NOTES

Milkdrop breast pump cushion pilot

Preliminary observations

Apr 2021

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Milkdrop

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SUMMARY

The Milkdrop breast pump cushion fits common breast pumps, and is designed to make pumping softer and more comfortable. Preliminary observations from a pilot conducted in February 2021 were that:

- Pumping with the cushion was more comfortable: 92% of participants found pumping with the cushion more comfortable, and the median score of comfort increased from 5 to 9 out of 10 (where 10 = "very comfortable").
- Pumping with the cushion decreased swelling, redness and chaffing, especially for participants already finding pumping uncomfortable, with the median score of swelling reducing from 6 to 0 out of 10 (where 10 = "severe" and 0 = "none").
- Participants reported feeling more relaxed, and pumping feeling more "like a baby", with median score increase from 5 to 7 out of 10 for both categories.
- Most participants collected similar amounts or more milk (73%), however some participants collected less milk. A second cushion design has been developed and tested with these women with good results and is now in production.

BACKGROUND

The Milkdrop breast pump cushion is a soft silicone standalone insert that fits Medela, Spectra and Philips Avent breast pump heads. It is included in the Australian Register of Therapeutic Goods (#352892) as a Class I non-sterile, non-measuring device.

The cushion is designed to make pumping more comfortable for women experiencing pain, damage or discomfort from using breast pumps by providing a softer interface between the breast and the pump.

We conducted a pilot in February 2021 to better understand whether the cushion design could help to improve the experience of women using breast pumps. Our objective was to gather early indications of:

- The ease of use and fit of the cushion.
- The effect of the cushion on comfort, pain and milk volume collected.
- Various marketing related topics (e.g. perceived value).

We also wanted to better understand the characteristics that might be associated with painful and uncomfortable pumping.

This note documents our early observations only, which will inform our design for a wider study, and our design for a new style of breast pump.

We will focus this note on our observations of the effect of the cushion on comfort, nipple swelling, redness and chaffing, feel of the cushion and milk volume collected.

METHOD

We recruited participants (n=28) through our network of community and mothers' groups. Our target population was lactating women who were using Medela, Spectra or Philips Avent pumps.

We divided the pilot participants into two based on their response to the question "How comfortable is your current pump without the



cushion? (0 – very uncomfortable \rightarrow 10 – very uncomfortable):

- Cohort A: scores of 5 or more out of 10 (COMFORTABLE), n=15
- Cohort B: score of less than 5 out of 10 (UNCOMFORTABLE), n=13

Each participant completed a pre-pump survey (n=28), tried the cushion on their pump and then completed a post-pump survey (n=26, 2 did not complete). Most participants also completed a follow-up interview.

The surveys were structured to gather information in five areas:

- Background information on breast pump use of participant
- 2. Comfort
- 3. Nipple redness, swelling, chaffing / broken skin
- 4. Feel
- 5. Volumes

The surveys included both quantitative and qualitative questions and can be found in the appendix.

RESULTS

Observations on breast pump use

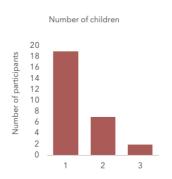
Figure 1 describes the distribution of participants across number of children, pump type, pumping sessions per day and session time per pump.

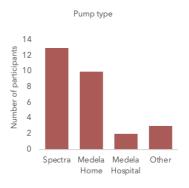
Observations on comfort and nipple swelling, redness and chaffing.

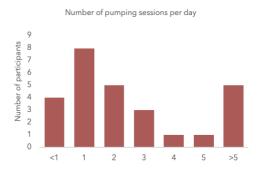
Figure 2a shows the distribution of comfort ranking (out of 10) with the cushion attached.

Note that our 'comfort' rating is inverse to 'pain' ratings where 10 represents "very comfortable" and 0 represents "very uncomfortable". Our swelling, redness and chaffing ratings are more typical, with 10 representing "severe" and 0 representing "none at all".

All participants (92%) except two found pumping more comfortable with the cushion. The two participants recording lower comfort were due to the cushion being heavy on the pump, and the cushion not fitting easily.







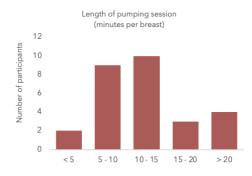


Figure 1: Study participants characteristics – number of children, pump type and use



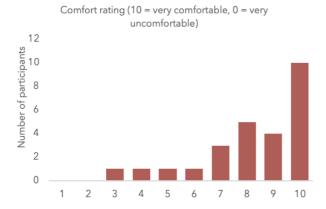


Figure 2a: Comfort rating of pumping with Milkdrop cushion attached (out of 10).

Figure 2b shows the change in median scores of nipple swelling, nipple redness / colour change, broken skin / chaffing and comfort, from using the pump without the cushion (dark) to using the pump with the cushion (light). The first chart shows all participants, the second and third charts show the results for each cohort: uncomfortable (comfort score starting at less than 5 out of 10) and comfortable (comfort score starting at more than 5 out of 10).

The following changes were observed:

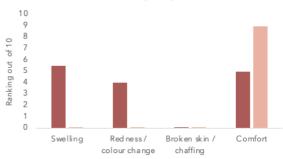
- increased comfort (median score: 5/10 to 9/10 for all cohort)
- relief from swelling (median score: 6/10 to 0/10)
- relief from redness and colour change (median score: 4/10 to 0/10)
- relief from broken skin and chaffing (4/10 to 0/10) for cohort of women self-describing as finding pumping uncomfortable without the cushion.

Observations on cushion 'feel'

Figure 3 shows the change in 'feel' of the cushion, starting from a set base of '5' for each variable. Participants recorded:

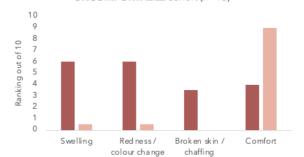
- feeling more 'like a baby' (median score: 5/10 to 7/10)
- feeling more relaxed (median score: 5/10 to 7/10)
- feeling 'empty' (median score: unchanged)

Median ranking out of 10 for each variable before (dark) and after (light) using the cushion, **FULL** cohort (n=26)



Median ranking out of 10 for each variable before (dark) and after (light) using the cushion,

UNCOMFORTABLE cohort (n=13)



Median ranking out of 10 for each variable before (dark) and after (light) using the cushion,

COMFORTABLE cohort (n=13)

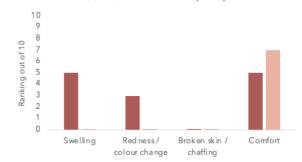


Figure 2b: Change in median scores of nipple swelling, nipple redness / colour change, broken skin / chaffing and comfort

Change in ranking out of 10 for each variable before (dark) and after (light) using the cushion, **FULL** cohort (n=26)

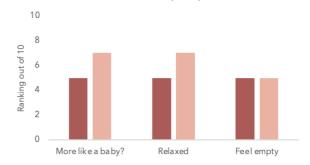


Figure 3: Change in 'feel' of the cushion, starting from 5/10 setpoint.



Observations on milk volumes collected

Figure 4 shows the change in perception of milk volume collected. Volumes weren't measured or tracked before or after; our objective was to identify if there was a major impediment to milk flow rather than identifying incremental and measurable changes in milk volumes. We may investigate this at a later stage.

Participants recorded no change in milk volume collected (median score unchanged). Most participants (73%) collected a bit less, same or more milk; however some participants (12%) were unable to gather milk or have a letdown at all.

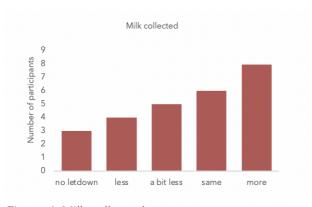


Figure 4: Milk collected

After interviewing these participants, we developed a second cushion with less 'bulk' that allows for more stimulation at the breast. This second cushion (Milkdrop Lite) is in testing, and preliminary results found that 5 out of 6 participants who had struggled with letdown or low volumes were able to collect equivalent or more milk than pumping without the cushion in addition to being more comfortable. We will send this second cushion to production for wider testing in August 2021.

FURTHER RESEARCH

There is selection error and sampling error due to our sample size and recruitment method, and analysis techniques were limited to descriptive statistics. As such, we present these results only as indicative observations that will help us refine our method for validation in a larger study. We are continuing to collect survey responses with women using the cushion.

Further research should refine the study design with a larger sample size and more defined selection criteria. Each topic (comfort, pain, feel and volumes) could be explored further, with particular attention to milk volumes and pain.

For questions, please contact Alex at alex@milkdroppumps.com

ACKNOWLEDGMENTS

Thank you to the participants in the study. Thank you to the Medical Mums and Mums to Be Lactation Interest Group for allowing us to seek participants within their community.

APPENDIX

Surveys

The following questions are extracted from the pre-pump and post-pump surveys. Questions about pricing and design features have been removed.

Pre-pump survey

Pilot consent form Basic details collection – name, contact details, number of children.

Q1: How many months have you pumped in total (across all children)? (number of months)

Q2: How often do you pump on a typical day? (multi-select: I only pump now and then, once, twice, three times, four times, five times, more than five times)

Q3: How long is a typical pumping session for you?

Q4: Which pump do you currently use? (multiselect: Medela (hospital grade), Medela (home grade), Spectra, Phillips Avent, Tommee Tippee, Other)

Q5: Why do you pump? (free text)

Q6: If you have breastfed, how comfortable did you find feeding?

Q7: Please describe the sensation you have at the nipple, areola and breast when



breastfeeding. If you haven't breastfed, please describe the sensation of hand expressing.

Q8: How comfortable is your current pump without the cushion? (0 – very uncomfortable \rightarrow 10 – very comfortable)

Q9: Please describe the sensation you have at the nipple, areola and breast when using your current pump (without the Milkdrop cushion)? (free text)

Q10: Have you experienced **swelling** of the nipple or areola from pumping? (0 – none at all \rightarrow 10 – severe)

Q11: Have you experienced redness or change in colour of the nipple or areola from pumping? (0 – none at all \rightarrow 10 – severe)

Q12: Have you experience **broken skin** or **chaffing** to the nipple or areola from pumping? (0 – none at all \rightarrow 10 – severe)

Q13: Please elaborate or describe any other symptoms you have had after you use your current pump. (free text)

Post-pump survey

Q1: How did pumping with the cushion make you feel? (free text)

Q2: How simple was it to attach the cushion to the pump, and then align your breast and nipple into the cushion? (0 – I couldn't make it work \rightarrow 10 – Simple)

Q3: With the milkdrop cushion attached, did you experience **swelling** of the nipple or areola from pumping? (0 – None at all \rightarrow 10 - Severe)

Q4: With the milkdrop cushion attached, did you experience **redness** or **change in colour** of the nipple from pumping? (0 – None at all → 10 - Severe)

Q5: With the milkdrop cushion attached, did you experience **chaffing** to the nipple or areola from pumping? $(0 - \text{None at all } \rightarrow 10 - \text{Severe})$?

Q6: Does the milkdrop cushion make your pump feel: (0 – Less comfortable → 10 – More comfortable)?

Q7: If you breastfeed, does the Milkdrop cushion make your pump feel: $(0 - less like my baby's suck \rightarrow 10 - more like my baby's suck)?$

Q8: Does pumping with the Milkdrop cushion help you feel: $(0 - less relaxed \rightarrow 10 - more relaxed)$?

Q9: Does pumping with the Milkdrop cushion help your breast feel: $(0 - less\ empty \rightarrow 10 - more\ empty)$?

Q9: Does pumping with the Milkdrop cushion collect: $(0 - \text{much less milk} \rightarrow 10 - \text{much more milk})$?

Q10: Please describe the sensation you have at the nipple, areola and breast when using your current pump with the Milkdrop cushion. (free text)

