ORIGINAL RESEARCH ARTICLE

Breast shield design impacts milk removal dynamics during pumping: A randomized controlled non-inferiority trial

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Abstract

Introduction: While many studies have investigated the importance of optimizing pumping patterns for milk removal, the influence of breast shield design on milk removal has not been the focus of extensive investigation. This study aimed to determine the effectiveness of breast shields with either a 105° or a 90° flange opening angle on breast drainage and milk volume expressed during pumping.

Material and methods: This study was a cross-over, randomized controlled non-inferiority trial (Registration; NCT03091985). Mothers (n = 49) of breastfeeding infants participated in the study over two study sessions. Participants were randomly assigned to pump both breasts simultaneously for 15 minutes with either the 105° or 90° breast shield in the first session, and the other shield in the second session. Effectiveness (breast drainage) and efficiency (volume expressed) of both breast shields were assessed after 15 minutes of pumping. Intention-to-treat and per protocol analyses were performed to determine if the 105° breast shield was non-inferior to the 90° breast shield for breast drainage and volume expressed. Perceived comfort was assessed via questionnaire.

Results: The 105° breast shield was both non-inferior and superior compared to the standard 90° shield for breast drainage (intention-to-treat, 3.87% (0.01-7.72), $P = .049$) and volume expressed (intention-to-treat, 9.14 mL (1.37-16.91), $P=.02$). In addition, the 105° shield was rated as feeling more comfortable ($P < .001$) and as having an improved fit to the breast ($P < .001$) compared to the 90° shield.

Conclusions: Expressing with the 105° breast shield was more efficient, effective and comfortable compared to the 90° shield. Breast shield design can significantly impact pumping outcomes, and an opening angle of 105° improves both the dynamics and comfort of milk removal.

KEYWORDS
breast expression, breastfeeding, breast pumping, infant, lactation

1 | INTRODUCTION

Expressing human milk with a breast pump has become increasingly common.[1-5] More than 80% of mothers in developed countries feed expressed human milk at some point in the first 6 months post-partum.[1,2,4] Improving pumping effectiveness is therefore critical for mothers who must rely on a pump for milk removal during brief[1,2] or prolonged maternal-infant separation.[6,7] The majority of pumping research has investigated vacuum patterns with a focus on efficiency (volume of milk removed over time) and effectiveness (breast drainage).[6,8-10] Conversely, the breast shield, the part of the pumping system that interacts directly with the breast, has undergone minimal research.[6]

Clinically the breast shield has been highlighted as a critical factor for pumping effectiveness.[7,11-13] A breast shield should feel comfortable, provide an appropriate seal to the breast and not cause trauma to the breast or nipple/areola.[7,11-13] The breast shield consists of two main parts; the tunnel within which the nipple should move freely; and the flange, which contacts and seals to the breast. The fit of the shield to the nipple and breast is important. A poorly fitting shield, where the tunnel is either too small or too large relative to the nipple diameter, is associated with discomfort, and restriction of milk flow.[13] As a result the breast shield is normally available in different tunnel diameters to fit a range of nipple diameters.

In addition to the tunnel, the opening angle of the breast shield flange and how it interacts with the breast tissue may be important. Ultrasound images of the lactating breast have demonstrated that milk ducts can lie superficially within a few millimetres of the skin surface, are narrow and easily compressible.[14] In addition, during milk ejection the ducts expand in diameter by more than 50%.[14,15] It is plausible that compression of the superficial milk ducts by a restrictive shield flange will reduce milk flow and breast drainage during pumping.[16]

It was hypothesized that a breast shield with a larger flange opening angle (105°) would better match the lactating breast anatomy by avoiding breast tissue compression caused by a narrower flange angle (90°).[17,18] Thus this study aimed to determine if expressing with a breast shield with a wider flange opening angle (105°) was non-inferior compared to using a standard breast shield flange opening angle (90°). Effectiveness, efficiency and comfort of both breast shields were assessed with effectiveness (breast drainage) as the primary outcome, and efficiency (volume of milk expressed), mid and last fat as secondary outcomes.

2 | MATERIAL AND METHODS

2.1 | Participants

Healthy lactating mothers were recruited within Switzerland through the Swiss midwife and social media platforms. Participants were included if they were ≥ 18 years; exclusively or predominantly breastfeeding infants aged 1-6 months, with no concern about their

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> **Key message**
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> Improving pumping effectiveness is critical for many women who express human milk. Breast shield design and fit are important factors that can improve milk removal, comfort and the overall pumping experience for women.

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milk production; and agreed to the study methodology (refrain from pumping/feeding 3 hours prior to study pumping session, photographs of the breast/upper abdomen (no face) and to conduct a 24-hour milk production at home). Mothers reporting mastitis/engorgement within 14 days prior to starting the study were excluded.

2.2 | Protocol and randomisation

This study was a single-center, cross-over, randomized-controlled trial. A non-inferiority approach was used to assess the new 105° breast shield relative to that of the standard 90° breast shield. This approach was used to demonstrate that the 105° breast shield removed milk in an acceptable manner relative the standard device (90°) already used by many women during pumping. Participants attended two study sessions at the study site. The two visits were attended within 7-21 days. Eligible participants were randomized to one of two study groups, using either the 90° shield at the first visit, and then the 105° shield at the second visit, or using the 105° at the first visit and the 90° at the second visit. Researchers could not be blinded to the assigned breast shield during the study session; however, the independent trial statistician was blinded during the primary statistical analyses.

In each session, breast shield size was determined prior to double pumping for 15 minutes, either with the 105° or 90° shield. Human milk samples of the first, mid and last part of expression were collected from the pumping sessions to determine first, mid and last fat (%). The volume of milk expressed at 15 minutes was used to determine efficiency. At the end of each visit, participants completed a short-structured questionnaire (5-point Likert scale) devised for this study, to assess the comfort of each breast shield. Between study visits, mothers completed a 24-hr milk profile which was used to determine the breast storage capacity. These data in combination with the volume of milk expressed and the milk samples from the study sessions were used to determine the effectiveness of the breast shield, for the primary outcome breast drainage.[8,19]

2.3 | Breast shields and Fitting

The breast shields differed in their opening angle and shape. The control shield (standard) had a 90° opening angle and a round shape and the new shield had a 105° opening angle and an oval shape (Medela AG, Switzerland). Both shields were available in tunnel diameter sizes (21, 24, 27, 30 and 36 mm) and were

connected to a pumpset and breast pump (Symphony, Medela AG, Switzerland). To choose the appropriate shield size, the mother's nipple diameter on both breasts was measured using a series of circular tunnels that ranged from 8-23 mm, increasing in 1 mm increments. The selected shield tunnel diameter for each breast was at least 4 mm larger than the nipple diameter to allow for nipple expansion during pumping.[20] The same shield tunnel size was used for both visits.

2.4 | Pumping and milk collection

Mothers were asked to refrain from removing milk from their breasts for three hours prior to the study session. During the study sessions the mother simultaneously expressed milk from both breasts with an electric breast pump (Symphony, Medela AG, Switzerland) described previously.[21,22] Briefly, the expressed milk of each breast was collected onto two separate ShowMilk devices (Medela AG, Switzerland), recording the cumulative weight (g) of milk, the rate of milk flow (g/second), and the breast pump vacuum (mmHg). The stimulation pattern was applied until the first milk ejection (≤2 mins or first jets of milk from the nipple) was observed; breast expression continued for a further 15 minutes using the expression pattern at the mother's maximum comfortable vacuum.

First-, mid- and post-expression milk samples (1-2 mL) were retained for analysis. The ShowMilk devices were connected to computers with customized recording software. Recorded data were de-identified and exported for analysis.[21,22]

2.5 | 24-hour milk profile

Milk production was measured by the participants over a 24-hour period of breastfeeding and/or expressing in their own homes between the first and last study sessions. This involved test-weighing their infants before and after each breastfeed (BabyWeigh Scale, Medela Inc, McHenry IL, USA), or weighing the collection bottle, using an electronic scale.[23,24] During this period, mothers' hand-expressed small milk samples (<1 mL) into 5 mL polypropylene plastic vials immediately before and after each breastfeed or expression.

2.6 | Determination of breast storage capacity and percentage available milk removed

The human milk volumes from the 24-hour profile and fat content of the milk samples (using the crematocrit method)[25] collected over the 24 hour period were used to determine the storage capacity of each mother's left and right breasts.[8,19,23,26] The fat content was used to determine the degree of fullness.[8,19,23,26] Degree of fullness of the breast is a measure of how much milk is stored in the breast at any one point in time. Since there is a relation between the fat content of the milk and the degree of emptying,[26] by measuring the fat content

of each sample, the change in the degree of fullness of the breast from before to after each breastfeed/expression can be calculated. Degree of fullness was thereby calculated as 1 - degree of emptying, obtained via inverse calculation of degree of emptying. This relation between degree of emptying and fat content was individualized, whereby for each woman, minimal, and maximal fat content over 24 hours was set to correspond to degree of fullness of 1, and 0, respectively. The storage capacity was determined using a regression line relating change in degree of fullness at each feeding to the amount of milk removed from the breast at that feeding. The change in the degree of fullness combined with the 24-hour volumes of each breastfeed/expression, were used to calculate the storage capacity of the breast (the amount of milk available to the infant when the breast is full).[8,19,23,26] Assuming that a change in degree of fullness of 0 corresponds to a feeding amount of 0, the regression line was forced to pass through the origin. Storage capacity then could be calculated as the amount of milk that corresponds to a change in degree of fullness of 1. The volume of available milk in the breast before each breastfeeding was calculated as the degree of fullness multiplied by the storage capacity of the breast.

From the on-site study sessions, the human milk volumes and the fat content of the first and last 1-2 mL expressed milk measured, were combined with that of the 24-hour profile to provide an updated breast storage capacity. In addition, the fat content of the initial milk sample from the study visit was used to calculate degree of fullness (the estimated amount of available milk at the beginning of that pumping session).[8,19] The percentage of available milk removed (PAMR) ie breast drainage from the study visits, was determined by dividing the volume of milk removed after 15 minutes of pumping, by the amount of milk available from the beginning of the pumping session.

2.7 | Comfort

Participants completed an identical questionnaire at the end of each on-site study session assessing the comfort, fit, and usability of the breast shield during pumping (Appendix S1).

2.8 | Statistical analysis

A primary and interim sample size calculation was performed to assess if the 105° breast shield was non-inferior to the 90° with regard to PAMR. The primary sample size was calculated based on a mean PAMR of 65%, a standard deviation of 25% and a 0.4 correlation between time points.[19,27] A non-inferiority margin of Δ = −10% was selected.

The required sample size to achieve 90% power at α = 0.05 (one-sided) was determined to be n = 66. After allowing for potential withdrawals, a total of n = 72 was calculated. The interim analysis (50% of recruitment) demonstrated a standard deviation of 19% and a correlation of 0.50, yielding a necessary sample size of 32. As the estimated sample size required for all outcomes had already been achieved, it was statistically justifiable to close the trial early.

Two analysis sets were predefined (1) The per-protocol (PP) sample received the correct order of treatment in relation to the randomisation results; the correct BS size, the 2nd visit between 14 ± 7 days of the first visit, and excluded participants missing any primary data; (2) The intention-to-treat (ITT) sample included all randomized participants regardless of any protocol violations. Statistical analysis was performed using Stata 14.2. (StataCorp. 2015). A P-value of ≤0.05 was considered significant. The primary outcome, breast drainage was determined by PAMR (%) after 15 minutes of expression. Secondary outcomes included the volume expressed (mL) at 15 minutes, as well as the human milk mid and last fat (%). Additionally, comfort questionnaires were analyzed.

After unblinding, post-hoc analyses analyzed included PAMR (%) and volume (mL) at 2, 5 and 10 minutes, mean and peak rate of expression (mL/min and mL/sec, respectively), the time to first milk ejection (min), and the vacuum applied in the stimulation mode and expression modes (mmHg).

Baseline characteristics were summarized with descriptive statistics. Linear mixed effects models were used to assess the primary/secondary outcomes. Fixed effects were shield type, visit and breast, with participant ID used as a random effect. A one-sided, 95% confidence interval was calculated to show non-inferiority. If the confidence limit in both the ITT and PP lay above the non-inferiority margin for the outcomes PAMR (−10%), mid fat (−1%), post-fat (−2%) and expressed milk volume (−11 mL), non-inferiority was established. If non-inferiority was demonstrated, superiority testing with a two-sided 95% confidence interval was performed. Questionnaire responses were analyzed using Wilcoxon signed-rank tests.

2.9 | Ethical approval

Participants provided informed written consent to participate in the study, which was approved by the Ethikkommission Nordwest- und Zentralschweiz (EKNZ) Swiss ethics commission (Approval: 13th March 2017, reference: 2017-00134). The trial was registered prior to beginning the study at ClinicalTrials.gov NCT03091985.

3 | RESULTS

3.1 | Participant characteristics

Of the 72 participants screened, 50 were eligible for the study. One participant did not attend the first study session; therefore 49 participants were enrolled. One participant who received an identical, but incorrectly-sized shield on both visits and another who attended the second visit outside of the 7-21 day period, were excluded from the PP group (Figure 1). Data from mother's 24-hour milk samples including; 24-hour milk production (850.6 ± 211.7 mL), milk intake per feed (76.3 ± 32.5 mL) and PAMR (70.6 ± 11.3%) were considered within the normal range. [24] Nipple diameters were on average 15 ± 2 mm (range 11-21 mm) (Supporting Information S2). The
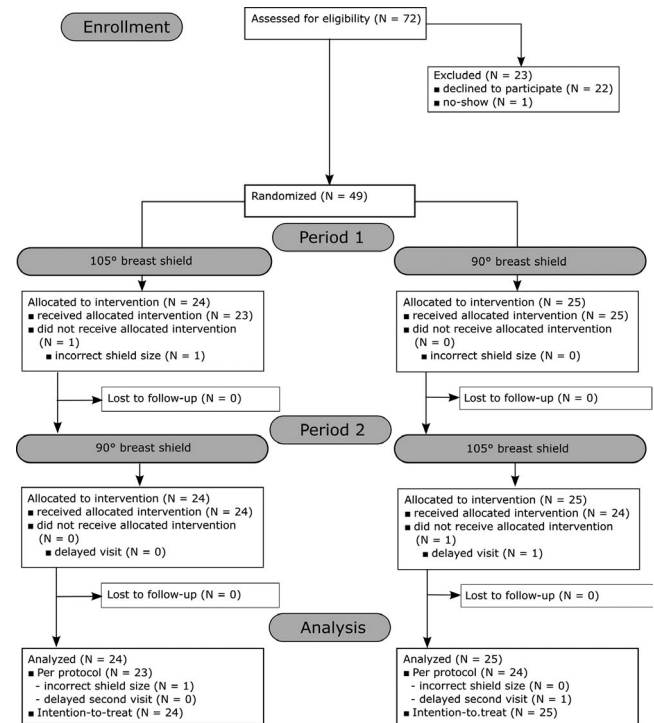
FIGURE 1 Consort Flowchart

majority of women expressed with a 21 mm (78.6%, nipple diameter: 15 ± 1 mm), followed by a 24 mm (20.4%, nipple diameter: 18 ± 1 mm) and 27 mm breast shield (1%, nipple diameter 20 ± 0 mm). Baseline characteristics for the study population are presented in Table 1.

3.2 | Effectiveness

For the primary outcome breast drainage, there was a positive mean difference in drainage of the 105° relative to the 90° breast shields in both the ITT 3.87% (CI; 0.01-7.72, P = .049) and the PP 4.54%; (CI; 0.59-8.49, P = .024). The 95% CI was above the specified non-inferior margin of −10%, demonstrating that the 105° breast shield was non-inferior to the 90° breast shield for PAMR. In addition, the positive mean difference demonstrated that the 105° shield was superior to the 90° (Table 2).

3.3 | Efficiency, mid and last fat

For the secondary outcomes, in both the ITT and PP analysis, the CI was above the specified non-inferiority margin of −11 mL, −1%, −2% and for expressed milk volume, mid-fat, and last-fat, respectively. For all secondary outcomes the 105° shield was therefore non-inferior to the 90° breast shield (Table 2). For the mid and last-fat variables, superiority was not demonstrated. There was a positive mean difference in volume of milk expressed with the 105° relative to the 90° breast shields. The PP 8.94 ml (CI; 0.94-16.94, P = .03) and the ITT 9.14 ml (CI;1.37-16.91, P = .02) demonstrate that the 105° shield was superior for volume of milk expressed (Table 2).

TABLE 1 Baseline and procedural characteristics of the participants. Values are mean (SD) or N (%) or median (interquartile range)

	105° at Visit 1, 90° at Visit 2	90° at Visit 1, 105° at Visit 2
Baseline characteristics		
N (participants)	24	25
Mother's age (years)	31.8 (2.9)	31.4 (3.5)
Infant's age (days)	115.0 (32.2)	120.8 (36.0)
Primiparous	17 (70.8%)	11 (44.0%)
Mulitparous	7 (29.2%)	14 (56.0%)
Previous breast-related surgery?		
No	23 (95.8%)	24 (96.0%)
Yes	1 (4.2%)	1 (4.0%)
Exclusive or predominant (>80% of feeds breastmilk)		
Yes	24 (100.0%)	25 (100.0%)
Currently using or has used a breast pump for the present infant		
Yes	24 (100.0%)	25 (100.0%)
Experience of Breast pump type used		
Electrical	23 (95.8%)	23 (92.0%)
Manual	1 (4.2%)	2 (8.0%)
Procedural characteristics	*105°*	*90°*
N (breasts)	98	98
Breastshield size used		
21 mm	77 (78.6%)	77 (78.6%)
24 mm	20 (20.4%)	20 (20.4%)
27 mm	1 (1.0%)	1 (1.0%)
Minutes since last breastfeed	210.0 (180.0-240.0)	195.0 (180.0-240.0)
First fat [%]	2.7 (1.9-3.8)	2.8 (1.8-4.1)

3.4 | Comfort factors

More participants strongly agreed that the "shield feels comfortable on the skin" with the 105° (88%) than with the 90° breast shield (48%) (*P* < .001). More participants strongly agreed that "the shield fits/adapts well to their breasts" after using the 105° (88%) than the 90° (50%) (*P* < .001). No statistical difference was observed for the sealing (*P* = .12) or ease-of-use questions (*P* = .70). Participants gave more positive answers to the question "With this pumpset I can pump in a comfortable position" using the 105° breast shield compared to the 90° breast shield (*P* = .03).

3.5 | Post hoc analyses

PAMR and volumes of milk expressed at 2, 5 and 10 minutes, mean and peak flow rates, were higher when using 105° compared to the 90° shield (Table 2, all *P* < .05). In addition, measured volumes of

milk expressed at 15 minutes were greater for the 105° (92.9 ± 41.7) compared to the 90° shield (83.8 ± 37.1; *P* < .05). Stimulation vacuum and time to first milk ejection (Supporting Information Appendix S2) were significantly stronger and faster respectively with the 105° compared to the 90° breast shield (all *P* < .05). There was no difference for expression vacuum applied between the breast shields (Table 2).

4 | DISCUSSION

Assessing which factors can influence pumping is essential to understand and improve expression. This study is the first to show that breast shield design influences milk removal dynamics during pumping. The 105° breast shield was non-inferior compared to the standard 90° breast shield in all primary and secondary outcomes, and was superior for PAMR, expressed milk volume, and was more comfortable. Expressing with the 105° breast shield was therefore more effective, efficient and comfortable than with the standard 90° breast shield.

Effectiveness was moderately but statistically significantly improved when expressing with the 105° breast shield. The breast was on average 4% more drained and an additional 9 mL of volume was expressed. Previous studies found that pumping with the highest comfortable vacuum compared to lower vacuums[19] and double pumping compared to single pumping, resulted in an approximate 10% improvement in breast drainage.[27] Whilst the additional difference in breast drainage and milk volume in this study may not be clinically relevant for women expressing occasionally, changing the breast shield flange angle appears to be an additional factor that can be incorporated alongside double pumping[27] with the highest comfort vacuum[19] to improve pumping performance for those women who are expressing frequently and reliant on the breast pump to maintain lactation.[7]

The effectiveness of the 105° opening angle may be explained by its impact on the breast anatomy and milk ejection. The oxytocin-mediated milk ejection reflex results in the contraction of the myoepithelial cells surrounding the alveoli in the breast, forcing milk into the milk ducts and towards the nipple. This results in increased intra-ductal pressure,[28] duct dilation and an increase in milk flow.[29] Ultrasound examination of the lactating breast has shown that a large proportion of the glandular tissue is located within a 30-mm radius of the base of the nipple (left: 72 ± 9%; right: 70 ± 8% of the total depth of tissue) and the milk ducts reside close to the skin surface. Therefore, pressure on the ducts and tissue in this area by a poorly fitting breast shield flange may restrict milk flow during milk ejection.[14] Thus, the higher breast drainage and perception of more comfort with the 105° shield, may suggest that the wider flange opening angle improved the fit to the breast during pumping compared to the 90° shield.

The higher volume of milk expressed, higher peak flow rates, and shorter time to first milk ejection indicate that over the entire duration of pumping, the 105° breast shield was more efficient than the 90°. Since the first milk ejection account for

TABLE 2 Relative modelled means and mean difference in the primary, secondary endpoints and post-hoc comparisons when using the 105°breastshield compared to the 90° breastshield

	Endpoint	105° Mean (95% CI)	90° Mean (95% CI)	105° relative to 90° Mean difference (95% CI)	P value
	Primary and secondary				
PP	PAMR at 15 mins (%)	63.45 (54.01 to 72.90)	58.91 (49.52 to 68.31)	4.54 (0.59 to 8.49)	.024*
ITT	PAMR at 15 mins (%)	62.48 (53.26 to 71.70)	58.62 (49.44 to 67.79)	3.87 (0.01 to 7.72)	.049*
PP	Mid fat (%)	6.98 (5.98 to 7.98)	6.90 (5.91 to 7.90)	0.08 (−0.33 to 0.49)	.71
ITT	Mid fat (%)	6.97 (6.00 to 7.93)	6.91 (5.95 to 7.87)	0.06 (−0.34 to 0.45)	.78
PP	Last fat (%)	10.85 (9.09 to 12.62)	10.22 (8.47 to 11.98)	0.63 (−0.07 to 1.33)	.08
ITT	Last fat (%)	10.99 (9.27 to 12.70)	10.42 (8.71 to 12.13)	0.57 (−0.11 to 1.25)	.10
PP	Expressed volume (mL)	105.86 (86.20 to 125.52)	96.92 (77.36 to 116.47)	8.94 (0.94 to 16.94)	.03*
ITT	Expressed volume (mL)	105.70 (86.64 to 124.76)	96.57 (77.60 to 115.53)	9.14 (1.37 to 16.91)	.02*
	Post-hoc comparisons				
	PAMR at 2 mins (%)	22.02 (18.11 to 25.92)	19.93 (16.04 to 23.83)	2.08 (0.24 to 3.92)	.03*
	PAMR at 5 mins (%)	42.72 (36.38 to 49.06)	38.78 (32.45 to 45.10)	3.95 (0.65 to 7.24)	.02*
	PAMR at 10 mins (%)	52.18 (45.02 to 59.34)	48.09 (40.95 to 55.23)	4.09 (0.33 to 7.84)	.03*
	Volume at 2 mins (mL)	32.79 (26.64 to 38.93)	29.60 (23.46 to 35.73)	3.19 (0.26 to 6.12)	.03*
	Volume at 5 mins (mL)	64.92 (53.38 to 76.46)	57.10 (45.58 to 68.61)	7.82 (2.08 to 13.57)	.01*
	Volume at 10 mins (mL)	80.45 (66.18 to 94.72)	71.29 (57.05 to 85.52)	9.17 (2.09 to 16.24)	.01*
	First milk ejection (min)	1.19 (1.01 to 1.36)	1.33 (1.16 to 1.50)	−0.15 (−0.22 to −0.07)	<.001*
	Peak flow rate (mL/sec)	0.40 (0.34 to 0.46)	0.36 (0.30 to 0.42)	0.04 (0.01 to 0.07)	.006*
	Mean flow rate (mL/min)	5.76 (4.72 to 6.79)	5.15 (4.12 to 6.18)	0.61 (0.09 to 1.13)	.02*
	Stimulation vacuum (mmHg)	−100.62 (−108.46 to −92.79)	−93.63 (−101.44 to −85.82)	−6.99 (−11.15 to −2.84)	.001*
	Vacuum applied (mmHg)	−201.5 (−175.0 to −223.0)	−198.0 (−175.0 to −220.0)	−3.78 (−0.67 to −8.23)	.09

Abbreviations: ITT, intention-to-treat; PAMR, percentage available milk removed; PP, per protocol.

*Denotes $P \leq .05$

approximately one third of the milk removed during pumping[6,30] it is plausible that optimizing milk flow during this time can be a driver for improved efficiency during pumping. Given that no difference was measured in vacuum during expressing and that this variable has been shown to affect milk removal,[19] the higher milk flow rates and shorter time to milk ejection observed with the 105° breast shield may therefore be a result of the improved fitting, reducing the amount of unnecessary tissue movement and enabling improved milk flow[17,18]

This research, however, is subject to several limitations. Firstly, this study constitutes industry-based research. To address this limitation, the study design and all methods employed were modelled on existing peer-reviewed research.[7,19,31] In addition, utilizing a blinded, independent statistician for analysis and interpretation of the results, minimized the potential for funding bias. Secondly, this study is limited by the fact that acute milk output was assessed at only two pumping sessions taking place 7-21 days apart, thus the long-term effectiveness of expressing with the 105° breast shield was not investigated. Nonetheless, the robust controlling of physiological factors related to pumping (at each visit mothers began the study with the same breast fullness, used the same breast shield size and pumped for the same duration) suggests that the results apply to the wider

pumping population. Future studies could randomise women to different shields, and measure outcomes over several weeks to determine if there are long term effects on milk production and factors associated with milk removal, such as mastitis.

5 | CONCLUSION

The opening angle of the breast shield is an important factor in the performance and comfort of breast pumping. The 105° breast shield improves the effectiveness, efficiency and comfort of milk removal. These data confirm that breast shield design significantly impacts pumping outcomes and should be considered as an important factor for optimizing breast expression.

CONFLICT OF INTEREST

This clinical study was conducted and financed by Medela AG, Switzerland. LJ, NGSH, LRM, and DKP are employees of Medela AG. VSS and LI were employees of Medela AG during the planning, data collection and manuscript preparation phases of the study. AGH is an employee of CTU Bern, The University of Bern, Switzerland. CTU Bern, University of Bern staff policy prohibits its employees from the direct acceptance of honoraria or consultancy fees.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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