

## SURGERY

## Penile Prosthesis Placement by a Dedicated Transgender Surgery Unit: A Retrospective Analysis of Complications

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## ABSTRACT

**Background:** Penile prostheses may be used as a component of genital gender affirmation surgery for the purpose of achieving penile rigidity after phalloplasty, and transgender individuals experience higher complication rates than cisgender individuals.

**Aim:** To observe complications with transmasculine penile prosthesis surgery over time and across surgical conditions.

**Methods:** Retrospective chart review of all transmasculine patients with phalloplasty undergoing penile prosthesis placement between 4/14/2017 and 2/11/2020 (80 patients).

**Outcomes:** Independent variables include implant type, previous genital surgeries, and simultaneous genital surgeries. Dependent variables include prosthesis infection and mechanical complication (device malfunction, dislodgement, erosion).

**Results:** There was an overall complication requiring surgery rate of 36% and infection rate of 20% (15/67 for inflatable prostheses and 1/13 for semirigid), with 14% (11/80) experiencing infection requiring removal. Differences in infection rates appeared insignificant across categories of previous surgery or with simultaneous surgery, but we did notice a markedly lower rate for semirigid prostheses compared to inflatable. There was a significant relationship between infection and case number, with the probability of infection decreasing over time. Device loss at 9 months was 21% overall. Preoperative conditions of the neophallus such as prior stricture correction and perioperative factors such as simultaneous clean and clean-contaminated procedures seemed to pose no additional increase in complication rates.

**Clinical Implications:** Type and number of prior and simultaneous non-prosthetic surgeries should not be considered as a risk factor for penile prosthesis after phalloplasty for transmasculine patients, even those that are clean-contaminated

**Strengths & Limitations:** Our cohort size is large compared to currently available studies, although not large enough to generate sufficient power for group comparisons. We have reported every genital surgical step between phalloplasty and penile prosthesis placement and recorded complications with subsequent devices after failure. Patient-reported outcomes were not collected.

**Conclusion:** We demonstrate that preoperative conditions of the neophallus, such as prior stricture correction, and perioperative factors, such as simultaneous clean and clean-contaminated procedures, seem to pose no additional increase in complication rates. Our data suggest that surgical experience may further decrease complications over time. **B. L. Briles, R. Y. Middleton, K. E. Celtik, et al. Penile Prosthesis Placement by a Dedicated Transgender Surgery Unit: A Retrospective Analysis of Complications. J Sex Med 2021;XX:XXX–XXX.**

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**Key Word:** Transgender; Transmasculine; Gender Affirming Surgery; Penile Prosthesis; Phalloplasty; Complications

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## INTRODUCTION

Penile prosthesis placement is a commonly desired step of transmasculine genital gender affirmation surgery, with up to 86% of patients requesting prosthesis placement after successful phalloplasty.<sup>1</sup> Penile prostheses have been found to increase levels of sexual satisfaction in individuals receiving them.<sup>2</sup>

Transgender men experience significantly higher complications with penile prostheses than cisgender men.<sup>3</sup> Severe complications requiring surgical intervention (implant removal, infection, major revision, re-anchoring, etc.) were seen in 36% of cases in a recent aggregate study of 792 patients.<sup>4</sup> In the aggregate analysis, 40% of patients no longer had their original implant after a mean follow-up of 2.6 years.

We are particularly interested in observing the impacts of concomitant neourethral or neophallic procedures on penile prosthesis infection. In theory, disrupting the protective epithelial or skin barriers with simultaneous procedures could pose a higher risk of infection. We will examine the impact of both clean and clean-contaminated procedures. Clean procedures are defined as those that create wounds under controlled sterile conditions, that are primarily closed without evidence of inflammation or infection, and do not enter the genitourinary tract. Clean-contaminated procedures are similarly carried out but do enter the genitourinary tract.

Over the past 4 years we have endeavored to optimize this procedure at our high-volume center and present analysis of the individual steps in the surgical history of transmasculine patients with penile prostheses that may be of interest to patients and providers alike.

## METHODS

After IRB approval, retrospective chart review of all phalloplasty patients undergoing penile prosthesis placement was completed between April 14, 2017 and February 11, 2020. Six months of follow up was the minimum for inclusion in the study. The natural history of each prosthesis was followed through time. Covariates included: age, date of surgery, type of previous genital surgeries, simultaneous surgeries, and complications, including the need for antibiotics, revision, removal, or replacement. Chi square tests of independence were used to compare complication rates across surgical condition and prosthesis type.

### Preoperative Preparation

All patients have a urine culture before surgery, and any patient with a true urinary tract infection (symptomatic, pyuria, high concentrations of bacteria) are treated before implant with culture-specific oral antimicrobials for at least 72 hours before surgery and



**Figure 1.** Stepwise technique of inflatable penile prosthesis insertion: (A) suprapubic incision, (B) penile dissection, (C) anchoring of periosteal Fiberwire suture, (D) final inflation. Color version of figure is available online.

7 days after surgery. Many patients are colonized with culturable bacteria and these patients (asymptomatic, no pyuria, low concentrations of bacteria) are treated with culture specific antimicrobials starting 3 days before surgery. In diabetic patients, HgA1c levels should be below 7.0, and pre and post-operative serum blood sugars should be in good control (<150 mg/dL if possible). Hospital protocol requires a standard soap and water shower at home before surgery in addition to cleansing with chlorhexidine gluconate solution (4.0%) at home or pre-moistened chlorhexidine towelettes in the preoperative holding area. We are aware that this has not been shown to specifically decrease infection after cisgender male penile prostheses.<sup>5</sup> Vancomycin 15 mg/kg and gentamycin 5 mg/kg are given within 30 minutes of incision. Patients are thoroughly surgically prepped: (i) clipping of hair, (ii) irrigation of the urethra with providone/iodine 10% solution, (iii) surgical prep with 70% isopropyl alcohol, (iv) surgical scrub with providone and/or iodine 7.5% soap and providone and/or iodine 10% paint, (v) prep with chlorhexidine gluconate (CHG) 2% and isopropyl alcohol 70% (ChlorPrep; Becton, Dickinson and Company; Franklin Lakes, NJ, USA).<sup>5</sup>

Devices are soaked before implantation in 10 cc sulfamethoxazole 80 mg/mL-trimethoprim 16 mg/mL sterile solution for intravenous infusion (Bactrim), diluted with 10 cc of injectable saline.<sup>6</sup> No-touch technique, meaning implants are only handled by fresh/new gloves and implants never contact skin, is used throughout.<sup>7</sup> We have eschewed the use of ioban or other barriers as has been described by others, as it limits our ability to palpate and manipulate the phallus and scrotum. Double gloving is used and outer gloves are changed before handling the prosthesis.<sup>5</sup> Surgery is performed on an outpatient basis, being discharged home after recovery.

### Surgical Technique-Inflatable Prosthesis

We use the Coloplast Titan inflatable penile prosthesis and implant a single cylinder, in all cases<sup>8,9</sup> through a 6-8 cm transverse infrapubic incision (Figure 1A). Two #2 titanium sutures (Fiberwire; Arthrex; Naples, FL, USA) are placed thoroughly through the periosteum and superficial bone of the inferior pubis (Figure 1B). The phallic dissection for the cylinder is judiciously performed using Metzenbaum scissors, being careful to avoid injury to skin, urethra and vascular pedicle of the flap, to a point about 20% of the way past the coronal ridge (Figure 1C). We avoid vascular pedicle injury by limiting dissection away from the side where the vessels have been placed. One of the cylinders is removed, and the tubing capped per manufacturer's instruction. Care is taken to place the single cylinder to maintain a healthy "cap" of glans tissue over the tip.

The scrotal dissection for pump placement is started bluntly on the side opposite the vascular pedicle and continued sharply using Metzenbaum scissors into the scrotal sac. Biasing the dissection plane towards the caudal surface of the scrotum may maximally preserve scrotal flap blood supply. The midline abdominal fascia is incised, and a sub-rectus space developed

bluntly. A 120 cc reservoir is placed into this space and inflated with 120 cc of injectable saline to check for backpressure that may cause auto-inflation. Then 40–60 cc of this fluid is removed, leaving 60–80 cc of fluid in the reservoir. Either a 75 cc or 120 cc reservoir can be used. We have found no significant clinical differences between the 2 sizes.

A Furlow dilator is placed into the phallus and the distal measurement is made. The Furlow dilator is then placed against the pubis where the cylinder should lie after placement of the rear sutures, and this provides the length of the device. The proximal 1–2 cm of the device is sharply removed and the previously positioned periosteal Fiberwire sutures are placed through the center of the rear tip and tied down. The suture is then brought around to entrap the rear tip against the bone, and tied again. Rear tip extenders or synthetic cylinder sleeves are never used. The cylinder is delivered into the phallus using the Furlow device. The pump is delivered into the scrotum and the reservoir connections completed per manufacturer's recommendation. Contralateral testicular implant is placed, if desired. Careful closure of deep fascial layers is completed, isolating pump tubing when possible, with 1-0 Vicryl (polyglactin 910) simple sutures (Figure 1D). Drains are never used.

### Surgical Technique-Semirigid Prosthesis

We use a single cylinder Coloplast Genesis semirigid penile prosthesis. We generally use a 13 mm wide device, but narrower models can be used if the phallus is narrow (9.5 mm, 11 cm). The cylinder is encased in a synthetic vascular graft only slightly wider than the implant, which is trimmed to length and oversewn at both ends with nonabsorbable suture. Vascular grafts are placed over the implant in order to decrease movement of the smooth device within the body and to promote ingrowth of the scar capsule into the covered device. Bilateral testicular implants are also placed through a separate upper scrotal incision, if desired.

**Table 1.** Baseline demographics and surgical history descriptors

| Parameter                            | Number          |
|--------------------------------------|-----------------|
| <i>Age</i>                           |                 |
| Mean                                 | 34 years        |
| Range                                | 18-64 years     |
| <i>Prosthesis length</i>             |                 |
| Mean                                 | 20 cm           |
| Range                                | 13-28 cm        |
| <i>Time to prosthesis insertion</i>  |                 |
| Mean                                 | 15 months       |
| Range                                | 6-48 months     |
| <i>Time to removal for infection</i> |                 |
| Mean                                 | 1.7 months      |
| Range                                | 0.03-4.3 months |
| <i>Time to mechanical failure</i>    |                 |
| Mean                                 | 9.09 months     |
| Range                                | 3.5-19.7 months |

## Testicular Prostheses

If desired by the patient, testicular implants are placed at the time of penile prosthesis surgery. We use either Coloplast Torosa (Minneapolis, MN, USA) saline-filled silicone implants size extra small (width 2.2 cm, length 3 cm, volume 7 cc), small (width 2.5 cm, length 3.5 cm, volume 11cc), or the AART (Carson City, NV, USA) solid silicone implants size 1 (width 2.5 cm, length 3.6 cm, volume 11 cc) or 2 (width 3.0 cm, length 4.2 cm, volume 19 cc), interchangeably. Testicular prostheses are placed after closure of the prosthesis incisions, maintaining “no touch” technique for the prosthesis.

## RESULTS

Eighty patients received a penile prosthesis over 34 months: 84% (67/80) were inflatable and 16% (13/80) were semirigid. A similar number of each type of prosthesis were used during each half of the study period, with a slightly smaller number of semirigid being used later on. The average duration of follow up was 26.5 months (range 10.3–44.2). Mean patient age was 34 years and mean time between phalloplasty and the first penile prosthesis insertion was 15 months. The mean measured length of cylinder was 20 cm (Table 1). Three patients had diagnosed diabetes mellitus in good control (hemoglobin A1c = 5.3%, 5.7%, 6.1%).

## Previous Penile Surgery

Liposuction of the phallus prior to penile prosthesis insertion was done in 16% (13/80) of patients [11 ALT, 1 MLD, and 1 RFF phalloplasty]. Prior urethral stricture surgery had been done in 34% (27/80) of the patients, requiring 1 (14/27, 52%), 2 (10/27, 37%), 3 (2/27, 7%) or even 4 (1/27, 4%) surgeries to cure the urethral stricture.

## Simultaneous Non-prosthetic Surgery

Primary testicular implant placement was done at the time of first penile prosthesis placement in 73% of patients (58/80).

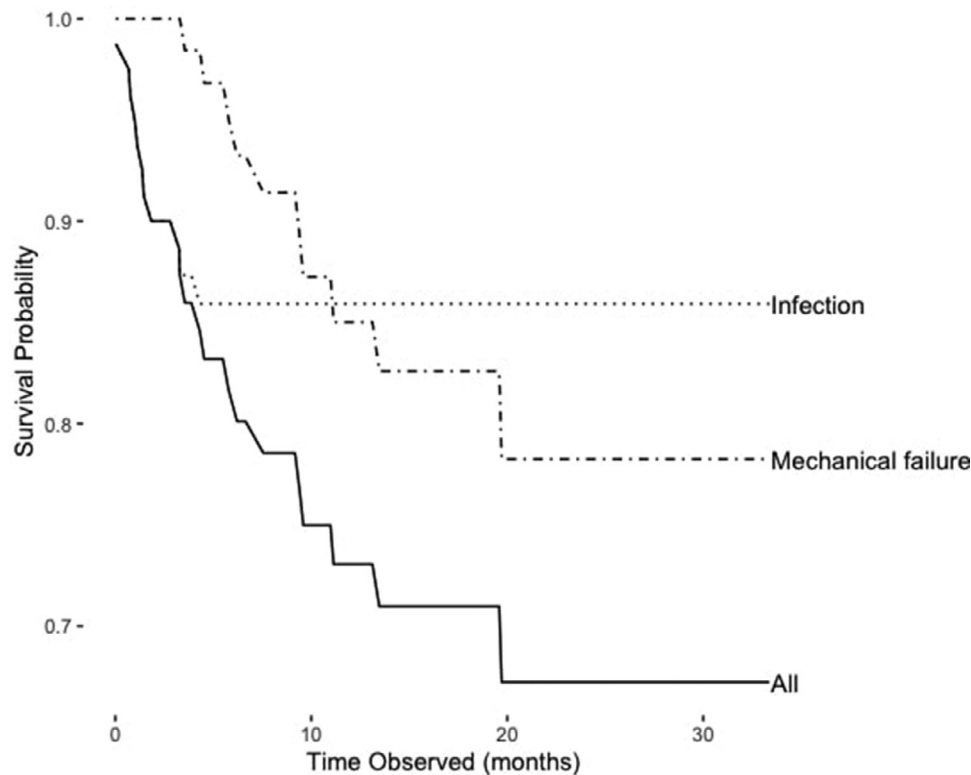
There were a variety of reasons why patients did not elect to have testicular implants (n = 22, 28%): small scrotum (11), did not want (4), already had testicular implants (2), and unknown (5). Among the 23 patients who elected not to undergo simultaneous testicular prosthesis placement, 17 (77%) had an inflatable prosthesis while 5 (23%) had semirigid. Simultaneous clean-contaminated surgical procedures were done in 10 (13%) cases. Clean-contaminated procedures included perineal wound repair (3), second stage meatal Johansson urethroplasty (2), meatal single stage urethroplasty (1), meatotomy (1), vaginectomy (1), urethral dilation (1), and urethral fistula repair (1). Simultaneous clean procedures were performed on/near the genitals at the time of penile prosthesis insertion in 29% (23/80) of patients. Clean procedures included glansplasty (8), glansplasty revision (7), monsplasty (6), glans implant (2), SP tube scar removal (2), and fat grafting of the phallus (1). Two of these patients had glans implant and monsplasty and one had glansplasty revision with scar removal. Fat grafting of the phallus was done in one patient at the time of penile prosthesis insertion, although it is generally reserved for well before or well after prosthesis placement.

## Complications

Thirteen patients required removal of their device due to infection (11/13, 84%), pain (1/13, 8%), or implant exposure (1/13, 8%). The average time between insertion and the first signs of infection was 35 days. Prosthesis infection occurred in 16 patients (20% overall), 11 of which required removal after unsuccessful antimicrobial therapy, while 5 were resolved with antimicrobial therapy alone. One patient received inpatient parenteral antibiotics and all others received outpatient oral treatment. Infections were identified clinically by the presence of pain, swelling, erythema, and at times exudate. Infection rates by prosthesis type and perioperative condition are shown in Table 2. The infection rate was 22% (15/67) for inflatable prostheses and 8% (1/13) for semirigid ( $P = .13$ ). Infection rates appeared similar amongst patients with

**Table 2.** Complications by pre/perioperative condition and prosthesis type

|                              | Overall (N = 80), N (%) | Inflatable (N = 67) | Semirigid (N = 14) | p overall |
|------------------------------|-------------------------|---------------------|--------------------|-----------|
| Clean procedure              | 23 (29)                 | 21                  | 2                  |           |
| Infection                    | 3 (4)                   | 3                   | 0                  | 0.89      |
| Mechanical failure           | 3 (4)                   | 3                   | 0                  | 1         |
| Clean-contaminated procedure | 11 (14)                 | 11                  | 0                  |           |
| Infection                    | 2 (3)                   | 2                   | 0                  | 0.87      |
| Mechanical failure           | 2 (3)                   | 2                   | 0                  | 0.61      |
| Testicular implant           | 58 (73)                 | 50                  | 8                  |           |
| Infection                    | 12 (15)                 | 12                  | 0                  | 0.80      |
| Mechanical failure           | 8 (10)                  | 7                   | 1                  | 0.54      |
| Previous liposuction         | 13 (16)                 | 12                  | 1                  |           |
| Infection                    | 3 (4)                   | 3                   | 0                  | 0.78      |
| Mechanical failure           | 3 (4)                   | 3                   | 0                  | 0.34      |
| Previous urethral stricture  | 27 (34)                 | 21                  | 6                  |           |
| Infection                    | 5 (6)                   | 5                   | 0                  | 0.81      |
| Mechanical failure           | 5 (6)                   | 5                   | 0                  | 0.30      |



**Figure 2.** Kaplan Meier survival curve of all-cause implant survival (solid) and implants removed for infection (dotted) or malfunction (dot dash). Color version of figure is available online.

(2/11, 18%) and without (14/69, 20%) simultaneous clean-contaminated surgery ( $P = .87$ ). Likewise, infection rates appeared similar amongst patients with and without simultaneous clean surgery ( $P = .89$ ) and testicular implant placement ( $p = 0.80$ ), although this study is not powered to definitively prove the same rate of infection in both groups. Of the 2 patients experiencing infection after having simultaneous clean-contaminated surgery, wound cultures were not available for both patients, and urine culture showed either *Escherichia coli* (1) or nonhemolytic streptococcus species (1) at the time of infection. Of the 13 patients experiencing prosthesis infection after having simultaneous clean surgery, 12 wound cultures were not available and one grew rare gram negative bacilli and staphylococcus species. Urine cultures amongst these patients grew mixed urogenital flora (2), *Citrobacter koseri* (1), enterococcus (1), *Escherichia coli* (1), nonhemolytic streptococcus (1), or streptococcus agalactiae (1), and 6 cultures were not available. Type and number of prior surgeries did not seem to affect the infection rate. There seemed to be no significant difference in infection rate for those who underwent prior liposuction ( $P = .78$ ) or urethroplasty ( $P = .81$ ).

Ten (13%) patients underwent replacement of the penile prosthesis due to device dislodgement (4), erosion (2), malfunction of inflatable device (2), and wanting to change from an inflatable to semirigid device (2). These patients did not have prosthesis infection, so simultaneous removal and replacement of the device was done. Erosions are classified as distinct from infections since true

infection with intact skin appears clinically distinct from erosions, where the fragile and highly operated tissues of the neophallus or scrotum become breached and expose the implant, requiring removal. There were an additional 5 patients who underwent repositioning of their device but did not require device replacement. Differences in mechanical failure rates were not significant across perioperative procedures (Table 2).

Infections requiring removal occurred a mean of 1.7 months after implant insertion, and mechanical failures occurred a mean of 9.1 months (Table 1) after surgery. Device loss at 9 months was 21% overall, 14% for infected prostheses requiring removal, and 9% for prostheses with mechanical failures (Figure 2). Case number, with one being the earliest case and 80 being the most recent case, was significantly associated with infection by linear regression ( $P = .03$ , McFadden's  $R^2 = 0.066$ ).

### Subsequent Prostheses

For the 10 patients undergoing replacement of the first penile implant, 70% (7/10) had no complications with their second device. For the other 3 patients' second device: 1 (10%) had poor deflation but did not have it removed, one (10%) required repositioning surgery, and another (10%) had it removed and replaced with a third device due to recurrent malfunction.

Of the 11 patients who had their first penile implant removed due to infection, 6 (55%) had it replaced with a second device at



a later date. Three (50%) of these patients experienced infection requiring removal of the second prosthesis, a mean of 9.1 months (8.7–9.5, one patient unknown) after insertion. One of these 6 patients (16%) did not experience infection of the second device but had malfunction that required removal and replacement with a third device. Another patient experienced persistent dysuria and increased urinary frequency with hematuria after the second device and elected to have replacement with a semirigid implant. This was potentially due to chemical irritation from urethral povidone-iodine irrigation. They subsequently experienced severe pain that was successfully treated with antibiotics for presumptive infection with their third device. Of the 3 patients who had their second device removed because of infection, 2 (67%) did not have a third penile prosthesis and 1 (33%) did have a third device placed.

## DISCUSSION

Penile prostheses amongst transmasculine patients with phalloplasty have an exceptionally high complication rate, but meticulously following proven anti-infection techniques and surgical experience over time appears to limit complications. Because conventional penile prosthesis implants are designed for cisgender male patients, these high rates of complications are thought to arise primarily from the surgical accommodations necessary for implantation in the complicated anatomical environment. Lack of divergent penile crura to anchor the prosthesis, lack of tunica albuginea to envelop the prosthesis, diminished cutaneous sensation leading to erosions, and diminished blood supply to the neophallus flaps<sup>3</sup> are unique to transmasculine patients' anatomy and contribute to complications seen along the prostheses' course. No prior study has analyzed the individual surgical steps involved in successful penile prosthesis implantation to determine which surgical aspects yield the most complications. Overall, 36% of patients receiving inflatable and 29% of patients receiving semirigid prostheses required surgery for complications with the first device. This compares favorably to Rooker's meta-analysis of penile prosthesis placements in phalloplasty patients (Table 3).<sup>4</sup>

The proportion of inflatable (83%) and semi-rigid (17%) implants in our study is nearly identical to proportions found in our previous systemic review of 792 transmasculine patients, with 83.6% inflatable and 16.4% semi-rigid implants.<sup>4</sup> Similarly, a report of 1,056 patients found that 84% of those receiving a penile prosthesis had an inflatable implant.<sup>10</sup> Average patient age at implantation of 34 years is also similar to ages found in both systemic reviews and in primary literature.<sup>4,11-14</sup>

Our average time between phalloplasty and penile prosthesis implantation (15 months) is safely outside of the 6-12 month range recommended for healing after phalloplasty.<sup>15-17</sup> Our average original cylinder length (20cm) used for implantation is not surprising, given that an aggregate study on length of neophallus

**Table 3.** Complication rates compared to aggregate analysis

|                                    | Our cohort<br>(N = 80), % (N) | Rooker et al. <sup>4</sup> |
|------------------------------------|-------------------------------|----------------------------|
| Total complication rate            | 35 (28)                       | 36.2 (287/792)             |
| Inflatable total complication rate | 36 (24)                       | 45.2 (217/480)             |
| Semirigid total complication rate  | 31 (4)                        | 41.5 (27/65)               |
| Infection                          | 20 (16)                       | 8.6 (61/707)               |
| Mechanical failure                 | 3 (2)                         | 12.0 (85/707)              |
| Malpositioning, migration          | 10 (8)                        | 5.2 (37/707)               |
| Erosion                            | 4 (3)                         | 3.4 (24/707)               |
| Patient dissatisfaction            | 3 (2)                         | 6.8 (48/707)               |
| Other                              | 1 (1)                         | 1.0 (7/707)                |

The total complication rates include those complications for which surgical intervention was required. Five of the infected prosthesis cases did not require surgical intervention but were treated with antimicrobials for presumed infection.

stratified by donor site found an average length of 10 cm, 14 cm, and 17 cm for ALT, RFF, and MLD, respectively.<sup>17</sup> Note that this tendency towards long implants is likely multifactorial, but could be because of the high number of ALT phalloplasty patients in our series (all who tend towards longer phallus length than RFF patients), the tendency of our high volume group to create longer phalluses when possible, and thorough dissection underneath the pubic bone which allows for the placement of a slightly longer device.

We found that type and number of prior non-prosthetic surgeries should not be considered as a risk factor for penile prosthesis after phalloplasty for transmasculine patients. One third of our patients receiving penile prostheses required prior surgeries to manage urethral stricture, compared with the urethral complication rate of 39.4% obtained in a meta-analysis study of 869 transmasculine patients.<sup>18</sup> A study of urethroplasty for stricture after phalloplasty found stricture recurrence after definitive urethroplasty in 41% of patients.<sup>19</sup> In our cohort of patients receiving penile prostheses after phalloplasty, 48% of patients needed more than one surgery to cure urethral stricture prior to penile prosthesis insertion.

Simultaneous non-prosthetic surgery did not appear to increase the rate of infection, even when that surgery was "clean-contaminated," such as minor urethral repairs or vaginectomy. Although, in these cases, care was taken to minimize cross-contamination by completing these non-prosthetic surgeries, then re-prepping and re-draping before the prosthetic component. This is consistent with past research findings that do not show an increase in prosthesis infections when concomitant circumcision, that is comparable to glansplasty or meatotomy in terms of bacterial exposure, is performed in cisgender men (Level 3 evidence).<sup>5</sup>

High volume centers have been proven in other types of surgery to result in lower rates of complications,<sup>20</sup> and in a recent review, many of the best practice techniques we have adopted have been shown to decrease prosthesis infection in cis male patients: no touch techniques (Level 3 evidence), appropriate preoperative intravenous antimicrobial prophylaxis (Level 2), control of blood sugar in diabetics (Level 2), antibiotic soaked implants (Level 2), hair clipping instead of razor shaving (Level 1), and use of chlorhexidine-based surgical scrub (Level 1).<sup>5</sup> These techniques were used for the complete duration of the study period. We performed linear regression on infections by case number to examine the secondary effect of a learning curve in a dedicated transgender surgery center, including 4 surgeons during the study period, yielding fewer complications, which showed that probability of infection decreased as the number of cases performed increased (Figure 3). Our overall survival rate of 79% at 9 months compares similarly to that of current studies.<sup>21</sup>

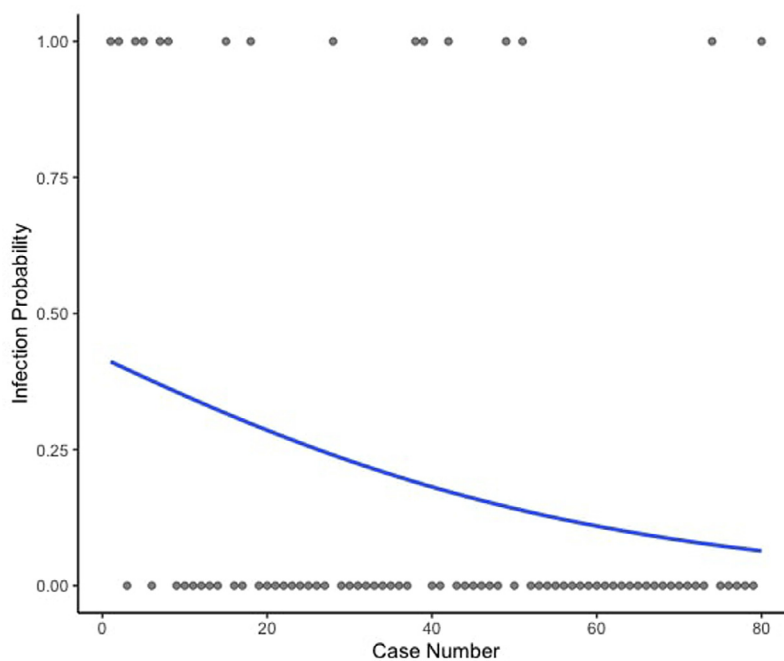
Although not statistically significant, we found it clinically significant to find that rate of prosthesis infection was markedly lower for semirigid prostheses (7%) than inflatables (22%), which was not observed in the aggregate analysis of published reports.<sup>4</sup> However, it may be that the true infection rates of semirigid prostheses have not been accurately reported in the past, as the data is based on only 65 patients reported in 9 studies, published over a span of 23 years. Or, as our data suggests, semirigid penile prostheses may have a much lower (1/3) rate of infections than inflatables. We hypothesize that the significantly less invasive nature of the dissection required by semi rigid prosthesis may partly explain their lower infection rate.

In analyzing infection rates for subsequent prostheses, we found that patients experiencing infection requiring removal of their first device are likely to have subsequent infections, although our sample size was small. We note that when a second prosthesis was placed after removal for infection, the infection rate was high at 50%, and the time to removal for infection was much longer (9 months compared to 1.7 months). The reasons for this are unclear. Because infection necessitated the majority of first (84%, 11/13) and second (50%, 3/6) device removals, it remains the biggest concern in successful penile prosthesis implantation. This is disturbing as it implies that patients with one prosthesis infection may have anatomic, physiologic, immune, or microbiota factors that increase risk for prosthesis infections.

When compared to our systemic review of complication rates for initial implantation, we obtained smaller incidences of erosions and mechanical failure. However, the incidence of mechanical failure increased above this aggregate value with the second device.<sup>4</sup> For the first time, we show increased risk of complication with subsequent prosthesis surgeries.

## LIMITATIONS

Due to small sample size, especially when dividing the cohort into subgroups by procedure and complication, we cannot say that our study is sufficiently powered to declare a definitive difference between groups. We are similarly concerned that the study may not be powered sufficiently to make conclusions regarding simultaneous surgeries.



**Figure 3.** Linear regression model predicting infection from case number. Scatterplot point indicate presence ( $y = 1.0$ ) or absence ( $y = 0$ ) of infection in our cohort. Color version of figure is available online.

Patients, while having at least 6 months of follow up, were not all followed for the exact same period of time. As most of our patients travel from out of town, we cannot be sure that they have followed up. However, we have very close follow up email, call, and text correspondence, and it is very unlikely that we would not have been notified of complications. This could impact the number events gathered and complication rates along the prostheses' histories. Patient-reported outcomes were not collected. Thus, we were unable to uncover the implications of penile prosthesis insertion following phalloplasty from the patients' perspective.

## CONCLUSIONS

We confirm the high rate of penile prosthesis complications in phalloplasty patients. We demonstrate that preoperative conditions of the neophallus, such as prior stricture correction, and perioperative factors, such as simultaneous clean and clean-contaminated procedures, seem to pose no additional increase in complication rates. Our data suggest that surgical experience may further decrease complications over time.

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## STATEMENT OF AUTHORSHIP

Conceptualization, R.A.S.; Methodology, B.L.B. and R.A.S.; Investigation, B.L.B., R.Y.M., K.E.C., and R.A.S.; Data Curation, B.L.B., R.Y.M., and R.A.S.; Validation-R.A.S.; Writing – Original Draft, B.L.B., R.Y.M., and R.A.S.; Writing – Review & Editing, B.L.B., R.Y.M., R.A.S., and K.E.C.; Visualization-B.L.B. and R.A.S.; Resources, R.A.S., C.N.C., and M.S.; Supervision, R.A.S., C.N.C., and M.S.

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