

ORIGINAL RESEARCH—SURGERY

Comparison of a New Length Measurement Technique for Inflatable Penile Prosthesis Implantation to Standard Techniques: Outcomes and Patient Satisfaction

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ABSTRACT

Introduction. Within a study evaluating the redesigned AMS 700MS inflatable penile prosthesis (IPP) (American Medical Systems, Minnetonka, MN, USA), one site used new length measurement technique (NLMT), a more aggressive dilation and measurement of the corpora cavernosa on a stretched penis, to address penile shortening.

Aim. To compare cylinder size and patient satisfaction, between a NLMT and traditional sizing for IPP implantation.

Methods. Fourteen men received IPPs using NLMT, and 55 with traditional sizing. Nationwide sales data from 2005 to 2008 for AMS 700 IPPs was obtained from AMS for comparison; additional surveys captured patient satisfaction.

Main Outcome Measure. Demographic data, cylinder sizes, and patient satisfaction were compared between the NLMT and standard techniques.

Results. The Fisher's exact test ($P < 0.001$) showed a significant difference between the cylinder sizes with NLMT as compared with standard techniques. Of the 14 NLMT patients, 71.4% (10) received cylinders >21 cm long and 28.6% (4) received cylinders <21 cm long, as compared with 12.7% (7) and 87.3% (48), respectively, for patients implanted by traditional techniques. There were ethnic differences between the samples: 42.9% (6) NLMT patients were of African-American descent, as compared with 10.9% (6) in the standard technique group. However, longer cylinders were utilized more often, with 83.3% (5) of African-Americans treated using the NLMT; as compared with 33.3% (2) of the standard technique group. Nationwide data reveal 12.3% of patients routinely receive 21 cm cylinders. At 6 months postimplantation, patient satisfaction with NLMT was no different than standard techniques. There were no distal erosions, complications, infections, or pain concerns reported through 24 months among the NLMT patients.

Conclusions. The NLMT resulted in a larger number of subjects implanted with larger cylinders. Satisfaction with performance and complication rates for NLMT patients was comparable to those implanted using standard techniques. **Henry G, Houghton L, Culkin D, Otheguy J, Shabsigh R, and Ohl DA. Comparison of a new length measurement technique for inflatable penile prosthesis implantation to standard techniques: Outcomes and patient satisfaction. J Sex Med 2011;8:2640–2646.**

Key Words. Erectile Dysfunction; Penile Prosthesis; Impotence Surgery; Patient Satisfaction Post-Op Penile Implant Surgery for Erectile Dysfunction

Introduction

The synthetic intracavernosal semirigid rod penile prosthesis was extensively used prior to the development of the inflatable penile pros-

thesis (IPP) [1–4]. It was taught to downsize a rod at the time of implantation [5]. Introduction of the original IPP for the treatment of erectile dysfunction (ED) occurred in 1973 by F.B. Scott [6], who first suggested that the best way to enlarge the

penis was with implantation of serially larger cylinders. Very high patient satisfaction rates with penile implants have been reported worldwide [7–10]. However, the biggest complaint of IPP patients 6 months postoperatively is penile shortening [11,12]. As satisfaction is a very important aspect of any method of correcting sexual function, ways to improve patient satisfaction is paramount in the treatment of ED.

The most common etiology of ED for a patient receiving an IPP is prostate cancer; and both radiation and radical prostatectomy have been shown to shorten the penis [13,14]. In the past, some experts taught urologic prosthetic surgeons to choose shorter instead of longer cylinder lengths at the time of cylinder implantation [14,15]. Moreover, one of these experts advocated that the correct way to properly measure the corpora was to measure distally from the distal aspect of the corporotomy and proximally from the proximal aspect, thereby deliberately downsizing 2 cm [15]. These prosthetic surgeons had extensive experience with semirigid rod implantation, with the subsequent complications of distal erosion that some associated with a rod that was too long. However, this is not a common occurrence with the IPP [16–18]. To address the patient-driven concern with penile length after IPP implantation, the new length measurement technique (NLMT) was developed, which promotes selecting a larger cylinder size at implantation than was traditionally instructed.

Aims

The purpose of the original multicenter study was to evaluate the new AMS 700 Momentary Squeeze (MS) pump and to identify factors related to device survival and patient satisfaction [19]. When analyzing the data, it was noted that at one site (which used the NLMT), the surgeons had implanted significantly larger cylinders than the other six sites. Thus, we initiated a retrospective review of the prospectively gathered data regarding size of implanted cylinders and patient satisfaction at the NLMT site relative to other sites and to nationwide historical data on cylinder sizes implanted by routine techniques. Moreover, we describe the NLMT in detail for the first time in the literature.

Methods

A single-arm, prospective, multicenter study evaluated the redesigned AMS 700 CX MS Pump IPP [19]. One site used a NLMT with more

aggressive dilation/measurement of the corpora cavernosa on a stretched penis (described below). The other six sites used the traditional method of measuring for length of cylinders implanted. Institutional Review Board approval was obtained at all study sites and all patients provided informed consent.

Subjects were among the population of men receiving implants in the multicenter study. Surveys in the prospective multicenter study group captured data on cylinder size and patient satisfaction. Fourteen subjects were implanted at the NLMT site, and 55 were implanted with standard techniques at six other sites. The NLMT subjects have been followed for 24 months for pain, erosion, or any complications. Nationwide cylinder sales data from 2005 to 2008 for AMS 700 IPPs was also obtained from AMS for comparison.

Surgical Technique

The NLMT is a more aggressive form of measurement developed to overcome the number one chronic complaint of IPP patients: penile shortening. The technique is only for primary implantation where there is no fibrosis, Peyronie's disease, or other corporal defects, and is done bilaterally. The NLMT may want to be done only by prosthetic surgeons who have developed a "feel" for correct dilation of the corpora cavernosa. There is no aggressive dilation of the corpora, only a more aggressive measurement method. For this technique, many prosthetic urologists start distal corpora cavernosa dilation with Metzenbaum scissors turned and angled laterally. The scissors are passed about two-thirds of the way distally to the glans to start the dilation tract. Some prosthetic surgeons advocate the use of the Metzenbaum scissors to complete the distal dilation into the glans. A size 11 Brooks dilator (Coloplast, Minneapolis, MN, USA) is passed distally and proximally, again staying laterally, trying to get *into the glans penis distally and into the lateral crux of the corpora down to the bone proximally*. The surgeon should protect the fossa navicularis during distal dilation with his nondominant hand bending the glans in the contralateral direction, with the ongoing dilation with the dilator in his dominant hand. The Metzenbaum scissors can extend the corporal dilation, even through fibrosis, when the Brooks/Hagar dilators cannot, with hopeful cylinder expansion down this tract; however, some surgeons prefer to use a knife or other specialized dilators for extending dilation of the corpora. Meanwhile, other prosthetic surgeons advocate

Table 1 Basic steps of the new length measurement techniques; for experienced prosthetic surgeons on uncomplicated primary IPP patients

Step 1: Distal dilation	If unable to get into the mid-glans of the penis, add 1 cm
Step 2: Proximal dilation	If unable to hit solid bone in the lateral crux, add 1 cm
Step 3: Bilateral length	If unequal by >2 cm, recheck, and go with the longer length
Step 4: Safety check	Must pass field goal test and distal fluid challenge for integrity

extending the corporotomy or make a separate distal incision for extending the dilation under direct vision.

The key point of the NLMT is that if the 11 dilator does not go all the way out into the glans, then the surgeon should add 1 cm of length to the total measurement being used for that patient's implantation. Moreover, if the dilator does not drop down proximally into the lateral crux of the corpora on to a firm bone stopping point (sometimes, proximally, there is a spongy feel instead of solid bone), then 1 cm is added to the total measurement length being used for that patient's implantation (Table 1).

Each side's length is calculated independently; corpora safety checks of the classic field goal test and distal fluid challenge are done. If there is a difference in the length measurement between the two sides, and a recheck of the field goal test is done with no evidence of perforation, crossover, or tunical defect, then the prosthetic surgeon goes with the larger measurement, instead of the shorter measurement, as has been classically taught. If there is a >2 cm measurement difference between the two sides, then there is probably a technical error, and the prosthetic surgeon should carefully reassess the corporal dilatation. The field goal test (Figure 1) is where two Brooks dilators are placed proximally inside the corpora and are then compared for same depth and same angle to evaluate for crossover/perforation. The distal fluid challenge is where a filled asepto syringe is inserted inside the corporotomy and injected distally: a failed test is when fluid shoots out around the Foley catheter at the meatus, indicating a perforation into the urethra.

Main Outcome Measures

The primary end point was differences between the NLMT patient group and the traditional technique patient group in cylinder and total IPP length (cylinder + rear tip extender [RTE]) used.

Table 2 Cylinder sizes used by sites

Cylinder size	NLMT site (N = 14)	Other sites (N = 56†)
12 cm	0 (0%)	1 (1.8%)
15 cm	1 (7.1%)	20 (35.7%)
18 cm	3 (21.4%)	27 (48.2%)
21 cm	10 (71.4%)*	7 (12.5%)

*Fisher's exact test $P = 0.0003101$.

†1 patient was not implanted.

Secondary end points were patient satisfaction and outcomes between the two groups. Moreover, nationwide cylinder sales data from 2005 to 2008 for AMS 700 IPPs were also obtained from AMS for comparison to the two different groups' cylinder sizes.

Results

Among the 14 NLMT study patients, 71.4% (10) received 21 cm-long cylinders and 28.6% (4) received cylinders <21 cm long, as compared with 12.5% (7) and 85.7% (48) of patients using the traditional technique (Table 2).

Variation in ethnicity was noted; 42.9% (6) of patients at this study site were of African-

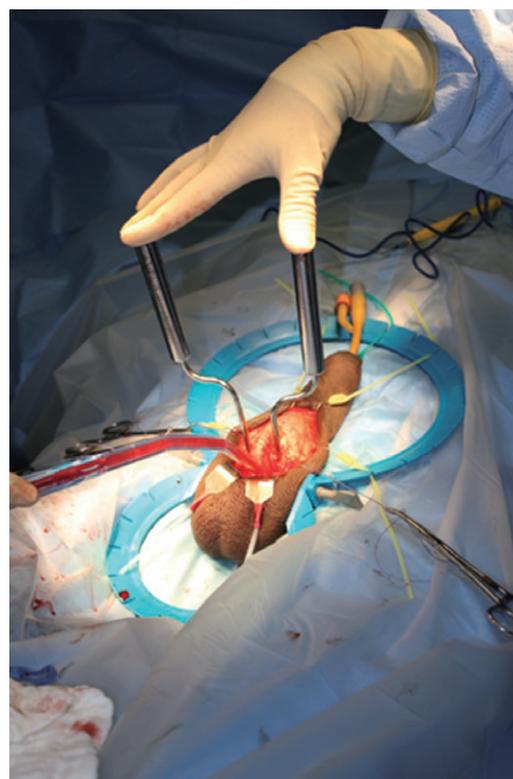
**Figure 1** Field goal test.

Table 3 Patient ethnicity

Ethnicity	NLMT site	Other sites
African-American	6 (42.9%)	6 (10.7%)
Other ethnicities	8 (57.1%)	50 (89.3%)

Table 4 Cylinder sizes in African-American patients

Cylinder size	Ethnicity	NLMT site	Other sites
≥21 cm	African-American	5 (83.3%)	2 (33.3%)
<21 cm	African-American	1 (16.6%)	4 (66.6%)

Table 5 NLMT site—cylinder size and max of total RTE length combination

Cylinder size (max of the left and right)	Max of total RTE length (left/right)	N (%)
15 cm	4.5	1 (7.14%)
18 cm	2	1 (7.14%)
18 cm	3	1 (7.14%)
18 cm	4	1 (7.14%)
21 cm	0	2 (14.29%)
21 cm	1	2 (14.29%)
21 cm	2	1 (7.14%)
21 cm	3	4 (28.57%)
21 cm	4	1 (7.14%)

American descent, relative to 10.7% (6) at the other six sites (Table 3). However, longer cylinder lengths were still comparatively utilized more with NLMT technique, with 83.3% (5) of African-American treated using the NLMT; as compared with 33.3% (2) of the standard technique group (Table 4).

Cylinder size and total RTE length were also analyzed by site. Table 5 presents the percentage of max RTE length for the different cylinder sizes at this study site. Four patients (28.57%) received 3 cm of RTE with 21-cm cylinders. At the other study sites, six patients (10.71%) received 3 cm of RTE with 15-cm cylinders, and six (10.71%) received 1 cm of RTE with 18-cm cylinders (Table 6).

The Fisher’s exact test ($P < 0.05$) showed a significant difference between the cylinder sizes used at the NLMT site compared to the other sites, controlling for race/ethnicity of patients. There was no statistical difference between the two groups in terms of age (61.4 vs. 59.7), presence of diabetes (14.3% vs. 19.4%), or Peyronie’s disease (14.3% vs. 9.7%) (Table 7).

At 6 months postimplantation, patient satisfaction at the NLMT site was no different clinically than other sites (Tables 8 and 9). For the question, “Overall, my satisfaction with my penile prosthesis

is . . . ,” there was a 93% (13/14) satisfaction rate at the NLMT site compared to the 84% (37/44) at the traditional technique sites. There were no distal erosions or pain issues through 24 months among the NLMT patients. The rest of the 55 study patients at the other sites were only required to be followed for 6 months per the study protocol. Among the nationwide comparison group, the percentages of cylinders of each size (21 cm [12.3%], 18 cm [48.5%], and 15 cm [35.6%]) were almost identical to those used by the six sites where the traditional measuring techniques were used.

Discussion

The number one complaint of an IPP patient 6 months after implantation is penile shortening [11,12]. As penile prosthesis surgery is an elective procedure to reestablish sexual function, patient satisfaction is of utmost importance. Most high-volume prosthetic urologists would agree that many patients complain about penile shortening, even though their IPP functioned well. To try to address this patient-driven problem, the NLMT was developed.

We propose that many experienced leaders in prosthetic urology primarily used semirigid devices early in their careers and/or were sternly taught by their surgical instructors (who had only used semirigid devices prior to the invention of the

Table 6 Other sites—cylinder size and max of total RTE length combination

Cylinder size (max of the left and right)	Max of total RTE length (left/right)	N (%)
Not implanted	N/A	1 (1.79%)
12 cm	6	1 (1.79%)
15 cm	2	5 (8.93%)
15 cm	3	6 (10.71%)
15 cm	3.5	1 (1.79%)
15 cm	4	4 (7.14%)
15 cm	5	3 (5.36%)
15 cm	6	1 (1.79%)
18 cm	0	1 (1.79%)
18 cm	0.5	1 (1.79%)
18 cm	1	6 (10.71%)
18 cm	2	4 (7.14%)
18 cm	2.5	1 (1.79%)
18 cm	3	7 (12.5%)
18 cm	4	3 (5.36%)
18 cm	4.5	1 (1.79%)
18 cm	5	1 (1.79%)
18 cm	6	1 (1.79%)
18 cm	6.5	1 (1.79%)
21 cm	1	3 (5.36%)
21 cm	2	1 (1.79%)
21 cm	3	3 (5.36%)

Table 7 Patient age and primary etiology of erectile dysfunction

Patient characteristics		NLMT site (N = 14)	Other sites (N = 55)
Age	Ave \pm SD, range	61.4 \pm 5.5, [49, 68]	59.7 \pm 10.4, [27, 82]
Primary etiology of erectile dysfunction	Diabetes mellitus	2 (14.3%)	12 (19.4%)
	Organic, nonspecific	1 (7.1%)	16 (25.8%)
	Pelvic trauma	1 (7.1%)	0
	Post-prostatectomy	6 (42.9%)	12 (19.4%)
	Peyronie's disease	2 (14.3%)	6 (9.7%)
	Vasculogenic	2 (14.3%)	9 (14.5%)
	Radical surgery (other than prostatectomy)	0	1 (1.6%)
	Priapism	0	1 (1.6%)
	Psychogenic	0	1 (1.6%)
	Other	0	4 (6.5%)

IPP) not to be aggressive with length measurements, due to high rates of distal erosions (with the semirigid device). These early experienced leaders published articles that advocated to deliberately downsize the total length used during implantation of a penile prosthesis [6,14,15,24]. Therefore, learning what would be the correct length for implantation was influenced by the experiences with semirigid rods and "passed down" to the IPP. However, the literature for IPPs shows little to no distal erosions (Table 10) [16–18].

Moreover, this difference in *distal erosion rates between semirigid rods and IPPs has been shown to be significant* in neurologically impaired patients, who classically had higher rate of distal erosion/infection, especially those who use the penile implant to "stent" the penis for ease of condom catheter placement/attachment [18]. For example,

Zermann et al. showed in a long-term follow-up of 245 neurologically impaired patients implanted, semirigid rod (147), self-contained inflatable (113), three-piece IPP (33), that there was an 18.1% perforation rate for semirigid rod, 2.4% for self-contained inflatable, and 0% for 3-piece IPP [18]. Moreover, Natali et al., in follow-up of 253 implants in Italy and Germany, found a much higher rate of erosion with semirigid rods than with inflatable devices [17]. It makes intuitive sense that an IPP, which is deflated the majority of the time, does not put the same pressure distally as a semirigid rod, which is not designed to contract in length.

These papers indicate that there is very little distal erosion of the IPP through the glans, and that maybe, there should be a different length measurement technique for IPPs than for

Table 8 Patient satisfaction at NLMT site

Question	Cylinder size	Answer	Frequency	Percent
I feel my prosthesis provides an erection with adequate rigidity (stiffness) for intercourse.	\geq 21 cm	Yes	10	100.0
	<21 cm	Yes	4	100.0
My satisfaction with the softness of my penis when the prosthesis is in its flaccid (deflated) position is . . .	\geq 21 cm	Satisfied	9	90.00
		Dissatisfied	1	10.00
	<21 cm	Satisfied	3	75.00
		Dissatisfied	1	25.00
Overall, my satisfaction with my penile prosthesis is . . .	All	Satisfied	13	92.86
		Dissatisfied	1	7.14

Table 9 Patient satisfaction at 6 other sites

Question	Cylinder size	Answer	Frequency	Percent
I feel my prosthesis provides an erection with adequate rigidity (stiffness) for intercourse.	\geq 21 cm	Yes	4	80.00
		No	1	20.00
	<21 cm	Yes	34	87.18
		No	5	12.82
My satisfaction with the softness of my penis when the prosthesis is in its flaccid (deflated) position is . . .	\geq 21 cm	Satisfied	5	100.00
	<21 cm	Satisfied	38	97.44
		Dissatisfied	1	2.56
Overall, my satisfaction with my penile prosthesis is . . .	All	Satisfied	37	84.09
		Dissatisfied	7	15.91

Table 10 Review of the literature evaluating distal erosion

Paper	# Implants	Type of implant	Erosion/Extrusion rate
Carson CC, et al. [16]	372 (primary)	■ 3 piece IPP (AMS 700 CX)	■ 5 patients (1.3%)
Zermann DH, et al. [18]	245 neurologically impaired patients	■ Rod (147)	■ 18.1%
		■ Self-contained inflatable (113)	■ 2.4%
		■ Three-piece IPP (33)	■ 0%
Natali A, et al. [17]	253 (primary)	■ Rods	■ 7 patients (17.5%)
		■ Self-contained inflatable (98)	■ 2 patients (5%)
		■ Three-piece IPP (62)	■ 4 patients (10%)

semirigid rods. Based on these differences, we contend that the NLMT should be only used for IPPs, not for semirigid rod implantation.

Another indication that the prosthetic surgeon may not be getting optimal length measurement is the report that at IPP revision for noninfectious reasons, most patients require a longer total length of reimplant, as compared with their original implant. Fogla et al. showed that there was a 2.5-cm increase in corporal length at the time of cylinder replacement for IPP revision/replacement. Wilson et al. showed in 2007 that placing a downsized cylinder into a patient with corporal fibrosis can be “used” to stretch the tissue enough to place standard size cylinders and an average of 2.2 cm-longer cylinders about a year later [20]. If diseased fibrotic tissue can stretch, it stands to reason that the same could be possible for patients who do not have scarred down fibrotic tissue. Moreover, patients whose tissue is not fibrotic should be able to stretch easier, faster, and more safely than those patients with corporal fibrosis. Furthermore, recently, it has been shown that a preoperative vacuum erection device (VED) protocol has resulted in longer cylinder implantation at the time of surgery [21]. The authors of this vacuum protocol feel that regular VED usage can stretch the penile tissue significantly. In addition, Dr. Shaeer has described surgical penile elongation and girth augmentation after penile prosthesis implantation [22].

Outcomes analysis, the gold standard for evaluating medical care, has shown the “Center of Excellence” (COE) concept, wherein all of a specific type of surgery is done by one surgeon rather than multiple surgeons in a group, and provides superior outcomes in total joint replacement, radical cancer, and heart valve surgeries. Recently, the same was shown to be true with penile prosthesis implantation [23]. Henry et al. compared penile prosthesis implantation outcomes (including cylinder length) between the COE approach and multiple-surgeon approach, within a large, single-specialty, urologic surgical group. The

median cylinder length of prostheses placed by the COE surgeon was 2 cm longer than those placed by the multiple surgeon team ($P < 0.0001$). The authors concluded that, “Based on our evaluation, with increased experience and appropriate surgical technique, it may be possible to have more confident and accurate dilation of the penile corporal bodies in order to accommodate the largest cylinders possible for each patient. This may lead to further increased patient satisfaction” [23]. We now propose that the NLMT provides a more confident and accurate dilation of the corpora, but longer follow-up of larger numbers of patients is needed. The authors note that NLMT patients are carefully instructed to “wear their penis up” the majority of the time for the first month postoperatively. Failure to perform this upward penile support can result in a “cobra head” deformity on inflation.

The NLMT is currently being used in two different multicenter prospective studies with larger numbers of patients. Moreover, the maintenance of penile length after prosthesis implantation is an area under current investigation, with prospective objective data being gathered.

An additional limitation of this current study was that because only surgeons who implant frequently were studied, it may not be possible to generalize the results to the surgeon who implant less frequently (less experienced). Also, patients were not randomized to the NLMT or standard technique.

Conclusions

The NLMT permitted larger cylinder size implanted in more patients, regardless of race/ethnicity of the patient. Patient satisfaction with IPP performance is comparable to that observed among patients implanted using traditional techniques. With follow-up of 24 months, there were no complications with the NLMT.

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Conflict of Interest: Gerard Henry: American Medical Systems, Consultant, Investigator Coloplast, Investigator Astellas, Consultant. Laura Houghton: American Medical Systems, Employee. Daniel Culkin: American Medical Systems, Consultant. Ridwan Shabsigh: Vivus Pharma, Investigator Warner Chilcot Pharmaceuticals, Investigator Dong-A Pharm, Consultant or Advisor Pfizer, Consultant or Advisor Lilly, Consultant or Advisor Boehringer Ingelheim, Consultant or Advisor Johnson & Johnson, Consultant or Advisor American Medical Systems, Consultant Bayer Schering Pharma, Consultant or Advisor Auxilium, Investigator Endo Pharma, Consultant or Advisor. Dana A. Ohl: American Medical Systems, Investigator, Consultant Coloplast, Investigator, Consultant.

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