CLINICAL ARTICLE SUMMARY

LONG-TERM FOLLOWUP OF TREATMENT FOR PEYRONIE'S DISEASE: MODELING THE PENIS OVER AN INFLATABLE PENILE PROSTHESIS

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ABSTRACT

Purpose: We originally reported inflatable penile implants used to treat impotence in patients with Peyronie's disease in 1993. We now present a historical prospective study of 104 patients in whom the modeling procedure was used to correct Peyronie's curvature after implantation with the Mentor Alpha 1 and AMS 700CX penile prostheses. We compared revision-free survival experience of these implants with 905 similar implants in men with nonPeyronie's disease.

Materials and Methods: The reasons for revision were classified as mechanical failure, patient dissatisfaction, infection and medical causes, including reoperation for straightening. Overall and cause specific revision-free survival in the 2 study cohorts was compared. Maximum follow-up was more than 12 years and average follow-up was more than 5.

Results: No significant difference in device survival was observed in the 2 study cohorts in 5 years. Similarly, each prosthesis provided the same permanent straightening without the need for revision. In Peyronie's disease cases mechanical survival of the Mentor Alpha 1 was superior to that of the AMS 700CX ($p = 0.0270$). There was no significant difference in mechanical reliability of the devices in nonPeyronie's disease cases.

Conclusions: Implantation and modeling appear to provide permanent straightening without an increase in revisions. In the nonmodeled group there was no significant difference in mechanical reliability of the AMS 700CX or Mentor Alpha 1. In modeled cases the Mentor Alpha 1 appeared less likely to fail mechanically than the AMS 700CX when followed more than 5 years. Based on this single series modeling may predispose the AMS 700CX to earlier mechanical failure.

COLOPLAST KEY TAKEAWAYS

- Modeling did not increase the rate of cause specific revision compared to no modeling. That is, there was no significant difference in survival for revision due to mechanical failure, patient dissatisfaction, infection or medical reasons between the Peyronie's Disease modeled cohort and the nonPeyronie's cohort.
- The Mentor Alpha 1 (now Coloplast) was superior to the AMS 700CX in terms of mechanical survival when implanted in patients with Peyronie's disease.
- Cylinder failure was the usual cause of mechanical failure in the AMS device while leakage in the tubing exit was the usual mechanical failure in the Mentor device (now Coloplast).
- While each device is effective in the modeling procedure, modeling may predispose the AMS 700CX to earlier mechanical failure.

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.

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

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