Complication Rates in Concurrent Inflatable Penile Prosthesis and Incontinence Surgery: Comparing the Penoscrotal Versus Perineal Incision Approach

Kyle Blum (kyle.a.blum@uth.tmc.edu)
University of Texas Houston https://orcid.org/0000-0002-2484-385X
Justin Mehr
University of Texas Houston
Travis Green
University of Texas Houston
Kirema Macharia
University of Texas Houston
Daniel Kim
University of Texas Houston
Ouida Westney
Run Wang
University of Texas https://orcid.org/0000-0002-6635-4093

Article

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Abstract

Introduction: Limited data exist on inflatable penile prosthesis (IPP) complication rates following dual implantation with an artificial urinary sphincter (AUS) or bulbourethral male sling via a single perineal incision. Herein, we assess IPP complication rates after dual implantation via a single perineal incision versus more traditional penoscrotal approach.

Methods: Patients with dual implantations of an IPP and AUS or sling between the 2011-2021 were identified. Postoperative IPP complications were assessed using the Clavien-Dindo (CD) classification at <30 days, 30 days–6 months, and >6 months. Treatment satisfaction was assessed using the validated EDITS questionnaire. IPP complication rates and mean EDITS scores were compared between the perineal and penoscrotal groups.

Results: A total of 38 patients underwent dual implantation; 24 perineal vs 14 penoscrotal. There was no statistical difference in rate of complications between the two groups. The penoscrotal group had only two CD Grade I complications reported in the 30-day period and one Grade III complication in the >30 day to 6-month postoperative period. The perineal group had only two Grade III reported complications in the >6 month time frame. One patient in the perineal group and two in the penoscrotal group reported device malfunction at any point during follow-up, with no statistical difference in the rate of device malfunction.

Conclusion: Patients undergoing dual IPP and AUS/sling placement via a perineal vs penoscrotal incision had similar IPP complication rates. A single perineal incision is a viable surgical approach for the dual implantation of an IPP and AUS or bulbourethral male sling.

Introduction

Placement of an inflatable penile prosthesis (IPP) is an option for the definitive management of erectile dysfunction (ED) [1]. To date, the placement of an IPP can be done using various approaches, including infrapubic, subcoronal, and penoscrotal incisions. The most common approach is through a penoscrotal incision where up to 80% of IPPs are placed using this approach [2, 3]. Generally, if another approach is used for IPP placement, infrapubic is utilized [4]. Indeed, comparisons between these various approaches have previously been conducted assessing risk factors for complications like infection or mechanical failure; with one technique not definitively determined to be superior over the other [5–9].

However, in certain populations, such as men who have undergone robotic-assisted prostatectomy [10], the presence of both refractory stress urinary incontinence and severe ED may require surgical correction with the use of an IPP and a continence device such as an AUS or urethral sling. The synchronous dual implantation of an IPP and artificial urinary sphincter (AUS) or bulbourethral sling has previously shown to be effective for concomitant treatment of erectile dysfunction (ED) and SUI [11–14]. Various incision and approach types exist in this procedure, such as a single transscrotal incision, dual incision approach involving a penoscrotal incision for IPP and transperineal incision for AUS cuff placement, as well as the modified single perineal incision [11, 15, 16]. Studies have attempted to compare satisfaction and

complication rates between these approaches; however these are generally limited to the single transcrotal or dual-incision approaches [16–19]. This is largely due to the single perineal incision for dual prosthetic implantation being a generally unique and lesser utilized approach, however, one that has been shown to be safe, efficient, and cost-effective [15]. It has been theorized that placement of an IPP through a perineal incision could lead to worse outcomes including device durability due to the proximal corporotomy placement and thus some tubing located in the perineum that could be more exposed to day-to-day manipulation.

Given that individual IPP placements are not routinely performed using a perineal incision, compounded by the paucity of literature assessing synchronous placement of implants via a perineal incisions in general, there remains a need to generate data on IPP complications rates for placements done via a perineal approach [15, 20]. Therefore, the main objective of this study is to assess complication rates of patients undergoing IPP placement via a single perineal incision compared to a traditional penoscrotal approach during synchronous dual implantation.

Materials And Methods

A cohort of patients who underwent synchronous IPP and AUS or male sling dual implantation was captured using our institutional electronic health record at a large tertiary referral center between 2011 to 2021, Fig. 1. A retrospective chart review of all patients was performed to identify demographics, including incision-type used during synchronous implantation and postoperative IPP complications reported using the Clavien-Dindo classification. Sexual satisfaction was also surveyed using a standardized 14-item validated EDITS validated questionnaire, Fig. 2 [21].

The primary endpoint of this study is comparison of rates of postoperative IPP complications between the two groups. This was quantified using the Clavien-Dindo classification (CD) for IPP complications. Complications were stratified by time of occurrence in one of three groups: <30 days; >30 days and < 6 months; >6 months. Type of complication and relevant interventions were recorded. Statistical analysis was conducted using R 3.6.2 where Fisher's exact test for categorical variables was used to determine differences in number of patients experiencing postoperative complications between the perineal and penoscrotal incision groups. Kruskall-Wallis test was used to compare median age at surgery, BMI at surgery, and follow up time. Chi-square and Fisher's exact test for categorical variables were used to compare pre-operative and concomitant risk factors between the two groups and two-tailed t-test was used to determine difference in mean EDITS score between the perineal and penoscrotal incision groups. $P < 0.05$ was considered to be significant.

Results

A total of 38 patients met criteria for inclusion and assessment, Table 1. There were 24 (63.2%) patients who underwent synchronous implantation via perineal incision and 14 (36.8%) via penoscrotal incision. Among the perineal incision cohort, 8 patients underwent AUS/IPP operation and 16 underwent male

sling/IPP operation and for the penoscrotal incision cohort, all 14 patients underwent AUS/IPP operation. Median age for the entire cohort was 62.0 years (IQR 58.24–66.71) at time of surgery, with a median follow-up time of 48.72 months (IQR 13.38–82.01) and a median BMI of 32.38 (28.80–34.90).

Table 1
– Perineal and Penoscrotal Cohort Demographics

Variables	All patients	Perineal	Penoscrotal	p-value
n, (%)	38 (100.0)	24 (63.2)	14 (36.8)	-
Age at Surgery, median (IQR)	62.0 (58.24–66.71)	61.12 (58.30-66.89)	63.35 (58.64–66.36)	0.717
BMI at Surgery, median (IQR)	32.38 (28.80–34.90)	32.11 (29.11–35.31)	32.38 (27.63–33.17)	0.739
Race, n (%)	-	-	-	-
White	30 (78.9)	16 (66.7)	14 (100.0)	
Black	7 (18.4)	7 (29.2)	0 (0.0)	
Hispanic	1 (2.6)	1 (4.2)	0 (0.0)	
Relationship Status at Surgery, n (%)	-	-	-	-
Married	36 (94.7)	22 (91.7)	14 (100.0)	
Single	2 (5.3)	2 (8.3)	0 (0.0)	
Etiology of ED, n (%)		-	-	
PCa related surgery _or treatment	36 (94.7)	22 (91.7)	14 (100.0)	
Other cancer _surgery or treatment	2 (5.3)	2 (8.3)	0 (0.0)	
Combination Surgery Done, n (%)		-	-	-
AUS/IPP	22 (57.9)	8 (33.3)	14 (100.0)	
Sling/IPP	16 (42.1)	16 (66.7)	0 (0.0)	
Risk Factors		-	-	-
HTN	22 (57.9)	12 (50.0)	10 (71.4)	0.197
CAD	4 (10.5)	3 (12.5)	1 (7.1)	1
Diabetes	10 (26.3)	5 (20.8)	5 (35.7)	0.449
Concomitant __Risk Factors	11 (28.9)	7 (29.2)	4 (28.6)	1
Median Follow Up, mo. (IQR)	48.72 (13.38–82.01)	26.03 (9.29–83.83)	72.02 (50.40-81.18)	0.036

Variables	All patients	Perineal	Penoscrotal	p-value

BMI = Body Mass Index; IQR = Interquartile Range; HTN = Hypertension; CAD = Coronary Artery Disease; ED = Erectile Dysfunction; PCa = Prostate Cancer; IPP = Inflatable Penile Prosthesis; AUS = Artificial Urinary Sphincter

Between the two groups, there was no significant difference in median age at surgery (p = 0.717) or median BMI (p = 0.739). There was a significant difference in median follow-up time (IQR) between the two groups, 26.03 (9.29–83.83) months for the perineal group and 72.02 (50.40-81.18) months for the penoscrotal group (p = 0.035). Recorded preoperative risk factors were hypertension, coronary artery disease, and diabetes. There was no significant difference in any of these risk factors or rate of concomitant risk factors compared between the two incision groups. The most common ED etiology was prostate cancer related treatment for both perineal and penoscrotal groups at 91.7% and 100%, respectively.

There was no statistically significant difference in rate of patients with complications between the two groups (p = 0.546), Table 2. Two patients in the perineal group and two patients in the penoscrotal group reported Clavien-Dindo classified complications, one of which in the penoscrotal group reported two separate complications. In the perineal group, complications included IPP explantation due to rectourethral fistula and IPP explantation due to chronic genital pain. In the penoscrotal group, complications included postoperative urinary retention requiring catheterization, incision site infection, and IPP explantation due to infection. No reported operative related morbidity in either group. In the < 30-day postoperative period, the penoscrotal group reported two Clavien-Dindo Grade I complications and in the > 30 day to < 6-month time frame reported one Grade III complication. The perineal group had no reported complications in either time frame. In the > 6-month postoperative period, the perineal group had two Grade III reported complications while the penoscrotal group had zero reported complications. In regard to device durability, one patient in the perineal group reported device malfunction at any point during follow-up, while two patients in the penoscrotal group reported device malfunction with no statistically significant difference in the rate of device malfunction (p = 0.26).

Table 2
– Postoperative complications by incision type

Variables	Perineal (n = 24)	Penoscrotal (n = 14)	p-value
Patients with complications	2 (8.3)	2 (14.3)	0.564
Total complications	2 (8.3)	3 (21.4)	
Time Frame of Post-Operative IPP Complications, n (%)	-	-	-
<30 days	0 (0.0)	2 (14.3)	
>30 days and < 6 months	0 (0.0)	1 (7.1)	
>6 months	2 (8.3)	0 (0.0)	
Clavien-Dindo Classification of IPP Complications, n (%)	-	-	-
Grade I	0 (0.0)	2 (14.3)	
Grade II	0 (0.0)	0 (0.0)	
Grade III	2 (8.3)	1 (7.1)	
Grade IV	0 (0.0)	0 (0.0)	
Grade V	0 (0.0)	0 (0.0)	
IPP Complications, n (%)	-	-	-
Post-Operative Urinary Retention	0 (0.0)	1 (7.1)	
Incision Site Infection	0 (0.0)	1 (7.1)	
IPP Explantation due to infection	0 (0.0)	1 (7.1)	
IPP Explanation due to rectourethral fistula	1 (4.2)	0 (0.0)	
IPP Explantation due to chronic genital pain	1 (4.2)	0 (0.0)	
IPP = Inflatable Penile Prosthesis; AUS = Artificial Urinary Sphincter			

Treatment sexual satisfaction captured using the EDITS validated questionnaire was completed by 33.3% (n = 8) of the perineal incision group and 28.6% (n = 4) of the penoscrotal incision group. There was no statistically significant difference in mean EDITS score among patients able to be contacted in the two groups, 64.20 in the perineal cohort and 54.55 in the penoscrotal cohort, respectively (p = 0.641), Table 3.

Table 3
EDITS Scores for Perineal and Penoscrotal Groups

Variables	Perineal	Penoscrotal	p-value
EDITS Questionnaire Available, n (%)	8 (33.3)	4 (28.6)	-
Mean EDITS Score (Range)	64.20 (0-93.18)	54.55 (13.64–90.91)	0.641
EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction, Patient Version			

Discussion

Stress urinary incontinence and ED are common patient ailments treated in a urologist's office, and its concomitant presentation can be seen in specific patient populations, such as those who undergo robotic-assisted prostatectomy for prostate cancer [10]. Specifically, in post-prostatectomy patients, for instance, the PIVOT study showed at 2-year follow-up, 17% of patients had SUI or required indwelling catheter. Rates of postoperative ED following RP can range from 14–90% in the literature, with a large variance between institutions [22–24]. Therefore, dual presentation of symptoms are not uncommon. Depending on the severity, surgical correction may be indicated with either a IPP and a AUS or urethral sling.

Combination prostheses therapy for ED and incontinence has been previously reported in the literature as both feasible and effective [15, 20, 25, 26]. Wilson and colleagues reported the first instance of dual IPP and AUS implantation through a single transverse scrotal incision[27]. Further work by Sellers and colleagues reported dual implantation of an IPP and AUS through a single penoscrotal incision compared to individual implantations to reveal a reduction in both operative time and $7,000 in cost savings [25]. Then in 2005, the first reported technique of concomitant penile prosthesis and bulbourethral sling implantation was published involving a perineal incision for a sling and a separate penoscrotal incision for the IPP[26]. Our group in 2010 modified this dual implantation procedure with the placement of the IPP through the same perineal incision that is normally created for sling and AUS implantation where we found no significant difference in operative time, EBL, or postoperative hospital stay when compared with individual incision procedures and a cost savings of over $9,000 when performing the simultaneous implantation[15].

In our current study, we build upon our previous work [15], and looked at an extended follow-up time of 49 months in a larger patient cohort where 24 patients underwent synchronous implantation via perineal incision and 14 via penoscrotal incision. Among the perineal incision cohort, 8 patients underwent AUS/IPP operation and 16 underwent male sling/IPP operation and for the penoscrotal incision cohort, all 14 patients underwent AUS/IPP operation. Demographically, the two groups were similar and exhibited no significant difference in age, BMI, or comorbidities. Notable findings included no significant difference in the rate of patients with complications between the two groups as well as no difference in treatment satisfaction scores. There was a significant difference in median follow-up time (IQR) between the two groups, 26.03 months for the perineal group and 72.02 months for the penoscrotal group ($p = 0.035$). This

difference may be due to our limited sample size and attempting to contact these patients to obtain extended follow-up information may be beneficial for longer-term device satisfaction rates.

The benefits of undergoing a single incision for dual implantation of devices can be thought of as both clinically and financially advantageous to the patient. Clinically, using a single incision minimizes risk of infection, decreased pain, and lowers the comorbidity of the procedure. Financially to the patient, undergoing a single setting implantation of dual devices results in a single fee for anesthesia and postoperative care (nursing, medications, and hospital stay charges). In addition, at our follow-up, there seems to be no significant difference in device durability despite the alternative approach. Since perineal incision is used for most AUS and sling procedures, surgical approach for synchronous penile implant should then be tailored accordingly to avoid any additional incision.

The evident limitations of this report are the retrospective manner of data collection, and the size of the study groups. However, our technical approach with a single perineal incision is unique and the procedure is well tolerated by the patients, without any increased risk of complications. We believe that the advantages of performing these procedures in a single event are a single exposure to anesthesia and its associated risks, presence of a single incision, cost efficiency and comparable complication and treatment outcomes.

Conclusion

Synchronous implantation of IPP and AUS or bulbourethral male slings using a single perineal incision is feasible and carries with it similar postoperative complication rates compared to penoscrotal incisions for IPP placement and should be considered as an option in the setting of dual implantation in patients requiring surgical intervention for severe stress incontinence and refractory ED.

Declarations

Data Availability Statement:

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Author Contributions:

Kyle A Blum – Drafting, Editing, Supervision

Justin P Mehr – Drafting, Editing, Data collection

Travis P Green – Drafting, Editing

Kirema Macharia – Data Collection

Daniel Kim – Data Collection

O Lenaine Westney – Drafting, editing, supervision

Run Wang– Drafting, editing, supervision

Author Competing Interests:

No author reports competing interests related to this study

Ethical Approval

This is an IRB approved Study

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Figures

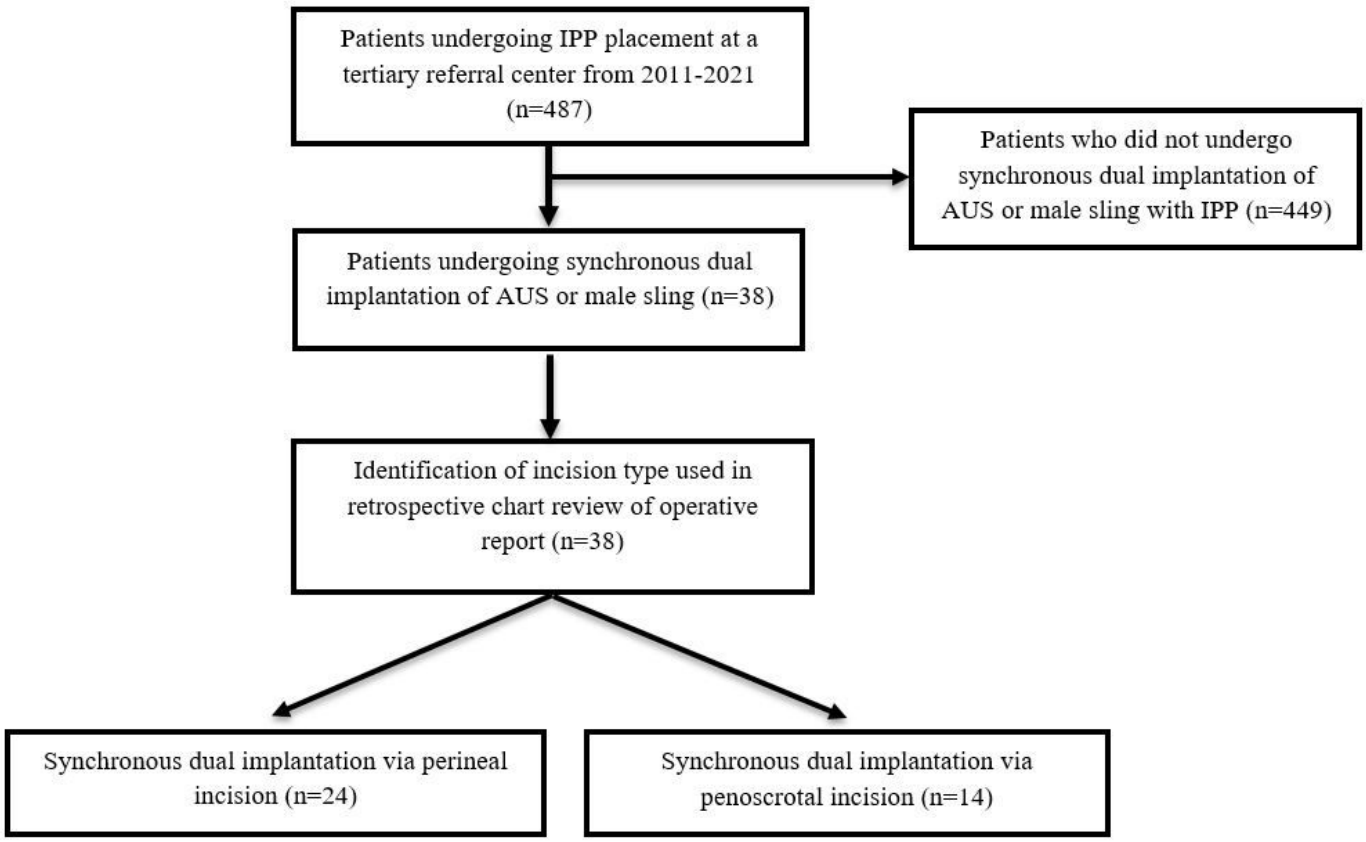

Figure 1

Diagram of patient selection for both groups

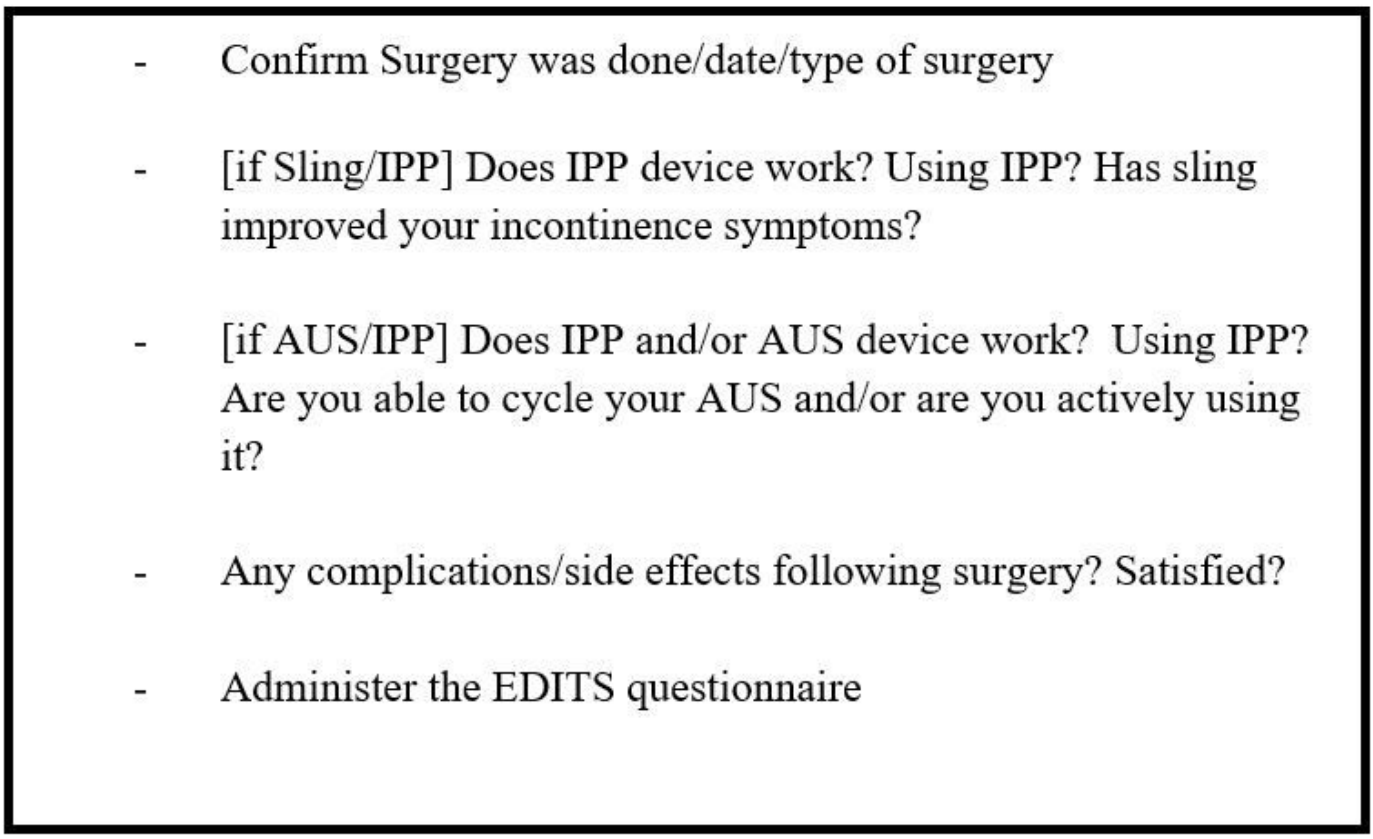

Figure 2

Patient Call Checklist Used During Patient Interview