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 limits the potential for error in operative placement of the devices as a confounder in the differences seen in our data. Weaknesses of our study include limited sample size including use of only 2 cadavers (due to financial cost and one being excluded due to Peyronie's Disease), no time after implantation for surgical capsule formation, and the fact that this was done in cadaver models and not real living patients as such no patient satisfaction or experience data could be concluded. Further, since only one AMS device was tested, this confounds our results as it makes it unclear if findings are due to rear tips specifically or if this characteristic of the increasing diameter Coloplast devices.

Conclusion

In this study, a biomechanical comparison of variable IPP cylinder and RTE lengths with XR photography our data suggest that for column load testing the maximum load before kink formation increases sequentially with decreasing RTE. The absence of RTE will translate to a high load tolerance for patients when we consider the physiologic act of intromission. We also noted with more RTE, shorter phalluses can resist higher loads. This study supports conventional expert opinion and previous physiologic studies of the biomechanics of the phallus during sexual intercourse. Surgeons should use this as a guide to maximize cylinder lengths when performing IPP surgery. Further research will be required to validate these findings.

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References

1. Pastuzak WP, Lentz AC, Farooq A, Jones L, Bella AJ. Technological Improvements in Three-Piece Inflatable Penile Prosthesis Design over the Past 40 Years. *J Sex Med.* 2015; 12: 415-421.
2. Al Ansari A, Talib RA, Canguven O, Shamsodini A. Axial Penile Rigidity Influences Patient and Partner Satisfaction after Penile Prosthesis Implantation. *Arch Ital Urol Androl.* 2013; 85: 138-142.



3. Udelson D, Nehra A, Hatzichristou DG, Azadzo K, Moreland RB, Krane RJ, et al. Engineering Analysis of Penile hemodynamic and structural dynamic relationships: Part II – Clinical Implications of Penile Buckling. *Int J Impot Res.* 1998; 10: 25-35.
4. Karacan I, Moore CA, Sahmay S. Measurement of Pressure Necessary for Vaginal Penetration. *Sleep Res.* 1985; 14: 269-272.
5. Wallen JJ, Barrera EV, Ge L, Pastuzak AW, Carrion RE, Perito PE, et al. Biomechanical Comparison of Inflatable Penile Implants: A Cadaveric Pilot Study. *J Sex Med.* 2018; 15: 1034-1040.
6. Scovell JM, Ge L, Barrera EV, Wilson SK, Carrion RE, Hakky TS. Longitudinal and Horizontal Load Testing of Inflatable Penile Implant Cylinders of Two Manufacturers: An *Ex Vivo* Demonstration of Inflated Rigidity. *J Sex Med.* 2016; 13: 1750-1757.
7. Pescatori ES, Goldstein I. Intraluminal device pressures in 3-piece inflatable penile prostheses: the “pathophysiology” of mechanical malfunction. *J Urol.* 1993; 149: 295-300.
8. ASTM D747-10, Standard Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam, ASTM International, West Conshohocken, PA. 2010.
9. ASTM D790-17, Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials, ASTM International, West Conshohocken, PA. 2017.
10. DeLay K, Gabrielson A, L Alzweri, FA Yafi, WJ Hellstrom. Rear tip extenders during inflatable penile prosthesis placement: impact on need for revision. *J Urol.* 2017; 197: e443-e444.
11. Romo PB, Chikkatur HP, Beldona S, Yi Y, Bruns TM, Malaeb BS. Comparative Evaluation of Physical Characteristics of Different Inflatable Penile Prostheses. *Scand J Urol.* 2017; 51: 420-425.
12. Thirumavalavan N, Cordon BH, Gross MS, Taylor J, Eid JF. Rear Tip Extenders and Penile Prosthesis Rigidity: A Laboratory Study of Coloplast Prostheses. *J Sex Med.* 2018; 15: 1030-1033.