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ORIGINAL ARTICLE

Nipple shield use does not impact sucking dynamics in breastfeeding infants of mothers with nipple pain

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Abstract

Nipple shields (shield) may reduce pain during breastfeeding, but the impact on infant sucking dynamics is not known. We examined the effects of shield use on sucking dynamics, milk removal and nipple pain in two groups of breastfeeding dyads: pain group (PG): shield used for nipple pain; comparison group (CG): no breastfeeding difficulties. Twenty PG (6 ± 4 weeks postnatal) and 28 CG dyads (8 ± 6 weeks postnatal) attended 2 monitored breastfeeding sessions with shield use randomised. Within-subject outcomes were compared. PG: shield use did not affect intra-oral vacuum (peak $p = 0.17$, baseline $p = 0.59$), sucking frequency ($p = 0.20$) or milk transfer (40 mL vs 48 mL, $p = 0.80$; percentage of available milk removed (PAMR) 55% vs 57%, $p = 0.88$), and reduced McGill pain scores ($p = 0.012$). CG: shield use increased non-nutritive sucking (10% more, $p = 0.049$), and reduced nutritive sucking (18% less, $p = 0.017$) and milk transfer (63 mL vs 31 mL $p < 0.001$, PAMR 65% vs 36% $p < 0.001$). For both groups, feeding duration increased by 2 min ($p < 0.0001$) and non-nutritive portions of the feed increased with shield use.

Conclusion: Nipple shield use improved maternal comfort and did not impact milk removal or sucking strength in PG, but significantly reduced milk transfer and nutritive sucking in CG.

What is Known:
- *Mothers report that nipple shields reduce nipple pain and enable continued breastfeeding.*
- *Concerns that nipple shield use may reduce milk transfer and alter infant sucking patterns are based on limited published evidence.*

What is New:
- *Nipple shield use is associated with a 25% reduction in pain scores in breastfeeding mothers with chronic nipple pain.*
- *Milk transfer is not reduced in dyads that regularly use a shield for chronic nipple pain.*
- *Intra-oral vacuums are not impacted by nipple shield use in mothers experiencing pain.*

Keywords Breastfeeding · Nipple pain · Nipple shield · Sucking dynamics

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Abbreviations

CG	Comparison group
IBCLC	International board-certified lactation consultant
MPQ	McGill Pain Questionnaire
NNP	Non-nutritive pause
NNS	Non-nutritive sucking
NP	Nutritive pause
NS	Nutritive sucking
PAMR	Percentage of available milk removed
PG	Pain group
VAS	Visual Analogue Scale

Introduction

Exclusive breastfeeding is recommended as the optimal feeding method for infants up to 6 months of age [1] yet many women stop breastfeeding before planned due to nipple pain [2]. When nipple pain is unable to be resolved by conventional methods such as positioning and attachment and treatment of the other possible causes [3, 4], a nipple shield may be introduced to help mothers manage nipple pain and continue breastfeeding. There are concerns that nipple shield use may impact infant sucking dynamics, reduce milk transfer and shorten breastfeeding duration [5–7], although mothers with breastfeeding problems are at higher risk of early weaning [8] regardless of nipple shield use. Concerns about altered infant sucking dynamics and reduced milk transfer are based on studies of nipple shields that are no longer available. Increased sucking frequency and pause durations and reduced milk transfer volumes were observed with use of a thick rubber 'Mexican Hat' shield, but not with a soft Latex nipple shield [5, 6]. Evidence for the positive effects of contemporary ultra-thin flexible silicone nipple shield use on breastfeeding outcomes is limited to hospitalised preterm infants, with increased milk transfer volumes reported [9].

It has been established that application of infant intra-oral vacuum (negative pressure) during milk ejection is the primary mechanism of effective milk removal during breastfeeding [10, 11]. Infants use their tongue and perioral muscles to attach to the breast by forming a seal around the nipple and areola. A baseline vacuum of approximately − 64 mmHg is applied, and inferior tongue movement to the lowest point from the palate coincides with creation of the strongest (peak) vacuum, on average − 145 mmHg, typically resulting in milk flow into the oral cavity [10]. Although baseline and peak vacuum weaken with age [12], some infants apply an extraordinarily strong vacuum during breastfeeding, which is associated with chronic maternal nipple pain [13, 14].

During breastfeeding, two different patterns of infant sucking are observed: nutritive sucking (NS) where milk is transferred and swallowed, and non-nutritive sucking (NNS) that occurs in the absence of milk flow. Both NS and NNS occur in bursts followed by nutritive pauses (NP) and non-nutritive pauses (NNP), respectively [12]. The volume of milk removed from the breast is partly dependent on the degree of breast fullness, and therefore, the volume of milk available in the breast. This varies throughout the day depending on how recently and adequately milk was last removed from the breast. Therefore, transfer volume is not an accurate indicator of breast emptying, and calculation of the percentage of available milk removed (PAMR) provides a more accurate measure that can be used to evaluate adequacy of milk removal [15].

The aim of this study was to investigate whether nipple shield use during breastfeeding altered infant intra-oral vacuum, infant sucking dynamics and maternal nipple pain when compared to breastfeeding without a nipple shield.

Materials and methods

Breastfeeding dyads (1 to 6 months postnatal) were recruited through international board-certified lactation consultants (IBCLC) and the community between July 2016 and June 2019. Two groups were recruited: pain group (PG) comprised dyads using an ultra-thin silicone nipple shield to manage persistent unexplained nipple pain, and comparison group (CG) comprised dyads with no breastfeeding difficulties. Inclusion criteria are as follows: birth at term (i.e. ≧ 37 completed weeks of gestation) and predominantly breastfeeding (i.e. feeding ≤ 1 bottle of formula/24 h). PG: breastfeeding dyads with nipple pain despite previous lactation advice from their care providers (midwives, community child health nurse, IBCLC and/or family doctor) and treatment of possible causes (e.g. infection, mastitis) using a nipple shield for most breastfeeds (≤ 2 breastfeeds/24 h without a shield). Exclusion criteria are as follows: mothers with a diagnosed cause of nipple pain, previous breast surgery or nipple piercing, < 18 years of age, unable to speak and read English without assistance, infants with a previous or current oral anomaly, oral surgery and/or diagnosed health condition.

The study was approved by the Human Research Ethics Committees of the Women and Newborn Health Service (2016124) and The University of Western Australia (RA/4/1/7863). Mothers provided written informed consent prior to participation.

Study design

A within-subject study was conducted at King Edward Memorial Hospital, Perth. Mothers completed a demographic questionnaire and attended two monitored study sessions within 7 days with the feeding breast side (CG only) and nipple shield use randomised. Maternal nipple diameters were measured using electronic callipers (CE Analogic Calliper, accuracy ± 0.2 mm, Anhui, China) to determine shield fitting (i.e. nipple shield diameter ≥ 4 mm than nipple base diameter). Available sizes were 16, 20 and 24 mm (Medela Contact Nipple Shields, Medela AG, Baar, Switzerland), 18 and 28 mm (Mamivac Conical Nipple Shields, KaWeCo GmbH, Ditzingen, Germany). An IBCLC placed the fitted nipple shield over mother's nipple and confirmed that it was centralised before the infant attached to the breast. PG mothers breastfed from the most painful breast and all mothers fed from the same breast side at both study sessions.

This paper reports the secondary clinical outcomes of infant sucking dynamics, intra-oral vacuum, milk transfer and maternal nipple pain with and without nipple shield use. The primary outcome of the study (total breastmilk volume (mL) transferred with and without nipple shield use in CG and PG dyads) and has been reported (Coentro et al. in press).

Breastfeeding assessments

Intra-oral vacuum, milk transfer and 24-h milk profiles were measured as previously described [10, 16]. Pre- and post-feed milk samples (< 1 mL) were collected in 5-mL containers (Techno Plas, St Marys, South Australia, Australia) and the milk cream content was analysed using the Crematocrit method [17]. Data from the 24 h milk profiles and Crematocrit analysis were used to estimate the percentage of available milk removed (PAMR). That is, a relationship exists between the milk fat content and degree of fullness of the breast. Milk sampled from a relatively full breast has a lower fat concentration and the fat concentration progressively increases as milk is removed from the breast. Therefore, it is possible to use a quadratic equation to estimate the PAMR for an individual mother when her 24-h data for breastfeeding and pumping volumes, and milk fat concentrations calculated from pre- and post-breastfeed/pumping milk samples are available [18].

Suck bursts and pauses were identified for each monitored breastfeed from the intra-oral vacuum trace. For each suck burst, burst state (NS or NNS), peak and baseline vacuum (mean minimum and maximum pressure, mmHg, respectively) and mean vacuum (mmHg), number of sucks (cycles) per suck burst (n), suck burst duration (s) and sucking frequency (sucks/min) were calculated. For each pause, the pause state (NP or NNP), mean vacuum (mmHg) and pause duration (s) were calculated [19]. Total durations of each suck and pause state were calculated as percentages of the total feed duration. Feed efficiency (mL/min) was calculated as milk intake divided by the total feed duration, and per total NS duration [19].

Mothers completed the Visual Analogue Scale (VAS) [20] and McGill Pain Questionnaire (MPQ) [21] after each monitored breastfeed to assess nipple pain.

Sample size determination

A sample size of 30 ($n = 30$) was required to detect an average significant difference in milk transfer volume of 20 ± 5 mL (power: 0.83, alpha: 0.05) between monitored breastfeeds with and without nipple shield use [22].

Statistical methods

Demographic data were analysed using chi-square tests or a Fisher's exact test (categorical variables) or a two-sided independent t test (continuous variables). 24-h milk production volumes were compared using paired t test. A series of linear mixed-effects models were fit to explore if group and/or shield (explanatory variables) influenced infant peak and baseline oral vacuum, suck burst frequency, suck burst duration, sucking rate, total feed volume, feed duration and feed efficiency (response variables). A series of linear mixed-effects models were fit to explore if group, shield or infant intra-oral vacuum (explanatory variables) influenced the feed volume, PAMR, VAS and McGill scores (response variables). A series of linear mixed-effects models were fit to explore if group, shield or feed volume (explanatory variables) influenced the measurements of the duration spent in each state (NS, NP, NNS and NNP) (response variable), and a series of linear mixed-effects models were fit to explore if group, shield or PAMR % (explanatory variables) influenced the measurements of the duration spent in each state (response variable). Additionally, for each of the explanatory variables described, Tukey-adjusted within-group comparisons were made to compare the effect of shield use.

Descriptive statistics are presented as frequencies and percentages for categorical variables and mean and standard deviation for continuous variables. The significance level was set at 0.05 and all analysis was carried out in R version 3.6.2 (The R Foundation for Statistical Computing).

Results

Dyads (PG $n = 25$, CG $n = 43$) were recruited. Of these, five PG dyads and six CG dyads were excluded from sucking dynamics analysis due to technical issues with intra-oral vacuum measurement, eight CG dyads were excluded as the infants refused to feed with the nipple shield, and one dyad was excluded as the infant refused to feed with the intra-oral vacuum tube in situ. Therefore, data for PG $n = 20$ and CG $n = 28$ were analysed. All PG mothers reported commencing nipple shield use within one week of birth. Maternal and infant demographic characteristics are presented in Table 1.

There was no significant difference in total 24-h milk production between PG (volume 671 ± 234 mL) and CG (volume 776 ± 166 mL, $p = 0.08$).

Table 1 Maternal and infant demographic characteristics

Variables	Pain group (n = 20)	Comparison group (n = 28)	p value
Maternal age (years)	33 ± 5[a]	33 ± 4	0.93
Birth gestation (weeks)	39.2 ± 1[a]	39.2 ± 1	0.98
Birth mode = vaginal	13 (65)[a]	18 (64)	0.81
Parity			
Primipara	14 (70)[a]	14 (50)	0.15
Multipara	4 (20)[a]	14 (50)	
Birth weight (g)	3514 ± 301[a]	3499 ± 447	0.89
Postnatal age (weeks)	6 ± 4[a]	8 ± 6	0.11
Infant sex = female	7 (35)[a]	16 (57)	0.36
Dummy use = yes	12 (60)[a]	17 (61)[a]	0.22

[a] Missing data n = 2

Results are reported as mean ± SD for maternal age, intended breastfeed duration, birth gestational age, birth weight and postnatal age. Birth mode, parity, infant sex and dummy use are reported as number and percentage (%)

When examining the impact of shield use within groups, nipple shield use did not impact PG infant mean peak and mean baseline intra-oral vacuum (p = 0.17; p = 0.59). More specifically there was no difference in NS and NNS peak and NS and NNS baseline vacuum. For CG infants, baseline intra-oral vacuum was weaker (no shield − 61 ± 5; shield − 48 ± 5.4, p = 0.019), and while NS peak, NS and NNS baseline vacuums did not differ, NNS peak intra-oral vacuum was stronger with shield use, average − 38 mmHg. The two groups did not differ with regard to NS and NNS peak and baseline intra-oral vacuums (Table 2 and Fig. 1).

The number of suck bursts per feed did not differ with shield use within or between groups. Linear mixed-effects modelling showed that for both PG and CG the average number of suck bursts per feed increased by 20 suck bursts when a shield was used (p = 0.04). The sucking frequency was similar between feeds with and without shield use for PG and between groups, but for CG shield use was associated with an increased sucking frequency (Table 2).

While the average NS and NNS bursts and NNP durations were similar between groups regardless of shield use, PG infants' NP duration was on average one second longer when feeding with a shield than when feeding without a nipple shield. Statistical modelling showed that when a shield was used, NNS and NNP durations were longer for both groups (p = 0.009; p = 0.009, respectively), and CG infants had 18% shorter NS burst duration (p = 0.017) and 10% longer NNS burst duration (p = 0.049).

For PG, milk transfer did not differ with shield use when considered as volume or PAMR. However, for CG, both volume and PAMR were 30 mL and 29.5% lower with shield use. For both groups, shield use increased the feed duration by on average 2 min (p < 0.0001) and therefore reduced feeding efficiency by 5 mL/min (Table 2).

McGill pain questionnaire scores were on average 25% lower for PG mothers when a shield was used (p = 0.012), but VAS scores were not different (p = 0.95). For PG, VAS scores, but not McGill scores, were higher with stronger peak and baseline intra-oral vacuum. For each − 10-mmHg increase in peak sucking strength, the VAS score increased by on average 0.11 (p = 0.004), while for every − 10-mmHg increase in baseline vacuum the score increased by on average 0.15 (p = 0.013).

- Linear mixed-effects modelling showed that for both PG and CG stronger peak intra-oral vacuum was significantly associated with increased feed volume (p = 0.03) and PAMR (p = 0.01). For each – 10-mmHg increment in peak sucking strength, there were average increases of 1.1-mL feed volume and 1.3% PAMR.

Discussion

For breastfeeding dyads regularly using a nipple shield to manage chronic nipple pain, shield use reduced maternal pain scores and did not impact infant intra-oral vacuum levels, sucking frequency, number of suck bursts per feed or milk removal. However, non-nutritive portions of the feed and total feed duration were longer resulting in reduced feeding efficiency. Results differed for dyads with no breastfeeding problems that used a nipple shield only for the purpose of this study, with milk transfer and nutritive sucking significantly reduced. These dyads also had marginally longer non-nutritive portions of the feed with shield use, with reduced feeding efficiency. Limited evidence from older style nipple shields [5] has caused health professionals to be concerned

Table 2 Infant sucking dynamics characteristics for mothers with nipple pain

Variables	Pain group (n = 20)			Comparison group (n = 28)			Comparison between groups*
	No shield	Shield	p value	No shield	Shield	p value	p value
Sucking pressure (mmHg)							
NS peak	− 157 ± 58	− 159 ± 51	0.99	− 141 ± 43	− 160 ± 50	0.48	0.50
NS baseline	− 71 ± 36	− 55 ± 34	0.27	− 54 ± 31	− 44 ± 32	0.62	0.10
NNS peak	− 144 ± 55	− 151 ± 51	0.97	− 124 ± 34	− 163 ± 59	0.03	0.81
NNS baseline	− 69 ± 35	− 56 ± 35	0.66	− 57 ± 34	− 43 ± 29	0.52	0.11
Sucking frequency (sucks/min)	83 ± 12	90 ± 13	0.20	83 ± 11	92 ± 13	0.004	0.71
Suck bursts (n)	63 ± 37	90 ± 58	0.25	51 ± 44	66 ± 42	0.66	0.07
Mean suck burst/pause duration (s)							
NS	9.4 ± 3.0	8.4 ± 3.4	0.90	11 ± 4.7	8.8 ± 6.6	0.34	0.41
NNS	5.3 ± 3.9	5.8 ± 3.9	0.98	5.4 ± 5.8	4.6 ± 2.5	0.87	0.49
NP	3.9 ± 2.4	3.7 ± 1.4	0.95	2.9 ± 1.7	2.7 ± 1.9	0.97	0.02
NNP	3.2 ± 2.7	4.3 ± 1.9	0.60	3.0 ± 4.3	3.9 ± 4.4	0.56	0.72
Total suck burst/pause duration (s)							
NS	203 ± 99	260 ± 150	0.51	196 ± 149	200 ± 190	0.99	0.36
NNS	49 ± 45	70 ± 63	0.46	29 ± 29	58 ± 55	0.09	0.14
NP	81 ± 48	122 ± 129	0.29	62 ± 74	69 ± 67	0.98	0.07
NNP	32 ± 33	60 ± 68	0.09	22 ± 29	38 ± 33	0.37	0.11
Suck/pause proportion of feed (%)							
NS	58 ± 13	51 ± 18	0.71	68 ± 18	49 ± 27	0.01	0.52
NNS	11 ± 7.3	15 ± 13	0.73	10 ± 9.5	21 ± 23	0.04	0.47
NP	24 ± 10	22 ± 6.7	0.82	18 ± 9.3	17 ± 13	0.99	0.04
NNP	7.3 ± 6.2	12 ± 9.1	0.48	6.3 ± 7.6	13 ± 14	0.05	0.93
Total feed duration; min	6.8 ± 3.2	10 ± 6.3	0.14	6.7 ± 4.6	7.7 ± 5.1	0.86	0.32
Volume (mL)	48 ± 28	40 ± 25	0.86	63 ± 28	31 ± 22	< 0.001	0.55
PAMR (%)	57 ± 29	55 ± 30	0.88	65 ± 21	36 ± 29	< 0.001	0.35
Feed efficiency—total (mL/min)	7.8 ± 3.8	4.57 ± 3.1	0.12	12 ± 6.6	6.1 ± 7.6	< 0.001	0.05
Feed efficiency—NS (mL/min)	17 ± 16	21 ± 53	0.97	27 ± 19	14 ± 14	0.45	0.77
VAS score	4.1 ± 2.7	3.50 ± 3.1	0.95	0.2 ± 0.4	0.1 ± 0.4	0.99	< 0.001
McGill score	20 ± 13	15 ± 13	0.01	0.7 ± 1.5	1.0 ± 2.0	0.99	< 0.001

Results are reported as mean ± SD for all variables.

*For variables that were not statistically significantly different between groups data were pooled and analysed by linear mixed-effects modelling

about impaired milk transfer with shield use [23]. However, the results of this study suggest that nipple shield use in mothers with ongoing nipple pain may facilitate continued breastfeeding with adequate milk removal while reducing maternal pain.

The effect of nipple shield use on intra-oral vacuum measurements in infants born at term has not been previously reported. For PG, we found no difference in NS and NNS peak and baseline intra-oral vacuum levels with shield use, and intra-oral vacuum levels were related to effectiveness of milk removal. The PG infants commenced nipple shield use during the first postnatal week when early imprinting occurs [24]. Abundant Merkel cells in the oral cavity detect intra-oral objects and communicate somatosensory information to the cerebral cortex [25]. It is therefore possible that with the early introduction of the nipple shield, PG infants did not recognise it as a foreign object and so intra-oral vacuums were unchanged, allowing effective milk removal from the breast. Published measures of intra-oral vacuum during nipple shield in dyads with chronic nipple pain is limited to a case report where baseline vacuum was normalised and peak vacuum increased [13]. Infant intra-oral vacuum and sucking pattern responses to nipple shield use may differ between infants depending on birth gestation, postnatal age and any underlying sucking anomalies.

In the comparison group, a weaker sucking baseline vacuum was observed during shield use suggesting that the structure of the nipple shield may mitigate the level of vacuum

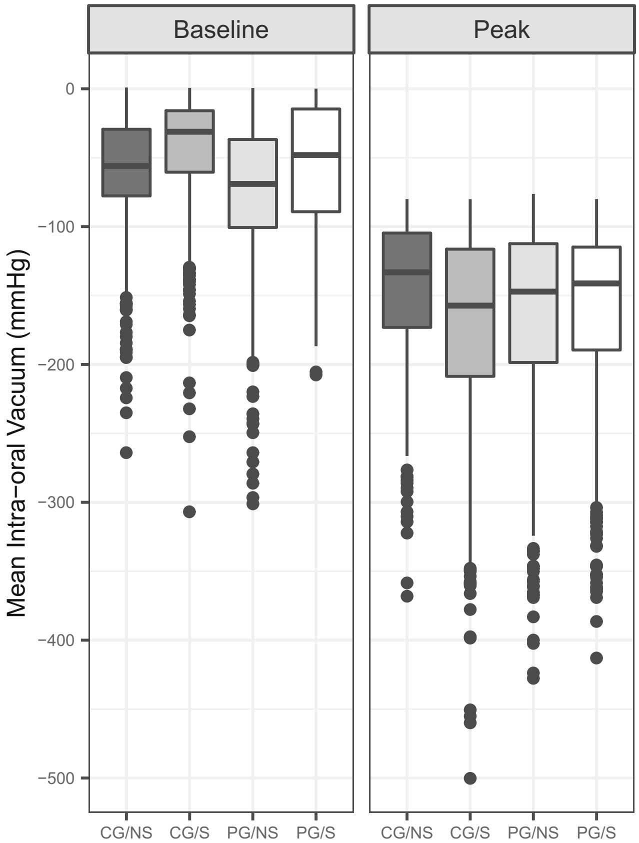

Fig. 1 Mean peak and baseline (base) intra-oral vacuum levels for comparison group (CG) and pain group (PG) infants during breastfeeds without (NS) and with (S) nipple shield use

typically required to extend the nipple and hold it close to the hard palate-soft palate junction [10]. In addition, CG infants had a stronger peak NNS, faster sucking frequency and weaker baseline vacuum that may have been a response to the novel sensory experience of this foreign object with subsequent reduced milk transfer. It may also explain our observations of recruited CG infants that refused to breastfeed with a nipple shield, and reports of exclusively breastfed infants' refusal of bottle teats beyond the perinatal imprinting period [26].

Nipple shield use extended the average feed duration by approximately 2 min, which is statistically, but not clinically, significant. For women with nipple pain during breastfeeding, the ability to continue feeding directly at the breast with reduced pain, albeit for a slightly longer feed duration, is likely more beneficial than the alternatives of increased pain with direct breastfeeding, or pumping and feeding of expressed milk.

The proportion of feed time spent in NNS and NNP increased with nipple shield use, resulting in reduced feeding efficiency for both groups. For CG infants, shield use was also associated with a faster sucking frequency and decreased NS proportion that likely contributed to the reduced milk transfer. Likewise, Woolridge [5] reported an increased sucking frequency, longer pause durations and decreased milk volume transfer with 'Mexican Hat' and Latex nipple shield use in mother-infant dyads without breastfeeding problems.

This study showed that milk transfer was not compromised in the PG group when a nipple shield was used, and between groups without a shield. Therefore, both nipple shield use and nipple pain did not impact milk removal in PG dyads. While psychological stress and pain have previously been demonstrated to inhibit the milk ejection reflex [27], it is possible that the intensity of pain experienced by PG mothers was not strong enough to impair oxytocin release.

Nipple shield use was associated with a moderate reduction in maternal nipple pain as seen in the average 25% reduction in McGill pain scores. This concurs with maternal reports of nipple shield use being 'helpful' and 'crucial to getting through that difficult period' when experiencing early postnatal nipple pain and damage [7]. Reduced pain levels were not reflected in the VAS scores, which may not be adequately sensitive to the nature of nipple pain [28].

Conclusion

This study shows that for mothers with nipple pain who initiate nipple shield use in the first postnatal week and continue its use for more than 1 month, there are no clinically significant changes to infant sucking dynamics or effectiveness of milk removal and a moderate reduction in maternal pain. Dyads commencing nipple shield use for reasons other than chronic nipple pain should be monitored for adequate milk transfer.

Authors' Contributions VSC designed the study and performed data collection, interpretation of the data and writing of the manuscript. SLP designed the study, assisted with data collection and interpretation and reviewed the manuscript. CTL assisted with data extraction and analysis. MD and AR provided statistical analysis. DTG designed the study, provided data interpretation and reviewed the manuscript. All authors reviewed and approved the manuscript prior to submission.

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Data availability All datasets generated or analysed during this study are available from the corresponding author on request.

Compliance with ethical standards

Conflict of interest VSC received a scholarship from Science without Borders, Government of Brazil. The salaries of SP, CTL and DG are paid from an unrestricted research grant paid by Medela AG to The University of Western Australia.

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Ethical approval The study was approved by the Human Research Ethics Committees of the Women and Newborn Health Service (2016124) and The University of Western Australia (RA/4/1/7863).

Informed consent Written informed consent was obtained from all individual participants included in the study.

Consent to participate Written informed consent to participation was obtained from all individual participants included in the study.

Consent for publication Written informed consent to publication was obtained from all individual participants included in the study.

Code availability Not applicable.

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