

## A Survey of Patients with Inflatable Penile Protheses: Assessment of Timing and Frequency of Intercourse and Analysis of Implant Durability

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DOI: 10.1111/j.1743-6109.2012.02729.x

### ABSTRACT

**Introduction.** This study was conducted to determine how long after inflatable penile prosthesis (IPP) surgery patients attempt sexual intercourse and the frequency of subsequent relations. We also examined survival-related factors for the AMS 700 CX, Mentor Alpha 1, and Mentor Alpha Narrow Base.

**Aims.** The aim was to survey men who received IPPs and collect information about their return to sexual function and frequency of use, and to assess the resilience of their devices.

**Methods.** Phase I involved retrospective chart review of 1,298 virgin IPP surgeries performed by one surgical team from January 1992 to December 1998. Phase II included 330 subjects selected by stratified, systematic, random sampling from phase I patients. Data were collected by computer-assisted telephone interview, using a 27-question survey. All patients had been instructed to wait 4 weeks before using the implant and were taught how to inflate/deflate their prostheses at the 4-week postsurgical visits.

**Main Outcome Measures.** The survey examines the length of time after surgery for men to resume sexual function. In the same study, information was garnered about mechanical durability of the device.

**Results.** Among phase I subjects, the 5-year survival rate was 83% (N = 1,069) for IPP revision for any reason. Of the 330 phase II subjects, 248 (75%) were successfully contacted; 199 (80%) responded to the full survey and 49 (20%) responded to selected parts of the survey. Sexual intercourse was resumed postoperatively at 1–4 weeks for 41% (78/190), at 5–6 weeks for 31% (59/190), at 7–8 weeks for 16% (30/190), and at >8 weeks for 12% (23/190) of the patients. More than 60% of patients reported using their IPP at least once weekly.

**Conclusion.** The three-piece IPP has excellent 5-year survival rates. Most patients return to sexual activity relatively quickly, with high frequency of usage of their prostheses. **Henry GD, Brinkman MJ, Mead SF, Delk JR II, Cleves MA, Jennermann C, Wilson SK, and Kramer AC. A survey of patients with inflatable penile prostheses: Assessment of timing and frequency of intercourse and analysis of implant durability. J Sex Med 2012;9: 1715–1721.**

**Key Words.** Outcomes; Penile Prosthesis; Impotence; IPP Survival

### Introduction

The purpose of the study was to investigate the timing and frequency of sexual intercourse among patients with inflatable penile prostheses (IPPs) postoperatively and to identify factors

There was no funding for this study.

related to device survival of three types of IPPs—AMS 700 CX, Mentor Alpha 1, and Mentor Alpha Narrow Base (NB). The first phase of the study examined the reasons for revision of the IPPs, including mechanical reliability, infection, patient and partner satisfaction, and iatrogenic/medical factors. The second phase of the study examined patient satisfaction with each

type of prosthesis, sexual satisfaction of the partner, and the timing and frequency of sexual activity after penile prosthesis implantation. The patient satisfaction aspect of this study has been previously published in the *Journal of Urology* as a Continuing Medical Education article [1].

Although there have been many articles published on implant survival, a literature search yielded a limited number of reports on the timing and frequency of sexual intercourse among patients with penile prostheses. The literature is also limited in level of detail. However, both timing and frequency of intercourse are necessary to understand patient satisfaction with treatment for erectile dysfunction (ED). According to a survey of female partners of men with ED, women reported that the frequency of sexual intercourse after the development of ED was significantly less than before the onset of ED [2]. The limited literature related to penile prostheses sexual intercourse frequency data indicates a range from 2 to 13 times each month [3–6]. We report patient and partner survey results of frequency and timing of sexual intercourse after IPP implantation.

### Aims

A computer-assisted telephone interview of penile implant patients postoperatively was used to assess various factors in the form of a 27-question survey. Among the information received was time to initial device usage after surgery and subsequent frequency of use. Longer-term follow-up helped to identify the durability and 5-year survival of these devices and predisposing factors in device longevity.

### Methods

*Phase I:* This phase involved retrospective chart review of 1,298 virgin (first-time placement) three-piece IPP surgeries completed by the same surgical team at one hospital between January 1992 and December 1998 (Table 1). Population demographics and etiology have been previously

reported [1]. The goal of this phase was to measure implant survival among all of the patients who had virgin implants during that time period. Revision could have occurred at any time during the study period in order to make the IPP satisfactory.

### Penile Implant Study Data Abstract Form

This phase included data abstraction on the population of 1,298 patients with virgin implants, using one form per implant, and has been previously described [7]. The same tool was used to abstract data on the reasons for the revision: (i) mechanical reliability; (ii) patient and partner satisfaction; (iii) infection; and/or (iv) iatrogenic/medical reasons.

### Data Analysis

Information collected included type of implant, implant date, patient birth date, and revision history, including date and reason for revision. Data concerning 14 different implant devices were collected, but only three implant types had sufficient numbers and follow-up time for meaningful analysis: Mentor Alpha NB, Mentor Alpha 1, and AMS 700 CX. Data management and analysis were performed using SPSS statistical software (SPSS Inc., Chicago, IL, USA). Survival estimates were calculated using the Kaplan–Meier product limit method and compared with the log-rank test for each implant type using Stata statistical software (Stata Corporation, College Station, TX, USA). The Kaplan–Meier method was used to analyze survival with regard to five categories: (i) mechanical reliability; (ii) infection; (iii) patient and partner satisfaction; (iv) iatrogenic/medical reasons; and (v) survival for any reason [8].

*Phase II:* The goal of this phase was to measure patient satisfaction, frequency, and timing of sexual intercourse. Subjects included 330 patients selected by stratified, systematic, random sampling by device type from among the pool of 1,298 phase I patients. Patients who, at the time of data collection, had a revised or new prosthesis, or who did not currently have prosthesis, were surveyed regarding the initial virgin implant received. Patients had been educated to wait 4 weeks after surgery before using their implant, and at 4 weeks the patients were taught how to inflate/deflate their penile prostheses.

The testing instrument was a survey developed through review of pertinent literature [9]. The final survey contained seven sections with a total of 27 questions and has been previously described [1]. Data for part II of the study were collected through a computer-assisted telephone interview.

**Table 1** Virgin implant by type of prostheses

Implant type	Virgin implant N
Mentor Alpha Narrow Base	101
AMS 700 series	93
Mentor Alpha 1	1,104
Total	1,298

**Table 2** Reasons for revision (failure) of implant

Reason for revision	N	%
Not revised within 5 years	1,069	83
Mechanical	82	6
Patient satisfaction	14	1
Infection	66	5
*Iatrogenic/medical	67	5
Total	1,298	100

\*Iatrogenic reasons for implant removal may imply a technical issue upon device placement that rendered it unusable or unsatisfactory, such as cylinder crossover or reservoir extrusion. It may also mean that the patient was being explored for unrelated reasons, and as the device was simply unwanted or posed a theoretical infection risk, it was removed at the same time electively at the patients' request

The interviewer was the PhD dissertation researcher. Institutional Review Board approval and informed consent were obtained, and confidentiality was assured for each patient participant. The patient interview data were entered into a SPSS survey computerized database (SPSS Inc.). If the patient did not want to participate in the entire interview, the questions were prioritized, with the patient initially being asked to response to the single question "Are you satisfied with the implant?" Data management and analyses were performed using SPSS statistical software (SPSS Inc.). The chi-square statistic was used to test categorical data. Descriptive statistics (counts and percentages) were used to describe and summarize the data reflecting patient timing and frequency of intercourse with the three types of penile implants.

**Main Outcome Measures**

The primary outcomes analyzed in the different phases of the study are time until initial device usage after surgery and longevity of the patients' devices. Data regarding the time to resumption of sexual function and the frequency of sexual activity were evaluated. Factors relating to device usage, satisfaction, and durability were garnered through the study and were suitable for reporting.

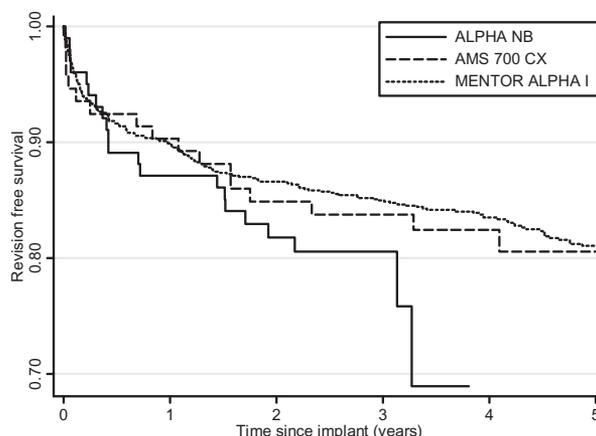
**Results**

*Phase I:* Summarized in Table 2 are the outcomes for the 1,298 virgin three-piece IPPs, with reasons for revisions, where applicable. There were no significant differences among the three types of prostheses in terms of the number of revisions for patient dissatisfaction, iatrogenic/medical, or mechanical failure.

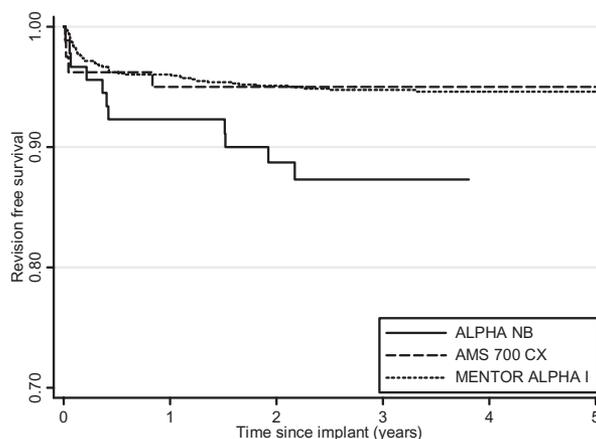
As shown in Figure 1, the 3-year Kaplan–Meier estimates of revision-free survival for any reason

for virgin implants by implant type were 85% for Mentor Alpha 1, 83.8% for AMS 700 CX, and 80.6% for Mentor Alpha NB. The 5-year Kaplan–Meier estimates of revision-free survival for any reason for virgin implants were 81.1% for Mentor Alpha 1, 80.6% for AMS 700 CX, and could not be determined for Mentor Alpha NB because these implants had only been followed for a maximum of 3.15 years, at time of data collection. The survival experience of the three virgin implant types for failure for any reason was not significantly different (log-rank test = 2.86, *P* = 0.2392).

As shown in Figure 2, the 3-year Kaplan–Meier estimates of revision-free survival because of infection, for virgin implants by implant type, were 94.8% for Mentor Alpha 1, 95% for AMS 700 CX, and 87.3% for Mentor Alpha NB. The 5-year Kaplan–Meier estimates of revision-free survival



**Figure 1** Kaplan–Meier estimates of revision-free survival for any reason for virgin implants by implant type.



**Figure 2** Kaplan–Meier estimates of revision-free survival for infection for virgin implants by implant type.

**Table 3** Frequency of sexual intercourse by type of prosthesis: number (%) of patients with each type of prosthesis

Frequency	Alpha Narrow Base	AMS 700s	Alpha 1	Total
Daily	2/18 (11)	0/12 (0)	15/167 (9)	17/197 (9)
Biweekly	2/18 (11)	5/12 (42)	49/167 (29)	56/197 (28)
Weekly	8/18 (45)	2/12 (17)	37/167 (22)	47/197 (24)
Bimonthly	2/18 (11)	1/12 (8)	21/167 (13)	24/197 (12)
Monthly	2/18 (11)	1/12 (8)	11/167 (7)	14/197 (7)
Other	2/18 (11)	3/12 (25)	34/167 (20)	39/197 (20)

for infection for virgin implants were 94.6% for Mentor Alpha 1, 95% for AMS 700 CX, and could not be determined for Mentor Alpha NB. The survival experience of the three virgin implant types for failure due to infection was significantly different at the 5% level (log-rank test = 7.72,  $P = 0.0211$ ). The difference was due to the higher infection failure rate of the Mentor Alpha NB implants.

In Table 2, iatrogenic removal of penile implant implies that the device was removed concomitantly either during another surgery due to patient lack of use and request for explant or a technical issue with the implant such as cylinder crossover or reservoir extrusion. Whereas a repair may have been feasible, in some cases explant was done, and they are reflected in this category on the table.

*Phase II:* A total of 330 patients were randomly selected to participate in the survey. Of these 330 patients, 39 (12%) were deceased and 43 (13%) could not be contacted. Of the remaining 248 patients, 199 (80%) responded to the full survey and 49 (20%) refused to participate in the full survey but agreed to respond to a selected part of the survey.

The length of time after surgery before sexual intercourse was resumed was 1–4 weeks for 41% (78/190), 5–6 weeks for 31% (59/190), 7–8 weeks for 16% (30/190), and >8 weeks for 12% (23/190) of patients. More than 60% of patients used their IPP for sexual intercourse at least once weekly (see Table 3).

## Discussion

Phase I of the study examined factors related to prosthesis survival. Phase II of the study examined resumption of sexual intercourse and frequency of sexual activity with the prosthesis.

*Phase I:* This study has reported findings relative to the experience of 1,298 patients with IPPs, categorized by implant type. The IPP has been available for more than 30 years. Wilson et al. reported that the early models had leakage rates as high as

70% [10]. The current models are results of multiple product enhancements and significant design improvements over many years.

While all IPPs were virgin implants, the practice was a tertiary referral center for IPPs, and many of the Mentor NB implants were placed into patients with corporal fibrosis. Corporal fibrosis cases require lengthier treatment, are more complicated, and result in greater tissue damage, thereby increasing the mechanical failure and infection rates in this population of patients. The Mentor NB would be expected to have higher baseline infection and revision rates because it was placed in many cases that were inherently more complex, given the scarring of the corpora.

In 2000, Carson et al. reported the results of Kaplan–Meier analysis of 372 patients implanted with AMS 700 CX penile prosthesis [3]. The 2-year Kaplan–Meier survival rate for freedom from failure for any reason was 89%. In this study, the 2-year Kaplan–Meier survival rate for freedom from failure for any reason for AMS 700 CX was 86%. In the study by Carson et al., the 5-year Kaplan–Meier survival rate of freedom from failure for any reason was as 79% as compared with 83% discovered in this study [3]. The survival rates of this study and the one from Carson et al. are similar [3].

The current study found that when infection was examined as a factor in survivability of implants, there was a significant difference by implant type ( $P = 0.0068$ ). The overall infection rate for all implant types was 66/1,298 (5%). This low infection rate (5%) is consistent with the rates found by other investigators of the era. For example, Carson et al. reported that device infection developed among 12 of the 372 (3.2%) patients with AMS 700 CX prostheses [3]. In this study, infection developed in four of the 93 (4.3%) patients with AMS 700 Series prostheses. These implants were placed in a period prior to many of the recent advances in infection reduction, such as infection-retardant coating and improved surgical skin preparations.

Wilson and Delk reported that the infection rate was 3% for primary implantations performed by the same team on 823 patients during a 7-year period from 1986 to 1993 [11]. The lower infection rate in the earlier study at the same center, as compared with this current study, may be due to the fact that in the pre-Viagra era, IPP patients were generally healthier than the patients of the current study who did not respond to Viagra. A substantial difference in rates was shown in a study by Jarow, who reported that the infection rate for the patients who underwent uncomplicated primary implantation was 2/114 (1.8%) [12]. The overall infection rate for the Jarow study was 11/167 (7%) [12]. In 1995, Parsons reported that infected penile prostheses may be the current major cause of implant failure [13]. This study showed that the primary reason for implant failure was mechanical and was done prior to any antibiotic coating on the IPP. In summary, there was a significant difference in the survival of virgin implants due to failure because of infection, but not for failure for any reason.

*Phase II:* In the present study, both timing to sexual intercourse following prosthesis implantation and frequency of sexual intercourse are reported. Despite the value of such outcomes, very few studies evaluating the efficacy of penile prostheses in the treatment of ED report these data.

Similar to the present study, Carson et al. utilized a telephone interview for analysis of postoperative patient satisfaction in a long-term multicenter study of AMS 700 CX [3]. Seventy-nine percent of survey respondents indicated that they used the device at least twice monthly. In the present study, we found that more than 60% of surveyed patients had sexual intercourse once every week; the remaining indicated that they had sexual intercourse bimonthly (12%) or monthly (7%). Through a mailed questionnaire following implantation with Ambicor (American Medical Systems, Inc., Minnetonka, MN, USA) in 146 men, Lux et al. report that among the 101 respondents, 88.9% reported continued use with an average frequency of coitus of 5.1 times per month, similar to the rate of one time per week reported in the present study [4]. According to the study by Lux et al., among men not using the prosthesis for sexual intercourse, the most commonly reported reasons were lack of partner (4%) and lack of interest in sex (4%) [4]. In this study, 68 of the 199 patients (34%) claimed to not currently be using the prosthesis regularly for intercourse. The primary reasons were loss of partner for 21% (14/68), personal health concerns in 16% (11/68),

partner health concerns in 7% (5/68), and perceived problems with their prosthesis in 56% (38/68).

Ferguson and Cespedes also evaluated reliability and patient satisfaction in a long-term study featuring the Dura-II (Timm Medical Technologies, Inc., Eden Prairie, MN, USA) penile prosthesis [14]. Over a 4-year period, 94 patients were implanted, 85 of which were available for long-term evaluation. At final data analysis, 76% of patients also reported continued sexual activity [14]. Among the sexually active, the average frequency of intercourse during the 3–6 months before the final questionnaire was six times per month, similar to the rates found in both the present study and that of Lux et al. [4,14]. In an outlying study, Salama evaluated the psychosocial aspects of penile prostheses among patients and partners receiving semirigid rods [6]. Average frequency of sexual intercourse was 13 times per month [6]. Eighty-nine percent of satisfied patients reported increased sexual desire and improved ability to achieve orgasm [6].

In general, data regarding frequency of intercourse are scarcely reported; however, data related to timing to sexual activity are even more difficult to ascertain in the literature. This study found that after surgery, sexual intercourse was resumed by 41% of patients at 1–4 weeks, 31% at 5–6 weeks, 16% at 7–8 weeks, and 12% at greater than 8 weeks. Surprisingly, 41% of patients admitted to using their IPP before device teaching at the 4-week postoperative visit. Goldstein et al. similarly reported timing-specific data in patients implanted with Mentor Alpha 1: this retrospective study found that 25% of patients resumed intercourse at 1–4 weeks after surgery, 35% at 5–6 weeks, 5% at 7 weeks, and 28% at 8 weeks or more [15]. Although frequency data were not outlined in detail due to the nature of the questionnaire, the authors do note that 60% of patients had sexual intercourse more often after surgery, 28% of patients maintained the same frequency of intercourse, and 12% had sexual intercourse less frequently [15]. In comparison, our study found an average frequency of sexual intercourse of once per week in more than 60% of surveyed patients. Timing to sexual intercourse was 6 weeks or less in 72% of patients. This study found frequency of sexual intercourse to be daily for 9% (17/197), biweekly for 28% (56/197), weekly for 24% (47/197), bimonthly for 12% (24/197), monthly for 7% (14/197), and other for 20% (39/197). The chi-square analysis indicated that frequency of intercourse was independent of prosthesis type ( $P = 0.893$ ). Of the patients who answered the survey question regarding length of

time with partner, the majority of patients had been with partner for over 10 years, 138/189 (73%). The next two most frequently answered categories for length of time with a partner were 4–5 years, 17/189 (9%), and 2–3 years, 15/189 (8%). Therefore, IPP patients in long-term stable relationships appear to benefit greatly from implantation in terms of satisfaction (as previously reported) and are open to answering survey questions about their implants [16]. As previously reported and documented in many studies, satisfaction remains and continues to be high among patients who undergo inflatable penile implant surgery [17–20].

Overall, information related to sexual timing and frequency after implantation of a penile prosthesis is infrequent and inconsistent. Limitations of this study include the following: the respective nature of the questionnaire; recall bias; surgery was done by experienced prosthetic urologists; implant durability may change with improvements in IPP design and/or surgical techniques; and lack of standardization in patient questioning and outcome reporting methods consequently inhibits a conclusive comparative analysis between studies. Further understanding of the sexual habits of couples is emerging as a valuable tool in treating their overall health and well-being [21,22].

## Conclusions

The three-piece IPP has high 5-year survival rates. Most patients return to sexual activity relatively quickly, with high frequency of usage of their prostheses. Mechanical reliability is high, though breakage does occur. Satisfaction with the IPP is highest in select patient populations, such as men in stable relationships, and those who set reasonable expectations. Some men, despite having a functional implant, ultimately do not use their devices. While the reasons for this vary, some of these causes are ongoing issues with device understanding and functionality and loss of sexual partner.

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*Conflict of Interest:* None.

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## Category 3

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All

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