# A SURVEY OF PATIENTS WITH INFLATABLE PENILE PROSTHESES FOR SATISFACTION

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### ABSTRACT

Purpose: We assessed patient satisfaction with 3 types of penile prostheses, namely the AMS 700 Series<sup>®</sup>, Mentor Alpha 1<sup>®</sup> and Mentor Alpha NB<sup>®</sup>.

Materials and Methods: The subjects consisted of 330 patients selected by stratified, systematic random sampling from among 1,298 subjects undergoing virgin 3-piece inflatable penile implant surgeries performed by the same surgical team at 1 hospital between January 1992 and December 1998. Data were collected by computer assisted telephone interviewing with a survey developed by the authors. The survey consisted of 37 questions in 7 sections, including 1 demographic section and 6 patient satisfaction sections.

Results: Of the 330 patients selected 248 (75%) could be contacted. Of these, 199 (80%) responded to the full survey and the remaining 49 (20%) agreed to respond only to the question, "How satisfied are you with the prosthesis?" Of the 199 full responders 12 (6%) had AMS implants and 187 (94%) had Mentor implants. Of the 49 single question responders 5 (10%) had AMS implants and 44 (90%) had Mentor implants. Of the 248 patients the overall satisfaction rate was 69%. Although there was no significant difference at the 5% level in patient satisfaction by implant type, responses tended to favor the Alpha IPPs in terms of overall sexual satisfaction (p =0.058), natural feeling of the prosthesis (p =0.061), flaccid appearance of the penis when deflated (p =0.054), and education with demonstration of inflation and deflation (p =0.075).

Conclusions: There was a high degree of overall patient satisfaction across implant types.

KEY WORDS: treatment outcome, penile prosthesis, impotence

A review of the literature from the last 70 years revealed an extensive search for a reliable surgical therapy to reestablish an acceptable penile erection. The original inflatable penile prosthesis (IPP) was introduced in 1973 by Scott et al.<sup>1</sup> While early experience showed a high rate of mechanical breakdown, multiple design changes in the device and surgical technique have greatly improved the IPP. High patient satisfaction rates with IPPs were reported.<sup>2-4</sup> In 1988 Furlow et al reported that the Mentor Alpha 1® and AMS 700® were the most mechanically reliable penile prostheses with the highest rates of patient satisfaction.<sup>5</sup> Today in the United States the multicomponent inflatable is the most frequently implanted type of penile prosthesis.

We identified factors related to patient satisfaction with 3 types of penile prostheses, namely the AMS 700 Series®, Mentor Alpha 1® and Mentor Alpha NB®. The survival data for these patients have been previously published.<sup>4,6</sup> No significant difference in device survival was observed between the Mentor Alpha 1® and the AMS 700 CX® IPP except for Peyronie's disease modeling cases. In patients who underwent the modeling procedure, the mechanical survival rate at 5 years for the Mentor Alpha 1® was superior to that of the

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AMS 700 CX® (p =0.0270).<sup>6</sup> We present a retrospective telephone questionnaire study. We investigated the relationship between patient satisfaction and the type of prosthesis implanted by examining patient overall satisfaction with the prosthesis as well as the sexual satisfaction of the patient and partner.

#### MATERIALS AND METHODS

Between January 1992 and December 1998 a total of 1,298 patients received for the first time an AMS 700 Series® (93 patients), Mentor Alpha 1® (1,104) or Mentor Alpha NB® penile implant (101). Of these patients 330 were randomly selected by stratifying based on implant type and asked to participate in the survey. During the interview patients who had a revised or a new prosthesis, or who did not currently have a prosthesis implanted, were asked about the initial virgin implant.

The survey instrument was developed by the authors based on a comprehensive review of pertinent literature. The survey, Questions to Assess Marital Satisfaction, developed by Young et al to test the relationship between the sexual satisfaction of married women and men, was used as a guideline for developing the testing instrument for this study.<sup>7</sup> The *Handbook of Sexuality-Related Measures* was a resource for questions and Likert scale responses.<sup>8</sup> Guidance was also taken from the Interpersonal Exchange Model of Sexual Satisfaction Questionnaire.<sup>9</sup> To check the validity of the survey 4 experts in the field of penile prostheses research were asked to review it, and determine if the questions were appropriate and clear. The survey was revised according to the

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	No. (%)				
	Alpha NB®	AMS Series®	Alpha 1®	Totals	
Cases selected	27 (8)	23 (7)	280 (85)	330 (100)	
Responders to full survey	18 (9)	12 (6)	169 (85)	199 (100)	
Responders to single question survey	5 (10)	5 (10)	39 (80)	49 (100)	
Total responders	23 (9)	17 (7)	208 (84)	248 (100)	
Lost to followup	3 (7)	3 (7)	37 (86)	43 (100)	
Deceased	1 (2)	3 (8)	35 (90)	39 (100	

TABLE 1 Responders and nonresponders by implant type

suggestions of the expert reviewers. The survey contained 7 sections with a total of 37 questions (see Appendix). Possible responses to the survey questions were satisfied, neither satisfied nor dissatisfied, and dissatisfied.

Data were collected by means of computer assisted telephone interviewing. The interviewer was an independent and unbiased researcher trained on the survey instrument. Informed consent was obtained and confidentiality was assured for each patient participant. If the patient refused to respond to the entire survey, he/she was asked to answer a single question, "How satisfied were you with the prosthesis?" These patients indicated whether they were satisfied, neither satisfied nor dissatisfied, or dissatisfied.

The data were entered into the SPSS® survey computerized database. Data management and analysis were performed using SPSS® statistical software.<sup>10</sup> The chi-square test statistic was used to perform categorical data analysis. Descriptive statistics were used to summarize the data reflecting patient satisfaction with 3 types of penile implants.<sup>11</sup>

#### RESULTS

Of the 330 patients randomly selected 39 (12%) were deceased and another 43 (13%) could not be contacted. The remaining 248 (75%) patients were contacted. Of these patients 199 (80%) responded to the full survey and 49 (20%) refused to respond to the full survey but agreed to respond to the single question, "How satisfied were you with the prosthesis?" The responders and nonresponders are presented in table 1 by implant type. An analysis of the internal consistency of the survey as a testing instrument was performed by examining the individual items of the survey and the reliability estimate was 0.92. Scale reliability was assessed by calculating coefficient  $\alpha$ . Cronbach's coefficient  $\alpha$  is a widely used method for computing survey item score reliability. Several items on the survey were composed to ask the same question using different words. The reliability estimate of 0.92 means that patients answered these questions the same way. Therefore, internal consistency was strong since the satisfaction items had good item-total correlations.

Selected characteristics of full survey responders are summarized in table 2. The opportunities for improvement identified in the survey may be relied upon to make clinical decisions since the survey is a reliable instrument. Slightly less than 20% of patients reported being dissatisfied with their implant. Approximately 82% reported having no fear of failure during intercourse, 72% reported that they would have the surgery performed again, 70% would have surgery to correct a problem with the prosthesis and 75% would recommend prosthesis surgery to someone else (table 3). Overall patients were satisfied with the actual functioning of the prosthesis. For all prostheses types, patient satisfaction with the operation of the inflate mechanism was 76%, patient satisfaction with the deflate mechanism was 50%, spontaneous inflation of the prosthesis was 69%, satisfaction with the rigidity of the prosthesis during intercourse was 79% and satisfaction with the suitable erectile function for intercourse was 80% (table 4). The single question, "How satisfied were you with the prosthesis?" showed 69% satisfaction (table 3). Overall sexual satisfaction of the patient and partner was 69% with chi-square analysis favoring the Alpha IPPs (p = 0.058, table 5). Three more patient satisfaction questions showed a similar finding based on natural feeling of the prosthesis (p = 0.061), flaccid appearance of the penis when deflated (p = 0.054), and education by demonstration of inflation and deflation (p = 0.075).

#### DISCUSSION

We reported on patient satisfaction with 3 types of penile prostheses, the Mentor Alpha NB®, AMS 700 Series® and Mentor Alpha 1®. The study examined various aspects of patient satisfaction. There was no significant difference at the 0.05 level in the measures (variables of interest) in each of 6 satisfaction subscales by prosthesis type. Of the 199 men interviewed 138 (69%) indicated that they were satisfied with the prosthesis, including 118 (70%) of the 169 men interviewed with the Alpha 1®, 7 (59%) of the 12 men interviewed with the AMS 700 Series® and 13 (72%) of the 18 men interviewed with the Alpha NB®. These rates are consistent with those found by other investigators. In 1995 Lewis wrote that 90% of patients had a functioning IPP at 5 years with 70% completely satisfied.<sup>12</sup>

Of our patients 66% used the prosthesis on a regular basis with 61% having sexual intercourse at least once a week. Sexton et al showed 70% of patients were still sexually active with their prosthesis at a mean followup of 5.4 years.<sup>13</sup> Moreover IPPs were shown to be used significantly longer than cavernosal injection therapy (p <0.01).<sup>13</sup> Jarow et al noted that ultimate satisfaction with therapy was highest for

TABLE 2. Selected characteristics of full survey responders
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Demographic Variables	No.	%
Miles traveled to get prosthesis:		
Local, less than 50	96	48.5
50-100	53	26.8
Greater than 100	49	24.7
Currently have sexual partner:		
Yes	176	88.4
No	23	11.6
Use prosthesis on regular basis:		
Yes	131	65.8
No	68	34.2
Primary reason for not using prosthesis:		
Loss of partner	14	20.6
Personal health concerns	11	16.2
Partner health concerns	5	7.4
Problems with prosthesis	38	55.9
Wks after surgery before intercourse:		
1-4	78	41.1
5-6	59	31.1
7–8	30	15.8
Greater than 8	23	12.1
Frequency of sexual intercourse:		
Daily	17	8.6
Biweekly	56	28.4
Weekly	47	23.9
Bimonthly	24	12.2
Monthly	14	7.1
Other	39	19.8

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	Satisfied No. (%)	Neither Satisfied Nor Dissatisfied No. (%)	Dissatisfied No. (%)
How satisfied were you with prosthesis?:			
Mentor Alpha NB®	13 (72.2)	0 (0)	5(27.8)
AMS 700 Series®	7 (58.3)	1 (8.3)	4(33.3)
Mentor Alpha 1®	118 (69.8)	21 (12.4)	30 (17.8)
All prostheses	138 (69.3)	22 (11.1)	39 (19.6)
		Chi-square $(4) = 4.66$ , $p = 0.324$	
No fear of failure at intercourse:			
Mentor Alpha NB®	14 (77.8)	3 (16.7)	1 (5.6)
AMS 700 Series®	9 (75.0)	2 (16.7)	1 (8.3)
Mentor Alpha 1®	141 (83.4)	12 (7.1)	16 (9.5)
All prostheses	164 (82.4)	7 (8.5)	18 (9.0)
		Chi-square $(4) = 3.16$ , $p = 0.531$	
Would have surgery performed again:			
Mentor Alpha NB®	14 (77.8)	1 (5.6)	3 (16.7)
AMS 700 Series®	8 (66.7)	0 (0)	4(33.3)
Mentor Alpha 1®	121 (71.6)	15 (8.9)	33 (19.5)
All prostheses	143 (71.9)	16 (8.0)	40 (20.1)
		Chi-square $(4) = 2.56$ , p = 0.633	
Would have surgery to correct problem with prosthesis:			
Mentor Alpha NB®	5 (83.3)	1 (5.6)	2 (1.1)
AMS 700 Series®	7 (58.3)	3 (25.0)	2(16.7)
Mentor Alpha 1®	117 (69.6)	21 (12.5)	30 (17.9)
All prostheses	139 (70.2)	25 (12.6)	34(17.2)
		Chi-square $(4) = 3.29$ , p = 0.510	
Would recommend prosthesis surgery:			
Mentor Alpha NB®	13 (72.2)	1 (5.6)	4(22.2)
AMS 700 Series®	11 (91.7)	1 (8.3)	0 (0)
Mentor Alpha 1®	126 (74.6)	15 (8.9)	28 (16.6)
All prostheses	150 (75.4)	17 (8.5)	32 (16.1)
		Chi-square $(4) = 3.05$ , p = 0.550	

TABLE 4. Patient satisfaction with function of the prosthesis Neither Satisfied Nor Dissatisfied Satisfied Dissatisfied No. (%) No. (%) No. (%) Operation of inflate mechanism: Mentor Alpha NB® 15 (88.2) 0 (0) 2(11.8)AMS 700 Series® 6(50.0)2(16.7)4(33.3)Mentor Alpha 1® 129(76.3)15(8.9)25 (14.8) All prostheses 150 (75.8) 17 (8.6) 31(15.7)Chi-square (4) = 6.44, p = 0.169Operation of deflate mechanism: Mentor Alpha NB® 11 (61.1) 2(11.1)5(27.8)AMS 700 Series® 6(50.0)4(33.3) $2\,(16.7)$ Mentor Alpha 1® 82 (48.9) 59(35.1)27 (16.2) All prostheses 99 (50.0) 65(32.8)34 (17.2) Chi-square (4) = 4.65, p = 0.325 No spontaneous inflation: 11 (61.1) 6 (33.3) 1 (5.6) Mentor Alpha NB® AMS 700 Series® 0 (0) 11(917)1(83)Mentor Alpha 1® 115 (68.0) 46(27.2)8 (4.7) 137 (68.8) 9 (4.5) All prostheses 53(26.6)Chi-square (4) = 3.52, p = 0.475Erectile function suitable for intercourse: 13(72.2)4(22.2)Mentor Alpha NB® 1(5.6)AMS 700 Series® 8 (66.7) 1 (8.3) 3(25.0)Mentor Alpha 1® 138 (81.7) 8 (4.7) 23 (13.6) All prostheses 159 (79.9) 10 (5.0) 30 (15.1) Chi-square (4) = 2.40, p = 0.663 Rigidity of prosthesis during intercourse: 14 (77.8) 4 (22.2) Mentor Alpha NB® 0 (0) AMS 700 Series 8 (66.7) 0 (0) 4 (33.3) Mentor Alpha 1® 12 (7.1) 22 (13.1) 134 (79.8) 12 (6.1) 30 (15.2) All prostheses 156 (78.8) Chi-square (4) = 6.07, p = 0.194

surgery vs all other alternatives for treating erectile dysfunction.<sup>14</sup> Rajpurkar and Dhabuwala compared satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice.<sup>15</sup> They concluded that "patients who underwent penile implant surgery had significantly better erectile function and treatment satisfaction than those receiving sildenafil citrate and intracavernous prostaglandin E1."<sup>15</sup>

Of the 68 patients who did not use their prosthesis on a regular basis, 38 of 68 (56%) did not use it because of prob-

lems with the prosthesis, with the other 30 (44%) having partner/personal concerns. With future IPP enhancements problems with the prosthesis should decrease and the percent of patients who use the IPP regularly will increase. Frequency of intercourse had a high correlation with patient satisfaction (p <0.0001) and sexual satisfaction (p <0.0001).

A recent patient satisfaction survey by Carson et al evaluated long-term patient satisfaction with the AMS 700 CX® penile prosthesis.<sup>16</sup> Computer assisted telephone interviews were conducted on 207 men who underwent implantation with the AMS 700 CX® penile prosthesis from 1987 to 1996.

	Satisfied No. (%)	Neither Satisfied Nor Dissatisfied No. (%)	Dissatisfied No. (%)
Natural feeling of prosthesis:			
Mentor Alpha NB®	14 (77.8)	0 (0)	4 (22.2)
AMS 700 Series®	6 (50.0)	1 (8.3)	5 (41.7)
Mentor Alpha 1®	122 (72.2)	23 (13.6)	24 (14.2)
All prostheses	142 (71.4)	24 (12.1)	33 (16.6)
		Chi-square $(4) = 9.01$ , p = 0.061	
Flaccid appearance of penis when deflated:			
Mentor Alpha NB®	12 (66.7)	1 (5.6)	5 (27.8)
AMS 700 Series®	7 (58.3)	0 (0)	5 (41.7)
Mentor Alpha 1®	126 (74.6)	20 (11.8)	23 (13.6)
All prostheses	145 (72.9)	21 (10.6)	33 (16.6)
		Chi-square $(4) = 9.28$ , $p = 0.054$	
Demonstration of inflation + deflation:			
Mentor Alpha NB®	16 (88.9)	2 (11.1)	0 (0)
AMS 700 Series®	8 (66.7)	0 (0)	4 (33.3)
Mentor Alpha 1®	138 (81.7)	11 (6.5)	20 (11.8)
All prostheses	162 (81.4)	13 (6.5)	24 (12.1)
		Chi-square $(4) = 8.49$ , p = 0.075	
Overall sexual satisfaction:			
Mentor Alpha NB®	13 (72.2)	0 (0)	5 (27.8)
AMS 700 Series®	6 (50.0)	3 (25.0)	3(25.0)
Mentor Alpha 1®	118 (69.8)	9 (5.3)	42 (24.9)
All prostheses	137 (68.8)	12 (6.1)	50 (25.1)
		Chi-square $(4) = 9.14$ , p = 0.058	

TABLE 5. Results of the chi-square analysis of satisfaction items at a significance level of 10%

This current study of 248 men was conducted during 7 years. The response rate of the Carson et al study was 207 of 372 (56%) compared with 199 of 330 (60%) in this current study.<sup>16</sup>

This current study evaluated a large number of patients who had undergone implantation 18 to 102 months before data collection to limit study bias. In addition this study was performed in a relatively short period to limit time bias, and the evaluation of patient outcome was broad to capture all morbidity and outcome determinants. This study also used several questions to evaluate patient satisfaction, to maintain internal consistency, and to ensure that patient attitudes and opinions were thoroughly queried.

Selected responses in our study showed that men reported a lower level of satisfaction for various aspects of the implant such as recommendation of the implant (75%), penile prosthesis implantation again (72%), erectile function suitable for intercourse (80%), operation of inflate mechanism (76%), rigidity of prosthesis during intercourse (79%), flaccid appearance of penis when deflated (73%), operation of deflate mechanism (50%) and lack of auto-inflation (69%).

This study examined 23 of 330 (7%) patients with AMS implant as well as 307 of 330 (93%) with Mentor implant. Responders to the full survey included 12 of 199 (6%) patients with AMS implant and 187 of 199 (94%) with Mentor implant. Responders to the single question survey included 5 of 49 (10%) patients with AMS implant and 44 of 49 (90%) with Mentor implant. In this study the same surgical team at 1 institution performed all of the prostheses implantations.

In evaluating the 4 questions relating to patient satisfaction at a significance level of 10% (table 5) 1 question that goes against traditional thought was regarding the flaccid appearance of the penis when deflated. When deflated Alpha IPPs can have bulges on the sides of the penis where the cylinders bend downwards. This phenomenon, known as dog ears, was thought to be a dissatisfaction issue with the Alpha, but the survey shows that patients prefer the Alpha flaccid appearance compared to that of the 700 series (p = 0.054). That the demonstration of inflation and deflation favored the Alpha compared to the 700 series is probably because the Alpha pump may be easier and faster to learn how to use than the 700 series pump. For questions on the natural feeling of the prosthesis and the overall sexual satisfaction, the favoring of the Alpha IPP compared to the 700 series may be due to the fact that the Alpha IPP expands to the full girth of each individual's penis whereas the AMS 700 CX® and 700 CXM® can only expand maximally to 18 and 12 mm, respectively. Presumably most men would prefer to have a fuller, wider erection than a limited one.

In terms of function of the prosthesis, specifically regarding no spontaneous inflation with the Alpha 1® and NB®, patient satisfaction rates were 68% and 61%, respectively, and these rates would probably be different if the question were asked of patients today. The Alpha IPPs now have a lock-out valve that prevents auto-inflation.<sup>17</sup> The question with the lowest percent satisfied for all prostheses (50%) regards the operation of the deflate mechanism. Both IPP manufacturing companies have been contemplating new pump designs to improve patient ability to operate the deflate mechanism. Early results of a new 700 series pump indicate inflation and deflation is easier to learn.<sup>18</sup> Patients were well satisfied with the rigidity of the prosthesis during intercourse in that it resulted in an erection suitable for intercourse.

The data in table 3 show that 72% of the patients would have surgery performed again. In addition, 70% of the patients would have surgery to correct a problem with the prosthesis. Furthermore, 75% of the patients would recommend prosthesis surgery. These findings are supported by the research of others. Tiefer et al found that the proportion of those who would choose to undergo surgery again decreased as the postoperative interval increased with 94% at 18 months, 81% at 19 to 29 months and 63% at 30 or more months after surgery.<sup>2</sup> The results of this study conducted in 2000 include patients who received implants from 1992 to 1998 or 2 to 8 years after surgery. Kearse et al reported that overall patient satisfaction in their survey, defined as an affirmative response to the question of whether the patient would have the prosthesis implanted again, was 83% to 91% at various followup intervals.3 With the patient questionnaire used by Goldstein et al inquiring whether the patient would recommend the Mentor Alpha 1® device or undergo surgery again, 86% of the patients responded that they would recommend the penile implant device and 78% of the patients responded that they would undergo this penile implant procedure again.<sup>19</sup> McLaren and Barrett mailed questionnaires to patients in whom the AMS 700® penile prosthesis was implanted.<sup>20</sup> When patients were asked if they would undergo the operation again, 85% replied that they would and 62% of the partners supported this choice.

A limitation of this study is the possible introduction of bias due to inability to contact all individuals sampled, although we do not have evidence that these individuals were different in any way from those who participated in the study. A second limitation in this study is the possible introduction of bias due to the small number of AMS implants represented. A third limitation is the involvement of only experienced surgeons, therefore, the results may not be able to be generalized to the less experienced surgeons. A fourth limitation of this study is the possible introduction of measurement errors due to recall bias. Although the survey was performed 2 to 8 years after surgery, we believe that recall bias could be less severe in this study than in other surveys because undergoing penile prosthesis implantation is a traumatic and life changing event that tends to be remembered well.

#### CONCLUSIONS

There was a high degree of satisfaction across implant types. Thus, implantation of IPPs remains a viable means of overcoming impotence.

APPENDIX: THE SEVEN SECTIONS OF THE SURVEY

- 1. The first section, "Demographic Variables," contained four questions.
- 2. The second section, "Satisfaction of Patient with Prosthesis," included 17 questions relating to how the patient felt about himself as well as about his relationship with his sexual partner since the implantation of the penile prosthesis. This section determined how the implant had impacted the patient's "quality of life."
- 3. The third section, "Satisfaction of Partner with Prosthesis," had three questions that measured various areas of relevance to sexual functioning. The questions determined satisfaction of the partner as seen through the eyes of the patient.
- 4. The fourth section, "Satisfaction of Patient with Single Surgery Team," contained three questions about the patient's perception of the surgery team.
- 5. The fifth section, "Satisfaction of Patient with Education Provided About the Prosthesis," included five questions. The questions measured how the patient thought he was prepared for the penile implant procedure and for coping with its effect on his life.
- 6. The sixth section, "Relationship Satisfaction of Patient and Partner," consisted of two questions which determined how much the success of prosthetic surgery depended on the quality of the relationship between the patient and his partner.
- 7. The seventh section, "Sexual Satisfaction of Patient and Partner," contained three questions which determined a patient's overall sexual satisfaction and fre quency.

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