CLINICAL ARTICLE SUMMARY

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

Jason M. Scovell, BBA, Liehui Ge, MSc, PhD, Enrique V. Barrera, BS, MS, PhD, Steven K. Wilson, MD, FACS, FRCS, Rafael E. Carrion, MD, and Tariq S. Hakky, MS, MD

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The study is a prospective, non-randomized, blinded, biomechanical comparison of two sizes of implantable cylinder-pump assemblies from two IPP manufacturers, tested for their ability to withstand longitudinal column loads (penetration) and horizontal forces (gravity) at various pressures.

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.

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COLOPLAST KEY TAKEAWAYS

- The Coloplast Titan® was superior to the AMS 700™ LGX in resisting longitudinal and horizontal forces in this study.
- 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.
- 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.
- Titan may be superior for the patient who has severe corporal fibrosis because it had a high kink load.
- 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.

Indications

The Titan family of Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are considered to be candidates for implantation of a penile prosthesis.

Contraindications

The Titan device is contraindicated in patients who have one or more of the following conditions: Patients with an active infection present anywhere in the body, especially urinary tract or genital infection. Patients with a documented sensitivity to silicone. Patients with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder. Patients unwilling to undergo any further surgery for device revision.

Warnings

Implantation of the device eliminates natural erections, as well as other related treatment options, impossible. Men with diabetes or spinal cord injuries, as well as immunocompromised patients, may have an increased risk of infection associated with a prosthesis. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical. The risks and benefits of implanting this device in patients with lupus, scleroderma, myasthenia gravis, or documented sensitivity to silicone should be carefully considered.

Precautions

A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits.

Potential Complications

Scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction/deflation, pain, difficulty with ejaculation, transient urinary retention, fever, migration, patient dissatisfaction, infection, hematoma wound leakage, bleeding, delayed wound healing, phimosis, sensory loss cylinder aneurysm, fibrous capsule formation, over/under inflation, erosion, scrotal erthema, genital change, inguinal hernia.

See the device Instructions For Use (IFU) for detailed information regarding the implant procedure, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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