Boston Scientific vs. Coloplast implants: A Prospective Analysis of a High-Volume Surgeon's Inflatable Penile Prosthesis Experience.

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Article

Keywords: Three-piece inflatable penile prosthesis, Coloplast Titan, AMS 700 CX, infection risk, revision risk.

Posted Date: July 6th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1785128/v1

Abstract

We compare using a prospective data collection the likelihood of infection and short-term revision in inflatable penile prosthesis (IPP) placements when using AMS 700 ^{TM} CX series versus Coloplast Titan®. The study included the first-time IPP implantations using both implants performed between January 2017 and December 2019. The surgeon alternated the implants every other week, and the patients were divided into two cohorts based on implant company for comparison and study. Data were collected on patient demographics, implant characteristics, perioperative features, and complications. Follow-up was carried out at 6 weeks, 3 months, and then annually. A total of 542 patients underwent IPP implantations during the two years, 301 (56%) were performed using AMS 700^{TM}CX and 241 (44%) using Coloplast Titan®. There was only one (0.18%) case complicated by infection. Seven cases (1.3%) required revision, five had been done using AMS 700^{TM} CX implants. Overall, the most common reason for revision was tube fracture (n=3). Diabetes, case time, reservoir type, and reservoir location were not significant prognostic factors for revision ($p>0.05$). We concluded that regarding manufacturing companies the risk of infection is not affected. Diabetes and drain placement for three days did not increase the risk of infection or overall revision.

Introduction

Erectile dysfunction (ED) is a chronic inability to achieve or maintain an erection sufficient for penetrative intercourse or other sexual activity (1). Estimates on the prevalence of ED range from 12 to 47% depending on age group but likely undervalue the true scale given expected under-reporting and differences in disease definition and treatment threshold (2). Nonetheless, ED and its surgical treatment represent a significant proportion of patients in a typical urology practice (3).

According to the American Urologic Association's published guidelines on erectile dysfunction, both medical and surgical options exist to treat ED once ruled out a reversible underlying etiology (4). Historically, oral phosphodiesterase type 5 inhibitors (PDE5i) have been a mainstay of medical therapy for ED and have often been used as a first-line treatment. In the face of oral treatment failure, other combination medical and non-surgical options such as intracavernosal injection, intra-urethral suppositories, and vacuum devices have also been widely utilized (5). Surgical implantation of a penile prosthesis may be offered as primary therapy for erectile dysfunction or as an alternative for those who are non-responders or have contraindications to the above therapies (4, 6).

Despite high five-year survival and satisfaction rates at over 89% (7) and 85% (8), respectively, risks of infection, erosion, malfunction, and need for revision exist (4, 9). Proposed risk factors such as diabetes, immunosuppression, and concomitant surgery have been inconclusive in the literature. Thus far, techniques such as the use of antibiotic-infused protheses and minimizing operative time have been shown to reduce infection and revision rates (10, 11). Mitigating these risks through patient selection, optimization of comorbidities, and device improvement continue to be the subject of ongoing research.

While one and two-piece implants are available, by far the most common implant utilized currently is the three-piece inflatable prosthesis as it mimics a physiologic erection (3). Currently, there are two FDA-approved three-piece devices, the AMS 700™ series (Boston Scientific, Massachusetts) and the Coloplast Titan® (Coloplast, Minnesota). Regarding comparisons, most of the published literature contrasting the two brands is retrospective in nature, being subject to the inevitable presence of cofounders or inaccuracy of the data collection. As these devices differ in their overall design, we aim primarily to evaluate prospectively whether device type is a significant independent risk factor for IPP revision. Furthermore, analysis of other considerations for reintervention, such as demographics and perioperative features, are included in the study.

Materials And Methods

A prospective analysis was performed on all patients who underwent three-piece IPP placement with AMS 700™ CX or Titan® between January 2017 and December 2019. After protocol review and approval by the institutional ethics review board under URN20-06_012, the patients were divided into two cohorts based on implant company for study and comparison by alternating IPP manufacturers each week. The included individuals provided consent to participate in prospective registries at their initial visit. All interventions were completed with a penoscrotal incision and a modified non-touch technique. We followed an infection prevention protocol in which urine tests were performed 1 week previous to the surgery. The patients received vancomycin 1 g IV and gentamicin 5 mg/kg IV before the procedure, and only disposable sheets were used during the interventions. Besides, a combination of rifampin and gentamicin antibiotic solutions was employed for surgical field irrigation with a 60 ml syringe in all the interventions and to immerse the Titan® implants. The average cylinder size used was 20.2 ± 2.48 cm.

Follow-up was carried out at 6 weeks, 3 months, and then annually. Data were collected prospectively including IPP company, age, diabetes mellitus diagnosis, anticoagulants intake, the reason for implant placement, operative time from incision to closure, reservoir shape and location, type of anesthesia, revision reason, and the number of days until revision. All the clinical information was collected into a HIPPA-compliant prospective registry with the help of Caisis software (BioDigital, NY, USA). Cases requiring revision due to secondary causes not related to the IPP, such as trauma or complications related to other urologic procedures, were excluded.

The cohorts were compared using chi-square tests for categorical variables and t-tests for continuous variables. Risk factors for infection and revision were evaluated with chi-square. Continuous variables are represented as mean ± standard deviation and categorical variables as n (%). $P \leq 0.05$ was considered statistically significant. All statistics were run using Stata 13.0 software (StataCorp, TX, USA).

Results

During the two years, 542 patients (mean age 69.2 ± 7.65) underwent first-time inflatable penile prosthesis placements. Of the 542 patients, 198 (36.5%) had diabetes mellitus, and only 2 (0.37%) were

on anticoagulation. The most common primary indication for IPP placement was isolated erectile dysfunction (n = 471, 87%), with erectile dysfunction combined with Peyronie's disease being the second most common (n = 71, 13%). Overall baseline characteristics of the study population can be found in Table 1. The mean follow-up was 29 months ± 9.9.

Table 1
Baseline Characteristics of patient population.

	Overall	Boston Scientific AMS 700™ CX	Coloplast Titan®	p-value
No. of Patients	542	301 (56%)	241 (44%)	N/A
Age (mean)	69.2 ± 7.67	69.7 ± 6.42	68.5 ± 8.96	0.07
Diabetes Mellitus	198 (36.5%)	107 (36%)	91 (38%)	0.63
On Anticoagulation	2 (0.37%)	1 (0.33%)	1 (0.41%)	0.88
Preoperative Diagnosis				
Erectile Dysfunction	471 (87%)	265 (88%)	206 (85%)	0.31
Peyronie's Disease	71 (13%)	36 (12%)	35 (14.5%)	0.39
Continuous variables represented as mean ± SD. Categorical variables presented as n (%).				

Of the 542 virgin implantations, 301 (56%) were performed using AMS 700™ CX and 241 (44%) using Coloplast Titan®. Between the two implant cohorts, there were no significant differences in baseline characteristics such as age, diabetes mellitus, anticoagulation, or pre-operative diagnosis ($p > 0.05$) (Table 1).

Concerning revision procedures, five replacement surgeries were performed on patients with AMS 700™ CX prostheses, and two were carried out on individuals with Coloplast Titan® (Table 2). There was no significant difference between the implant companies regarding reintervention ($p = 0.39$). The most common reason for reimplantation was tube fracture (n = 3). A defect in the AMS 700 ™ CX MS (Momentary Squeeze) Pump, which prevented initial device activation and eventually led to a product recall, was responsible for two of the reinsertions performed on Boston Scientific patients. A supersonic transporter (SST) deformity and subsequent infection 2 weeks after the procedure in the same patient resulted in the other two revision procedures, amounting to seven total cases requiring reintervention.

Table 2
Comparison of AMS700™ and Coloplast Titan® cohorts.

	Boston Scientific AMS 700™ CX	Coloplast Titan ®	p-value
No. of Cases Requiring Revision	5 (1.7%)	2 (0.8%)	0.39
Revision Reason			
Post-Op Infection	0 (0%)	1 (0.41%)	0.45
Supersonic Transporter (SST)	1 (0.33%)	0 (0%)	1.0
Tube Fracture	2 (0.67%)	1 (0.41%)	1.0
Pump Defect	2 (0.67%)	0 (0%)	0.51
Mean No. of Days until Revision (range)	225 (60–539)	450 (56–847)	0.42
Operative Time (mean in minutes)	50.4 ± 14.63	48.1 ± 4.61	0.08

Categorical variables presented as n (%). Number of Days until Revision shown as mean (range). Case Time represented as mean ± SD in minutes.

Regarding the average days until revision, first exchanges of AMS 700™ CX implants were required sooner than Titan® on average, with a non-statistically significant difference between the devices (225 days vs. 450 days postoperatively, p = 0.42). Additionally, there was no significant difference in operative times when using the two devices, with AMS 700™ CX cases lasting 50.4 ± 14.63 minutes and Titan® taking 48.1 ± 4.61 on average (p = 0.08).

With only one case of infection out of the 549 procedures investigated; the overall infection rate was 0.18%. Thus, IPP manufacturer was not a statistically significant risk factor for postoperative infection (p = 0.45) (Table 2). Of note, as this event occurred in a Coloplast Titan® placed after a revision of an SST deformity, the infection rate in virgin placements for this series was 0%. Furthermore, drains were placed for three days in all cases and did not result in an increased rate of infection. Diabetes mellitus, general vs. spinal vs. local anesthesia, reservoir type (flat vs. spherical), reservoir location (space of Retzius vs. ectopic rectal sheath vs. ectopic lateral), and performing hospital were not prognostic factors for infection or revision (p > 0.05) (Table 3). Case time was not a significant prognostic factor for revision (p = 0.97) (Table 3). The mean case time for procedures requiring revision was 49.6 minutes ± 3.87 versus 49.4 ± 0.66 for operations that did not.

Table 3
Analysis of risk factors for revision.

Risk Factor	Cases not Requiring Revision	Cases Requiring Revision
Diabetes Mellitus		
No DM	346 (98.9%)	4 (1.1%)
Type 1 DM	162 (98.2%)	3 (1.8%)
Type 2 DM	33 (100%)	0 (0%)
		p = 0.65
Performing Hospital		
CGH	283 (98.3%)	5 (1.7%)
PGH	178 (98.9%)	2 (1.1%)
		p = 0.59
Anesthesia		
General	283 (98.6%)	4 (1.4%)
Spinal	257 (98.8%)	3 (1.2%)
Local	1 (100%)	0 (0%)
		p = 0.96
Reservoir Shape		
Spherical	495 (99.0%)	5 (1.0%)
Flat	46 (95.8%)	2 (4.2%)
		p = 0.062
Reservoir Location		
Space of Retzius	85 (100%)	0 (0%)
Ectopic Rectal Sheath	1 (100%)	0 (0%)
Ectopic Lateral	454 (98.5%)	7 (1.5%)
		p = 0.52
Case Time (minutes)	49.4 ± 0.66	49.6 ± 3.87
		p = 0.97

Categorical variables presented as n (%). Continuous variables represented as mean ± SD. CGH = Coral Gables Hospital. PGH = Palmetto General Hospital.

Discussion

Since their original conception, inflatable penile prostheses have undergone many modifications and technological improvements resulting in decreased infection and revision rates as well as improved patient satisfaction (12). While significant research has been aimed at delineating patient risk factors, surgical techniques, and their optimization, many questions remain as to whether specific innovations have rendered a particular device superior (13).

Overall, the need for revision in the study was low (1.3%). This high rate of success in both devices speaks to the frequent innovation each prosthesis has undergone since their inception (12). These modifications, such as alterations in the tubing to prevent kinking, changes in more durable and infection-resistant coatings to the cylinders, rear tip extenders enabling better device fit, valves that prevent auto-inflation, and as shown in this series, fixing pump malfunctions which led to a product recall, have helped optimize both brands of devices for long-term success (14). Although, we obtained encouraging outcomes, a short period of follow-up may have limited the potential for uncovering a particular device's advantage as they undergo expected mechanical wear and tear over time (15).

Regarding the revision rate of the cohorts, we found no statistically significant difference among the two device groups. Again, this mirrors the current literature. Chung et al., in a retrospective evaluation of patients who underwent IPP placement for Peyronie’s disease, demonstrated no difference ($p > 0.05$) in the revision rate in AMS series versus Coloplast devices over five years (16). However, in contrast to our findings, they did note a small trend favoring AMS series.

Concerning the infection rate between AMS 700™ CX and Titan®, our study indicates device choice was not a significant prognostic factor. This outcome is similar to prior studies published in the literature. Dhabuwala et al., in their retrospective analysis, investigated IPP infection rates in groups with different anti-microbial coatings/washings specific to each device (17). This study also showed no significant difference in infection rate with 4.4% and 1.3% among Coloplast and AMS devices, respectively.

Our overall and virgin IPP infection rates were low in this study (0.18% and 0%, respectively) relative to the established literature (18). First-time placements have previously been shown to exhibit a typical infection rate ranging from 0.5–3% (18–21), with a higher risk in patients undergoing revision (22). As presented in this series, the only infectious episode was in a non-virgin IPP placement. Longer operative times have also been connected with higher rates of infection (10, 23). Although case time was not a significant factor for revision or infection in our analysis, our operative times were lower on average than previously published work (23). Surgeon expertise in a high-volume center and strict adherence to an infection prevention protocol also may have contributed to the low infection rate as well (24).

A unique aspect of this study was the exclusive placement of an intra-operative drain in all cases. This did not appear to increase infection or revision rate as previously discussed; since both were low as compared to published work. Drain placement has been a controversial point in the literature, with some authors more concerned about the risk of seeding an infection than the benefit of hematoma prevention

(25). A large retrospective study focused on infection complications after drain placement previously showed no increase in infection rate (26). Our data corroborate this finding and show an even lower infection rate. Unfortunately, both ours and this previous study lack a direct comparison with a control group.

Diabetes mellitus was not found to be a risk factor for infection or revision in our analysis. As previously mentioned, evidence for diabetes as a true risk factor for complications has been inconsistent, with some studies supporting (27) and some contradicting the association (24, 28). Our findings align with Pineda et al. who, in a comprehensive review of IPP literature, could not conclusively name diabetes a risk factor for IPP infection or revision (10).

Moreover, our results did not show any significant association between reservoir location or shape and rates of revision. Although all seven reimplantation procedures occurred in patients with ectopic reservoir placements, none of the complications leading to revision were related to reservoir palpability, auto-inflation, erosion, or mechanical failure. Previous series have established the safety of ectopic reservoir placement within the abdominal wall as an alternative to the Space of Retzius (29, 30), and it has been successful in our center as the primary method of reservoir placement.

In summary, the strengths of our study are based on the prospective data collection, decreasing the potential sources of bias and confounding compared with the many retrospective series published. Concerning limitations, our series examines a single-surgeon, high-volume center cohort. As mentioned before, this may have led to lower-than-average infection and revision rates, which may mask some unseen patient or device risk factors and limit its reproducibility. This focused scope and prospective design, however, does help prevent the potential for confounding factors between the groups, such as surgeon expertise and/or technique.

Future directions could include longer-term follow-up to capture some potential differences in device durability over time. Additionally, a direct focus on patient satisfaction and ease of use would be an interesting area of study in a similar cohort of patients. We would also encourage multi-centered prospective randomized studies to verify and support our findings.

Conclusion

Device choice of AMS 700 ^{TM} CX versus Titan® does not significantly affect the short-term mechanical or infection revision rate. Of note that the frequency of infection was minimal despite universal drain placement for 3 days. Diabetes mellitus considered a controversial point in IPP surgeries, was not found to be a significant risk factor for infection or overall revision in this series. High-volume prosthesis centers with reduced operative times can perform IPP placement with very low complication rates compared to the current literature.

Declarations

Data availability statement

Deidentified raw data that support the findings are available in http://caisis.org/demo/login.aspx , previous authorization from corresponding author upon request.

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Funding sources/Competing interest: None.

Ethical approval: The study was conducted in accordance with the Declaration of Helsinki previous Institution Review Board approval under the label URN20-06_012.

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