Peer Review File

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Reviewer A

This is a well-done retrospective study on a single institution's experience with the use of counter-incisions (CI) for reservoir placement in IPP surgery. While I think that the study is well-thought out and executed, I think more transparency is needed, and the the authors should respond to several concerns:

1) While the utility of CI is well-stated, namely the potential risks of submuscular reservoir placement, the authors only quoted the literature and did not reveal their own experience with submuscular reservoir placement. Did they have a rash of complications that required them to look into alternative means of reservoir placement? I would want to know why they started using the CI technique. To me, citing reference #16 does not add much in this study, since it was a cadaver study. The outcome of greatest importance with regard to reservoir positioning are those patients that need revision surgery due to reservoir-specific complications, such as herniation or bothersome palpability. Irrespective of which cadaveric plane the reservoir is in, if the patient is happy with a functional device, then the location of the reservoir could be considered immaterial.

Reply 1: We did not personally experience a rash of complications leading to this practice pattern, but noted an uptick in referrals for reservoir complications from "occasional implanters". This led to the realization that these providers were not adept with alternative reservoir placement techniques, so we started using counter incisions in part to train our residents/fellows a safe and reproducible option for the more hostile pelvis.

While we agree with the reviewer that reference 16 is limited as a cadaver study, and that the ultimate outcome is reservoir related complications, it does demonstrate the potential inaccuracy with blind placement.

Changes to text: Page 4, Line 68: added "by cadaveric studies" for transparency when citing #16.
Page 5, Line 82 added: "Anecdotally we noted an increase in referrals for reservoir complications from occasional implanters not familiar with alternative reservoir placement, and in response, wanted to ensure the institution's trainees had a safe,

reproducible option for the IPP placement in a hostile pelvis."

2) Aside from the ESRD patients where the CI utilization is justified, the authors do not say why the CI was used in men with prior hernia repair or prostatectomy, or any other situation (this relates to the above point). I think this should be explained, since in general this is not a commonly utilized approach in IPP surgery. They clearly stated that this was used in a higher proportion of removal/replacement cases, but do not say why. I agree that these are more challenging cases, and if their approach is to use it, then so be it, but it should be stated as such. They do not address issues with reservoir removal via peno-scrotal incision, which is likely a reason, nor do they mention the "drain-and-retain" approach, which is considered acceptable in non-infected cases. What concerns were they having with the former, and why not employ the latter?

Reply 1: As with point #1, counter incision was used as a safe alternative to a hostile pelvis, such as a previously operated field in patients with prior inguinal hernia/prostatectomy. We did not use it in all removal/replacement cases but was at the discretion of the surgeon and often was performed to ensure safe removal. Our surgeon does use the "drain-and-retain" approach on occasion, and these patients are included in the 101 (20.9%) remove and replace cases in the non-counter incision cohort. Unfortunately, our database currently does not include that data, however if it is critical to the reviewer we can collect it. We elaborate on the typical approach to the reservoir during a removal/replacement in the methods section and recognize that this introduces selection bias (Page 14, Line 279).

Changes to text:
Page 7, lines 120-126: "In general, in patients with a normal contralateral inguinal canal and pelvis, we make an initial attempt at removing the reservoir from the penoscrotal incision. If not removed easily, or is deep in the pelvis, it is drained and decommissioned. In patients with a significant pelvic surgery history (prostatectomy, inguinal hernia, cystectomy, abdominal perineal resection, low anterior resection, femoral arterial bypass) we typically used a counter incision for reservoir removal. Blind reservoir removal through a penoscrotal incision can be very treacherous due to nearby vascular structures and potential for reservoir migration."

3) I would like more info on the intravesical reservoir complication they had with non-CI surgery. This is a very rare complication, and it likely did not happen exclusively because standard reservoir placement was attempted.

Reply 1: We agree that the rarity of this requires more elaboration and have added detail

as requested. In this case, it was likely the patient's scarring from prior IPP surgeries which placed him at an increased risk of intravesical reservoir placement.

Changes to text: Page 10, Lines 192-199: "The intravesical reservoir placement occurred in a removal and replacement case for malfunctioning prosthesis placed 13 years prior. The old reservoir was drained and decommissioned, and a new reservoir placed in the contralateral space of Retzius. Flexible cystoscopy at the completion of the case demonstrated an intravesical placement of the new reservoir, which was then removed, but the cylinders and pump were left in situ. After foley catheter drainage for 1 month and a negative cystogram, the patient underwent submuscular placement of a new reservoir via counter incision 4 months later which was connected to his cylinders and has since recovered without issue."

4) I have a difficult time understanding the need for a counter-incision in an infrapubic approach-can this be clarified?

Reply 1: We have added additional clarification on this one patient who had a counter incision with infrapubic approach. As described below, he had an extensive prior surgical history including inguinal hernia repair and recent Mulcahy salvage procedure for an infected IPP placed by an outside urologist.

Changes to text: Page 9, lines 164-171: "There was only one infrapubic approach (2%) that used a counter incision, compared to 38 (8%) in the non-counter incision cohort. This was in patient who had undergone a Mulcahy salvage procedure through an infrapubic incision 4 months prior. His surgical history was also notable for prior inguinal hernia repair, laparoscopic sigmoidectomy, vasectomy, and open cholecystectomy. The malleable prosthesis was removed and inflatable cylinders inserted through the infrapubic incision, and due to the patient's extensive past surgical history a counter incision was used for left lower quadrant submuscular reservoir placement"

5) I agree with the comments about surgeons not being comfortable with reservoir placement, but if they are, should they truly be doing these surgeries? Not saying this is a problem point, because the CI approach could afford them another tool in their (limited) IPP armamentarium. Nevertheless, these surgeons are likely doing a disservice to their ED patients. The cited reference is quoting residents, so this may not be an appropriate reference.

Reply 1: While we tend to agree that ED patients would be better served by high volume

rather than occasional implanters, the reality is that this isn't always feasible, and as such we hope our work shows these occasional implanters that there are simple options for alternative reservoir placement. Furthermore, we acknowledge the limitations of this paper citing trainees, however it is not unreasonable to extrapolate these findings to urologists early in their career who may not have had a robust complex IPP exposure in their training.

Changes to text: Page 12, Lines 235 – 237 "While the trainee findings may not be generalizable to all practicing urologists, these were 1-2 years from practice and therefore it is not unreasonable to assume representative of many young urologists"

Reviewer B

This is a retrospective review of 534 IPP surgeries over 5 years in which the authors compare a group of patients who underwent counter incision (CI) for reservoir placement to a group of patients who did not undergo counter incision. Primary outcome was 90 day device infection. Secondary outcomes were herniation, hematoma, device malfunction, operative times. Patients who had CI were more likely to be obese and to have had RALP/RRP. CI was associated with a longer operative time (17 minutes), but no difference in complication rates. Additionally, the authors evaluated complication rates after stratifying by virgin vs remove/replace cases and found no differences. The authors conclude that CI is safe compared and that this study supports the use of CI. This is a well done study that will be a useful addition to the literature. My concerns are minor...

1) The study failed to show any differences between CI and non-CI group. Was this study powered to detect differences in any of their primary or secondary outcomes?

Reply 1: We agree that this study is potentially underpowered, as mentioned in limitations section of discussion (page 14, lines 284-286), no power analysis was performed and these complications are rare, so possible the study is underpowered to detect a difference. We added the following text for emphasis.

Changes to text: Page 14, Lines 287-288 "Being a retrospective database study, no power analyses were performed as we had no control over our sample size."

2) The authors state that this study supports the use of CI, which is not the case. They go on to say that for surgeons who are not comfortable with alternative placement this offers a safe alternative, which is fair although they should also concede that the authors experience (high volume implanter) with CI may not be generalizable to low volume surgeons - they may run into problems with a CI, as the authors did in one case.

Reply 1: While it is true a tertiary referral center population may not be completely generalizable, the use of a counter incision is simple and safe technique, which we do feel is generalizable even to low volume surgeons (unlike other methods of alternative reservoir placement). We have re-worded our conclusions to better align with our findings.

Changes to text: Page 3 lines 36-39 "For physicians not comfortable with alternative placement through a penoscrotal or infrapubic incision, this offers a reasonable alternative and permits use of 3-piece devices in patients with a hostile pelvis."
Page

Page 14, lines 295-299 "Overall, our experience using a counter incision for reservoir placement in this high-risk patient cohort demonstrates comparable safety and efficacy to standard technique and supports the consideration of counter incisions for alternative reservoir placements in prostate cancer survivors, who make up an overwhelming fraction of the erectile dysfunction population."

Reviewer C

Overall, the author should be commended on their research study. I think it adds to the literature base and is clearly well-written. However, I would suggest the following:
Your title and conclusions need to be tempered to some degree. This is a single center retrospective study with only 51 patients in the CI group. Saying that CI's are safe and effective is an over-reach. Stating that CI's and standard technique may share comparable outcomes is more reasonable. You did not perform a trial to evaluate safety and effectiveness (and I realize that a trial is not always the best method for evaluation).
Abstract
In the abstract, please organize the results so the estimates are in the same order (CI vs. non-CI). When I read the abstract, I thought the infection rate was 4% for the CI group.

Reply 1: We appreciate the reviewers comments, and have changed the wording of our conclusions accordingly to better reflect our methodology and findings. Furthermore, we corrected the abstract to use consistent order of groups.

Changes to text: Page 3, Line 30-32: "Median operative time was 17 minutes longer in the CI group (74 vs 57 minutes, $p < 0.001$). Device infection rates were similar (2.0 vs. 4.1%, $p = 0.71$), as were rates of hematoma (5.9 vs 2.7%, $p = 0.19$), and device malfunction (0.0 vs 1.4% $p = 1.00$). "
Page 3 lines 37-39 "For physicians not comfortable with alternative placement through

a penoscrotal or infrapubic incision, this offers a reasonable alternative and permits use of 3-piece devices in patients with a hostile pelvis."
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Page 14, lines 296-298 "Overall, our experience using a counter incision for reservoir placement in this high-risk patient cohort demonstrates comparable safety and efficacy to standard technique and supports the consideration of counter incisions for alternative reservoir placements in prostate cancer survivors, who make up an overwhelming fraction of the erectile dysfunction population."

The conclusions are reasonable as stated.
Introduction - No issues. Well stated.

Methods
BMI significantly differed between the CI and non-CI groups. Why was this not controlled for in the multivariate analysis? BMI has not only been found to be linked to increased device infection risk (especially fungal), but also likely plays a significant role in operative time and outcomes related to making a CI into extensive subcutaneous tissue.

Reply 1: We agree with the reviewer that BMI should have been included, methods, results and Table 3 have been updated.

Changes to text: Page 8, line 151-152- "Covariates used included age, smoking status, BMI (Body Mass Index), diabetes, removal and replacement, use of a counter incision, and operative time."
Page 10, lines 188-189- "After correcting for potential confounders using the multivariate models, use of a counter incision was not associated with total complications (OR 1.57 [0.50-4.30] p=0.410) or device infection (OR 1.01 [0.99-1.03] p=0.810), (Table 3)."

Results
I would add an intra-operative figure that shows how you make your counter incision in an obese patient.

Reply 1: In obese patients, the counter incision is still placed in the same location, however the patient is positioned in Trendelenburg to allow the pannus to fall back from the field. Of note, in obese patients we are more likely to use alternative reservoir placement (submuscular via counter incision or through penoscrotal incision) as

patients are less likely to palpate the reservoir.
Changes to text: Page 7, line 117-118: "Obese patients were positioned in Trendelenburg to allow the pannus to fall away from the operative field."

Discussion
Operative time needs to be discussed in the context of the surgeon's experience with counter incision reservoir placement. Was this person just learning how to do CI's? Or were they an experienced surgeon? Novice surgeons unfamiliar with the CI may have longer operative times. Similarly, please comment on the ease of the CI versus standard placement.

Reply 1: This is a valid point and we have elaborated on the experience of our single surgeon series – GURS fellowship trained with a practice focusing on complex IPP surgeries, so an experienced surgeon not just learning how to do CIs. Compared to standard alternative reservoir placement, we feel a CI is easier and more predictable as it involves simply dissecting through subcutaneous tissue and directly visualizing the rectus body behind which the reservoir is placed, rather than trying to place it blindly through an penoscrotal incision as is commonly done for high submuscular technique.

Changes to text: Page 6, Lines 96-98: "These represent a single reconstructive urology fellowship trained surgeon's series at a tertiary referral center with an emphasis on complex IPP surgeries."

Do your results advocate for CI in all patients, not just post-RALP patients? There are injuries with standard technique despite having an intact Retzius space.

Reply 1: While it is true that there are injuries in patients without a violated space of Retzius, these are exceedingly rare and so we do not advocate for use of CI in all patients. However, as it provides similar outcomes to standard technique (albeit with potential selection bias in a retrospective study) it is a reasonable approach in patients with a hostile pelvis for alternative reservoir placement.

Was a pre-operative skin wash completed leading up to surgery (e.g. hibiclens scrub)? Did the scrub area include the abdomen? Were patient's tested for MRSA colonization prior to surgery?

Reply 1: Patients used a hibiclens scrub at home the night before surgery, but were not tested for MRSA colonization. A 10-minute betadine scrub followed by chlorhexidine and alcohol based prep was used to prep past the patient's umbilicus.

Changes to text: Page 6, Lines 104-109: “Preoperatively all patients used a hibiclens scrub the night before surgery, underwent hair removal, and were given pre-operative antibiotics in accordance with contemporary AUA guidelines. There was no difference in perioperative antibiotics between single incision and counter incision patients. A 10-minute betadine scrub followed by chlorhexidine and alcohol based prep was used for surgical prep.”

What specific antibiotic regimens were used? A number of new publication have suggested that AUA antibiotic prophylaxis is likely inadequate in preventing device infections.

- https://pubmed.ncbi.nlm.nih.gov/32519913/
- https://pubmed.ncbi.nlm.nih.gov/28189561/
- https://pubmed.ncbi.nlm.nih.gov/31255212/

Reply 1: We used cefazolin, vancomycin, and gentamycin for antibiotic prophylaxis for the majority of cases, and have stated this in the methods section.

Changes to text: Page 6, Line 106: “and were given pre-operative antibiotics in accordance with contemporary AUA guidelines – vancomycin, gentamycin, and cefazolin for the majority of cases.”

What organisms were responsible for the device infections/explantations?

Reply 1: Unfortunately, we do not have complete microbiological data on most of the removal and replacements in the database. Of the 19 results we do have, 47% grew multiple organisms including typical urinary pathogens - E. coli, Klebsiella, streptococcus viridians, yeast, and enterococcus faecalis, as well as skin flora such as MSSA/MRSA and coagulase negative staphylococci. We are willing to add this, but given the significant amount of missing data opted not to.