Prospective analysis of the surgical outcomes and patients' satisfaction rate after the AMS Spectra penile prosthesis implantation.

Prospective Analysis of the Surgical Outcomes and Patients' Satisfaction Rate After the AMS Spectra Penile Prosthesis Implantation

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Abstract

Objective

To evaluate the outcomes, the patients', and their partners' satisfaction concerning the AMS Spectra penile prosthesis implantation.

Methods

Twenty-two unresponsive or dissatisfied patients with phosphodiesterase 5 inhibitor oral therapy or prostaglandin intracavernous injection underwent a Spectra penile prosthesis implantation. No major intraoperative or postoperative complications were observed. The preoperative erectile dysfunction (ED) was rated by the International Index of Erectile Function (IIEF) questionnaire. The patients and their partners were submitted to the IIEF and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaires through telephonic interviews at the third, sixth, and 12th months after the penile surgery.

Results

This study demonstrates that 86.4% of the patients and 52.6% of their partners are satisfied by the AMS Spectra penile prosthesis. The preoperative average IIEF score was equal to 28.5 (range 13-39). The postoperative IIEF rates were 47.7 (43-53), 51.8 (48-58), and 53.9 (50-58) at the third, sixth, and 12th months, respectively. The patient average EDITS score amounted to 39.5 (31-48), 43.4 (36-50), and 45.2 (38-50) at the third, sixth, and 12th months, respectively. The increase between the preoperative and postoperative IIEF parameters resulted to be statistically significant (P <.05) as well as the increase in EDITS at the third, sixth, and 12th months postoperatively.

Conclusion

The AMS Spectra is a reliable device to treat ED as shown by the high grade of the patients' satisfaction. Moreover, the AMS Spectra is highly convenient in terms of cost savings in comparison to an inflatable device. In selected patients, this prosthesis should be considered as an effective solution to treat severe ED.

Erectile dysfunction (ED), which is defined as the impossibility to obtain an adequate penile erection for a satisfactory sexual intercourse, is one of the most common male sexual disorders. According to the results of the Massachusetts Male Aging Study,[1] 52% of men aged between 40 and 70 years are affected by ED.

The development of new synthetic materials in the 50s gave way to the introduction of prosthetic devices in all surgical specialities.[2] In 1973, Scott et al[3] published the first report concerning the

experience of an inflatable prosthesis for the management of erectile impotence. In 1975, Small et al[4] reported the implantation of the first semirigid penile prosthesis. For the time being, the surgical implantation of a penile prosthesis is the definitive solution for patients who are unwilling to consider, fail to respond to, or are unable to continue with the medical treatment or external devices.5 and 6 In a recent update on ED, the European Association of Urology considers the penile prosthesis implantation to be a third-line therapy, in case the oral and the intracavernosal therapies happen to be unsatisfactory.[5] The penile prosthesis implantation is also indicated in patients with Peyronie disease (PD) and refractory ED.[7] The advantages of a penile implantation include high technical success rates, strong long-term mechanical reliability, and good patient and partner satisfaction rates. Moreover, success is independent from injections or taking tablets, and this approach is particularly valuable in patients with penile fibrosis. In these patients, the penile prosthesis implantation may provide penile rigidity and straightening, re-establishing the patients' normal sexual functions.8, 9,10 and 11

However, these advantages come together with a certain number of disadvantages, for instance, the fact that the implantation is an invasive surgical procedure with its attendant risks: the infection of the prosthesis (although the risk of infection has decreased since the introduction of antibiotic-coated implants), the cosmetic claims, a malfunctioning mechanical device, and persistent penoscrotal pain are commonly widespread contraindications to the implantation.12 and 13 The advent of new surgical tools and new infection-resistant materials has significantly reduced the risk of intra- and postoperative complications.[13] Surgical techniques, complications, and comparisons of various prosthesis types have been well reported. Two different devices can be implanted. The malleable/semirigid implant, or the inflatable 3 or bicomponent prosthesis. The non-inflatable devices are characterized by a simpler surgical technique and a reduced risk of mechanical failure. On the one hand, the inflatable devices are characterized by excellent cosmetic results; however, on the other hand, there is an increased risk of mechanical problems. Moreover, usually, hydraulic implants have a significantly higher cost than semirigid implants.

Since the beginning of 2010, the AMS Spectra penile prosthesis can be used to treat ED. The Spectra is a non-inflatable, concealable penile prosthesis composed of a pair of cylinders, each with a central malleable section of an articulating polymer and metal segments. A cable extends through the center of these segments. The articulating segments, held together by the cable and the spring assemblies, provide sufficient friction and rigidity for sexual intercourse and a significantly major bending angle for better concealment when not in use.

In the last decade, numerous studies reporting the outcomes, and the patients' and their partners' satisfaction after the penile prosthesis implantation have been published. No articles are available about the AMS Spectra penile prosthesis. The purpose of this article was to evaluate the outcomes, and the patients' and their partners' satisfaction at the third, sixth, and 12th months after the AMS Spectra penile prosthesis implantation.

Materials and Methods

In the current study, 22 patients aged 66 years on average (range 58-84 years), underwent the AMS Spectra penile prosthesis implantation.

Among the patients taken into account in this study, the etiology of ED was linked to PD in 17 patients (77%), to retropubic radical prostatectomy (RRP) in 3 patients (14%), and to PD+RRP in 2 patients (9%).

All the patients were selected from the Andrology Unit of our Urology Department.

ED was assessed by the International Index of Erectile Function (IIEF) score questionnaire preoperatively. All the patients were screened to detect the endocrine causes of ED by a hormonal assay, excluding hypogonadism, hyper/hypothyroidism, or hyperprolactinemia. Moreover, these same patients were all screened by a duplex color ultrasound to assess their vascular supply, their

responsiveness to inflammatory cell intensity, and to quantify the degree of the penile curvature (in patients affected by PD).

In the group of patients affected by PD, surgery was executed when the disease had been stable for at least 6 months, according to the International Society for Sexual Medicine guidelines.[7]
All the patients chose the AMS Spectra penile prosthesis after an extensive interview with a surgeon from our department. The models' technical features of the available prosthesis (inflatable or non-inflatable) were pointed out. All the patients gave an informed consent to the penile prosthesis implantation.

The surgical procedures were performed between February 2010 and February 2012 at our hospital's Department of Urology by a three-surgeon team. The implantations were performed with the patients under spinal anesthesia.

The procedures were carried out as such: in case a post-RRP ED was assessed, a single penoscrotal approach was used; in 1 single case, an infrapubic approach was used in order to permit a section of the suspensory ligament; in case of PD (17 patients), a double penoscrotal and coronal incision was used to allow a concomitant plaque incision and grafting. We performed a standard corporotomy of 4 cm in all our patients (Figs. 1 and 2).

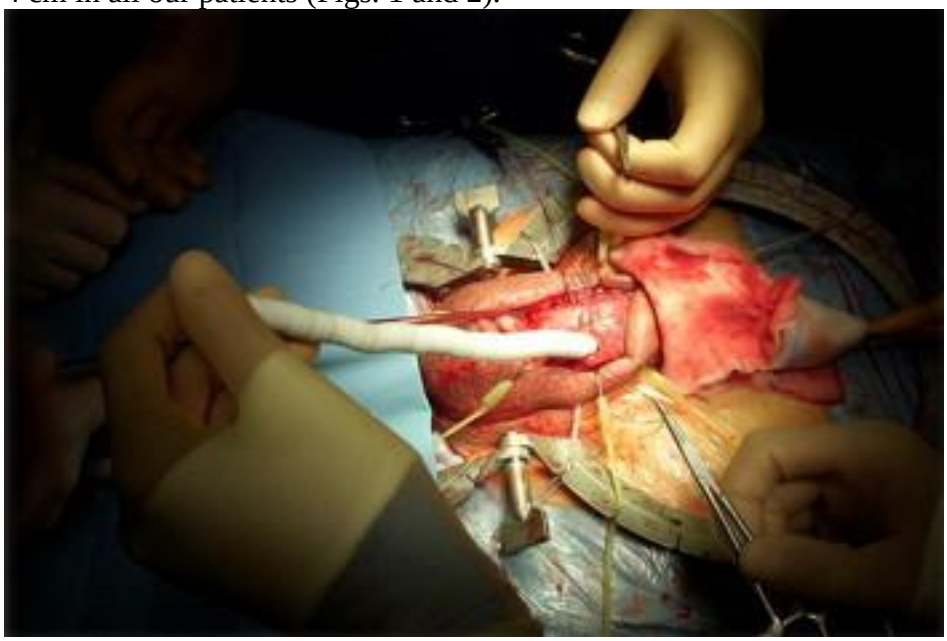

Figure 1.

Spectra penile prosthesis implantation by a single penoscrotal incision. (Color version available online.)

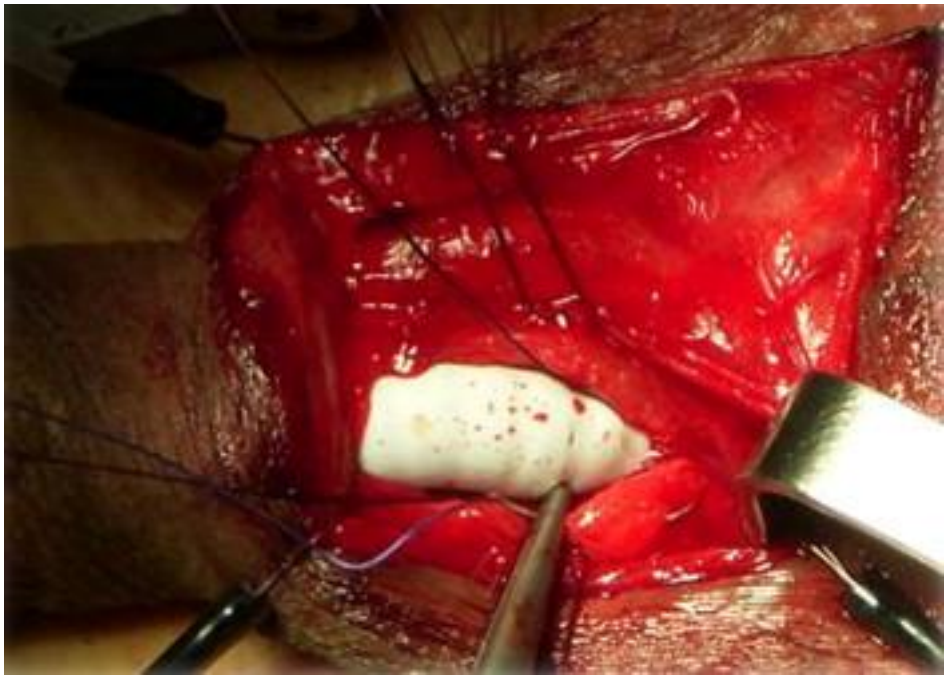

Figure 2.
Corporotomy during a Spectra penile prosthesis implantation. (Color version available online.)

Intraoperative or postoperative complications have been recorded.

The preoperative ED was assessed by the IIEF questionnaire. In order to evaluate the satisfaction score, the patients and their partners were completed the IIEF and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaires through telephonic interviews at the third, sixth, and 12th months after the penile surgery. The average follow-up amounted to 24.3 months (range 14-38 months).

The data were analyzed with the SPSS statistics program. The *t* test for pair samples was used to compare the IIEF and EDITS evaluations at the third, sixth, and 12th months after the device's surgical implantation.

Results

No intraoperative complications emerged in our series of patients (grade I). No major complications, such as gland severe ischemia, necrosis, or persistent anesthesia, arose postoperatively. Few minor complications occurred in terms of gland transient hypoesthesia or gland superficial slough (grade I).

Up to this time, no mechanical failures were detected and no surgical revisions were needed.

The preoperative average IIEF score amounted to 28.5 (13-39). The postoperative IIEF scores were rated at 47.7 (43-53), 51.8 (48-58), and 53.9 (50-58) at the third, sixth, and 12th months, respectively. The patients' average EDITS score ranked 39.5 (31-48), 43.4 (36-50), and 45.2 (38-50) at the third, sixth, and 12th months, respectively. The increase between the preoperative and postoperative IIEF parameters resulted to be statistically significant (P <.05), as well as the increase in EDITS at the third, sixth, and 12th months postoperatively.
Moreover, the partners' EDITS average scores graded 14.9 (10-20), 16.7 (11-24), and 17.8 (11-24) at the third, sixth, and 12th months, respectively.

A total of 86.4% of patients and 52.6% of their partners confirmed to feel completely satisfied with the AMS Spectra penile prosthesis implantation and that they would have undergone that same surgical procedure with the identical device if asked again.

Comment

Many authors have reported the results concerning the patients and their partners' satisfaction since the first implantation in 1973.

The efficacy of the 3-piece penile prosthesis has been widely analyzed by many investigators with excellent results in the patient's safety and the overall satisfaction.

Several articles have reported the findings related to an AMS 700 CX penile prosthesis implantation.

In their series of patients, Bettocchi et al[13] registered frequent use of the AMS 700 CX penile prosthesis with a satisfaction rate of 90%.
Natali et al[14] published a 3-European center study reporting the patient's satisfaction with the AMS penile implants. This study reported an overall satisfaction with the AMS 700 CX inflatable penile prosthesis scoring 97%.
Montorsi et al[15] studied the AMS 700 CX in 200 patients and 120 partners. In their report, the postoperative sexual activity was considered excellent in more than 90% of the patients and their partners.
In 2012, Levine et al[16] reported their experience with the inflatable penile prosthesis implantation in PD, registering a patients' satisfaction rate scoring 84%.
Some other authors analyzed the outcome of the Mentor Alpha-1 penile prosthesis implantation. Garber[17] described his experience in the Mentor PP implantation in a series of 50 patients. In this study, 98% of the patients and 96% of their partners were completely satisfied with the device. In 1993, Goldstein et al[18] followed 112 patients after the Mentor Alpha-1 implantation, reporting high satisfaction rates among the patients.
Other scientific researchers presented their results concerning the Coloplast Titan penile prosthesis implantation. Ohl et al[19] recently reported in a single-armed, prospective, multicenter international study, an overall satisfaction with the redesigned Coloplast Titan One Touch Release pump inflatable penile prosthesis of 90.6% and 90.0% at the sixth and 12th months, respectively.
Unfortunately, few articles reported the outcome on malleable penile prosthesis implants.

In 1989, Krauss et al[20] underlined the good results in terms of partner satisfaction and the increase in sexual intercourse frequency after the malleable penile prosthesis implantation in a series of 14 patients.
In 1993, Montorsi et al[21] reported the low satisfaction rate after the semirigid penile prosthesis implantation in patients with PD.
In 2004, Salama[22] experienced 50 implantations with the AMS 650 or Acu-form penile prosthesis with 70% patients' and 57% partners' satisfaction rates, respectively.
Considering the scarce reports in the scientific literature, we may argue that nonhydraulic prosthesis are associated with a slightly lower patient and partner satisfaction rates compared to hydraulic devices. This could be explained by the difficulty of the malleable implants to be completely concealed. Notwithstanding, the reports on malleable penile prosthesis are rare and the articles reporting the patients' and their partners' satisfaction of hydraulic penile prosthesis implantation are not well standardized. These biases limit the possibility to reliably compare the 2 devices.

We personally consider that, in selected patients, the implantation of a malleable prosthesis still plays a major role in the surgical treatment of ED. This consideration involves those patients not in need of the cosmetic advantages given by an inflatable device or preferring an “easy to use” penile prosthesis or are willing to bear the risk of a mechanical failure.

Up to this time, no reports on the AMS Spectra concealable penile prosthesis exist in the scientific literature.

Our study demonstrates that the AMS Spectra is a reliable device to treat ED. The procedure of the Spectra implantation does not differ substantially from the standard procedure of a semirigid prosthesis implantation. In the clinical practice, because of the technical features of the Spectra penile prosthesis, in particular the difficulty to bend the device, we noticed that a longer corporotomy (average 4 cm) is needed compared to the other semirigid prosthesis implantation (average 2.5 cm in our personal series). In the case of PD, a double subcoronal and penoscrotal incision with a large corporotomy (average 4 cm) is preferred to implant the device. This double incision, in our experience, is needed in order to achieve an easy implantation of this device.

The patients' satisfaction rate has increased significantly compared to other competitors' reports on non-inflatable prosthesis approaching the hydraulic device satisfaction rate. In our opinion, this feature can be explained by the development of a new technology giving the AMS Spectra penile prosthesis an excellent ability to be concealed. Indeed, this peculiarity makes the patient more confident in his sexual intercourse approach and it significantly increases the postoperative satisfaction rate.

Moreover, the AMS Spectra has sensible advantages in terms of cost savings in comparison to an inflatable penile prosthesis.

In our opinion, considering the situation of the world's economic crisis and the difficulties of many health national systems to provide the necessary health services for the patients, this prosthesis should be considered as an effective solution to treat severe ED in selected patients. However, our data should be confirmed by multicenter prospective studies with longer follow-ups.

Conclusions

The AMS Spectra is a reliable device to treat ED with a high grade of the patients' satisfaction rates. Moreover, the AMS Spectra offers sensible advantages in terms of cost savings in comparison to an inflatable penile prosthesis. For all the reasons mentioned above, this prosthesis should be considered as an effective solution to treat severe ED in selected patients.

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