Outcomes and Satisfaction Rates for the Redesigned 2-Piece Penile Prosthesis

Matthew Lux, Luis Reyes-Vallejo, Abraham Morgentaler and Laurence A. Levine*

From the Rush University, Chicago, Illinois, and Beth Israel Deaconess Medical Center, Harvard Medical School (LRV, AM), Boston, Massachusetts

Purpose: We evaluated long-term viability, quality of life and satisfaction with the redesigned 2 piece Ambicor® inflatable penile prosthesis. This device underwent revision of the rear tip extender and reinforcement of the pump tubing connection to decrease fluid leak failure in 1998.

Materials and Methods: In this retrospective analysis we evaluated 146 men with erectile dysfunction at 2 centers who underwent device implantation between June 1999 and October 2004 with the redesigned prosthesis. Patient information forms were completed, including patient history, surgical information and revision data. Patients were mailed a modified Erectile Dysfunction Inventory of Treatment Satisfaction questionnaire, a modified Erectile Dysfunction Inventory of Treatment Satisfaction Partner survey and a questionnaire regarding pertinent inflatable penile prosthesis questions.

Results: A total of 146 men with a mean age of 58.7 years (range 25 to 78) were evaluated after inflatable penile prosthesis placement. Time from implant to followup was 3 to 73 months (mean 38). Only 1 device (0.7%) was removed due to infection. One implant (0.7%) was replaced due to fluid loss and 1 (0.7%) was revised due to improper sizing. Kaplan-Meier life table analysis indicated that the percent of patients free from reoperation was 99.2% at 12 months, 99.2% at 36 months and 91% at 48 months or greater. Of the 101 subjects completing the survey the average patient used the prosthesis 5 times monthly and 88.9% reported continued use. Of the patients 91% said that it was easy to use and 95% had little to no trouble learning to use it, while 84% stated that the inflatable penile prosthesis provided good to excellent rigidity for coitus. Overall patient and partner satisfaction was 85% and 76%, respectively. Of the patients 86% said that they would recommend the prosthesis to friends or if need be undergo the procedure again.

Conclusions: The redesigned Ambicor 2-piece penile prosthesis appears to be safe and effective. It is associated with a low rate of revision as well as high patient and partner satisfaction.

Key Words: penis, impotence, prostheses and implants, questionnaires, patient satisfaction

Since the development of the first IPP in 1973 by Scott et al, there has been continual evolution in the materials and design used to improve performance and longevity.[1] The Ambicor 2-piece IPP was introduced in 1994 as a successor to the now unavailable 1-piece Dynaflex (American Medical Systems, Minnetonka, Minnesota).[2] In 1998, 2 design changes were made to the 2-piece IPP in an effort to improve durability. One revision involved modifying the RTEs. The original model was configured with snap-on cones. This version caused the risk of fracture of the proximal tip, resulting in mechanical failure.[2] To eliminate the risk of fracture the proximal tip of the prosthesis and the RTE were modified with stacking sleeves. This configuration provides better proximal support and decreases stress to the proximal tip. The other modification involved redesign of the pump at the tubing insertion. This site had been isolated as a point of mechanical strain with resultant leakage in the original model. The new model provides added stress protection at the point of flex (figs. 1 and 2).

We evaluated the patient and partner satisfaction of various aspects pertaining to their experience with the revised Ambicor 2-piece IPP, in addition to adverse events, including mechanical failure, the need for revision surgery, infection and durability. To our knowledge this is the first objective and subjective report of the performance of the revised 2-piece Ambicor IPP.

MATERIALS AND METHODS

Between June 1999 and October 2004, 146 men with ED underwent implantation of the newly designed Ambicor at 2 centers, as performed by surgeons (LAL, AM) experienced with this device. All patients underwent preoperative evaluation, including medical and sexual history, physical examination and testosterone analysis. In all patients conservative medical management had failed, including 1 or more phosphodiesterase type 5 inhibitors, intracavernous injections, intraurethral drug instillation or vacuum therapy. Standard surgical protocol was followed for IPP placement, including preoperative intravenous antibiotics, a 10-minute scrub of the surgical field and an intraoperative antibiotic irrigation. Postoperatively patients received 500 mg cepha-

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* Correspondence: 1725 West Harrison, Suite 352, Chicago, Illinois 60612 (telephone: 312-563-5000; Fax: 312-563-5007; e-mail: drlevine@hotmail.com).

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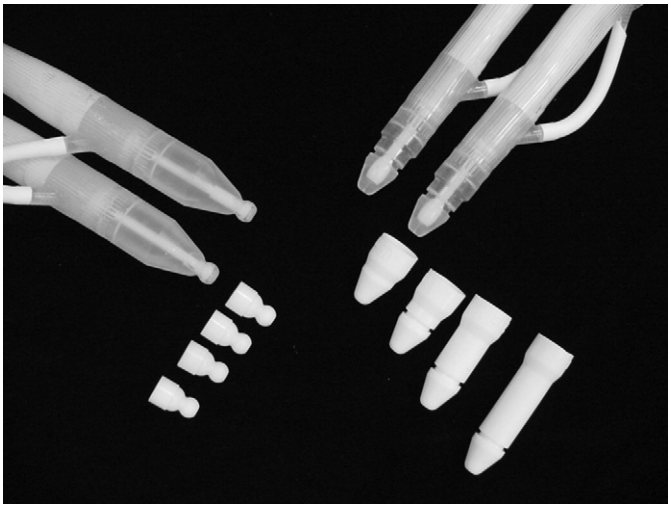

FIG. 1. Prior RTE (left) and current model (right). Reprinted with permission from American Medical Systems, Minnetonka, Minnesota.

lexin orally twice daily or 500 mg levofloxacin orally daily for 2 weeks.

A retrospective chart review was performed in all patients, including preoperative patient characteristics, operative reports and postoperative assessment. Kaplan-Meier survival analysis was performed to determine the end point of Ambicor IPP mechanical failure. Analysis was performed using commercially available statistical software.

All subject names were coded to ensure anonymity. These subjects were then mailed informed consent regarding this survey, cover letters describing the research and questionnaires. The informed consent emphasized anonymity and the intent of using the garnered information to encourage confidence and candid responses. According to informed consent if the questionnaires were returned uncompleted by the subject, this conferred refusal to participate. If the coded subject failed to return a completed or uncompleted questionnaire after 1 month, the coded subject was called and the survey was completed over the telephone if the patient agreed to participate in this manner.

All surveys included a modified version of the EDITS and partner EDITS questionnaire.[3] An additional questionnaire created for this study addressed the patient perception of procedure outcomes, including overall satisfaction, ease of use, rigidity, appearance and concealment.

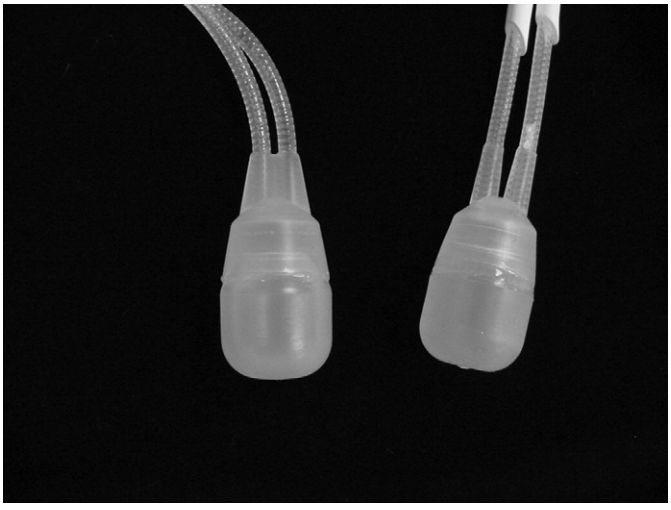

FIG. 2. Prior (left) and new (right) model of pump tubing strain relief design. Reprinted with permission from American Medical Systems, Minnetonka, Minnesota.

RESULTS

A total of 146 men with a mean age of 58.7 years (range 25 to 78) underwent implantation with the new Ambicor 2-piece IPP between June 1999 and October 2004. Time from surgery to time of questionnaire followup was 3 to 73 months (mean 38). The etiology of ED in this study was vascular in 82 men (56%), after radical prostatectomy in 24 (16%), diabetes mellitus in 19 (13%), Peyronie's disease in 16 (11%), after other radical pelvic surgery in 4 (3%) and following spinal cord trauma in 1 (1%). In all patients conservative medical therapy had failed, as noted.

Of the 146 men undergoing IPP placement 106 (72.6%) returned the questionnaire and 101 (69.2%) answered the questionnaires. A total of 40 patients were lost to followup and did not complete the survey. The results of the phone survey revealed that 3 patients did not answer the questionnaire due to dissatisfaction, 2 were dead and 1 refused because he was uncomfortable answering personal questions. Of the 101 patients who completed the questionnaire 97 (96%) were still using the IPP at the time of the questionnaire.

Only 3 of the 146 IPPs were removed. One IPP (0.7%) underwent revision 2 months postoperatively due to pain associated with device sizing. One IPP (0.7%) was revised due to fluid loss. Only 1 implant (0.7%) became infected, and it was salvaged and replaced using the Mulcahy protocol.[4] No patients had the prosthesis removed due to dissatisfaction or erosion and there were no other complications. All 3 revisions were replaced successfully with another Ambicor IPP. Kaplan-Meier survival analysis revealed that the percent of patients free from reoperation was 99.2% at 12 months, 99.2% at 36 months and 91% at 48 months or greater (fig. 3).

Of the men 88.9% stated they were still using the IPP for sexual intercourse with an average frequency of coitus of 5.1 times monthly (range 0 to 25). In the men not using the IPP for intercourse the most commonly reported reasons were lack of a partner in 4% and lack of an interest in sex in 4%. Only 1 patient reported discomfort during sex. This was

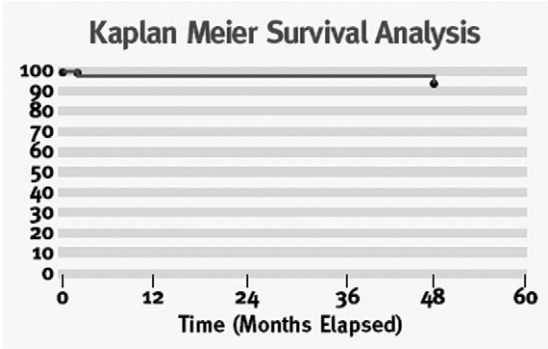

FIG. 3. Kaplan-Meier survival analysis

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determined to be due to a device that was too long and it was rectified by removing the RTE only.

Responses to the questionnaire revealed that 91% of the men found the IPP easy to use and 95% had little or no trouble learning to use it. Only 1 patient (1%) reported any significant problems with inflation or deflation. Overall 97 of the responders (98%) stated that they were able to inflate the prosthesis at the time of the survey and 94 (95%) stated that erection with the device was suitable for sexual intercourse. Of the men 84% stated that the IPP provided good to excellent rigidity for coitus. When asked about position and support, 81 men (82%) stated that the entire penis, including the glans, was supported in the normal anatomical position when erect.

Spontaneous deflation was reported by 23% of patients. In all cases this was described as occurring occasionally or rarely. Only 3 men reported rare, complete deflation and 20 reported partial deflation that did not interfere with the completion of coitus.

Change in length was reported by 54% of respondents, of whom 30% said that the penis was longer by an average of 1.2 inches. Conversely 70% of the men stated that the penis had decreased by an average of 1.5 inches. A lower percent of partners than patients noticed a change in penile length (29.3%). In contrast to patients, partners noticing a change in penile size were evenly split with 50% believing that the penis of the partner was an average of 1.6 inches longer and 50% believing that it was an average of 1.1 inches shorter.

When asked to rate overall satisfaction on a 5-point scale of 1—not at all satisfied, 3—satisfied and 5—extremely satisfied, 88% of respondents rated overall satisfaction as 3 or higher, while 86% said that they would recommend this IPP to friends. Patients expressed a positive view of the erect and the deflated IPP with 91% and 88%, respectively, ranking them 3 or higher. In conjunction with this, 92% of the men ranked its ease of concealment when deflated and rigidity upon inflation as 3 or higher. When asked if they would undergo the procedure again if the need arose, 86% answered affirmatively (tables 1 to 4).

DISCUSSION

In this 2-center study we evaluated various aspects of the redesigned Ambicor 2-piece IPP, including the infection rate, malfunction, patient and partner satisfaction, and survival analysis. To our knowledge this is the first study of the redesigned Ambicor IPP. The previous design was known to carry the risk of fracture at the proximal tip near the RTE and at the insertion of the tubing into the pump. The design modifications of the current Ambicor prosthesis appear to have been effective since none of the 146 implants in this series failed mechanically at the RTE or at the tubing insertion into the pump.

The primary findings of this study of the redesigned penile prosthesis include high device viability, low reoperation and infection rates, and high patient and partner satisfaction. The mechanical failure in 1 of 146 cases (0.7%) at a mean followup of 38 months compared favorably with that of the previous version of the Ambicor IPP (2.3%) and with reported rates for 3-piece IPPs available today.[2] Reported rates of 3-piece IPP mechanical failure are 4.1% to 44.7% at a followup of 3 to 11 years.[5–13] In 1998 Duboq et al compared the only other 2-piece IPP at the time, the since discontinued Mark II to the Alpha-I (Mentor Corp., Santa Barbara, California) and AMS 700™ Ultrex™ 3-piece penile prostheses.[9] In that study the Mark II had a higher mechanical failure rate of 14% at a mean followup of 34.4 months compared with the 7% failure rate of the 700 Ultrex IPP at a mean followup of 47.2 months. The low failure rate of the Ambicor prosthesis in the current series as well as for the earlier version of the device (0.7% and 2.3%, respectively) suggests that the 2-piece IPP is no less reliable than 3-piece devices at a followup of more than 3 years. Although this 38-month followup approximates much published data on 3-piece prostheses, additional followup is needed to determine how 7 to 10-year results compare for 2 and 3-piece devices.[5–13]

One of the most serious complications following IPP placement is device infection. Decreasing infection rates following IPP placement recently became an active area of design development.[14–16] Several products recently reached the market or are under evaluation. An example of this is InhibiZone®, a surface treatment combining rifampin and minocycline hydrochloride on AMS 700 series IPPs. In a study of 4,200 men receiving InhibiZone treated IPPs the infection rate in the treated and control groups at 180 days was 0.7% and 1.6%, respectively.[14] Other reviews of untreated devices indicate an IPP infection rate of 2.1% to 3.7%.[17] In our series the infection rate of 0.7% (1 of 146

TABLE 1. *Perceptions of Length Changes*

	%	Mean Length Change (inches)
Men perceiving length change:	54	
Longer	30	1.2
Shorter	70	1.5
Partners perceiving length change:	29	
Longer	50	1.6
Shorter	50	1.1

TABLE 2. *Modified EDITS patient survey*

	Question	Response (%)
1	Overall how satisfied are you with the penile prosthesis?	Somewhat to very satisfied (85)
2	To what degree has the penile prosthesis met your expectations?	Considerably to completely (77)
3	How likely are you to continue to using the penile prosthesis?	Moderately to very likely (75)
4	How easy was it for you to use your penile prosthesis?	Moderately to very easy (91)
5	How confident has the penile prosthesis made you feel about your ability to engage in sexual activity?	Somewhat to very confident (88)
6	How satisfied is your partner?	Somewhat to very satisfied (79)

TABLE 3. *Select modified EDITS partner survey questions*

	Question	Response (%)
1	Overall, how satisfied are you with the penile prosthesis for your husband's or partner's erection problem?	Somewhat to very satisfied (76)
2	To what degree has the penile prosthesis met your expectations?	Considerably to completely (69)

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TABLE 4. *Patient satisfaction and experience with prosthesis*

	% Greater Than 3
On a scale of 1 to 5, how satisfied were you in the following aspects where 1 is not at all and 5 is extremely?	
Satisfaction:	
When deflated	88
When erect	91
Prosthesis function	91
Ease:	
Concealment when deflated	92
Inflation	89
Rigidity when inflated	92
Erection length with prosthesis	80
Thickness of erection (size around)	78
Sensation during intercourse	84
IPP appearance:	
Inflated	83
Deflated	88

cases) at a mean of 38 months compares favorably with standard IPP infection rates as well as with those of new antibiotic coated IPPs. Since the Ambicor is packaged wet and prefilled, the InhibiZone surface cannot be applied. To our knowledge it is unknown whether the low infection rate is due to any mechanical aspect of the device, surgeon experience or patient selection.

Overall satisfaction in our patients was 88% according to the modified EDITS questionnaire with 86% willing to recommend the IPP to friends. This is similar to the 93% rate in our earlier Ambicor series. Although there are differences between satisfaction rates in the surveys of the original Ambicor and the revised model, we suspect that these small differences were more likely to occur as a result of patient selection and slight differences in the questionnaire. In addition, the 88% satisfaction rate is similar to that of the 700 CX study (88%).[6] This satisfaction rate is noteworthy since 3-piece IPPs have greater capacity than the Ambicor to transfer fluid into and out of the cylinders due to the separate reservoir. It is worth noting that manufacturer data indicate that the Ambicor has greater axial rigidity than any 3-piece devices. There does not appear to be any compromise of rigidity with the 2-piece device.

Penile prosthesis rigidity is a significant concern for the surgeon and patient. Conventional wisdom has it that the rigidity of the inflated 3-piece device exceeds that of a 2-piece device. In fact, buckling pressure studies done by the manufacturer demonstrated greater axial rigidity with the Ambicor than the CX or Ultrex 3-piece device.[18] Several factors are responsible for cylinder rigidity, including cylinder length, girth, wall thickness, elasticity and pressure in the cylinder. Further studies on prosthesis rigidity are warranted and they are in progress to clarify this point. Another concern is decreased ability to achieve full flaccidity due to the limited volume of fluid transferred out of the cylinders in the Ambicor. However, inadequate concealment was reported by only 5 responders (4.7%). In this study 92% of respondents also ranked the Ambicor as good to excellent regarding its rigidity when erect and its ease of concealment when deflated. This corresponds to our clinical experience, in which some men seem to enjoy the appearance of partial penile fullness in the deflated state.

Although we did not measure penile length before and after the survey, we questioned patients on their perception of penile length following surgery. Patient and partner perceived changes in length revealed subtle differences (table 1). Men more frequently than women reported a change in penile length (54%) and more believed that there was a shortening of the phallus (70%) following surgery. On the other hand, women were much less likely to notice a change in length (29%) but if a length change was noted, they were equally likely to find it longer or shorter. It appears that perceived length is much in the eye of the beholder.

Although it has generally been suggested that 3-piece penile prostheses are superior to 2-piece devices, the results of this survey suggest that the Ambicor 2-piece device is no less satisfactory to the patient. Considering the followup in this study, device survival, infection rates, and patient and partner satisfaction for the Ambicor appear as good as those in previously published series of 3-piece devices. Moreover, there are some advantages to the Ambicor over 3-piece devices. For instance, the device is easier to inflate and in most cases it requires only 3 to 6 pumps.[19] Deflation is also simpler in some men, especially those with thick fingers or compromised manual dexterity, since it is achieved by bending the entire penile shaft, rather than needing to find a relatively small deflation area on the scrotal pump. Finally, the Ambicor may an ideal IPP in men with prior complicated pelvic surgery, in whom placement of a reservoir may be difficult. In conclusion, the redesigned Ambicor 2-piece prosthesis appears to be a safe and effective penile prosthesis with a low rate of revision and infection as well as excellent patient and partner satisfaction rates.

Abbreviations and Acronyms

ED	=	erectile dysfunction
EDITS	=	Erectile Dysfunction Inventory of Treatment Satisfaction
IPP	=	inflatable penile prosthesis
RTE	=	rear tip extender

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