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The Who, How, and What of Real-World Penile Implants Patients in 2015: The Propper (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration) Registry Baseline Data

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Title: THE WHO, HOW, AND WHAT OF REAL-WORLD PENILE IMPLANTS PATIENTS IN 2015: THE PROPPER (PROSPECTIVE REGISTRY OF OUTCOMES WITH PENILE PROSTHESIS FOR ERECTILE RESTORATION) REGISTRY BASELINE DATA.

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Running Head: A look at penile prostheses baseline characteristics in a large, prospective, monitored, multi-center database.

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Abstract

Purpose: Heretofore, the published data on penile implant patients consisted generally of small series of single-surgeon, retrospective experiences rather than prospective or large, multicenter evaluations. This study establishes a baseline of data collection from PROPPER (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration). PROPPER is the first large, prospective, multicenter, multinational, monitored, and internal review board (IRB) - approved study of real-world outcomes for penile implant patients.

Materials and Methods: Data from the PROPPER study was examined to determine patient baseline characteristics and primary and secondary etiologies prior to ED treatment, to include: type and size of implant received; surgical steps/techniques utilized during implantation; and duration of hospital stay.

Results: Through April 2, 2015, a total of 1019 patients were enrolled in the study at 11 sites, withradical prostatectomy (RP) being the predominant etiology in 285 (28%) subjects. Of those 285 RP patients, 280 (98.2%) received an AMS 700. Of these patients, 65.0% (182/280) had placement of the reservoir in the traditional retropubic space, versus 31.8% (89/280) in a submuscular location. For those non-RP patients receiving an AMS 700, less patients underwent reservoir placement in the submuscular location (17.7% (124/702), versus 80.9% (568/702), p-value:<0.001). For those patients receiving an AMS 700, RP and diabetic patients had more outpatient admissions (<24 hours) (56.8% and 52.1%) compared with cardiovascular and Peyronie's disease patients (42.0%and 35.6%, p-value: <0.001).

Conclusions: This first-of- its-kind, large, prospective, multi-center study reveals most penile implant patients in North America receive an IPP and that RP is the most common primary etiology of penile implant surgery. Moreover, RP patients were more likely to have the reservoir

placed in a submuscular location, experience longer OR time, and be admitted overnight as compared with other patient groups.

Introduction

Historically, early surgical treatment for erectile dysfunction involved the placement of rigid devices extra-corporally. This practice resulted in high rates of erosion and infection. Advancements in biomaterials and surgical techniques have led to most U.S. urologists placing an inflatable penile prosthesis (IPP) with an infection-retardant coating inside the corpora cavernosa. Heretofore, the published data on penile implant patients consisted mostly of small series of single-surgeon, retrospective experiences rather than a prospective, large, multicenter evaluation.[1-5] Indeed, this endeavor does not have many registries with which this study can be compared, particularly in the context of urological surgery study.[6-10] A desire for a large advocacy study in the field of surgical men's health lead to the creation of Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration (PROPPER).

In addition to changes in the type of implant used, surgical techniques have evolved greatly in recent years, resulting in reduced operating times, lower infection rates, and improved outcomes.[11]For the first time in the published literature, this study includes the comparison of penile prosthesis (PP) implantation techniques utilized and provides data on follow-up care, such as when the patient went home, and whether they were discharged with or without a catheter. Moreover, the PROPPER study may be used for future FDA labeling changes, as several commonly employed surgical techniques currently constitute "off-label" usage.[12-18]

The authors now report the first prospective, multicenter, international, four-figure-patient-count evaluation to determine baseline penile implant patient characteristics. Surgical outcomes, complications, and follow-up data are not presented in this baseline paper; however, the authors' study plan will yield multiple papers revealing these future data points. This clinical study entitled, "Prospective Registry of Outcomes with Penile Prosthesis for Erectile

Restoration" (PROPPER) collects real-world data for patients undergoing penile implant surgery.

Materials &Methods

Data from the PROPPER study was examined to determine patient baseline characteristics, primary and secondary etiologies, prior ED treatment, type and size of implant received, surgical techniques during implantation, and duration of hospital stay.

PROPPER Study Objective and Design:

PROPPER (clinicaltrials.gov identifier NCT01383018) collects data for patients implanted with AMS 700, AMS Ambicor, and Spectra penile implants. AMS sponsors the study and only AMS penile implants were included in the study. PROPPER was designed to quantify penile prosthesis durability, complications, and effectiveness, which includes patient-reported functionality, satisfaction, and quality of life outcomes. Patients scheduled for penile implantation were invited to participate in the study if they were so willing, and these patients provided informed consent for study enrollment. Internal review board (IRB) approval was obtained at all sites and study consent process was conducted according to site requirements.

The PROPPER registry was initiated in June, 2011, with 14 sites initially agreeing to participate. Current patients with AMS penile prostheses continue to be enrolled at 11 North American sites. Preoperatively, physician investigators recorded baseline patient characteristics such as age, penile measurements, and primary etiology, as well as completing the International Index of Erectile Function-5 / Sexual Health Inventory for Men (IIEF-5/SHIM), SF-12 Health-related Quality of Life (HRQOL) Questionnaire, Erectile Hardness Questionnaire (EHS), American Urological Association – Symptom Index (AUA-SI), and UCLA-Prostate Cancer Index (UCLA-PCI) Questionnaire. Surgical techniques evaluated included: drain usage, Foley

usage, dressing usage, sutures utilized, technique for closing corporotomy, and equipment and technique for corpora dilation. Surgery type included: original, revision/replacement, salvage, and replacing into a previously explanted corpora.

At follow-up, which extends from one to five years post-implant, patients are asked two standardized questions to assess their device use and satisfaction: whether they use the device and, if used, with what frequency. This satisfaction question is gauged on a 5-point Likert scale ("very satisfied", "satisfied", "neither satisfied nor dissatisfied", "dissatisfied" and "very dissatisfied") The baseline questionnaires are also repeated at follow-up, with these questionnaires obtained in person, by mail, or via telephone by the surgeon or authorized study personnel. Complications assessed by the investigator as related to the device and/or procedure are also reported. Data is collected in an online secured database. Study site monitors periodically visit sites (at a yearly minimum) and inspect data for compliance and adverse event reporting. The study sponsor, AMS, is responsible for funding, online database maintenance, monitoring, and statistical analysis.

Baseline Data Assessment

All subjects with signed informed consent and implant information as of April 2, 2015, were included in this analysis. Comparisons on continuous variables were evaluated using Wilcoxon rank-sum test, or one-way analysis of variance (ANOVA). Categorical variables were evaluated using Chi-square test or Fisher's exact test, when appropriate. A p-value <0.05 was considered statistically significant. Statistical analysis was performed using SAS software for Windows Version 9.2 (SAS Institute Inc., Cary, NC, USA).

Results

PROPPER Study Analysis Results:

Penile Implant Results

Through April 2, 2015, a total of 1019 patients were enrolled in the study at 11 sites. Of these subjects, the majority of patients (n=983) were implanted with an AMS 700 IPP, of which 495 received the LGX model (Figure 1). Twenty-six (26) received an AMS Ambicor, and 10 underwent placement of an AMS Spectra.

The average age of the patient in the study was 63.6 $\pm$ 10 (21 to 87). Patient ethnicity was: 792 (77.7%) White/Caucasian, 135 (13.2%) Black/African American, 53 (5.2%) Hispanic/Latino, 12 (1.2%) Asian, and 27 (2.6%) other/missing. Primary ED etiology totals were broken down by implant type and appear in Table 1. Radical prostatectomy (RP) was the predominant etiology in 285 subjects (28%). The other major contributing etiologies included: diabetes (n=220, 21.6%), cardiovascular disease (n=200, 19.6%), and Peyronie's disease (n=91, 8.9%). Of those 285 RP patients, 280 (98.2%) received an AMS 700. Of those patients, 65.0% (182/280) received placement of the reservoir in the traditional retropubic space, versus 31.8% (89/280) with reservoir placement in a submuscular (ectopic) location (p-value:<0.001)[Table 2].Table 3 shows the list of concomitant conditions or impacting medications at baseline. Overall, cardiovascular disease was the most common reported condition (31.1%), followed by diabetes (11.8%), and Peyronie's disease (11.7%).

Of patients receiving the AMS 700, 53 (18.9%) RP patients had concomitant stress urinary incontinence (SUI), while only 8 (1.1%) non-radical prostatectomy patients had concomitant SUI (p<0.001). Sixteen patients underwent concomitant placement of an AUS and 15 patients underwent concomitant male sling at the time of their penile implant. Nine RP patients had climacturia at baseline, compared with only one of the non-radical prostatectomy patients experiencing climacturia at baseline (p<0.001).

Overall duration of ED was 6.9 ± 4.7(n=713, 5.0, 0.1 - 30.0) years for all subjects. Previous ED treatment is shown in Table 4. Patient status in terms of hospital length of stay revealed that 523 patients (51.3%) were under 24 hour observation, while 441 (43.3%) underwent same-day surgery discharge and 54 (5.3%) were admitted to the hospital > 24 hours [Table 5]. For those receiving an AMS 700, RP and diabetes patients had more outpatient admissions (<24 hours) (56.8% and 52.1%), compared with cardiovascular disease and Peyronie's disease patients (42.0% and 35.6%, p-value: <0.001).

Surgical approach and surgery type are broken down by implant and are reported in Table 5. Independent of their admission status, an overwhelming percentage of patients received a mummy wrap/compression dressing; however, drain presence was strongly correlated with an overnight hospital stay, while a lack of drain placement was associated with same day discharge (p-value: <0.001) [Figure 2].

The average length of procedure is significantly shorter for the 700 patients (47.0± 28.7 minutes) compared with those who received Ambicor (71.4± 27.3mins) and Spectra (62.2± 21.0 mins, p-value: <0.001) (Figure 3a). Statistically significant differences were also observed in the length of procedure between 700 patients with cardiovascular disease and those who were post radical prostatectomy (41.3± 20.7 minutes vs. 49.4±28.0 minutes, p-value: 0.018)[Figure 3b].

At baseline, the UCLA-PCI Sexual Function score and the Urinary Function score for all patients was 21.6 ± 16.4 and 79.4±24.6, respectively. There was a statistically significant difference in UCLA Sexual Function and Urinary Function scores observed in different, primary etiology groups. Patients with a RP had the lowest scores (18.0±14.7 for UCLA Sexual Function, 69.7±27.4 for Urinary Function) (p-values<0.001, Table 6). Urinary function [total

79.4 ± 24.6(n=567, 86.8, 0.0 - 100.0) versus RP 69.7 ± 27.4(n=221, 75.0, 0.0 - 100.0)] for baseline scores was significantly lower than other patient groups (p-value: <0.001).

Discussion

The authors now report the first prospective, multicenter, international, large cohort evaluation of baseline penile implant patient characteristics with the hope that this study can be an advocacy study for surgical men's health.

This registry revealed several interesting data in contrast to conventional wisdom about penile prostheses. For example, the traditional belief was that malleable and two-piece prosthetics are faster to place than an IPP. However, this study found a statistically significant shorter OR time when placing an IPP as compared with the malleable and two-piece implants [Figure 3a]. The longer OR time for malleable and two-piece implants could be due to the typical need for a longer corporotomy, with subsequent longer closure with multiple sutures. However, this could be due to the fact that the majority of the authors have greater experience with three-piece IPP implantation and less experienced implanters would have shorter OR time with malleable and two-piece implants. Another surprising finding was that surgery for patients whose primary etiology was Peyronie's disease (PD) was shorter than for their post radical prostatectomy counterparts [Figure 3b]. The radical prostatectomy patient subgroup is discussed in more detail below.

Also of note is the fairly impressive inversion of 700 device series utilized compared with ten years ago as shown in Figure 1. In 2004, 80% of 700 series IPPs implanted in the US were Controlled Expansion (CX), while our data reveals a majority of LGX / Ultrex are currently utilized (Table 1).[11] The AMS 700 series LGX can provide length expansion up to 25% more than the CX, which only expands in girth. However, some prosthetic surgeons prefer to avoid the

21 cm LGX due to axial rigidity concerns.

Reservoir placement for the three-piece inflatable penile prosthesis (IPP) has been associated with some of the most devastating complications during the implantation procedure.[14] Even though the incidence of these problems is estimated to occur in less than one percent of all cases, blind reservoir placement causes surgical anxiety during implantation. Additionally, there has been increasing concern among surgeons when placing an IPP in patients who underwent robotic assisted laparoscopic prostatectomy (RALP).[19] In the RALP approach during transperitoneal surgery, the Space of Retzius (SOR) is violated when the peritoneal veil is taken down and the bladder is mobilized aggressively with respect to the traditional open retropubic prostatectomy approach. These placement concerns are demonstrated by the increased usage of a submuscular location in radical prostatectomy patients as compared with patients with other ED etiologies [Table 2]. Moreover, there is a traditional narrative that encourages greater utilization of malleable and two-piece prosthetics to minimize these risks, despite the higher patient satisfaction rates associated with the three-piece prosthesis.[13] Quite possibly, submuscular reservoir placement with a three-piece implant may be preferred over utilization of a malleable or two-piece prosthetic, as more than 96% of registry patients received a three-piece IPP.

While there was a higher rate of submuscular reservoir placement, radical prostatectomy patients had longer OR times and a higher rate of spending at least one night in the hospital as compared with patient groups of other primary etiologies [Figure 3b, Table 5]. RP patients are considered by some prosthetic urologists to be the typical patient for an IPP, as they have strong motivation and a lack of competing comorbidities. Regardless, RP patients have a defined need for reconstruction after prostate cancer treatment.

This study shows significantly higher rates of stress urinary incontinence and climacturia

in the radical prostatectomy group as compared with other patient groups. These findings were also seen with lower UCLA-PCI urinary function scores. Table 6 reveals that the radical prostatectomy group had significantly lower UCLA-PCI scores for sexual function, urinary function, and urinary bother. This study suggests that the primary etiology group, radical prostatectomy, has multiple factors that need to be addressed after prostate cancer therapy.

Ten years ago, essentially every penile implant patient spent at least one night in the hospital with extensive dressings and drains. Now, almost half of the patients in the study were discharged the day of surgery. The complicated, compressive “spider web” tape dressing and/or placement of a drain encourages the physician to utilize an overnight stay in the hospital. However, with insurance reimbursement changes forcing many cases to become truly outpatient (same-day) surgeries, a quandary remained for using dressing to prevent hematomas. This predicament inspired creation of the “Mummy Wrap” with over 97% of cases using a compressive, mummy-type wrap that essentially did not exist ten years ago. The economics of health care can be a driving force in the evolution of care, as evidenced by these changes. Figure 2 reveals that most patients who underwent drain placement also spent at least one night in the hospital. If health care economics mandates more same-day discharge in the future, drain usage may decrease at that time.

In addition to changes in the type of implant used, surgical techniques have evolved greatly in recent years. This has resulted in reduced operating times, lower infection rates, and improved outcomes. However, the study population reveals the traditional 80%/20% split of penoscrotal vs. infrapubic approach and an 84% /13% /1% split on primary/revision/salvage procedures. These patients are prospectively followed for five years with annual follow-up and validated questionnaires. The authors hope to report significant data with which to supplement

these different groups. Additionally, this study collects data on different surgical techniques, which is a much debated, but poorly studied topic in prosthetic urology.

Study limitations include that all participating prosthetic urologists are high volume implanters and these results may not be representative of those of general urologists or another group of high volume implanters. A second limitation is that the study aims to represent "real world" experience and none of the patients were randomized. A third limitation is that while most of the study points are mandatory, some of the data collection was optional, with not all sites participating. A fourth limitation of the study is that only AMS implants were used and the results may not be generalized to all penile prostheses. Also, because this is essentially the first prospective, multicenter study of such magnitude, there is a dearth of prosthetic urology literature with which it can be compared. The authors hope to update the published literature as the data matures over the course of this five-year study. Once the data matures, the findings of this study could change various aspects of the authors' future surgical penile prosthetic practice.

Conclusion

This first-of- its-kind, prospective, multi-center study reveals most patients in North America receive a three-piece inflatable penile prosthesis and that radical prostatectomy is the most common primary etiology of penile implant surgery. Moreover, radical prostatectomy patients were more likely to have the reservoir placed in a submuscular location, experience longer OR time, and be admitted overnight as compared with other patients groups.

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REFERENCES

1. Quesada, E. T., Light, J. K.: The AMS 700 inflatable penile prosthesis: long-term experience with the controlled expansion cylinders. J Urol, **149:** 46, 1993
2. Govier, F. E., Gibbons, R. P., Correa, R. J. et al.: Mechanical reliability, surgical complications, and patient and partner satisfaction of the modern three-piece inflatable penile prosthesis. Urology, **52:** 282, 1998
3. Lotan, Y., Roehrborn, C. G., McConnell, J. D. et al.: Factors influencing the outcomes of penile prosthesis surgery at a teaching institution. Urology, **62:** 918, 2003
4. Henry, G. D., Wilson, S. K., Delk, J. R., 2nd et al.: Penile prosthesis cultures during revision surgery: a multicenter study. J Urol, **172:** 153, 2004
5. Brant, M. D., Ludlow, J. K., Mulcahy, J. J.: The prosthesis salvage operation: immediate replacement of the infected penile prosthesis. J Urol, **155:** 155, 1996
6. Chen, V. W., Eheman, C. R., Johnson, C. J. et al.: Enhancing Cancer Registry Data for Comparative Effectiveness Research (CER) Project: Overview and Methodology. J Registry Manag, **41:** 103, 2014
7. de Oliveira, R. B., Barreto, F. C., Custodio, M. R. et al.: Brazilian Registry of Bone Biopsy (REBRABO): design, data elements and methodology. J Bras Nefrol, **36:** 352, 2014

8. Augustin, M., Spehr, C., Radtke, M. A. et al.: German psoriasis registry PsoBest: objectives, methodology and baseline data. J Dtsch Dermatol Ges, **12:** 48, 2014
9. Iorio, A., Oliovecchio, E., Morfini, M. et al.: Italian Registry of Haemophilia and Allied Disorders. Objectives, methodology and data analysis. Haemophilia, **14:** 444, 2008
10. Miner, M. M., Khera, M., Bhattacharya, R. K. et al.: Baseline data from the TRiUS registry: symptoms and comorbidities of testosterone deficiency. Postgrad Med, **123:** 17, 2011
11. Henry, G. D., Wilson, S. K.: Updates in inflatable penile prostheses. Urol Clin North Am, **34:** 535, 2007
12. Karpman, E., Brant, W. O., Kansas, B. et al.: Reservoir alternate surgical implantation technique: preliminary outcomes of initial PROPPER study of low profile or spherical reservoir implantation in submuscular location or traditional prevesical space. J Urol, **193:** 239, 2015
13. Lux, M., Reyes-Vallejo, L., Morgentaler, A. et al.: Outcomes and satisfaction rates for the redesigned 2-piece penile prosthesis. J Urol, **177:** 262, 2007
14. Levine, L. A., Hoeh, M. P.: Review of penile prosthetic reservoir: complications and presentation of a modified reservoir placement technique. J Sex Med, **9:** 2759, 2012
15. Hartman, R. J., Jr., Helfand, B. T., McVary, K. T.: Outcomes of lateral retroperitoneal reservoir placement of three-piece penile prosthesis in patients following radical prostatectomy. Int J Impot Res, **22:** 279, 2010
16. Perito, P. E.: Ectopic reservoir placement--no longer in the space of Retzius. J Sex Med, **8:** 2395, 2011
17. Perito, P. E., Wilson, S. K.: Traditional (retroperitoneal) and abdominal wall (ectopic) reservoir placement. J Sex Med, **8:** 656, 2011
18. Henry, G., Hsaio, W., Karpman, E. et al.: A guide for inflatable penile prosthesis reservoir placement: pertinent anatomical measurements of the retropubic space. J Sex Med, **11:** 273, 2014

19. Henry, G., Hsiao, W., Karpman, E. et al.: A guide for inflatable penile prosthesis reservoir placement: pertinent anatomical measurements of the retropubic space. J Sex Med, **11:** 273, 2014

Tables:

Table 1.Primary ED etiology totals broken down by implant type

Primary ED etiology Category	Total (N=1019)	AMS 700 (3-pc infl) (N=983)	AMS Ambicor (2-pc infl) (N=26)	AMS Spectra Concealable (N=10)
Organic Cause				
Diabetes	220 (21.6%)	213 (21.7%)	3 (11.5%)	4 (40.0%)
Cardiovascular disease	200 (19.6%)	193 (19.6%)	5 (19.2%)	2 (20.0%)
Neurologic disorder	7 (0.7%)	7 (0.7%)	0 (0.0%)	0 (0.0%)
Peyronie's disease	91 (8.9%)	90 (9.2%)	0 (0.0%)	1 (10.0%)
Priapism	11 (1.1%)	10 (1.0%)	1 (3.8%)	0 (0.0%)
Venous Leak	33 (3.2%)	32 (3.3%)	1 (3.8%)	0 (0.0%)
Other organic	87 (8.5%)	84 (8.5%)	3 (11.5%)	0 (0.0%)
Acute Cause				
Radical prostatectomy (RP)	285 (28.0%)	280 (28.5%)	4 (15.4%)	1 (10.0%)
Radical pelvic surgery (other than RP)	15 (1.5%)	13 (1.3%)	2 (7.7%)	0 (0.0%)
Pelvic radiation therapy	18 (1.8%)	17 (1.7%)	1 (3.8%)	0 (0.0%)
Pelvic trauma or injury	8 (0.8%)	6 (0.6%)	2 (7.7%)	0 (0.0%)
Spinal cord injury	12 (1.2%)	9 (0.9%)	3 (11.5%)	0 (0.0%)
Other acute	31 (3.0%)	28 (2.8%)	1 (3.8%)	2 (20.0%)
Not reported	1 (0.1%)	1 (0.1%)	0 (0.0%)	0 (0.0%)

Table 2.AMS 700 Reservoir Replacement by Etiology

AMS700 Reservoir Placement	**Total**	**Radical prostatectomy (N=280)**	**Cardiovascular disease (N=193)**	**Peyronies disease (N=90)**	**Diabetes (N=213)**	**Others (N=206)**
Space of Retzius	750 (76.4%)	182 (65.0%)	154 (79.8%)	80 (88.9%)	171 (80.3%)	163 (79.1%)
Sub-muscular (intrafascial) below muscle	213 (21.7%)	89 (31.8%)	36 (18.7%)	10 (11.1%)	39 (18.3%)	39 (18.9%)
Other*	19(1.9%)	9 (3.2%)	3 (1.6%)	0 (0.0%)	3 (1.4%)	4 (1.9%)

*Other includes: sub-scarpas fascia (intrafascial) - 13, below external oblique fasciaabovemuscle– 1, under external oblique, anterior to muscle layer – 1, between external and external fascia – 1,intraperitneal– 1,N/A – 2.

Table 3: Patients with concomitant conditions or impacting medications.

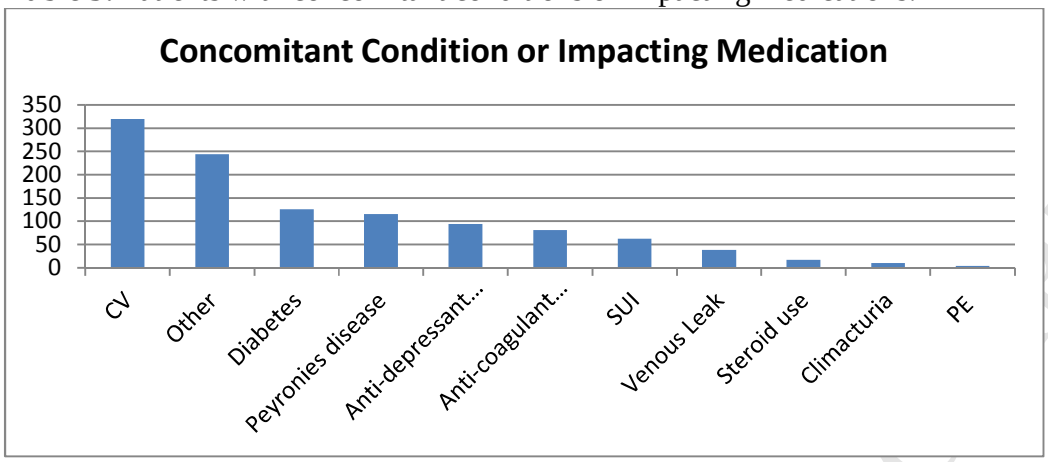


Table 4. Previous ED treatment used by patients.

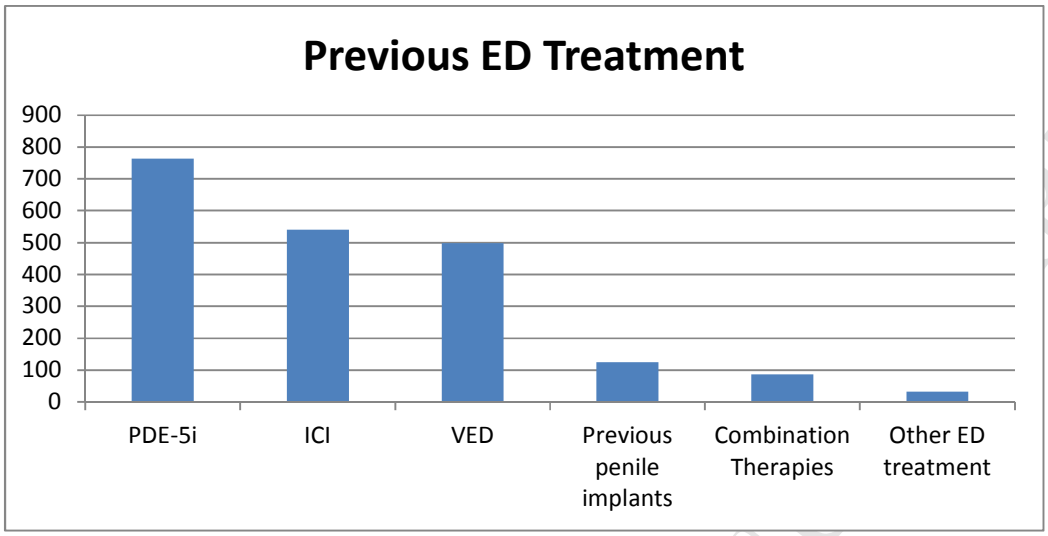


Table 5. Patient status, surgical approach and surgery type by Device Type

Variable	Total (N=1019)	AMS 700 (3-pc infl) (N=983)	AMS Ambicor (2-pc infl) (N=26)	AMS Spectra Concealable (N=10)
Surgical Approach				
Penoscrotal (PS)	821 (80.6%)	787 (80.1%)	25 (96.2%)	9 (90.0%)
Infrapubic (IP)	196 (19.2%)	195 (19.8%)	1 (3.8%)	0 (0.0%)
Perineal	1 (0.1%)	1 (0.1%)	0 (0.0%)	0 (0.0%)
Penoscrotal extended to penile midshaft due to patient body habitus	1 (0.1%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
Surgery Type				
Original (virgin)	857 (84.1%)	833 (84.7%)	19 (73.1%)	5 (50.0%)
Revision (clinically uninfected)	135 (13.2%)	126 (12.8%)	5 (19.2%)	4 (40.0%)
Salvage (clinically infected)	11 (1.1%)	10 (1.0%)	1 (3.8%)	0 (0.0%)
Replacement (previous explanted device)	11 (1.1%)	9 (0.9%)	1 (3.8%)	1 (10.0%)
Unknown	5 (0.5%)	5 (0.5%)	0 (0.0%)	0 (0.0%)
Patient Status				
Admitted/inpatient/>= to 24 hours	54 (5.3%)	46 (4.7%)	8 (30.8%)	0 (0.0%)
Same day discharge (before midnight)	441 (43.3%)	433 (44.0%)	3 (11.5%)	5 (50.0%)
Outpatient/< 24 hours	523 (51.3%)	503 (51.2%)	15 (57.7%)	5 (50.0%)
Not indicated	1 (0.1%)	1 (0.1%)	0 (0.0%)	0 (0.0%)

Table 6. QoL score summary at baseline for AMS 700 patients by primary etiology group

Variables	Total (N=892*)	Radical prostatectomy (N=280)	Peyronies disease (N=90)	Cardio-vascular disease (N=193)	Diabetes (N=213)	Others (N=206)	P-Value
IIEF-5 Total Score	6.3 ± 5.1 (n=825)	5.8 ± 5.6 (n=230)	6.4 ± 4.3 (n=77)	6.2 ± 4.2 (n=161)	6.2 ± 4.7 (n=183)	7.1 ± 5.7 (n=174)	0.162
Erection Hardness Scale	1.0 ± 1.1 (n=830)	0.8 ± 1.1 (n=233)	1.2 ± 1.0 (n=74)	1.0 ± 1.1 (n=162)	0.9 ± 1.0 (n=187)	1.2 ± 1.2 (n=174)	0.002
AUA-SI total score	8.7 ± 6.8 (n=753)	7.8 ± 6.1 (n=223)	9.6 ± 7.9 (n=70)	9.5 ± 7.6 (n=150)	9.3 ± 6.6 (n=170)	8.3 ± 6.5 (n=140)	0.071
UCLA-PCI							
Sexual function	21.6 ± 16.3 (n=578)	18.0 ± 14.7 (n=223)	27.2 ± 18.9 (n=53)	23.4 ± 17.1 (n=113)	21.7 ± 16.5 (n=106)	24.6 ± 15.4 (n=83)	<.001
Urinary function	79.4 ± 24.6 (n=567)	69.7 ± 27.4 (n=221)	83.3 ± 19.6 (n=52)	86.9 ± 19.7 (n=110)	85.0 ± 21.0 (n=101)	85.8 ± 21.4 (n=83)	<.001
Bowel function	85.2 ± 15.3 (n=557)	86.9 ± 14.2 (n=218)	84.4 ± 16.4 (n=51)	81.7 ± 17.7 (n=111)	85.2 ± 13.8 (n=97)	86.0 ± 15.5 (n=80)	0.061
Sexual bother	11.1 ± 23.3 (n=568)	12.2 ± 25.0 (n=219)	13.4 ± 26.9 (n=54)	8.5 ± 19.8 (n=115)	10.1 ± 23.1 (n=99)	11.4 ± 20.9 (n=81)	0.614
Urinary bother	75.9 ± 32.1 (n=565)	70.0 ± 32.9 (n=221)	81.3 ± 26.6 (n=52)	83.5 ± 28.3 (n=109)	74.8 ± 35.1 (n=100)	79.5 ± 31.8 (n=83)	0.003
Bowel bother	85.8 ± 24.1 (n=555)	87.4 ± 22.0 (n=218)	87.3 ± 24.2 (n=51)	83.4 ± 26.9 (n=110)	85.3 ± 24.7 (n=97)	84.2 ± 25.1 (n=79)	0.628

*one subject with missing etiology information was not included. Data are presented as Mean ± SD (n).

Figure 1: Summary of AMS 700 Device Types

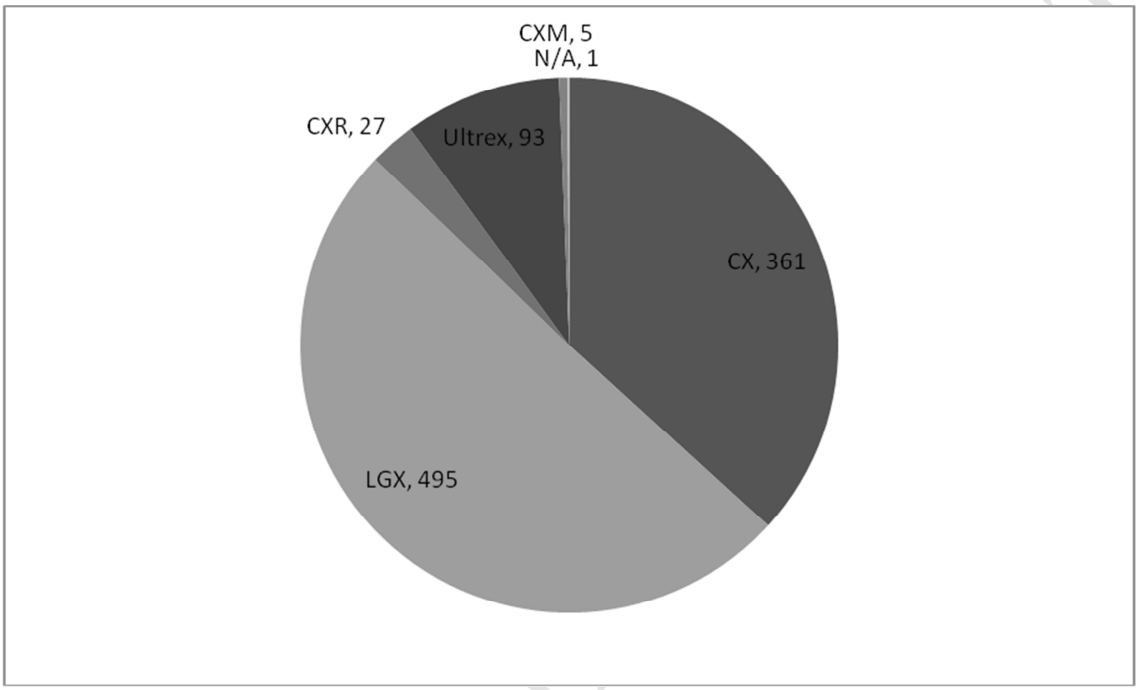


Figure 2: 700 patients admission status and drain placement status.

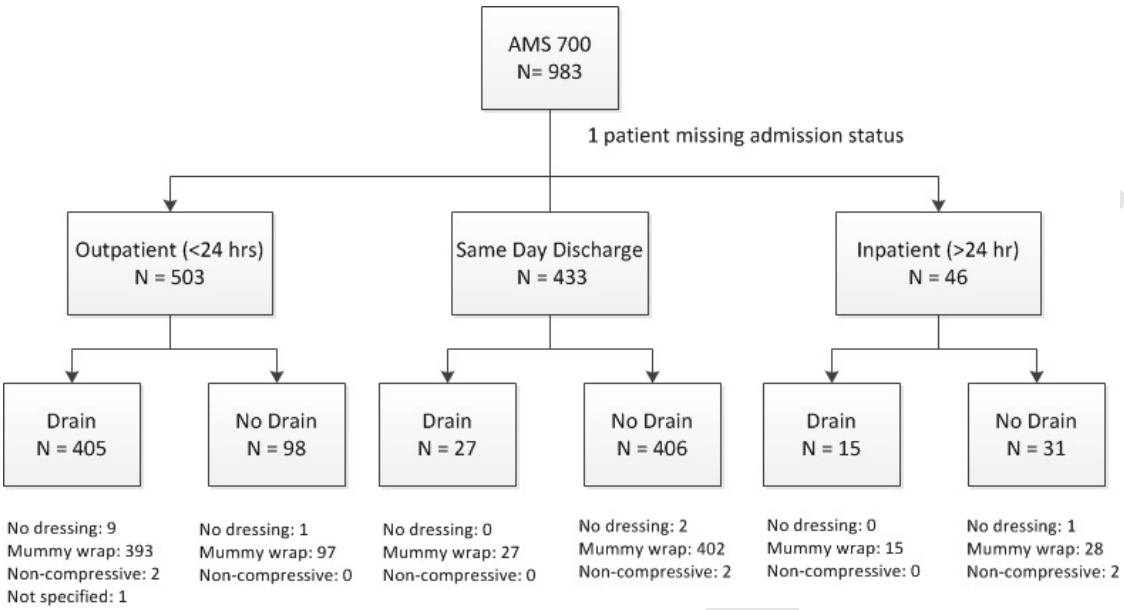
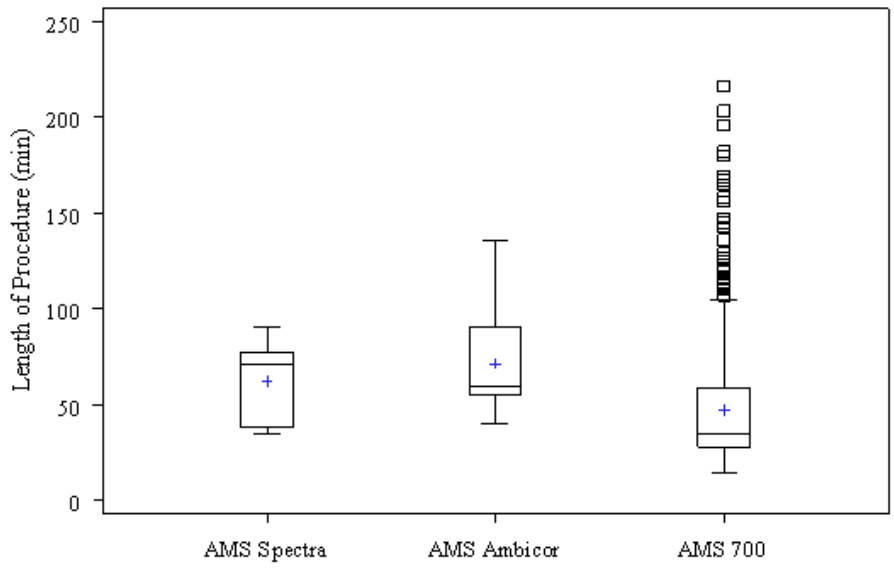
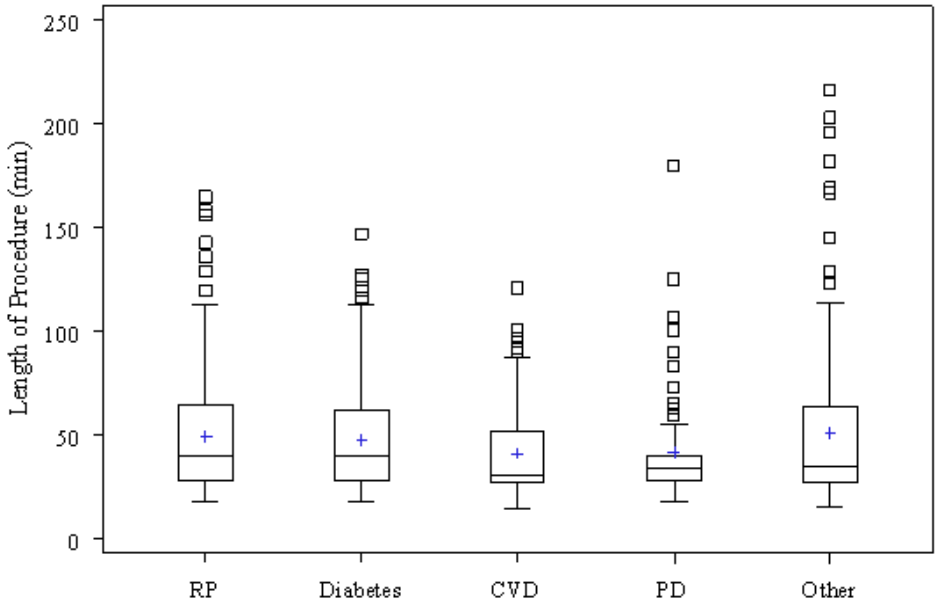


Figure 3: Summary of Length of Procedure (min)

a) All Implanted Patients By Device Type



b) AMS700 Patients by Etiology



List of Abbreviations: IPP = Inflatable Penile Prosthesis, SOR = Space of Retzius, PROPPER = Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration, OR = Operating Room, RP = Radical Prostatectomy, AMS = American Medical Systems