

Penile Implantation in Europe: Successes and Complications with 253 Implants in Italy and Germany

Alessandro Natali, MD,* Roberto Olianas, MD,[†] and Margit Fisch, MD[‡]

*Uro-Andrological Unit, Department of Urology, University of Florence, Florence, Italy; [†]Städtisches Klinikum Lüneburg, Gemeinnützige GmbH, Lüneburg, Germany; [‡]General Hospital Hamburg, Department of Urology and Pediatrics, Hamburg, Germany

DOI: 10.1111/j.1743-6109.2008.00819.x

ABSTRACT

Introduction. Results for prosthesis implantation from everyday clinical practice within Europe are few. This report provides data on the most commonly used penile prostheses (the American Medical Systems [AMS] series).

Aim. The study aimed to assess, retrospectively, complications and patient satisfaction with AMS penile implants in 253 consecutive patients with erectile dysfunction from three European centers.

Methods. Pre, intra- and postoperative data were obtained from chart review, with a mean follow-up of 60 months; 200 patients were available for evaluation. Patient satisfaction data were collected using the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire.

Main Outcome Measure. Complications and patient satisfaction were assessed. Patient satisfaction was evaluated using a standardized assessment tool (the modified EDITS questionnaire).

Results. Major postoperative complications occurred in 40 (20%) patients, including 9 (22.5%) prosthesis infections, 18 (45%) mechanical failures, and 13 (32.5%) erosions. Patient satisfaction with the AMS 700CX, AMS Ambicor, and AMS 600-650 was 97%, 81%, and 75%, respectively; dissatisfaction was 0%, 5%, and 6%, respectively. Partner satisfaction with the AMS 700CX, AMS Ambicor, and AMS 600-650 was 91%, 91%, and 75%, respectively; dissatisfaction was 0%, 5%, and 6%, respectively. Erections were more natural (harder) than before with the AMS 700CX, AMS Ambicor, and AMS 600-650 in 91%, 85%, and 88%, respectively; hardness was the same as before in 9%, 15%, and 13%, respectively; no erections were less hard than before.

Conclusions. Postoperative complications differed from those reported in the literature, while patient satisfaction rates were roughly similar. The reporting of specific data for different implant types, plus the use of standardized assessment tools for patient satisfaction is significant as in the future, it will allow comparison of data between centers performing penile prosthesis implants using these devices. **Natali A, Olianas R, and Fisch M. Penile implantation in Europe: Successes and complications with 253 implants in Italy and Germany. J Sex Med 2008;5:1503–1512.**

Key Words. Penile Prosthesis; Erectile Dysfunction; Patient Satisfaction; Prosthesis Infection

Introduction

Surgical implantation of a penile prosthesis is often the best treatment for patients whose erectile dysfunction has an organic cause and who are unwilling to consider, fail to respond to, or who are unable to continue with medical treatment or external devices [1–4]. Pharmacotherapy often fails in patients with diabetes, radical prostatectomy, Peyronie's disease, and severe penile fibrosis [5]. In a recent update on erectile dysfunction

by the European Association of Urology, penile prosthesis implantation is considered to be third-line therapy when oral and intracavernosal therapy fail [6]. The advantages of penile implantation include high technical success rates, high long-term mechanical reliability, good patient satisfaction rates, success is independent of injections or tablet taking, and this approach is particularly valuable in patients with penile fibrosis [1,7–10]. These advantages, however, must be balanced against a number of disadvantages, including the

fact that implantation is an invasive surgical procedure with its attendant risks, infection can be a problem (although the risk of infection has decreased since the introduction of antibiotic-coated implants), cosmetic, as the semirigid and malleable devices protrude, mechanical device problems, and the fact that perineal pain can persist for 1–2 months [7,11–13].

Results for prosthesis implantation often come from centers with a large amount of experience in this type of surgery, and these results may not be reproducible in general urological practice [8]. While numerous data are available from the United States [2,14–17], in general, reports of the experience of European patients and clinics with penile prosthesis implantation are more limited [8]. Furthermore, different types of prostheses present slightly different advantages and disadvantages [2]. Data relating to the American Medical Systems (AMS) two-piece Ambicor prosthesis (AMS, Minneapolis, USA), for example, appear to be few [2,14]. It is important, therefore, that clinicians communicate the challenges and successes associated with this approach and with different implant types so that the management of erectile dysfunction in these patients can be optimized.

The aim of this study was to assess, retrospectively, complications and patient satisfaction over a 60-month period with three types of AMS penile implants (AMS Ambicor, AMS 700CX, AMS 600-650 [AMS, Minneapolis, USA], the most commonly used penile prostheses) in 253 consecutive patients with erectile dysfunction. These patients underwent surgery in three European centers. Discussion of specific surgical approaches for prosthesis implantation is outside the scope of this article.

Methods

Data were collected from 253 consecutive patients with erectile dysfunction who underwent elective primary penile prosthesis implant surgery in two centers in Germany and one center in Italy during the period 1990–2004. Surgical and demographical data were collected on the day of surgery, and follow-up data were obtained from chart review. The data collected included patient and implant characteristics, details of the cause and severity of erectile dysfunction, and information about intra- and postoperative complications. Following implantation, the patients were followed for a mean of 60 months (range 12–156 months).

Descriptive statistics were utilized to obtain information on clinical outcomes. The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire is often used to assess satisfaction with medical treatment for erectile dysfunction and to explore the impact of patient and partner satisfaction on treatment continuation [18]. Feedback on prosthesis function and patient satisfaction in this study was obtained using a version of the questionnaire modified by Levine and colleagues [14]; this was mailed to patients. This questionnaire evaluates patient satisfaction, the degree to which prostheses meet patient expectations, the likelihood of continued use, ease of use, confidence in ability to engage in sexual activity, patient assessment of partner satisfaction, patient assessment of partner feelings about continuing use of the prosthesis, and the naturalness (hardness) of erections compared with the period before implantation. The study was carried out with the approval of the Ethics Committee of the appropriate Faculty of Medicine and all patients provided informed, written consent.

Results

Penile implants were performed in 253 patients; 53 patients were lost to follow up leaving 200 patients and implants suitable for evaluation. The age of the 200 evaluated patients ranged from 35 to 78 years (mean 58.9) and the causes of erectile dysfunction were diabetes mellitus in 82 patients (41%), other vascular diseases in 22 patients (11%), radical retropubic prostatectomy in 45 patients (22.5%), radical pelvic surgery in 31 patients (15.5%), and Peyronie's disease in 20 patients (10%). The number and types of prostheses implanted, and the surgical approaches used are outlined in Table 1.

Intra-operative Complications

Intra-operative complications occurred in 15 of the 200 patients (7.5%), consisting of crural perforation in 8 patients (4%) and cavernosal crossover in 7 patients (3.5%). All intra-operative complications were resolved during surgery and the implantation was completed successfully.

Postoperative Complications

Postoperative complications occurred in 51 patients (25.5%); these complications were minor in 11 cases (5.5%) and major in 40 cases (20%). The minor postoperative complications consisted of five cases of wound hematoma and six cases

Table 1 The number and types of prostheses implanted, implant characteristics and the surgical approach used in the 200 implants

Implant type	Implant characteristics	Surgical approach	Number implanted
AMS 700CX Three-piece inflatable prostheses	Diameter: 9.5–18 mm (mean 11 mm) Rear tip extender: 0–4.5 cm (mean 2 cm) Length of the implanted cylinders: 13–24 cm (mean 19 cm)	Penoscrotal plus infrapubic	62
AMS Ambicor Two-piece inflatable prostheses	Diameter: 11–15 mm (mean 13 mm) Rear tip extender: 0–4.5 cm (mean 2 cm) Length of the implanted cylinders: 14–22 cm (mean 18.4 cm)	Penoscrotal	98
AMS 600-650 Malleable prostheses	Diameter: 11.5 and 13 mm Rear tip extenders: 0–3 cm (mean 1.5 cm) Length of the implanted cylinders: 12–18 cm (mean 17.4 cm)	Penoscrotal	40
Total			200

AMS = American Medical Systems.

of superficial wound infection that was resolved with antibiotic therapy. The major complications included prosthesis infection, mechanical failure, and erosion. Details of the numbers of these complications and type of prosthesis affected are shown in Table 2.

All cases of postoperative infection occurred within 6 months of implantation, and in 4 out of 40 of the cases, the patients had diabetes mellitus with disturbed glucose metabolism and elevated glycosylated hemoglobin levels (mean HbA_{1C} 8.5%). The implant was removed in all instances, and a replacement implant (the same type of implant) was carried out in four cases 12 months later.

The 10 cases of mechanical failure that occurred with the 18 AMS 700CX devices took place at a mean of 25.2 months (range 12–48) following implantation. The causes of failure were leakage from the cylinder in four cases (40%), leakage from the reservoir in four cases (40%), and leakage from the tubing in two cases (20%). The six cases of mechanical failure that occurred with the AMS Ambicor device took place at a mean of 29.3 months (range 16–48) following implantation. All were caused by leakage from the

tubing at the bulb pump. The two cases of mechanical failure that occurred with the AMS 600-650 took place after 60 and 72 months; both were caused by rod fracture. A replacement device was implanted at the time of surgery to investigate the cause of the mechanical failure in 6 out of 10 AMS 700CX patients, 5 out of 6 AMS Ambicor patients, and 1 of the 2 AMS 600-650 patients.

The four cases of erosion that occurred with the AMS 700CX device took place at a mean of 21 months (range 8–36) following implantation. In two cases, erosion occurred distal to the gland level and in two cases erosion occurred in the scrotal skin at the bulb pump level. The two cases of erosion that occurred with the AMS Ambicor device took place at a mean of 22 months (range 8–36) following implantation. In both cases, erosion occurred at the penoscrotal level where the tubing was superficial. The seven cases of erosion that occurred with the AMS 600-650 all occurred after 96 months. Replacement devices were implanted 6 months or longer after the erosion occurred in three patients who had received AMS 700CX devices, in one patient who had received an AMS Ambicor device, and in five patients who had received AMS 600-650 devices.

Table 2 Major postoperative complications reported during the study

Type of complication	Type of prosthesis affected			Total number (%)
	AMS 700CX number (%)	AMS Ambicor number (%)	AMS 600-650 number (%)	
Prosthesis infection	5 (12.5)	3 (7.5)	1 (2.5)	9 (22.5)
Mechanical failure	10 (25)	6 (15)	2 (5)	18 (45)
Erosion	4 (10)	2 (5)	7 (17.5)	13 (32.5)
All major postoperative				40 (100)

AMS = American Medical Systems.

Patient and Partner Satisfaction

A total of 160 patients without major postoperative complications were surveyed about satisfaction with their prosthesis using the mailed, modified EDITS questionnaire [14,18]. Of the 160 patients who received the questionnaire, 115 patients (72%) responded: 33 patients who received an AMS 700CX prosthesis, 66 who received an AMS Ambicor, and 16 who received an AMS 600-650. The responses to the questionnaire are presented in Table 3. Overall satisfaction with the penile implant varied with the different prosthesis types; the percentage of patients who reported that they were very satisfied plus somewhat satisfied was 97% (22 + 10 patients, 67% + 30%) with the AMS 700CX, 81% (44 + 9 patients, 67% + 14%) with the AMS Ambicor, and 75% (9 + 3 patients, 56% + 19%) with the AMS 600-650 (Figure 1). The percentage of patients who reported that they were very dissatisfied was 0% (0 patients) with the AMS 700CX, 5% (3 patients) with the AMS Ambicor, and 6% (1 patient) with the AMS 600-500. The percentage of patients who reported that they were very likely plus moderately likely to continue using their prosthesis was 97% (30 + 2 patients, 91% + 6%) with the AMS 700CX, 92% (59 + 2 patients, 89% + 3%) with the AMS Ambicor, and 75% (9 + 3 patients, 56% + 19%) with the AMS 600-500. Patient-reported partner satisfaction with the penile implant varied with the different prosthesis types; overall partner satisfaction (very satisfied plus somewhat satisfied) was 91% (26 + 4 patients, 79% + 12%) with the AMS 700CX, 91% (49 + 11 patients, 74% + 17%) with the AMS Ambicor, and 75% (7 + 5 patients, 44% + 31%) with the AMS 600-650. The percentage of patients who reported that they believed that their partner was very dissatisfied was 0% (0 patients) with the AMS 700CX, 5% (3 patients) with the AMS Ambicor, and 6% (1 patient) with the AMS 600-500. Comparison of the naturalness (specifically hardness) of erections before and after implantation revealed that hardness varied with the different prosthesis types; erections were harder than before (a lot harder or somewhat harder than before) in 91% (21 + 9 patients, 64% + 27%) of patients with the AMS 700CX, 85% (35 + 21 patients, 53% + 32%) with the AMS Ambicor, and 88% (10 + 4 patients, 63% + 25%) with the AMS 600-650; erections were of the same hardness as before in 9% (three patients) of patients with the AMS 700CX, 15% (10 patients) with the AMS Ambicor, and 13% (two patients) with the AMS 600-650. None of the patients receiving

any implant type reported that erections were less hard (somewhat or a lot less hard) than before implantation.

Discussion

This report provides—for the first time from a single study—data on the implantation of AMS three-piece, two-piece, and malleable penile prostheses. These are currently the most commonly used penile prostheses. Information on surgical procedures, minor and major postoperative complications, and patient and partner satisfaction assessed using a standardized assessment tool (modified EDITS questionnaire) is provided. In view of the relative lack of European data on experiences with penile prosthesis implantation, this article provides useful new data on clinical experiences and patient satisfaction with the three types of AMS penile implants in 200 consecutive patients in three European centers during the period 1990–2004. As data on the use of the AMS Ambicor prosthesis are limited [2,14,19], the data reported here for this device are of particular interest. In the future, this will allow comparison of data between centers performing penile prostheses implants using these AMS devices.

The overall intra-operative complication rate reported in the present study was 7.5%, consisting of crural perforation in 4% and cavernosal crossover in 3.5% of patients. This complication rate is higher than the 3% intra-operative complication rate reported by Minervini and colleagues in a similar retrospective review of the notes of 447 men who had received primary penile prosthesis (of 10 implant types, including 52 AMS 600-650 and 53 AMS 700CX) implantation in the United Kingdom [20]. These complications included urethral perforation, crural perforation, and cavernosal crossover.

Rates of postoperative infection, mechanical failure, and erosion reported in the literature vary widely and often include lots of different implant types. In the present study, a standard preoperative procedure was used in the three centers. In the 5 days prior to surgery, the patient was asked to scrub the genital area with an antiseptic solution twice daily. This was followed by antibiotic prophylaxis (vancomycin plus gentamicin) prior to surgery [21]. Finally, immediately before surgery in the operating theater, the genital area was shaved and scrubbed with an antiseptic solution. With this protocol, the infection rate was 12.5% with the AMS 700CX, 7.5% with the AMS

Table 3 Results obtained using the modified Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire for all three types of prosthesis (not all patients answered all questions; percentages may not always equal 100 because of rounding)

EDITS questions	AMS 700CX		AMS Ambicor		AMS 600-650	
	Number	(%)	Number	(%)	Number	(%)
Overall how satisfied are you with penile prosthesis?						
• Very satisfied	22	(67)	44	(67)	9	(56)
• Somewhat satisfied	10	(30)	9	(14)	3	(19)
• Neither satisfied nor dissatisfied	1	(3)	4	(6)	1	(6)
• Somewhat dissatisfied	0	(0)	6	(9)	2	(13)
• Very dissatisfied	0	(0)	3	(5)	1	(6)
	Total n = 33		Total n = 66		Total n = 16	
To what degree has penile prosthesis met your expectations?						
• Completely	19	(61)	21	(32)	8	(50)
• Considerably	11	(35)	33	(50)	4	(25)
• Halfway	1	(3)	7	(11)	2	(13)
• A little	0	(0)	1	(2)	2	(13)
• Not at all	0	(0)	4	(6)	0	(0)
	Total n = 31		Total n = 66		Total n = 16	
How likely are you to continue using penile prosthesis?						
• Very likely	30	(91)	59	(89)	9	(56)
• Moderately likely	2	(6)	2	(3)	3	(19)
• Neither likely nor unlikely	1	(3)	2	(3)	2	(13)
• Moderately unlikely	0	(0)	2	(3)	1	(6)
• Very unlikely	0	(0)	1	(2)	1	(6)
	Total n = 33		Total n = 66		Total n = 16	
How easy was it for you to use penile prosthesis?						
• Very easy	17	(52)	29	(44)	13	(81)
• Moderately easy	10	(30)	21	(32)	2	(13)
• Neither easy nor difficult	3	(9)	5	(8)	1	(6)
• Moderately difficult	2	(6)	8	(12)	0	(0)
• Very difficult	1	(3)	3	(5)	0	(0)
	Total n = 33		Total n = 66		Total n = 16	
How confident has penile prosthesis made you feel about your ability to engage in sexual activity?						
• Very confident	25	(76)	38	(58)	10	(63)
• Somewhat confident	5	(15)	19	(29)	5	(31)
• It has had no impact	0	(0)	0	(0)	1	(6)
• Somewhat less confident	2	(6)	5	(8)	0	(0)
• Very much less confident	1	(3)	4	(6)	0	(0)
	Total n = 33		Total n = 66		Total n = 16	
Overall how satisfied do you believe your partner is with effects of penile prosthesis?						
• Very satisfied	26	(79)	49	(74)	7	(44)
• Somewhat satisfied	4	(12)	11	(17)	5	(31)
• Neither satisfied nor dissatisfied	3	(9)	0	(0)	2	(13)
• Somewhat dissatisfied	0	(0)	3	(5)	1	(6)
• Very dissatisfied	0	(0)	3	(5)	1	(6)
	Total n = 33		Total n = 66		Total n = 16	

Table 3 Continued

EDITS questions	AMS 700CX		AMS Ambicor		AMS 600-650	
	Number	(%)	Number	(%)	Number	(%)
How does your partner feel about your continuing to use penile prosthesis?						
• Absolutely wants me to continue	27	(82)	51	(77)	8	(50)
• Generally prefers me to continue	5	(15)	9	(14)	6	(38)
• Has no opinion	1	(3)	3	(5)	2	(13)
• Generally prefers me to stop	0	(0)	3	(5)	0	(0)
• Absolutely wants me to stop	0	(0)	0	(0)	0	(0)
	Total n = 33		Total n = 66		Total n = 16	
How natural did the process of achieving erection feel when you used penile prosthesis over the last 4 weeks?						
• Very natural	20	(61)	33	(50)	6	(38)
• Somewhat natural	10	(30)	21	(32)	8	(50)
• Neither natural nor unnatural	3	(9)	6	(9)	2	(13)
• Somewhat unnatural	0	(0)	3	(5)	0	(0)
• Very unnatural	0	(0)	3	(5)	0	(0)
	Total n = 33		Total n = 66		Total n = 16	
Compared to before you had erection problem, how would you rate the naturalness of your erection when you used penile prosthesis over the last 4 weeks in terms of hardness?						
• Lot harder than before	21	(64)	35	(53)	10	(63)
• Somewhat harder than before	9	(27)	21	(32)	4	(25)
• Same hardness as before	3	(9)	10	(15)	2	(13)
• Somewhat less hard than before	0	(0)	0	(0)	0	(0)
• Lot less hard than before	0	(0)	0	(0)	0	(0)
	Total n = 33		Total n = 66		Total n = 16	

AMS = American Medical Systems.

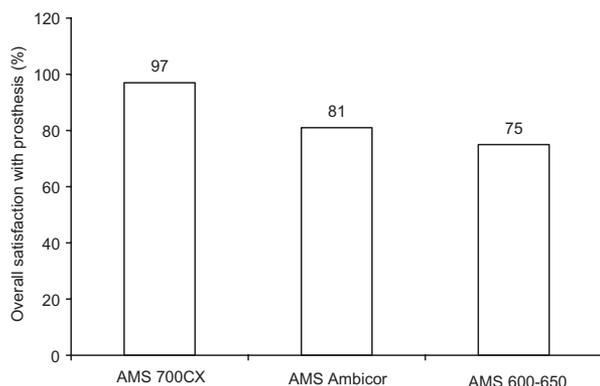


Figure 1 Overall satisfaction with penile implants; the percentage of patients who reported that they were very satisfied plus somewhat satisfied.

AMS = American Medical Systems.

Ambicor, and 2.5% with the AMS 600-650. These results compare favorably with the infection rates reported by Minervini and colleagues, where infection occurred in 15% of three-piece inflatable prostheses and in 5.1% of malleable prostheses, although specific infection rates for AMS 700CX and AMS 600-650 implants were not reported [20]. An infection rate of 3.2% was reported by Carson et al. among 372 men in the United States who received an AMS 700CX implant [16], and an infection rate of 6% was reported by Montorsi et al. among 200 patients in Italy who received AMS three-piece inflatable implants (AMS 700CX or CXM) [8]. The 7.5% infection rate observed with the AMS Ambicor in the present study was much higher than the 2% and 0.7% infection rates reported among patients in the United States who received the same type of prosthesis [14,15]. The role of diabetes in the development of infection following the implantation of penile prostheses remains controversial [22,23]. Our (anecdotal) experience in the clinic leads us to believe that a high serum HbA_{1c} is not important in determining diabetic patients at high risk of developing a prosthesis infection. However, we do believe that to minimize the risk of infection, it is extremely important to limit the traffic of personnel in the operating theater, to conduct surgery as quickly as possible, and to wash the corpora cavernosa and operative field copiously with antibiotic solution during surgery.

In the current study, mechanical failure with all implant types was higher than that reported in specific studies in the literature. The mechanical failure rate of the AMS 700CX was 25%. This failure occurred at a mean of 25.2 months (range

12–48) following implantation and was because of fluid leakage in all cases. Minervini et al. reported a 21% mechanical failure rate for the AMS 700CX; this failure occurred after a mean of 25 months (range 1–74) following implantation and was because of fluid leakage in about 50% of cases [20]. Mechanical failure rates for the AMS 700CX reported in the United States range from 9% to 17.5% [16,17,24], and a 10-year estimate of mechanical failure of approximately 19% has also been reported (Kaplan–Meier estimate of mechanical survival 81.3%, 95% confidence interval 75.7–87.3) [25]. Evaluation of a series of AMS 700CX penile implants in patients in Korea revealed a mechanical failure rate of 10.5% (in 2 out of 19 patients) during a mean follow-up of 79 months [26]. Montorsi et al. reported mechanical failure in only 1% of patients (two cases) in Italian patients who received AMS three-piece inflatable implants (AMS 700CX or CXM) [8]. These failures occurred at 58 and 69 months after implantation and involved the pump and reservoir, although it was not clear whether this failure was because of leakage. In the current study, the rate of mechanical failure was 15% with the AMS Ambicor, and this failure took place at a mean of 29.3 months (range 16–48) following implantation. In the study by Levine and coworkers, the mechanical failure rate was reported to be 2.3% among patients receiving an AMS Ambicor prosthesis, occurring at a mean of 22.3 months (range 8–47) following implantation [14]. In the current study, the rate of mechanical failure was 5% with the AMS 600-650. In the study by Minervini et al., a failure rate of 0.5% was reported for the AMS 600-650 [20]. Lux and coworkers reported a 0.7% mechanical failure rate among 146 patients who received AMS Ambicor prostheses [15].

Erosion is more common with semirigid or malleable prostheses than with inflatable prostheses [7], so the finding of a higher erosion rate with AMS 600-650 prostheses than with other implant types in the present study was not unexpected. Furthermore, most of the 40 AMS 600-650 implants were inserted into relatively elderly patients (>74 years of age) who also had comorbid conditions (diabetes mellitus and vascular disease). The erosion rate was 10% with the AMS 700, 5% with the AMS Ambicor, and 17.5% with the AMS 600-650. Interestingly, in the study by Minervini and colleagues, the erosion rate was similar (8%) for AMS 600 prostheses and for three-piece inflatable prostheses that included some AMS 700 implants [20].

The modified EDITS questionnaire was used to gather psychometrically sound responses that were valid and reliable. Overall patient satisfaction (very satisfied plus somewhat satisfied, assessed using the modified EDITS questionnaire) was 97% with the AMS 700, 81% with the AMS Ambicor, and 75% with the AMS 600-650. The 81% level of patient satisfaction with the AMS Ambicor prosthesis in this study compares with 91% of patients in the study by Levine and colleagues [14] and with 85% in the study by Lux and coworkers [15], who also used the modified EDITS questionnaire to assess patient satisfaction. Direct comparison of data on patient satisfaction from this study with published data can be done only cautiously where different measurement tools are used. Data from Italy (collected using a detailed patient interview) revealed that among 200 patients who received an AMS three-piece prosthesis, erections were excellent in 48%, satisfactory in 50%, and poor in 2% of cases [8]. In the present study, patients who received the AMS 700CX implant reported that overall, they were very satisfied in 67%, somewhat satisfied in 30%, and very dissatisfied in 0% of cases. In the study by Minervini and colleagues, patient satisfaction was assessed by face-to-face or telephone interview [20]; once again and similar to the study by Montorsi and colleagues, these are not standardized measurement tools, unlike the modified EDITS questionnaire used in the current study. The outcome was considered to be satisfactory if the patient reported satisfactory intercourse and that he was happy with the results of the implantation, and a total of 54% reported that they were satisfied with the AMS 700. Carson and colleagues used a structured telephone interview to assess patient satisfaction with the AMS 700CX and reported that 87% had an erection suitable for intercourse, 79% used it at least twice a month, and 88% would recommend an implant to a relative or friend [16]. Candela and Hellstrom used a mailed questionnaire and reported overall patient satisfaction of 85% with the AMS 700CX [27]. In the study by Minervini and colleagues, 71% of patients reported that they were satisfied with the AMS 600-650 [20], compared with 75% of patients in the current study who were satisfied overall (very satisfied plus somewhat satisfied using the modified EDITS questionnaire) with the AMS 600-650. In the study by Chiva Robles et al., 54% of patients reported adequate satisfaction with the AMS 600-650 by telephone interview [19]. One of the limitations of this study is that partner satisfaction

was assessed indirectly by the patient rather than directly with the partner.

Few data are available in the literature on the naturalness (hardness) of erections obtained with the different implant types. Levine and coworkers used the modified EDITS questionnaire and reported that erections with the AMS Ambicor were harder than before (a lot harder or somewhat harder than before) in 88% of patients, the same hardness in 12% of patients, and no patients reported that erections were less hard (somewhat or a lot less hard) than before implantation [14]. Lux and coworkers also assessed rigidity using the modified EDITS questionnaire and reported that 84% of patients found that the AMS Ambicor prosthesis provided good to excellent rigidity for coitus [15]. The findings of the current study are in line with these findings; erections with the AMS Ambicor were harder than before (a lot harder or somewhat harder than before) in 85% of patients, the same hardness in 15% of patients, and no patients reported that erections were less hard (somewhat or a lot less hard) than before implantation. Montorsi and colleagues reported (from a detailed patient interview) that flaccidity was complete in 70% of cases and incomplete in 30% of cases in patients who received an AMS three-piece inflatable implant (CX or CXM device) [8]. In the current study, erections were harder than before (a lot harder or somewhat harder than before) in 91% of patients with the AMS 700CX, the same hardness as before in 9% of patients with the AMS 700CX, and no patients reported that erections were less hard (somewhat or a lot less hard) than before implantation with the AMS 700CX. Penile shortening has been suggested as a specific cause of dissatisfaction by patients receiving penile implants [3,27,28]. Unfortunately, data on penile shortening were collected from only a few patients in this study, so these data were not presented and no conclusions were drawn regarding this aspect of patient satisfaction.

A number of pointers for future research are highlighted by these findings. When attempting to compare results across different studies, it was found that reports in the literature do not always differentiate complication rates in patients receiving primary implants and those receiving revisions, but it would have been helpful if these data had been reported separately. It would also have been useful if clinical and patient satisfaction data had been reported separately for individual implant types to allow more accurate comparisons. A variety of methods were used for assessing patient and

partner satisfaction, which made comparison of results difficult. The use of standardized, validated measurement tools (such as the modified EDITS questionnaire used in the current study) for assessing patient and partner satisfaction would enable findings to be compared more accurately. Agrawal and Ralph have proposed that surgeon expertise has a significant influence on the clinical outcome of penile implant surgery [11], so data on surgeon expertise may need to be collected and reported in future studies. The patchy data available for European patients highlight the importance of documenting and sharing experience with different implant types so that patients across Europe benefit from this knowledge and improvements can be made in prosthesis design.

Conclusions

This report provides—for the first time from a single study—data on the implantation in three European centers of the most commonly used penile prostheses: the AMS three-piece, two-piece, and malleable penile prostheses. Information on surgical procedures, minor and major postoperative complications, and patient and partner satisfaction assessed using a standardized assessment tool (the modified EDITS questionnaire) is reported. New data are presented to add to the limited data available on the AMS Ambicor prosthesis. Intra- and postoperative complications (infection, mechanical failure, and erosion) differed from those reported in the literature, although specific European data for comparison are limited. Patient satisfaction rates were roughly similar to those reported in the literature. The reporting of specific data for different implant types plus the use of standardized assessment tools for patient and partner satisfaction is significant as in the future, it will allow comparison of data between centers performing penile prosthesis implants using these AMS devices.

Corresponding Author: Alessandro Natali, MD, Uro-Andrological Unit, Department of Urology, University of Florence, Viale Pieraccini 18, 50139 Florence, Italy. Tel: +39 055417645; Fax: +39 0554377755; E-mail: anatali@dada.it

Conflict of Interest: None declared.

Statement of Authorship

Category 1

(a) Conception and Design

Alessandro Natali; Roberto Olianas; Margit Fisch

(b) Acquisition of Data

Alessandro Natali; Roberto Olianas; Margit Fisch

(c) Analysis and Interpretation of Data

Alessandro Natali; Roberto Olianas; Margit Fisch

Category 2

(a) Drafting the Article

Alessandro Natali; Roberto Olianas; Margit Fisch

(b) Revising It for Intellectual Content

Alessandro Natali; Roberto Olianas; Margit Fisch

Category 3

(a) Final Approval of the Completed Article

Alessandro Natali; Roberto Olianas; Margit Fisch

References

- Ralph D, McNicholas T. UK management guidelines for erectile dysfunction. *BMJ* 2000;321:499–53.
- Montague DK. Penile prosthesis implantation for end-stage erectile dysfunction after radical prostatectomy. *Rev Urol* 2005;7:S51–7.
- Mulcahy JJ, Austoni E, Barada JH, Ki Choi H, Hellstrom WJG, Krisnamurti S, Moncada I, Shultheiss D, Sohn M, Wessells H. Implants, mechanical devices and vascular surgery for erectile dysfunction. In: Lue TF, Basson R, Rosen R, Giuliano F, Khoury S, Montorsi F, eds. *Sexual medicine: Sexual dysfunctions in men and women*. Paris: Health Publications; 2004:469–98.
- Sadeghi-Nejad H. Penile prosthesis surgery: A review of prosthetic devices and associated complications. *J Sex Med* 2007;4:296–309.
- McMahon CN, Smith CJ, Shabsigh R. Treating erectile dysfunction when PDE5 inhibitors fail. *BMJ* 2006;332:589–92.
- Wespes E, Amar E, Hatzichristou D, Hatzimouratidis K, Montorsi F, Pryor J, Vardi Y, EAU. EAU guidelines on erectile dysfunction: An update. *Eur Urol* 2006;49:806–15.
- Evans C. The use of penile prostheses in the treatment of impotence. *Br J Urol* 1998;81:591–8.
- Montorsi F, Rigatti P, Carmignani G, Corbu C, Campo B, Ordesi G, Breda G, Silvestre P, Giammusso B, Morgia G, Graziottin A. AMS three-piece inflatable implants for erectile dysfunction: A long-term multi-institutional study in 200 consecutive patients. *Eur Urol* 2000;37:50–5.
- Montague DK. Nonpharmacologic treatment of erectile dysfunction. *Rev Urol* 2002;4:S9–S16.
- Montague DK, Angermeier KW. Contemporary aspects of penile prosthesis implantation. *Urol Int* 2003;70:141–6.
- Agrawal V, Ralph D. An audit of implanted penile prostheses in the UK. *BJU Int* 2006;98:393–5.
- Droggin D, Shabsigh R, Anastasiadis AG. Antibiotic coating reduces penile prosthesis infection. *J Sex Med* 2005;2:565–8.

- 13 Moncada I, Martinez-Salamanca JI, Allona A, Hernandez C. Current role of penile implants for erectile dysfunction. *Curr Opin Urol* 2004;14:375–80.
- 14 Levine LA, Estrada CR, Morgentaler A. Mechanical reliability and safety of, and patient satisfaction with the Ambicor inflatable penile prosthesis: Results of a 2 center study. *J Urol* 2001;166:932–7.
- 15 Lux M, Reyes-Vallejo L, Morgentaler A, Levine LA. Outcomes and satisfaction rates for the redesigned 2-piece penile prosthesis. *J Urol* 2007;177:262–6.
- 16 Carson CC, Mulcahy JJ, Govier FE. Efficacy, safety and patient satisfaction outcomes of the AMS 700CX inflatable penile prosthesis: Results of a long-term multicenter study. AMS 700CX Study Group. *J Urol* 2000;164:376–80.
- 17 Daitch JA, Angermeier KW, Lakin MM, Ingleright BJ, Montague DK. Long-term mechanical reliability of AMS 700 series inflatable penile prostheses: Comparison of CX/CXM and Ultrex cylinders. *J Urol* 1997;158:1400–2.
- 18 Althof SE, Corty EW, Levine SB, Levine F, Burnett AL, McVary K, Stecher V, Seftel AD. EDITS: Development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. *Urology* 1999;53:793–9.
- 19 Chiva Robles V, Llanes González L, Pascual Mateo C, Espinales Castro G, Romero Cajigal I, Berenguer Sánchez A. Penile prosthesis. Quality outcomes and morbidity. *Arch Esp Urol* 2005;58:925–30.
- 20 Minervini A, Ralph DJ, Pryor JP. Outcome of penile prosthesis implantation for treating erectile dysfunction: Experience with 504 procedures. *BJU Int* 2006;97:129–33.
- 21 Carson CC. Infections in genitourinary prostheses. *Urol Clin North Am* 1989;16:139–47.
- 22 Bishop JR, Moul JW, Sihelnik SA, Peppas DS, Gormley TS, McLeod DG. Use of glycosylated hemoglobin to identify diabetics at high risk for penile periprosthetic infections. *J Urol* 1992;147:386–8.
- 23 Wilson SK, Carson CC, Cleves MA, Delk JR. Quantifying risk of penile prostheses infection with elevated glycosylated hemoglobin. *J Urol* 1998;159:1537–40.
- 24 Nickas ME, Kessler R, Kabalin JN. Long-term experience with controlled expansion cylinders in the AMS 700CX inflatable penile prosthesis and comparison with earlier versions of the Scott inflatable penile prosthesis. *Urology* 1994;44:400–3.
- 25 Dhar NB, Angermeier KW, Montague DK. Long-term mechanical reliability of AMS 700CX/CXM inflatable penile prosthesis. *J Urol* 2006;176:2599–601.
- 26 Kim SC. Mechanical reliability of AMS hydraulic penile prostheses. *J Korean Med Sci* 1995;10:422–5.
- 27 Candela JV, Hellstrom WJ. Three-piece inflatable penile prosthesis implantation: A comparison of the penoscrotal and infrapubic surgical approaches. *J La State Med Soc* 1996;148:296–301.
- 28 Miranda-Sousa A, Keating M, Moreira S, Baker M, Carrion R. Concomitant ventral phalloplasty during penile implant surgery: A novel procedure that optimizes patient satisfaction and their perception of phallic length after penile implant surgery. *J Sex Med* 2007;4:1494–9.