Reviewer's report

Title: Effect of nipple shield use on milk removal in mothers with pain: a mechanistic study.

Version: 2 Date: 17 Mar 2020

Reviewer: Lydia Furman

Reviewer's report:

This is an interesting study and an important clinical question. However, overall, it is concerning that there are such big differences between "all data" and the "subset data" for both volume and PAMR. This suggests that these results reflect technical problems with the study rather than findings related to the use of the nipple shield. Why would volume be significantly different for shield vs. not shield in the "all data" group and not be significantly different for the "subset" group? It is not clear that you are able to conclude, "This study has shown that use of a fitted nipple shield during pumping reduces effectiveness of milk removal." Additional information would be needed to make this conclusion, for example, that it did not really matter whether "applied vacuum" reached "set vacuum."

Abstract - The results section does not align with the methods section. You describe 3 randomized (in sequence presumably) pumping sessions for the Pain Group and the Control Group. However the results section describes 31 and also 10 paired sessions - it is not clear (1) if this is for the Pain or Control Group, (2) what the difference between the 31 and 10 are, and (3) why there are two not three types of sessions being compared. Additionally if "percent available milk removed" is included in the Abstract there should be a definition.

Page 6 - Since "percentage of available milk" is not a widely used measurement, some explanation within the text in addition to the reference would be helpful.

Page 7 - Does it make a difference if the "applied vacuum" did not reach the "set vacuum"? What does this mean for mothers pumping at home? This is really beyond a technical or statistical question since it impacted the data validity. Also please explain exactly what is meant by these terms - even though they seem intuitive this is a scholarly paper.

Please clearly explain the discrepancy between the description of 3 nipple shield groups (page 5, lines 13-20; non-use, fitted and small nipple shield groups) and 2 groups (page 7, line 42) in which use and non-use of the nipple shield are compared. It is not until page 7, line 58 that there is an explanation that the small nipple shield group was dropped.

Please explain why you believe that only 2 women have valid data with a small nipple shield, and perhaps more importantly, can you justify inclusion of a small nipple shield group? It would seem that a small nipple shield is likely to induce pain.

Page 9 - Please compare the subset of those with "valid data" to the remaining subjects for all parameters in Table 1. It is not clear why some data were "valid" and some not, and this is a meaningful study limitation.

The issue of pain with pumping is difficult to assess. It is confounded by your choice of groups (pain versus no pain) and thus it is difficult to know if the pain participants experienced pain related to 1-the breast pump settings, 2- their initial and prior pain experiences, or 3- the nipple shield. This must be addressed as a limitation of the study.
Please include a section on study limitations.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?
5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors’ responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal