

## Intraluminal Device Pressures in 3-Piece Inflatable Penile Prosthesis: The 'Pathophysiology' of Mechanical Malfunction

Edoardo S. Pescatori, MD  
Irwin Goldstein, MD  
Department of Urology,  
Boston University  
School of Medicine,  
Boston, MA

The Journal of Urology  
Vol. 149, 295-300,  
February 1993

### ABSTRACT

**Objective:** The overall goal of this study was to understand better the role of intraluminal device pressures in the pathophysiology of mechanical malfunction in 3-piece inflatable penile prostheses.

**Methods:** Intraluminal pressures of 3-piece devices inflatable penile prosthesis devices were recorded in vitro without the constraint of the surrounding tunica in the empty, partially and fully filled states before and during external loading. In addition, a 4-year clinical review at our institution was performed to compare the type and location of mechanical malfunctions experienced in 3-piece inflatable devices with and without connectors in the pump-cylinder units.

*Intraluminal device pressure recordings:* Eight standard sized (18 cm) 3-piece inflatable penile prostheses were studied. Those with connectors and connector components in the pump-cylinder unit included the Mentor IPP (2 samples), AMS 700 CX (2 samples) and AMS Ultrex (2 samples).

*Clinical review:* From January 1988 to December 1991 a retrospective review was performed of 101 consecutive 3-piece inflatable penile devices implanted by the senior author. There was minimal variation of technique for surgical insertion of a 3-piece inflatable prosthesis during the 4-year follow-up period. A penoscrotal approach was used in the first year while a transverse scrotal incision was used in the following 3 years.

**Results:** The compliance characteristics of the Bioflex® lining of the Mentor cylinders and the Dacron-Lycra lining of the AMS 700 CX cylinders are such that at volumes greater than 50 ml. fluid constraint develops, thus, dramatically elevating intraluminal device pressures. However, at maximum fluid volume the Mentor cylinders reached approximately 200 and 550 mm. Hg lower mean intraluminal device pressures compared to that for the AMS 700 CX cylinder at rest and following external loading, respectively. This difference in pressures reflects the different compliance characteristics of the walls of the 2 cylinders.

**Conclusion:** It is the conclusion of this study that the high intraluminal device pressures in inflated 3 -piece penile prostheses are the pathophysiology of the mechanical malfunctions in such devices. The device with the highest mean intraluminal device pressure, the AMS 700 CX, was associated with the greatest number of tubing fluid leaks .

## COLOPLAST KEY TAKEAWAYS

- Bioflex® withstands higher pressures than silicone.
- Coloplast Titan implant has a tensile strength of 7,500 psi vs AMS 700 CX implant with a tensile strength of 900psi, eight times more strength.
- The Bioflex lining material of the Mentor cylinder has greater compliance with an ability to stretch circumferentially during inflation and increase girth to values exceeding 21 mm.
- The Dacron-Lycra sleeve surrounding the AMS 700 CX cylinder has virtually no compliance, restricting girth expansion to 18 mm.
- The device with the highest mean intraluminal device pressure, the AMS 700 CX, was associated with the greatest number of tubing fluid leaks.

### Indications

The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are candidates for implantation of a penile prosthesis.

### Contraindications

The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients with an active infection present anywhere in the body, especially urinary tract or genital infection; with a documented sensitivity to silicone; with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder; or, unwilling to undergo any further surgery for device revision.

### Warnings

Implantation of the device may make latent natural erections, as well as other interventional 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.

### Precautions

Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.

### Potential Complications

Potential complications include scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention. The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at [www.coloplast.us](http://www.coloplast.us).

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