Original Article - Sexual Dysfunction/Infertility

Korean J Urol 2015;56:461-465.
http://dx.doi.org/10.4111/kju.2015.56.6.461
pISSN 2005-6737 • eISSN 2005-6745

Long-term survival and patient satisfaction with inflatable penile prosthesis for the treatment of erectile dysfunction

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Purpose: We investigated the long-term survival and patient satisfaction with an inflatable penile prosthesis as a treatment for refractory erectile dysfunction (ED).

Materials and Methods: Between July 1997 and September 2014, a total of 74 patients underwent implantation of an inflatable penile prosthesis. The present mechanical status of the prosthesis was ascertained by telephone interview and review of medical records, and related clinical factors were analyzed by using Cox proportional hazard regression model. To investigate current status and satisfaction with the devices, novel questionnaires consisting of eight items were administered.

Results: The mean (±standard deviation) age and follow-up period were 57.0±12.2 years and 105.5±64.0 months, respectively. Sixteen patients (21.6%) experienced a mechanical failure and 4 patients (5.4%) experienced a nonmechanical failure at a median follow-up of 98.0 months. Mechanical and overall survival rates of the inflatable penile prosthesis at 5, 10, and 15 years were 93.3%, 76.5%, and 64.8% and 89.1%, 71.4%, and 60.5%, respectively, without a statistically significant correlation with host factors including age, cause of ED, and presence of obesity, hypertension, and diabetes mellitus. Overall, 53 patients (71.6%) completed the questionnaires. The overall patient satisfaction rate was 86.8%, and 83.0% of the patients replied that they intended to repeat the same procedure. Among the 8 items asked, satisfaction with the rigidity of the device received the highest score (90.6%). In contrast, only 60.4% of subjects experienced orgasm.

Conclusions: The results of our study suggest that excellent long-term reliability and high patient satisfaction rates make the implantation of an inflatable penile prosthesis a recommendable surgical treatment for refractory ED.

Keywords: Erectile dysfunction; Patient satisfaction; Penile prosthesis; Survival

INTRODUCTION

Erectile dysfunction (ED) has been defined as the inability to achieve or maintain an erection sufficient for sexual performance [1]. Implantation of a penile prosthesis, the third-line treatment for ED, is one of the successful surgical treatments for ED. Penile prosthesis implantation is indicated for the treatment of organic ED in men who have failed or refused other available treatments, such as oral pharmacotherapy, a vacuum erection device, intracavernosal

Received: 23 February, 2015 • **Accepted:** 14 May, 2015
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injection, and intraurethral suppositories [2].

Since Scott et al. [3] introduced the inflatable penile prosthesis in 1973, the devices have been greatly improved for better mechanical and functional outcomes [4,5]. One of the most widely used inflatable penile prostheses is produced by American Medical Systems (AMS, Minnetonka, MN, USA). The AMS 700 CX inflatable penile prosthesis has an advanced cylinder that expands in girth only and is designed to resist uneven inflation to minimize cylinder aneurysms. The CXM cylinder, a modification of the CX cylinder, was introduced in 1990. It is appropriate for use in men with smaller cavernosal length and diameter.

With continuous improvements of penile prostheses and surgical techniques, mechanical failure and postoperative complications, such as prosthesis infection and erosions, have been decreasing since the penile prosthesis was first introduced to the market. Several studies reported that mechanical and overall survival rates at 5 years of AMS 700 CX/CXM range from 85% to 93% and from 77% to 91%, respectively [6-8]. According to a recent study, overall satisfaction rates for the AMS 700 CM/CXM are more than 80%. Reported factors contributing to decreased satisfaction included penile shorting, poor glandular engorgement, and lack of natural feeling of the erection [9,10].

Although several studies have been reported on outcomes and patient satisfaction with inflatable penile prostheses, there are few long-term data over 15 years, especially in Asians, who generally have smaller physical characteristics than in a Western population. Therefore, the aim of this study was to investigate the long-term mechanical and overall survival rate of the AMS 700 CXM inflatable penile prosthesis and the patient satisfaction rate.

MATERIALS AND METHODS

1. Recruitment of the patients

Between July 1997 and September 2014, a total of 74 patients underwent for the first time implantation of an AMS 700 CXM inflatable penile prosthesis in our institution. ED was diagnosed after careful history taking, physical examination, and laboratory tests including total and free testosterone and lipid profile. For further evaluation, the cause of ED was investigated by penile duplex sonography and neurologic examination. ED was defined as over 50% failure on sexual intercourse (minimum of four attempts) and a score of less than 25 on the International Index of Erectile Function (IIEF) erectile function (EF) domain for a minimum of 6 months. The indication for a penile prosthesis as a treatment for ED in our institution (Yeungnam University Hospital, Daegu, Korea) was a patient with no response to conventional approaches including oral phosphodiesterase-5 inhibitors with a maximal dose for four attempts or failure of intracavernosal injection therapy or vacuum devices. The penile prosthesis was also available for patients who had no intention of maintaining nonsurgical options as a treatment for ED.

2. Implantation procedure

The procedure for implantation of the penile prosthesis was performed by a single experienced surgeon following an identical protocol, through a penoscrotal approach with the patient under general or spinal anesthesia. To minimize the risk of infection, the device and corpus cavernosa were irrigated with saline and mixed antibiotics prior to implantation, and prophylactic antibiotics were administered preoperatively and until postoperative day 5. Patients were admitted to the hospital 5 to 7 days postoperatively. Patients were taught how to inflate and deflate the implant and to use the prosthesis 6 weeks after surgery.

3. Acquisition and analysis of data

After receiving approval from the Institutional Review Board in Yeungnam University Hospital (Daegu, Korea; IRB No. 2015-05-005), data on enrolled patients were collected retrospectively. Information regarding the present mechanical status of the prosthesis, which was answered with either yes or no, was obtained by a telephone interview conducted by a single disinterested coordinator. To investigate the functional status of the devices, we introduced a novel questionnaire consisting of eight items that assessed convenience of use, natural feeling, rigidity obtained, improvement in sexual life, general satisfaction, recommendation for others, and intention to repeat the procedure. Each question was asked by an identical investigator, and the degree of satisfaction for each question was categorized by one of following three entries: satisfied, neither satisfied nor dissatisfied, and dissatisfied.

Mechanical survival rates of the inflatable penile prosthesis were assessed by using Kaplan-Meier analysis. The related clinical factors included age, the cause of ED, and the presence of obesity, hypertension, and diabetes mellitus, which were analyzed by using Cox proportional hazard regression model. All statistical analyses were performed with IBM SPSS Statistics ver. 21.0 (IBM Co., Armonk, NY, USA), by use of two-sided tests with a significance level of 5%.

http://dx.doi.org/10.4111/kju.2015.56.6.461

RESULTS

1. Characteristics of the study subjects

The characteristics of the patients are summarized in Table 1. The mean (±standard deviation) age and follow-up period for all patients were 57.0±12.2 years (range, 27–86 years) and 105.5±64.0 months (range, 8–206 months), respectively. The organic cause of ED was as follows: vascular insufficiency in 15 patients (20.3%), diabetes mellitus in 16 patients (21.6%), Peyronie disease in 6 patients (8.1%), neurogenic cause in 9 patients (12.2%), and trauma-related in 10 patients (13.5%). No organic cause was identified in 18 patients (24.3%). Intraoperatively, the mean length of the right and left corpus cavernosum were 17.0±1.5 cm and 17.1±1.5 cm, respectively.

Table 1. The clinical characteristics of patients (n=74)

Variable	Value
Age (y)	57.0±12.2
Follow-up period (mo)	105.5±64.0
Cause of ED	
Vascular insufficiency	15 (20.3)
Diabetes mellitus	16 (21.6)
Peyronie disease	6 (8.1)
Neurogenic cause	9 (12.2)
Trauma related	10 (13.5)
Others	18 (24.3)
Length of corpus cavernosum (cm)	
Right	17.0±1.5
Left	17.1±1.5
Hospital day (d)	5.42±1.55

Values are presented as mean±standard deviation or number (%).
ED, erectile dysfunction.

2. Long-term survival of the device

Sixteen patients (21.6%) experienced a mechanical failure and 4 patients (5.4%) experienced a nonmechanical failure at a median follow-up of 98.0 months. Mechanical failure of the implant was due to cylinder leakage in 6 patients (8.1%), pump failure in 1 patient (1.4%), and reservoir leakage in 1 patient (1.4%). Eight patients with mechanical failure underwent implant removal or prosthesis replacement. In 8 patients (10.8%), the cause of mechanical failure was not determined because the patients did not undergo reoperation. Nonmechanical failure of the implant was due to erosion in 2 patients (2.7%), device infection in 1 patient (1.4%), and another medical problem in 1 patient (1.4%). All of the patients with nonmechanical failure underwent surgical exploration with implant removal. The numbers of patients with follow-up durations over 5, 10, and 15 years were 50 (67.6%), 32 (43.2%), and 17 (23.0%), respectively. The mechanical survival rate of the inflatable penile prosthesis at 5, 10, and 15 years was 93.3%, 76.5%, and 64.8%, respectively (Fig. 1A), and the overall survival rate of the inflatable penile prosthesis at 5, 10, and 15 years was 89.1%, 71.4%, and 60.5%, respectively (Fig. 1B). Cox proportional hazard regression model regarding device survival revealed no significant correlation with clinical host factors including age, cause of ED, and the presence of obesity, hypertension, and diabetes mellitus.

3. Present satisfaction of the patients with the devices

Overall, 53 patients (71.6%) completed the questionnaires. A total of 42 patients (79.2%) replied that the devices were easy to use, and 48 patients (90.6%) reported that the devices had adequate rigidity during sexual intercourse (Table 2). The overall patient satisfaction rate was 86.8%, and 43

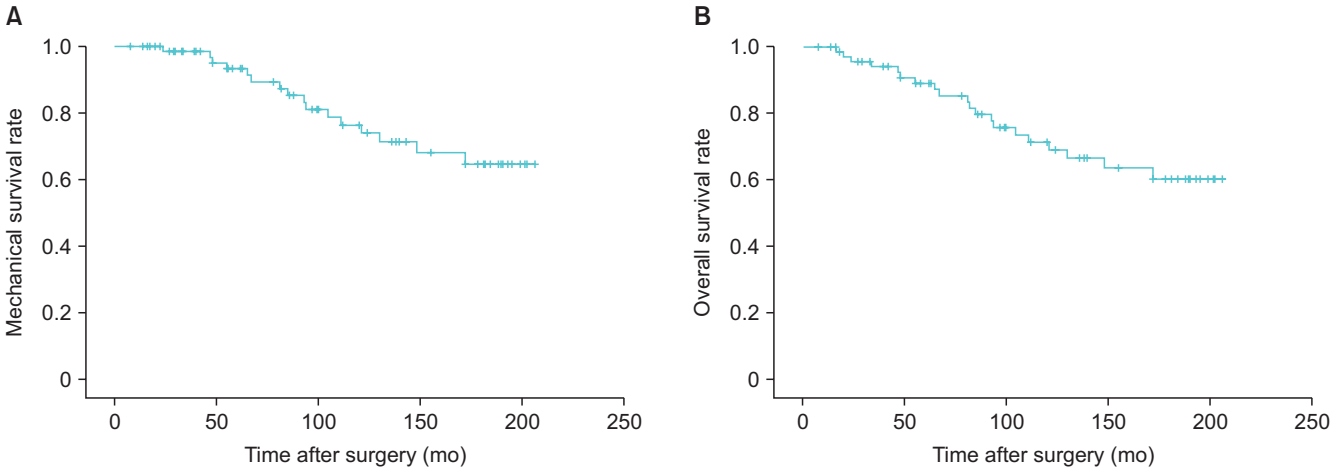

Fig. 1. Kaplan-Meier mechanical survival curve (A) and overall survival curve (B) according to time after implantation of AMS 700 CXM (AMS, Minnetonka, MN, USA) inflatable penile prosthesis.

Table 2. The domains of questionnaire for estimating patient satisfaction and results

Questionnaire	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied
Is the device easy to use?	42 (79.2)	8 (15.1)	3 (5.7)
How about the natural feeling of device?	39 (73.6)	11 (20.8)	3 (5.7)
Is the rigidity of device adequate to penetrate?	48 (90.6)	2 (3.8)	3 (5.7)
Do you experience an orgasm?	32 (60.4)	15 (28.3)	6 (11.3)
Do you consider that the device improves your sexual life?	43 (81.1)	6 (11.3)	4 (7.5)
Are you satisfied with the device?	46 (86.8)	3 (5.7)	4 (7.5)
Would you recommend the device to a friend?	47 (88.7)	4 (7.5)	2 (3.8)
Would you undergo the same procedure?	44 (83.0)	5 (9.4)	4 (7.5)

Values are presented as number (%).

patients (81.1%) answered that the device improved their sexual life. A total of 44 patients (83.0%) would undergo surgery again and 47 patients (88.7%) would recommend a friend to undergo the same surgery. Compared with the high patient satisfaction rate, only 32 patients (60.4%) replied that they experienced an orgasm.

DISCUSSION

The ideal prosthesis would provide its recipient with a penis that resembles as closely as possible normal penile flaccidity and erection, without compromising ejaculatory function, granting long-term mechanical and functional survival. In this study, we reported the long-term outcomes of the AMS 700 CXM inflatable penile prosthesis as assessed by Kaplan-Meier analysis and a questionnaire on patient satisfaction. The mechanical and overall survival rates of the inflatable penile prosthesis at 5, 10, and 15 years were 93.3%, 76.5%, and 64.8% and 89.1%, 71.4%, and 60.5%, respectively. These results are similar to data from other previous studies. Wilson et al. [7] reported that the mechanical and overall survival rates of the AMS 700 CX inflatable penile prosthesis at 5, 10, and 15 years were 85%, 68%, and 57% and 77%, 59%, and 48%, respectively. Similarly Dhar et al. [11] reported that the 10-year mechanical and overall survival rates of the AMS 700 CX/CXM were 81.3% and 74.9%, respectively. Kim et al. [8] showed that the Kaplan-Meier estimates at 3, 5, and 10 years for the AMS 700 CX/CXM provided for mechanical survival (97.6%, 93.2%, and 78.2%, respectively) and overall survival (95.0%, 91.0%, and 75.5%, respectively). To evaluate the clinical factors related to the survival rate, we analyzed patient age; presence of obesity, hypertension, and diabetes mellitus; and cause of ED by using the log-rank test. These factors were not associated with device survival.

There are potential complications of an inflatable penile prosthesis including mechanical failure (such as cylinder leakage, pump failure, and reservoir leakage) and nonmechanical failure (such as device infection or erosion) [12]. In our study, mechanical and nonmechanical failure occurred in 16 patients (21.6%) and 4 patients (5.4%), respectively, with a median follow-up of 98.0 months. The incidence of mechanical or nonmechanical failure is known to be associated with the period of follow-up.

Implantation of a penile prosthesis is known to have an excellent long-term patient satisfaction rate compared with other managements including oral pharmacotherapy and penile injection therapy [13]. Candela and Hellstrom [14] used a mailed questionnaire and reported overall patient satisfaction of 85% with the AMS 700 CX. In a European multi-institutional study with 200 consecutive patients, Montorsi et al. [9] reported that the overall patient and partner satisfaction rates were 92% and 96%, respectively. That study also identified that adequate erection for sexual intercourse was achieved in 98% of patients. Another recent study from Italy was conducted on 80 patients to evaluate patient satisfaction by use of validated questionnaires such as the IIEF and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) [15]. In that survey, the authors reported that the median postoperative IIEF5 and EDITS scores were 21.46 and 73.11, which showed a high level of satisfaction. Natali et al. [16] also reported the satisfaction rate with the AMS 700 CX by using the EDITS questionnaire. In that study, the patient and partner satisfaction rates were 97% and 91%, respectively. Similarly, our long-term patient satisfaction rate was 86.8%, and 83.0% of men replied that they intended to repeat the same procedure. Furthermore, 88.7% of the men reported that they would recommend an implant to a friend.

The current study had several limitations. This study had a retrospective design and a relatively small number of patients. Patient satisfaction was assessed by telephone interview, which has relatively low accuracy compared with a face-to-face interview. Furthermore, our eight questions

http://dx.doi.org/10.4111/kju.2015.56.6.461

were not a standardized measurement tool, unlike the IIEF or EDITS. Other limitation was that the study did not have a control group. Despite these limitations, our study provides data on long-term outcomes and patient satisfaction with an inflatable penile prosthesis in Korea.

CONCLUSIONS

Despite the decline in survival of the device with the passage of time, patient satisfaction with an inflatable prosthesis remains relatively high. This study demonstrated that implantation of an inflatable penile prosthesis is a safe and effective treatment for refractory ED in Korea, with excellent long-term reliability and high patient satisfaction rates.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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