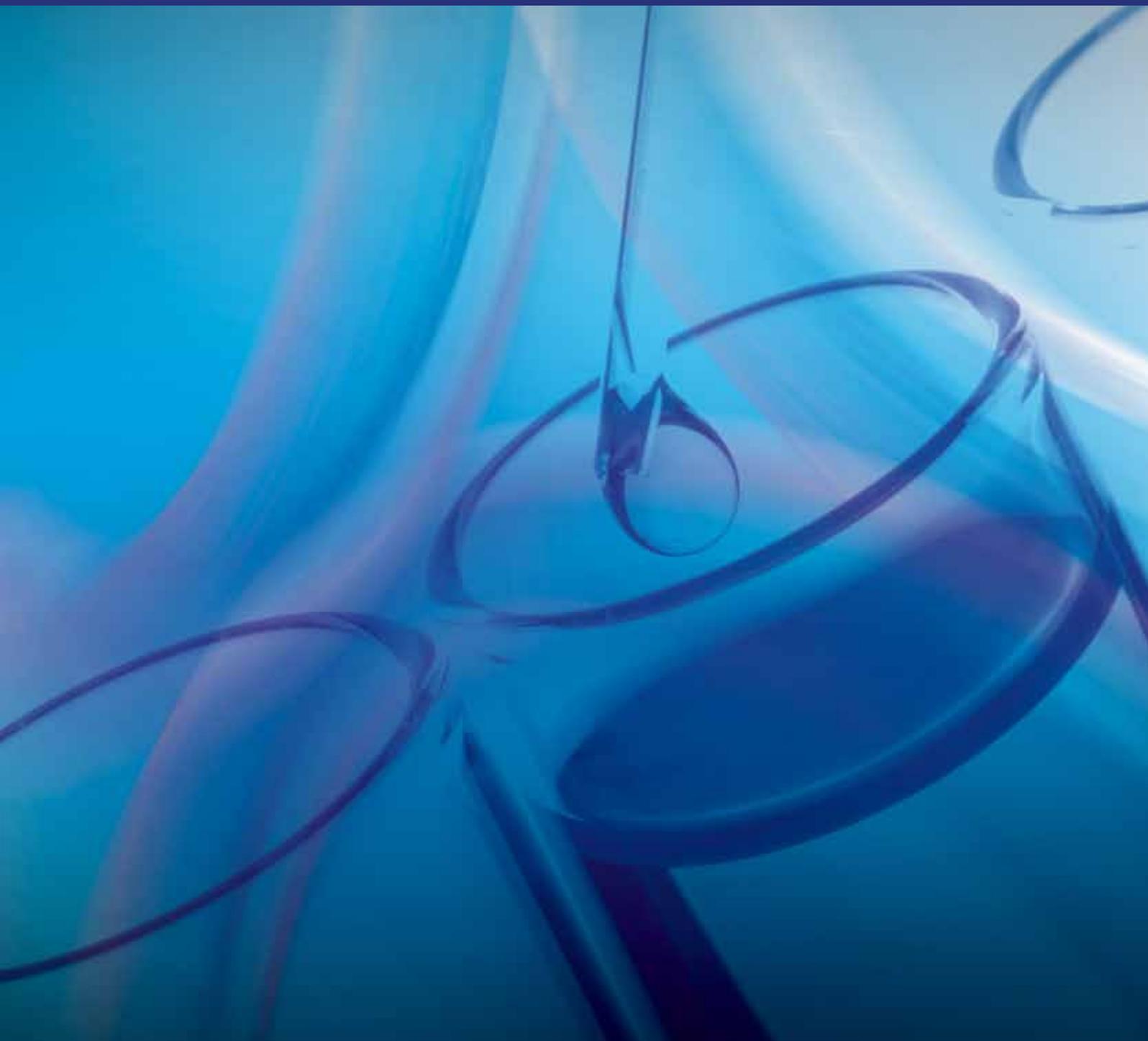


Advances in Urology

Advances in Prosthetic Urology

**Guest Editors: Gerard D. Henry, Andrew C. Kramer,
Rafael E. Carrion, and Brian Christine**





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Editorial

Advances in Prosthetic Urology

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The inflatable penile prosthesis (IPP) has become the gold standard treatment for erectile dysfunction among men refractory to medical therapies. Among the many treatments for erectile dysfunction, implantation of a penile prosthesis has been associated with high patient satisfaction rates and low mechanical failure rates. In this special issue, seven articles are presented, including primary research, reviews, and methodological reports, to highlight outcomes related to patient satisfaction with IPPs, advances in surgical placement techniques, and methods for penile size enhancement concomitant with implant placement.

The safety and efficacy of the IPP have been well documented, but in spite of this, urologists may be reluctant to offer an IPP to older patients due to various concerns, including impaired dexterity of older patients and their ability to operate an inflatable device. To determine the outcomes of and satisfaction with the multicomponent IPP in the elderly male, Villarreal and Jones retrospectively assessed patients using chart review and telephone interview. To analyze overall patient satisfaction with IPPs with a consistent approach, Bernal and Henry conducted a review of the literature over the past 20 years. Nine articles met inclusion criteria for analysis and data collation. Despite the fact that varied metrics were used to determine patient satisfaction, they found that patients in general were very satisfied with their three-piece IPPs and restoration of sexual function, and they identified common reasons for patient dissatisfaction.

The number one patient complaint after IPP placement is loss of penile length. One IPP company has recently remade a product that has longer length cylinders than those

formerly available. However, traditionally, longer cylinders were believed to lack axial rigidity. Henry et al. present a prospective, multicenter research study, performed on the new product to address this concern. In a methodology report, Hakky et al. present an overview of various techniques performed concomitantly with IPP placement surgery to enhance penile length and girth. Outcomes can be improved by combining the use of adjunct surgical techniques; these adjuvant procedures are a key addition in the armamentarium for the serious implant surgeon.

In two methodological articles, surgical techniques and outcomes are described related to surgical treatment of erectile dysfunction. First, Martinez et al. describe common surgical techniques for treatment of Peyronie's disease, a clinical condition that interferes with erectile function. Despite attempts to uncover the pathophysiology behind Peyronie's disease, it remains an enigma, with a reported incidence that is rising, in part because more men come forth to seek treatment. Second, Karpman reports on a streamlined approach for infrapubic placement of an IPP. A better understanding of operative techniques and recent clinical outcome studies have led to an evolution of the original infrapubic approach with significant contributions by Dr. Perito as discussed in the errata. Small incisions and efficient operative maneuvers can shorten operative times and expedite postoperative recovery.

Finally, Henry et al. present a review of outcomes for subarachnoid versus general anesthesia during IPP surgery. The leading patient complaint during the perioperative period for penile prosthesis implantation is postoperative pain, while emesis and urticaria also affect the procedure's

perceived success. This paper retrospectively reviews 90 consecutive, primary inflatable penile prosthetic operations performed by a single surgeon at one private medical center.

As erectile dysfunction is highly prevalent in our society, increasing with age, and life expectancy continues to increase, continued research and development regarding IPPs remain an important area of work.

*Gerard D. Henry
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Research Article

Evaluation of Satisfaction and Axial Rigidity with Titan XL Cylinders

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The inflatable penile prosthesis (IPP) has high patient satisfaction rates and good mechanical reliability rates in multiple studies. The number one patient complaint at six months is penile length. Recently, new technique for aggressive sizing of the cylinders has been published on in the literature. One IPP company has produced a new product that has longer length cylinders (XL) than those available. However, traditionally long cylinders were felt to lack axial rigidity. Therefore, a prospective, multicenter, central IRB-approved, monitored study was performed on the new product to address these concerns. At 2 centers, a total of 17 patients underwent surgical implantation of these new XL cylinders. These patients were questioned for patient satisfaction and tested for axial rigidity using a Fastsize Erectile Quality Monitor. The results showed excellent patient satisfaction rates and great axial rigidity with the Fastsize Erectile Quality Monitor. The XL cylinders appear to give the IPP surgeon the ability to use longer cylinders with good patient satisfaction and great axial rigidity.

1. Introduction

Scott et al., [1] who introduced the first inflatable penile prosthesis (IPP), first suggested implantation of serially larger cylinders to enlarge the penis. Although overall patient satisfaction with the IPP is high [2, 3] the most common complaint among IPP patients 6 months postoperatively is penile shortening [4, 5]. Recently, Henry et al. reported a new length measurement technique that resulted in more patients being implanted with larger cylinders, with satisfaction rates comparable to standard measurement techniques [6]. Longer cylinders allow surgeons the option of using more of the cylinder rather than more of the rear-tip extenders (RTEs), giving the patient a more natural appearing penis in erection and in flaccidity. The traditional Titan IPP line offers cylinder sizes up to 22 cm, but recently larger sizes (24 cm, 26 cm, and 28 cm) have been reintroduced. Titan XL large cylinders, made of bioflex, are developed to meet the needs of those subjects with larger penis sizes and revision subjects needing a cylinder size greater than 22 cm. However, in the past, concerns of the lack of axial rigidity have been bought up when

using longer cylinders and whether this would affect patient satisfaction.

Therefore, a prospective, multicenter, central IRB-approved, monitored study was performed on this new product to address these concerns. The primary objective of the study was to assess the rigidity of the Titan IPP cylinders ≥ 24 cm using the Fastsize Erectile Quality Monitor (EQM) postimplant. Secondary objectives include assessment of subjects' and investigators' perception of sufficient rigidity for sexual function; subject satisfaction via postimplantation questionnaires; revision patients' satisfaction with the new large cylinder device as compared to their previous device; investigators' perception of what device they would have implanted if the large cylinders were not available.

2. Methods

2.1. Titan IPP. The Titan IPP is a hydraulic system designed to be surgically implanted into the penis for the management of ED. The implant provides the subject with voluntary control over the erect and flaccid states of the penis.

TABLE 1: Demographic data of study subjects.

Characteristic	<i>n</i>	Mean \pm SD	Median (Min, Max)	95% CI
Age at implant	16	66.8 \pm 7.0	67.0 (53.6, 79.4)	63.0, 70.5
Height (cm)	16	180.9 \pm 11.9	184.0 (142, 191)	174.5, 187.2
Weight (kg)	16	105.6 \pm 14.0	106.5 (83, 126)	98.2, 113.1
Body mass index (kg/m ²)	16	32.5 \pm 5.0	32.5 (24.8, 41.7)	29.8, 35.2

Note: SD: standard deviation; CI: confidence interval.

The implant consists of two inflatable penile cylinders manufactured from Bioflex that are implanted in the corpora cavernosum of the penis. The cylinders are attached to the pump, which is placed in the subject's scrotum, and the pump is connected to a fluid reservoir that is implanted in the abdomen. The fluid reservoir is filled with a sterile saline solution. All components of the Titan are coated with a hydrophilic coating, a slick lubricious coating that rapidly absorbs aqueous solutions. The hydrophilic coating allows antibiotic solutions to be absorbed onto the IPP prior to implantation.

2.2. *EQM.* The Fastsize EQM is a device that measures and monitors the strength of erections through a noninvasive pressure measurement. Erection strength is a measurement of penile axial rigidity. Measurements of 800 grams or more indicate a rigid penis. Measurements less than 500 grams indicate erections not strong enough for sexual intercourse involving penetration [7]. All subjects implanted with a Titan IPP with a cylinder size ≥ 24 cm were considered for enrollment.

2.3. *Subject Participation.* To be included in the investigation, the subject must have met the following selection criteria: the subjects were males at least 18 years of age who received an implant or revised implant with a Titan IPP cylinder size ≥ 24 cm within the last year. In addition, the subject had to be informed of the nature of the study and agree to its provisions and provide written informed consent as approved by the Institutional Review Board.

Subjects were excluded based on the following criteria. The subject who was unable or unwilling to sign the Informed Consent Form was implanted with a cylinder size ≤ 22 cm or was unable to comfortably cycle the device at the time of enrollment. Written informed consent was obtained from all subjects. Enrollment and data collection were conducted at a follow-up visit at least 90 days and up to 1 year after implantation.

2.4. *Data Collected.* At the follow-up visit (90 to 365 days post-implantation), medical history and demographic data were collected, along with operative data, the subject questionnaire, and rigidity measurements. Rigidity measurements were performed by subjects and study physicians with the FastSize EQM using the following procedure.

- (1) After ensuring the IPP was completely deflated, the subject was asked to inflate his device to a point where he thought it would be sufficient for sexual intercourse.

- (2) The number of pumps used to inflate the device was recorded.
- (3) The EQM was turned on by pressing the on/off switch.
- (4) The subject held the EQM unit in their primary hand and pushed the EQM pressure pad on the head of the penis.
- (5) The pressure pad was held for at least 5 seconds.
- (6) The output from the Fastsize EQM was recorded. If penis buckled, the output from the Fastsize EQM as the buckling force was recorded.
- (7) After the measurement was taken, the device was completely deflated.
- (8) The investigator repeated these steps for the investigator measurement of rigidity.

Standard summary statistics were calculated for all study variables. For continuous variables, statistics included means, standard deviations, and 95% confidence intervals for the means when normal distribution assumptions are not violated. Statistical analyses were conducted in SAS version 9.2 or above (SAS Institute, Cary, NC, USA).

3. Results

A total of 17 patients were enrolled in the long cylinders study. Implantation dates ranged from 2/11/2009 to 10/16/2009 with baseline assessment dates from 9/21/2009 to 6/10/2010. All assessments were within the study-specified time range of 90 to 365 days after implantation (minimum 99 days, maximum 309 days, median 208 days). Of the 17 subjects enrolled, one did not meet inclusion criterion #3 (the subject received an implant or revised implant with a Titan IPP cylinder size of greater than or equal to 24 cm within the last year). No implant characteristics, rigidity measurements, or physician feedback data were available for this subject. Only the medical history and subject questionnaire data are available. These results are excluded from the summaries below. The demographic data (age, height, weight, and body mass index) are given in Table 1.

The etiology of ED among the study subjects, as well as presence of and information regarding Peyronie's disease, was noted (Table 2). Within this sample of patients, the most common etiology of ED was post-cancer treatment or vascular disease. Only 19% had peyronie's disease.

Characteristics of the implants placed are described in Table 3. All implants were placed through a scrotal approach. Distal and proximal measurements were not provided in

TABLE 2: General ED etiology and presence of peyronie's disease.

Medical history condition	n/N (%)
Diabetes mellitus	1/16 (6%)
Vascular disease	6/16 (38%)
Pelvic surgery	0/16 (0%)
Pelvic trauma	0/16 (0%)
Post-cancer treatment	5/16 (31%)
Psychological causes	0/16 (0%)
Other	6/16 (38%)
Hypertension	2/16 (13%)
Malfunctioning penile prosthesis	3/16 (19%)
Severe impotence	1/16 (6%)
Peyronie's Disease	3/16 (19%)
Modeling conducted	2/3
Device maintained enough pressure to sufficiently model subject's anatomy	2/3

88% of cases. Cylinder sizes used were primarily 24 and 26 cm (7 patients each size, 44%), with only 2 (12%) receiving 28 cm implants. Rear tip extension was not required for about half of the patients (9/16, 56%).

The physician feedback results are found in Table 4. Most physicians rated the final result as excellent (14/16, 88%), and the remaining two ratings were very good (2/16, 12%). With prior cylinders used, the mean rear tip extension utilized was 3.7 ± 1.4 cm. Only 3 of 16 subjects in this study were revisions patients (all previous implants were Titan). For the two revision subjects with data available on the size of the previous implant: one had a previous implant of 22 cm with 3 cm RTE and a new implant of 28 cm (no RTE); the other had a previous implant of 18 cm with 2 cm RTE and a new implant of 24 cm (no RTE).

Rigidity measurements are shown in Table 5. In general, the physicians performed a greater number of pumps to achieve perceived full inflation ($P = 0.0003$) than the patients and as a result achieved a higher rigidometer reading ($P < 0.0001$) and demonstrated less buckling than achieved when patients inflated the implants themselves.

Results for the subject satisfaction questionnaires are shown in Table 6 (initial implantation) and Table 7 (revisions). Although the number of subjects is small, patients with their first implant reported greater satisfaction than revision patients. However, among the nonrevision patients, a greater percentage did not find the implant soft enough to conceal when deflated. Nonrevision patients reported greater ease of inflation than deflation, as compared with revision patients. All patients (revision and nonrevision) responded with strong agreement or agreement with the statement that they were pleased with the hardness of their erections with inflation; yet, satisfaction, specifically with girth and length when inflated, was more varied among both groups of patients, with some (3/13, 23%) reporting disagreement (dissatisfaction) that the length was adequate, among nonrevision patients.

TABLE 3: Characteristics of implants assessed.

	n/N (%)
Implant approach/technique:	
Scrotal	16/16 (100%)
Infrapubic	0/16 (0%)
Right proximal measurement	
10 cm	2 (12%)
NA ¹	14 (88%)
Right distal measurement	
16 cm	2 (12%)
NA ¹	14 (88%)
Left proximal measurement	
10 cm	2 (12%)
NA ¹	14 (88%)
Left distal measurement	
15 cm	1 (6%)
16 cm	1 (6%)
NA ¹	14 (88%)
Cylinder size	
24 cm	7/16 (44%)
26 cm	7/16 (44%)
28 cm	2/16 (12%)
Right RTE	
None	9 (56%)
1 cm	5 (31%)
2 cm	2 (12%)
3 cm	0 (0%)
Left RTE	
None	9 (56%)
1 cm	6 (38%)
2 cm	1 (6%)
3 cm	0 (0%)
Reservoir size	
100 cc	15/16 (94%)
130 cc	1/16 (6%)

Note: ¹NA: not available; no result given.

4. Discussion

Results have varied among studies evaluating postoperative penile length, both flaccid [8] and erect, [9] and the relation to subjective treatment satisfaction among patients with IPP. Yet, the most common etiology of erectile dysfunction for a patient receiving an IPP is prostate cancer, and both radiation and radical prostatectomy have to be shown to shorten the penis [10, 11].

Various methods that affect patients' satisfaction with penile length following IPP surgery have been studied. These include penile lengthening by circumferential graft at the time of IPP placement [12]; external traction therapy [13]; PDE5 inhibitors and glans injection [14]; girth- and length-expanding cylinders [15]. In addition, surgical techniques, such as release of the suspensory ligament [16] and release of the penoscrotal web [17] have been shown to produce greater

TABLE 4: Physician feedback.

	<i>n/N (%)</i>
Rate final result (5 = excellent, 1 = poor):	
5	14/16 (88%)
4	2/16 (12%)
3	0/16 (0%)
2	0/16 (0%)
1	0/16 (0%)
What device would you have previously used?	
Titan	15/16 (94%)
AMS CX	1/16 (6%)
AMS Ultrex/LGX	0/16 (0%)
AMS Ambicor	0/16 (0%)
What cylinder size?	
21	1/16 (6%)
22	14/16 (88%)
24	1/16 (6%)
What RTE size?	
<i>N</i>	16
Mean \pm SD	3.7 \pm 1.4
Median (Min, Max)	3.8 (2, 7)
95% CI	2.9, 4.4
Revision subject (yes)	3/16 (19%)
Previous device	
Titan	3
AMS CX	0
AMS Ultrex/LGX	0
AMS Ambicor	0
Cylinder size	
18 cm	1
22 cm	1
RTE size	
2 cm	1
3 cm	1

satisfaction with penile length following IPP placement. Since satisfaction is a very important aspect of any method of correcting sexual function, ways to improve patient satisfaction paramount in the treatment of erectile dysfunction.

Traditionally, prosthetic urologists were taught to down-size or use a nonaggressive approach to measuring corpora length for choosing implant sizing, opting to choose smaller lengths when there was any question. This was done to prevent distal erosion with the commonly used semirigid rod implants. However, this is not a common occurrence with IPPs. Thus recently, Henry et al., reported a new length measurement technique that resulted in more patients being implanted with larger cylinders, with satisfaction rates comparable to standard measurement techniques [6]. Longer cylinders may give the patient a more natural appearing penis in erection and in flaccidity, because the RTE length is replaced by more cylinder length. Surgeons are finding that revision subjects are implanted with a larger size than their previous device. This can account for their original device

TABLE 5: Rigidity measurements.

	Patient	Physician
Number of pumps until perceiving full inflation		
<i>N</i>	16	16
Mean \pm SD	30.4 \pm 14.6	44.4 \pm 8.3
Median (Min, Max)	28.5 (9, 58)	44.5 (33, 62)
95% CI	22.6, 38.2	40.0, 48.9
Rigidometer reading (g)		
<i>N</i>	16	16
Mean \pm SD	1500.0 \pm 342.5	1787.5 \pm 212.5
Median (Min, Max)	1600 (800, 2000)	1800 (1400, 2000)
95% CI	1317.5, 1682.5	1674.3, 1900.7
Did the penis buckle?		
No (<i>n/N (%)</i>)	5/16 (31%)	16/16 (100%)
Yes (<i>n/N (%)</i>)	11/16 (69%)	0/16 (0%)

expanding the corpora and creating a dynamic stretch over time, which results in increasing penile length [18].

With the new Titan XL cylinders, the prosthetic surgeon now has the ability to use more cylinder length and less RTE's for patients with the longer penis. The data show that in this prospective multicenter study, this new product can be successfully implanted as there were no infections and all IPPs cycled well at followup. In addition, the surgeons report no problems in implanting the new XL cylinders.

The primary objective of this study was to assess the rigidity of the Titan IPP cylinders ≥ 24 cm using the Fastsize EQM postimplant. Secondary objectives included assessment of subjects' and investigators' perception of sufficient rigidity for sexual function; subject satisfaction via postimplantation questionnaires; revision patients' satisfaction with the new large cylinder device as compared to their previous device; investigators' perception of what device they would have implanted if the large cylinders were not available. The results show that the XL cylinders had great rigidity both objectively using the Fastsize EQM and subjectively by implanting surgeon questionnaire. These two results will hopefully quell the concern that longer cylinders may have too weak axial rigidity for sexual intercourse. Moreover, patient satisfaction rates with the XL cylinders were excellent too.

Limitations to the study were that high-volume surgeons were used in this study and the average urologist may not have the same results. Another is that the patients were not randomized to receive the older version of what would have been implanted versus the new XL cylinders. A third limitation is that there were only 17 patients in the study, but these patients are only occasional, even at high-volume centers. Another limitation is that the study stopped enrolling after 17 patients because the Fastsize EQM was seized by the FDA in 2010 and states "The FastSize EQM Erectile Quality Monitor are misbranded and adulterated because they, among other things, are unapproved and were manufactured under conditions that did not meet current Good Manufacturing

TABLE 6: Satisfaction of initial implantation patients.

How satisfied are you with the following aspects of your implant?	N = 13				
	Strongly agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly disagree N (%)
Overall function	8 (62%)	3 (23%)	2 (15%)	0 (0%)	0 (0%)
Soft enough to conceal when deflated	4 (31%)	4 (31%)	1 (8%)	4 (31%)	0 (0%)
Ease of deflation	4 (31%)	5 (38%)	3 (23%)	1 (8%)	0 (0%)
Ease of inflation	7 (54%)	6 (46%)	0 (0%)	0 (0%)	0 (0%)
Hardness of erection when inflated	11 (85%)	2 (15%)	0 (0%)	0 (0%)	0 (0%)
Girth when inflated	6 (46%)	3 (23%)	4 (31%)	0 (0%)	0 (0%)
Length when inflated	6 (46%)	2 (15%)	2 (15%)	3 (23%)	0 (0%)

TABLE 7: Satisfaction of revision patients.

Compared to your previous implant, how satisfied are you with the following aspects of your new large cylinder implant?	N = 3				
	Strongly agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly disagree N (%)
Overall function	1 (33%)	2 (67%)	0 (0%)	0 (0%)	0 (0%)
Soft enough to conceal when deflated	2 (67%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)
Ease of deflation	1 (33%)	2 (67%)	0 (0%)	0 (0%)	0 (0%)
Ease of inflation	1 (33%)	1 (33%)	0 (0%)	1 (33%)	0 (0%)
Hardness of erection when inflated	1 (33%)	2 (67%)	0 (0%)	0 (0%)	0 (0%)
Girth when inflated	1 (33%)	1 (33%)	1 (33%)	0 (0%)	0 (0%)
Length when inflated	1 (33%)	1 (33%)	1 (33%)	0 (0%)	0 (0%)

Practices (cGMP) requirements.”, and this calls into question the accuracy of this device.

5. Conclusion

The new XL cylinders appear to give the prosthetic urologist the ability to use longer cylinders with apparently good patient satisfaction and great axial rigidity. Prosthetic urologists should feel more comfortable with placing longer cylinders (greater than 22 cm) in terms of minimal buckling when using the new XL cylinders and carefully showing the patient to apply more pumps during inflation.

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Erratum

Erratum to “Streamlined Approach for Infrapubic Placement of an Inflatable Penile Prosthesis”

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With reference to the paper “Streamlined Approach for Infrapubic Placement of an Inflatable Penile Prosthesis”, we want to change in the introduction section paragraph 3 on page 1 to read “our streamlined approach for infrapubic placement of penile prosthesis is a variation of the minimally invasive approach originally published by Perito [1, 2].”

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Methodology Report

Peyronie's Disease: Still a Surgical Disease

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Peyronie's Disease (PD) remains a challenging and clinically significant morbid condition. Since its first description by François Gigot de la Peyronie, much of the treatment for PD remains nonstandardized. PD is characterized by the formation of fibrous plaques at the level of the tunica albuginea. Clinical manifestations include morphologic changes, such as curvatures and hourglass deformities. Here, we review the common surgical techniques for the management of patients with PD.

1. Introduction

Before the times of François Gigot de la Peyronie, men have been plagued with the disfiguring and painful disease eventually known as Peyronie's disease (PD). Curvature develops from the rigid inelastic tunical scar, secondary to macro-/microtrauma in individuals either predisposed genetically or with an underlying disease process of the network of elastic fibers and collagen bundles. This condition causes severe psychological, mental, and physical stress. The pain, erectile dysfunction, and curvature/defect caused by the plaque can prevent proper coitus, potentially resulting in embarrassment and frustration, which may lead to inability to maintain sexual relations.

Despite the attempts to uncover the pathophysiology behind PD, it still remains an enigma. It has an estimated prevalence of 3–9% although its incidence has increased in recent years [1]. This is partly because men are less embarrassed and more willing to come forth for treatment, rather than silently suffer the pain and difficulties associated with PD.

PD can be characterized by two separate phases. The active (acute) phase is characterized by a painful and evolving plaque, inflammation, and progression of the curvature. This usually lasts 6 to 18 months. Approximately 10% of patients will have improvement in their disease. The majority of patients will experience maintenance or worsening of the defect. Once the disease has been stable for approximately

6 months, this is considered the stable (chronic) phase, at which time surgical treatment is appropriate [2, 3].

In the 18th century, de la Peyronie attempted to treat this ailment by recommending mercurial rubs and bathing in the waters of the River Berges [1, 4]. A multitude of minimally invasive therapies currently exist, including but not limited to, vitamin E (Tocopherol), aminobenzoate potassium (Potaba), colchicine, tamoxifen, intralesional injection therapy with verapamil, interferon, and steroids. Medical treatments have been plagued with flawed results, poorly designed studies, and conflicting data [4]. Surgery remains the mainstay in treatment. However, prior to choosing surgical correction of PD more conservative therapies should have been attempted and failed.

Once the surgeon has determined that the plaque is stable and painless a surgical approach can be taken. Surgical approaches in treating PD have also evolved over time. Table 1 summarizes the current treatments available for PD (Table 1). We review the history and modifications that have been developed, including the classic Nesbit and modified Nesbit operation, penile plication, and incision or excision and grafting. The inflatable penile prosthesis is not reviewed in this paper, but it should be noted that for patients with moderate to severe erectile dysfunction, and complicated plaque defects, the inflatable penile prosthesis either in conjunction with other surgical procedures or as a sole method of therapy is most appropriate.

TABLE 1

Reconstructive surgery	Prosthesis with or without grafting or molding
Shortening	
Plication, wedge resection	
Lengthening	
Autologous	
Dermis, tunica vaginalis, buccal mucosa, saphenous vein, temporalis fascia	
Synthetic	
Gortex, silastic, Dacron	
Cadaveric	
Tutoplast (human pericardium) Surgisis ES (porcine small intestine submucosa)	
Xenform (acellular bovine dermal matrix)	

2. Nesbit and Modified Nesbit Operations

In 1965, Nesbit reported his technique for the treatment of congenital chordee [5]. This involved shortening of the longer side of the phallus, thus, the advent of tunical shortening procedures for the treatment of penile curvature was born. Nesbit described making a 5–10 mm transverse elliptical incision of the tunica albuginea on the convex side of the phallus, or approximately 1 mm for each 10° of curvature. This incision was then closed with running nonabsorbable suture.

It was not until 1979 that Pryor and Fitzpatrick applied this technique to the treatment of PD [6]. Since then, this penile shortening technique remains the most popular among urologists, due to its technical simplicity, minimal surgical risk, and quick patient recovery. It has, however, been modified by multiple surgeons.

Rehman et al. also reported their modification to the classic Nesbit operation [7]. In their approach, they used partial-thickness shaving of the tunica in order to avoid bleeding from the incision site. They would then plicate this area with nonabsorbable suture and buried knots.

In 1990, Yachia reported his variation to the classic Nesbit operation by incorporating the Heineke-Mikulicz principle [8]. He made a longitudinal incision in the tunica albuginea, followed by a horizontal reapproximation of the edges.

A number of studies have been performed showing a wide range of patient satisfaction and successful correction of the penile curvature with these tunical shortening surgeries. However, due to the disruption of an intact tunica, and the dissection necessary to expose the area of interest, the Nesbit and Yachia techniques have also been plagued with some degree of erectile dysfunction, increase in patient discomfort, and some reported loss of penile tactile sensation [8]. This led to further modification to the Nesbit procedure and the subsequent development of the Essed-Schroeder technique in 1990.

Essed and Schroeder introduced the simplest way to surgically treat PD. They described shortening the longer side of the phallus by simple plication with nonabsorbable sutures [9]. Without the need to excise or incise the tunica albuginea or excessive dissection and mobilization of the neurovascular bundle, the hypothetical risks of causing venous leak resulting in erectile dysfunction, or causing loss of penile tactile sensation are decreased. However, this procedure was not without its complications, including tunical tearing by excessive force on the suture, pain from bulky knots, and recurrence of curvature. This led to later modification by Gholami and Lue in 2002 who popularized plication surgery for the treatment of PD, with their 16- or 24-dot minimal tension technique, which is currently the most popular and most performed tunical shortening method for the treatment of PD [10].

3. Penile Plication Procedures

With the advent of simple penile plication procedures for the treatment of PD, the armamentarium for treating this condition has grown. The plication technique allows for a rapid and simple surgery, without necessitating dissection of the neurovascular bundle or urethra. It also spares the tunica from being excised or incised, decreasing the morbidity associated with the surgery, and may even be performed under local anesthesia [3].

After the initial introduction of simple penile plication for the treatment of PD pioneered by Essed and Schroeder, there have been a number of modifications to the technique. The initial reports involved shortening the longer side of the tunica albuginea, and applying the necessary amount of stress to the knot required to straighten the phallus, without the need to excise or incise the tunica [9].

In 2002, Gholami and Lue introduced a modification to the original penile plication surgery. Their “16-dot” plication technique allows for distribution of knot tension, making the suture less likely for the suture to tear through the tunica. This also allows less patient discomfort and less episodes of recurrence. They reported that 85% of patients maintained a straight erection over 2.6 years. There was however, some shortening involved, but in only 7% of patients did this cause any functional problems. Twelve percent of patients reported bothersome knots and 11% reported some penile pain with the use of the 2-0 braided, permanent polyester sutures [10].

One of the downsides to the penile plication technique is permanent palpation of the knots, leading to discomfort, focal or erectile pain, and penile induration. This has led to yet another modification, the use of absorbable suture in penile plication surgery.

In 2001, the concept of using absorbable suture was first introduced. Hsieh et al. reported using 2-0 absorbable polygalactac acid (Vycril) suture for their modified tunical plication technique for the treatment of congenital curvature [11]. In a later article Hsieh reported, 81.5% of patients were either very or moderately satisfied with the surgical outcome, with suture-related complications being very rare. At 6-month follow-up, 86% had straight erections or minimal



FIGURE 1

residual/recurrent curvature, well beyond the 8 weeks that Vicryl lasts [12].

At our institution, we have one of the first series utilizing absorbable suture and longitudinal incisions for the treatment of PD [13]. We have incorporated absorbable monofilament 3-0 glycomer (Biosyn) sutures to the 8-dot and 16-dot plication techniques, with resultant correction of the curvature in all patients (Figure 1). In addition to the standard dot plication technique, we favored using longitudinal incisions. In our series of six patients, all report being very satisfied with their surgical results and all have straight erections or minimal recurrent/residual curvatures at 6-month follow-up [13]. A monofilament suture (Biosyn) was used because, as compared with braided suture (Vicryl), the monofilament suture was found to be significantly stronger over 4 weeks of placement, was associated with less local reaction, handled better, and required fewer knots to secure.

Most critics of absorbable sutures state that they result in a higher rate of curvature recurrence, because of the possibility of plication breakdown after suture material has been reabsorbed. When compared to nonabsorbable suture, absorbable sutures have been shown to result in similar suture failure rates, likely secondary to tissue cut-through of the tunica. Basiri et al. compared plication using absorbable Vicryl suture versus nonabsorbable nylon suture. Both groups had some mild recurrence of curvature and had high-success rates, but patient satisfaction was found to be higher in the Vicryl group because the occurrence of palpable knots was lower in the Vicryl group [14].

Despite multiple advances in penile plication procedures, its applicability to PD is still limited. Those with complex deformities such as hourglass deformities, lateral indentations, or curvatures >60 – 70° may not be appropriately treated with this technique [2].

Since penile plication is considered a tunical shortening procedure, it is not recommended for patients with shorter phallic lengths. Penile shortening has been reported among 41–90% of patients in the literature, but most patients do not report enough shortening to prevent coitus [3]. In a study conducted by Pryor and Fitzpatrick, they reported the majority of patients having shortening of <1 cm. Only

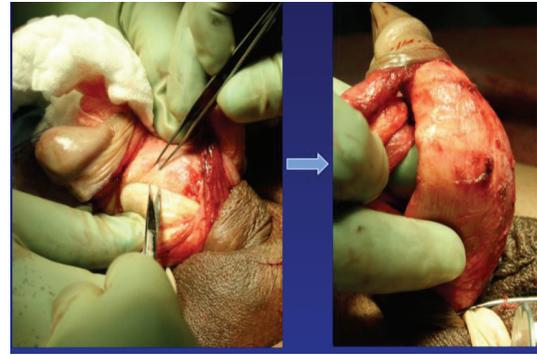


FIGURE 2



FIGURE 3

8.6% reported shortening between 1-2 cm and 4.7% reported >2 cm, but only 1.7% of their patient population reported shortening to the point that precluded sexual intercourse [6]. This possibility leads us to the discussion of the next surgical option for the treatment of PD: the tunical lengthening procedure, and incision or excision of Peyronie's plaque with patch graft.

4. Incision or Excision and Patch Graft

Patients with good erectile function with complex curvatures, those with $>60^\circ$ defects, destabilizing hinge defects, and/or shorter phallus, the ideal treatment choice is incision or excision of the plaque and patch grafting. In 1950, Lowsley and Boyce first reported performing plaque excision and grafting with fat for the treatment of PD [15]. Unfortunately, they did not report on follow-up, but this development led the way to the tunical-lengthening procedure for the treatment of PD.

A number of different graft materials have been used over the past decades, and the search for the ideal graft—readily available, pliable, inexpensive, nonthrombogenic, and resistant to infection—has yet to be discovered. Grafts can be divided into three groups: autologous, synthetic, and nonautologous (Table 1).

Autologous grafts include dermis, vein, tunica vaginalis, temporalis fascia, and buccal mucosa. They have the advantage of causing less inflammatory reaction and lower potential for wound infection as compared with synthetic

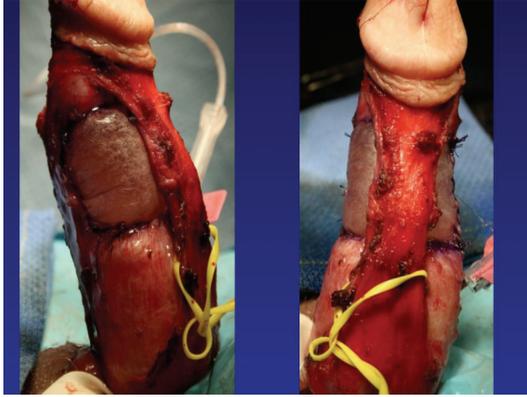


FIGURE 4

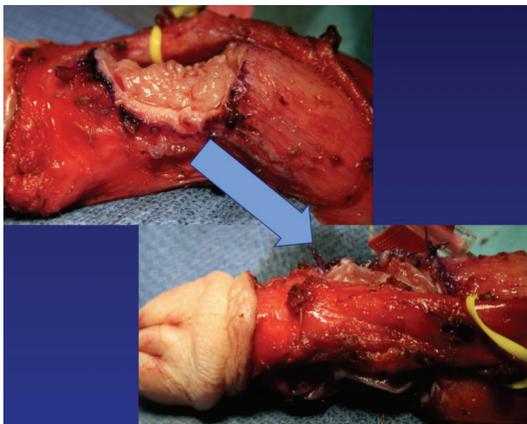


FIGURE 5

nonautologous grafts. Unfortunately, autologous grafts are associated with higher surgical morbidity and increased surgical time, because a separate incision has to be made and the graft tissue harvested. This can lead to infection and pain at the graft site.

There have been many studies involving the use of vein grafts for the treatment of PD, especially when patients have more complex anatomical abnormalities. Studies have shown that using a venous graft allows for better elasticity and durability. The vascular endothelium of the graft provides a more physiologically compatible tissue. Usually, the saphenous vein is used because of its ease in harvesting, large surface area providing sufficient length and width, and, when compared to other vein-grafting sites, lower morbidity [16]. Hypothetically, when comparing venous graft (autologous tissues) to synthetic grafts, there are a number of benefits to choosing the former. Synthetic grafts tend to be less elastic, can potentially cause a local inflammatory response, and have a higher potential for wound infection.

Patch grafts for PD using venous tissue have historically had high patient satisfaction and penile straightening rates, upwards into the 90%, especially within the first 12 months. Interestingly, long-term follow-up shows a decrease in satisfaction and straightening. Kadioglu et al., reported their experience with 145 patients, with a mean follow-up of 41.7

months. Only 75.7% reported “completely straightened” penile curvature, while the other 12.8% had less than 20°, and 11.4% reported curvatures >20° residual curvature [17].

Synthetic grafts are no longer recommended because of increased risk of infection, allergic reaction, enhanced inflammation causing fibrosis, and higher rates of contracture [2]. In a study comparing the classic Nesbit, modified Nesbit, and plaque incision and grafting with synthetic grafts, Licht and Lewis reported poor patient satisfaction with synthetic grafts [18].

Nonautologous grafts include pericardium, dermis, fascia lata, dura mater, and porcine dermis. These are divided into two groups: allografts and xenografts. Currently, the two most popular nonautologous xenografts are bovine pericardium and porcine small intestinal submucosa grafts. These two grafts have the advantage of reducing morbidity associated with harvesting of an autologous graft and decreased hypothetical risk of transferring prions and other infectious processes associated with allografts. Serefoglu and Hellstrom compared dermal, pericardial, and small-intestinal submucosal (SIS) grafting, showed similar satisfaction rates and penile curvature correction rates [2]. However, porcine SIS grafts and (human and bovine) pericardium, both, may not be accepted in certain patient populations, for religious reasons.

Plaque incision involves initial evaluation in the operating room with an artificial erection, followed typically by a circumcising incision and degloving of the penis. If a ventral plaque is easily accessible via a direct ventral incision, this can be performed longitudinally over the plaque. Next, the neurovascular bundle is dissected off the tunica albuginea within Buck’s fascia, with sharp dissection when necessary (Figure 2). Many different incision shapes have been attempted, including but not limited to, an H-shape or “Mercedes-Benz” shape. If larger or calcified plaques are encountered, then an excision of the plaque is performed (Figure 3). The graft is cut 20% larger than the measured defect. The graft is sutured to the tunica albuginea with separate running, locking (or nonlocking) 3-0 or 4-0 polydioxanone suture (Figure 4). An artificial erection is again utilized to assess sufficient correction of the curvature (Figure 5). If necessary, additional plications can be used opposite the graft to improve any residual curvature, or if the curvature is large, a second incision and graft can be utilized. Lastly, Buck’s fascia and skin are closed [1].

The “Achilles Heel” of plaque excision or incision and patch grafting has always been worsening erectile dysfunction because of the more extensive dissection and tunical manipulation necessary. For this reason, proper preoperative erectile function evaluation should be undertaken. This includes history and physical, standardized erectile function questionnaires, and possibly intercavernosal injection with Doppler ultrasound examination to assess for arterial insufficiency, venous leak, and evaluation of the plaque.

Interestingly enough, even with penile lengthening procedures, such as incision or excision and grafting, a proportion of patients still subjectively report a significant decrease in penile length. Some studies report a 35% rate of subjective penile shortening. In 2000, Montorsi et al. objectively

reported regarding patient penile length after excision and patch grafting. At 32-month follow-up they noted no change in mean penile length postoperatively, when compared to preoperative length. Regardless, up to 40% of patients still reported subjective shortening [19].

In 1997, Licht and Lewis compared the classic Nesbit, modified Nesbit, and tunical incision and grafting procedures [18]. They showed the greatest amount of satisfaction and lowest erectile dysfunction rate in the group of patients having the modified-Nesbit technique. They also reported the highest rate of phallic shortening in the classic and modified Nesbit groups, but noted that most patients were not bothered by it as long as they were counseled preoperatively [18]. These results are consistent with more contemporary series satisfaction rates that range 67–100% with modified Nesbit procedures [1].

In 2008, Kim et al. reported a study comparing tunical plication versus plaque incision and saphenous vein grafting [20]. At 1-year follow-up there were no statistically significant differences when comparing penile straightening, overall patient satisfaction, erectile pain, and penile shortening in the two groups. The penile plication group did however complain about palpable sutures, but most reported that this was not a significant concern. The incision and graft group reported some loss of sensation. The biggest complaint was loss of erectile rigidity, making intercourse less likely among patients having incision and graft. Operative times also differed greatly, 71 minutes for the plication group versus 234 minutes for the plaque incision and vein-grafting group [20].

5. Conclusion

To date, there is no high level of evidence-based data to suggest, which is the best surgical treatment of PD. The perfect treatment choice must be determined by a two-way conversation between the urologist and the patient, keeping in mind the severity of disease, patient preference, and surgeon comfort. There have been studies comparing the different surgical modalities, but the results have not been consistent. A major pitfall includes a lack of standardized training regimens throughout teaching facilities. Moreover, due to the specialized nature of this pathology few providers the morphologic deformities associated with PD.

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Research Article

Subarachnoid versus General Anesthesia in Penile Prosthetic Implantation: Outcomes Analyses

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The leading patient complaint during the perioperative period for penile prosthesis implantation is postoperative pain, while emesis and urticaria also affect the procedure's perceived success. In analyzing surgical outcomes, assessment of the anesthetic for postoperative pain and side effects should be included. This paper retrospectively reviews 90 consecutive, primary inflatable penile prosthetic operations performed by a single surgeon at one private medical center. Fifty-seven patients were included in final analysis. Patients who had more than one procedure that day or who used chronic pain medication were excluded. The type and amount of each drug used for each respective side effect (within the first 24 hours after procedure) were compared to determine relative benefit. Twenty patients received general anesthesia (denoted herein as "GA") and 37 received spinal (or also known as subarachnoid) anesthesia (denoted herein as "SA"). Patients receiving GA had significantly greater ($P < 0.0001$) occurrence and amount of intravenous pain treatment than those receiving SA. Patients with SA required less intravenous pain medication and less treatment for nausea/emesis.

1. Introduction

Penile prosthetic surgery has undergone significant changes since its introduction in the 1970's and it is now considered a safe and effective method of treating end organ failure impotence. As established by Pearman, an early leader in research in the field of surgical erectile dysfunction, impotence is defined as the inability to gain or maintain an erection sufficient to sustain satisfactory intercourse due to pathology or deformation of the penis [1]. The history of modern surgical treatment for erectile dysfunction began with the development of the inflatable penile prosthesis by Scott in the 1970s [1]. The popularity of inflatable penile prosthetics has increased since, and as the early designs yielded high failure rates, multiple revisions to the design and material have taken place. Current penile prosthetic implantation procedures prove to be both reliable and durable, with

approximately 18,000 devices implanted annually worldwide [2]. With increased social awareness regarding erectile dysfunction, it appears there will be significant increases in penile prosthetic implantations in the future.

In the past, postoperative complications of penile prosthetic surgery included, but were not limited to, infection, mechanical failure, device migration, sizing issues, and patient dissatisfaction. As penile prosthesis surgery remains elective, patient satisfaction is of paramount importance. In the immediate postoperative period, patients judge the success or failure of their implant surgery, in part, by the extent of postoperative pain. Prior studies have shown that patients have disparate views of their surgical experience which can be attributed to the type of anesthetic administered [3–13]. In an effort to resolve this disparity, we performed an outcome analysis of general anesthesia versus subarachnoid anesthesia to evaluate side effects of penile prosthesis implantation in

the immediate postoperative period. Many of these data endpoints are being reported for the first time in the literature as they pertain to surgical treatment of erectile dysfunction/penile prosthesis implantation.

We evaluated immediate postoperative pain, urticaria, and nausea/emesis between the two major types of anesthesia currently used. Our hypothesis was that due to the drastic evolution of penile prosthetic surgery, coupled with numerous technical improvements, the necessity for GA should be lessened. We contend that not only have these advancements lessened the necessity for GA they have also lessened the status of GA as the preferable anesthetic. It is our opinion that SA may provide improved analgesia for this short procedure while sparing patients the systemic effects of GA.

2. Materials and Methods

A retrospective study was conducted by reviewing medical records for 90 consecutive penile prosthetic implantation procedures which were performed by one surgeon at a private institution. There was no standard anesthetic in existence at this center. All patients provided written, informed consent as approved by the local hospital institutional review board.

We determined *a priori* to exclude all cases that included more than one procedure during the operating room time. In addition, age, race, etiology of impotence, and presence of chronic pain medication usage were noted and evaluated. If a patient had been treated for chronic pain with medication, his records were excluded from the study. Data was collected for only the first 24 hours post-procedure as all patients stayed overnight under observation status. All patients had standardized orders for postoperative nursing care for medical treatment of their pain, nausea, and urticaria. The standard order for urticaria was diphenhydramine (0.5 mg/kg, maximum dose 50 mg). For nausea/emesis in the postanesthesia care unit, the order was ondansetron (0.1 mg/kg, maximum dose 4 mg), whereas on the inpatient ward, the standard order was promethazine (25–50 mg).

For pain in the after anesthesia care unit, with a visual analog scale (VAS) of 4 or greater on a scale of 0 to 10, the standardized order was for hydromorphone (0.5 mg IV, titrated to 2 mg). For the treatment of pain on the inpatient ward, a VAS was used to give oxycodone and morphine as part of the standardized nursing orders.

Data were collected based on each variable for either GA or SA. The side effects observed included urticaria, emesis, and pain. The variables included: operation time, anesthetic time, and the administration of oxycodone, hydromorphone, morphine, promethazine, ondansetron, and diphenhydramine. The medication and dosage used to treat each side effect were recorded in milligrams and the time was recorded in minutes during the postoperative period. Each variable for each type of anesthetic was placed in a spreadsheet and the data were analyzed using Wilcoxon's rank-sum (Mann-Whitney *U*) test and Fisher's exact test.

3. Results

Fifty-seven patients who underwent penile prosthetic implantations were included in the study: 20 surgeries were performed under GA and 37 were performed under SA. There was no significant difference in age (63.1 GA versus 60.8 SA), race, or etiology of impotence (23% diabetic GA versus 31% diabetic SA) between the GA and SA groups.

To determine the efficacy of each type of anesthetic, both operative and anesthesia time were measured. The GA mean anesthesia time was 91.7 minutes, with a standard deviation of 15.82 minutes. The SA cohort mean anesthesia time was 85.3 minutes, with a standard deviation of 15.7 minutes. The GA mean operative time was 35.4 minutes with a standard deviation of 7.4 minutes. Finally, the SA population had a mean operative time of 35.9 minutes with a standard deviation of 8.2 minutes. There were no differences between groups for anesthesia time or operative time ($P = 0.2991$ and $P = 0.9399$, resp.).

Comparisons were made as to whether the patient was treated for nausea/emesis and the specific treatment used for it (medication and dose). The two medications evaluated were promethazine and ondansetron (amount in milligrams). Within the GA sample, the mean doses of promethazine and ondansetron administered were 6.25 ± 13.1 mg and 0.2 ± 0.89 mg, respectively. Within the SA sample, the mean doses of promethazine and ondansetron administered were 7.77 ± 9.48 and 0.11 ± 0.66 , respectively. There was a significant difference in whether or not the patient was treated for nausea/emesis with promethazine and ondansetron between GA and SA ($P = 0.0489$).

To determine whether or not patients experienced urticaria after SA or GA in penile prosthetic implant procedures, the dose (in milligrams) of diphenhydramine was compared. None of the 20 patients receiving GA were treated for urticaria, whereas 14% of the patients receiving SA were treated for urticaria, with 4.73 ± 12.95 mg of diphenhydramine. These results did not reach statistical significance ($P = 0.1041$).

In evaluating whether GA or SA benefited the patient in terms of postoperative pain, the doses of oxycodone, hydrocodone, morphine, and hydromorphone were compared. Data were analyzed by the number of tablets ingested and/or amount of intravenous medications administered. Hydromorphone was administered in the post-anesthesia care unit and morphine was administered while under observation on the inpatient ward. The dosages of oxycodone and hydrocodone were consistent (see Figures 1 and 2). There was no statistically significant difference at a 95% confidence interval ($P = 0.4805$) between anesthesia groups observed for pain which required treatment with oral medications.

The amount of intravenous pain medications administered was compared between GA or SA group with hydromorphone and morphine recorded in milligrams. The GA group required a significantly greater dosage of intravenous treatment for pain, in both the post-anesthesia care unit (hydromorphone) ($P < 0.0001$) and while under observation (morphine) ($P = 0.05$) on the inpatient ward (Figures 1 and 2). Additionally, there was a significant

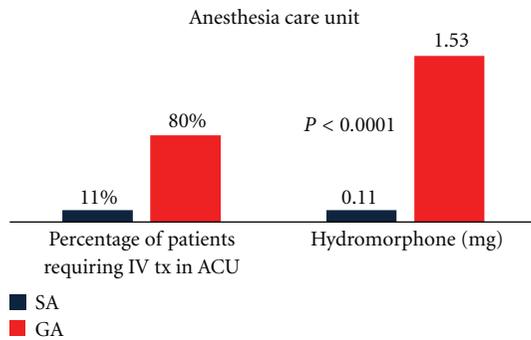


FIGURE 1: Percentage of patients requiring IV Hydromorphone and the dosage amount received by patients in the recovery room: spinal anesthesia in black versus general anesthesia in red.

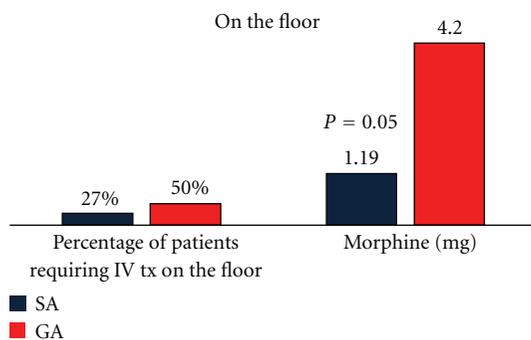


FIGURE 2: Percentage of patients requiring IV morphine and the dosage amount received by patients on the floor in the first 24 hours after surgery: spinal anesthesia in black versus general anesthesia in red.

difference as to whether or not the patients required treatment with intravenous pain medications ($P < 0.0001$).

Adding patients to each group would add credence to the study conclusions. Additionally, anesthesia varies among medical institutions. It remains unclear how these results might be affected by anesthesiologist experience in administering spinal and general anesthetic. It should also be noted that these results were taken from a private institution as opposed to a teaching hospital where SA administration can take considerably longer than GA administration.

4. Discussion

The major complaint of patients undergoing penile prosthesis surgery in the perioperative period is surgical pain [14]. A review of the literature revealed no prior published papers addressing this complaint among patients undergoing an elective procedure where patient satisfaction remains of paramount importance. The overall purpose of this study was to explore the administration of GA and SA in primary penile prosthetic implantation procedures and determine whether there is any benefit of one anesthetic over the other. Previous studies have compared GA versus SA in terms of intraoperative and postoperative outcomes [15–24], with varying conclusions. Our study is the first to compare

outcomes in penile prosthesis surgery; comparisons to existing literature possess limitations due to differences in the procedures which are performed.

Although there was no significant difference in operative or anesthetic time, a difference was discovered regarding need for intravenous pain medications and treatment of nausea/emesis. Of note, the study was done at a private hospital, so the anesthetic time could vary more at an academic setting with students/residents learning SA techniques. The treatment of urticaria trended toward significance, with a greater occurrence with the SA group. While comparing GA and SA in outpatient urological surgery, Erhan et al. [15] found no statistical differences in terms of urticaria (only 2 patients in the SA group) and their results were concordant with ours concerning the use of analgesia in GA group [15].

The question of whether regional anesthesia is better than general anesthesia has been debated since the inception of spinal anesthesia at the turn of the 20th century [16]. Regarding its efficacy, we did not find a significant difference between GA and SA in primary penile prosthetic implantations as measured by operative and anesthesia time. Many studies, including a large number of randomized control trials which assessed the effects of neuraxial anesthesia and analgesia on surgical outcome, have shown specific benefits of regional anesthesia. These benefits have included acceptable postoperative pain management, reduced thromboembolism, decrease in blood loss, and favorable postoperative effects on bowel motility. However, these studies have not consistently shown a difference in the realm of serious, life-threatening morbidity or mortality [16].

One obstacle in proving our hypothesis is that in most studies addressing the efficacy of SA compared to GA the differences in morbidity and mortality between any anesthetic techniques may be subtle. As a result, very large studies involving a multitude of patients would be required to power a comparison study [16]. A meta-analysis submitted by the University of Auckland in New Zealand, in which regional anesthesia was compared to general anesthesia, included 142 separate trials with a total of 9,553 patients. The regional anesthesia groups presented decreased overall mortality in the first month after surgery by approximately 30% (roughly one less death per 100 patients). Moreover they presented reduced incidence of deep vein thrombosis, pulmonary embolism, myocardial infarction, pneumonia, respiratory depression, need for blood transfusion, and post-operative renal failure. The researchers concluded that regional anesthesia is better than general anesthesia with regards to mortality and serious (but not fatal) morbidity [17].

For the benefit of reduced nausea/emesis after GA or SA, our study found a notable difference. Despite advances made in anesthesia, postoperative nausea and vomiting remains a dreaded anesthetic concern [18]. Antiemetic prophylaxis is effective, albeit expensive and is currently not recommended when there is little expectation of postoperative nausea and vomiting [18]. Nausea with emesis in the postoperative period is multifactorial and requires a review of multiple patient risk factors, including pre- and

post-operative variables [19]. Some issues that increase the risk of postoperative nausea include female sex, obesity, prior history of anesthetic nausea, anxiety, opioid administration, use of volatile anesthetic agents, increased duration of surgical procedure, dehydration, and hypoxia [19]. Proper risk stratification may be beneficial in identifying those at risk in order to administer prophylactic antiemetics.

A publication from Segovia, Spain, revealed significant reduction in intra-operative and postoperative nausea and vomiting in patients undergoing Cesarean section who received ondansetron or metoclopramide as compared with placebo [20]. Another study of men undergoing outpatient surgery cites that postoperative nausea and vomiting is perceived to be as debilitating as the consequences of surgery. Ondansetron (4 mg IV) given prophylactically was shown to be effective in the prevention of postoperative nausea and vomiting in the initial 24 hours [20].

Concerning urticaria, though insignificant, there was a trend toward a significant result demonstrating that SA recipients were more likely to experience urticaria. Although severe allergic reactions to medications in any setting are rare, certain patients do have increased sensitivity to injected agents. The importance of a thorough patient history is paramount whenever administering anesthesia. For patients with prior anaphylactic reactions to anesthetic agents, skin prick testing is available and may be used to identify agents responsible for the reaction in an effort to prevent peri-operative anaphylaxis and urticaria [21].

For postoperative pain control, there was a significantly lower requirement for IV pain medications among SA group patients yet there was no significant difference between SA and GA with respect to the administration of oral pain medications. Other studies have also shown that SA can result in less postoperative pain as compared with GA. A pilot study in urological practice was done by Salonia et al., evaluating postoperative outcomes among patients undergoing radical retropubic prostatectomy. In this study, patients with clinically localized prostate cancer were randomized into either a GA or SA group. SA resulted in decreased postoperative pain and faster postoperative recovery and proved to be a safe and effective alternative to GA in this study [22]. In a related clinical trial, researchers from Italy also compared different types of anesthesia for patients undergoing prostatectomy. Although this trial showed no significant improvement in operative conditions, it was found that arterial oxygen levels, gastrointestinal motility, and ambulation were superior in patients given SA. Furthermore, the patients that received SA had less postoperative pain [23]. A study by Gonano et al. compared the efficacy of GA versus SA in patients undergoing total hip or knee replacements. This study revealed SA to be the more effective anesthetic secondary to lower cost for anesthesia and with no appreciable difference in total anesthesia-related times. Additionally, the patients in the SA group reported lower postoperative pain scores in the post-anesthesia care unit [24].

This study is limited by small sample size and inconsistent anesthesia protocols. In addition, the study is limited in that the time spent in PACU was not standardized and that these results may not translate to outpatient (same day

surgery) results. In the author's practice, SA is preferred for overnight observation but is not practical for outpatient (same day surgery) recovery time. The administration of spinal anesthetics, and to a lesser extent general anesthesia, may vary from case to case. Future research should include a prospective, randomized study in which the variables for each type of anesthetic can be controlled. Ideally, we envisage the possibility of a standard general anesthesia protocol for each patient. There might also be a standard protocol for SA to determine whether Duramorph had been administered intravenously or in the subarachnoid space in conjunction with the local anesthetic. Additionally, when comparing side effects experienced after surgery, notation should include what anti-emetic medications may have been administered intraoperatively. The variables in our retrospective study varied with each type of anesthetic and between each patient receiving the different types of anesthetics.

5. Conclusions

Based upon our analysis, there is no significant difference between GA and SA in terms of operative time, anesthetic time, and oral pain medications among the patients who received penile implantations. However, with spinal anesthesia, the patients presented with more urticaria. Conversely, greater amounts of intravenous pain medications and treatment of nausea/emesis medication were necessitated by general anesthesia use.

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Review Article

Contemporary Patient Satisfaction Rates for Three-Piece Inflatable Penile Prostheses

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Among the many treatments for erectile dysfunction, implantation of a penile prosthesis has been associated with high patient satisfaction rates. Specifically, the placement of a three-piece inflatable penile prosthesis (IPP) confers the highest rates of satisfaction. We reviewed the literature over the past 20 years regarding satisfaction rates for penile prostheses, with a focus on patients who had undergone an initial IPP implantation for erectile dysfunction. In all, 194 articles were reviewed, and of these, nine met inclusion criteria for analysis and data collation. We determined contemporary satisfaction rates to reflect patients' experiences with newer products and surgical approaches. Of importance, we noted that varied metrics were used to determine patient satisfaction, and overall satisfaction could not be precisely determined. Nevertheless, we found that patients in general were quite satisfied with their three-piece IPPs and restoration of sexual function. We also identified reasons for patient dissatisfaction and reviewed the literature to find ways by which satisfaction could be improved. Given the various means by which patient satisfaction was determined, future efforts should include standardized and validated questionnaires.

1. Introduction

The placement of a patient-activated inflatable penile prosthesis (IPP) to treat erectile dysfunction has allowed patients to achieve dependable spontaneity for intercourse. As compared with other treatments for erectile dysfunction, including oral medication, transurethral suppositories, injectable medications, and vacuum-assisted devices, patients who have a penile prosthesis have reported the highest satisfaction rates [1–4].

Early satisfaction rates had been determined by physicians' assessments. However, discrepancy has been shown between satisfaction rates determined by physicians and those determined by patients [5]. It is generally thought that patient self-administered questionnaires are more reliable than those administered by a physician. As such, over the past several years, penile prosthesis satisfaction rates have been captured by self-administered surveys. However, relatively few studies have been conducted utilizing validated surveys.

Early satisfaction rates for penile prosthetic implants do not reflect contemporary device improvements or surgical

technique. Indeed, over the years, device manufacturers have modified their penile prostheses to improve device satisfaction and longevity rates. Having evolved from malleable and two-piece penile implants, the three-piece inflatable penile prosthesis reflects the most modern implantable device. The highest patient-reported rates of satisfaction have been associated with the three-piece IPP [6]. The most commonly implanted multicomponent prostheses today are manufactured by two companies: American Medical Systems (AMS, Minneapolis, MN) and Coloplast (Copenhagen, Denmark). We review the literature specifically pertaining to satisfaction rates after three-piece IPP implantation over the past 20 years. Moreover, we investigate if satisfaction rates changed over time, based upon the self-report instruments, new device modifications, improvements in surgical techniques, and realization that preoperative counseling is important.

2. Methods

A Pubmed literature search was conducted using the search terms "penile prosthesis" and "satisfaction", "quality of life",

or “outcomes”. A total of 194 abstracts were identified that noted satisfaction rates associated with penile prostheses. Literature that reported patient satisfaction for initial “virgin” recipients of three-piece IPPs were identified and analyzed.

Articles published more than 20 years ago were excluded, as were those written in non-English language. Articles that did not specify the type of prosthesis implanted, as well as those that grouped self-contained prostheses into their satisfaction analyses, were not considered. Series with less than 30 patients were not included. Articles that included concurrent operations that may have influenced satisfaction, such as release of the dorsal penile suspensory ligament, were also excluded.

3. Results

Nine articles that were published over the past 20 years met criteria for review, such that we might address patient satisfaction rates after initial three-piece IPP placement specifically (see Table 1). All questionnaires used in these studies were self-administered, but only one article determined satisfaction by means of a validated questionnaire.

Bettochi and colleagues from Italy collected information from 79 patients and their partners after implantation of an AMS CX 700 prosthesis [7]. This was a single-surgeon and single-center study for implantations performed from 2004 to 2008. To help eliminate bias, a nine-point questionnaire was administered by telephone by a neutral interviewer. Among the 79 patients, 97% noted frequent use of the prosthesis. Those who did not use it frequently were no longer sexually active. At the time of interview, 85% of patients and 98% of partners reported no problems with the prosthesis. And 79% of patients and 82% of their partners indicated that penile prosthesis implantation led to satisfying improvements in their sexual life, with an additional 13% of patients reporting slight improvements. Of the 8% who were unsatisfied, reported reasons included insufficient rigidity and penile length for normal intercourse. On a note of interest, despite dissatisfaction with the device, four of these six patients said they would still recommend surgery, because they observed an improvement in couple relationship satisfaction. Overall, 97% of patients would suggest this treatment to a friend or relative with erectile dysfunction [7].

Another European study from Natali and colleagues sought to quantify satisfaction with AMS penile implants from 253 consecutive patients at three European centers in Italy and Germany [8]. Satisfaction data were determined by using a self-administered modified EDITS (erectile dysfunction inventory of treatment satisfaction) questionnaire, which is a validated instrument. It should be noted that of the 253 consecutive patients, 53 were lost to followup, and of the remaining 200, 40 had postoperative complications. These patients were excluded, and of the 160 patients without major postoperative complications, 115 returned the mailed EDITS questionnaire, 33 of which had a three-piece IPP implanted. With these limitations in mind, and acknowledging that postoperative complications are lower in the United States, overall patient satisfaction for the AMS 700CX in those surveyed was 97%. Specifically, 67% were very satisfied,

30% were somewhat satisfied, 3% noted neither satisfaction nor dissatisfaction, and 0% reported dissatisfaction; 91% felt that expectations were at least considerably met and 97% were likely to continue using their prosthesis. Furthermore, 91% felt confident in having sex and that their partner was satisfied [8].

Brinkman and colleagues identified 1298 patients who received various virgin three-piece IPPs and randomly sampled 330 patients [9]. These patients’ surgeries were performed by the same surgical team at one hospital between 1992 and 1998. Three types of prostheses were implanted, including the AMS 700 Series, Mentor Alpha 1, and Mentor Alpha NB. Patients were interviewed by telephone using a survey developed by the authors. In all, 248 patients responded to the question: “How satisfied are you with the prosthesis?” Of these, 17 had AMS implants and 231 had Mentor implants. The overall satisfaction rate was 69%, and there were no statistically significant differences among satisfaction rates based on implant type. An additional 11% were neither satisfied nor dissatisfied, 80% would have the implant surgery repeated, and 84% would recommend surgery to others [9].

Carson and colleagues performed a multicenter study regarding the AMS 700CX implantation in men with a mean followup of four years [10]. Seven “frequent implanter” surgeons contributed to this study of patients from 1987 to 1996, which included a telephone survey of 207 men by a neutral interviewer. At the time of the interview, 178 men still had their implant, including 89.7% with a regular sexual partner. Of these, 87.1% were able to generate erections sufficient for intercourse and 79% used it at least twice monthly. In addition, 76.2% of surveyed men were satisfied or highly satisfied with device function, 86.5% would undergo the penile prosthesis implantation again, and 88.2% would recommend an implant to a relative or friend [10].

Montorsi and colleagues studied AMS three-piece IPPs in 200 patients and 120 partners at a mean of 59 months (range 6–130) postsurgery, and they were extensively questioned about function of the device and its impact on the couple’s sexual life [11]. At the time of inquiry, 185 patients (92.5%) were still engaging in sexual intercourse with a mean frequency of 1.7 times per week. Patients and partners reported prosthetic erections as excellent or satisfactory in 98% of cases and 83% of cases, respectively. Postoperative sexual activity was considered excellent or satisfactory in 92% of patients and 96% of partners, respectively [11].

Holloway and Farah looked at 145 patients who underwent implantation of an AMS700 Ultrex penile prosthesis with a mean followup of 42 months [12]. Patient responses to the authors’ questionnaire showed that 85% were satisfied. Overall, 85% had durable and reliable implant function and 86% had a sustained level of satisfaction with the implant. Overall satisfaction with the device reported by the sexual partner was 76% [12].

Goldstein and colleagues conducted a two-phase study based on 434 implantations from seven surgeons from March to October 1993 [13]. Results from implantation of Mentor Alpha-1 three-piece IPPs were studied, with 234 responding to a mailed questionnaire. Satisfaction responses of 80% or

TABLE 1: Summary of studies.

Author	Number of patients	Time of implant placement	Mean followup (yrs)	Satisfaction metrics	%
Bettochi et al. [7]	79	2004–2008	2.8	Frequent use of penile prosthesis	97
				Improvement in sex	92
				Would recommend surgery to others	97
Natali et al. [8]	33	1990–2004	5	Patient satisfaction	97
				Considerably met expectations	91
				Likelihood of continued use	97
				Lack of difficulty in use	91
				Confidence in having sex	91
				Assessment of partner satisfaction	91
				Feels partner wants continued use	97
				Same or improved hardness before ED	100
Brinkman et al. [9]	248	1992–1998	range: 2–8 years	Satisfied	69
				Satisfied or ambivalent	80
				Would have surgery again	80
				Would recommend surgery	84
Carson et al. [10]	207	1987–1996	7.2	Satisfied 4-5 on 5-point scale	76
				Erection suitable for sex	87
				Use at least twice monthly	79
				Recommend to friend/relative	88
Montorsi et al. [11]	200	1986–1997	4.9	Still having sex	93
				Satisfactory erections	98
				Satisfactory sexual activity	92
Holloway and Farah [12]	145	1990–1994	3.5	Overall satisfaction	85
				Sustained satisfaction	86
				Partner satisfaction	76
Goldstein et al. [13]	234	1989–1993	1.9	Fulfilled expectations	89
				Ability to have intercourse	83
				Confidence with intercourse	80
				Device rigidity	84
				Device function	84
				Recommend surgery	86
Garber [14]	50	Pre-1994	1.25	Satisfied with device	98
				Partner satisfied with device	96
				Would undergo procedure again	98
				Would recommend surgery	98
Goldstein et al. [15]	96	1989–1991	2.25	Fulfilled expectations	82
				Satisfaction 9 or better on 12-pt scale	77

greater were noted with regard to intercourse ability (83%) and confidence (80%), as well as device rigidity (84%) and function (84%). Among the respondents, 89% of patients reported fulfilled expectations with the Alpha-1 prosthesis as treatment for their erectile dysfunction [13].

Garber evaluated a series of 50 men implanted with a Mentor Alpha 1 at a mean followup of 15 months [14]. In this study, 98% of the patients and 96% of their partners were satisfied with the device, and 94% and 96% thought the device was easy to inflate and deflate, respectively. All

were satisfied with the girth and rigidity, but only 92% were satisfied with the length; yet 98% said they would undergo the procedure again and would recommend this implant to other patients [14].

Goldstein and colleagues followed 112 patients after implantation of a Mentor Alpha-1 IPP [15]. Surgeries were performed by 12 implanters with varied surgical backgrounds. At a mean followup of 27 months, 96 of 112 surveys were returned and analyzed. Among these patients, 82% stated that the device fulfilled expectations as a treatment for

impotence, and 83% had improved sexual intercourse by 8 weeks after implantation. Patient satisfaction was computed on a scale of 12 equally weighted interrelated variables. Among the patients, 77% recorded nine or more cumulative satisfaction points [15].

4. Discussion

Only one of the nine studies used a validated patient self-reported questionnaire to assess satisfaction rates. The EDITS questionnaire was first validated in 1999 as an instrument by which patients' and partners' satisfaction with treatments for erectile dysfunction could be assessed. This was done in acknowledgement of the subjective nature of patient satisfaction and that it encompassed more than treatment efficacy [16]. Satisfaction rates in articles that met inclusion criteria were self-reported by patients, but the assessment of patient satisfaction across all studies was not standardized. Overall satisfaction rates, satisfaction with the device, satisfaction with sexual relationship postprocedure, willingness to undergo the procedure again, and willingness to suggest implantation to family and friends as a treatment option were different metrics by which satisfaction could be suggested. The Carson et al. and Brinkmann et al. studies obtained all these data and more with excellent satisfaction rates across multiple questions [9, 10]. Because authors' definitions of patient satisfaction were not consistent across studies, as some used graded scales to assess satisfaction while others used single questions to assess satisfaction, total overall satisfaction in this paper cannot be determined. Significant additional limitations to these studies include sampling bias, loss of patients to followup, the varied experience of the prosthetic surgeons, and relatively small numbers of patients surveyed. Nevertheless, all of the studies that met inclusion criteria showed that patients are highly satisfied with implantation as a method of treatment for their erectile dysfunction.

Satisfaction can be affected by many variables. Partners' attitudes may play a role [17] and patient expectations can have a great impact [18]. Poor outcomes requiring explanation and secondary procedures affected responses. For patients who reported being dissatisfied with their IPPs, noted complaints included loss of perceived length [11, 19], poor glandular engorgement [11], report of unnaturalness by partner [20], pain [21], difficulty with pump inflation and deflation [22], partner feelings of dissatisfaction [13], and complications requiring device removal, such as infection or erosion [23]. However, it is not surprising that there were no statistical differences between the two companies' IPP products, as shown in the Brinkmann et al. study [9].

Modifications of the devices and surgical techniques, as well as medication and behavioral therapies, have been developed to address some of these complaints. Prosthetic companies have made improvements in their pump hydraulic systems to allow easier handling and deflation. Modifications in pump and coating characteristics of the cylinders have increased long-term mechanical reliability [24]. The tips of the prostheses have been made softer for a more natural feel during intercourse. Surgical techniques have been described

to maximize penile length. New length measurement techniques (NLMT) used to allow for use of larger cylinders have been described [25]. A ventral phalloplasty technique may increase patients' perception of phallic length [26].

Methods by which satisfaction can be improved after implantation have been described. For patients who complain of cold glans syndrome, oral PDE-5 inhibitors, as well as intraurethral alprostadil suppositories, can be utilized to help with glans engorgement [27]. The use of a vacuum erection device has been suggested to help augment rigidity and engorgement in patients unfit for or unwilling to undergo implantation surgery [28]. Behavioral strategies, including the use of foreplay and different sexual positions, can be used to make intercourse more enjoyable. Sex therapy and counseling can also augment satisfaction after implantation [29]. As the Holloway and Farah study shows, usually the patient satisfaction rates are higher than the partner satisfaction rates; thus, sex therapy and counseling could possibly help partner rates even more than patient satisfaction rates [12].

Of the 8% who were unsatisfied in the Bettocchi et al. paper, the main reasons given were insufficient rigidity and penile length, which some experts feel could be addressed by better instructions on using the pump given to the patient and use of the NLMT, respectively [7, 25]. Moreover, the same could be said for the Garber study where 8% were dissatisfied with penile length. Again, perhaps applying NLMT, which consists of surgeons choosing longer instead of shorter lengths for cylinder and rear tip extenders, may improve satisfaction rates [14, 25]. Natali et al. had 40 or 200 patients with post-operative complications, with improved devices and better surgical techniques that complication rate could be lowered significantly [8]. Therefore, despite already high rates of patient satisfaction rates with IPPs, there are several means by which to pursue even higher rates in the future.

5. Conclusion

Nine studies over the past 20 years show that patients with erectile dysfunction who undergo three-piece IPP placement report high satisfaction rates. Patient satisfaction is clearly affected by many parameters, including patient expectations, partner attitudes, and the presence or absence of surgical complications and premature device failures. By choosing the appropriate candidate for surgery and with careful attention to surgical technique, infection prophylaxis, and post-operative counseling, satisfaction rates can be optimized. Unfortunately, given the variability by which satisfaction rates were assessed in these articles, precise enumeration of overall patient satisfaction could not be determined. However, it is evident that three-piece IPP recipients are generally satisfied with their device and restoration of erectile function. Future efforts to determine patient satisfaction rates should include standardized and validated questionnaires to assess treatment outcomes.

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Research Article

Penile Enhancement Procedures with Simultaneous Penile Prosthesis Placement

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Here we present an overview of various techniques performed concomitantly during penile prosthesis surgery to enhance penile length and girth. We report on the technique of ventral phalloplasty and its outcomes along with augmentation corporoplasty, suprapubic lipectomy, suspensory ligament release, and girth enhancement procedures. For the serious implanter, outcomes can be improved by combining the use of techniques for each scar incision. These adjuvant procedures are a key addition in the armamentarium for the serious implant surgeon.

1. Introduction

Penile length and girth has long been a source of anxiety for men and still is today. Through the ages men have undergone a myriad of different measures for penile enhancement. Historically, holy men in India and Cholomec tribesmen in Peru used weights to increase penile length, while Dayak tribesmen in Brazil allowed poisonous snakes to bite their penises to enlarge them [1]. Men often feel a need to optimize their penile dimensions in order either to improve their self-esteem and or to impress their partners. In the modern era, a significant number of men who have radical surgery will suffer from loss of stretched penile length from 0.5 to 5 cm [1, 2]. Additionally, apparent loss of length occurs in many men as a consequence of weight gain in which the penis is “buried” under the excess skin of a panniculus.

Penile prosthesis surgery is a widely accepted treatment for men with erectile dysfunction refractory to pharmacologic therapy. It is associated with satisfaction rates of greater than 90% [3]. In patients requiring implantation of a penile prosthesis many report that their prosthetic erection is shorter than their former natural erection [1–4]. Different strategies have been implemented in order to increase phallic length. This includes penile rehabilitation such as oral phosphodiesterase-5 inhibitors, muse, vacuum

erection devices, and intercavernosal injections. Several intra-operative techniques such as ventral phalloplasty, corporoplasty, and suprapubic lipectomy have been described as intraoperative techniques to improve phallic length.

Through simple adjuvant procedures, it is possible to maximize the perception of size concomitantly during penile prosthesis surgery. To enhance patient perception of penile length, it is feasible to perform simple procedures that will increase perceived or true penile length. Here we present an overview of various techniques, which improve the surgical armamentarium of the serious implanter.

2. Ventral Phalloplasty

Up to 84% of patients who have undergone successful placement of penile prosthesis often complain of penile shortening [5]. To combat this one may take down the penoscrotal web to enhance patient satisfaction. The use of scrotoplasty has been described in pediatric literature to improve the projection of the webbed variant of inconspicuous penis [5].

By holding the scrotum along the median raphe and stretching it out, one delineates the extent of the penoscrotal web. An Alice clamp may be used to assist in the elevation

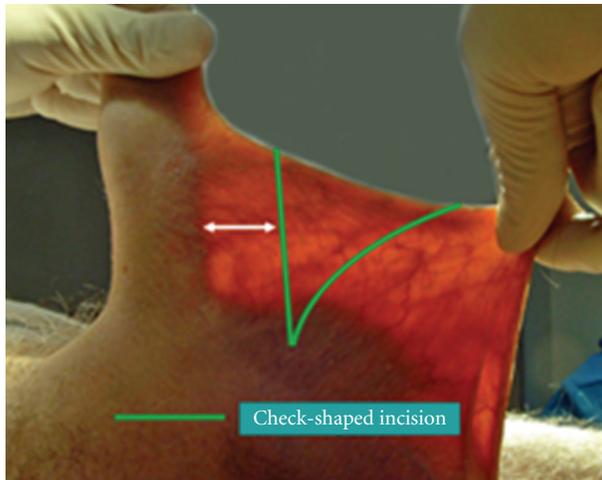


FIGURE 1

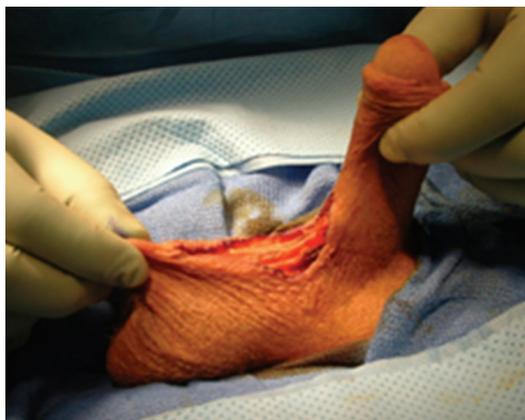


FIGURE 2

the penoscrotal web. One may enhance the dissection by placing a light source behind the web, causing a silhouette on the penile shaft and testicles clearly delineating the extent of the web (Figure 1). A “check mark” incision is marked [5]. Along the Y axis one marks at the incision line with one fingerbreadth's clearance from the shaft allowing for adequate skin closure. This line is carried down to the penoscrotal angle. At this point a convex curve is taken up to the scrotal skin resembling a “check mark” [4, 5]. This skin is removed leaving a diamond-shaped defect in the scrotum (Figure 2). A thick layer of dartos fascia is preserved to ensure adequate healing. The dartos is reapproximated with interrupted stitches along the axis of the shaft. The scrotal skin is brought together with interrupted horizontal mattress sutures (Figure 3).

As reported by our original investigation on a group of 43 patients undergoing phalloplasty and penile prosthesis placement, 84% of patients reported some increased degree of phallic length while 12% reported no significant change in penile length after phalloplasty [5]. Ventral phalloplasty can enhance patient perception of penile length and improve overall satisfaction and can concomitantly be performed during penile implant surgery [3–5]. Release of penoscrotal



FIGURE 3

web is a simple, safe, and reproducible procedure that can enhance patient perception of penile length and further improve satisfaction.

3. Augmentation Corporoplasty

The tunica albuginea is composed of elastic fibers, collagen, and has a wide network of perforating vessels. Corporoplasty is the ability to modulate the tunica albuginea. The most ideal graft should be elastic with minimal resistance and fibrosis. This patch grafting is commonly used in the setting of Peyronie's disease but can be an adjuvant in the setting of penile prosthesis placement.

After placement of a penile prosthesis, several different corporal maneuvers can cause phallic shortening such as incorrect dilation or improper sizing of the penile prosthesis. Additionally, a high riding pump can also have a penile shortening effect. Corporal augmentation is the most direct method of elongating the phallic length. There are three main classes of biological material used for corporoplasty, which include human grafts, treated biological materials, and synthetic materials [6, 7]. Human venous grafting in the setting of corporoplasty avoids a fibrous reaction on the erectile tissue; however, it requires vascular support and therefore cannot come into direct contact with the prosthesis [6]. Additionally, there is patient morbidity associated with the harvesting of saphenous vein or dermis. Austoni et al. have described a method making incisions in the tunica albuginea and suturing a saphenous vein graft material into the created space [6]. Treated biological material such as AlloDerm or Tutoplast has decreased inflammatory activity that promotes natural tissue remodeling, with minimal

fibrosis. There is little to no harvesting, and they are antigen-free with multidirectional collagen fibers yielding excellent tensile strength. Paradiso et al. implanted SIS in several penile prosthesis patients that demonstrated rapid attachment with minimal fibrosis and improved penile lengthening [8]. Various series have reported the use of synthetic products such as Gore-Tex or Silicone [6, 7]. However, the complication rate following penile grafts of these synthetic materials is high and includes a greater risk of fibrosis and the absence of elasticity. While synthetic graft always produces macrophage activity followed by intense fibroblasts activity, we favor pretreating our patients with vacuum erection device and intraoperative corporal molding at the time of penile prosthesis. In the setting of penile prosthesis placement, the implementation of these products can be a tricky. The use of biological material for corporoplasty requires more experience before it can be widely used in clinical practice.

In patients with corporal fibrosis, Wilson et al. reported on the use of downsizing the penile prosthesis cylinders, which were then used as tissue expanders in patients [7]. During a 12-month period of intracorporal stretching, the patient was instructed to inflate the prosthesis for up to 3 hours a day. The resultant expansion of an average 2.2 cm was noted. The newly molded intracorporal cavity allowed for the subsequent placement of wider and longer implants [7]. While this sound enticing, it subjects the patient to yet another surgery, which can be simply avoided with the use of a preoperative vacuum erection device along side judicious intraoperative prosthesis oversizing.

4. Suprapubic Lipectomy

Apparent loss of length occurs in many men as a consequence of weight gain, in which the penis is buried under the excess skin of the panniculus. There have been a variety of techniques described for the treatment of buried penis. The surgical technique for buried penis was first described by Horton et al. [9]. Initially, the suprapubic fat is excised with release of the suspensory ligament of the penis and dartos fascia. At this point, the suprapubic skin is secured to the rectus fascia [9]. Recently, panniculectomy with suction-assisted lipectomy and anchoring of herniated pubic skin to the abdominal wall has been utilized with satisfactory results. The technique includes preoperative marking of the patient in the standing position as the landmarks of resection and amount of pannus to be removed become obscured in the supine position (Figure 4). The suprapubic area and lower abdomen are then infiltrated with tumescent solution. Suction lipectomy is performed (Figure 5) in this area with care to protect the testicles and spermatic cords. Next, the panniculectomy is performed (Figure 6). The suspensory ligament may be separated if indicated. After excision of excess skin and fat, the pubic skin and base of the penis are sutured to the rectus fascia. The wound is then closed in a layered fashion over a drain (Figure 7). Postoperatively, a pressure garment may be worn for 4–6 weeks [10]. Other techniques described in literature include Z plasties with circumcision, release of dartos tethering bands, pedicled



FIGURE 4



FIGURE 5

preputial flaps, and/or split-thickness skin graft to the penile shaft with vacuum-assisted closure negative pressure dressing [11]. Addressing this issue in patients involves the coordination and planning between the plastic surgeon and urologic surgeon. Each patient will require a personalized plan and may require a modification of or combination of any of the above-mentioned procedures [11]. For the serious implanter, this can be challenging, but in a team setting along side the plastic surgeons this technique can increase patient satisfaction. Suprapubic lipectomy can give the morbidly obese patient an improved sex life safe and feasible in the team setting.

5. Suspensory Ligament Release

The penile suspensory ligament is composed of the suspensory ligament and the arcuate ligament. The ligation of the penile suspensory ligament permits the penis to drop into a more dependent position. This gives the patient a perceived gain in phallic length; on average this procedure adds 1 cm of flaccid penile length. The technique most commonly used



FIGURE 6



FIGURE 7

for releasing the suspensory ligament is in combination with an inverted V-Y skin plasty; however, V-Y half-skin half-fat advancement flap and T closure have also been reported [11]. After ligation, it is essential that a weight or stretch device be used as failure to do so can lead to reattachment of the ligament and possible decrease in phallic length [12, 13]. Average length gained in certain series was 2.4 cm with motivated patients gaining up to 3.2 cm [12, 13]. Insertion of a silicone buffer has been reported, and the placement of this spacer is used to prevent reattachment [13]. Borges et al. performed suspensory ligament release in 303 patients at the time of penile prosthesis placement. They report a 93% satisfaction with penile prosthesis performance and penile length. Additionally, they demonstrated that none of their patients reported penile shortening [14]. The release of the suspensory ligament is a quick simple procedure with minimal patient morbidity that is another tool for the serious implanter to gain penile length during concomitant penile prosthesis placement. Alongside the risk of reattachment this adjuvant procedure may mean a second incision if penile prosthesis placement is performed from a penoscrotal approach.

6. Girth

Various materials have been tried to increase phallic girth that include but are not limited to paraffin, mercury, silicon, petroleum jelly, stone, and cod liver oil [14]. These materials can cause foreign body reaction, scarring, deformity, and

sexual dysfunction. We do not recommend their use with concomitant penile prosthesis surgery. Recently, Al-Ansari et al. reported on the application of a thigh flap with a vascular pedicle from the superficial circumflex iliac artery as a means to increase in penile girth through augmentation [15]. They noted an 8 cm increase in erect girth after augmentation [15]. While this surgery is a monumental reconstructive effort, it creates considerable increase in girth. However, the thigh flaps come at a high price to the patient with risks of graft loss and wound infections, and this would obviate the need for revision which is especially grave in the setting of a penile prosthesis. For the serious implanter, this technique may be of benefit; nonetheless, the risk benefit ratio is one to be questioned. We would not routinely recommend this technique unless the implanter is comfortable with safely mobilizing the vascular flap.

More recently, autologous tissue engineering and biodegradable scaffolds have been used as a new option to increase penile girth. After cells are harvested and cultured on a pretreated tube shaped, it is transplanted between dartos and Buck's fascia. Reports have shown an average gain in girth ranging from 1.9 to 4.1 cm [16]. More prospective controlled analyses are needed to help protocolized girth enhancement techniques. While many of these practices have yet to reach the mainstream, this is a future avenue for penile prosthesis placement in patients who lack girth.

7. Conclusions

With an estimated 20,000 penile prosthesis placed every year, the potential for actual and perceived loss in penile length is apparent [17]. The implementation of simple adjuvant surgical procedures may increase phallic length. These techniques increase patient satisfaction when performed in concert with penile prosthesis placement and promote the perception of increase phallic length. Over the years, multiple surgical approaches have been suggested to facilitate this difficult situation. Approaches include ventral phalloplasty, augmentation corporoplasty, suprapubic lipectomy, and suspensory ligament release. At this time we do not recommend routine implementation of girth enhancement during penile prosthesis placement due to lack of protocolized enhancement techniques. For the serious implanter, outcomes can be improved by combining the use of techniques for each scar incision, for example, performing a suspensory ligament release during an infrapubic penile prosthesis placement. Surgical strategies like upsizing prosthesis and intraoperative molding, alongside suspensory ligament release, phalloplasty, or suprapubic lipectomy must be kept in mind as adjuvant procedures in the different approaches to the placement of penile prosthesis.

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Research Article

Outcomes of and Satisfaction with the Inflatable Penile Prosthesis in the Elderly Male

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Objective. To determine the outcomes of and satisfaction with the multi-component inflatable penile prosthesis (IPP) in the elderly male (age >71). **Methods.** Using a chart review and telephone survey, we retrospectively assessed patients who underwent IPP or combined IPP/artificial urinary sphincter (AUS) from 2004–2006. **Results.** We identified 56 patients that underwent IPP (48) or IPP/AUS (8). The age range was 71–86 (mean 74.3) at the time of surgery, with a follow-up range of 0.5–2.4 years (mean 1.5). The overall complication rate was 3.8% (2 of 56) with one device removed for infection and a second patient requiring exploration for a postoperative hematoma. The telephone interview was conducted with 35 of 56 patients. Patients rated ease of use (a scale from 1–5, 5 meaning very easy) and overall satisfaction (a scale of 1–5, 5 meaning very satisfied) at an average of 4.1 and 4.3, respectively. IPP usage varied from 0–7 times per month (mean 3.3). 32 of 35 patients (91%) said they would undergo the procedure again. **Conclusion.** Our review demonstrates that the IPP is well tolerated in the elderly male population, who report a high degree of satisfaction and ease of use with this device.

1. Introduction and Objective

Erectile dysfunction is highly prevalent in our society and this prevalence will increase with age. Life expectancy continues to increase with US men now living greater than 75 years [1]. It is estimated that up to 70% of males aged 70 have erectile dysfunction. The advent of oral phosphodiesterase type 5 inhibitors has allowed many men to regain normal sexual function and has placed the treatment of erectile dysfunction at the forefront of men's health issues. When conservative therapy fails or when patients are not candidates for oral therapy, the multicomponent inflatable penile prosthesis (IPP) remains the gold standard of treatment. The safety and efficacy of the IPP has been well documented, but in spite of this, urologists may be reluctant to offer an IPP to older patients due to various concerns, including those regarding impaired dexterity of older patients and their ability to operate an inflatable device. There is little published data specifically examining results of the IPP in elderly men. The objective of this study was to determine the outcome and

satisfaction of the inflatable penile prosthesis in the elderly male (age >70 years).

2. Methods

We conducted a single-center, two-phase analysis of patients over age 70 that underwent either IPP or combined IPP/Artificial Urinary Sphincter (AUS) from 2004 to 2006. All patients received routine preoperative counseling regarding risks, benefits, and realistic expectations of the surgery. Preoperative medical clearance was obtained if deemed necessary by the surgeon. All penile implants were from the AMS 700 series with Inhibizone and tactile pump. Our routine is to administer intravenous cefazolin preoperatively and perform a 10-minute surgical prep with betadine. However, since conclusion of this study, we have modified our surgical prep to chlorhexidine gluconate due to its recently proven superiority to povidone-iodine for surgical site antisepsis [2]. All implants were performed by a single experienced

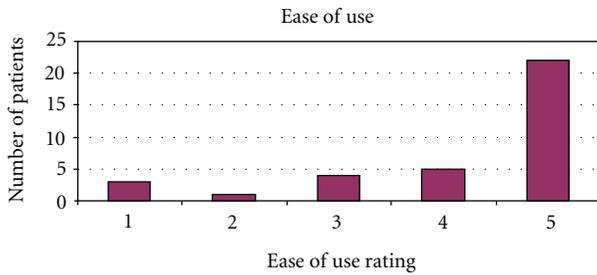


FIGURE 1

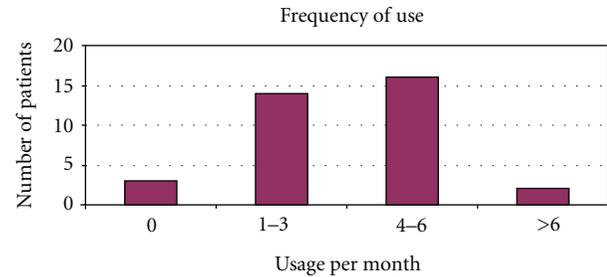


FIGURE 3

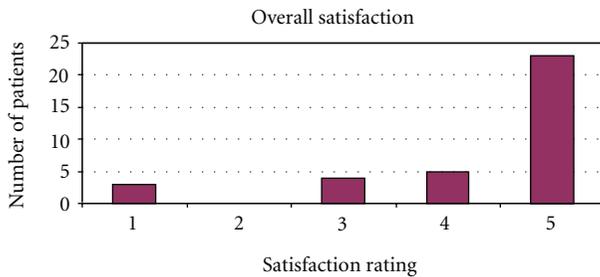


FIGURE 2

prosthetic surgeon (LAJ). The initial phase consisted of a retrospective chart review and data collection with regards to patient age at implantation, type of surgery (IPP or dual IPP/AUS implantation), length of follow-up, and complications. The second phase involved a voluntary telephone survey conducted by a neutral party to assess ease of use and overall satisfaction (see the Appendix).

3. Results

We identified 56 men that underwent either IPP (48) or IPP/AUS (8). Age ranged from 71 to 86 (mean 74.3) years of age at time of surgery. The postoperative follow-up range was 0.5–2.4 years (mean 1.5). In this group of patients, one device (IPP only patient) was removed for infection 8 months after implantation (infection rate 1.7%). Another patient had a postoperative hematoma requiring exploration, resulting in an overall complication rate of 3.4% (2 of 56). The telephone interview was performed on 35 of the 56 patients for a response rate of 62%. One patient had died and the remaining patients were unable to be contacted resulting in a nonresponse rate of 38% (21 of 56). No patient declined participation. Patients rated ease of use (on a scale from 1 to 5, with 5 meaning very easy to use) at an average of 4.1 (Figure 1) with difficulty inflating the device cited as a particular issue impairing use. Patients also rated overall satisfaction (on a scale from 1 to 5, with 5 meaning very satisfied) at an average of 4.3 (Figure 2). 28 of 35 patients (80%) rated their overall satisfaction 4 or 5. 32 of 35 patients (91%) rated their overall satisfaction 3 or higher. The most common complaint was dissatisfaction with penile length, reported by 3 of the responding patients, which is a complaint consistent with other previously published studies

in the urologic literature [3]. Patients reported frequency of use of the IPP at 0–7 times per month (mean 3.3) (see Figure 3). 32 of 35 patients (91%) said that they would choose to undergo the procedure again. Those declining noted poor rigidity (2) or partner dissatisfaction (1). 29 of 35 patients (83%) stated that they would recommend this procedure to a friend.

4. Discussion

The safety and efficacy of the IPP has been well documented with long-term follow-up. Carson and associates from the AMS 700 CX study group evaluated patient satisfaction outcomes in 372 men [4]. They found that at a median follow-up of 47 months, 79% used their prosthesis at least twice monthly and that 88% would recommend this procedure to others. The mean age of their population was 57.6 years. Levine et al. reviewed 131 men with a mean age of 56.8 years implanted with the 2-piece Ambicor inflatable penile prosthesis [5]. They report an overall satisfaction rate 90% of patients and 82% of partners using the Erectile Dysfunction Inventory of Treatment (EDITS) questionnaire. 93% of their patients and 90% of partners would recommend the implant to others. A prospective approach using pre- and postoperative EDITS as well as IIEF scores was by Mulhall and colleagues who evaluated 96 men with a mean age of 56 years [6]. They confirmed statistically significant improvement over baseline in both inventories at 12 months after IPP placement.

There are additional studies that support the overall efficacy of the IPP, but there is little that examines this issue exclusively in an elderly population. This is an important issue considering the continual increase in life expectancy and a sense that longevity should be accompanied by quality of life. Due to increasing life expectancy, the population of Americans aged 65 years or older is anticipated to double in the next 25 years [7]. As a result, we anticipate a significant increase in the number of elderly men seeking penile prosthesis implantation. Lindau et al. recently reported that elderly couples remain sexually active even into the eighth decade of life [8]. The mean age of patients in our study was 74.3 years at the time of surgery and no patient younger than 71 years old was included. Most previous studies have examined populations with an average age in the 1950s, though Goldstein and associates examined Mentor Alpha-1 prostheses in a population with a mean age of 61 in whom

89% “had fulfilled expectations” [9]. O’Connor et al. recently evaluated a group of elderly men (above age 75) who had undergone implantation of the artificial urinary sphincter and found overall success with satisfactory results in terms of continence, complications, and longevity of the device [10].

In general, results in this elderly cohort are comparable to those of younger patients. Our infection rate and overall complication rate, 1.7% and 3.4%, were low and comparable to others reported in the general population [11]. The previously cited paper by Levine notes a 7.6% complication rate, though with longer follow-up of 43 months. The decreased dexterity of elderly patients or other comorbidities such as arthritis and neuropathy might be of concern when choosing an IPP as opposed to a malleable implant. This is certainly a reasonable concern, but the average score of 4.1 (scale of 1–5, 5 being easiest) for ease of use demonstrates that age alone should not favor a malleable device over an inflatable one. Patients should be honestly evaluated based on their current functional status. Overall satisfaction was also high, with an average score of 4.3 (5 being the most satisfied), and this satisfaction was evident in the frequency of implant use. Dissatisfaction due to subjective loss of penile length was reported by 3 of 35 surveyed patients. The previously referenced study by Deveci et al. evaluated penile length alterations after penile prosthesis surgery and did not note a negative impact on stretched penile length following surgery in their cohort [3]. In fact, despite any evidence in penile length alteration, >70% of men in their study had subjective loss of penile length. We use traditional sizing and corporeal dilation techniques at the time of IPP placement. It is our practice to counsel the patient extensively regarding the anticipated appearance and function of the penis after prosthetic implant, and as a result, we find that patients with complaints of loss of penile length are in the minority. The frequency of implant use ranged from 0 to 7 with a mean of 3.3 times per month, comparing favorably with the younger group evaluated by Carson et al. where 79% of the patients used their device for intercourse at least twice monthly. For comparison purposes, about an equal percentage (86%) of our older population used their IPP at least twice monthly. Direct comparison between this group of patients and younger groups is difficult for several reasons. We used a telephone survey which lends itself to brief encounters and therefore involves a simple but invalidated instrument instead of longer validated ones such as the IIEF or EDITS. We are also keenly aware of the biases that accompany a survey. The 38% nonresponse rate may bias the results towards increased satisfaction and more positive results. Furthermore, though differences in patient satisfaction and ease of use between patients undergoing IPP compared to those undergoing dual implant (IPP/AUS) may exist, our limited sampling of patients undergoing dual implant precluded us from adequately assessing for this potential confounder. Nevertheless, we have demonstrated that even in an elderly population, the IPP is very safe and met with a high degree of patient satisfaction. Future evaluation in a prospective manner with validated instruments will further solidify this conclusion. Prospective evaluation of the partners of these elderly men would also be a valuable

addition to the body of literature and would aid in better counseling of elderly patients.

5. Conclusions

Implantation of the inflatable penile prosthesis should not be avoided in elderly males based solely on the age of the patient. Our paper demonstrates that the IPP is well tolerated in this patient population, who report a high degree of satisfaction and ease of use with this device.

Appendix

IPP Questionnaire

(1) Ease of use:

How would you rate the ease of use of the IPP on a scale from 1 to 5, with 1 being very difficult to use and 5 being very easy to use.

(2) Overall satisfaction:

How would you rate your overall satisfaction with the IPP on a scale from 1 to 5, with 1 being very unsatisfied and 5 being very satisfied.

(3) Frequency of use:

How often would you say that you are using the IPP on a monthly basis?

None, 1–3 times, 4–6 times, or greater than 6 times

(4) Would you recommend the IPP to a friend?

(5) Would you undergo this procedure knowing what you know now about the IPP?

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Methodology Report

Streamlined Approach for Infrapubic Placement of an Inflatable Penile Prosthesis

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The streamlined approach for infrapubic placement of an inflatable penile prosthesis is a variation of the traditional infrapubic approach. A better understanding of operative techniques and recent clinical outcome studies have led to an evolution of the original infrapubic approach. Small incisions and efficient operative maneuvers can shorten operative times and expedite postoperative recovery.

1. Introduction

The penile prosthesis is the gold standard of treatment for men with erectile dysfunction (ED) refractory to more conservative therapy [1]. Placement of the inflatable penile prosthesis (IPP) has been reported from several different approaches including penoscrotal, infrapubic, suprapubic, and perineal locations [2–4]. Each approach has its own unique advantages and disadvantages and it is ideal that any surgeon performing penile prosthetic surgery has some familiarity with at least a few of the approaches. Oftentimes, unique patient anatomy or previous surgery can make one approach more difficult, or easier, over another. The penoscrotal (PS) technique is currently the most popular approach with approximately 80% of IPPs placed in this manner based on manufacturer data [5].

Historically, the suprapubic approach was the initial approach for IPP placement [2]. Large incisions were required to bury the tubing under the fascia to prevent kinking and malfunction. The development of kink-resistant tubing was one of the major advancements for IPP surgery allowing for smaller incisions and more options for surgical incision sites. The infrapubic approach (IP) was a natural transition to a less invasive approach utilizing the same principles and orientation of the suprapubic approach. The penoscrotal approach was developed shortly thereafter. It offered the advantages of close proximity to the corpora, visualization for placement, and fixation of the pump in

the scrotum and less concern for damaging the penile neurovascular bundle. However, the PS approach made reservoir placement more difficult raising the potential risk of reservoir herniation postoperatively [6].

The streamlined approach for infrapubic placement of a penile prosthesis is a variation of the traditional IP approach. This approach utilizes smaller incisions and corporotomies, minimizes corporal dilation and decreases tissue dissection allowing for shorter operative times and early return to sexual function.

2. Technique

2.1. Patient Preparation. The patient is laid supine on the operating table with the table flexed. The bladder is catheterized and the catheter is removed. The patient is prepped with 70% isopropyl alcohol, Hibiclens, and ChlorPrep [7, 8]. An artificial erection is established with rapid infusion through an 18 gauge butterfly needle of dilute lidocaine and saline solution prior to incision (10 mL 1% lidocaine and 50 mL saline) after manual occlusion of the base of the penis. This helps identify any penile deformity such as Peyronie's disease, hydrodistend the corpora, and establishing local anesthesia in the penis.

2.2. Incision. A 3 cm incision is made at the inferior border of the pubis (Figure 1). In obese patients, the incision should be made closer to the penis to facilitate identification and



FIGURE 1



FIGURE 3



FIGURE 2

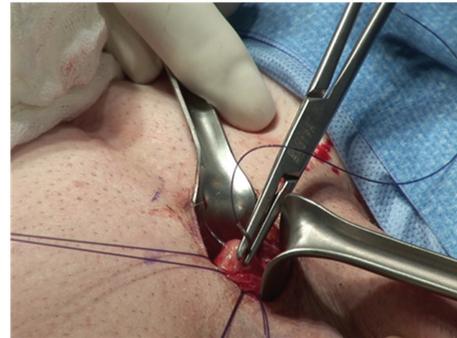


FIGURE 4

dilation of the corpora. Sharp dissection is carried down through Scarpa's fascia.

Blunt manual dissection is then used to develop a space down to the corpora and on each side of the corpora (Figure 2).

Lone Star retractors are not necessary for the IP approach. Two-hand held retractors give adequate exposure. The corpora are easily visualized and the neurovascular bundle is identified and avoided during the corporotomies (Figure 3).

Two 2-0 Monofilament stay sutures are placed in a parallel fashion in each corpora (Figure 4).

A corporotomy is made in between the stay sutures using a number 12 scalpel (Figure 5). The length of the corporotomy is 1.5 cm, the minimum size to accommodate the proximal end of the penile implant.

The Furlow instrument is passed once proximally and once distally with simultaneous measurement (Figure 6). Sequential dilation is not required during most first time penile implant surgeries unless there is a history of priapism [9]. A distal fluid challenge can be performed after dilation to exclude the possibility of a distal urethral perforation. This is accomplished by irrigating the distal corpora with a bulb syringe. Fluid exiting from the urethra confirms a distal perforation. Additionally, a field goal test is performed to exclude proximal urethral perforation by placing two Brooks dilators simultaneously in the proximal corpora. The level appearance of the dilators in the form of a "field goal" excludes a proximal perforation.

The reservoir is placed through the external inguinal ring with the aid of a 4 inch nasal speculum (Figure 7). The external inguinal ring is easily visualized through the IP incision. Both traditional placements in the space of Retzius and ectopic placement are facilitated by the IP approach. The bladder should be decompressed prior to placement of the reservoir to prevent iatrogenic bladder injury.

After measuring the corpora, the appropriate implant is selected and prepared for implantation (Figure 8). The Furlow instrument is used to seat the implant proximally and distally.

The implant is inflated prior to closure of the corporotomy, further seating the implant proximally and distally. The tips of the implant should be confirmed to be in the mid glans of the penis, the cylinders in each corpora and no buckling or folding of the implant (Figure 9). If there is any concern for crossover, the implant should be removed and redilated with a Hagar dilator in the presumably normal corpora.

The corporotomies are closed with the 2 previously placed stay sutures. Additional suture placement is not required for watertight closure if the corporotomies are kept to a minimum (Figure 10).

The pump is then placed in the scrotum (Figure 11). A 4-inch nasal speculum is passed lateral to the corpora and posterior and medial to the testes creating a space. The pump is easily placed in the pocket created by the open jaws of the nasal speculum. It is important to note that this is the extent of scrotal surgery and dissection during the IP approach.

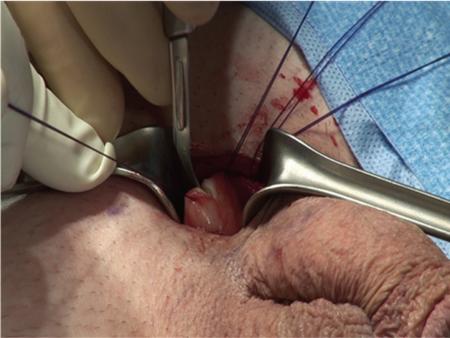


FIGURE 5



FIGURE 9



FIGURE 6



FIGURE 10



FIGURE 7



FIGURE 11

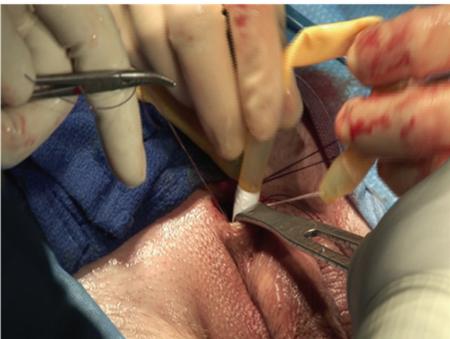


FIGURE 8



FIGURE 12



FIGURE 13

The redundant tubing is trimmed and the manufacturer-provided quick connector system is used to connect the pump to the reservoir. A closed suction drain is left in the dependent portion of the ipsilateral hemiscrotum of the pump. The implant is left fully inflated (Figure 12).

The penis and scrotum are wrapped in a modified Mummy dressing and scrotal support [10] (Figure 13).

3. Conclusion

Prosthetic surgeons should be familiar with more than one approach for placement of an inflatable penile prosthesis. The streamlined infrapubic approach is a variation of the traditional IP approach and may benefit the surgeon in terms of efficiency and the patient in terms of recovery.

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