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Clinical Trial
Summary

Ultrasound video analysis for understanding infant breastfeeding



Authors:

Gianluca Monaci

Video and Image Processing, Philips Research, Eindhoven, Netherlands.

Mike Woolridge

School of Healthcare, University of Leeds, UK

Source:

Paper presented at the 18th Institute of Electrical and Electronics Engineers (IEEE) International Conference on Image Processing, 11th–14th Sep. 2011

Key study findings

- Philips Avent and the University of Leeds (UK) researchers, have developed a new way of analysing ultrasound videos, enabling, for the first time, quantitative indications of infants' sucking/swallowing behaviour during breastfeeding
- Proposed methodology can discriminate peristaltic and vacuum tongue action based on analysis of the phase-shift between image intensity signals for the frontal and posterior part of the infant's tongue

Background

The exact methods used by infants to breastfeed are yet to be confirmed. Historically, infants were believed to extract milk by predominantly drawing the nipple into the mouth and performing a cyclic wave-like pressure on the nipple, known as peristaltic action.¹ However, new evidence suggests that the infant's tongue moves up and down to induce milk flow, creating a vacuum in the infant's palate in front of the nipple.²

Objective

To develop novel methods to automatically detect and classify relevant events in ultrasound videos of breastfeeding infants, for better understanding of sucking and swallowing behaviour of infants during breastfeeding.

Method

- Pilot analysis was performed on an archetypal ultrasound video sequence of submental scans of the midline of the infants' oral cavities during breastfeeding
 - Recording was undertaken at the University of Leeds School of Healthcare
 - This video was subjectively labelled and consisted of 1500 consecutive ultrasound images
- The recorded sequences show infants doing nothing, stimulating the mother's nipple, without swallowing milk (non-nutritive sucking) or sucking and swallowing milk (nutritive sucking, or swallowing).
 - A typical frame is shown in Figure 1, with the main anatomic structures labelled
- Image intensity variations in different regions of the ultrasound scan were analysed

Results

- The overall intensity of ultrasound images varies over time and is closely related to the infant's sucking rhythm
- The average image intensity for three key regions of interest on the ultrasound image were computed (these key regions are highlighted as red, green and blue in Figure 2)
 - Signals from the red and green areas evolve in a very similar way and local minima in these signals closely reflect the infant's sucking activity
 - The signal from the blue region detects swallowing activity
 - When a non-nutritive sucking event occurs, the intensity signal of the red area drops to a minimum.
 - When a nutritive sucking event (swallowing) occurs, the intensity signal of the blue region drops drastically
- The detection of sucking and swallowing events using this automatic technique closely matched those manually determined by expert analysis of the video sequence
- Figure 3 shows the phases and actions of the infant during breastfeeding in the analysed sequence

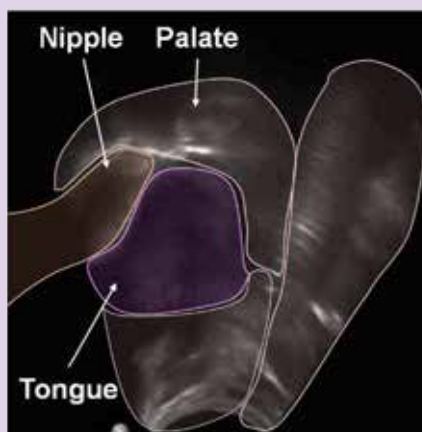


Figure 1: Submental ultrasound scans of the midline of the infant's oral cavity. The nipple and the infant's tongue and palate are labelled

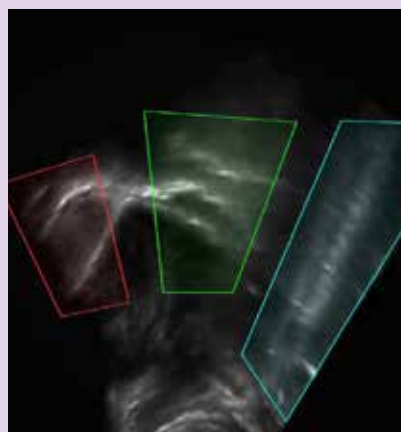


Figure 2. Analysis focused on three areas: The nipple and the frontal part of the tongue are in the red region (left). The posterior part of the tongue and the soft palate are in the green area (middle). The blue region (right) is a broad area where swallowing activity occurs.



Phase 1: Peristaltic tongue movements



Phase 2: Vacuum

Figure 3: Phase and actions of the infant during breastfeeding in the analysed sequence

Phase 1: Infant action: Infant sucks the nipple to stimulate milk release
Tongue movement: Tongue moves in a characteristic peristaltic motion (travels left to right in a wave-like motion)

Phase 2: Infant action: Swallowing corresponds to each suck: there is a more pronounced vacuum action
Tongue movement: Tongue moves up and down and assumes a distinctly flatter profile

Conclusions

The proposed new methods enabled the quantitative analysis of ultrasound images of infants' breastfeeding, allowing analysis of the relative amount of peristaltic and vacuum action during feeding. Application of this method to ultrasound videos of other infants will lead to a better understanding of breastfeeding mechanisms and will help to lead to better feeding alternatives to help mothers prolong breastfeeding.

References: 1. Woolridge MW. The 'anatomy' of infant sucking. *Midwifery* 1986;2:164–171 2. Geddes DT, et al. Tongue movement and intra-oral vacuum in breastfeeding infants. *Early Hum Dev* 2008;84:471–477

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Clinical Trial
Summary

Cross-sectional prospective study examines the fundamental biomechanical requirements needed for an effective feed in infants



Principal investigators:

Ms Marloes Lagarde, MSc., Dr Lenie van den Engel-Hoek
Radboud UMC, Department of Rehabilitation, Donders Institute for Brain
Cognition and Behavior, Nijmegen, the Netherlands

Source:

Biomechanical aspects of nutritive sucking in infants: November 2017

Introduction

This was a cross-sectional prospective study, performed at the Radboud UMC in Nijmegen, the Netherlands. The results describe the biomechanical aspects of nutritive sucking in infants that were 2–5 months of age, while drinking from infant feeding bottles with the Philips Avent Natural bottle and teat. Nutritive sucking is considered one of the most complex activities of infancy, and is an indicator of central nervous system integrity. As such, Philips Avent, together with researchers and health care professionals, examined the biomechanics of nutritive sucking in newborns, and found distinct physiological patterns during the sucking and swallowing phases of breastfeeding. When examining these patterns with the Natural bottle, the flexible, breast-like design of the teat resulted in similar nutritive sucking behaviors.

Key study findings

- Infants between the ages of 2 – 5 months who receive feedings with the Philips Avent Natural bottle and teat show variations in suck-swallow ratios of 1:1 to 4:1 within a single feeding session
- Infants also show variance in inhalation and exhalation after swallowing; exhalation after swallowing occurs often and this variation and adaptive variability is characteristic for typical human (oral) motor development. The Philips Avent teat enables these variable actions during nutritive sucking
- The occurrence of the swallow non-inspiratory flow (SNIF) is significantly influenced by suck-swallow ratios, suggesting a possible role of the intra oral vacuum in SNIF
- Ultrasound videos during nutritive sucking with the Philips Avent Natural teat show normal peristaltic tongue movements, causing a natural deformity of the teat
- The study authors concluded that the ultrasound videos during nutritive sucking using the Philips Avent teats showed normal peristaltic tongue movements causing deformity of the teat. This was similar to the pattern seen in breastfeeding infants in an earlier ultrasound study.

Objective

The aim of this study was to describe the biomechanical aspects of nutritive sucking in infants of 2–5 months old while drinking with the Philips-Avent (Classic+, and Natural 2.0) teats

- Improve the understanding of the process involved in “normal” feeding in infants
- Examine the impact of design on nutritive feeding processes in infants

Methods

Sixteen (6 boys and 10 girls) term-born infants participated in this study, which was conducted at the Radboud University Medical Centre in Nijmegen, the Netherlands, between February 2017 and September 2017. The study population included healthy infants who were enrolled after the parents had given written informed consent.

The biomechanics of different feeding teats during feeding were examined using ultrasound imaging and/or combined measurements of sucking, swallowing, and breathing, using the Digital Swallowing Station (DWS, Kay Pentax).

The biomechanics of different feeding bottles during feeding were examined using ultrasound imaging and/or combined measurements of sucking, swallowing, and breathing, using the Digital Swallowing Station (DWS, Kay Pentax).

- In total, 935 swallowing movements were analyzed
- Swallowing-rate per minute ranged between 23 – 64, with a mean of 38 swallows/minute with the Natural teat
- Preliminary results of the qualitative analysis of the ultrasound measurements during nutritive sucking using the Philips Avent Natural teat show elevation of the medial part of the tongue in a backward moving peristaltic wave, similar to what is seen during breastfeeding, as shown in the Phase 1 and Phase 2 illustrations in Figure 1
- Figure 2 shows the ultrasound images during bottle feeding with the Philips Avent Natural teat, and the deformity of the teat caused by the peristaltic tongue movements

Figure 1. Phase and actions of the infant during breastfeeding in the analyzed sequence. In Phase 1, the infant sucks the nipple to stimulate milk release, and the tongue moves in a characteristic peristaltic motion, traveling from left to right in a wavelike motion. In Phase 2, swallowing corresponds to each suck, with a more pronounced vacuum action. The tongue moves up and down, and assumes a flatter profile.

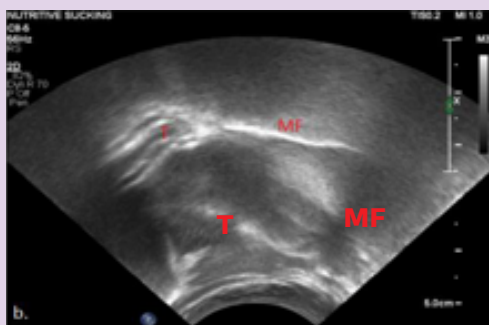
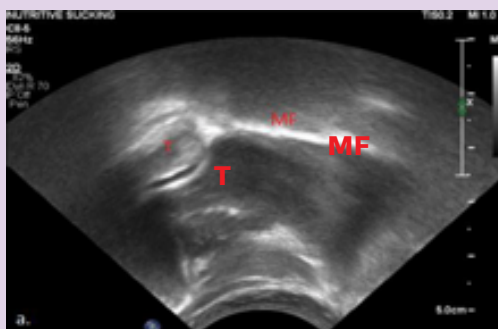


Phase 1



Phase 2

Figure 2. Ultrasound imaging during bottle feed with Philips Avent Natural teat. Ultrasound images show the teat (T) and milk flow (MF) from the teat. The peristaltic movement of the tongue is shown in both images. In the top image, the medial part of the tongue is down (suction phase of sucking); in the bottom image, the medial part of the tongue is up (expression phase of sucking), resulting in deformity of the teat.



Conclusions

The variability in sucking demonstrated by the infants in this study reflects what is seen during normal human oral motor development. The Philips Avent Natural teat enables this variability during nutritive sucking. This may result in a more natural feeding experience for the infant.

References:

1. Howe TH, Sheu CF, Hsieh YW, Hsieh CL. Psychometric characteristics of the neonatal oral-motor assessment scale in healthy preterm infants. *Dev Med Child Neurol.* 2007;49:915-9.
2. Lagarde MLJ and den Engel-Hoek L. Biomechanical aspects of nutritive sucking in infants. Philips Avent, data on file.



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Clinical Trial
Summary

Real-time 3D ultrasound imaging of infant tongue movements during breastfeeding



Author:

Burton P, Deng J, MacDonald D, Fewtrell MS.

Source:

Real-Time 3D Ultrasound Imaging of Infant Tongue Movements During Breast-Feeding. *Early Hum Dev.* 2013; 89(9): 635-41. doi:10.1016/j.earlhumdev.2013.04.009.

Key study take-aways

- Opposing theories in literature have led to an incomplete understanding of the physiology of breast-feeding, which is crucial for the minimization of potential breast-feeding issues.
- This pilot study confirmed that 3D ultrasound imaging is a suitable technique for viewing infant tongue movements during breast-feeding.
- This is the first study to show that peristalsis can be observed in the majority of breast-feeding infants, if the probe is positioned on the mid-sagittal† plane of the infant's tongue.
- This progressive study has contributed to the further understanding of the mechanics of breast-feeding, and these data should be considered in future study designs investigating the relative importance of vacuum and peristalsis in milk extraction.

Background and study rationale

Over the years, the mechanics involved in infant milk extraction from the breast has been at the heart of much controversy, with theories either pointing to vacuum being solely responsible (see image 1)^{1,2} or compression of the areola and surrounding tissue (see image 2), occurring in conjunction with peristaltic tongue movements³ (see image 3).

As 2D ultrasound imaging is not a reliable technique for confirmation of breast-feeding physiology, this pilot study was conducted to confirm whether 3D ultrasound scanning can be used to non-invasively observe infant tongue movements (study objective 1) and whether peristalsis is evident during breast-feeding (study objective 2).

Methods

The study was carried out at the Great Ormond Street Hospital, London, UK or the UCL Institute of Child Health, London, UK and was approved by the National Research Ethics Committee, London, UK. Infant inclusion criteria: healthy babies (born >37 weeks' gestation), aged 2 weeks to 4 months, birth weight >2.5 kg.

Each infant, from the enrolled 15 mother-infant pair, was studied using 3D ultrasound (either via the X-plane or Live-3D approach) and data was collated via a 7MHz transducer probe, placed sub-mentally* during each feed.

† A vertical plane through the midline of the body; divides the body into right and left halves

* Located in, affecting, or performed on the area under the chin (courtesy of /medical).

Results

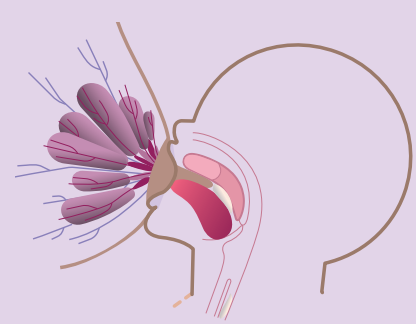
- No breast-feeding infants showed any signs of anxiety during scanning, and mothers were happy with the techniques used.
- The first study objective was successful in that 72% of X-plane and 56% of Live-3D datasets provided adequate coverage (>75%) of the infant's tongue, with the Live-3D approach proving to be superior to identification of the truly mid-sagittal plane.
- The second study objective was met as peristaltic tongue movement was observed in 13 of 15 infants (87%), when viewing was through the mid-sagittal plane of the tongue.



1. Vacuum



2. Compression



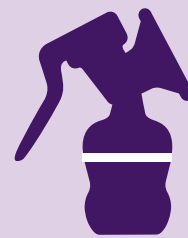
3. Peristaltic tongue movements

Conclusion

3D ultrasound scanning can be used to view an infant's tongue movements during breast-feeding. Probe positioning on (and not just along) the mid-sagittal plane is crucial to the observation of peristaltic movement during breast-feeding, as with even a small shift off this plane, less peristaltic movement is seen. These findings bring us closer to understanding the physiology of breast-feeding and should be considered in future studies investigating the relative importance of vacuum and peristalsis in milk extraction.

References: 1. Smith WL, Erenberg A, Nowak AJ. Imaging evaluation of the human nipple during breast-feeding. *Am J Dis Child* 1988;142:76–8.
2. Waller H. The force exerted by the baby. William Heinemann Ltd: Clinical studies in lactation; 1936. 3. Woolridge MW. The anatomy of infant sucking. *Midwifery* 1986;2(4):164–71.

Randomized trial comparing the efficacy of a novel manual breast pump with a mini-electric breast pump in mothers with term infants



Authors:

Mary S Fewtrell, MD, FRCPC, Penny Lucas, SRN, RSCN, Sharon Collier et al.
MRC Childhood Nutrition Research Centre, Institute of Child Health, London, England

Source:

Journal of Human Lactation Vol 17 No 2 May 2001

Study objective:

- To compare the efficacy of a mini-electric pump (MEP; Medela mini-electric) versus a novel manual pump (MP; Philips Avent manual pump) when used in mothers of term babies.

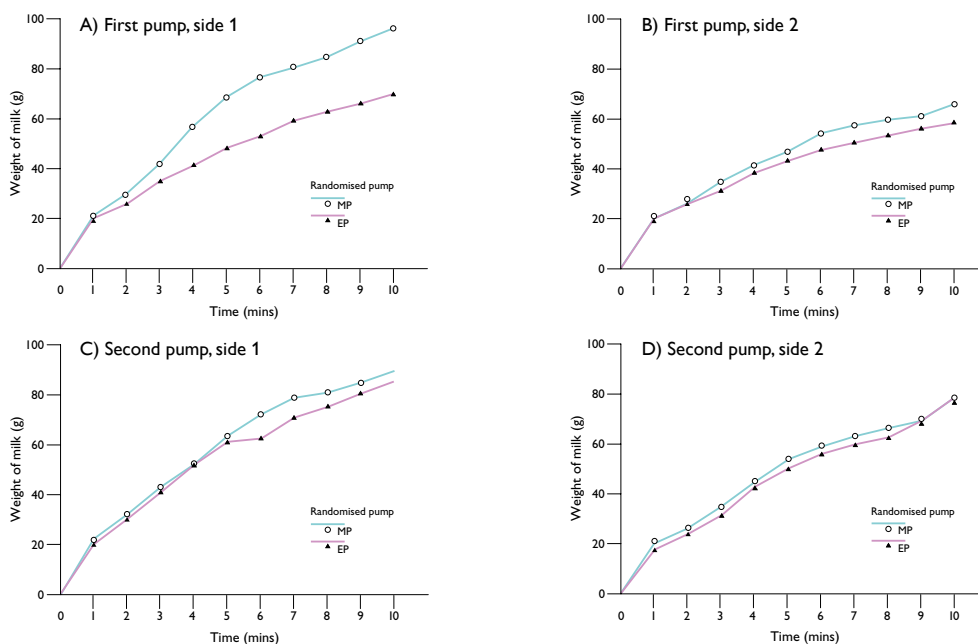
Method

Sixty breastfeeding mothers (Full-term births) used both the MP (n=32) and the MEP (n=28) in randomised order at 8 weeks postpartum. Mothers were asked to pump from each breast for 10 minutes in the presence of two research staff and the following measurements were made:

- the total volume of milk produced per breast;
- weight of milk produced at each 1 minute period (examination of milk flow); and
- creatocrit (fat content) at 1 minute intervals.

Mothers were also asked to complete a questionnaire about each pump and maternal ratings on the pump characteristics such as ease of use, amount of suction, comfort, pleasant to use and overall opinion of pump were noted.

Figure 1:
Weight of milk expressed over a 10-minute period according to pump used



Results

- The total weight of milk produced over the 20 minute period was not significantly different in the MP (144 ± 64g) as compared to the MEP (146 ± 65g)
- There was no significant difference in the mean weight and fat content of milk produced throughout the study
- When analysing the pattern of milk production over each 10 minute period for the first pump and first breast the milk flow was significantly greater in mothers using the MP rather than the MEP (P = 0.008), however there was no significant difference in the second breast, or for either breast using the second pump. (Please refer to Figure 1)
- Mothers awarded significantly higher scores for the MP than the MEP in 3 out of 5 categories; 'comfort', 'pleasant to use' and 'overall opinion of the pump'. (Please refer to Table 1)
- Significantly more mothers choose to keep the MP (64%; n =37) as compared to the MEP (36%; n=21) [P= 0.049]. Two mothers did not keep either pump.

Parameter		1	2	3	4	5	6	7
		n (%)						
Ease of use	Manual	18 (30)	20 (33)	9 (15)	9 (15)	2 (5)		
	Mini-electric	23 (38)	16 (27)	9 (15)	11 (18)		1 (2)	
Amount of suction	Manual	19 (32)	1 (35)	11 (18)	6 (10)	1 (2)	1 (2)	
	Mini-electric	29 (48)	14 (23)	6 (10)	6 (10)	2 (3)	3 (5)	
Comfortable to use	Manual**	27 (45)	17 (28)	8 (13)	5 (8)	2 (3)		
	Mini-electric	3 (5)	9 (15)	9 (15)	27 (45)	7 (12)	4 (7)	1 (2)
Pleasant to use	Manual**	23 (38)	12 (20)	9 (15)	10 (17)	4 (7)	1 (2)	
	Mini-electric	2 (3)	10 (17)	9 (15)	20 (33)	14 (23)	2 (3)	3 (5)
Overall opinion	Manual*	19 (32)	22 (37)	12 (20)	5 (8)	1 (2)		
	Mini-electric	4 (7)	21 (35)	18 (30)	10 (17)	6 (10)	1 (2)	

Table 1: Questionnaire results. 1 = best score, 7 = worst score; *P=0.001, **P<0.001, Wilcoxon signed rank test for manual pump versus mini-electric pump

Conclusion

The authors concluded that despite the greater complexity and expense of the MEP, both pumps showed similar overall efficacy. However the MP was clearly preferred by mothers.

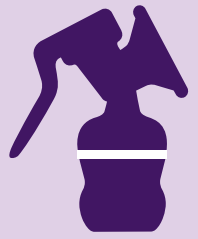


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Clinical Trial Summary

Randomized trial comparing the efficacy of a novel manual breast pump with a standard electric breast pump in mothers who delivered preterm infants



Authors:

Mary S Fewtrell, MD, FRCPCH, Penny Lucas, SRN, RSCN, Sharon Collier et al.
MRC Childhood Nutrition Research Centre, Institute of Child Health, London, England

Source:

Paediatrics : Paediatrics Vol 107 No 6 June 2001

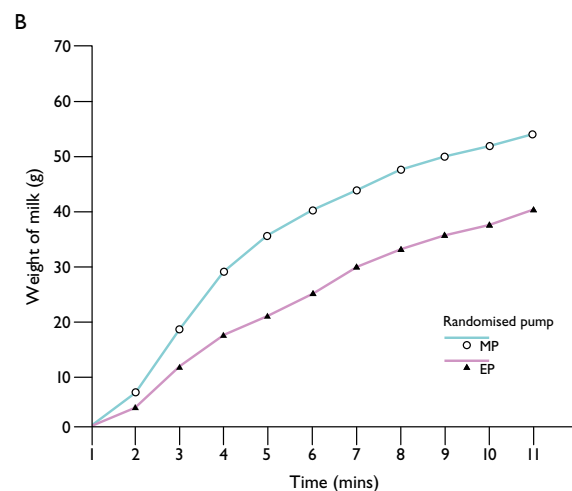
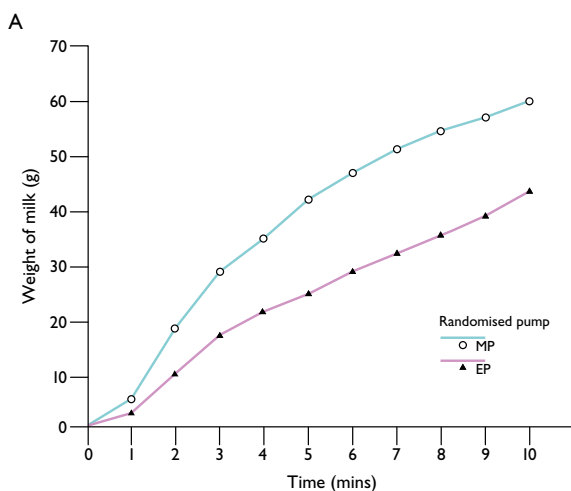
Study Objective

- To compare the efficacy of a standard hospital grade electrical pump used in 94% of UK neonatal units at the time (EP; Egnell Ameda Elite Pump) versus a novel manual pump (MP; Philips Avent Manual Pump).

Method

One hundred and forty five women who delivered infants of <35 weeks gestation were randomised to use either the MP (n=74) or EP (n=71). Mothers were asked to complete a form each time they expressed milk recording the amount of milk produced and time taken. Milk production was measured over a fixed 20 minute period of expression during the second week postpartum, and at 7- 10 days postpartum, mothers were asked to complete a questionnaire about their assigned pump. Research nurses collected information on the infants' progress each day. The primary outcome measurement was the total volume of milk expressed by the mother during the trial and the secondary outcome measures were:

- the volume of milk expressed in a set 20 minute period during the second week postpartum
- the time taken to express a designated volume of milk during the second week postpartum
- the creatatocrit (fat content) of milk expressed during the set period in the second week postpartum
- maternal ratings on the pump characteristics (ease of use, amount of suction, comfort, pleasant to use and overall opinion of pump).



Results

- The total milk production over the whole study period was similar in the two groups, although mothers who used the EP and double pumped showed shorter expression times than mothers that used the MP (single pumping)
- When mothers who were using the MP were compared with mothers who were using the EP and who double pumped exclusively, the calculated milk output per breast per minute for the whole study was higher in the MP group (3.1 ml/breast/min [SD = 2.5] vs 2.4 ml/breast/min [SD = 1.9]; P = 0.2), and the estimated time spent expressing per session if sequential rather than double pumping had been used was significantly lower in the MP group (20 minutes [SD = 6] vs 25 minutes [SD = 9]; P = 0.004)
- When compared on equal terms with both groups of mothers expressing milk sequentially over a fixed period of 20 minutes at a mean of 11 days (SD =2.5) postpartum, mothers using the MP showed a significantly greater milk flow and volume expressed, (112ml [SD =69] for MP versus 76 ml [SD =44] for EP), suggesting a quicker let-down. In addition, the volume of milk expressed was higher at each measurement time point for mothers using the MP than the EP. (Please refer to Figure 1)
- Creatocrit was unaffected by pump type
- Similar proportions of mothers from each pump group developed sore nipples (7% both groups) or engorgement (4% MP vs 6% EP). Similar numbers of infants from each group developed necrotizing enterocolitis (4 MP vs 5 EP)
- Results from the consumer questionnaire showed that the MP significantly outperformed the EP in all 5 categories; 'ease of use', 'amount of suction', 'comfort' and 'pleasant to use' and 'overall opinion'. (Please refer to Table 1).

Parameter		Score					P (χ ²)
		1	2	3	4	5	
Ease of use	MP	43	41	9	7	0	0.03
	EP	33	27	25	10	6	
Amount of suction	MP	26	47	14	10	4	0.05
	EP	29	24	25	16	10	
Comfort	MP	29	43	9	17	1	0.003
	EP	12	25	29	25	7	
Pleasant to use	MP	24	35	17	21	3	0.01
	EP	6	20	27	37	10	
Overall opinion	MP	26	47	19	5	3	0.003
	EP	12	22	41	18	6	

Table 1: Results of Breast Pump Questionnaire: Numbers are the percentages of mothers in each pump group awarding each score. For each parameter, 1 is the most favourable and 7 is the least favourable score. (MP, n=58; EP, n=49)

Conclusion

The authors concluded that, despite its significantly lower cost, the Philips Avent manual pump showed similar efficacy to the EP in everyday clinical practice. Furthermore, when compared on equal terms (sequential pumping), mothers who were using the Philips Avent pump showed greater milk flow and produced more milk in a fixed time period, perhaps reflecting a more physiologic pump design.

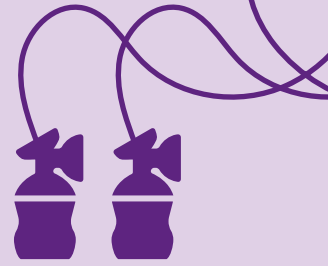


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Clinical Trial
Summary

Randomized trial comparing the effectiveness of two electric breast pumps in the NICU



Authors:

Summary of Burton P, Kennedy K, Ahluwalia JS, Nicoll R, Lucas A, Fewtrell MS.

Source:

Randomized trial comparing the effectiveness of 2 electric breast pumps in the NICU. *J Hum Lact.* 2013; 29(3):412-9. doi: 10.1177/0890334413490995

Key study take-aways

- All preterm infants should receive human milk¹, and this may have to be expressed milk. Every effort must be made to optimize breast pump designs so as to maximize the amount of expressed milk and the efficiency of the process.
- This study concluded that the breast pumps in question performed equally in terms of effectiveness of milk expression and maternal opinions; however, pump design may have an impact on the proportion of infants breastfeeding at time of NICU discharge.

Background and study rationale

It is well known that preterm infants need human milk² to thrive but many are too weak to breastfeed, leading to a reliance on expressed milk. As most neonatal intensive care units (NICU) recommend the use of a double electric breast pump, this randomized, controlled trial was conducted to compare the effectiveness of the Medela Symphony Pump (Pump S) versus the novel Philips Avent twin electronic breast pump (Pump A) in the NICU.

Methods

The study was conducted in two UK NICUs, where Pump S was the default pump. The study had ethics approval from the UCL Institute of Child Health ethics committee, and was registered at www.ClinicalTrials.gov (NCT00887991). Inclusion criteria: babies born <34 weeks gestational age and <72 hours old at randomization, expected to stay in the NICU for at least 10 days and with mothers planning to express milk.

During the 10 day study period, 36 mothers were randomized to use Pump A and 35 to use Pump S. They recorded various variables such as weight of expressed milk, and start and end time of milk expression. On Day 10, mothers completed a perception questionnaire on pump parameters. A physiological test was also performed during a single 15-minute breastfeeding session between Days 3-10, with the milk weighed at 1-minute intervals.

Results

Primary outcomes

Initial 10 day study period:

- No significant difference between randomized groups in total weight of expressed milk.

Physiological test

- Total weight of expressed milk was significantly greater and time taken to produce specific volumes was significantly less for mothers using Pump S.
- Non-significant trend for target weights to be reached more quickly by mothers using Pump S, with a significant difference for the first appearance of milk and for 5 g of milk.

Secondary outcomes

Initial 10 day study period:

- No significant difference between randomized groups in total number of pumping sessions, time spent expressing or efficiency of expressing.
- Pump A received significantly better scores than Pump S for “location of control button” and “ease of use”.

Analyses beyond 10 day study period

- No significant difference between groups in the total volume of milk expressed in the NICU, volume of milk expressed and fed to infant, time taken for infants to reach full enteral feeds, or the median volume of milk expressed per day.
- Significant association between pump and whether or not mothers were breastfeeding their infant(s) at the time of NICU discharge (21/29 of group A mothers versus 8/21 group S mothers).

Conclusions

The proportion of infants in this study receiving breast milk at discharge and the volumes received during the hospital stay were not significantly different between the pump groups in the initial 10-day study period or until discharge from the NICU (although pump S performed better during the physiological test). However, mothers randomized to the Philips Avent pump were significantly more likely to be directly breastfeeding their infant (although the relatively small sample size did limit confidence in the size of the effect). Even though the reasons for this are unclear, the finding of a greater likelihood of breastfeeding at NICU discharge is an important outcome that requires further study.

References: 1. Breastfeeding. Policy statement: breastfeeding and the use of human milk. *Pediatrics* 2012;129(3):e827-e84. 2. Agostoni C, Buoncore G, Carnielli VP, et al. Enteral nutrient supply for preterm infants: commentary from the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition Committee on Nutrition. *J Pediatr Gastroenterol Nutr* 2010;50(1):85-91.

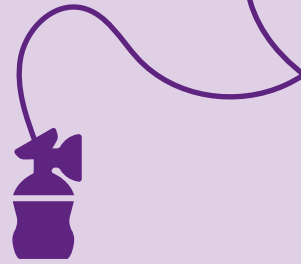


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Clinical Trial
Summary

Randomised, multicentre trial of two single electric breast pumps in full-term mothers: effect on expressed milk weight and maternal satisfaction at 6 weeks post-partum



Principal investigators:

Professor Mary Fewtrell, Ms Kathy Kennedy, Professor Alan Lucas
Childhood Nutrition Research Centre, University College London Institute of Child Health, UK

Source:

Randomised trial comparing the efficacy and acceptability of the Philips Avent Comfort single electric breast pump and the Medela Swing single electric breast pump in mothers exclusively breastfeeding their healthy term infant: analysis of primary outcomes, March 2016

Introduction

This was a randomised multicentre study, performed in four worldwide locations: China, Russia, UK, USA. It provides rare physiological data on milk expression patterns around the globe and the effectiveness of the Philips Avent Comfort single electric breast pump in a broad population with varying physiologies. Reported here are the results relating to women's use of breast pumps with respect to volume of milk expressed and level of comfort experienced.

Key study findings

- The Philips Avent Comfort single electric breast pump extracts as much milk as the Medela Swing single electric breast pump;
 - In less than 20 minutes, the pump enables a mother to express enough milk for a feed¹
- The Philips Avent Comfort single electric breast pump was found to be significantly more comfortable.
- It was judged significantly better on the expressing position (i.e. no lean forward) and on the feel of the breast pump insert.
- The study authors concluded that the Philips Avent Comfort single electric breast pump is an effective and significantly more comfortable breast pump than the Medela Swing single electric breast pump.

Objective

Investigate the influence of breast pump design on:

- the amount of milk expressed; and
- the mother's experience and comfort when using the breast pump.

Methods

One hundred and seventy mothers with full-term infants (<1 month) were recruited from Beijing, China (n=45), Moscow, Russia (n=51), London, UK (n=68) and New York, USA (n=6). Mothers were randomised to receive a single electric pump and bottle system from Philips Avent or from Medela.

At 6 weeks, mothers were asked to express milk for 10 minutes per breast. The weight of milk expressed every minute was recorded; this was converted to volume for the results shown here. Mothers were also asked to give their opinions of the pump they were assigned to use. A number of usage characteristics were recorded using visual analogue scales 10= best and 1=worst score).

Results

- Baseline characteristics, milk volume and pattern of milk production did not differ between the two pump groups
- The total milk expressed over 20 minutes was predicted by time since last feed (adjusted mean 0.58g more/minute $P=0.003$), parity (primips 128.7g, multips 173.9g, $P=0.001$) and study site (China 120.8g, UK 140.3g, Russia 192.8g, $P<0.001$)
- Figure 1 shows the cumulative results for milk volume expressed over 10 minutes for both the first and second breast
- The Philips Avent Comfort single electric pump scored significantly more favourably on pump comfort, ease of use, feel of the cushion, pleasant to use and non-necessity to lean forward (Figure 2)

Figure 1. Cumulative milk volume over 10 minutes according to pump (estimated means; differences were not statistically significant)

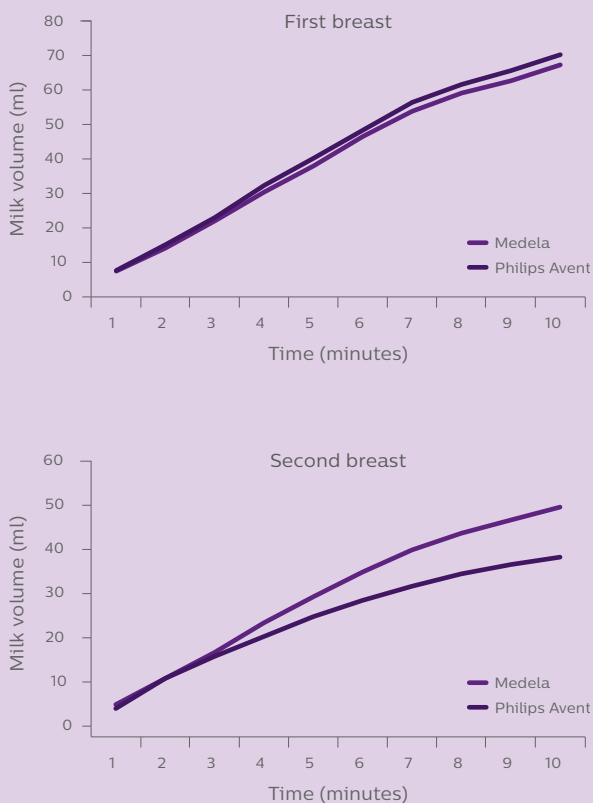
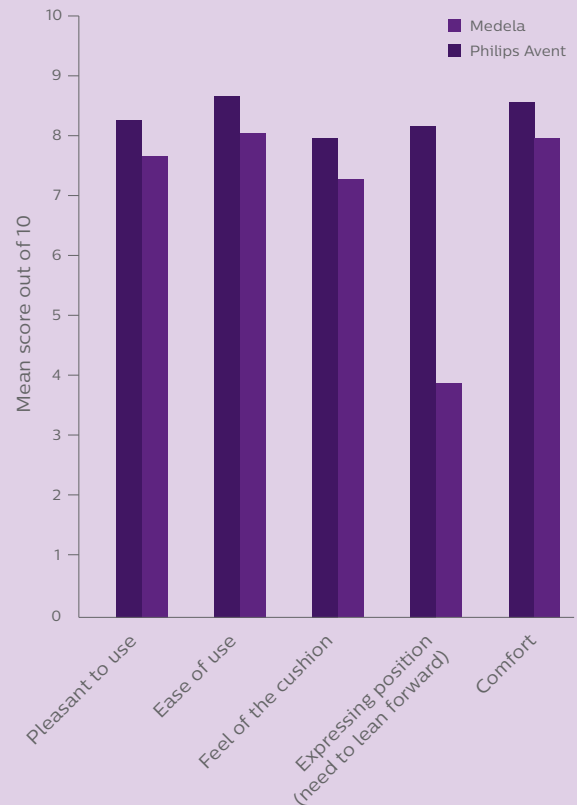


Figure 2. Mean scores for opinions on comfort of use for mothers randomised to use the different breast pumps (10=best, 1=worst score); all differences were statistically significant



Conclusions

Two modern single electric pumps were found to be equally as effective for milk expression at 6 weeks post-partum. The Philips Avent Comfort single electric breast pump was found to be significantly better on a number of comfort attributes. The possibility that greater maternal satisfaction with the Philips Avent Comfort single electric breast pump may translate into longer breastfeeding duration/breastmilk provision requires further investigation.

References: 1. John Hopkins Medicine. Feeding guide for the first year. Available at: http://www.hopkinsmedicine.org/healthlibrary/conditions/pediatrics/feeding_guide_for_the_first_year_90.P02209/; accessed July 2016;

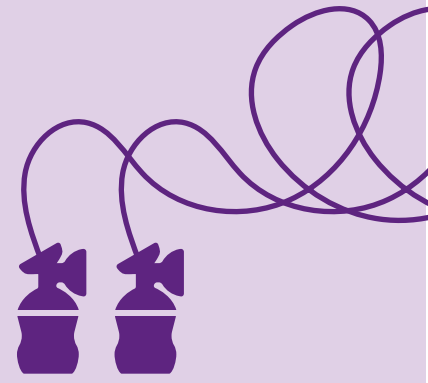


PHILIPS

AVENT

Clinical Trial
Summary

Predictors of expressed breast milk volume in mothers expressing milk for their preterm infant



Authors:

Mary Fewtrell, Kathy Kennedy, Alan Lucas and Patricia Burton

Childhood Nutrition Research Centre, UCL Institute of Child Health, London, UK

Jag Ahluwalia

Neonatal Intensive Care Unit, Addenbrookes Hospital, Cambridge, UK

Richard Nicholl

Neonatal Intensive Care Unit, Northwick Park Hospital, Harrow, UK

Source:

Archives of Disease in Childhood – Fetal and Neonatal Edition 2016;0:F1–F5

Key study findings

- In a randomised controlled trial of electric breast pumps, conducted in UK neonatal intensive care units (NICUs), multivariate analyses found that double pumping, early establishment of milk production, and perceived comfort of the breast pump were the strongest predictors of high milk volume production

Background

Breast milk is considered the optimum nutrition for pre-term infants.¹ Infants are, however, unable to effectively breastfeed prior to 34 weeks, thus mothers of pre-term infants are required to express milk for prolonged periods while often feeling stressed and being separated from their infant.

Objective

To investigate predictive factors of high expressed milk volumes by women with pre-term infants in the NICU setting.

Method

- Data were collected retrospectively, during a randomised controlled trial comparing two electric breast pumps in the NICU setting, to investigate factors predictive of the volume of breast milk expressed
- The study was conducted in two UK NICUs among women who had delivered before 34 weeks' gestation and were expected to stay in the NICU for ≥ 10 days
- Within 72 hours of giving birth, women were randomised to use one of two electric breast pumps for 10 days and to keep a diary of their experiences. Many women continued with diary entries for the duration of their infant's stay in the NICU
- Participants were encouraged to express milk as often as they would for a full-term infant (minimum of six to eight times per day, and once at night)
 - At hospital A, participants used the electric breast pump immediately after birth, and double pumping was encouraged \
 - At hospital B, participants used manual expression for 48 hours before switching to the electric pump, and single pumping was recommended

Results

- Sixty two women provided diaries for milk expression over the 10-day study period and 47 provided data up until their infant left hospital
- The type of breast pump used did not significantly impact on the volume of milk expressed, and therefore in this analysis data from the two study arms were combined
- The mean number of milk expressions per day was 3.6; 68% of women predominantly used single-pump expression and 32% predominantly used double-pump expression
- Univariate and multivariate analysis found double pumping and the number of episodes of skin contact / infant being put to breast were significant predictors of greater weight of milk over 10-days
- For women completing diaries up until infant discharge from the NICU (mean stay: 36 days), stepwise regression analysis of statistically significant variables in a univariate analysis found the following were significant predictors of milk production:
 - Double vs single pumping
 - Reaching a volume of milk expression of 500 mL/day by day 10
 - Higher score for comfort of breast pump on day 10
- These results are displayed in Figure 1.

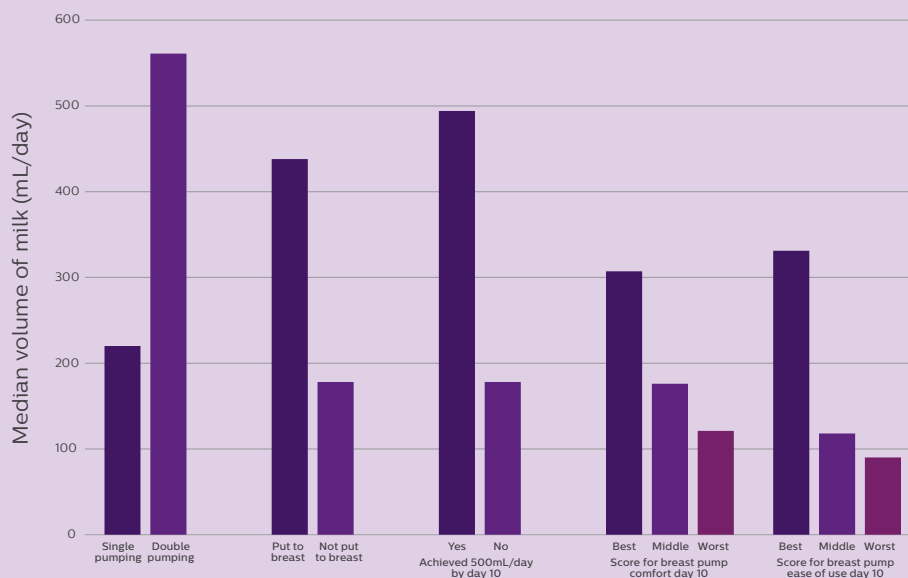


Figure 1. Predictors of the amount of milk expressed for the duration of the infants' stay in the NICU

Conclusions

Women's comfort while expressing milk and their method of expressing significantly impacts on the volume of milk expressed. For successful milk expression in the NICU setting and, ultimately, to encourage the continuation of breastfeeding, it is important for women to use a breast pump that they find comfortable. The study also found that double pumping can produce twice as much milk per day on average compared with single pumping.

References: 1. Agostoni C, et al. Enteral nutrient supply for preterm infants: commentary from the European Society of Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition. *J Pediatr Gastroenterol Nutr* 2010;50:85–91



PHILIPS

AVENT

Clinical Trial
Summary

Barriers to breastfeeding - a global survey on why women start and stop breastfeeding



Authors:

Marko de Jager and Katy Herley

Philips Avent, Amsterdam, Netherlands

Juliette Terrazas and Julia Merrill

One VOICE Measurement, New York, USA

Source:

European Obstetrics and Gynaecology Supplement 2012;7(Suppl. 1):25–30

Key study findings

- Overall, 94% of women surveyed (N=3,994) stated that they wished to breastfeed; 88% went on to breastfeed, but only 59% of women were still breastfeeding their infant at 6 months of age
- The main reasons given for ceasing breastfeeding were: perceived insufficient milk supply, infant no longer wanting to nurse, pain, time needed to breastfeed/pump, returning to work and awkwardness about breastfeeding outside of the home

Background

Although many countries support the World Health Organization's recommendation for women to exclusively breastfeed their infant for the first 6 months,¹ studies show that many women never start, or fail to continue to breastfeed for 6 months.²⁻⁴

Objective

To investigate women's attitudes towards breastfeeding and their perceptions of the breastfeeding experiences in order to identify common themes that could help women to breastfeed for longer.

Method

- This survey was part of a larger worldwide survey commissioned by the Philips Center for Health and Well-being and Philips Avent⁵
- The survey was conducted in 2011 in seven countries: USA, Brazil, UK, Egypt, South Africa, China and India
- Survey participants comprised of women aged 18–40 years, who were either pregnant with their first child, or who had one or more children under the age of 5; they were asked to answer questions either with regard to their youngest child, or their intentions if pregnant with their first child
- Participants completed structured questionnaires either by phone interviews, in person (India) or online (UK)

Results

- 3,994 women took part in this survey (volunteer demographics shown in Table 1)
- Overall, 94% of women stated that they wished to start breastfeeding; this ranged from 100% in India to 63% in the UK
- Reasons given for wishing to breastfeed were: it is healthier for the infant (63%), the most natural thing to do (16%) and safer than formula milk (10%)
- 12% of women did not start to breastfeed and a further 29% stopped before 6 months; overall 41% were no longer breastfeeding after 6 months (Figure 1)
- The reasons women gave for not continuing to breastfeed are shown in Figure 2; perceived decrease in milk supply was the most common reason stated by women in five out of the seven countries surveyed (overall 40%; range 9–70%)
- 60% of women stated that they had inadequate support to initiate breastfeeding (range 45–78%)

Country	N	Mean age, years	Socioeconomic class	Working, %	Married, %	College education, %
US	401	28.7	General population	55	86	33
UK	789	31.8	General population	55	62	26
China	403	29.0	Middle-higher income in major urban areas	69	100	51
Brazil	400	29.6	Middle-higher income in major urban areas	67	74	16
India	1,501	25.0	Upper middle-high income in urban areas	7	100	20
Egypt	250	28.7	General population	17	100	9
South Africa	250	28.7	Middle-higher income	32	32	12
All	3,994	28.8		43	79	24

Table 1. Demographics of survey participants

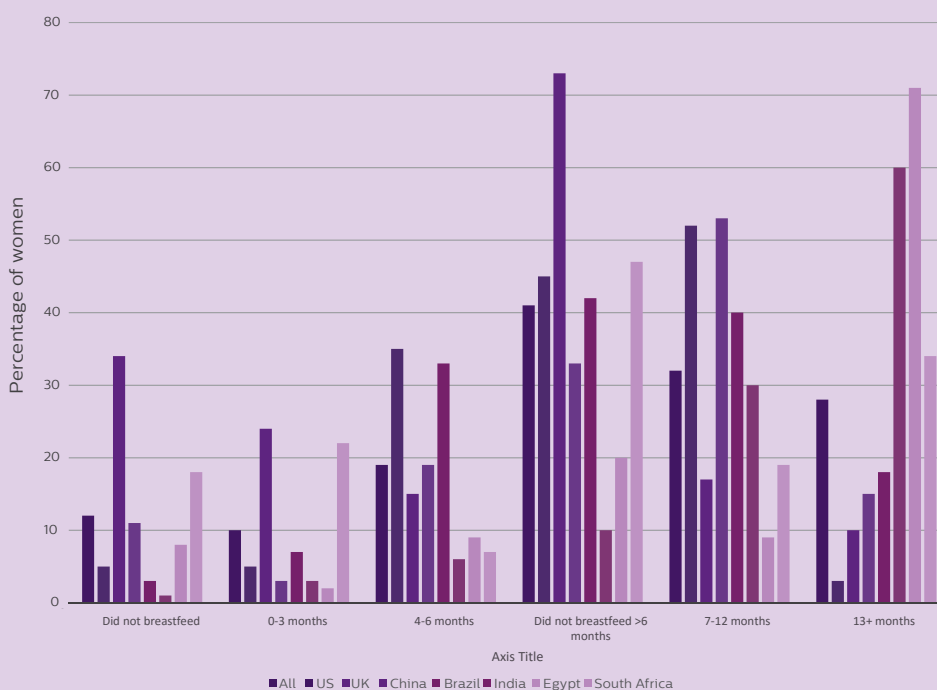


Figure 1. Duration of breastfeeding in women surveyed (N=3,994); overall and by individual countries



PHILIPS

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Clinical Trial
Summary

The 'Niplette™': an instrument for the non-surgical correction of inverted nipples



Author:

Mr D McGeorge FRCS(Plast)

Department of Plastic and Reconstructive Surgery, Queen Mary's University Hospital, Roehampton, London

Source:

British Journal of Plastic Surgery (1994) Vol 47, Pages 46–49

Background

Inverted or non-protractile nipples are a common problem affecting up to 10% of the female population. This can cause psychological distress and interfere with a woman's ability to breastfeed. The anatomical fault lies with a short lactiferous duct which tethers the nipple and prevents it from projecting out. The mainstay of treatment has been breast surgery, where the lactiferous ducts are sectioned out. However this destroys the breast tissue/function and thus prevents breastfeeding.

Objective

To assess the efficacy of a new instrument, the 'Niplette™', as a non-surgical correction device for inverted nipples.

Product information

The 'Niplette™' uses suction to stretch the lactiferous ducts gently in a manner analogous to tissue expansion. It is a simple washable device which incorporates a transparent nipple mould with a sealing flange attached to a valve and a syringe port. (Please refer to Figure 1).

The mould is held over the nipple areola and air is withdrawn using a 5 ml syringe so that the nipple can be sucked into it. The pull is controlled by the patient and they are instructed to pull on the nipple as firmly as comfortable. Initial usage is encouraged as much as possible (day and night). Once the nipple has pulled out to fill the mould, usage is then reduced at a rate dependent upon any tendency to retract.

Method

Twenty two female patients who were considered for surgical treatment (duct divisions) for their inverted nipples were fitted with the 'Niplette™'. Sixteen of these patients were referred from the Roehampton Plastic Surgery Centre and aged between 19–44 yrs (mean 30 years). Two of these patients had failed surgical corrections carried out previously. Another 6 patients were referred from ante-natal clinics because of their nipple inversion and wished to breast feed (they did not want surgical interventions).

Outpatient review occurred monthly until complete sustained nipple correction occurred and then follow-up occurred by telephone to confirm maintenance of the correction.

Results

- All patients found the 'Niplette™' easy to apply and use
- The length of time worn differed between each patient according to their lifestyle; no accurate records were kept
- All patients were able to expose their nipples from the inverted position immediately
- 18 out of 22 patients were able to pull their nipples to fill the mould in first follow-up appointment. The rate was dependent on the degree of deformity and the amount of usage. At best the nipple filled the mould within 2 days
- Four patients were able to stop using the 'Niplette™' by 2 months and 13 patients by 3 months (Please refer to Figure 2)
- 2 patients had a slight bleeding from their nipples (one patient pulled their nipples too hard as they were deeply inverted and the other patient fitted the device during late pregnancy). For both patients this was no more than just a nuisance.



Figure 1: The 'Niplette™' – for the non-surgical correction of inverted nipples

Figure 2: A) Patient pre-treatment with deeply inverted nipple

Figure 2: B) Sustained correction after using the 'Niplette™' for 2 weeks (no further use was required)

Conclusion

This study concluded that the 'Niplette™' effectively corrected inverted nipples in all cases (even in those patients with deeply inverted nipples) without the need for invasive surgery. As a result underlying breast anatomy was unaffected and mothers could continue to breastfeed without any problems.

Pilot study: Tactile stimulation of the nipple by a novel breast shield results in more efficient milk expression



Principal investigators:

Lucja Segaar MSc; Lili-Marjan Boelens-Brockhuis, MSc; Daan Gosenshuis, MSc

Submitted for publication

Introduction

To establish and maintain milk production it is important that the lactating breast is both stimulated and emptied sufficiently. The milk ejection reflex (MER) is a vital mechanism in the lactation process and it is triggered by tactile stimulation of the nipple-areola complex of the mother's breast. The MER occurs much faster due to nipple stimulation by the baby during breastfeeding compared to stimulation patterns of conventional breast pumps during milk expression. Without MER, no significant amount of milk can be removed from the breast and even when using a strong vacuum pump only a small amount of milk can be expressed. Conventional breast pumps use vacuum at a certain frequency (usually around 2 Hz) as stimulation for milk ejection reflex, but the principle of tactile stimulus is not included. There has been some efforts to investigate the effect of a compression or tactile component in a breast pump design. However, these studies mainly focus on compression implemented as a mechanical component rather than a sensory stimulus of the tactile receptors.

Key study findings

- There was a significant reduction of 1m39s ($p < 0.05$) in time to first milk ejection reflex when using the novel breast shield. (Figure 2)
- The novel breast shield significantly reduced expression time by 3m39s ($p < 0.05$) minutes compared to the conventional breast shield, with the same amount of milk expressed.
- Significantly more milk was expressed in the first 5 minutes after the start of expression using the novel breast shield. (Figure 1)

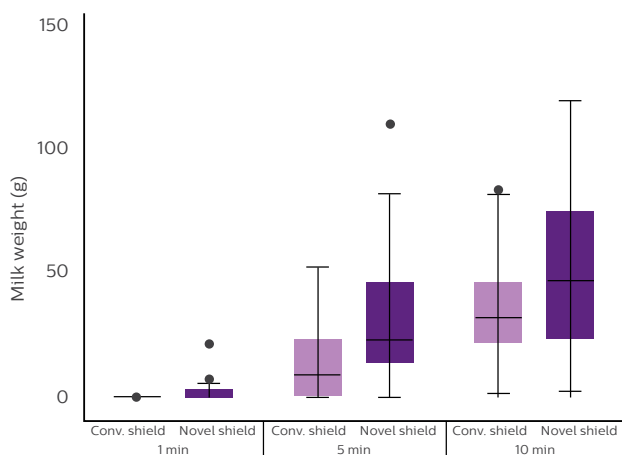


Figure 1. Box plot of milk weight extracted from the right breast at 1, 5 & 10 minutes after start of expression, comparing the novel breast shield (dark purple) to the conventional breast shield (light purple).

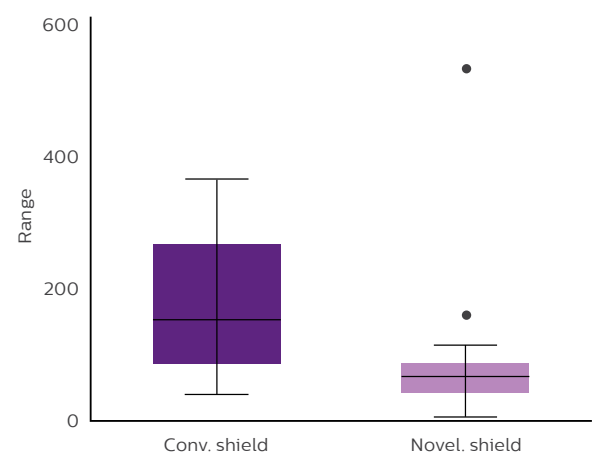


Figure 2. Boxplot of time to MER for the right breast. The variation in time to MER is much smaller for the novel breast shield.

Objective

We aimed to investigate the concept of tactile stimulation, implemented in a novel breast shield designed to mimic the baby, by including active touch of the nipple-areola complex during milk expression

Methods

During 6 milk expression sessions of 8 lactating women we collected data on milk weight, comparing the novel breast shield to a conventional breast shield. Milk flow data was calculated from the milk weight measurements. The main outcome parameters were milk weight, expression time and time to MER. Questionnaires were used to capture perception of breast pump performance.

During each milk expression session a milk collection bottle was placed on an electronic balance (Sartorius BP 410) and a tube was attached between the breast pump body and the milk collection bottle. A schematic of the set-up is shown in Figure 3, the resulting measurement in Figure 4.

For the left breast, a milk collection bottle was attached to the breast shield as during regular use of the breast pump. After each expression session participants were asked to fill out a questionnaire to determine satisfaction on several aspects of the breast pump, including comfort and effectiveness.

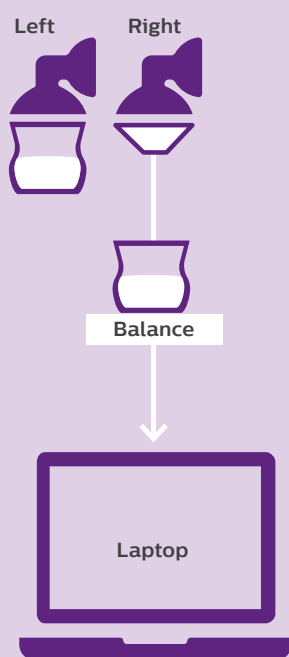


Figure 3. Schematic of the set-up during the milk expression settings. The weight of the milk of the right breast was continuously measured using an electronic balance.

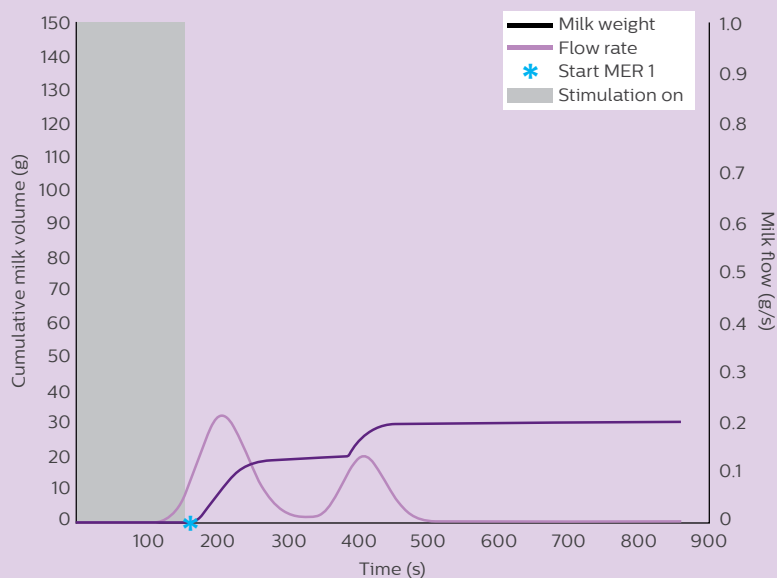


Figure 4. Example of measured milk weight (dark purple) and calculated milk flow (light purple) during an expression session. The grey area on the left is an indication of the time spend in stimulation mode (as annotated by the participant). The blue star (*) indicates when the start of the first milk ejection is detected by the software program

Conclusion

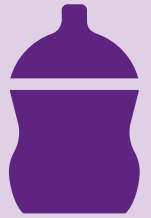
This study shows that the novel breast shield with an active touch of the nipple-areola complex designed to mimic natural sucking behavior of a baby, results in more efficient milk expression. Although milk volume at the end was the same with both breast shields, the expression time was significantly shorter with the novel breast shield. The time to the first milk ejection reduced significantly and the amount of milk in the first 5 minutes was significantly higher with the novel breast shield. The measured time to first MER in this study with the novel breast shield is in the same range as the time to first MER during breastfeeding as reported in literature. This result shows that imitating infants sucking behaviour with active touch in the novel breast shield is close to the natural nipple stimulation of the baby.

PHILIPS

AVENT

Clinical Trial
Summary

A randomised prospective observational study comparing colic, crying, fussing and feeding in a conventional vacuum bottle (CV) versus an Philips Avent non-vacuum bottle (ANV)



Authors:

Professor Alan Lucas MB, BChir, MA, MD, FRCP

MRC Clinical Research Professor, Childhood Nutrition Research Centre, Institute of Child Health, London, England

Ian St James-Roberts, PhD

Senior Lecturer in Child Development, London University Institute of Education, London, England

Source:

Presentation at the 105th Ross Conference on Paediatric Research, Florida, November 1994

Note: This study also explored three areas related to feeding in the context of colic such as; breastfeeding versus bottle feeding and the design of the feeding bottle on growth rates during the early weeks of life. However, this summary focuses only on the findings related to feeding bottle design.

Background

Roberts et al 2004¹ discussed that excessive crying in the first few months of a babies life can be alarming for both physicians and parents. Colic typically begins at 2 weeks of age and usually resolves by four months of age. During this time infants cry an average of 2.2 hours per day, peaking at 6 weeks of age and then gradually decreasing thereafter.

This study showed that at 2 weeks the prevalence of crying for > 3hrs per day was 43% amongst formula fed infants as compared to breast fed infants (16%). However, at 6 weeks of age the prevalence was 12% amongst formula fed infants and 31% amongst breast fed infants.

Objective

To test the hypothesis that feeding bottle design could influence colic or crying.

Method

One hundred and forty five healthy, full term infants (78 males, 67 females) were studied at 2 and 6 weeks of age. Mothers kept 3 day diaries at 2 and 6 weeks. Each diary was divided into four 6 hour periods and within each time of day mothers shaded in 5 min periods coded for sleeping, feeding, awake and content, fussing (baby unsettled, irritable and /or vocalizing but not continuously crying), crying and colic.

Results

- At 2 weeks infants fed with ANV bottles spent significantly more time awake and content especially at night and in the morning as compared to CV bottles. [265 [SE, 20] minutes versus 220 [SE, 13] minutes respectively $P < 0.05$]. (See Figure 1)
- At 2 weeks, less colic was recorded with the ANV bottles and the duration of colic was closer to that of breast feeding. (See Figure 2)
- For all infants (with or without colic) the mean colic duration was 13 (4) minutes with ANV bottle as compared to 22 (7) minutes on the CV bottle (a difference of 9 minutes). For those infants with colic the mean colic duration was 31 (8) minutes with ANV bottle as compared to 52 (15) minutes on the CV bottle (a difference of 21 minutes).
- However, at 6 weeks there was no difference seen in terms of colic between the two bottle types.

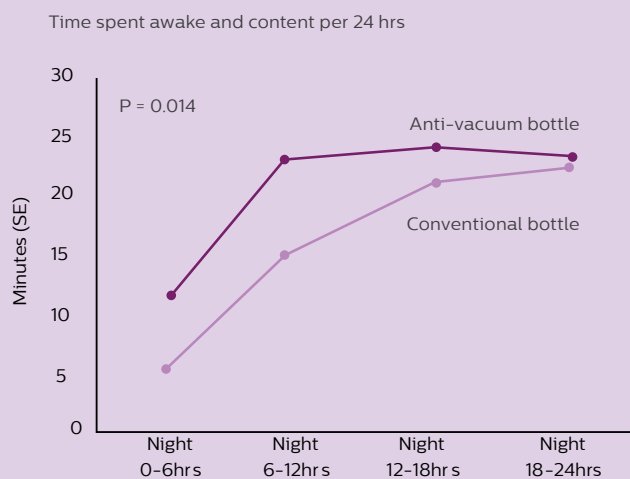


Figure 1: Comparison of ANV and CV bottles at 2 weeks – time spent awake and content

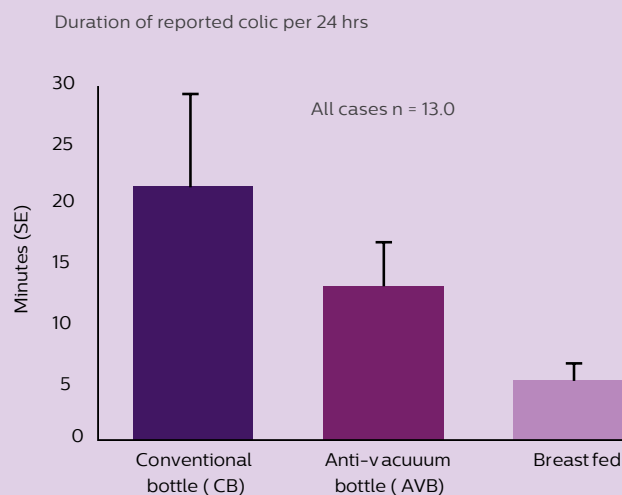


Figure 2: Comparison of ANV and CV bottles at 2 weeks – duration of colic

Conclusion

The study showed that 2 weeks of age (an important time for colic and crying) bottle design can influence the behavioural outcomes for infants.



PHILIPS

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Clinical Trial
Summary

Infant feeding bottle design, growth and behaviour: results from a randomised trial



Authors:

Professor Mary Fewtrell, Ms Kathy Kennedy, Dr Richard Nicholl, Dr Abbas Khakoo and Professor Alan Lucas
Childhood Nutrition Research Centre, University College London Institute of Child Health, UK

Source:

BMC Research Notes 2012;5:150

Introduction

Philips Avent has been conducting clinical studies on colic and infant feeding for over 20 years, developing its first anticolic bottle design in 1985. In this study, the Philips Avent one-way air valve bottle, which allows air to flow into the bottle to replace milk as the infant sucks, was compared in a randomised trial with the Dr Brown's internal venting system bottle, which allows air to flow continuously into the bottle when it is inverted.

Key study findings

- In infants of 2 weeks of age, the Philips Avent one-way air valve bottle was associated with significantly less infant fussing, a symptom associated with colic by many mothers,¹ compared with the Dr Brown's internal venting system bottle
- Significantly less fussing was reported for infants, in both the day and night, with the Philips Avent one-way air valve bottle, but the difference was greater at night

Background

Colic is defined as a persistent, unexplained crying in a healthy baby between 2 weeks and 5 months of age,² although many symptoms are associated with colic by mothers and healthcare professionals.³ In a survey of 400 mothers (UK/USA), who were bottle feeding their babies, colic was typically described as intense inconsolable crying (72–75%) or fussing (49–76%), often accompanied by a pained facial expression and tense body.¹ These mothers associated gas with colic and ~40% attributed colic to the baby swallowing air during a feed.

Objective

To explore in a randomised controlled trial whether the design of an anti-vacuum infant feeding bottle influences infant behaviour.

Methods

Sixty three healthy, exclusively formula-fed term infants were randomised to either use the Philips Avent one-way air valve bottle (n=31) or the Dr Brown's internal venting system bottle (n=32). Infant behaviour was measured at 2 weeks, validated by a 3-day diary.

Results

- At 4 weeks, data were available for 29 infants randomised to the Philips Avent one-way air valve bottle and 25 infants randomised to the Dr Brown's internal venting system bottle
- No mothers reported their infants as experiencing colic during this study and the Philips Avent one-way air valve bottle was associated with a mean of 0 minutes crying compared with an average of 1 minute for the Dr Brown's internal venting system bottle
- Infants randomised to use the Philips Avent one-way air valve bottle reported significantly less fussing than those randomised to the Dr Brown's internal venting system bottle (mean 40 versus 85 minutes/day, $p < 0.05$) (Figure 1)
- When analysed separately for the periods 'day' (6 am to 6 pm) and 'night' (6 pm to 6 am), reduced fussing was reported in Philips Avent one-way air valve bottle infants during both periods, although the difference was greater at night (day: 25 vs 39 minutes, $p = 0.2$; night: 13 vs 33 minutes, $p < 0.05$)

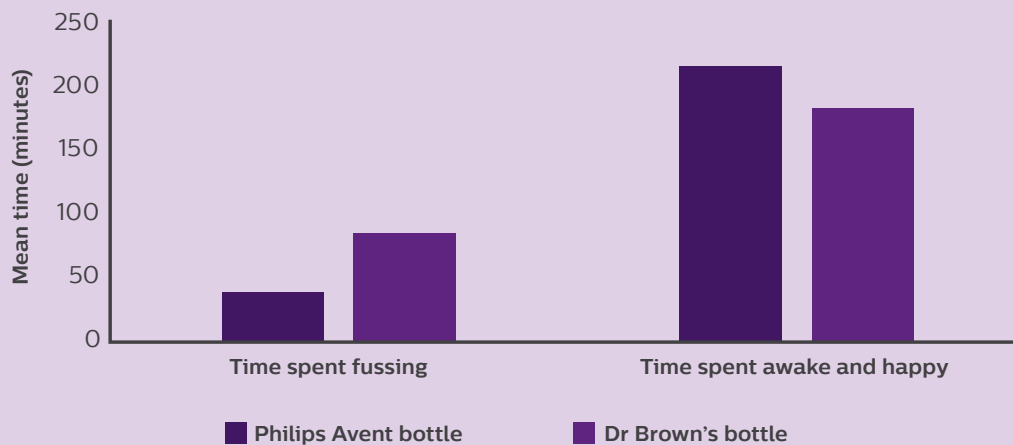


Figure 1: Mean time spent fussing and awake and happy for infants randomised to the Philips Avent one-way air valve bottle and the Dr Brown's internal venting system bottle

Conclusions

Bottle design may have short-term effects on infant behaviour which merit further investigation. These results support previously reported studies showing the beneficial effect on infant behaviour associated with the Philips Avent one-way air valve bottle vs the Dr Brown's internal venting system bottle⁴. It also supports studies showing that a vented bottle design was associated with significantly more time awake and content and a trend toward less recorded colic compared with a conventional bottle design.³

References:

1. Philips Avent data on file: Colic Exploration UK/USA Results: February 2016
2. <http://medical-dictionary.thefreedictionary.com/colic>
3. Lucas A, James-Roberts I: Crying, fussing and colic behaviour in breast and bottle-fed infants. *Early Hum Dev* 1998, 53(1):9-18.
4. Fewtrell M, Kennedy K, Lucas A. Impact of feeding bottle design on infant growth and behaviour. *Arch Dis Child* 2008;93:pw51



PHILIPS

AVENT

Clinical Trial
Summary

Data-driven innovation: tracker-based personal advice to support the baby's healthy development in a novel parenting app



Principal investigators:

Renée A. Otte¹, PhD, MA; Alice J. E. van Beukering², MSc; Lili-Marjan Boelens-Brockhuis¹, MSc

¹ Philips Research, Family Care Solutions (FCS)

² Philips Consumer Lifestyle, Mother and Childcare (M&CC)

Submitted for publication

Introduction

The current generation of millennial parents make use of apps on a daily basis to find information about child-rearing topics. Given this, an increasing amount of parenting apps have become available. These apps allow parents to track the baby's development with increasing completeness and precision. The often large amounts of data collected in this process provide ample opportunities for data-driven innovation (DDI). Subsequently, apps are increasingly personalized by offering information based on the data tracked in the app. In line with this, Philips Avent has developed the uGrow app, a medical grade app dedicated to new parents for tracking their baby's development. Via so-called insights the uGrow app seeks to provide a data-driven solution by offering parents personal advice based on user-tracked behavioural and contextual data.

Key study take-aways

- Quality of insights can be guaranteed by ensuring insights are relevant, appropriate, and evidence-based.
- Health-care professionals thought the concept of insights a supportive tool for parents for understanding and being reassured about their baby's development.
- Parents experienced the insights in the uGrow app as useful and reassuring, and as adding enjoyment.
- By increasing parents' sensitivity and knowledge, and reducing distress insights may contribute to a healthier parent-infant relationship.

Objective

The goal of this study was twofold. Firstly, it aimed to give a description of the development process of the insights for the uGrow app. Secondly, it examined parents' experiences with the insights and explored whether insights could contribute to a baby's healthy development.

Methods

The study consisted of three phases: a formative, development and summative phase. In the formative phase three sub-studies were executed in series to understand and identify parents' and health-care professionals' (HCPs) needs for insights, using qualitative and quantitative methods. After completion of the formative phase, insights were created during the development phase. Subsequently, in the summative phase these insights were validated on parents' experience using a quantitative approach.

Results

As part of the formative phase, parents indicated a need for smart information based on data analysis of the data they track in an app. HCPs supported the general concept of insights for the uGrow app, although specific types of insights were considered irrelevant or even risky. On implementing a preliminary set of insights in uGrow, the majority of parents (87%) were satisfied with them. Based upon these outcomes, a total of 107 insights were implemented in the uGrow app. In the summative phase, the majority of the parents reported experiencing these insights as reassuring and useful (94%), adding enjoyment (85%), and motivating for continuing tracking for a longer period of time (77%).



Figure 1. Insights development process

Conclusion

Parents experienced the insights in the uGrow app as useful and reassuring, and adding enjoyment. The insights development process that was followed showed how quality of the insights can be guaranteed by ensuring insights are relevant, appropriate, and evidence-based. In this way, insights are an example of meaningful data-driven innovation. Furthermore, based upon the results it can be argued that insights contribute to a healthier parent-infant relationship.



PHILIPS

AVENT

Clinical Trial
Summary

Performance study of the Philips Avent Electric Breast Pump



Authors:

Dr. Pearl Vyas, MD, MBA. (Philips Avent, Medical Advisor)

Lili-Marjan Boelens-Brockhuis, MSc (Philips Research, Senior Scientist)

November 2019

Introduction

There is professional consensus that breast pumps are a useful technology in supporting new parents to provide their infant with breast milk. Combined with the added benefits of skin-to-skin contact, demand feeding patterns and allowing for organic hormone stimulation via suckling, it is regarded that an infant suckling directly at breast is the most effective and efficient at expressing the breast milk.

Much of the conventional breast pumps available on the market have primarily focused on utilizing vacuum, with varying profiles of frequency and intensity, as an effective method in removing milk from a lactating breast.

However, studies show that there is a possibility that the Milk Ejection Reflex (MER) in breastfeeding occurs much faster (between 50–60 seconds^{1,2}) due to stimulation by baby compared to the different stimulation patterns of a breast pump. This has prompted some investigation into the effect of a compression or tactile component in a breast pump design.^{3,4,5}

Notably, these studies mainly focus on compression implemented as a mechanical component rather than a sensory stimulus of the tactile receptors.

As the effective stimulation of the nipple-areola complex remains essential in the routines of women who wish to feed their infant's breast milk, either directly or through milk expression using a breast pump, Philips Avent has developed an expression kit that provides tactile stimulation directly upon the areola and nipple (collapsing funnel that compresses areola and nipple), known as the "natural motion technology". In addition, the adjoining electric motor unit has optimized vacuum profiles that better mimic the suckling pattern of an infant (particularly the transition time from NonNutritive Suckling (NNS) to] Nutritive Suckling (NS).

Key study take-aways

- Conventional breast pumps are focused primarily on utilizing vacuum, with varying profiles
- A faster time to MER may occur due to tactile stimulation directly upon areola and nipple, similar to infant suckling
- Philips Avent's novel technology uses a collapsing expression kit design, with 'Natural motion technology' to initiate milk ejection in as little as 46 seconds
- Direct tactile stimulation on the areola and nipple results in almost four times faster milk flow than the conventional breast pump technology

Objective

Philips Avent conducted a community-based clinical study with lactating mothers who are experienced with the use of breast pumps. The aim of the study was to measure the critical success factors MER during milk expression using the newest Philips Avent Breast Pump with a novel collapsing expression kit.

Methods

This performance study was a randomized crossover trial evaluating the performance of single and double electric breast pumps, with a novel collapsing expression kit, in healthy lactating mothers. Each expression session took place at a subject's home and was led by a lactation specialist. Each subject performed a total of four expression sessions, a single and double expression regimen twice, resulting in a total of 80 sessions. During each single expression session, the subjects

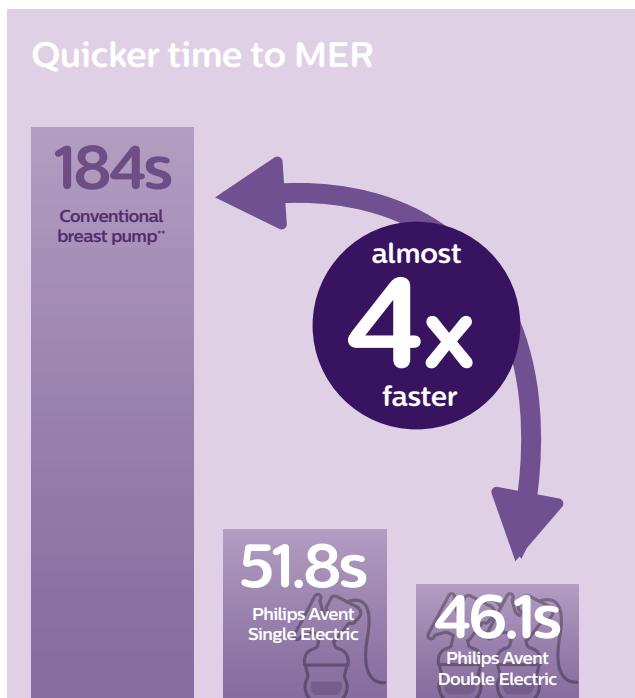


Figure 1 – Time to MER results

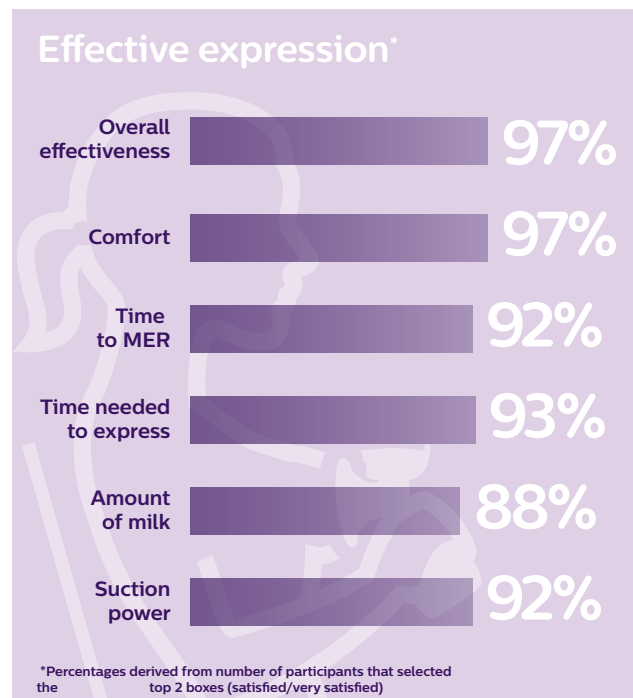


Figure 2 – Mothers feedback on overall effectiveness of the Philips Avent Electric Breast Pump

Pumped both breasts sequentially (right followed by left).

Data was collected in the form of objective measurements of the time to milk ejection reflex and milk volume, and questionnaires completed before and after expression sessions, to collect subjective opinion on the breast pump and overall session.

Results

Compared with the predecessor device a significant faster time to MER and a significant higher end milk volume is observed. With the use of the novel breast pump technology, it took on average 46.1 seconds for the MER to occur with the double pumping regimen and 51.8 seconds with the single pumping regimen.

Parental feedback showed an overall satisfaction with the effectiveness of the breast pump, in addition to other features (see graph)

Conclusion

By harnessing physiologic insights on tactile stimulation and infant suckling patterns, the new Philips Avent Electric Breast Pump is clinically proven to provide a comfortable and effective experience. With a faster milk ejection reflex, in as little as 46 seconds, mothers were able to elicit a quicker milk flow than the conventional breast pump available on the market.

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