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Flange Size Matters: A Comparative Pilot Study of the Flange FITS™ Guide Versus Traditional Sizing Methods

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Abstract

Background: Pumping is a common practice in the United States, but it can be uncomfortable and lead to concerns about milk supply. The fit of the flange, or breast shield, used while pumping can contribute to or alleviate these problems. Flanges are available in a wide variety of sizes, and there are inconsistencies in guidance provided by healthcare providers and pump manufacturers for parents choosing a size. There have been no studies comparing different methods of sizing in terms of comfort and milk output.
Research Aims: The aim of this research was to examine differences in milk output and comfort using two methods of flange sizing.
Method: A within-subject cross-over design with a convenience sample of parents exclusively feeding their own human milk was used to compare comfort and milk yield between using smaller-fit and standard-fit flanges. Participants pumped for 1 week with each set of flanges and recorded milk output and comfort outcome measures. Data were collected on participant demographics, nipple measurements, and flange sizes used.
Results: When compared to the newer small-size fitting, participants using the standard fit flanges had significantly less milk output (mean difference $=-15.0$ g, 95% CI [−25.0, −5.0], $d=-0.51$, $p=0.004$) and less comfort (mean difference $=-1.2$, 95% CI [−1.6, −0.91], $d=-1.23$, $p<0.001$).
Conclusion: Flange fitting is a process that should be individualized to the patient and may require a trial of one or more sizes during a pumping session. Smaller sizes determined using this individualized process and starting with nipple tip measurement may be used without compromising milk output or comfort.

Keywords

breastfeeding, breastfeeding experience, breast pumping, human milk, human milk expression, lactation

It is well-established that human milk is optimal nutrition for infants, and it is recommended that infants receive human milk exclusively for the first 6 months of life (Meek et al., 2022). Globally, this goal is met for 48% of infants less than 6 months of age. Seventy-one percent of infants still receive any human milk at 1 year of age. While breastfeeding is traditionally thought of as an act taking place at the breast with the infant removing milk directly, breastfeeding, as defined by the World Health Organization (WHO), encompasses any method by which human milk is expressed from a breast. This includes any human milk that is fed to an infant, whether the milk is the birth parent's milk or the milk of another lactating person (Noel-Weiss et al., 2012). Many parents around the world who feed human milk to their infants use mechanical pumps to express their milk (pumping) to feed to their infants via bottles or other methods.

Pumping is a common practice. In the United States, 94% of parents feeding human milk have pumped at some point in the first year, and up to 7% pump exclusively (O'Sullivan et al., 2019). In Hong Kong, China, and Singapore, 19.8%, 22.6%, and 16.5% of human milk feeding parents, respectively, have been found to exclusively pump their milk exclusively rather than feed directly at the breast (Bai et al., 2017; Jiang et al., 2015; Pang et al., 2017). Pumping human milk is also critical for medically fragile infants, such as those born prematurely (Belfort et al., 2022), and is used as a strategy to increase milk supply (Dietrich Leurer et al., 2020).

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Pumping allows parents to feed their infants human milk when separated from their infants for any reason and can be used as a tool to continue human milk feeding when feeding at the breast is not possible or is challenging for either the parent or infant. However, parents complain that pumping is time-consuming, inconvenient, and expensive when they are navigating finding the right fit for pump parts using trial-and-error (Anders et al., 2022; Felice et al., 2017). Pumping can also be uncomfortable or even painful (Flaherman et al., 2016; Yamada et al., 2016). Milk supply is also a common concern among parents who pump (Anders et al., 2022; Dietrich Leuerer et al., 2020). Since pain and concerns about making enough milk are commonly reported as reasons for cessation of breastfeeding (Gianni et al., 2019; Morrison et al., 2019), it is troubling that these are commonly reported experiences of pumping. These factors could undermine a parent's ability or desire to continue pumping. It is crucial to investigate ways to improve these difficulties.

It has long been asserted that improper fit of the flange, also known as the breast shield, which is the funnel-like piece that fits over the nipple and breast, can contribute to pain and inefficiency of milk removal while pumping (Berens et al., 2016; Biancuzzo, 1999; Wambach & Riordan, 2016). Pump manufacturers suggest that optimal fit can be achieved by measuring the base of the nipple and adding up to 9 mm, depending on the brand (Forton Higgins, 2022), and several sources have supplied visual guidance on flange fit that shows space between the tunnel of the flange and the nipple on all sides (Medela, 2021; Spectra, n.d.). This has been considered the best fit and, therefore, has been the standard of care by lactation care providers giving sizing guidance to patients. However, there has been little investigation in this area, and empirical evidence to support this as the standard of care is lacking. Furthermore, growing anecdotal reports suggest that a much smaller fit, starting at a size closest to the exact nipple tip diameter, is ideal and provides more comfort and more efficient milk removal (Clark & Linda, 2022; Mesite Frem, 2022). However, there are no studies comparing this fit to the standard fit. This has led to confusion about proper flange fit amongst providers (Anders & Yasin, 2023).

The Flange FITS™ Guide

The Flange FITS™ Guide sizing method was developed by the second author, an International Board Certified Lactation Consultant (IBCLC). In private practice, she saw that when parents trialed multiple sizes, they experienced better clinical outcomes, including higher milk volume yield, greater comfort, and shorter pumping sessions when using flanges that fit closely to the nipple tip with the nipple gliding against the sides of the tunnel. The guide is available for free in 21 languages and serves as the basis for courses available to IBCLCs and other lactation care providers. Feedback from those who have used the guide or completed one of the courses includes observations consistent with those that led to the development of the guide: higher milk yield and comfort using flanges closely fit to the nipple tip diameter along with higher client satisfaction.

> **Key Messages**
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> - Flanges, also known as breast shields, come in sizes ranging from 10 mm to 36 mm. Yet, there are no published studies examining sizes less than 21 mm for comfort and milk output.
> - Smaller-fit sizing, determined using the Flange FITS™ Guide, led to significantly higher self-reported comfort and, on average, more milk output per pumping session compared to standard-fit sizing.
> - The most common smaller-fit sizes used by participants in this study were 15 mm and 17 mm.
> - This is the first study providing evidence that smaller flange sizes based on nipple tip measurement can be comfortable and effective.

Using the Flange FITS™ Guide requires an interactive process between the parent and lactation care provider during a pumping session. The basic instructions outlined in the guide are to measure the tip of the nipple, start with the size that most closely matches the measurement, and begin pumping. While pumping, one to two sizes above and below the nipple tip measurements are also trialed, with both parent and provider observing the flow of milk and staying aware of comfort. The parent and provider discuss the trial results and choose the size that produces the most milk flow and comfort. This method of sizing results in using smaller flanges than what has been considered the standard of care, with the size often being the same or similar to the corresponding nipple tip measurement. Because using the Flange FITS™ method usually results in smaller sizes, hereafter, these flanges will be referred to as "smaller-fit" flanges.

Parents and lactation care providers need evidence-based recommendations for flange fitting techniques to optimize comfort and milk yield while pumping. It is unclear whether the current standard of care for finding flange size ("standard-fit") is best for patient comfort and milk output over new methods like the Flange FITS™ method. Therefore, the aims of this study were to examine the preliminary efficacy of Flange FITS™ sizing by assessing whether there was a difference in self-reported comfort and milk yield between standard-fit and smaller-ft flanges.

Method

Research Design

A within-subject cross-over design was used to compare comfort and milk yield between using smaller-fit and standard-fit flanges, with participants randomized to ordering of fit (standard/smaller vs. smaller/standard) using a block randomization number generator. Using this design, each participant served as their own control (Louis et al., 1992) to account for variations in milk production and perception of comfort between individuals. The Institutional Review Board at the University of North Carolina at Greensboro approved the study. (IRB-FY23-162, Approved February 9, 2023).

Setting and Relevant Context

This study took place in three locations across the United States: North Carolina, Texas, and Massachusetts. In the United States, employers do not have to provide paid parental leave, and many employees are not eligible to receive unpaid parental leave (Jou et al., 2018). Approximately 68% of mothers of children less than 6 years of age are employed (U.S. Department of Labor Bureau of Labor Statistics, 2024). Because many parents return to work within 12 weeks of birth, milk expression is common when the parent wants to continue feeding human milk. Most parents who feed human milk express their milk at some point within the first year (O'Sullivan et al., 2019). Most health insurance plans must cover the cost of breastfeeding supplies, including breast pumps (The Patient Protection and Affordable Care Act, 2010). As of the summer of 2024, on the U.S. market, there were approximately 75 different pumps available, including manual, single-sided, double-sided, single-user, multiple-user, and wearable. There are approximately 43 types of flanges and 15 types of inserts for those flanges, taking into account various sizes, shapes, and materials (e.g., silicone, hard plastic).

Sample

The target population for this study was healthy birth parents of healthy, term infants in the United States who owned a double-electric breast pump. Inclusion criteria for this study were that parents had to be over 18, between 1- and 6-months postpartum, and have given birth to healthy, term newborns to whom they were exclusively feeding their own human milk. Exclusively feeding human milk was defined as the infant receiving only human milk, including expressed milk, with nothing else other than vitamin or mineral supplements. This was in accordance with the World Health Organization (WHO) definition of exclusive breastfeeding (Noel-Weiss et al., 2012), although participants receiving human milk from wet nurses or donors were excluded to ensure that all participants were entering the study with an adequate supply to support their infant's growth. Parents were excluded from participating if they or their infant had health conditions that affected infant feeding or the ability to produce human milk, were supplementing with formula, donor milk, or other foods, or if there were infant growth concerns while exclusively feeding human milk.

A convenience sample was obtained by sharing virtual flyers with a study description on social media groups and pages. Private lactation practice clinic providers also distributed flyers. The study sample size was determined a priori to have at least 80% power to detect a medium effect size ($d = .50$) for differences between standard and smaller flange sizes, assuming a two-sided test at the $\alpha = 0.05$ significance level using nonparametric Wilcoxon signed-ranks testing (which is conservative if effect sizes are larger or if paired *t*-test assumptions hold) assuming a minimum asymptotic relative efficiency (ARE; Faul et al., 2007). This effect size target was chosen due to the pilot nature of the study and the paucity of research on output, comfort, and yield around our flange parameters. Participants who completed the study and all data collection were given a US$75 Amazon e-gift card as compensation for their time.

Measurement

Demographic variables. Demographic variables were measured by self-report and included the participant's age in years, marital status, level of education, race, length of maternity leave in weeks, number of live births (parity), and infant age at the time of enrollment in months.

Feeding and pumping practice history. Information about pumping practices was collected by self-report and included: whether and how previous children were fed human milk, the number of weeks postpartum the participant began pumping, the average number of pump sessions per day at the time of enrollment, whether the participant had attended any breastfeeding classes prenatally, whether the participant had received any pumping-specific education prenatally, flange size in millimeters used prior to enrollment, and how the participant had determined to use that size.

Nipple measurements. Participants' nipple tips (defined as the diameter of the distal end of the nipple) and nipple bases (defined as the proximal point where the nipple meets the areola) were measured in millimeters using digital calipers accurate to 0.1 mm. Study personnel conducted several participant measurements together to ensure consistency in determining the placement of the calipers for each measurement.

Comfort. Comfort was defined as the subjective physical feeling of being comfortable. The researchers developed a 5-point Likert scale to measure this. Participants self-reported their comfort with each size flange. On the scale, 1 was painful, 2 was very uncomfortable, 3 was tolerable, 4 was fine or okay, and 5 was very comfortable or felt like nothing.

Average milk yield. Milk yield, defined as the amount of milk extracted from the breast, was measured in grams using a food-grade scale with an accuracy of 0.1 g. Each scale was calibrated using a 5 g test weight before being distributed to the participant. Participants weighed the empty collection containers before the pump session and the filled collection containers at the end. Average milk yield (g) per session was measured by dividing the total number of grams from all pump sessions minus the collection container weights by the total number of pump sessions.

Flange size order. To determine whether using the smaller-fit or standard-fit size first moderated the effect of differences in comfort or yield, participants were randomized to the ordering of the sizes. A block randomization number generator was used to assign an equal number of participants to each order of sizing.

Pumping session time. Participants recorded each pumping session's start and finish times, which the researchers then calculated as the number of minutes.

Data Collection

Participants attended one study visit between March and December of 2023 to be fitted for flanges and instructed on study procedures. Study information was provided via an informed consent form. One copy was signed and returned to the researchers, and another was given to the participant. The Primary Investigator (PI), who was a PhD-prepared nurse IBCLC, or the second author, an IBCLC, conducted all study visits with participants face-to-face in private practice lactation offices. After signing an informed consent form, participants completed a demographic survey on paper.

At the study visit, the participants' nipple tips and bases were measured and recorded by the PI and/or second author. Participants were then sized for a set of smaller-fit flanges and standard-fit flanges. Hard plastic "MyFit" flanges from Maymom LLC in the traditional conical shape with a detachable, straight tunnel in sizes 13, 15, 17, 19, and 21 were used, as well as the 21, 24, 25, 27, or 28 mm flanges that came with a participant's pump. The smaller-fit flange size was found using the Flange FITS™ guide (see Supplement 1 in the online supplemental material). The procedure outlined by this guide was: (1) start with the flange size closest to the nipple tip measurement; (2) while pumping, try multiple flange sizes nearest to the nipple tip size; and (3) choose the size that was both most comfortable and resulted in the most milk sprays (as outlined in the Flange FITS™ Guide under "Feel" and "Supply"). The participant and researcher collectively decided on the final size based on reports of comfort and visualizing stronger and/or more milk sprays. Manufacturer instructions for each participant's pump brand, which consisted of adding a certain number of millimeters to the nipple base measurement, were used to find standard-fit size. Since standard-fit sizing is based on manufacturer instructions, the standard-fit size flanges used in the study were limited to sizes available from the participants' pump manufacturers, with the smallest being 21 mm. Comfort was also considered for standard-fit sizing so that nobody left using flanges that they already considered painful. For cases where the standard-fit measurement was painful, participants were put in the next larger size, consistent with manufacturer recommendations.

Each participant was instructed to pump for 1 week, at least 3 times, with each size. Participants were randomized to the ordering of using standard-fit or smaller flanges first. Participants used their own, double-electric, non-wearable breast pump and used the same pump for the entirety of the study. Participants were instructed to pump at similar times during the day with each set of flanges to control for circadian variations in milk volumes (Kent et al., 2006; Stafford et al., 2008) and at least 2 hours after the previous feeding or pumping session. They were given a paper recording packet and instructed to record the start and end time of each pumping session, the weight in grams of the empty collection containers, followed by the total weight of the filled collection containers at the end of the pumping session. They recorded the comfort of the flanges once at the end of each week. The data record also included space to share qualitative remarks about how the flanges felt. Recording packets were returned via email or text to the PI and kept in a password-protected folder. All demographic data, measurements, and data returned by participants were de-identified by assigning participant identification numbers and entered into an Excel spreadsheet by the PI.

Data Analysis

Descriptive statistics such as frequency (n), percentage (%), mean (M), and standard deviation (SD) were estimated to describe the characteristics of the study sample. Paired t tests or Wilcoxon signed-ranks tests (if paired t-test assumptions were not satisfied) were performed to test for significant differences in yield and comfort by flange size (standard, smaller). Normality and presence of outliers were assessed using boxplots, Normal Quantile-Quantile (Q-Q) plots, and Shapiro-Wilk tests. Linear mixed-effects modeling similarly tested for differences after adjusting for yield time and randomized ordering of flange size used first (standard/smaller vs. smaller/standard). In these adjusted analyses, a random intercept for participants was specified, while fixed effects for flange type and randomized order were specified. Kenward-Rodger degrees of freedom were used for this modeling (Kenward & Roger, 1997). Effect sizes, 95% confidence intervals (CI), and p values were reported. All analyses performed were done using SAS software (Version 9.4; SAS Institute Inc., Cary NC). A two-sided p value < 0.05 was considered statistically significant.

Results

Sample Characteristics

A total of 36 participants completed the study and comprised the analysis sample. The average participant was 32.0 years

Table 1. Demographic Characteristics of Enrolled Participants (*N*=36).

Characteristic	*n* (%)
Age (Years)	
18–24	2 (5.6)
25–29	7 (19.4)
30–34	17 (47.2)
35–39	10 (27.8)
Marital Status	
Married	32 (88.9)
Unmarried, Cohabitating	2 (5.6)
Single	2 (5.6)
Level of Education	
High School Diploma	2 (5.6)
Some College	2 (5.6)
Undergraduate Degree	11 (30.5)
Graduate Degree	21 (58.3)
Race	
White, Non-Hispanic	23 (63.8)
White, Hispanic	3 (8.3)
Asian	5 (13.9)
Pacific Islander	2 (5.6)
Eastern European	1 (2.8)
Mixed Race	1 (2.8)
Black	1 (2.8)
Length of Maternity Leave (Weeks)	
Not Employed or Not Returning	6 (16.7)
6–10	2 (5.6)
11–15	20 (55.6)
16–20	4 (11.1)
> 20	4 (11.1)
Parity	
1	23 (63.8)
2	11 (30.5)
3	1 (2.8)
4	1 (2.8)
Infant Age at Enrollment (Months)	
1–1.9	12 (33.3)
2–2.9	8 (22.2)
3–3.9	5 (13.9)
4–4.9	4 (11.1)
5–5.9	7 (19.4)

Table 2. Feeding and Pumping Experiences and Practices (*N*=36).

Characteristic	*n* (%)
Previous Human Milk Feeding Experience (Prior Children)	
None	24 (66.7)
At Breast Only	0 (0.0)
Combination Breast and Pumped	11 (30.6)
Mostly Pumped	1 (2.8)
Exclusively Pumped	0 (0.0)
Start of Pumping (weeks postpartum)	
< 1	8 (22.2)
1–2	11 (30.6)
3–4	5 (13.9)
5–6	2 (5.6)
7–8	8 (22.2)
> 8	2 (5.6)
Average Number of Pump Sessions per Day	
< 1	3 (8.3)
1–3	20 (55.6)
4–6	8 (22.2)
> 6	5 (13.9)
Attended Breastfeeding Class Prenatally	
Yes	15 (41.7)
No	21 (58.3)
Received Pumping Specific Education Prenatally	
Yes	9 (25.0)
No	27 (75.0)
Flange Size Used Prior to Enrollment	
< 21	10 (27.8)
21	7 (19.4)
24	17 (47.2)
27	2 (5.6)
How Pre-Enrollment Flange Size Was Determined	
IBCLC Recommendation	13 (36.1)
Manufacturer Instructions	2 (5.6)
Nurse or Other Healthcare Provider Recommendation	3 (8.3)
Used Size That Came With Pump	12 (33.3)
Personal Research (e.g. Social Media, Trial and Error)	4 (11.1)
Not Sure	2 (5.6)

Note. IBCLC = International Board-Certified Lactation Consultant.

old (*SD*=4.02; range: 23-39), 64% (*n*=23) were non-Hispanic White, 14% (*n*=5) were Asian, and the remaining 22% (*n*=8) were from other races/ethnicities. More than four-fifths (89%, *n*=32) had attained an undergraduate degree (31%, *n*=11) or graduate degree (58%, *n*=20), and 89% (*n*=32) were married. Prior to study enrollment, the mean number of pump sessions per day was 3 times per day (*SD*=2.39; range: 0-8). Seventy-two percent of participants were using sizes greater than or equal to 21 mm prior to enrollment (*M*=21.5; *SD*=3.53; range = 13–27). Participant demographics and pumping characteristics of the sample can be found in Tables 1 and 2.

Flange Size Comparisons

The average nipple tip measurement was 12.63 mm (*SD*=1.84, range = 9–16), while nipple bases averaged 17.09 mm (*SD*=2.48, range = 11.5–22). For standard-fit flanges, two sizes were used, 21 mm and 24 mm. On the right side, 22 participants used 21 mm flanges and 14 used 24 mm flanges for their standard-fit size. On the left side, 20 participants used 21 mm flanges, and 16 used 24 mm flanges. For smaller-fit flanges, four sizes were used, 13 mm, 15 mm, 17 mm, and 19 mm. On the right side, the most common size used was 15 mm (*n*=18), while nine participants used 17 mm, seven used 13 mm, and two used 19 mm. On the left side,

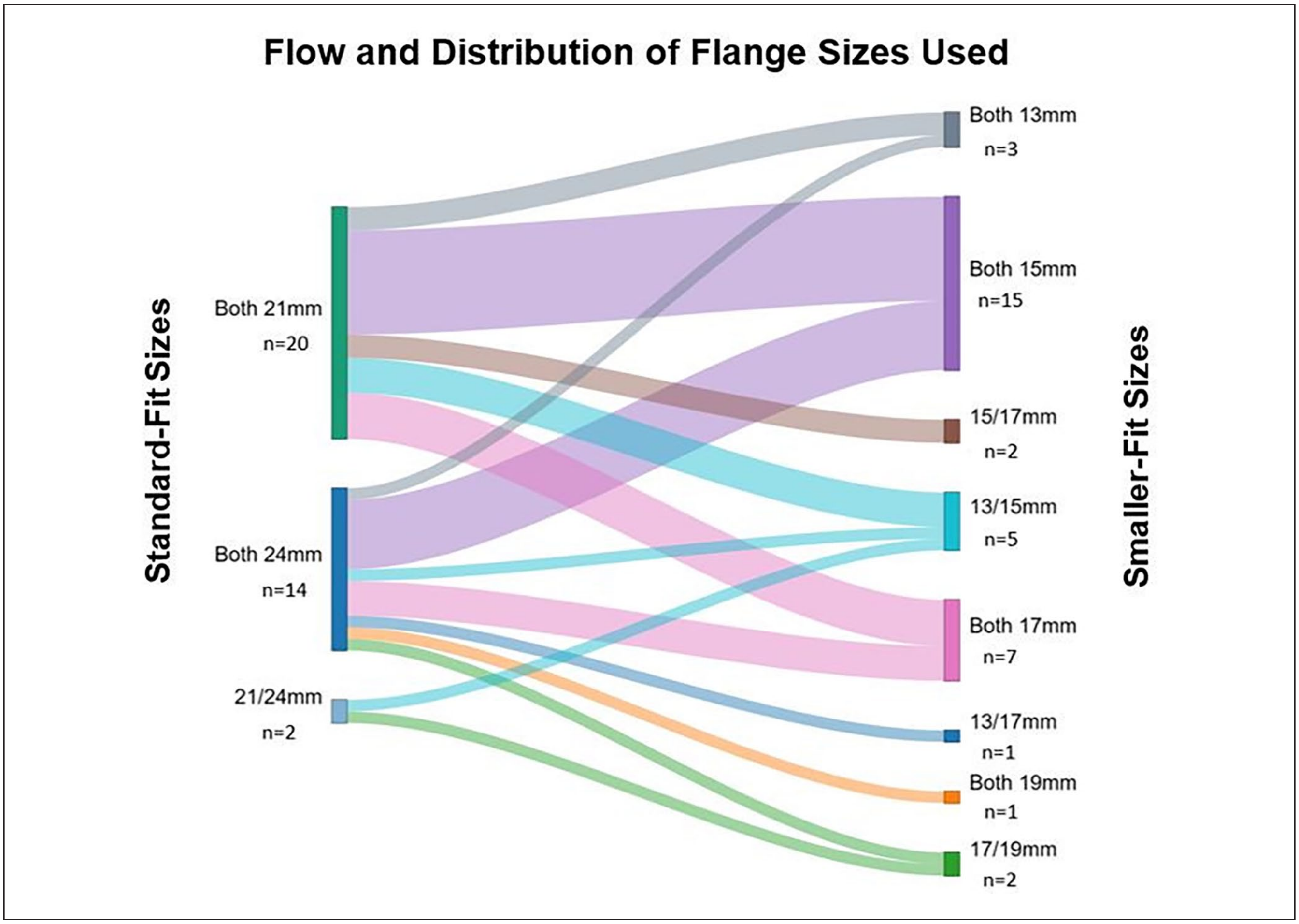

Figure 1. Flow and Distribution of Flange Sizes.

15 mm was also the most common size ($n=20$), while 10 participants used 17 mm, four used 13 mm, and two used 19 mm. The flow and distribution from participants' standard-fit sizes to their smaller fit sizes is illustrated in Figure 1. Participants pumped an average of 4.62 times during the week with the standard-fit flanges ($SD=2.64$, range = 3–11), and an average of 4.71 times during the week with the smaller-fit flanges ($SD=2.12$, range = 3–11).

We used the results of a linear mixed-effects model to compare the mean yield for the standard-fit flange size, which was 138.2 grams ($SD=55.34$) to the mean yield with smaller-fit flange size, which was 153.2 grams ($SD=64.24$; mean difference = −15.0 g, 95% CI [−25.0, −5.0], Cohen's $d=-0.51$), which was significantly smaller ($p=0.004$). This effect remained after controlling for randomized flange order and time for yield ($p=0.006$). The mean milk yield with smaller flange sizes compared to standard flange sizes is shown in Figure 2. The average comfort rating for the standard flange size was 3.3 ($SD=0.94$), which was significantly less than the smaller flange size 4.5 ($SD=0.61$; mean difference = −1.2, 95% CI [−1.6, −0.91], Cohen's $d=-1.23$, $p<0.001$). This effect remained after controlling for randomized flange order and yield time ($p<0.001$). Comfort ratings of smaller size flanges compared to standard are shown in Figure 3, along with ratings distributions in Figure 4. Individual participant changes in milk yield are demonstrated in Figure 5.

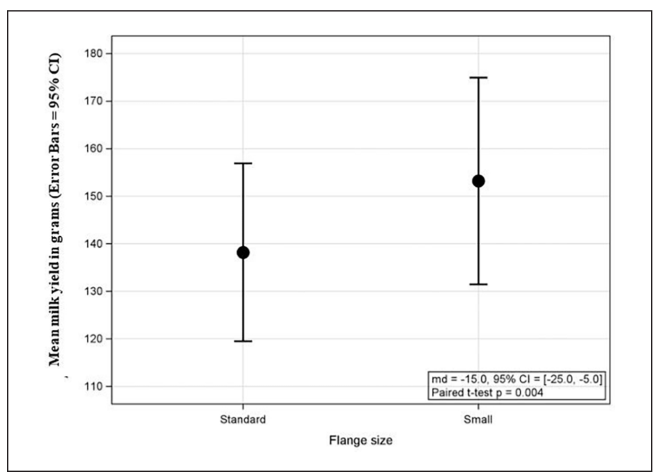

Figure 2. Mean Milk Yield of Standard-Fit Compared to Small-Fit Flanges.

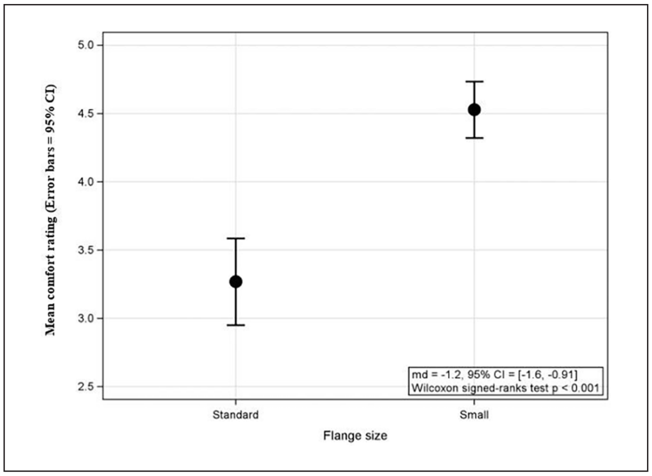

Figure 3. Comfort Ratings of Standard-Fit Compared to Small-Fit Flanges.
Note. 1 = Painful, 2 = Very uncomfortable, 3 = Tolerable, 4 = Fine or okay, 5 = Very comfortable or feels like nothing

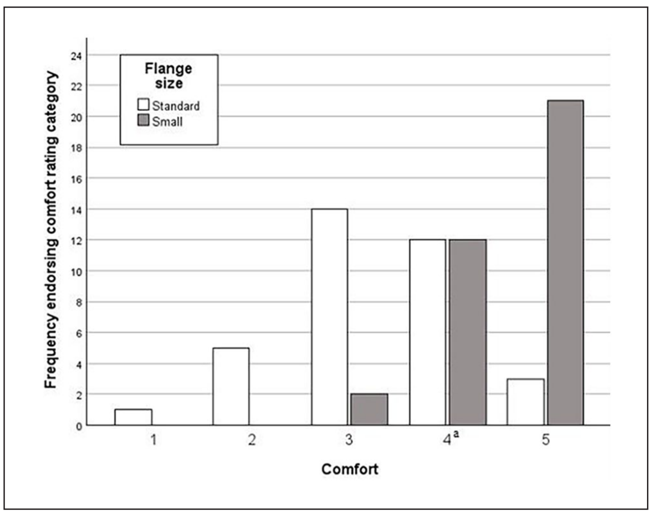

Figure 4. Distribution of Comfort Scores for Standard and Small Flanges.
Note. 1 = Painful, 2 = Very uncomfortable, 3 = Tolerable, 4 = Fine or okay, 5 = Very comfortable or feels like nothing
[a]One participant provided comfort ratings for all sessions rather than an overall rating. The average of their ratings was 3.66 and was rounded to 4 for this figure.

Discussion

This is the first study to examine comfort and milk output using flanges smaller than 21 mm compared with standard-fit sizing. The prevailing hypothesis on flange sizing has been that flanges that were too small would cause compression of the milk ducts, therefore limiting the flow of milk (Jones & Hilton, 2009; Jones & Spencer, 2007). However, there has yet to be empirical evidence demonstrating what sizes would be "too small." Earlier research has been used to support the use of 24 mm and 27 mm flange sizes, in which persons with larger nipple diameters or higher levels of intraglandular fat benefitted from 27 mm or larger over 24 mm (Kent et al., 2012). Participants in the current study yielded more milk when using flanges smaller than 21mm, yet, it is unknown why these participants benefitted from the use of smaller flanges. An in-depth study of breast characteristics, like intraglandular fat, may be needed to better understand who may benefit from the use of smaller flanges and why. During flange fittings, the authors took into account stronger milk sprays when determining the participants' flange sizes. Because the milk ejection reflex is the result of a neuro-endocrine response to tactile stimulation of the nipple (Moberg et al., 2020), investigation of the influences of different size flanges on the oxytocinergic system and the milk ejection reflex may also be warranted. Pumping triggers this response through vacuum pressure exerted on the nipple, but can also be triggered by tactile stimulation (Yokoyama et al., 1994). As vacuum pressure was not measured or recorded in this study, it may be possible that either the changes in vacuum exerted on the nipple or the amount of contact with the sides of the tunnel changed the oxytocinergic response.

In this study, participants' nipple bases ranged between 10 mm and 22.2 mm. Despite nipples being as small as 10 mm and the average base measurement being 17.09 mm, many major pump manufacturers lack sizes less than 21 mm. According to manufacturers' instructions and available sizes, almost all participants should have been using 21 mm flanges. However, for some participants, 21 mm was too uncomfortable during the flange fitting session, so they used the 24 mm for their standard-fit size. This may provide insight into previous recommendations to size up for comfort provided by lactation and other health care providers. Given this information, lactation care providers should be cautioned against simply going smaller without measurement or trying multiple sizes to find a comfortable fit. Measuring the nipple tip rather than the base and using sizes smaller than what was available from the pump manufacturers was also a more appropriate starting point for finding the most comfortable fit. The limited sizes offered by manufacturers may be due to previous research documenting nipple base measurements of breastfeeding parents being closer to 24 mm (Ventura et al., 2021). Yet, others found an overall mean nipple diameter of 14 mm (Francis & Dickton, 2019). There is a need for clarification and consensus on where to measure to determine average nipple sizes that may be helpful for manufacturers to offer a range of sizes in alignment with the needs of lactating parents.

The average comfort rating for standard-fit flanges used in this study only equated to a description of "tolerable" on the Likert scale, and comfort was significantly higher for smaller sizes. Discomfort while pumping can lead to early cessation of human milk feeding (Odom et al., 2013; Puapornpong et al., 2017). Pain may be a common occurrence among pumping parents, given that, in one study, 91%

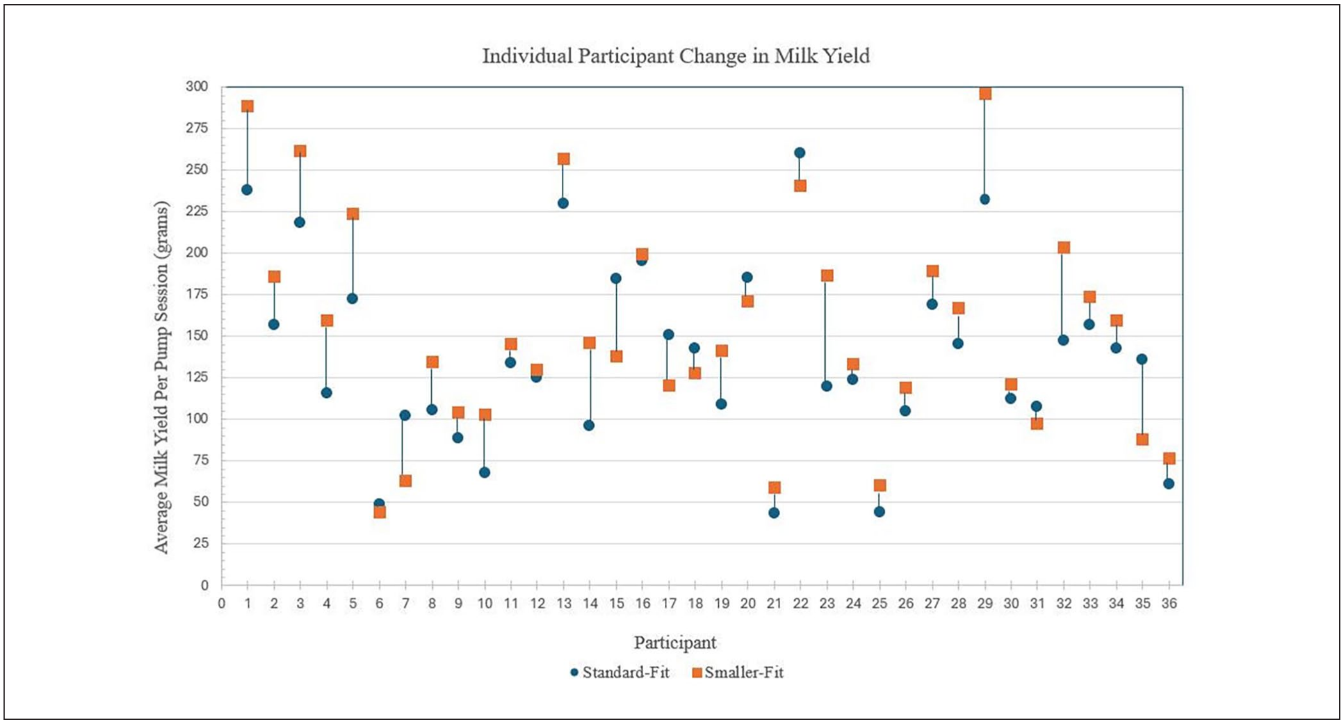

Figure 5. Individual Participant Change in Milk Yield Between Standard-Fit and Smaller-Fit Flanges.

of participants reported pain greater than 3 out of 10 after pumping (Francis & Dickton, 2019). On the contrary, 58% of participants reported the smaller flanges to be very comfortable or feel like nothing, and none rated these sizes as painful. While flange sizes used were not reported by Francis and Dickton (2019), it is reasonable to assume that standard-fit sizing was used due to the time the study was conducted and the relatively recent emergence of sizes used in the current study. It is promising that a broader range of available sizes and different sizing techniques may offer a more comfortable pumping experience that could lead to a longer duration of human milk feeding. However, comfort needs to be reassessed as this study only examined comfort over the course of 1 week with each size. All flanges used in this study were hard plastic, conical in shape, and only odd-numbered measurement sizes were available. Since data collection, sizes 12 mm, 14 mm, 16 mm, 18 mm, and crater-shapes have been introduced. Comfort may be affected by these different shapes, sizes, and materials, such as silicone. More research is needed on comfort and flange characteristics, but flange fitting should be an individualized process led by participant reports of comfort and milk yield.

In addition to pain, injuries to the nipple and breast tissue are concerns related to breast pump usage. In a large sample of mothers in the United States, it was found that 14.6% experienced injuries like sore nipples, pressure bruises, and nipple injuries related to breast pump usage (Qi et al., 2014). These data were collected prior to the availability of flanges smaller than 21 mm. More recently, researchers found that of breast pump related adverse events reported to the U.S. Food and Drug Administration, 33% were reports of injuries, with some of those being related to incorrect breast shield (i.e., flange) size (Leiter et al., 2022). All participants in the current study were able to complete both weeks with each set of flanges without experiencing an injury. However, participants were only followed for 1 week. Longitudinal research across the duration of breast pump usage is needed to assess rates of complication or injury related to smaller flange sizes. As existing research shows that injuries are possible with even larger sizes if there is an incorrect fit, it is imperative that lactation care providers follow-up with all patients using breast pumps to ensure proper usage, fit, and continued safety.

Limitations

There are limitations to the generalizability and conclusions from the findings of this study. Participants only pumped for 1 week with each size. While the ordering of the sizes did not affect differences in output or comfort, there was no washout period between sizing which could affect these outcomes if they had been used for a more extended period of time. Also, long-term influences on milk output cannot be determined from these results and need to be studied. Measuring milk output in grams may not accurately describe the efficacy and efficiency of different sized flanges. In the future, researchers should consider measuring the percentage of available milk removed to represent these outcomes more accurately.

Participants were not asked to record pump settings such as vacuum strength or cycle speed, both of which may affect comfort and milk output. It is unknown how these were affected by the change in flange size and how that may have influenced the milk output differences observed in the study. Because participants used their own pumps, the vacuum pressure may have responded differently with flange size changes in different brands and models, affecting the resulting milk yield difference. Although the authors conducted measurements together to come to a consensus on the placement of the calipers, variations in nipple shape and appearance also could lead to variances in where base and tip measurements were taken. There also was no control over the amount of time since the previous milk removal. While participants were instructed to wait at least 2 hours after the last feed or pump session, the exact amount of time was not recorded, and this could have influenced the amount of milk available in the breast at the time of the recorded pump sessions, which could account for the observed differences in milk yield. Relying on self-report measures of comfort could also bias the results.

Conclusion

While standard-fit sizing has led to sizes larger than 21 mm being included with most pumping kits, lactation care providers should consider educating parents on the availability of smaller sizes. Caution should be taken not to provide blanket recommendations to use smaller sizes. Flange fitting is a process that should be individualized to the patient and may require a trial of one or more sizes during a pumping session. Smaller sizes determined using this individualized process may be used without compromising milk output or comfort, as demonstrated in this study. No matter the method used, follow-up is necessary after a flange fitting to ensure continued comfort and maintenance of supply over the duration of human milk feeding. Choosing pumps, flanges, and inserts can be overwhelming for parents and providers, given the number of products available. Now, more than ever, it is vital that those helping pumping people understand these variations and how they affect comfort, milk yield, and efficiency.

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Author Contributions

Lisa Anders: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Writing - original draft, Writing - review & editing.

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Prior Reporting

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Supplemental Material

Supplementary Material may be found in the "Supplemental Material" tab in the online version of this article.

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