

Comparison between AMS 700™ CX and Coloplast™ Titan Inflatable Penile Prosthesis for Peyronie's Disease Treatment and Remodeling: Clinical Outcomes and Patient Satisfaction

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ABSTRACT

Introduction. The implantation of inflatable penile prosthesis (IPP) with simultaneous manual penile remodeling allows for men to undergo a single procedure aimed at correcting both the penile deformity/curvature and erectile dysfunction (ED).

Aim. To evaluate the clinical outcomes and patient satisfaction in men with Peyronie's disease (PD) and ED who underwent AMS 700™ CX and the newer Coloplast™ Titan inflatable penile prosthesis (IPP) implant.

Main Outcome Measures. Patient demographics, type of IPP, clinical outcomes, post-implant sexual characteristics, and overall patient satisfaction.

Methods. A single-center retrospective review of clinical database and prospective telephone survey were conducted in all men with PD who underwent IPP between January 2006 and November 2010.

Results. A total of 138 patients with an average age of 57.7 (32 to 80) underwent AMS 700 CX (88 patients) and Coloplast Titans (50 patients) IPP implantation during the 5-year period. The majority of patients (91%) had only one IPP implantation. The IPP clinical outcomes include eight (6%) revision surgery for device malfunction and three (2%) device explantation for prosthesis infection. While there was no statistically significance in device survival between the two devices, the trend favored AMS 700 CX over Titan (5-year Kaplan-Meier estimates of mechanical survival were 91% vs. 87%, $P > 0.05$) and both IPPs provided similar penile straightening without the need for revision surgery. Most men (79%) reported great satisfaction following CX or Titan implants with greater than two thirds of men reported greater self-confidence and 82% of patients would undergo the same operation again.

Conclusions. AMS 700™ CX and Coloplast™ Titan IPP implantation and penile remodeling appeared to provide permanent penile straightening and high patient satisfaction without an increase risk of revision surgery. **Chung E, Solomon M, DeYoung L, and Brock GB. Comparison between AMS 700™ CX and Coloplast™ Titan inflatable penile prosthesis for Peyronie's disease treatment and remodeling: Clinical outcomes and patient satisfaction. J Sex Med 2013;10:2855–2860.**

Key Words. Peyronie's Disease; Inflatable Penile Prosthesis; Penile Remodeling; Device Survival; AMS 700 and Titan Device; Patient Satisfaction

Introduction

The idea of penile prosthesis remodeling in men with Peyronie's disease (PD) and erectile dysfunction (ED) was first conceived by Dr. Scott and later popularized by Wilson and Delk in the early 1990s [1]. The implantation of inflatable penile prosthesis (IPP) with simultaneous

manual penile remodeling allows for men to undergo a single procedure aimed at correcting both the penile deformity/curvature and ED [2,3]. However, there is an increased risk of IPP mechanical failure and/or component malfunction, due to mechanical stress on the penile prosthesis components during the manual prosthesis remodeling process, resulting in the need

for replacement of component(s) or the entire IPP device.

In the late 1980s, AMS 700™ (American Medical Systems, Minneapolis, MN, USA) CX (controlled expansion) and Mentor™ (Mentor, Minneapolis, MN, USA) cylinders were introduced and manual penile modeling of the IPP implant became a realistic possibility in men with PD and ED [4]. Early publication by Wilson [1] showed that the Alpha-1™ (Mentor) device was almost three times less likely to require revision surgery than AMS 700 CX device among men with PD who had undergone penile remodeling. Comparing the various AMS 700 cylinders, Montague [5] found that AMS 700 CX cylinders are superior to Ultrex cylinders in PD patients due to less post-operative buckling of the IPP device. However, a recent publication by Wilson reported that the newer generation of AMS 700 CX with parylene coating has greater mechanical reliability and device survival from revision surgery compared to the earlier non-coated cylinder model [2]. The addition of parylene coating on the outer layer of silicone appeared to minimize the problem of premature cylinder wear in PD men following penile remodeling. The current literature supports the use of a three-piece IPP as it offers a much stronger support during the penile remodeling maneuver than malleable penile prostheses [6].

The process of penile remodeling, that is, the forcible counter-flexion of the penis away from the plaque with the device semi-inflated has been shown to result in penile curvature correction in 86% to 100% of patients who has undergone this maneuver [1,2,4]. Wilson and Delk, in their original series, demonstrated an 86% success rate using penile remodeling [1] while Carson cited a success rate of 80% for modeling in 30 patients in whom he used this maneuver [4]. Montague showed that all patients in their small series (34 patients undergoing AMS 700CX device implantation) had correction of the penile curvature with modeling [5]. The long-term 5-year follow-up study by Wilson demonstrated that IPP implantation with penile remodeling was associated with similar incidence of device revision when compared to men who had IPP implantation without penile modeling [2].

Aims

To our knowledge, there is no published literature comparing the surgical and clinical outcomes of AMS700 CX and newer Titan™ (Coloplast, Minneapolis, MN, USA) IPP implantation with

manual penile remodeling in men with PD and concomitant ED. This study was undertaken in an effort to evaluate the mechanical reliability and clinical outcomes of the two IPP devices among a cohort of men with PD and concomitant ED, as well as examine the patient usage and satisfaction following IPP implantation with manual penile remodeling in the last 5 years.

Materials and Methods

Following approval from our institutional ethics review board, a review of all patients undergoing IPP surgery for PD and ED from January 2006 to December 2010 was undertaken. All patients received preoperative counseling on the expectation of IPP and penile color Duplex ultrasonography (CDU) with erectogenic agent to induce an artificial erection was performed to evaluate the PD characteristic and underlying vascular status. Abnormal arterial hemodynamics on penile CDU was defined as peak systolic velocity (PSV) < 30 cm/s while cavernosal veno-occlusive dysfunction (CVOD) was defined as end-diastolic velocity (EDV) > 5 cm/s. Clinical variables analyzed include patient demographics, length of time to surgical intervention, preoperative PD characteristics, preoperative International Index of Erectile Function (IIEF-5) score, previous PD therapies, the types of IPP (AMS 700 CX or Titan) implanted, and operative complications were retrospectively reviewed. Men with penile curvature greater than 90° were excluded from this study. Prosthesis malfunction was defined as malfunction of the IPP requiring revision and replacement of at least one components of the IPP while prosthesis infection was defined as infection requiring surgical removal of IPP with or without salvage IPP replacement. An independent follow-up telephone survey was conducted to ascertain the current IPP usage and status as well as record patient satisfaction with the IPP. Patients were surveyed on IPP clinical outcomes, such as ease and frequency of use, patient and partner satisfaction, and self esteem.

Patients were randomized to receive either AMS 700CX or Titan penile prosthesis at the time of surgery. All implants were performed under antibiotic cover through a transverse penoscrotal incision following 10 minute of povidine betadine scrubbed. Dilametz dilator was routinely used to dilate the corporal bodies while serial dilators, Rosello dilators and OTIS urethrotomes were utilized if significant corporal fibrosis was encountered.

Minimally invasive subtunical intracorporeal plaque incision was performed if there was significant plaque associated with penile curvature. The penile prosthesis inflated to maximum distension and manual penile remodeling was carried out several times by cross-clamping of the tubing to the cylinders with rubber-shod hemostats to prevent pump damage from excessive backpressure while great care was undertaken to avoid urethral injury, as previously described in the literature [2,6,7].

Postoperative care included oral quinolones for 2 weeks and patients were encouraged to position the penis cephalad in the underwear to encourage capsule development around the cylinders, which promotes the natural cephalad extension of penile erection. At 4–6 weeks postoperative, the IPP was recycled and further penis remodeling was undertaken in the outpatient clinic if there was residual curvature greater than 10°. A successful postoperative outcome was classified as a straight penis (<10° curvature) with IPP in an optimum position, easy to recycle, and provide adequate rigidity for sexual intercourse.

Results

Patient Characteristics, Risk Factors, and Preoperative Findings

A total of 138 patients with severe PD with concomitant ED underwent insertion of either AMS 700 CX (88 patients) or Coloplast Titans (50 patients) IPP over the 5-year period. None of the patients had significant plaque ossification. Of these men, 132 patients (96%) have intact IPP and are sexually active at the time of review. The mean follow up for AMS 700 CX was 40.6 (1 to 72) months and Titan was 35.4 (12 to 68) months.

The average age of the patients was 57.7 (32 to 80) years with average follow up of 45.6 (6 to 66) months. Among common risk factors associated with ED and PD, 65 (47%) had hypertension, 57 (41%) had dyslipidemia, 46 (33%) had diabetes mellitus, 70 (51%) had a positive smoking history, and 22 (16%) had known ischemic heart disease.

The mean duration from the onset of PD symptoms to IPP implantation was 5.7 (1 to 15) years. The mean degree of penile curvature preoperatively was 49° (15°–90°). All patients had abnormal arterial hemodynamics on at least one side and 75 (36%) patients demonstrated CVOD on penile CDU studies. The mean preoperative IIEF score was 5.4 (1 to 24) and all men had previously tried pro-erectile drugs and/or vacuum erection devices. Five patients had a previous penile plication for

PD and eight patients had Peyronie's graft repair surgery in the past.

There was no statistical significant difference in patient demographics and preoperative characteristics between the two groups.

Surgical Outcomes

By placement and full inflation of the IPP, curvature was corrected (<10° residual curvature) in 127 (92%) men. The majority of patients (98%) with preoperative curvature $\leq 60^\circ$ had complete resolution of penile curvature with inflation of IPP and penile remodeling alone. In patients with preoperative curvature between 60° and 90°, 10 (7%) patients received minimally invasive subtunical intracorporeal plaque incision, and 1 (1%) patient underwent additional tunical incision and graft.

At the time of review, eight (6%) underwent revision surgery for IPP. The etiologies for IPP revision were mechanical malfunction in seven (5%) and personal dissatisfaction in one (1%) men. The average time to IPP revisions was 2.3 (0.4 to 5) years. IPP cylinder wear and subsequent leakage were the predominant reason for mechanical failure. There was no significant correlation between the size of IPP cylinder and the cause of mechanical failure ($P > 0.05$). However, penile curvature greater than 60° and concomitant subtunical intracorporeal plaque incision was associated with higher mechanical failure rate but this was not statistically significant ($P > 0.05$). The 5-year Kaplan-Meier estimates of mechanical survival in AMS700 CX and Titan were 91% and 87% ($P > 0.05$) (Figure 1).

There were three (2%) IPP removals and they occurred on average of 6 (11 days to 3 years) months after the initial operation. Of the IPP infection, one patient received immediate salvage as per Mulcahy's protocol, one IPP were explanted with delayed IPP implantation performed at a later date, and one patient decided against further implant surgery. There was no significant difference between the two IPP devices in terms of infection and/or erosion.

Patient Satisfaction and IPP Use (Table 1)

Among the survey respondents, 109 (79%) patients scored at least 4 on a 5-point scale of overall satisfaction with the cosmetic and functional outcomes. The most common reason for dissatisfaction was shortened penile length with 18 (62%) patients reported a decreased penile length post-operatively. Eighty-two percent of patients reported they would undergo the same operation

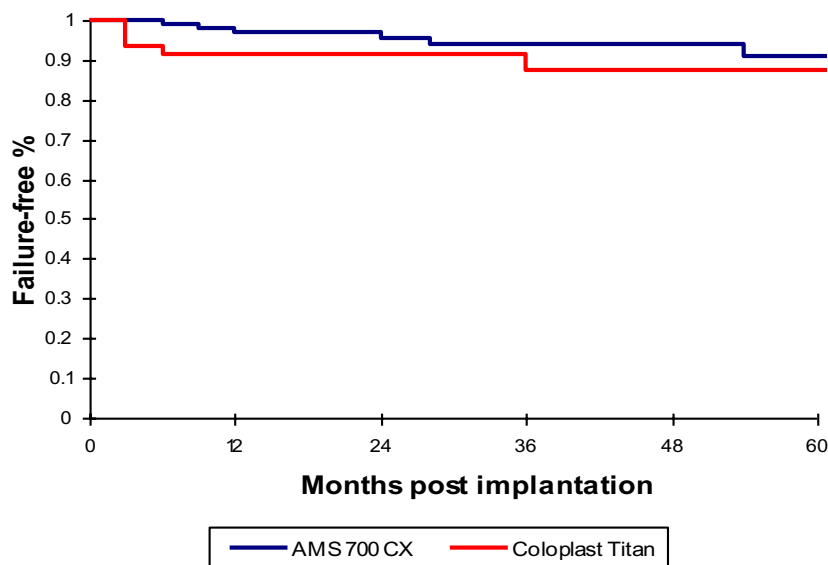


Figure 1 Kaplan-Meier estimates of survival from mechanical failure showed trend toward enhanced AMS 700 CX over Titan IPP that did not reach statistical significance at 5 years ($P > 0.05$). The overall 5-year mechanical failure rate for AMS 700 CX and Titan were 91% and 87%.

again and recommend IPP to others. More than 60% of patients utilized their devices more than twice a month. In terms of IPP recycling, 80% of patients described the inflation and deflation of IPP as easy, with only 80% of patient inflated the IPP completely full for sexual penetration. More than two-thirds of patients reported greater self-confidence following IPP implantation.

There was no correlation between the frequency of sexual penetration, degree of device inflation, and device malfunction. There was no statistically significant difference in patient usage and satisfaction rates between AMS 700 CX and Titan IPPs ($P > 0.05$).

Table 1 Patients' penile prosthesis usage and satisfaction rates between AMS 700 CX and Titan

Demographic variables	AMS 700 CX (%)	Titan (%)	<i>P</i> value
Total number of IPP implanted	88 (64)	50 (36)	N/A
Overall satisfaction			
Rating 1–3	12 (14)	5 (10)	0.57
Rating 4–5	76 (86)	45 (90)	0.46
Would undergo surgery again			
Yes	72 (82)	44 (88)	0.68
No	18 (18)	6 (12)	0.62
Primary reason for dissatisfaction			
Decreased penile length	12 (14)	6 (12)	0.69
Problems with prosthesis	2 (2)	1 (2)	0.50
Personal health concerns	2 (2)	3 (6)	0.36
Loss of regular sexual partners	3 (3)	0 (0)	0.35
Frequency of sexual intercourse			
At least once a week	25 (28)	17 (34)	0.56
Fortnightly	30 (34)	22 (44)	0.65
At least once a month	22 (25)	5 (10)	0.41
Other	11 (13)	6 (12)	0.70

Discussion

The AMS 700 CX cylinder construction consists of a middle layer of fabric of woven Dacron and Lycra in between the two silicone layers and serves to restrict expansion of the cylinder to a predetermined amount. The introduction of parylene coating to the silicone layers of the CX cylinders further improves the lubricity and mechanical reliability [8]. In contrast, the Coloplast Titan cylinder was introduced in 2002 to replace Mentor Alpha-1 cylinders and is made of Bioflex, a material similar to polyurethane, and the cylinder also has an outer hydrophilic coating. These Bioflex cylinders in testing appeared to be more abrasion resistant than silicone cylinders, and large series publication showed virtually no failure rates in the Titan cylinders [9]. While early publication by Wilson reported superior mechanical survival of Mentor Alpha 1 over AMS 700 CX ($P = 0.027$) devices [2], more recent publication from the same authors showed that the new parylene coating in AMS 700 CX minimizes the issue related to premature cylinder wear in Peyronie's implantation with manual penile remodeling [8]. In our study, the Kaplan-Meier estimates of survival from mechanical failure showed trend toward enhanced AMS 700 CX over Titan IPP that did not reach statistical significance at 5 years (91% vs. 87%; $P > 0.05$). One possible explanation for this difference in mechanical reliability of CX cylinder over Titan device relates to the design of CX cylinder that its middle layer is woven unidirectionally, permitting only girth expansion and

hence lowering the risk of mechanical malfunction from uneven cylinder inflation.

Manual penile remodeling produced splitting and rupturing of the fibrotic Peyronie's plaque following significant repetitive buckling forces to the inflated IPP, potentially compromising the fabric integrity of the device and resulting in cylinder aneurysm. Therefore manual penile remodeling should only be performed if the Peyronie's curvature is not too excessive and that rigorous repetitive attempt at penile remodeling should be limited [2]. In this study, we excluded men with penile curvature greater than 90° as there is increased likelihood that these men will require concomitant corpora-plasty and graft repair. Frequently, the simple insertion of the cylinder in the corpora after dilatation and dissection of the underlying intracavernosal fibrosis can result in complete straightening of the penis. Furthermore, one of the senior authors (GGB) described a new technique of minimally invasive PD corrective surgery using subtunical intracorporeal incision at the time of IPP implantation to avoid the need for additional Peyronie's grafting surgery in severe penile curvature [10]. With this minimally invasive method, all patients with penile curvature greater than 60° were able to avoid additional graft surgery during IPP implantation with manual penile remodeling. Earlier study by Montague [5] demonstrated significantly decreased mechanical survival for Ultrex cylinder over CX/CXM devices. The Ultrex cylinder was the predecessor to LGX cylinder, and most authorities do not advocate the use of LGX cylinder in PD patients because of postoperative implant buckling and potential higher risk of IPP malfunction.

Recent publication by Kaufman [11] described two cases of cylinder aneurysm in parylene-coated prostheses occurring more than 3 years following IPP implantation and this finding was also echoed by Salem [8] in their series with three patients presenting parylene-coated cylinders aneurysms. It appears that cylinder aneurysm is more common in men with longer prosthesis cylinders (18 and 21 cm cylinders) and that the aneurysm occurred due to disruption of the central layer of fabric rather than wear and tear of the parylene-coated silicone layers. Interestingly we did not detect any increased rate of cylinder aneurysm in men implanted with prosthesis cylinders greater than 18 cm, or in men with IPP implanted longer than 3 years. Furthermore we failed to detect any significant correlation between the frequency of sexual intercourse and prosthesis malfunction and revision.

The functional results with an inflatable penile prosthesis are considered excellent when the patient can operate the device without discomfort and can achieve sexual penetration with no difficulty resulting in satisfactory sexual intercourse. Montorsi [12] reported that the common reasons for patient dissatisfaction were postoperative penile shortening (30%) and in our study, more than 60% of men reported a decrease in penile length. However, the majority of patients would undergo the same operation again and recommend IPP to others. While a survey of patients satisfaction with IPP reported that patients prefer the Alpha-1 flaccid appearance, compared to that of the AMS 700 series ($P=0.054$) [13], our study found no trend favoring Titan over AMS 700 CX IPP ($P=0.46$). We believed proper counseling and informed consent improve patient acceptance and satisfaction.

To our knowledge, this is the first study that compares AMS 700 CX and Coloplast Titan implants with manual remodeling in the literature. We reported no statistical significant difference between the two IPP devices in terms of mechanical revision, cylinder failure rates and patient satisfaction. We acknowledged several limitations in our study. While there was smaller numbers of Titan compared to AMS 700 CX implants, patient demographics including duration of follow up were matched. Our series comprised of patients treated in a single high volume prosthesis institution, potentially limiting its applicability to the general population undergoing IPP implantation. Furthermore, the intermediate-term follow-up in our study may not address long-term mechanical failure. We also acknowledge the lack of a control group in our series and the potential for delayed curvature correction with active cycling of the device over time as an alternative approach. While some men continue to describe improvement in their penile curvature with repeated cycling of penile prosthesis implant, several studies have shown that adjunctive measures are required to correct penile curvature greater than 60° [2,3,6] and that delayed correction with repeated cycling of penile prosthesis may take many months. Despite these limitations, we feel that our study design with matched patient demographics, high numbers of sexually active men with IPP implants at the time of review, and the exclusion of patients who required concomitant graft surgery with IPP implant, provided a strong evidence for the continued use of IPP and penile remodeling for men with PD.

Conclusions

AMS 700™ CX and Coloplast™ Titan IPP implantation and penile remodeling provide excellent penile straightening and high patient satisfaction without an increase risk of revision surgery. There were no statistical significant difference between the two IPP devices in terms of mechanical revision, cylinder failure rates and patient satisfaction.

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Conflict of Interest: Gerald B Brock is a consultant for AMS and Coloplast.

Statement of Authorship

Category 1

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(c) Analysis and Interpretation of Data

Eric Chung; Matthew Solomon

Category 2

(a) Drafting the Article

Eric Chung; Matthew Solomon; Ling DeYoung

(b) Revising It for Intellectual Content

Eric Chung; Gerald B. Brock

Category 3

(a) Final Approval of the Completed Article

Eric Chung; Matthew Solomon; Ling DeYoung; Gerald B. Brock

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