ORIGINAL RESEARCH—SURGERY

Physician and Patient Satisfaction with the New AMS 700 Momentary Squeeze Inflatable Penile Prosthesis

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ABSTRACT

Introduction. A single-armed, prospective, multicenter study evaluated the redesigned American Medical Systems (AMS) 700 Momentary Squeeze (MS) pump inflatable penile prosthesis (IPP) with enhanced features for ease of implantation and patient manipulation. The device incorporates design changes to all components: pump, cylinders, rear-tip extenders, and reservoir.

Aim. To assess physician and patient satisfaction with the new AMS 700 MS pump.

Methods. Patients were selected from the existing population experiencing erectile dysfunction (ED) without previous prosthetic implantation.

Main Outcome Measures. Survey questionnaires were used to capture physician feedback on ease of implantation and patient education. Patient satisfaction with the device and existence of autoinflation were assayed.

Results. Sixty-nine patients were implanted at seven U.S. sites. Mean age was 60.1 ± 9.6 years. History of ED was >5 years in 34 (44.7%) patients. Main ED etiology was organic, nonspecific (32%). Eighty-four percent of the physicians felt proximal cylinder insertion was easier because of the smaller angle of cylinder input tubing and narrower base diameter. The new pump was felt easier to implant than the previous model by 57% of the physicians. The patients found the manipulation of the pump simple at device activation, with 96% easily locating the inflation bulb and 94% deflating the device with one push of the deflation button. Reviews were mixed among physicians concerning ease of training compared with the Tactile pump. Patient training was easier in 71%, harder in 21%, and same in 8%. Nevertheless, 67% of the patients were trained in 6 minutes or less. At 6 months, 77% of the patients were very satisfied, 9% somewhat satisfied, and 14% dissatisfied. Autoinflation occurred in two patients (3%).

Conclusion. The new AMS 700 MS IPP seems a distinct improvement over previous devices with most physicians feeling implantation and patient instruction were easier. The device also satisfied 86% of the users and virtually eliminated autoinflation. **Knoll LD, Henry G, Culkin D, Ohl DA, Otheguy J, Shabsigh R, Wilson SK, and Delk J II. Physician and patient satisfaction with the new AMS 700 Momentary Squeeze inflatable penile prosthesis. J Sex Med 2009;6:1773–1778.**

Key Words. Erectile Dysfunction; Penile Prosthesis; Impotence Surgery; Penile Implant Surgery

Introduction

Erectile dysfunction (ED) is a major quality-of-life disorder that affects approximately 152 million men worldwide, and this number is expected to reach 322 million by 2025 [1]. The introduction of phosphodiesterase type 5 (PDE5) inhibitors in 1998 has markedly contributed to increased awareness and patients requesting therapy for ED. The introduction of these oral

medications initially decreased the number of patients seeking correction of their ED with a penile prosthesis. Over the years, however, increasing numbers of patients who are intolerant or do not respond to PDE5 inhibitors exhibit interest in seeking other treatment options.

Penile prosthesis implantation has been the most effective treatment for ED over the past 35 years when other more conservative treatment options have proven unsatisfactory or contraindicated by comorbidities. Intracavernosal implantation of semirigid rod prostheses was introduced in the early 1960s. Initially, the semirigid or malleable prostheses were much more popular than the three-piece implant because of ease of installation and better mechanical reliability. Since the development of the first inflatable penile prosthesis (IPP) in 1973 by Scott et al. [2], designs and materials have greatly improved, and new surgical techniques have made implantation easier. Over the years, product enhancements have occurred that resulted in better mechanical reliability, greater patient freedom from revision surgery, and decreased patient implant infections [3,4]. Presently, inflatable implants are done six times more often than rod implants in the United States because of this improved reliability and high patient satisfaction. Present long-term revision-free survival for the three-piece inflatable is probably the highest of any medical devices currently implanted in humans [5].

Aims

This publication is the written report of the study of the new design for all the components of the AMS 700 Momentary Squeeze (MS) inflatable three-piece penile prosthesis. The purpose of the study was to evaluate the new modifications to the AMS 700 MS IPP Series pump, cylinders, reservoir, and rear-tip extender (RTE) design. The design changes were meant to impact ease of use for the patient, eliminate the annoying condition of autoinflation, and improve ease of implantation for the physician.

Methods

This was a single-armed, prospective, multicenter study evaluating the redesigned AMS 700 MS IPP with enhanced features meant to improve ease of implantation and patient manipulation of the device. The new device incorporates design changes to the pump, cylinders, reservoir, and RTEs.

Patients were recruited from the existing population experiencing ED at seven U.S. sites. All seven sites received Institutional Review Board (IRB) approval, and the study was conducted in accordance with the ethical standards of the IRBs. Of the 76 patients enrolled, 69 were implanted; 15 subjects were discontinued prior to the end of the study. Reasons for discontinuation included the subject withdrawing consent prior to the procedure (6), aborting the procedure (1), explanting the device (1), or lost to follow up (7). Following implantation, the patients were evaluated at regularly scheduled follow-up visits: activation (4–6 weeks according to surgeon preference), 3-month and 6-month intervals from the time of implantation. All patients returned for activation and instruction visit. Sixty-one patients returned at 3 months and 60 returned at 6 months for evaluation of the device.

The mean age of the patients was 60.1 ± 9.6 years. Patient ethnicity was 63 (82.9%) Caucasian, 12 (15.8%) African American, and 1 (1.3%) Asian. History of ED was >5 years in 34 (45%) study patients and over 1 year in 92% of the subjects. All patients had either failed oral or injection therapy and did not wish to use a penile vacuum device. Etiology of ED was post prostatectomy in 24% (18), diabetes in 18% (14) vascular in 15% (11), and Peyronie's disease in 11% (8). The remainder (32%) was listed as organic, nonspecific, or other. Eighteen of the patients (26%) were implanted using the infrapubic approach, and 51 (74%) received their implants via a penoscrotal incision.

In this study, physicians were queried for ease of device implantation, ease of patient instruction, and their assessment of the quality of erection. The patients were questioned on ease of finding and using the pump, erection quality compared with a natural one, overall satisfaction with the implant, and the existence of autoinflation.

Results

Physicians at Implantation

After surgically implanting the device, physicians were asked if the device enhancements improved ease of implantation. Cylinder insertion was rated easy or very easy in 84% of the subjects. When compared with inserting other cylinders, a majority (65%) of the physicians felt the new cylinders were easier to implant (Table 1).

Physician ratings of the ease of surgical implantation with the new MS pump compared with other pumps they had used in the past showed no

Table 1 Physician ratings of AMS 700 Momentary Squeeze inflatable penile prosthesis cylinder implantation

Overall ease of proximal insertion	N = 69 (%)
Very easy	39 (56.5)
Moderately easy	19 (27.5)
Neither easy nor difficult	11 (15.9)
Moderately difficult	0 (0.0)
Very difficult	0 (0.0)
Ease of proximal insertion compared with other cylinders	N = 69 (%)
Much easier	19 (27.5)
Slightly easier	26 (37.7)
Same	23 (33.3)
Somewhat more difficult	1 (1.4)
More difficult	0 (0.0)

significant improvement. Similarly, the new reservoir design did not change the ease of implanting that component.

Physician satisfaction regarding the new snap on RTE, its stability, and overall satisfaction are shown in Table 2.

Physicians at Activation Visit and Instruction

Sixty-six patients returned as early as 2 weeks, up to 6 weeks for device activation and cycling by the physician and for patient training. The physician easily located the inflation bulb and deflation button in all patients. Physician evaluation deemed 100% of the erections suitable for sexual intercourse. The device was successfully deflated with a single push of the deflation button in 62 patients (93.9%), and after deflation, the penis appeared flaccid in 65 patients (98.5%). The patients were instructed to only push the deflation button once. The patients and/or their interested partners were thoroughly instructed in cycling the device. Physician evaluation of the new device's rigidity and flaccidity at device activation was rated good to excellent in all patients. No physicians reported that the new cylinder design produced worse flaccidity.

Table 2 Physician ratings of AMS 700 Momentary Squeeze inflatable penile prosthesis rear-tip extenders (RTEs) at surgical implantation

Satisfaction with the new snap on design	N = 66 (%)
Very satisfied	33 (50.0)
Moderately satisfied	11 (16.7)
Neutral	19 (28.8)
Moderately dissatisfied	1 (1.5)
Very dissatisfied	2 (3.0)
Satisfaction with the stability compared with the stackable AMS 700 RTE configuration	N = 66 (%)
Very satisfied	34 (51.5)
Moderately satisfied	15 (22.7)
Neutral	17 (25.8)
Moderately dissatisfied	0 (0.0)
Very dissatisfied	0 (0.0)
Overall satisfaction compared with current stackable AMS 700 RTE and other stackable RTE configurations	N = 66 (%)
Much better	27 (40.9)
Somewhat better	17 (25.8)
Same	21 (31.8)
Somewhat worse	1 (1.5)
Much worse	0 (0.0)

Table 3 Physician evaluation of AMS 700 Momentary Squeeze (MS) inflatable penile prosthesis subject training compared with other pumps at device activation

Ease of training subjects with the AMS 700 MS compared with other pumps	AMS Tactile pump N = 66 (%)	Standard AMS 700 pump N = 66 (%)
Much easier	36 (54.5)	39 (59.1)
Somewhat easier	11 (16.7)	18 (27.3)
Same	5 (7.6)	4 (6.1)
Somewhat harder	13 (19.7)	4 (6.1)
Much harder	1 (1.5)	1 (1.5)

After training, the physicians evaluated the manipulation of the device by the 66 patients. The inflation bulb was easily located in 63 (96%). The median time for patients to inflate the device was 30–60 seconds. The median time that was required by physicians or their staff to train subjects on the use of the device was 3–4 minutes (range 30 seconds to 10 minutes.) Table 3 shows the physician evaluation of patient training with the new MS pump when compared with other pumps.

Physicians at 3- and 6-Month Follow-up Evaluation

Sixty-one patients returned for a 3-month evaluation, and 60 presented at 6 months. Physicians were asked to assess ease of use of the implant and quality of the erection and flaccidity compared with previous devices they had used. The erection seemed adequate for intercourse in all patients, and the physicians were able to easily locate the device in all but one subject at 3 months and 100% of patients at 6 months. Erection and flaccidity were judged similar to the condition observed at the device activation visit. Table 4 indicates physician rating overall of the AMS 700 MS IPP at 3 and 6 months. It is notable that by 6 months, 90% of the physicians rated the new device moderately or very satisfactory.

Patient Assessment at 3 and 6 months

The responses to inflating and deflating the device of 61 patients at 3 months and 58 patients at 6 months were captured on a questionnaire. The force required to inflate the device was reasonable for 85% of patients at both time intervals. Virtu-

Table 4 Physician rating of overall AMS 700 Momentary Squeeze inflatable penile prosthesis function at 3 and 6 months

Overall function of device	3 months N = 61 (%)	6 months N = 59* (%)
Very satisfactory	40 (65.6)	37 (62.7)
Moderately satisfactory	4 (6.6)	16 (27.1)
Satisfactory	15 (24.6)	4 (6.8)
Moderately unsatisfactory	2 (3.3)	2 (3.4)
Very unsatisfactory	0 (0.0)	0 (0.0)

*One physician did not complete the questionnaire.

ally all patients felt the time to inflate was reasonable (97%), and the erection had adequate rigidity for intercourse (92%). Approximately 90% felt the force and time to deflate to be reasonable, but only 57% were able to deflate with one hand at the 6-month visit. Table 5 indicates overall subject satisfaction with the new device.

Two patients were very dissatisfied at 3 months. One felt it was hard to hold the pump to deflate the device, while the second felt it took too much force to inflate the device and had difficulty holding the pump bulb. At 6 months, four subjects had become very dissatisfied. Two felt the pump was difficult to hold and too much force was needed to inflate and deflate the device. Two other patients felt the prosthesis provided poor rigidity for intercourse.

The lock-out valve in the pump proved to virtually eliminate the condition of autoinflation. At 6 months, only two patients (3%) reported the condition.

During the study period, one device became infected when an artificial urinary sphincter developed urethral erosion following trauma. The subsequent infection required the removal of both devices. Another device was removed after the patient punctured the cylinders with injection needles. Only one device required revision for mechanical reasons. The patient reported autoinflation and difficulty activating inflation at 3 and 6 months.

Table 5 Overall subject satisfaction

Overall satisfaction with device	3 months N = 61 (%)	6 months N = 58 (%)
Very satisfied	27 (44.3)	30 (51.7)
Moderately satisfied	13 (21.3)	15 (25.9)
Somewhat satisfied	10 (16.4)	5 (8.6)
Somewhat dissatisfied	9 (14.8)	2 (3.4)
Moderately dissatisfied	0 (0.0)	2 (3.4)
Very dissatisfied	2 (3.3)	4 (6.9)

Discussion

All of the components, pump, cylinders, RTEs, and reservoir, had undergone enhancements. Study design included a prospective study of patient and physician opinions at implantation, activation visit, and 3- and 6-month intervals. The study tracked physician evaluation regarding ease of implantation, quality of erection, naturalness of flaccidity, and ease of activating and/or teaching the device to patients. The patients were queried as to the quality of erection, ease of manipulation of the device, and satisfaction with the IPP.

Pump changes included a smaller size pump with ridges on the inflate bulb to make identification easier for the patient. The total MS pump size was decreased to 26.5 mL compared with 30.2 mL for the Tactile pump; therefore, there is minimal tissue disruption for placement in the scrotum. Deflation mechanism was changed from two platforms requiring a two-finger squeeze for the entire deflation to a single button whose depression for a few seconds would deactivate the device without the necessity to depress for the entire deflation—thus the term "momentary squeeze." The MS pump has a lock-out valve to prevent autoinflation when the patient had an increase in abdominal pressure (Figure 1).

Cylinder changes were designed to make implantation for the physician easier. Dilatation to only 11 Hegar was necessary to implant the base, whereas previous standard cylinder bases required dilatation to 12 Hegar. The new narrower base of the standard sized cylinder was within 1 mm of the downsized CXR prosthesis from AMS. This nar-

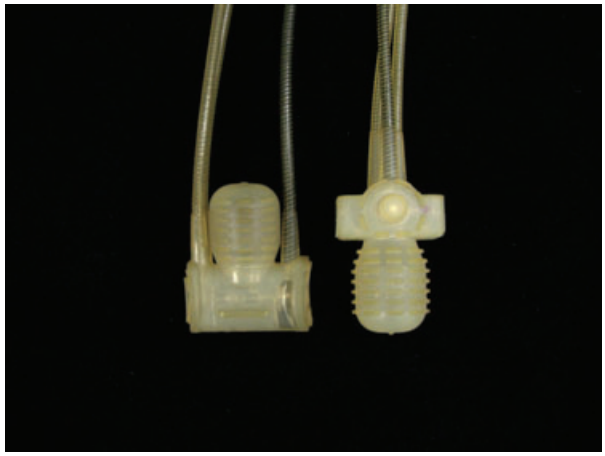

Figure 1 Tactile pump (on left) and new Momentary Squeeze pump.

rower diameter base was accompanied by a less acute angle of input tubing that was meant to further facilitate easier insertion of the cylinder base (Figure 2).

RTE changes were a complete departure from previous designs that used 1-, 2-, or 3-cm RTEs and necessitated stacking the extenders to achieve longer lengths. Stacking the RTEs increased cylinder base diameter on the previous models of inflatables, making insertion of the cylinder base even more problematic. The new device features RTEs that snap on and vary in length from 0.5 to 7.5 cm with the width identical to the cylinder base. This new RTE design eliminates two issues: stacking with the resultant increase in cylinder base diameter and reduces the potential for the RTE to detach from the cylinder, remaining within the deep proximal corpora in the event the cylinder need to be extracted (Figure 2).

Reservoir changes include coating of the reservoir with Parylene to decrease the potential for silicone fatigue and subsequent leakage from crease fold failure. Placing this coating on the cylinders had markedly reduced cylinder wear [6].

Historically, autoinflation has commonly occurred in inflatable prostheses [7]. It is annoying to the patient and physician. With capsular formation around the reservoir, the increased pressure on the reservoir transfers fluid to the cylinders and, without the lock-out valve, results in autoinflation. Patient's complaints of autoinflation are bothersome enough to consider revision in 8–11% in previously published series [8,9]. Years of experience with implant patients tells us the true occurrence is considerably higher.

The formation of a constricted reservoir capsule contracting around the reservoir forces fluid back in the cylinders causing autoinflation [10]. The patient maintaining partial inflation in his cylinders during the first 3 months postoperatively causes this constricted capsule. The capsule forms around the relatively empty reservoir, and when the patient subsequently deflates his device, the fluid returns to the cylinders causing autoinflation. The lock-out valve worked very well in this study with only two patients (3.4%) reporting autoinflation upon specific questioning.

Manipulation of the pump in inflation and deflation was addressed in this new model of the AMS 700 MS IPP. The new MS pump requires only pressing the button for a few seconds and the device deflates without further manipulation. This study shows well over 90% of the patients and physicians found the deflation button easy to locate and use. The goal of a one-handed pump still remains elusive, as only 57% of patients were able to do this with the new MS pump at 6 months. Reorientation of the pump functions with the pumping bulb inferior and the deflation button superior also added to ease of use of the new pump, and 79% of physicians rated the MS pump easier or the same to train their patients when compared with the AMS Tactile pump. Perhaps to possibly decrease the percentage of patients that are not satisfied with the IPP, daily cycling and stretching of the tissue may be beneficial.

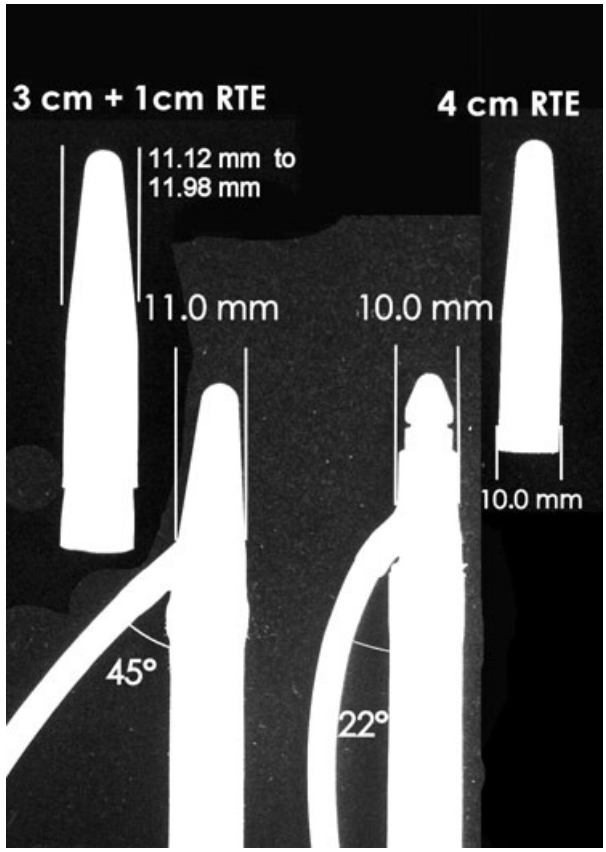

Figure 2 Old cylinder base (on left) with larger diameter, stacking rear-tip extender (RTE), and wider tubing input angle compared with the new Momentary Squeeze cylinder base and Snap Fit RTE.

The two patients reporting autoinflation bear additional comment. The one patient requiring revision surgery had trouble manipulating the pump from the beginning of his postoperative course. The pump, at times, did not lock out and, at other times, would not inflate. During the periods of time when inflation was not possible, the pump had a dimple as if there was no fluid in

the system. After the removal of the pump, the investigation of the pump at the AMS factory did not reveal any mechanical problem. The second patient reporting autoinflation experienced a similar situation but did not seek a revision surgery. After conclusion of this study with the generalized availability of the devices to all physicians, a few more episodes of this pump malfunction, or "autoinflation," occurred in patients outside of the study. As a result of these events, we have now learned the problem is not mechanical failure of the pump but inadequate lubrication of the lock-out valve. With experience, we have learned that the problem can be corrected by forcefully pressing the pump once and then the deflation valve once repeatedly in a rapid fashion. This seems to assure saline lubricates the poppet valve that prevents autoinflation. In fact, prevention of the problem is now advocated by the company—during the preparation of the device, this maneuver should be performed while filling the pump with saline and before evacuating all the air in the system. Once filling of the pump is complete, syringe pressure should not be applied to input tubing to not disrupt the valve.

Conclusion

The new AMS 700 MS IPP features changes to all the components: pump, reservoir, cylinders, and RTEs. The physicians found the enhancements made the device easier to implant and somewhat easier to teach patients than previous models of the AMS 700 line. The patients found the new MS pump easy to locate and manipulate. The new device seemed to eliminate autoinflation as reported with older models of the AMS 700 line IPP.

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Statement of Authorship

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