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Qualitative Assessment by Lactating Mothers of a Novel Breastfeeding Appliance Designed for Infants with Cleft Lip and Palate

by
Deborah Lee

THESIS
Submitted in partial satisfaction of the requirements for degree of
MASTER OF SCIENCE

in

Oral and Craniofacial Sciences

in the

GRADUATE DIVISION
of the
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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Abstract

Qualitative Assessment by Lactating Mothers of a Novel Breastfeeding Appliance Designed for Infants with Cleft Lip and Palate

Deborah Lee

Cleft lip and/or palate (CLP) is one of the most frequently occurring birth defects, affecting approximately 1 in 700 live births. A cleft of the palate (CP) creates a communication between oral and nasal cavities, making it difficult to generate negative pressure needed for proper sucking and swallowing. Furthermore, regurgitation of milk through the nasal cavity and frequent choking contribute to feeding problems in babies with CLP that can lead to low nutritional intake if left untreated. Feeding in babies with CLP on the breast is so rarely successful that the large majority of babies with CLP are fed using specialized bottles to overcome the absence of intraoral suction—often with formula instead of breast milk. Breast milk protects against infant mortality by providing antibodies, which bolster infants' immunity to infections, diarrhea, pneumonia, and other diseases. A breastfeeding appliance (BA) that can create enough negative pressure to draw milk into the baby's mouth can potentially allow mothers to directly nurse their babies who have CLP. In our clinical study, we gather observational data and test the ergonomics, safety, and efficacy of this BA on lactating women. The specific aims of our project are: 1) to test the prototype BA on lactating mothers to improve product design, 2) to quantify the amount of breast milk that is able to be expressed from hand compressions using the BA, and 3) to obtain a qualitative description of the appliance's comfortability, ease of use, and effectiveness.

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List of Abbreviations

CLP	Cleft lip and palate
CL	Cleft lip only
CP	Cleft palate only
WHO	World Health Organization
BA	Breastfeeding appliance
IRB	Institutional Review Board

Introduction

Cleft lip and/or (or, with or without cleft) palate (CLP) is one of the most frequently occurring birth defects, affecting approximately 1 in 700 live births (Mossey 2003). The etiology of CLP is multifactorial with both genetic and environmental factors playing a role. Some of the environmental factors associated with CLP are maternal smoking (Shi 2008), other prenatal disturbances including folate deficiency (Wehby 2010), and some distinct genetic linkages (Marazita et al. 2009); however, its complex etiology remains unclear (Stainer and Moore 2004). CLP causes significant morbidities, including problems with feeding, speech, hearing, and self-esteem (Dixon 2011). Taken together, these effects of CLP impose a large burden and impact on the quality of life at both societal and individual levels (Wehby 2010).

Clefts of the lip and palate originate from disruptions in the embryonic fusion process of the craniofacial complex that result in abnormal development of the lip, primary palate, or secondary palate (Ferguson 1988). CLP management and surgical interventions occur as early as around 10 weeks after birth, when the cleft lip is usually repaired, and extends all the way into adulthood, when orthognathic surgery and any revisions usually take place. There are various surgical protocols for cleft palate repair, ranging from early to late revision to two-staged revisions (Farronato 2014). The factors to consider in the timing of CLP repair are speech, feeding, hearing, and growth and development (Rohrich 2000). Currently at UCSF, palatal repair is performed around 10 months of age. At this age, most babies are eating table foods and can drink from a sippy cup, so they do not need to drink from a bottle, which has the potential to damage the newly repaired cleft palate site. Furthermore, research has shown that repair of the

palate before a baby begins speaking, allows for more proper speech development, in terms of phonation (Dorf 1982).

Feeding issues in infants with CLP

Infants with cleft lip only (CL) can generally feed from the breast, as they often do not have issues creating suction (Reilly et al. 2013). There are some alternative feeding methods such as spoon-feeding that are encouraged after cleft lip repair so as to not impact surgical wound dehiscence, but breastfeeding or bottle-feeding was found to place less tension on the surgical wound and facilitate wound healing and weight gain even immediately after cleft lip repair (Matsunaka 2015). On the other hand, a cleft of the palate (CP) creates a communication between oral and nasal cavities, making it difficult to generate negative pressure needed for proper sucking and swallowing (Masarei et al. 2007). Suction occurs when oral cavity forms a closed chamber, or seal, and then enlarges, drawing liquid from nipple, and velopharyngeal closure acts as a valve to separate oral and nasal cavities. When that closed chamber, or separation between the cavities is compromised, as is the case in babies with CLP, the suction is compromised. Furthermore, regurgitation of milk through the nasal cavity and frequent choking contribute to feeding problems in babies with CLP that can lead to low nutritional intake if left untreated (Reid 2006, Amstalden-Mendes 2007).

Feeding in babies with CLP on the breast is so rarely successful that the large majority of babies with CLP are fed using specialized bottles to overcome the absence of intraoral suction. For mothers motivated to feed their babies breastmilk instead of formula, breast pumping equipment is required for frequent and regular pumping

sessions. A study at a North American Cleft Center found that breast milk feeding using specialized bottles in the cleft population occurred at a lower rate and for a shorter duration of the baby's life than in the non-cleft population (Alperovich 2017). In the U.S., the American Academy of Pediatrics recommends exclusive breastfeeding for about 6 months followed by continuous breastfeeding after the introduction of solid foods for at least one year (AAP 2012).

Benefits of breast milk and breastfeeding

The benefits of breast milk have been extensively studied, the most important benefit being that it can be potentially life-saving due to its association with a reduction in risk for postnatal death (Chen 2004). Breast milk protects against infant mortality by providing antibodies, largely secretory IgA, which bolster infants' immunity to infections, diarrhea, pneumonia, and other diseases (Slade 1987). Furthermore, breast milk has other proteins and molecules that bind to microbes in the lumen of the gastrointestinal tract, blocking harmful microbes from penetrating the epithelium and establishing healthy flora that line the intestinal tract. Beyond the nutritive and protective elements contained in breast milk itself, breastfeeding provides emotional benefits to both mother and baby. The early skin-to-skin contact and suckling motion is thought to improve cognitive development in babies (Feldman 2016). For mothers, the release of hormones prolactin and oxytocin during breastfeeding, create reported feelings of nurture and love towards their babies. Additionally, breastfeeding mothers recover from childbirth faster, have a reduced risk of ovarian and breast cancer, arthritis, type 2 diabetes, and cardiovascular disease (Anstey et al. 2017). In fact, the World Health Organization

(WHO) extends this recommendation further by promoting at least two years of breastfeeding (WHO 2001). While these recommendations apply to all babies including those with CP, the often arduous task of pumping breastmilk around the clock without the ability to nurse the baby from the breast is a major roadblock for many mothers. Exclusively pumping also diminishes the milk supply, as nursing consistently results in the optimal amount of milk extraction, and thus production by the body to replenish the milk supply.

Roadblocks to feeding breast milk to infants with clefts

Exclusively pumping breast milk requires proper equipment, several parts that need to be sterilized before each use, and rigorous adherence to a schedule to maintain milk supply. Furthermore, in underdeveloped regions where breast pumping equipment is not available or affordable, feeding pumped breast milk to a child with CLP is not even an option. These areas often lack other essential resources such as formula, a clean water supply to mix with the formula, and specialized bottles for the babies with clefts. At an average price of $0.20/ounce for formula, the cost of feeding an infant through its first year of life is around $1500, which is a heavy economic burden to many. In some of these places, breast milk directly from the mother's breast can be life-saving, as there is no simple alternative to feeding.

Specialized cleft bottles

For babies with clefts that impede good suction, there are currently numerous specialized bottles that can be used (Devi 2012). Mizuno et al. (2002) found different suction and compression readings based on different artificial nipples. The Cleft Lip/Palate Nurser by Mead Johnson is a very simple solution, which involves squeezing the bottle every time the baby sucks. This requires adjusting the firmness of the squeeze to match the baby's pace, pausing the squeeze when the baby breathes, and watching the baby closely to prevent too much milk, which can lead to coughing and sputtering. The SpecialNeeds Feeder by Medela, formerly known as the Haberman feeder, allows the baby to feed through tongue and gum pressure. In addition, there is a chamber that needs to be squeezed rhythmically by the caregiver to allow for a steady flow of milk. Before the start of feeding, air is squeezed out of the teat and replaced by formula or breastmilk through the valve. The one way valve prevents the milk from going back into the bottle and also replenishes the teat as the baby feeds. A slit valve at the opening of the teat opens with jaw compressions and shuts in between jaw compressions. By turning the nipple, and thus the slit valve in the baby's mouth, the flow rate can be varied. Dr. Brown's Specialty Feeding System with a one-way valve is similar to the SpecialNeeds Feeder by Medela, but excluding the squeezable chamber and including a patented air flow system that helps babies with colic, reflux and/or gas. The Pigeon Feeder also has a one-way valve, but the nipple has a firm side that goes against the palate, and a softer side that goes on the baby's tongue. It has an air control feature that allows the flow of milk to be adjustable by simply loosening or tightening the

cap.

Quantity of breast milk needed to nourish a growing infant

Newborns vary in the amount and frequency of breast milk intake, but generally begin with frequent feedings (8-12 sessions a day) of small amounts of milk (1 ounce or less), and soon increase the intake amount over fewer sessions (5-6 sessions). As a rule of thumb, babies who are at least 2 weeks of age need 2-2.5 ounces of milk a day, per pound of body weight. In a pooled study from 12 countries worldwide, the overall mean breastmilk intake was 780g/day or 27.5 ounces/day, and the age-specific estimates indicated that intake increased over the first 3-4 months and remained above 800 g/d or 28 ounces/day until 6–7 months (Da Costa 2010), at which point the WHO recommends implementing solid foods. The amount of time needed to feed a baby adequately should not exceed 30 minutes a session, as any time beyond that means a baby is burning too many calories in the process of trying to obtain calories. Therefore, whether an infant around the age of 6 months is fed through a bottle, the breast, or an alternative method, the baby should be able to obtain at least 4 ounces of breast milk per 30-minute session.

Compression as an alternative to suction in infants with CLP

The components of sucking in a newborn were studied (Sameroff 1968) and shown that at birth, compression is the main component of nutritive feeding and occurs more than suction. However, very soon after birth, babies become a lot more effective at suction because they are able to draw in more milk that way. Sameroff demonstrated

that when fluid flow responded only to compression, suction diminished, and conversely when fluid flow responded only to suction, suction increased. Therefore, babies with clefts learn to use compression instead of suction as the main mechanism to feed. Another study using an artificial nipple/bottle system connected to a blood pressure transducer, measured the amount of suction and compression produced by babies with CLP (Reid 2007). The study found that both the amount of suction and compression measured were associated with the extend of the cleft malformation. Babies with both cleft lip and cleft palate generated less compression and less suction than babies with cleft lip only or cleft palate only. Also, in some babies with small cleft palates, pressure measures fell within the normal range consistent with healthy babies, which may indicate that tongue and palatal contact anterior to small palatal cleft can create closure of the oral cavity (Kogo et al. 1997). Furthermore, Reid demonstrated that good feeding ability, measured in feeding time and weight gain, was generally associated with suction.

Breastfeeding Appliance and its characteristics

Although our preliminary market research showed 100% interest from mothers of babies with CLP in using a breastfeeding appliance (BA) that can create enough negative pressure to draw milk into the baby's mouth, currently no effective device or method exists. We began the development of a simple, silicone device that can attach directly to the mother's breast, in hopes to allow babies to directly feed from the device (**Figure 1**). The BA needed to meet certain requirements in order for it to function properly and be a feasible alternative to bottle feeding. First, the BA nipple needed to fit

into the baby's mouth and respond to the compression of the reflexive tongue and jaw movement, which is intact in babies born with CLP. Previous studies found that arch length measured to the tuberosity in 1-month old infants was measured to be 24.9-25.1 mm (Botticelli 2019). Similarly, another study (Hoffmanova et al. 2016) found one-week old babies to have a palatal length of 22.9mm and ten-month old babies to have a palatal length of 25.8mm. The BA nipple was developed to fall within these size ranges for babies with CLP.

Secondly, there needed to be enough negative pressure created inside the nipple when the device returns to its original shape after compression in order for milk to be expressed. In the development phase prior to this study, benchtop testing was performed to measure the amount of vacuum created at different force intervals. The testing rig involved hand compressions by a single experimenter as well as a force meter at increasing fixed values. The testing rig measured compression vs. force, which we plotted on a graph to help us identify the highest achievable pressure difference with the least amount of force. This test was repeated with different prototypes of varying durometers, or hardness of silicone, to develop a BA that yield the greatest vacuum when compressed while also feeling comfortable on the breast and specifically the nipple, during compressions.

Third, the BA had to fit on a wide range of breasts and to stay suctioned to the breast tissue during compressions. A study done in Japan involving 600 breasts found that the mean diameters of the areola and nipple were 40 mm and 13 mm, respectively. The mean height of the nipple was 9 mm, and the size of areolas varied greatly (Sanuki 2008). The BA was designed to fit the entire range of the women in this study, although

the efficacy of the BA in regards to size of nipple and breast was yet to be elucidated, prior to the study. In addition to relying on literature, a fabricated silicone breast model was used during the development phase to identify an optimal lip design (the undercut edge that acts as suction) at an optimal durometer that can be gripped under the highest amount of added weight. The BA was designed with an upper inner lip and base inner lip, to create a second suction chamber to ensure the device would stay attached to the breast even if the seal was broken on the upper inner lip. This would effectively prevent milk from escaping out of the base of the device.

Finally, the valve at the tip of the BA nipple had to be a one-way valve, allowing milk to flow out into the baby's mouth when open, and preventing milk from flowing back towards the breast when closed (while creating the vacuum during its return to shape). The BA has a duckbill valve that acts as backflow prevention, and is intended to allow the release of milk with little pressure. In designing the BA, we also angled the tip of the device to direct the milk to pool at the tip and reduce the amount of milk that pooled toward the base. We also found this to be more ergonomic for a baby with CLP to latch on with the device pointed downward since babies with CLP must be in a more vertical position to breastfeed.

Figure 1: Diagram showing how the BA is designed to work, *starting with "STEP 1" on the left and ending with "STEP 5" on the right.*

Clinical study to test and improve the current BA

The development of this BA has spanned multiple iterations, benchtop testing showing increasing rates of vacuum, and fit testing on breast models; however we needed this clinical study to gather observational data and test the ergonomics, safety, and efficacy of this device on lactating women as the first step to bringing the BA to the market as an FDA approved, Class I medical device in the United States. Before any testing could take place on a baby with CLP, it was necessary to answer some experimental questions that could be elucidated on lactating mothers alone. To do a proper test fitting on women first, we designed this study to use hand compressions to

mimic the compressions of a baby with CLP. We wanted to know whether the BA fit on a large number of breast and nipple sizes, even though anatomical measurements described in literature were used to size the BA. We also wanted to know if the suction created from our double lip design was enough to keep the device attached to the breast tissue during hand compressions. Furthermore, we wanted to know if our duckbill valve functioned as we intended it to, allowing for the milk to come out of the valve and not back up towards the breast. Most importantly, we needed to test whether there was adequate negative pressure when the BA was attached to a women's breast to expel a quantity of milk that is sufficient for a growing baby.

The prototype that we used in our study is portable, easy to clean, easy to use, and a potentially inexpensive solution for mothers who wish to breastfeed babies with CLP at any location, without the need for an electrical outlet, sterile water, or specialized equipment. This BA can allow both mother and child to reap the physical and emotional benefits of breastfeeding, eliminating one challenge in the long list of challenges that children with CLP will face throughout his/her life.

Our hypothesis is that lactating mothers will be able to express breast milk through manual compressions using the BA at a rate of 3.68 mL per 2.5-minute time frame, which extrapolates to 1 ounce of breastmilk within a 20 minute session. The specific aims of our project are: 1) to test the prototype BA on lactating mothers to improve product design, 2) to quantify the amount of breast milk that is able to be expressed from hand compressions using the BA, and 3) to obtain a qualitative description of the appliance's comfortability, ease of use, and effectiveness. The long-term goal remains to develop a BA as a convenient substitute for a breast pump to deliver enough breast

milk to foster normal growth in a newborn with CLP until palatal surgery, usually at 10 months of age.

Materials and Methods

Study design

Our evaluation was a cross-sectional, observational study of lactating mothers using our breastfeeding appliance (**Figure 2**), for purposes of further improving the device and making it an effective alternative to feeding in babies with CLP. This study utilized a mixed-methods design, which involved a qualitative questionnaire assessing the women's experience with the BA, and a quantitative component involving anatomical measurements as well as measurements of breast milk expressed from the participants' breasts using the BA (**Figure 3**). The observational period spanning approximately 30 minutes involved data collection by a single researcher, who recorded and collected the data.

Consenting mothers were instructed not to pump for two hours prior to the study to ensure a normal milk supply. We asked a series of questions regarding their breastfeeding experience and then proceeded to have them use a disposable measuring tape to take anatomical measurements of their breast, nipple, and areola. We had the participants stretch the breastfeeding appliance over their nipple and breast tissue. The BA is a single silicone component with the larger end of the device sealing directly to the mother's breast as shown in **Figure 4**. To emulate babies with CLP who

feed via compression cycles with their jaw, we instructed mothers to carry out hand compressions while wearing the BA.

The negative pressure was created within the device, pulling milk from the breast and exiting the device through the one-way duckbill valve at the tip. We instructed mothers to hold a collection cup to the tip of the BA, collecting the milk expressed out of the valve. After 2.5 minutes of hand compressions, the amount of milk collected was measured with a 10mL syringe. The qualitative data was recorded and further qualitative questions regarding the participants' subjective impressions, how the device fits, how difficult they found the appliance to be, were recorded. The entire testing protocol can be viewed in **Figure 2**.

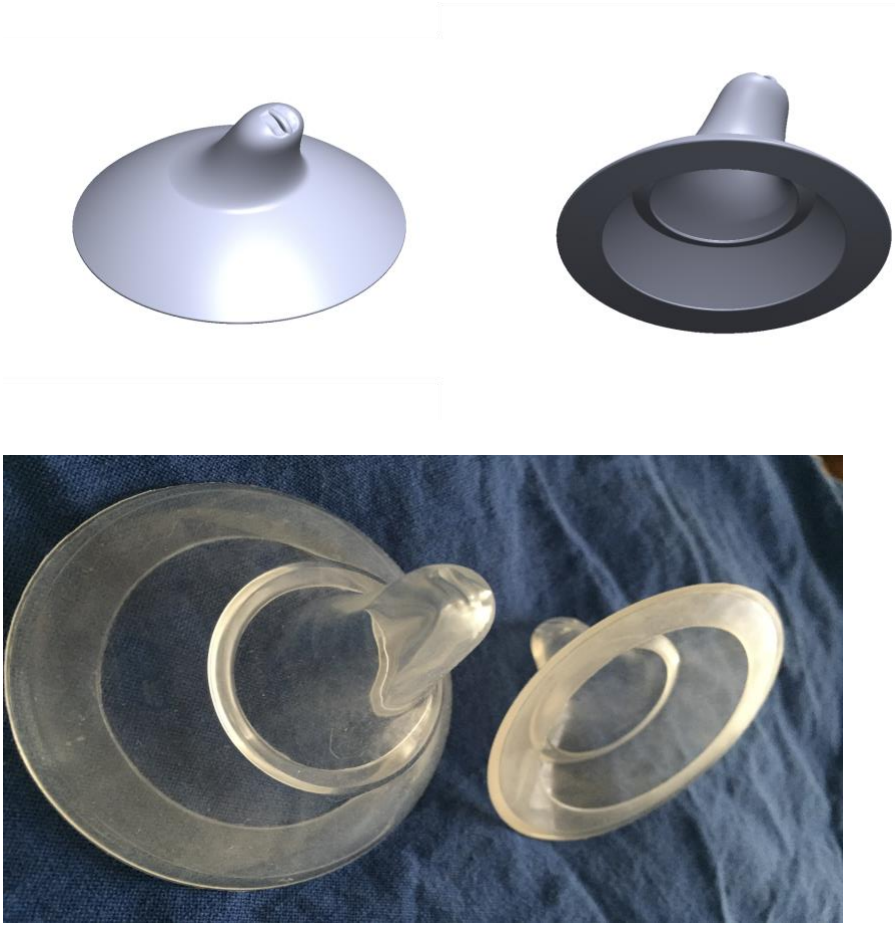

Figure 2: Breastfeeding appliance, *CAD design (top) and manufactured product (bottom). This BA design was has an upper inner lip and base inner lip, with an elongated Duckbill valve to allow for more milk flow.*

Testing protocol

1. Prior to administering the study, communicate to the mother that she should not pump or nurse right before the meeting time.

2. Date: ___/____/_____
   Participant age:
   Last pump or breastfeeding: _____ minutes prior
   Any problems breastfeeding? No____ Yes____ What kind? _____
   Inverted nipple? No____ Yes_____

3. Measurements:

	Before Use (mm)
Areola (diameter)	
Nipple (length)	
Nipple (diameter at tip)	

4. Tell mother to hand express a small amount of milk. Then have her stretch the breastfeeding appliance (BA) over her nipple and areola, and try to get a seal around the breast. Have her place a bowl or cup under her nipple to collect the milk.

5. Ask mother to begin hand compressing the BA at the base of her nipple using her thumb and index finger in a "c shape" until milk flows. When milk starts flowing, count 30 compressions.

6. Have the mother use the syringe to measure the volume of breast milk expressed:
   _____Prototype: _____mL
   _____Prototype: _____mL

7. Measurements:

	After Use (mm)
Areola (diameter)	
Nipple (length)	
Nipple (diameter at tip)	

8. Did the device stay on the breast? No____ Yes____

   Did you feel any discomfort or pain from using the BA? No____ Yes_____
   If Yes, explain:_____

   On a scale of 1-5, how difficult was your experience using the BA?
   1 2 3 4 5
   Please explain:_____

Figure 3: Study questionnaire, administered by a single researcher conducting the study on a single participant in a 30-minute time period.

Figure 4: Rendering to show how the BA fits over the mother's breast, with the base of the BA intended to suction onto the breast tissue and the tip of the BA intended to cover the nipple and create negative pressure to draw milk from the nipple and out through the one-way valve.

Recruitment

Participants were recruited through referrals from the community, such as lactation support groups at various UCSF locations, and word of mouth through the project's

association with the Craniofacial Clinic at UCSF. Informed consent was obtained by each participant prior to administering the study.

Inclusion criteria consisted of any healthy woman who is currently lactating, has an established milk supply, and is breastfeeding a baby or pumping to bottle-feed a baby. Exclusion criteria consisted of any woman who has an active injury, infection, or deformation of the breast. Examples for infection include thrush, mastitis, Staphylococcus aureus infection or Candida albicans infection. Deformation includes nipple piercings or open wounds. Any woman who has given birth less than 3 weeks prior to the study will be excluded as well.

Participants

15 lactating mothers participated in our study after meeting the inclusion requirements. They were given a brief explanation of the study and received an Informed Consent that they agreed to and signed.

COVID-19 related amendments

Due to COVID-19 restrictions, changes were made to our study protocol and approved through the Institutional Review Board (IRB) at UCSF. Participant packages (see Figure 3) were assembled and consisted of the breastfeeding appliance, measuring tape, a medicine cup, a mL syringe, and the informed consent form. Packages were then mailed out to the participants' preferred addresses. One BA was provided and tested per study appointment. We instructed our mothers to wash the BA with soap and water immediately

prior to testing and subsequently to discard the milk that was expressed after the quantity was measured. Mothers had the option of keeping the expressed milk, but were required to sterilize the BA as well as the collection cup prior to their use.

All testing was conducted remotely over Zoom, video conferencing software, with the participants in an individual private location of their choice. The two researchers conducting the studies did so individually in locked, private rooms with no other observers. Participants were not asked for any names or identifiers, and were given the option to keep their faces out of the camera's view for privacy purposes.

Figure 3: Participant packages during COVID-19 restrictions, consisting of the BA, measuring devices, and informed consent.

Data analysis

Data was collected by two researchers during the 30-minute Zoom study period. The resulting quantitative data was analyzed through ANOVA post hoc comparisons. Using regression analysis, potential correlations between two isolated variables were identified in the following configurations: breast size versus device adherence; breast size versus milk volume expressed; having challenges with breastfeeding versus milk volume expressed; device adherence versus milk volume expressed; and nipple circumference and milk volume extracted. The data was plotted in x-y graphs, and the coefficient of determination was evaluated to explain regression model fit to the data.

Results

Participant data

Characteristics of the participants (n=15) are shown in Table 1. Out of the 15 participants, 9 had problems breastfeeding at least at one point in time. These issues included latching issues (n=3), cracked nipples (n=2), low milk supply (n=2), flat nipples (n=2), inverted nipples (n=3), and having a baby with a “tongue tie” (n=1).

Table 1: Characteristics of the participants (n=15), showing averages of Mother's age, Baby's age, and anatomical measurements.

	Mother's Age (years)	Baby's age (months)	Areola diameter (mm)	Nipple length(mm)	Nipple circumference (mm)
Average	32.1	6.7	53.5	10.9	44.5
Range	26-38	3-15	38-120	6-20	40-55

Observational data

In 10 of the participants, the device stayed on the breast the entire duration of the study, while in 5 of the participants, the device dislodged from the breast tissue at least one time during the study period.

The quantity of milk expressed in the 2.5 minute period of hand compressions ranged from 1-5mL, with the average amount measured to be 2.78mL.

Qualitative data

None of the participants experienced any discomfort or pain during the study period. On a scale of 1-5 ("1" being very easy and "5" being very difficult), the participants reported an average difficulty level of 2.3. Their self-reported scores and the corresponding explanations as to why they chose a certain difficulty score can be found in **Table 2.**

Several consistent phrases were noted and included “felt loose”, and “difficult to get milk out of valve”.

Table 2: Self-reported levels of difficulty in using the BA, as well as their explanation for why they chose their difficulty scores.

	Difficulty score (1-5)	Qualitative explanation
	4	Would not stay on breast, milk was not coming out of valve, device too small
	4	Hard to stretch on and hard to get milk to come out of valvue
	3	Putting it on is easy and it stays on, but keeping it on while compressing is hard, device too small
	3	Not enough suction, felt loose, worked well with fingers on top and stroke toward tip
	3	Hardest part putting it on, and did not stay on well
	2	The only hard part was making sure the device didn't come off. It stayed on but didn't feel secure
	2	The hardest part was getting it on and getting it to stay initially
	2	The suction wasn't strong and I had to turn the tip of the nipple up for the milk to come out
	2.5	The initial fitting was not very easy, but while compressing, I felt a lot more vacuum
	2	Learning curve to getting it on
	2	Some difficulty in bending edge out and stretching device over nipple, milk also accumulated at base before valve opened
	2	Easy to use but difficult to get milk out of the valve unless I squeeze the tip
	1	Stayed on well and it was a better fit than the Medela shield, which I used before
	1	Wasn't difficult at all
	1	The only thing is that when I compress, the suction feels loose but it doesn't come off all the way

Correlations

One experimental question that we wanted to answer was if issues with breastfeeding had any relationship to milk volume expressed, see **Table 3.** We found that there was not a significant difference in having problems breastfeeding versus not having breastfeeding in milk volume. This may be due to the short duration of time (2.5 minutes) that we had them compress for, or the fact that many of the women experienced breastfeeding problems soon after birth that were resolved.

A second experimental question we wanted to answer was whether breast size had an impact on device adherence. We found that approximately two-thirds of participants in each breast size category (XS, S, M, L, XL) experienced good adherence of the device to the breast, see **Figure 5**. Since the proportion of women in each size category who experienced good adherence was similar across all sizes, it remains unclear whether size is a variable that impacts adherence to the breast.

A third experimental question we wanted to answer was whether breast size had an impact on milk volume expressed. We found that participants with small and medium sized breasts had greater milk volume output, whereas participants with extra small sizes had the least amount of milk volume extracted, see **Figure 6.**

A fourth experimental question we wanted to answer was whether nipple circumference had an impact on milk volume extracted. We found that for participants with smaller nipples, there was a positive trend of nipple circumference and milk volume. However, participants with larger nipple circumferences experienced a decreasing trend of milk

volume extracted. Because the adherence between the breast and the device occurs at the device's inner ring, the results suggest that the current design is more suitable for breastfeeding women with nipple circumference in the small to medium range, specifically up to about 44mm, see **Figure 7.**

Table 3: The amount of milk expressed in two groups of women, one without breastfeeding problems and one with breastfeeding problems, to see if there was a significant correlation.

Any problems breastfeeding?	Average milk volume (mL)	S.D. milk volume (mL)
N- Had no problems breastfeeding	2.62	1.36
Y- Had problems breastfeeding	2.89	0.93

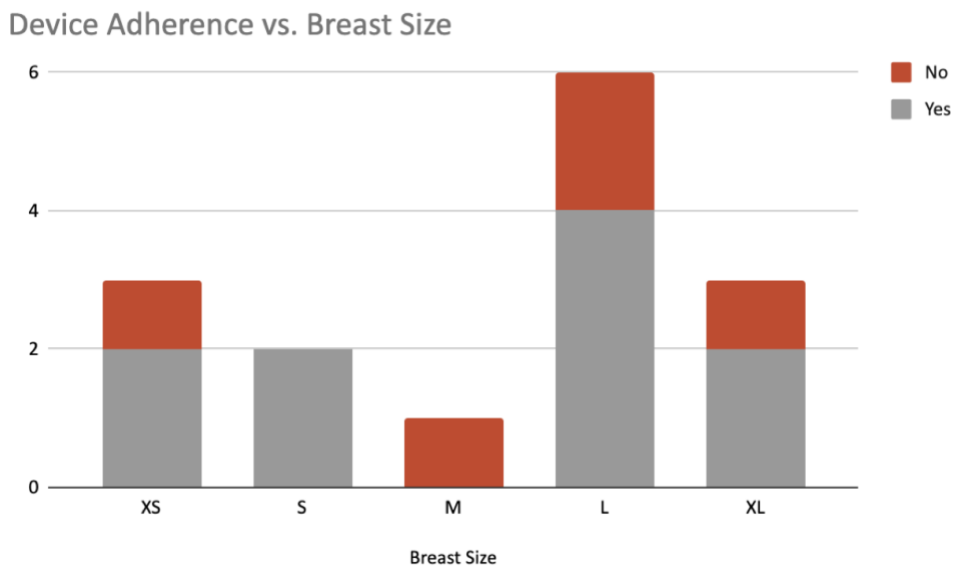

Figure 5: The participants categorized by breast size, and if the device adhered to their breast for the duration of the study period.

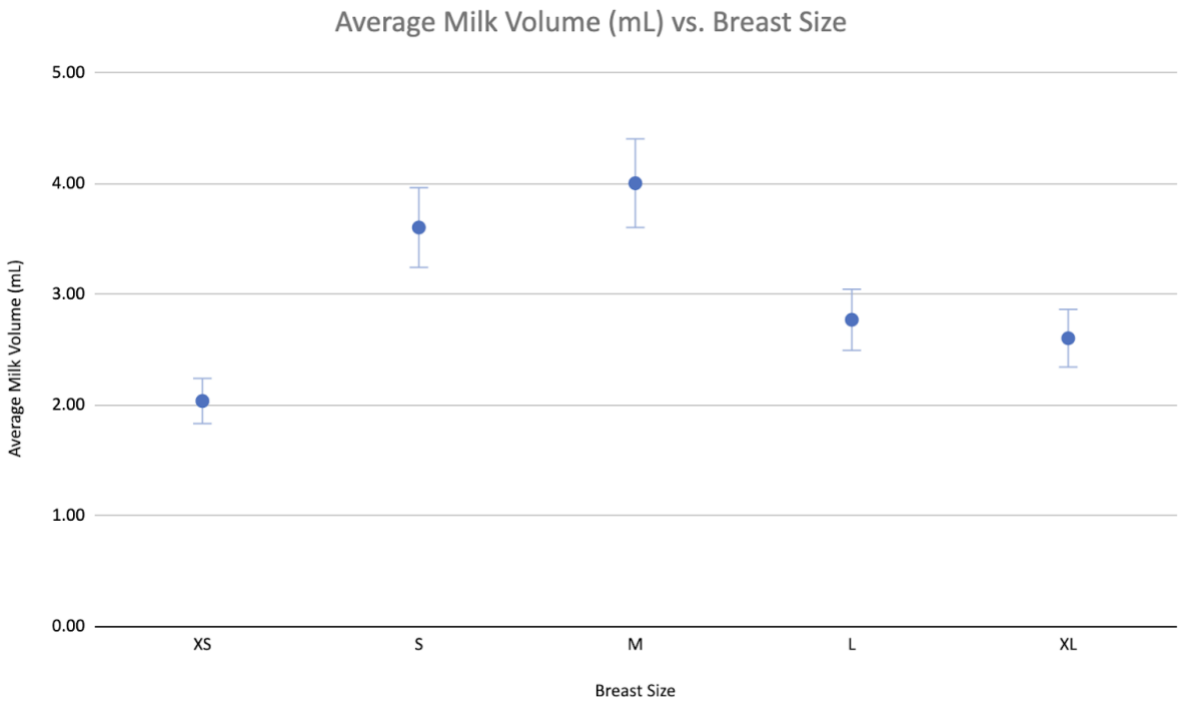

Figure 6: Average milk output based on breast size, showing greater output in small and medium sized participants.

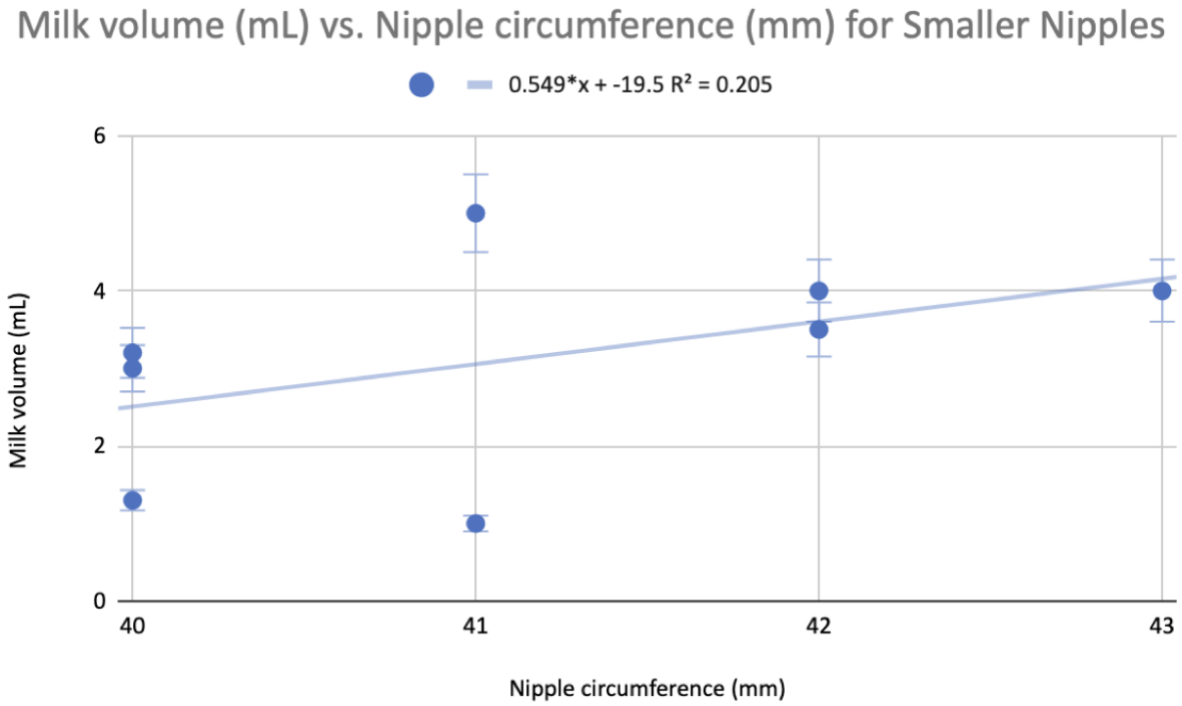

Figure 7: Milk volume expressed using the BA versus nipple circumference, showing an upward trend up to 44mm nipple sizes.

Discussion

While breast milk can prevent infant mortality in some babies with CLP, the main concern is their failure to thrive soon after birth. A study in Uganda found that about 70% of babies with CLP were malnourished, and mothers lacked the proper support to deal with infant nutrition and health (Tungtoyo 2017). Furthermore, in low socioeconomic regions such as Uganda, there is a strong social stigma again CLP, adding to the difficulty mothers face in finding guidance on how to nourish their babies. Even in developed countries like the U.S., a much lower percentage of mothers of infants with CLP fed breast milk to their babies compared to the national average of mothers with healthy babies (Madhoun 2020). The survey showed that a common barrier to feeding breast milk was

the lack of medical and psychosocial support that is needed to ensure breast feeding success (Madhoun 2020). The BA can simplify this complex issue because it is only one device that needs to be used and washed. Furthermore, the BA will eventually be cost-effective if used as the primary feeding device, as it will eliminate the need for specialty bottles, breast pumps, formula, and clean water.

This study elucidated important information about the BA, which has been benchtop tested numerous times and continuously modified, but never tested on a lactating mother. We were able to see, firsthand, how the BA fits on women of all breast/nipple shapes and sizes. It was also helpful to see the strength of adherence to the breast, which we determined needs improvement, as the BA had issues staying on in 1/3 of the women who tried it. It was interesting to note that the BA adhered to all the breasts prior to hand compressions but was unable to stay on once compressions began. This may be related to the stiffness of the silicone and its deformation during compressions, or simply the lip design. One participant wet the device, unprompted, and found that it adhered better. In future studies, it might be useful to measure the level of moisture on the skin and whether that improves the attachment of the device.

The valve also has potential for improvement, as some participants found it difficult for the milk to escape the slit opening. Due to this issue, in several of the participants, the milk flowed back up and leaked out the base of the appliance. We plan to improve the slit design, possibly increase its size, to ensure that milk easily flows out of the tip. Further studies need to be done to determine the durometer of silicone at the tip that can allow for an easier opening during compression while ensuring closure after compression is released.

The amount of negative pressure, or vacuum, created inside the BA while on the women was difficult to measure or even decipher through the Zoom study. Although benchtop testing provided us with quantitative information, it was important to experience how the negative pressure translates into more milk being expressed. The average amount of milk expression in a 2.5 minute period was 2.3 mL or 0.08 ounces. If we assume that a nursing session take 20 minutes and the rate of milk flow is constant, this amount of milk translates to 0.61 ounces of milk in a typical breastfeeding session, which falls under the normal range of milk for a single infant's feeding. Still, it's hard to extrapolate whether the BA suction was significant. For future studies, we plan to have participants hand express for 2.5 minutes to use as a control that can be compared against the amount of milk expressed for 2.5 minutes using the BA. This would allow us to make a more statistically robust dataset that we can use to conduct a two-sample t-test on.

The study also pointed us in the direction of varying the BA sizes to fit women with breasts and nipples outside of the 25^{th}-75^{th} percentile. Although our sample size was small, the current design seemed to fit small and medium sizes well and extract the most milk from those sizes as well. We may need to explore a range of sizes down the line, perhaps small, medium, and large sizes both for nipple diameter and base length, to ensure that milk volume for most breastfeeding people is optimal. A large number of health professionals who work in lactation commonly recommend a nipple shield for various breastfeeding issues (Eglash 2010). Many of these nipple shields on the market have proven to be most effective in various sizes.

There were a few limitations to our study. We were not able to recruit a large number of lactating mothers in our timeframe. Given the small sample size for quantitative analysis, some of the comparisons were not statistically significant to establish robust conclusions. Furthermore, some of the women who initially agreed to participate were not comfortable with the COVID-19 amendment, requiring them to expose their breasts during testing through the Zoom platform. Even beyond the privacy concerns, video conferencing had other limitations. Visually, it was difficult to see what was happening at the valve, or which areas around the base of the BA were gripping better to the breast. It was also challenging to guide mothers on how to put on and how to use the BA remotely, as it would have been much simpler to put it on them during an in-person session. The anatomical measurements were also done by the participants themselves, and could not be verified by us for accuracy. Overall, the reproducibility and reliability of this study were compromised because we had to rely on the individual participants to administer much of the study themselves, although we did our best to direct them through Zoom.

The goal is that this study can help further develop a simple, silicone device that can attach to the mother's breast to allow babies with CLP to directly feed from the device. While the study revealed a lot of useful information, there is still a lot of development that needs to take place to solidify the design and improve its efficacy. There is a significant need for the BA worldwide and our mission is to enable these mothers to breast feed their babies with CLP so they can thrive.

Conclusions

This novel BA was able to express some breastmilk in all participants. The BA adhered to the breast during compressions in 2/3 of the women, while in the remaining 1/3 of the women, it fell off the breast at least once during the 2.5-minute study period. This is not a one-size-fits-all device and it is clear from this study that it needs to be made in a range of sizes. The current prototype seems to work better on women in small and medium breast and nipple size ranges. Beyond the anatomical sizes of breast or nipple, the suction needs to be made stronger and the valve needs to be improved to open when compressed and to shut when not compressed. None of the women experienced any pain or discomfort from using the device. In the future, a larger sample size is needed to draw better conclusions and correlations, and ultimately improve the design of the BA to be effective on a wide range of nursing mothers.

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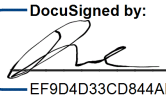
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