

Peer Review File

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<mark>Reviewer A</mark>

Introduction:

Please list an estimate of the prevalence of tissue expander loss. Some of this is in the discussion, but this should also be discussed in the introduction in setting the stage for the problem.

Reply: The prevalence of tissue expander loss varies by study and institution, and there is no overall consensus, but one of the largest studies has shown a prevalence of 0.8%.

Changes in the Text: We added this information to lines 65-69 in the introduction.

Line 81, the author states "unlike many prior studies", can you please reference some of these to provide context.

Reply: Yes, please see Changes in the Text.

Changes in the Text: Lines 85-91 have been edited to include in-text references as well as an elaboration on the point that our study is smaller, but has less variability so that comparison is more accurate.

Methods:

It is unclear why delayed patients are excluded.

Reply: We wanted to have as homogeneous study group as possible. While the work of placing the expander and doing the postoperative expansions is very similar, the entire operative procedure is quite different due to the mastectomy. In general, the operative time is longer, the risk of skin necrosis is greater, and the drain use is different. There is also generally a smaller incision whose location is driven by the prior mastectomy scar. Because of these issues, we decided to look at only immediate reconstructions."

Changes in the Text: Lines 139-144 were added to clarify the above point.

Line 125-126 - it would be better to add your hypothesis in the methods that drain duration and total expander capacity may have a relation to BMI to the introduction. This needs to be explained in the introduction and backed by current literature. Furthermore, how does this hypothesis tie in with the purpose of the study to determine expander loss?



Reply: This line was removed because the authors agree that this is not the appropriate location for a hypothesis statement.

Changes in the Text: We included our hypothesis statements in the Background section and expanded upon our hypothesis of drain duration and expander capacity being related to BMI in lines 97-115 of the Introduction.

It would be helpful to have a clear indication of the surgical protocol. Though the authors state this is standardized across the surgeons, it remains unclear what the protocol is. For instance, are patients admitted for 24h? Are they placed on IV abx? Do all patients get drains placed? Similarly, it is unclear from the text what the intraoperative process is – are expanders placed sub-pec or pre-pec, is there use of acellular dermal matrix or artificial matrix, are there use of antibiotic irrigations, what method is used for expander placement (e.g. changing gloves)?

Reply: Patients are admitted for at least 23h. They are placed on ppx abx, usually cefazolin but on clindamycin or vancomycin in PCN-allergic patients. All patients get breast drains. Expanders are placed sub-pec and ADM was used in the vast majority of patients. Antibiotic irrigation was used and gloves were changed for expander placement.

Changes in the Text: Details about surgical protocols were added to the Methods section, see lines 172-185.

Results:

The crux of this paper revolves around risk factors for TE loss, I would recommend a table or figures that expresses these results and odds ratios as opposed to only a description in text.

Reply: Noted

Changes in the Text: Odds ratios and 95% confidence intervals have been added to Table 2. Statistical analytics were trimmed down within the Results section. Figures 3, 4, and 5 have been added.

Since you have both patients and events, it would be helpful to have the number of patients included. It seems the data is reported in terms of events.

Reply: Data analysis in this study was conducted in terms of events, not patients. We added patient counts where it made sense.

Changes in the Text: Patient counts were added to figure 1, lines 208-210,

Line 132-133, can you comment on what happened with the 50 events with permanent removal? Was autologous reconstruction offered or did these patients not pursue additional reconstruction.

Reply: The majority did not choose to pursue reconstruction. Some patients were



offered autologous reconstruction and some were offered delayed reconstruction with expanders.

Changes in the Text: See lines 194-196.

Line 134, you say mechanical issues with the expander, it would be helpful to specify or elaborate on this.

Reply: Mechanical issues refers to expander rupture or filling defect due to a leak. Changes in the Text: Text was added in line 164-165 that defines what mechanical issues are in the context of the study.

Line 135, it should be made clearer how "low infection risk" patients were determined. Was this based on a WBC, clinical signs, physical exam? Was this consistent among the authors?

Reply: This was based on clinical exam – typically imminent infection secondary to a wound issue, increased drainage from JP. This was consistent among the surgeons. Some patients with mechanical issues were also offered exchange. Changes in the Text: We added text clarifying this point in lines 197-203.

Line 148-158, please include the number of patients in each statement. It gives the reader more context, especially since patients have been excluded if they were missing variables.

Reply: Data analysis in this study was performed by event, not by patient, but we can see why not specifying proportions by event AND patient can be confusing in this instance.

Changes in the Text: Lines 212-214 were updated to include both number of patients and number of events.

Line 163, were there differences in use of ADM and plane of expander placement in patients below and above BMI 23?

Reply: No, virtually all patients regardless of BMI had ADM placed. Plane of expander placement was not a variable in this study because all surgeons employed a subpectoral technique at the time of data collection. Changes in the Text: See Lines 91-93.

Figure 1, it would be helpful to see the number of patients in the lower half of the boxes. **Reply: Patients were added to the boxes for clarity. Please keep in mind that for our analysis, exchanges and removals were counted as separate events even if they occurred within the same patient which explains why there are more patients in the TE removal box than expected.**

Changes in the Text: See Figure 1.

Figure 2, please label the y-axis



Reply: Noted

Changes in the Text: The y-axis of Figure 2 has been labeled appropriately.

Table 3, number of variables per participant is listed, but most of the other results are in terms of number of expanders/events, it would be helpful to have these number of variables expressed as a percentage of total number of patients per group or number of events per group.

Reply: Noted.

Changes in the Text: Table 3 has been changed to be expressed in terms of % of total number of patients per group.

Discussion

The discussion could benefit from trimming down and better context of results in how it should inform discussions with patients.

Reply: Noted.

Changes in the Text: The discussion section was trimmed down. See lines 311-318.

Line 195-204, could likely be edited out as all of this is based on postulation and not on the actual results.

Reply: These lines have been removed as suggested.

Changes in the Text: The lines have been removed as suggested.

Infection is briefly mentioned in the discussion, primarily in the context of drain duration. The authors should mention if their patients are placed on antibiotics till drains are in place. What is their practice. It is also unclear if an analysis was performed on the predictive value of having an infection and TE loss.

Reply: Patients are placed on prophylactic antibiotics within 60 min before incision. Patients were not placed on antibiotics postoperatively or in the follow-up period unless there was a clinical indication of infection. There was no analysis performed on the predictive value of having infection and TE loss, this information as included to provide context.

Changes in the Text: Lines 178-185 were added to the Methods section to clarify antibiotic practices.

Similarly, the authors should discuss their postoperative patient follow-up practices. Are drains left in longer because of patient related factors, long intervals in postoperative follow up, or is this based primarily on drain output levels.

Reply: Drain duration was based primarily on drain output levels, not on other factors.

Changes in the Text: This was added to line 180.



Line 223-234 would benefit from a more thorough discussion of SE status and its impact on reconstruction success/failure by citing some of the current literature. The authors mainly list the limitations of their method in this paragraph.

Reply: Noted

Changes in the Text: Lines 283-297 were added to expand upon this point.

In the limitations, please talk about the limitations of external validity of your results. How does your population compare to national means?

Reply: Our study is small and our patient population is more homogeneous than the national population. Furthermore, our study is at one institution that employs the same procedures for each patient. This can impact the external validity of the study.

Changes in the Text: Please see lines 304-317.

Conclusion

Line 265-267, I'm not sure if this conclusion can be made based on the findings of this study. It is better to focus on the use of these variables in risk-discussions as mentioned in the abstract and introduction.

Reply: We changed this conclusion to fit more into the risk-discussion. Changes in the Text: Please see lines 338-344.

Minor

There are many typos throughout the manuscript. Please review (e.g. different colored fonts, missing words, additional brackets, etc.)

Reply: Noted.

Changes in the Text: All grammatical and formatting errors have been corrected.

<mark>Reviewer B</mark>

It is a relatively well-written paper but is based on a small sized population. **Reply: Thank you for your comment. Changes in the Text: No changes applicable**.

This paper is in short of the extent of reference research. For example, only 12 references they relied on in their paper. In the background part, it seems like that the authors took only two groups $(1\sim4, 5\sim6)$ of references to support their argument. I would like to recommend the authors to find out more previous studies regarding to their manuscript in the background part as well as in the discussion part.

Reply: In our post-review editing process, we have added several sources to



support our paper.

Changes in the Text: Please see the in-text citations and References section to see the additional sources we have included.

Figure 1 is not clearly visible. **Reply: Noted. Changes in the Text: Figure 1 has been changed to a PDF and this should make viewing easier.**

It would be nicer if they added the illustration of each incision in figure 2. Reply: Noted Changes in the Text: Incision drawing has been added as figure 3

I could not find any p-value to express the statistical significance in table 2. Reply: This was originally just a qualitative table, but now has been updated to include statistical analysis. Changes in the Text: OR and 95% CI were added to Table 2.

It looks like that there were significantly higher chance of TE loss in prophylactic mastectomy patients. In this paper, I could not find the explanation or discussion for that.

Reply: Prophylactic mastectomy was not a significant risk factor for TE loss (OR = 2.324, p = 0.1407)

Changes in the Text: A statement was added to the manuscript in lines 140-142 to clarify that prophylactic mastectomy is not a significant risk factor for TE loss.

