

Inflatable penile prosthesis implant length with baseline characteristic correlations: preliminary analysis of the PROPPER study

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Background: “Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration” (PROPPER) is a large, multi-institutional, prospective clinical study to collect, analyze, and report real-world outcomes for men implanted with penile prosthetic devices. We prospectively correlated co-morbid conditions and demographic data with implanted penile prosthesis size to enable clinicians to better predict implanted penis size following penile implantation. We present many new data points for the first time in the literature and postulate that radical prostatectomy (RP) is negatively correlated with penile corporal length.

Methods: Patient demographics, medical history, baseline characteristics and surgical details were compiled prospectively. Pearson correlation coefficient was generated for the correlation between demographic, etiology of ED, duration of ED, co-morbid conditions, pre-operative penile length (flaccid and stretched) and length of implanted penile prosthesis. Multivariate analysis was performed to define predictors of implanted prosthesis length.

Results: From June 2011 to June 2017, 1,135 men underwent primary implantation of penile prosthesis at a total of 11 study sites. Malleable (Spectra), 2-piece Ambicor, and 3-piece AMS 700 CX/LGX were included in the analysis. The most common patient comorbidities were CV disease (26.1%), DM (11.1%), and PD (12.4%). Primary etiology of ED: RP (27.4%), DM (20.3%), CVD (18.0%), PD (10.3%), and Priapism (1.4%), others (22.6%). Mean duration of ED is 6.2±4.1 years. Implant length was weakly negatively correlated with White/Caucasian ($r=-0.18$; $P<0.01$), history of RP ($r=-0.13$; $P<0.01$), PD as comorbidity ($r=-0.16$; $P<0.01$), venous leak ($r=-0.08$; $P<0.01$), and presence of stress incontinence ($r=-0.13$; $P<0.01$). Analyses showed weak positive correlations with Black/AA ($r=0.32$; $P<0.01$), CV disease as primary ED etiology ($r=0.08$; $P<0.01$) and pre-operative stretched penile length ($r=0.18$; $P<0.01$). There is a moderate correlation with pre-operative flaccid penile length ($r=0.30$; $P<0.01$).

Conclusions: Implanted penile prosthesis length is negatively correlated with some ethnic groups, prostatectomy, and incontinence. Positive correlates include CV disease, preoperative stretched penile length, and flaccid penile length.

Keywords: Inflatable penile prosthesis; erectile dysfunction

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Introduction

In modern society, men have perseverated over penile length. This biometric parameter has been a source of consternation for adolescent boys and mature men alike. Since the 1950's, several studies have reported penile parameters of men from all corners of the world (1-3). As recently as April of 2015, national media was set ablaze by a large study reporting and reviewing nomograms of flaccid and erect penile size measurements (4). In developing the nomograms, Veale showed a strong and consistently statistically significant correlation was between flaccid stretched or erect length and height.

Penile length holds a strong psychological grip on the psyche of man as a measure of strength, potency, masculinity, and virility. However, as men age, comorbid conditions such as hypertension, diabetes mellitus, hyperlipidemia, and treatment for pelvic cancers may negatively affect penile size. As an example, it has been shown that men lose penile length and girth after undergoing a radical prostatectomy (RP) (5). Penile length loss in this situation may be the result of structural changes from fibrosis of the corpora cavernosa (6). This may be the sequelae of nerve injury, ischemia from accessory pudendal artery ligation, or unopposed sympathetic tone leading to corporal smooth muscle contraction and a hypertonic retracted penis (7,8). The natural history of Peyronie's disease may also be responsible for the alterations in penile length (9).

Currently, there is a paucity of data regarding how these and other factors influence penile length. As part of a large, multi-institutional, prospective clinical trial, the "Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration (PROPPER)" is designed to collect, analyze, and report real-world outcomes for men implanted with penile prosthetic devices (10). This trial is the first of its kind and, to our knowledge, the only prospective, multi-institutional data-set that explores the correlation of co-morbid conditions and demographic data with implanted penile prosthesis size. Moreover, these intra-op measurements are of the total corpora length of the penile erectile tissue using solid metal instruments and can be argued to be the best way to measure true erectile length. This study aims to report clinical outcomes of penile prosthesis, many of which have not been previously discussed in the literature.

Methods

PROPPER (clinicaltrials.gov identifier NCT01383018)

collects data on patients implanted with AMS 700, Ambicor, and Spectra penile implants. PROPPER was designed to quantify penile prosthesis durability, complications and effectiveness, including patient reported functionality, satisfaction and quality of life outcomes. The study was initiated in June 2011 and patients with AMS penile prostheses continue to be enrolled at a total of 11 high-volume implant centers in the United States and Canada.

Patients diagnosed with erectile dysfunction who underwent penile implantation were invited to participate in the study if they were willing and provided consent for study enrollment and were willing to answer at least two questions related to satisfaction and device use 1 year following implantation. Men deemed not suitable for a penile implant by their physician were excluded from the study. Institutional Review Board approval was obtained at all sites (Shulman IRB # 201101681) and the study consent process was conducted based on site requirements.

We report PROPPER patient data through June 2017. Demographic, etiology of ED, duration of ED, co-morbid conditions, and pre-operative penile length (flaccid and stretched), operative technique, implant type and length, and duration of surgery were evaluated.

Physician investigators recorded baseline patient characteristics and surgical implantation details, including etiology of ED, duration of ED, co-morbid conditions, pre-operative penis length (flaccid and stretched), operative technique, implant type and length, and duration of surgery. Patient responses to treatment with penile prostheses were prospectively measured at regular intervals during a 1- to 5-year post-implantation period using optional validated patient survey questionnaires and electronic data collection. Follow-up questionnaires were obtained in person, by mail and telephone by the surgeon or authorized study personnel. Data were collected in an online secured database.

During initial annual evaluation, optional patient reported data include responses on the International Index of Erectile Function-5/Sexual Health Inventory for Men, SF-12—health related quality of life, Erectile Hardness Score questionnaires, and the American Urological Association Symptom Index and UCLA Prostate Cancer Index. Patients were asked two standardized questions to assess device use and satisfaction, including (I) whether they use the device and (II) if used, with what frequency. Satisfaction was gauged on a 5-point Likert scale of very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied and very dissatisfied. The question on use is

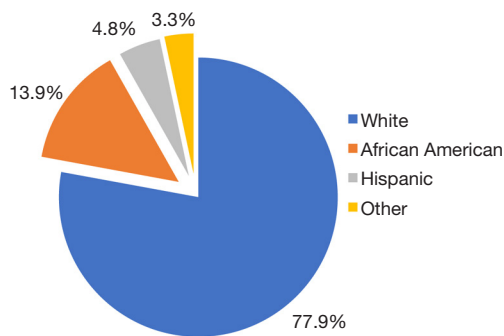


Figure 1 Demographics.

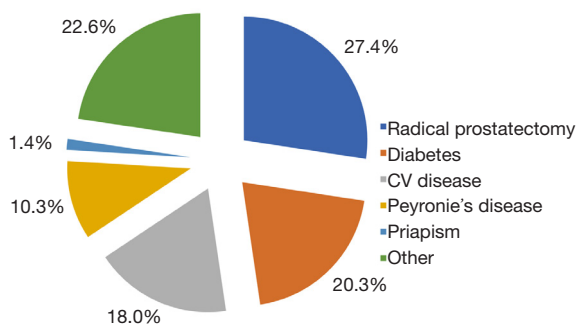


Figure 2 Primary etiology of erectile dysfunction.

answered yes or no. A study outlining baseline patient characteristics has been previously published (10).

Statistical analysis

Statistical analysis has been previously described (10). Continuous variables were summarized using mean ± SD and categorical variables were summarized using count and percent. Pearson correlation coefficient was estimated for the correlation between demographic, etiology of ED, duration of ED, co-morbid conditions, pre-operative penile length (flaccid and stretched) and length of implanted penile prosthesis.

A multivariate linear regression model for the length of implanted penile prosthesis was developed with selected baseline covariates from the univariate analyses. A P<0.05 is considered statistically significant. All statistical analyses were performed using SAS 9.4 (SAS Institute, Inc., Cary, NC, USA).

Results

From June 2011 to June 2017, 1,135 men underwent

primary implantation of a penile prosthesis at 11 study sites. Men receiving a malleable prosthesis, a 2-piece Ambicor, or a 3-piece AMS 700 CX/LGX were included in the analysis cohort. All subjects underwent primary implantation; no replacement implant patients were included in the study.

The majority of study participants were White (77.9%), with African Americans making up 13.9% of the study population followed by Hispanics (4.8%) and other (3.3%) respectively (Figure 1). The “other” category included men who did not identify as African Americans, Hispanic or White. As depicted in Figure 2, the most common primary etiology of erectile dysfunction was RP (27.4%), followed by diabetes (20.3%), cardiovascular disease (18.0%), Peyronie’s disease (10.3%), and priapism (1.4%). Twenty three percent (257 men) had an etiology of ED that was different than the aforementioned categories. The most common concomitant conditions were cardiovascular disease (26.1%), diabetes (11.1%), and Peyronie’s disease (12.4%). Mean duration of erectile dysfunction was 6.2±4.1 years.

Pearson correlation coefficients between implanted penile cylinder length and other parameters are shown in Table 1. Pearson correlation was weakly negatively correlated with White/Caucasian (r=-0.18; P<0.01), RP as primary etiology (r=-0.13; P<0.01), history of Peyronie’s disease as comorbidity (r=-0.16; P<0.01), venous leak (r=-0.08; P<0.01), and presence of stress incontinence (r=-0.13; P<0.01). Implant length was weakly positively correlated with African American (r=0.32; P<0.01), CV disease as primary etiology (r=0.08; P<0.01) and pre-operative stretched penile length (r=0.18; P<0.01). There was a moderate correlation with pre-operative flaccid penile length (r=0.30; P<0.01). These significant risk factors were included in a linear regression model for multivariate analysis (Table 2). In this analysis, patients with CV disease had the highest average device length. In addition, White and Black or African American patients, compared to other ethnicities, had larger average device lengths. As concomitant conditions, Peyronie’s disease and stress incontinence were negatively associated with implant length. Figures 3-5 depict total device length by ethnicity, primary erectile dysfunction etiology and comorbidities.

Discussion

The generation and maintenance of an erection is a complex process that involves both biologic and psychological factors (11). Biologically, this phenomenon requires smooth muscle relaxation, arterial dilation and venous constriction.

Table 1 Pearson correlation coefficients between total device length and various parameters

Variable	n	Simple statistics	Correlation coefficients	P value
Total device length (cm)	1,135	21.17±2.40	1.00	–
Age (years)	1,135	63.39±9.72	0.02	0.423
White/Caucasian	1,135	884 (77.9%)	–0.18	<0.01
African American	1,135	158 (13.9%)	0.32	<0.01
Hispanic/Latino	1,135	55 (4.8%)	–0.08	0.011
Other race/ethnicity	1,135	38 (3.3%)	–0.11	<0.01
Primary ED etiology				
Radical prostatectomy (RP)	1,135	311 (27.4%)	–0.13	<0.01
Diabetes	1,135	230 (20.3%)	0.07	0.024
Cardiovascular disease	1,135	204 (18.0%)	0.08	0.005
Peyronie's disease	1,135	117 (10.3%)	–0.06	0.049
Priapism	1,135	16 (1.4%)	–0.05	0.101
Other primary etiology of ED	1,135	257 (22.6%)	0.05	0.102
ED duration (years)	776	6.19±4.10	–0.04	0.276
Concomitant medical conditions				
Premature or rapid ejaculation (PE)	1,135	4 (0.4%)	0.01	0.627
Cardiovascular disease	1,135	296 (26.1%)	–0.06	0.047
Diabetes	1,135	126 (11.1%)	0.02	0.455
Peyronie's disease	1,135	141 (12.4%)	–0.16	<0.01
Stress urinary incontinence (SUI)	1,135	67 (5.9%)	–0.13	<0.01
Venous leak	1,135	32 (2.8%)	–0.08	0.008
Other concomitant medical condition	1,135	407 (35.9%)	–0.03	0.384
Pre-operative penile length-flaccid (cm)	569	8.38±2.25	0.30	<0.01
Pre-operative penile length-stretched (cm)	750	12.16±2.48	0.18	<0.01

There are a number of elements that may lead to an impaired erectile response; radical pelvic surgery, pelvic radiation, hypercholesterolemia, cardiovascular disease, diabetes mellitus, and hypogonadism. These disease states result in the alteration of the elastic and distensible characteristics of the penile smooth muscle which may lead to penile length alterations, as well as, veno-occlusive dysfunction (12). Interestingly, the percentage of penile smooth muscle is intimately related to the ability to engage adequate veno-occlusion, however the concentration of collagen fibrils is correlated to stretched longitudinal penile length (13). Cavernal tissue is rich in collagen I, III and IV. Type I collagen is poorly compliant while type III is expandable and

elastic. Collagen IV is found in the basal lamina and is large composition of blood vessels (14,15). Some investigators have noted that elastic fibers wane with aging furthermore contributing to penile length alterations (16,17).

To our knowledge, this is the first study attempting to correlate penile prosthesis length with demographics and comorbid conditions in a prospective fashion. This large, multi-institutional registry elucidates several important concepts that have been debated in the past. We postulated and found that a history of a RP is weakly negatively correlated with implanted penile prosthesis length. We also observed that stress urinary incontinence correlated with shorter penile prosthesis length. This is likely because

Table 2 Multivariate regression model for total device length and selected baseline variables

Variable	Coefficient (SE)	P value
Intercept	16.38 (0.57)	<0.001
Race		<0.001 ^a
White	1.12 (0.39)	0.004
Black	2.75 (0.42)	<0.001
Hispanic	0.14 (0.53)	0.794
Other (reference)	N/A	N/A
Primary etiology		<0.001 ^a
Diabetes	0.24 (0.23)	0.291
Peyronie's disease	-0.25 (0.27)	0.357
Priapism	-2.18 (0.72)	0.003
Radical prostatectomy (RP)	-0.35 (0.22)	0.111
Cardiovascular disease	0.28 (0.23)	0.211
Other (reference)	N/A	N/A
Concomitant condition—Peyronie's disease	-1.01 (0.23)	<0.01
Concomitant condition—stress urinary incontinence	-1.03 (0.30)	<0.01
Concomitant condition—venous leak	0.47 (0.87)	0.591
Pre-operative flaccid length	-0.10 (0.05)	0.048
Pre-operative stretched length	0.45 (0.05)	<0.01

^a, type III P value for the significance test of the variable.

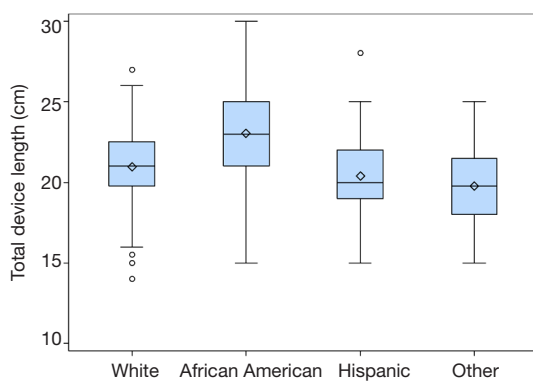


Figure 3 Boxplot for total device length by ethnicity.

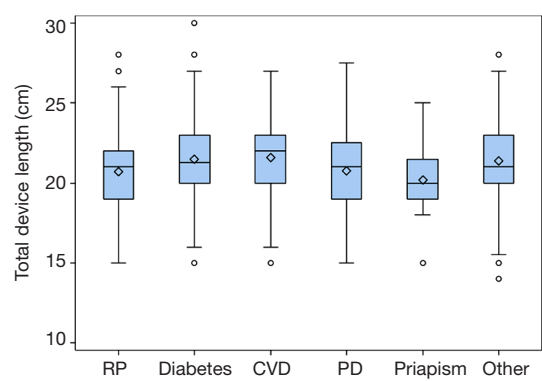


Figure 4 Boxplot for total device length by primary ED etiology. RP, radical prostatectomy.

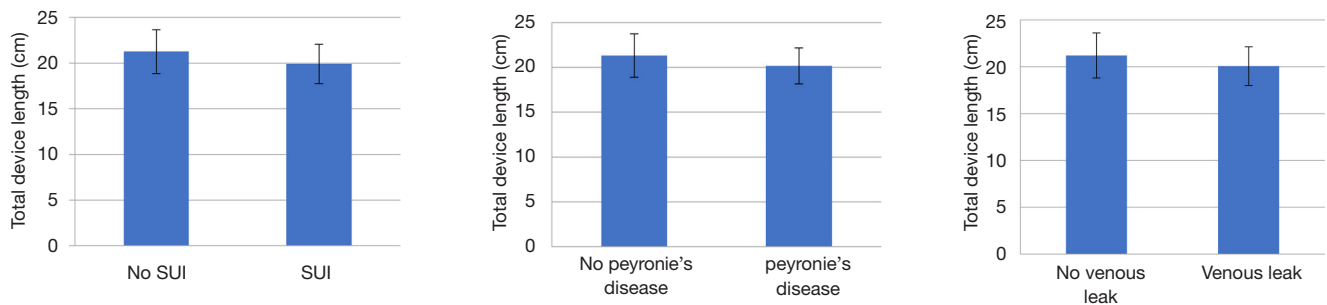


Figure 5 Total device length by comorbidities. SUI, stress urinary incontinence.

many of the cases of SUI were caused by radical pelvic surgery. We also confirmed that pre-operative penile length was correlated with implanted penile prosthesis length as Devעי previously noted in 2007 (18) in 56 men undergoing first-time implantation. There was no statistical difference noted between pre- and postoperative penile lengths (18). A surprising outcome was the positive correlation between cardiovascular disease and penile prosthesis length. Additional research into possible explanations for this observation is warranted.

Prior studies have disputed the impact of RP on penile length. In Savoie's 2002 study of 124 men, penile morphological parameters were measured before and 3 months after RP (5). They found that post-operative flaccid penile length, stretched penile length, and penile circumference were significantly smaller than pre-procedure values (5). The rationale for this phenomenon is likely due to neuropraxia secondary to nerve damage and possibly decreased arterial inflow from ligation of the accessory internal pudendal arteries leading to ischemic apoptosis. Conversely, Briganti evaluated 33 patients prior to, and 6 months after, RP (19). Penile length and circumference measurements in the flaccid and the erect state were obtained. The investigators reported no significant differences in penile length and circumference between the preoperative and postoperative evaluation either in the flaccid or in the erect state (19). Similarly, Berookhim conducted a prospective study of penile length changes after RP in 33 men (20). There was evidence of stretched penile length loss at 2 months, but not at 6 months after RP. Interestingly, patients who regularly used PDE5i had no measured penile length loss.

This study disclosed that penile prosthesis length is weakly negatively correlated with Peyronie's disease. Although this finding is not surprising, there is a dearth of scientific data characterizing the effect of Peyronie's

disease on penile length. Chitale measured the erect penile length in men with stable PD on day one and again 6 months later (21). His team found that 28.5% of the men had a shortened penile length, 38.09% reported penile lengthening, and 33.3% had no change in length. Raheem *et al.* evaluated the role of the vacuum erection device (VED) in 31 patients with Peyronie's disease (22). In 11 on these men, penile length increased by a mean of 0.5 cm (0.5–1.5 cm) after VED use over 12 weeks. Lastly, Mulhall showed that the natural history of Peyronie's disease portends a statistically significant decrease in penile length as the disease progresses (9). These studies give credence that Peyronie's disease can have a negative effect on penile length.

Our study relied on internal penile length for appropriate sizing for the penile prosthesis and not on stretched flaccid penile length. Internal corporal length measurement, we believe is the most accurate way of penile measurement. As one would suspect, there are inherent issues using stretched penile length as a definitive measure (20,23). The accuracy in of this measurement is diminished when different practitioners have performed preoperative and postoperative measurements. This may potentially account for some changes in length. The proximal starting point of the measurement should be the pubic bone. This will factor in the changes on pre-pubic fat pad changed over the study. Lastly, measurement to the tip of the penis may be interfered with by the observer's hand. Using the coronal sulcus as the proximal measurement end-point provides the most consistent results (23).

In the past, penile length has been thought of as a static element. A few investigators have published studies confirming that penile size can be enhanced by inserting a penile prosthesis with oversized corporal cylinders or using a VED in the post-operative setting (24). Wilson and Salem evaluated 37 patients who had a narrow base penile prosthesis placed into scarred corporal bodies (25). Patients

were asked to inflate their implant for up to 3 hours daily. After several months of intracorporal stretching, the patients had their penile prosthesis replaced. Upon reoperation, it was possible to insert corporal penile cylinders that were an average of 2.2 cm longer (25). Similarly, Khera and Moskovic reported a 4.4 cm increase in stretched penile length after using a VED and a penile traction device prior to penile prosthesis revision (26).

This study has a few limitations. Although this is a prospective study, none of the patients were randomized, and causation cannot be inferred from the associations found in this cross-sectional design. Additionally, while all implants were AMS products, not all patients had the same model of penile prosthesis or the same site of insertion (penoscrotal or infrapubic). Lastly, all participating prosthetic urologists are high volume implanters and these results may not be representative of those of general urologists. However, it should be noted that an effort was made to include a combination of academic and private institutions in addition to sites that were geographically dispersed throughout North America.

The results of this study provide important insight into factors that may affect penile length following implantation. Future research should further explore these predictors to enable clinicians to discuss potential surgical outcomes based on one's medical history, physical exam and ethnicity prior to implantation.

Conclusions

This first-of-its-kind prospective, multi-institutional study elucidates the real-world factors that affect the length of implanted penile prostheses. We have reported that implanted penile device length is negatively correlated with certain ethnicities, RP and presence of stress urinary incontinence. Penile implant length is positively correlated with CV disease, non-caucasian ethnicity, preoperative stretched penile length, and flaccid penile length.

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Footnote

Conflicts of Interest: The authors are consultants for Boston Scientific, Inc.

Ethical Statement: Institutional Review Board approval was obtained at all sites (Shulman IRB # 201101681) and the study consent process was conducted based on site requirements.

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