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Original Research

Subcoronal inflatable penile prosthesis implantation: indications and outcomes

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Abstract

Background: While implantation of an inflatable penile prosthesis (IPP) is commonly performed via infrapubic or penoscrotal approaches, the subcoronal (SC) approach for IPP implantation may safely and reliably allow for additional reconstructive procedures through a single incision.
Aim: The aim of this study is to report outcomes, including complications, of the SC approach and to determine common characteristics of patients undergoing the SC approach.
Methods: A retrospective chart review from May 11, 2012, to January 31, 2022, was performed at a single, tertiary care institution to identify patients with IPP implantation via the SC approach.
Outcomes: Postoperative information was reviewed and extracted from all clinic notes available following the date of IPP implantation in the electronic medical record, detailing any complications including wound complications, need for revision or removal, device malfunction, and infections.
Results: Sixty-six patients had IPP implantation via the SC approach. Median follow-up duration was 29.4 (interquartile range 14.9-50.1) months. One (1.8%) patient had a simple wound complication. Two (3.6%) experienced postoperative infection of the prosthesis, which resulted in explantation of the device. One of these infected prostheses later experienced partial glans necrosis. Revision for mechanical failure or unsatisfactory cosmetic result was performed in 3 (7.3%) IPPs placed via a SC incision.
Clinical implications: The SC approach for implantation of IPP is safe and feasible with low complication and revision rates. It offers urologists an alternative to the classic infrapubic and penoscrotal approaches, both of which would require a second incision for additional reconstructive procedures required to adequately address deformities associated with severe Peyronie's disease. Therefore, urologists who treat these specialized populations of men may benefit from having the SC approach in their array of techniques for IPP implantation.
Strengths and limitations: The limitations of this study include its retrospective nature, risk of selection bias, lack of comparison groups, and sample size. This study reports on early experience with the SC approach performed by a single high-volume reconstructive surgeon, who treats a specialized population of patients requiring complex repair during implantation of an IPP, particularly those with Peyronie's disease.
Conclusion: The SC incision for IPP implantation has low rates of complications and remains our approach of choice for IPP implantation in patients with severe Peyronie's disease, including curvatures >60°, severe indentation with hinge, and grade 3 calcification, which are unlikely to respond adequately to manual modeling alone.

Keywords: Peyronie's disease; inflatable penile prosthesis; subcoronal; erectile dysfunction; reconstruction.

Introduction

Implantation of an inflatable penile prosthesis (IPP) is the gold standard surgical treatment for men with erectile dysfunction (ED) refractory to medical therapy with or without Peyronie's disease (PD). Since the first description of IPP implantation in 1973 by Scott et al,[1] a number of different prosthesis designs and surgical techniques for implantation have been developed. However, there remains an ongoing debate as to which surgical approach for implantation is optimal. The infrapubic (IP) and penoscrotal (PS) approaches have classically been favored for routine IPP implantation, given their reliably good outcomes, but offer limited exposure to the shaft for additional reconstructive maneuvers in patients with concomitant PD.[2]

A subcoronal (SC) incision was first described in 1981 by Smith[3] as an alternative approach for the implantation of a semi-rigid prosthesis. He noted excellent cosmetic results as well as decreased risk of crossover during corporal dilation.[3] Then, in 2016, Weinberg et al,[4] published the first description of utilizing the SC incision for multicomponent IPP implantation. Their group found that the SC approach was (1) safe with low complication and low infection rates and (2) efficient with reasonable operative times. Since then, Sung Hun Park in South Korea has implanted more than 700 IPPs with the SC approach and remains one of the leading IPP implanters using the SC approach to date with low complication rates.[5] Although these studies establish the SC approach as a viable method of IPP implantation, there remains little to no literature on the adoption of the SC approach in higher-risk ED patient populations, particularly those with concomitant PD requiring complex reconstruction for repair.

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The benefits of a SC approach to IPP implantation includes exposure and access to the entire pendulous penile shaft back to the mid bulb to allow for additional reconstructive procedures, such as plaque incision and grafting for PD, which previously would require an additional incision if the prosthesis was placed via an IP or PS approach.[4] This positions the SC incision as the optimal approach for IPP implantation in patients with severe PD that require supplementary reconstructive techniques to achieve acceptable penile straightness and caliber.

The aim of this study is to describe the outcomes of IPP implantation via the SC approach and to identify common characteristics amongst patients who underwent IPP implantation via the SC approach. Furthermore, we hope that this article may initiate a discussion within the sexual medicine literature regarding potential indications for which the SC approach for IPP implantation is the most beneficial.

Methods

A retrospective, institutional review board–approved (#16022204) chart review from May 11, 2012, to January 31, 2022, was conducted on IPP implantation performed at a single, tertiary care institution by a single surgeon to identify patients with IPP implanted via the SC approach. Data collected included preoperative evaluation, intraoperative details, and postoperative follow-up information. The preoperative evaluation included a detailed medical history, physical exam, and other workup when indicated. Patient characteristics such as age, calculated body mass index, and comorbidities were obtained. All patients underwent preoperative penile duplex Doppler assessment during induced erection by injection of TriMix vasoactive agent. The degree of curvature was measured with goniometer by the same practitioner. Girth discrepancies were measured with a string and ruler. Intraoperative information detailed the IPP device type, postoperative use of a drain, and any concurrent reconstructive procedures. If a drain was placed, a #10 fully-perforated flat Jackson-Pratt drain was placed in the scrotum with the end of the drain at the base of the penile shaft. Postoperative information was reviewed and extracted from all clinic notes available following the date of IPP implantation in the electronic medical record detailing any complications including wound complications, need for revision or removal, device malfunction, and infections.

Statistical analysis was performed using SAS version 7.15 (SAS Institute). A Fisher exact test was used to compare categorical variables. Comparisons between continuous variables were conducted using the Mann Whitney *U* test when appropriate. For all analyses, an alpha level of 0.05 was utilized to determine statistical significance of associations between variables.

Results

Sixty-six patients had IPP implantation via the SC approach between May 11, 2012, to January 31, 2022. Median age at the time of surgery was 58 (interquartile range [IQR] 52.5-64) years. In our patient population, all patients had IPP implanted for ED with concurrent PD, or PD with need for grafting and unacceptably high risk for de novo ED.

The median primary degree of penile curvature in the 66 patients who underwent SC IPP implantation for PD was 60° (IQR, 50°-75°). Of these patients, 23 (35.9%) had a secondary penile curvature. Median secondary penile curvature, when present, was 30° (IQR, 20°-40°). Median composite curvature, which was defined as the sum of primary penile curvature and secondary penile curvature, was 70° (IQR, 51°-85°). Seven (10.6%) patients had hourglass deformity. Forty-six (69.7%) were noted to have an indentation deformity, while 32 (48.5%) patients had a hinge defect. Hourglass, indentation, and hinge deformities can collectively be considered girth loss deformities. When combined, 48 (72.7%) of 66 patients were noted to have at least 1 girth loss deformity.

Table 1. Baseline preoperative characteristics of patients undergoing SC IPP implantation (N = 66).

Age at surgery, y	58 (52.5-64)
BMI, kg/m^2	27.4 (25.8-29.8)
Primary curve degree	60 (50-75)
Secondary curve degree, if present	30 (20-40)
Composite curve degree	70 (51-85)
Presence of plaque calcification	18 (27.3)
Grade 1 calcification	2 (3.03)
Grade 2 calcification	9 (13.6)
Grade 3 calcification	7 (10.6)
Indentation defect	46 (69.7)
Hourglass deformity	7 (10.6)
Hinge deformity	32 (48.5)
Hypertension	29 (43.9)
Diabetes mellitus	20 (30.3)
Hyperlipidemia	22 (33.3)
Prior tobacco use	28 (42.4)
Current tobacco use	6 (9.1)

Values are median (interquartile range) or n (%). Abbreviations: BMI = body mass index; IPP = inflatable penile prosthesis; SC = subcoronal.

Table 2. Intraoperative characteristics and additional reconstructive maneuvers (N = 66).

Drain placement	60 (90.9)
Tunica albuginea plication	7 (10.6)
Plaque incision and grafting	56 (84.9)
Circumcision	7 (10.6)
Glanspexy	24 (36.4)

Values are n (%).

Additional baseline preoperative patient characteristics are reported in Table 1. Despite incomplete chart data and non-numeric responses given by patients, a majority of patients (46 of 66 [69.7%]) endorsed preoperative loss of penile length following development of PD. Unfortunately, many patients could not quantify their loss of penile length due to the presence of ED, but of those who did provide a numeric response, penile shortening ranged from 1 cm to 15 cm with median of 2 (IQR, 1.5-2) cm. The maximum of this range was a clear outlier and represented the patient's own perceived loss of penile length preoperatively due to their PD, rather than objectively measured lost length.

Using the SC approach for IPP implantation, a variety of additional penile straightening maneuvers could be performed concurrently through the same incision. Seven (10.6%) patients underwent concurrent tunica albuginea plication to correct curvature, while the vast majority of this cohort (56 patients [84.9%]) underwent Peyronie's plaque incision and grafting. Glanspexy was performed in 24 (36.4%) cases, and circumcision in 7 (10.6%) patients. A Jackson-Pratt drain was placed in 60 (90.9%) patients. A summary of intraoperative details can be found in Table 2.

Median time of follow-up was 29.4 (IQR, 35.2) months. Only 1 (1.8%) patient experienced a minor surgical wound complication, which involved a small skin separation at the circumcision line and was managed with a single suture in the office. Revision was performed in 3 (5.4%) patients. One revision was performed to release prosthesis tubing that had become adherent to the left base of the penile shaft, which was causing the patient discomfort. A circumcision revision was performed during the same procedure due to redundant skin along the patient's circumcision line. The other 2 revisions were performed for mechanical failure: one prosthesis developed "buckling" 3 months after the initial operation, leading to a ventral curvature requiring release of scar contraction, and the other prosthesis developed a proximal aneurysm requiring removal and replacement after 3 years. All revisions were performed via a penoscrotal approach. Two (3.6%) patients experienced prosthesis infection postoperatively—one of which was further complicated by partial glans necrosis. Both infections were managed with explantation of the device. Of note, there were no preoperative patient characteristics or intraoperative variables that appeared to be statistically significantly associated with any complication in this study.

Discussion

This study aimed to help address the current paucity of literature evaluating the SC approach for implantation of IPPs. While our study is the second article to our knowledge to describe low complication rates with the SC approach, it is the first article to describe specific patient selection characteristics for which the SC approach for IPP implantation may be preferred compared with traditional approaches. In our tertiary referral center patient population, many patients undergoing penile prosthesis implantation have concurrent PD. The SC approach is our preferred approach for severe curvature (>60°), severe girth loss deformity, indentation causing instability, and extensive (grade 3) calcification—who present more challenging operative considerations when it comes to correcting penile deformity during the same procedure.

Grading of Peyronie's plaque calcification was assessed routinely in this patient population during penile duplex ultrasonography and remains a clinically significant indicator of severity of PD. Levine et al[6] utilized a large PD database and found that men with grade 3 calcification were significantly less likely to respond to nonsurgical management and more likely to require more complex surgical intervention, including plaque incision/excision and grafting, when compared with their noncalcified counterparts, even when matched for degree of curvature and plaque location.

Although the PS and IP approaches have been classically favored for the implantation of routine IPPs given their safety and reliability,[7] patients with more severe PD may not be able to achieve the desired penile straightness and/or girth correction through these approaches. Therefore, the advantage of the SC approach is that it readily provides exposure and access to the entire pendulous penis to the mid bulb and allows for proper proximal insertion of the prosthesis cylinders and additional reconstructive procedures, such as plaque incision and grafting for PD and glanspexy for unstable or floppy glans, which previously would require an additional incision.

Incidence of infection following IPP implantation, particularly in the PD population, has been reported in current literature to occur in 2.6% to 8.9% of cases.[8-10] In the present study, rates of IPP infection after SC approach for IPP implantation in a PD population are within that range, at 3.6%. Furthermore, DiBlasio et al[11] found that compared with patients without PD, patients with PD undergoing IPP implantation have a statistically significant higher risk of IPP component malfunction, with rates as high as 30% in a comparative study with small cohorts. This increased risk was theorized to be due to the extra stress placed on the device during additional reconstructive maneuvers to achieve penile straightness, particularly manual modeling.[11] In our cohort, revision was performed in 5.4% of cases for mechanical issues with a multicomponent IPP. Therefore, complication rates following the utilization of the SC approach for IPP implantation appears to be low in the PD patient population when compared with those reported in the literature.

Weinberg et al[4] also described a significant gain in penile length with IPPs implanted via the SC approach. These authors proposed that the SC approach allowed the release of Dartos fascial attachments, particularly at the base of the shaft, which was thought to restrict penile length. Theoretically, releasing the Dartos in this way may provide added length to the shaft by increasing overall laxity of the connective tissue that otherwise limits penile length.[12] As we did not routinely measure postoperative erect length, we cannot objectively determine changes in pre- and postoperative penile length in this study. Future studies may benefit from including this assessment.

Revisions in this cohort of patients were generally performed for mechanical failure of the devices. The PS approach was used in all cases requiring revision after initial IPP implantation via the SC incision, as the penile shaft can be more difficult to deglove after the first operation and is not needed when shaft exposure is not necessary. In our experience, simple exchanges of IPP devices for mechanical failure via a PS incision are easier than degloving the penis, where previous complex reconstructive maneuvers had been performed. Notably, we did not have any patients necessitating revisions for recurrent curvature or girth loss deformities. We also do not believe that the single revision performed for adherent tubing was related to the SC incision, but rather was related to the development of scar tissue around the device tubing near the penoscrotal junction, which was bothersome to the patient. Tubing irregularities such as this can also occur when the IP or PS approach is used.

An important concern with the SC approach is the risk of distal glans necrosis especially when performing multiple shaft maneuvers to correct deformity in a population of men, many of whom have significant vascular co-morbidities causing their erectile dysfunction. In 2017, Wilson et al[13] published results in which 14 (67%) of their 21 cases of glans necrosis underwent IPP implantation via the SC approach. Based on postoperative photos, they theorized that hematoma formation underneath the circumcising incision, in combination with the intracorporal pressure from the prosthesis and extrinsic compression by an elastic dressing, may contribute to glans ischemia and possible glans necrosis. Other factors contributing to glans necrosis in their study included patient comorbidities such as diabetes mellitus, positive smoking history, and arteriosclerotic cardiovascular disease.[13]

In our study, no specific comorbidities were detected to have an association with postoperative complications, despite our cohort having multiple factors that would be considered

at higher risk for complications following IPP implantation. Our study population comprised patients with severe PD, drug-refractory ED, and/or high rates of systemic vascular comorbidities. The most common of these comorbidities were hypertension (43.9%), prior smoking history (42.4%), and hyperlipidemia (33.3%).

Concurrent circumcision at the time of implantation was not found to have a statistically significant association with any postoperative complication among our population. Of note, we routinely recommend that all uncircumcised patients undergo concurrent circumcision when the SC approach is used to reduce the risk of developing preputial edema, chronic lymphedema and paraphimosis. There were no complaints of chronic lymphedema postoperatively. Temporary postoperative SC skin edema was occasionally noted but would resolve over the first few months after surgery with no complaints of sensory deficit.

A Jackson-Pratt drain was placed in 60 (90.9%) patients, which is higher than reported rates of drain placement with the PS approach, reflective of concern for higher risk of bleeding following the additional reconstructive maneuvers associated with the SC approach. It is our practice to leave a drain for any case in which plaque incision and grafting or substantial reconstruction is required.

Because glans necrosis remains the most serious concern with a SC incision, an alternative approach described by Wang et al[13,14] was developed in order to avoid obtaining exposure via the circumcising incision and complete penile degloving, as these specific steps have been theorized to be a potential risk for ischemic injury to the glans. Instead of a circumcising incision, Fang and Wang[15] described the use of a longitudinal ventral incision in conjunction with retraction of skin, fascia, and neurovascular bundles dorsally to allow for exposure of the penile shaft. The IPP was then implanted with the sliding technique and the use of a double dorsal-ventral patch graft. Their nondegloving technique was associated with no vascular complications when performed on a relatively small series of 12 patients with severe curvature requiring greater exposure for additional reconstructive maneuvers, such as the patients in our study.[14] This novel technique represents one alternative for providing penile shaft exposure while theoretically reducing the risk of ischemic injury to the glans. Larger studies are needed to further validate the safety and efficacy of this approach. In our limited experience with this technique, full dorsal exposure remains challenging and may make elevation of Buck fascia and the neurovascular bundles difficult. Also, postoperative scarring from an extended ventral incision may introduce tethering of the shaft skin and subcutaneous tissue resulting in ventral curvature. Therefore, we believe that the SC incision provides the optimal exposure for complex PD repairs, which in turn may lead to improved cosmesis and shorter operative time.

In our population who underwent a SC approach, we only reported 1 patient with partial glans necrosis. Interestingly, he did not have any increased vascular risk factors such as diabetes mellitus, smoking, or cardiovascular disease. However, he did have a concomitant glanspexy performed at the time of IPP implantation and release of severe indentation associated with extensive plaque calcification, which involved partial mobilization of the urethra in that area. In this single case, we hypothesize that the combination of elevation of Buck fascia and the urethra with dissection for glanspexy distal to the circumcising incision may have contributed to the ischemic insult in this otherwise healthy patient. Unlike most cases reported by Wilson et al[13] in which ischemia was noted within the first 24 hours after surgery, in this case, glans ischemia was noted 14 days postoperatively.

We acknowledge that although glans necrosis is rare in both the literature and in our cohort, it is a serious and devastating complication. Given our working hypothesis that the mobilization of urethra combined with the elevation of neurovascular bundles may have compounded to lead to this outcome, it is our practice now that we never mobilize the urethra and neurovascular bundle in the same case. For example, if a ventral dissection is required, the neurovascular bundles will be not be elevated. Conversely, if dorsal reconstruction is necessary, then the urethra will not be mobilized. Following the adoption of this principle, there have been no further cases glans necrosis.

It is important to note, though, that concurrent glanspexy performed at time of IPP implantation via the SC incision was not found to be associated with postoperative complications in this study overall. In fact, there were no preoperative patient characteristics or additional intraoperative procedures, including circumcision, that were found to be statistically significantly associated with complications in our report. We acknowledge that these findings may be largely due to this relatively small patient population.

The limitations of this study include its retrospective nature, risk of selection bias, lack of comparison groups, and sample size. All surgeries were performed by a single high-volume reconstructive surgeon, who sees a large population of men with complex PD. Our outcomes may not be able to be generalizable to all surgeons performing IPP implantation. Furthermore, as discussed previously, given such low rates of complication in our limited study population, the power of this study may not be adequate to capture true associations between other variables and complication rates. We will continue to treat appropriate patients utilizing the SC approach and will track outcomes and complications in order to appropriately power future studies to detect any association affecting complication rates.

Future directions for this work include continuing to increase our sample size as well as capturing additional data on patient/partner satisfaction and quality-of-life outcomes. Importantly, the recent development and validation of the Satisfaction Survey for Inflatable Penile Implant[16] will allow for improvement in the standardization of data collection, and in turn, broaden the scope of our analysis to include crucial aspects in determining what we as urologists consider successful IPP procedures—the whole patient experience.

Conclusion

The SC approach for implantation of an IPP is safe and effective with low complication and revision rates. It allows for all surgical deformity correction maneuvers and IPP implantation through a single incision. It is our approach of choice for curvatures >60°, severe girth loss deformities, or grade 3 calcifications, which are not expected to be sufficiently corrected to functionally straight (ie, curvature <20°) by manual modeling alone. One concern with the SC approach is the risk of distal glans ischemia/necrosis, which occurred once in this study. Clearly, addressing these complex deformities must be performed by experienced prosthetic surgeons with comprehensive preoperative patient consent.

Supplementary material

Supplementary material is available at *The Journal of Sexual Medicine* online.

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Conflict of interest: Dr. Laurence Levine is a consultant to Boston Scientific, Irrimax, Absorption Pharmaceuticals, Hybrid Medical, and International Medical Devices. Dr. Petar Bajic serves on the advisory board for Endo Pharmaceuticals, acts as a consultant for Coloplast Corporation, and has received an investigator-initiated research grant from Coloplast Corporation.

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