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Clinical 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:

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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

145 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.

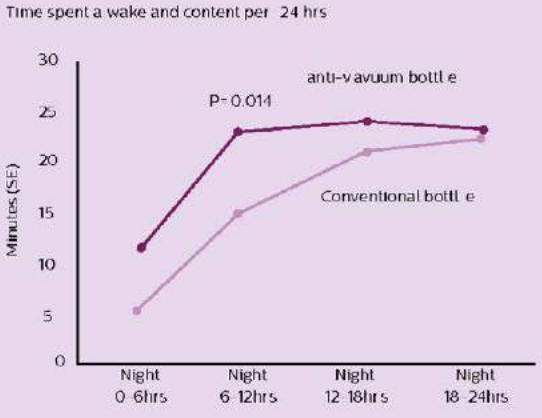

Figure 1
Comparison of ANV and CV bottles at 2 weeks – time spent awake and content

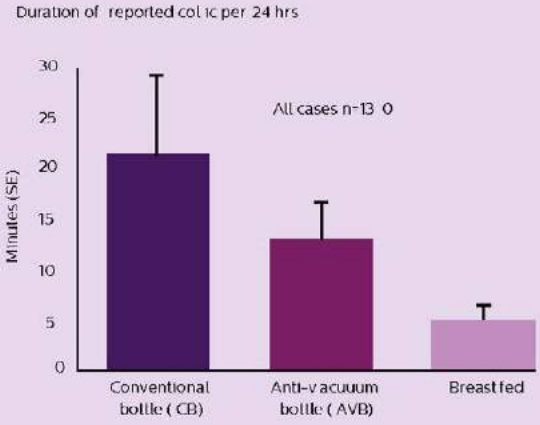

Figure 2
Comparison of ANV and CV bottles at 2 weeks – duration of colic

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.

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.

Study 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

22 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

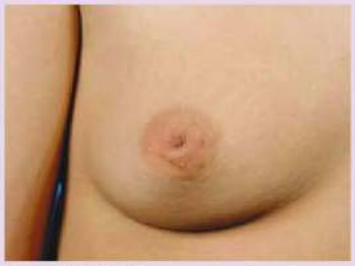

Figure 2: A) Patient pre-treatment with deeply inverted nipple

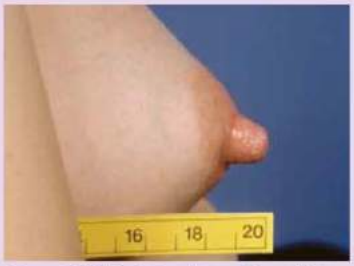

Figure 2: B) Sustained correction after using the 'Niplette™' for 2 weeks (no further use was required)

Conclusion

This study concluded that the 'Niplette™' effectively corrected inverted nipples 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.

Clinical trial summary

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, FRCPCH, 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; AVENT manual pump) when used in mothers of term babies.

Method

60 term breastfeeding mothers 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)
- creamatocrit (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.

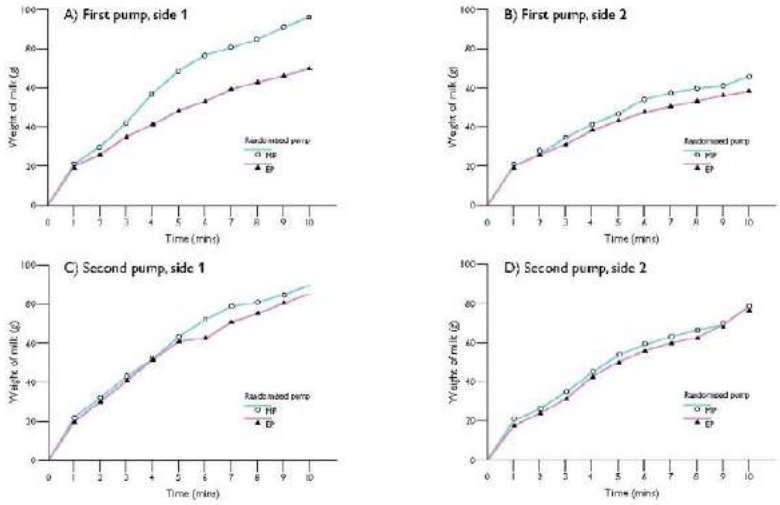

Figure 1: Weight of milk expressed over a 10-minute period according to pump used

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 (3)		
	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.

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

145 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 post-partum, 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 creamatocrit (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).

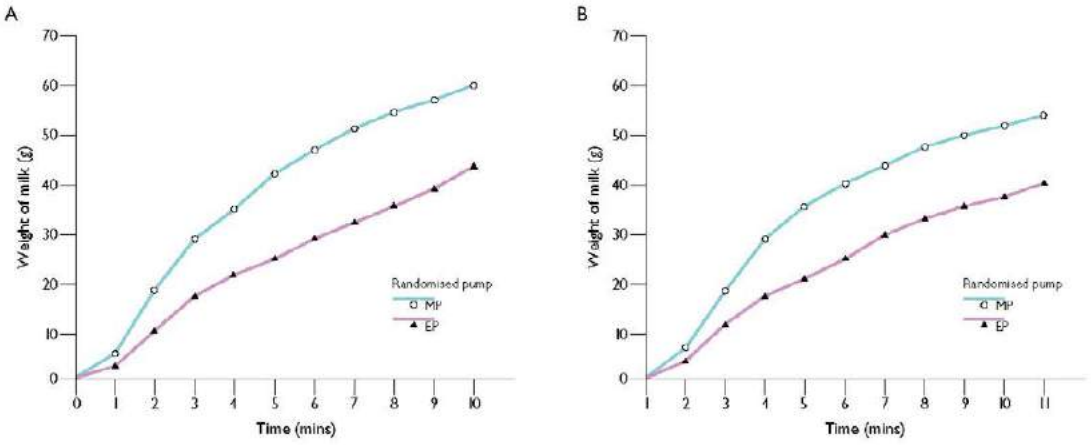

Figure 1: Weight of milk at 1 minute intervals according to pump used A) first breast, B) second breast (MP, n=24; EP, n=21)

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 fl ow 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)
- creamatocrit 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 fl ow and produced more milk in a fixed time period, perhaps reflecting a more physiologic pump design.

Clinical summary

Randomized trial comparing the effectiveness of 2 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 milk[1], 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 milk[1,2] 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: Breastfeeding. Policy statement: breastfeeding and the use of human milk. Pediatrics 2012;129(3):e827-e84.

2. Agostoni C, Buonocore 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.

Clinical trial summary

Ultrasound video analysis for understanding infant breastfeeding

Authors:
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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

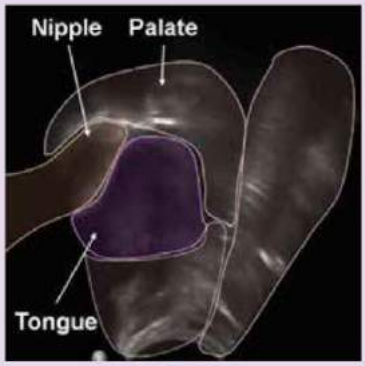
To develop novel methods to automatically detect and classify relevant events in ultrasound videos of breastfeeding infants, for better understanding of sucking and swallowing behaviour of infants during breastfeeding.

Methods

- 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



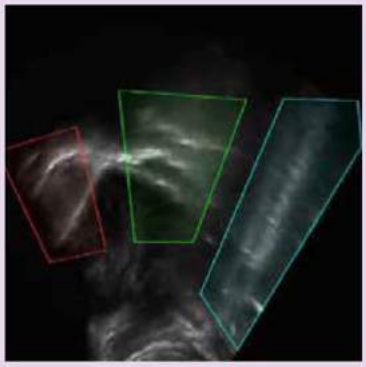
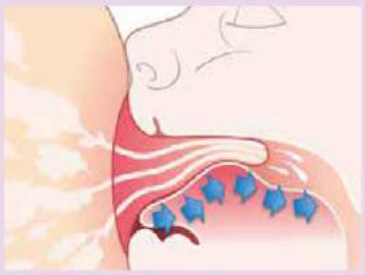
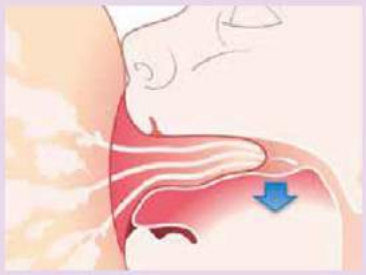


Figure 1: Submental ultrasound scans of the midline of the infant's oral cavity. The nipple and the infant's tongue and palate are labelled

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: Vaccum

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

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

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

Clinical trial summary

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

Authors:
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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, $p < 0.05$)

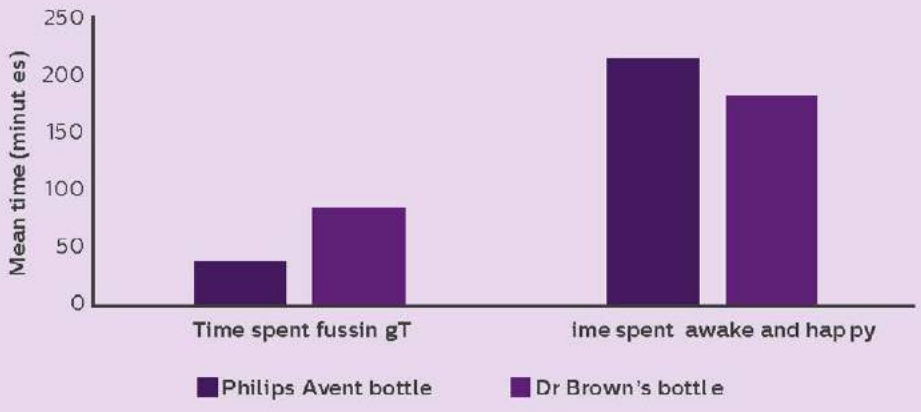

Figure 1: Mean time spent fussing and awake and happy for infants randomised to the Philips Avent one-way air valve bottle and the Dr Brown's internal venting system bottle

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 bottle[4]. 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:

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Philips AVENT: Helping mothers breastfeed longer

At Philips AVENT, we are dedicated to helping mothers breastfeed longer because we recognise the importance of breastfeeding for the healthy development of the infant and the health of the mother.

To give babies the healthiest start in life, we support the WHO recommendations [1] and the recently reaffirmed AAP guidelines [2] to help mothers aim for 6 months of exclusive breastfeeding and continued breastfeeding onwards while other foods are being introduced. We provide parents with educational materials, online forums, professional support and evidence-based products and we work with healthcare professionals to support them in helping parents achieve breastfeeding success.

Ever since AVENT started 27 years ago, we have been combining professional expertise with consumer understanding in working with scientific experts, clinical researchers, healthcare professionals and parents alike to research breastfeeding and to develop and evaluate our products and services, as shown through our extensive collection of research and network of experts.

More comfort, more milk

Published research has shown that when a mother is stressed, breastfeeding is more difficult because stress inhibits milk ejection and decreases milk volume [3-5]. Conversely, it has been postulated that for an adequate let-down response, psychological relaxation is necessary: the more comfortable a mother feels, the more relaxed she will be, and the easier the milk will start and continue to flow. Only a few studies have investigated this, either in a hospital setting or with infants still hospitalized while the mother had returned home, and the results indicate that relaxation improves milk expression [6-8]. Our most recent clinical study on evaluating the efficacy and preference of electric breast pumps with mothers of pre-term babies strengthen these results: we found that the subjective evaluation of comfort in using a breast pump was a significant predictor of milk production, with higher comfort ratings associated with greater milk volume, irrespective of the breast pump used [9-10]. We also found that ease-of-use was positively associated with greater milk volume.

To seek confirmation of these indications, we specifically investigated whether more comfort results in more milk as this was yet to be demonstrated in a clinical study using breast pumps.

Methods

With Philips Research Shanghai, we have investigated the hypothesis that greater relaxation results in greater milk volume in a clinical study evaluating the effect of relaxation on the efficacy of milk expression [11].

Figure 1 summarizes the study design. In this study, 48 lactating and breast pumping mothers were asked to express milk with their breast pump on two consecutive days: once directly after a relaxation exercise and once without this exercise. By random assignment, half the mothers had the relaxation exercise on the first day, whereas the other half had it on the second day. To relax, mothers could choose from either a breathing exercise or listening to music for about 10-15 min.

We then used questionnaires to measure the extent of which the mothers were relaxed and felt comfortable. Relaxation was measured with the validated STAI questionnaire (State-Trait Anxiety Inventory) which measures the level of anxiety on a 60 point scale with 20 being fully relaxed and 80 being least relaxed. The level of comfort and relaxation were also measured with VAS (Visual Analog Scale) ranging from 0 to 100 (maximum). Next, the mothers were asked to express their breast milk from both breasts using their own pumps after which we measured the total amount of milk produced.

By comparing the situation with and without relaxation exercise, we could compare the change in relaxation with changes in milk volume and comfort.

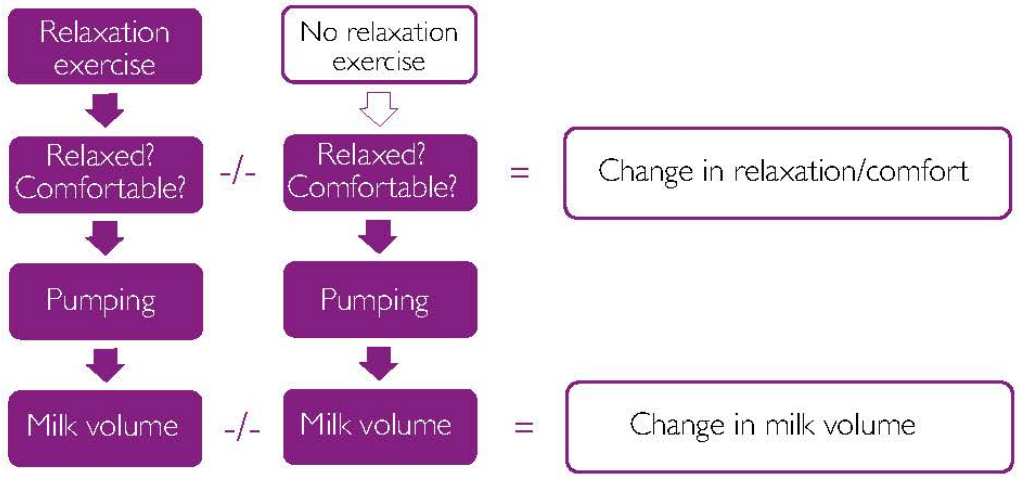

Figure 1: Overview of clinical study design

Results

As shown in Figure 2, we found for most mothers that when they were more relaxed they produced more milk. The horizontal axis shows whether mothers became more or less relaxed, and the vertical axis shows whether they produced more or less milk. The upper-left corner then demonstrates that the majority of mothers (21 out of 48) was both more relaxed and produced more milk.

Only 2 mothers became somewhat less relaxed and expressed slightly less milk – thus also supporting the hypothesis. In 13 mothers, the relaxation score did not change, though 9 expressed more milk and 4 less milk after the relaxation exercise. Finally, 12 mothers expressed less milk despite having an improved relaxation score – thus, contradicting the hypothesis.

Overall, after the relaxation exercise, 33 mothers became more relaxed and 30 expressed more milk. Taking all data points together of these 48 mothers, on average they became more relaxed and produced significantly more milk after the relaxation exercise. This confirms that greater relaxation results in more milk while breast pumping.

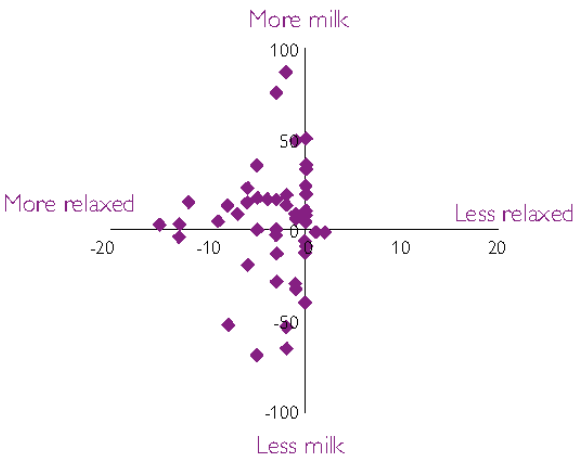

Figure 2. The relationship between change in STAI score and the change in total milk volume (in gram) of each mother following the relaxation exercise when compared to no relaxation.

Similarly we also found that when mothers were more relaxed they also felt more comfortable. In Figure 3 we correlated how relaxed they felt, either using the STAI or VAS score, respectively, with how comfortable they were. The correlation was strong to very strong with correlation coefficients of -0.67 and 0.95, respectively. Also, the correlation between STAI and the VAS for relaxation was -0.74. This confirms that greater relaxation results in more comfort.

Taken together, these results demonstrate that when mothers were more relaxed they felt more comfortable and were able to express significantly more milk.

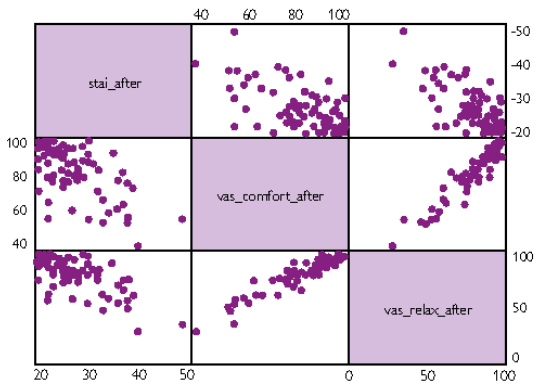

Figure 3. Correlations between STAI score for relaxation and the VAS for relaxation and comfort after the relaxation exercise

Conclusion

The results of this study confirm that for greater milk flow mothers would need to be as relaxed and comfortable as possible while expressing.

Implications for breast pump design

Thus, to minimize anxiety with breastfeeding and to enhance relaxation, breast pumps should be designed such that they are most comfortable to use, so that milk ejection and milk flow are promoted. In working with mothers we have identified that critical aspects of overall comfort include a relaxed expressing position, ease of use, and a gentle experience while expressing. As a result, The Philips AVENT Comfort breast pump range has been designed to provide more comfort for more milk.

Philips AVENT Comfort single electric breast pump

Philips AVENT Comfort manual breast pump

Philips AVENT Comfort double electric breast pump

Unique, natural expressing position

Clinically proven to be effective

Effortless expressing

Simple settings*

Philips AVENT Classic breast pump

New Philips AVENT Comfort manual breast pump

*Comfort electric breast pumps only

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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 feed[1]
- 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
- 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)

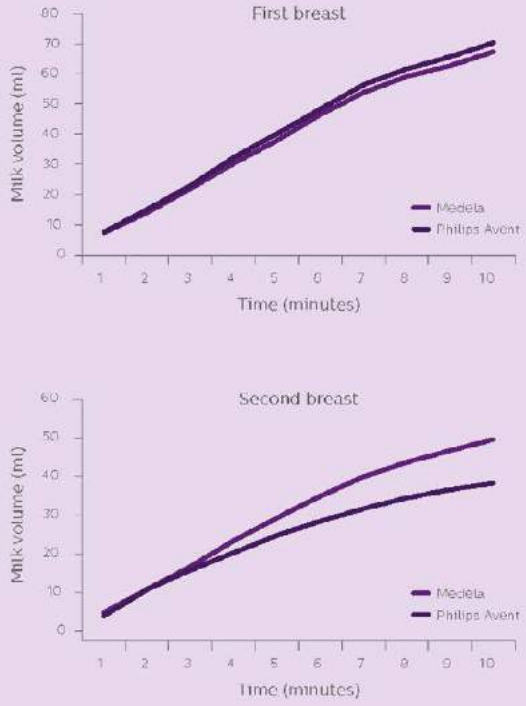
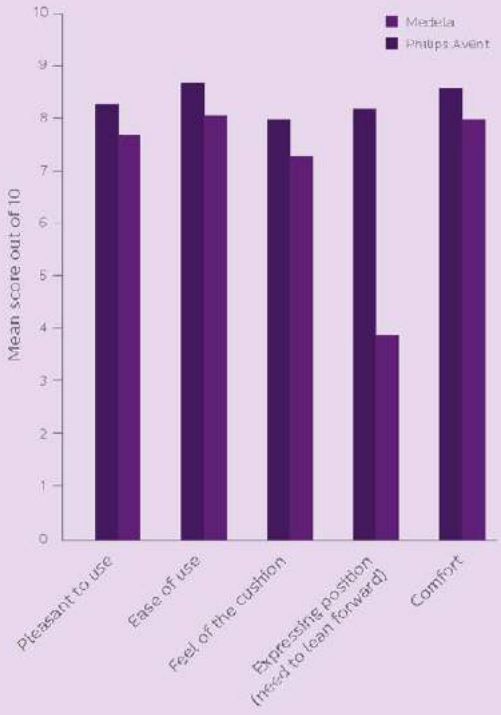


Figure 2. Mean scores for opinions on comfort of use for mothers randomised to use the different breast pumps (10=best, 1=worst score); all differences were statistically significant



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.

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BMC Pediatrics

Poor oral habits and malocclusions after usage of orthodontic pacifiers: an observational study on 3-5 years old children.

--Manuscript Draft--

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Full Title:	Poor oral habits and malocclusions after usage of orthodontic pacifiers: an observational study on 3-5 years old children.
Article Type:	Research article
Section/Category:	Behavior and development
Funding Information:	
Abstract:	Background. Pacifier sucking has been associated in literature with alterations of the teeth occlusion, and it could be a predisposing factor for other poor oral habits in children. Orthodontic pacifiers have been introduced in the market to reduce these inconveniences. The aim of this retrospective study was to evaluate the prevalence of poor oral habits and malocclusions, in children with primary dentition after usage of orthodontic pacifiers. Methods. A sample of 198 pre-school children, aged 3-5 years, (96 males and 102 females) who had exclusively used an orthodontic pacifier were included in the sample in order to evaluate their poor oral habits, behavior and teeth occlusion. Firstly, children's parents/legal guardians were given a questionnaire. Then, the children were clinically examined in a dental clinic. Results. Most of the children (79.79%) had started using the orthodontic pacifier within the first 3 months of life, and the 43.49% of the sample continued using it over 2 years. The percentage of children who had used it during sleep was 89.39%. Mouth breathing during the night was reported for 36.04% of the children. Tongue thrust swallow affected 16.16% of the sample. The 5.56% of the sample showed fingersucking/thumbsucking. The proportions of children with lip biting, or tongue interposition between the teeth at rest, and with nail biting, were 5.56%, 12.63% and 15.15%, respectively. The multivariate regression revealed a significant contribution of the beginning to use orthodontic pacifier in the prevalence of fingersucking/thumbsucking (OR 0.13, 95% CI 0.04-0.47, p=0.0004). About the prevalence of malocclusions, significant contributions of the female gender (OR 2.74, 95% CI 1.42-5.31), and the absence of exclusive breastfeeding (OR 2.26, 95% CI 1.17-4.37) in increasing the probability of developing malocclusion were detected. Conclusions. Orthodontic pacifiers does not favor the development of poor oral habits, even when used over two years in children with primary dentition. Children who begin to use orthodontic pacifier between 0 and 3 months, are less likely to develop fingersucking/thumbsucking. The use of an orthodontic pacifier appears not correlated to the prevalence of malocclusions in primary dentition differently from what reported in literature for conventional pacifiers.
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Poor oral habits and malocclusions after usage of orthodontic pacifiers: an observational study on 3-5 years old children.

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Poor oral habits and malocclusions after usage of orthodontic pacifiers: an observational study on 3-5 years old children.

Abstract

Background. Pacifier sucking has been associated in literature with alterations of the teeth occlusion, and it could be a predisposing factor for other poor oral habits in children. Orthodontic pacifiers have been introduced in the market to reduce these inconveniences. The aim of this retrospective study was to evaluate the prevalence of poor oral habits and malocclusions, in children with primary dentition after usage of orthodontic pacifiers.

Methods. A sample of 198 pre-school children, aged 3-5 years, (96 males and 102 females) who had exclusively used an orthodontic pacifier were included in the sample in order to evaluate their poor oral habits, behavior and teeth occlusion. Firstly, children's parents/legal guardians were given a questionnaire. Then, the children were clinically examined in a dental clinic.

Results. Most of the children (79.79%) had started using the orthodontic pacifier within the first 3 months of life, and the 43.49% of the sample continued using it over 2 years. The percentage of children who had used it during sleep was 89.39%. Mouth breathing during the night was reported for 36.04% of the children. Tongue thrust swallow affected 16.16% of the sample. The 5.56% of the sample showed fingersucking/thumbsucking. The proportions of children with lip biting, or tongue interposition between the teeth at rest, and with nail biting, were 5.56%, 12.63% and 15.15%, respectively. The multivariate regression revealed a significant contribution of the beginning to use orthodontic pacifier in the prevalence of fingersucking/thumbsucking (OR 0.13, 95% CI 0.04-0.47, p=0.0004). About the prevalence of malocclusions, significant contributions of the female gender (OR 2.74, 95% CI 1.42-5.31), and the absence of exclusive breastfeeding (OR 2.26, 95% CI 1.17-4.37) in increasing the probability of developing malocclusion were detected.

Conclusions. Orthodontic pacifiers does not favor the development of poor oral habits, even when used over two years in children with primary dentition. Children who begin to use orthodontic pacifier between 0 and 3 months, are less likely to develop fingersucking/thumbsucking. The use of an orthodontic pacifier appears not correlated to the prevalence of malocclusions in primary dentition differently from what reported in literature for conventional pacifiers.

Key-words:

Fingersucking; Thumbsucking; Pacifiers; Malocclusions; Tongue Habits; Oral habits

Background

The use of pacifiers is accepted during the first year of life, because it decreases the risk of sudden infant death syndrome, due to its influences on autonomic and cardiovascular control; in addition, it could help to calm the children and improve his/her psychological development [1]. Also other non-nutritive habits, such as thumbsucking or fingersucking are often used to calm and comfort infants, because sucking is a natural instinct for a baby, and is the baby's earliest coordinated muscular activity. [1] However, from the craniofacial development point of view, the use of a conventional pacifier for a long time (over 2 years) [2] and with high frequency (a "daily use", as recently stated by Ling et al. [1]) has been associated in literature with some alterations of the occlusion, such as anterior open bite and posterior crossbite [3–5].

For this reason, the so-called orthodontic pacifiers have been introduced into the market, designed with a flattened nipple to simulate mothers' nipple anatomy, to maintain the necessary pressure of tongue on the palatine vault and to obtain a more acceptable lip seal, allowing its physiological development and reducing the side effects related with the use conventional pacifiers [6–9]. In fact, the use of such pacifiers should induce patterns of muscle contraction, tongue position and nasal breathing similar to the ones occurring during breastfeeding, whereby they would not interfere with the growth and development of the face and occlusion [10].

The first systematic literature review on the differences between conventional and orthodontic pacifiers [11], was not able to draw any conclusion due to the low level of evidence of the available studies, requesting more data on this field. This systematic review did not include parameters such as frequency and duration of pacifier usage. Another recent systematic review [12] including five trials about the comparison between orthodontic and conventional pacifiers [6, 7, 10, 13, 14] concludes that a proper definition for a functional or orthodontic pacifier is missing, and that functional orthodontic pacifiers seem to cause less anterior open bite than conventional ones, while no statistical difference in the prevalence of posterior crossbite seemed to be associated with the use of orthodontic pacifiers [6, 10]. Thus, the main conclusion was that currently available evidence is

insufficient to support the concept that the usage of orthodontic pacifiers is able to prevent malocclusion traits when compared to the usage of conventional pacifiers, and that new data on orthodontic pacifiers effects are necessary in literature [8].

Orthodontic pacifiers, while reducing the occurrence of malocclusions, also should potentially not encourage the acquisition of additional poor oral habits, harder to stop in children, as for example, fingersucking/thumbsucking. The rationale is that if the child gets the maximum satisfaction from orthodontic pacifier sucking (a non-dangerous sucking), he will not feel the need to acquire other poor habits. In addition, as an orthodontic pacifier can enhance the coordination between breathing and sucking-swallowing by oral stimulation, it could also prevent mouth breathing.

As poor oral habits and mouth breathing may be predisposing factors for the appearance of malocclusion, [4, 15, 16] knowledge of how orthodontic pacifiers contributes to or prevents them, could help in determining better options for children's oral health care. But unfortunately, literature still lacks data on the frequency of poor oral habits and of the breathing pattern among pacifier sucking children using an orthodontic pacifier.

Thus, the aim of this observational study was to investigate the prevalence of poor oral habits and malocclusions, in children using an orthodontic pacifier.

Methods

In this observational study, conducted at the University of l'Aquila (Central Italy), on the base of a database, including customers who gave their consent to Philips S.p.A. (Viale Sarca 235, 20126 Milano, Italy) for being contacted for screening procedures, a potential sample of pre-school children who had exclusively used the orthodontic pacifier called Philips Avent (Philips S.p.A., Viale Sarca 235, 20126 Milano, Italy) was individuated. Children aged 3-5 years were selected from this database at the beginning of the present research protocol. Then, student of the school of orthodontics from the University of L'Aquila gave information about the research protocol by phone call to the children's parents/legal guardians. A free clinical oral examination in the dental clinic of the University was offered to all the contacted parents/legal guardians in order to

encourage the participation in the study. The protocol agrees with the declaration of Helsinki and was approved by the ethical committee of the University of L'Aquila.

The sample size was calculated using data from a previous cross-sectional study on the same topic, [17] in which it was assumed a prevalence of malocclusion of 50%, a 95% confidence interval, and a standard error of 7%. The sample size calculation resulted in a minimum of 195 children. Thus, an initial sample of about 250 children were contacted.

About 210 children accepted to participate to the study, and an appointment with them has been scheduled by telephone. At the appointment, the parents/legal guardians were firstly requested to sign an informed consent form about the study and the clinical examinations of their children. Then, a questionnaire about the oral habits and general behavior about oral health of their children was given to the parents/legal guardians of the enrolled children. Because of the importance of the results of the questionnaire, the parents/legal guardians were asked to answer very sincerely to the questionnaire. They were also asked not to hesitate to request clarifications in case of unclear questions. Lastly, the children were clinically examined on the dental chair, to assess the presence of malocclusion, crossbite, tongue thrust swallow and tongue interposition between the dental arches at rest. The clinical examination was made by an experienced specialized orthodontist (S.C.), the principal investigator, with more than 5 years of orthodontic training and blind to the answers given to the questionnaire.

After the examination, to maintain the integrity of the study results, data from participants with severe skeletal discrepancy or craniofacial anomalies as cleft lip or palate, assessed during the clinical examination, were excluded from the present analyses. In addition, also data from subjects with alterations of number, size, and shape of deciduous teeth, or with major tooth destruction or reconstruction, systemic diseases and/or neurological diseases were excluded from analyses.

Therefore, data from a final sample of 198 children aged 3-5 years, with primary dentition were finally included in the present investigation.

Statistical analyses

A descriptive statistical analysis was conducted to illustrate the characteristics of the sample, the data from the questionnaires, and the prevalence of poor oral habits and malocclusions. In order to analyze the relationship between orthodontic pacifiers sucking, poor oral habits and malocclusion, cross-tabulations were performed among variables. In addition, the association between duration of pacifier sucking and the occurrence of other poor oral habits was calculated as ORs with a 95% confidence interval, between the presence/absence of poor habits, placed as a dependent variable, and the duration of pacifier sucking as independent variable.

Then, based on the presence/absence of malocclusion, the sample was stratified into two groups compared to each other. The statistical significance of the differences in the distribution of frequencies of the investigated variables was analyzed through the $\chi 2$ test. The statistically significantly associated variables were then introduced in a multivariate logistic regression model in order to evaluate their association, expressed as Odds Ratio (OR) with a 95% confidence interval (CI), correlating the presence/absence of malocclusion, placed as a dependent variable, and the explanatory variables, adjusted for the effects of the other variables.

For each analysis, the threshold for statistical significance was set at $p < 0.05$.

Results

Table 1 reports the characteristics of the present sample. Among 198 subjects, aged 3-5 years, the male/female ratio was 0.94 (96/102). For the 91.41% of the children (181 subjects over 198), the mothers reported having been properly informed, at the birth of their child, about how to make their child sleep safely. For the 56.06% of the children (111 subjects over 198), the mothers reported having been informed at birth about the benefits and disadvantages of using pacifiers. It emerged that most of the children (79.79%, 156 children over 198) started using the orthodontic pacifier early, within the first 3 months of life, and often continued using it over 2 years (43.94%, 87 children over 198). The percentages of children who gladly used their orthodontic pacifier (78.28%, 155 children over 198) and those who used it during sleep in the first year of life (89.39%, 177 children over 198) were also very high. The majority of the sample (66.67%, 132 children over 198)

had been exclusively breastfed during the first months. The percentage of children who had problems with weaning was very low, of 2.54% (5 children over 198). The 10.10% (10 children over 198) of the children suffered of recurrent otitis problems, and the 18.69% of the children (37 children over 198) suffered gastroesophageal reflux problems. The percentage of children able to self-practice oral hygiene maneuvers was 70.20% (139 children over 198). Mouth breathing during the night was detected in 71 children over 198 (36.04% of the sample). Tongue thrust swallow affected 16.16% of the sample (32 children over 198). The 5.56% of the sample (11 children over 198) of the children showed fingersucking/thumbsucking. The percentages of children with lip biting, tongue interposition between dental arches at rest, or nails biting, were 5.56% (11 children over 198), 12.63% (25 children over 198) and 15.15% (30 children over 198), respectively. The 35.86% of the sample (71 children over 198) had a malocclusion; 14.14% (28 children over 198) showed unilateral cross and 4.04% (8 children over 198) showed bilateral crossbite.

When the sample was stratified into two groups, based on the presence/absence of a malocclusion, compared to each other, statistically significant differences for gender distribution, with a significantly higher percentage of females with malocclusions compared to the males (63.38% vs 44.88%, $p = 0.012$), and for breastfeeding, which interested a lower proportion of children in the malocclusion group (71.65% vs. 57.75%, $p = 0.046$) were detected. The estimates of the ORs - adjusted for the effects of the other factors - are presented in the model (**Table 2**), through a multivariate regression, that revealed a significant contribution of female gender (OR 2.74, 95% CI 1.42-5.31), and the not exclusive breastfeeding (OR 2.26, 95% CI 1.17-4.37) in increasing the probability of developing a malocclusion.

The regression revealed a significant contribution of the beginning of orthodontic pacifier sucking on the prevalence of fingersucking/thumbsucking, because children who began to use orthodontic pacifier very early, between 0 and 3 months, were less likely to develop fingersucking/thumbsucking respect to children who begun after 3 months (OR 0.13, 95% CI 0.04-0.47, $p=0.0004$) (**Table 3**).

No other associations were detected among the poor habits and the orthodontic pacifier sucking.

Discussion

This observational study aimed to evaluate the prevalence of poor oral habits and malocclusions among children after usage of an orthodontic pacifier. The sample (198 children, ranging between 3 and 5 years of age) is undoubtedly the most extensive report in the literature recording these data in children who have exclusively used an orthodontic pacifier. Thus, the collected data can be generalized for the population of children who use orthodontic pacifiers. In addition, previously, no study has looked into whether or how orthodontic pacifier sucking is interrelated with poor oral habits, mouth breathing and tongue thrust swallow.

In the present sample, the great part of children (78.28% of the whole sample) gladly started using their orthodontic pacifier and began before the 3 months of life (78.79% of the whole sample), adopting it regularly during the night, almost in the first year of age (89.39% of the whole sample). Thus, the present data can confirm that orthodontic pacifier was generally well accepted by children, as well as it has already been reported in literature [6, 10, 18]. In addition, the data from the present sample revealed that the 91.41% of the parent/guardians had been properly informed about the risks involved in the prolonged use of pacifiers and the advantages of its use, before beginning to adopt orthodontic pacifiers. This is also evidenced by the circumstance that the great part of children were given their pacifiers during the night (89.39% of the whole sample), following the recommendations of pacifier usage, i.e. that it should be used when the infant is sleeping and not reinserted if the child lets it drop during sleep [19] (today, the recommended usage would be for sleeping and for less than 4–6 h per day) [20]. These data are in line with the fact that an orthodontic pacifier is adopted - above all - by those mothers who are better informed about the risks of using pacifiers, because if there is no adequate information, mothers can be brought to choose conventional pacifier. The present data also reveal an acceptable general health status of the children, as recurrent otitis were recorded only for 20 children over 198 (10.10%), and no significant correlation was detected between the duration of the pacifier sucking and the prevalence

of recurrent otitis, despite a previous study that stated that pacifier sucking increases the risk of recurrent otitis after ten months of use [21].

Mouth breathing during the night was present in 71 children over 198 (36.04% of the sample). These data suggest a predominant pattern of nasal breathing children in the present sample. In addition, no correlation between the breathing pattern and orthodontic pacifier sucking was observed. In a previous sample of 36 pre-school children with primary dentition using conventional pacifier, Nihi et al. found that 22.2% of conventional pacifier sucking children (8 subjects over 36) had mouth breathing at rest, while only of 8.3% (4 children over 48) of pacifier non-users showed mouth breathing [2]. The higher prevalence of mouth breathing among pacifier users respect to controls, was associated by Nihi et al. to the altered position of the tongue in the mouth, which causes these subjects to keep their mouth open and consequently develop a mouth-breathing pattern. This explanation could be assumed both for conventional as well as for orthodontic pacifiers, although the present data failed to evidence any correlation between pacifier sucking and mouth breathing. Thus, it must be concluded that the pacifier sucking is not associated to the breathing pattern during the night.

In the present sample, the tongue thrust swallow affected 16.16% of the sample (32 children over 198), and no significant correlation was observed with pacifier sucking duration or beginning. In the sample analyzed by Nihi et al., tongue thrust swallow was detected in 27.8% (10 over 36 subjects) of children, a percentage higher respect to the one of the present study (16.16%; 32 children over 198) [2]. Nihi et al. associate the tongue thrust swallow with a prolonged pacifier-sucking habit, which delays maturation of the swallowing reflex. The present data suggest that the thin neck nipple of an orthodontic pacifier could be able to reduce the occurrence of tongue thrust swallow, as also hypothesized previously [13]. With regard to the poor oral habits, the 5.56% of the present sample (11 children over 198) reported fingersucking/thumbsucking, but no relationship was detected between breastfeeding and fingersucking/thumbsucking. In addition, those children who began to use orthodontic pacifier very early - between 0 and 3 months of life – showed a lower risk to

develop fingersucking/thumbsucking respect to children who begin after 4 months (OR 0.13, 95% CI 0.04-0.47, p=0.0004) (**Table 3**). This result could agree with the Canadian Dental Association and the American Dental Association, which recommend pacifiers over finger/thumb sucking because it is easier for a parent to control the sucking habit, as it is easier to wean a child's sucking habit from a pacifier, than from a thumb [22, 23].

This finding appears to disagree with what is generally believed for conventional pacifiers, *i.e.* that if conventional pacifiers are given to infants in the early postpartum period, when they are learning to suck from their mothers' breasts, the use of the pacifier may interfere with proper sucking and cause nipple confusion, favouring a late fingersucking/thumbsucking habit [24]. In agreement with this statement, Ling et al. reported, from a sample of 1034 Asian children aged 2 to 5 years old, that children who use conventional pacifiers "daily" have significantly higher chances of developing fingersucking/thumbsucking habits [1]. The present study doesn't confirm this association in case of orthodontic pacifiers, because fingersucking/thumbsucking resulted not correlated to the duration of orthodontic pacifier sucking. The present data states the opposite concept, i.e. that children who began to use orthodontic pacifier very early - between 0 and 3 months - are less likely to develop fingersucking/thumbsucking respect to children who had begun after 4 months (OR 0.13, 95% CI 0.04-0.47, p=0.0004). It must be noted that Ling et al. report data on conventional pacifiers, and didn't analyze the beginning of the pacifier sucking, but only its frequency (a "daily" use or "not daily" use) (OR 2.136; 95% CI 1.11-4.10) [1]. These factors could explain the different conclusions between the two studies. Not many other studies in literature have focused on the relationship between pacifier sucking and fingersucking/thumbsucking, except for another study, published in 1977 that found an inverse association between the two habits, more in accordance to what is reported in the present sample [25]. Probably, the infants that early begin to use orthodontic pacifiers, obtain satisfaction from one habit, and this may reduce the urge for addiction to the sucking sensation, preventing them to develop other habits as fingersucking/thumbsucking to help them to fulfil their needs, and the same is for other poor habits.

About the other poor oral habits, the proportions of children who referred lip biting, tongue interposition between dental arches, or nails biting were 5.56% (11 children over 198), 12.63% (25 children over 198) and 15.15% (30 children over 198), respectively. In addition, the use of an orthodontic pacifier for more than 2 years seems not to favor the acquisition of additional poor oral habits, even when used for more than 2 years. These percentages appear low and acceptable. In addition, no association was detected between the duration or the beginning of orthodontic pacifiers sucking, and the frequencies of these poor oral habits. These data suggest that orthodontic pacifier sucking doesn't bring to the acquisition of other poor oral habits. Only a few studies in literature had analyzed the relationship between pacifier sucking and other oral bad habits. Thus, the present findings can be compared only with data recorded from children using conventional pacifier. About the tongue interposition between dental arches at rest, it was previously investigated in a sample of 36 pre-school children with primary dentition using conventional pacifiers, and it was found in 38.9% of children (14 subjects over 36) [2], a percentage higher respect to the present one of 12.63% (25 children over 198).

In general, the low frequencies of poor oral habits in the present sample could indicate that the use of orthodontic pacifiers do not represent a promoting factor. It could be hypothesized that infants could experience improved safety and satisfaction due to the unrestricted (not dangerous) sucking, as previously reported for breastfeeding [1] and thus no other sucking actions are needed, leading to a low frequency of fingersucking/thumbsucking and other poor oral habits in children using orthodontic pacifiers, differently from what reported with conventional ones.

With regard to the prevalence of malocclusions, in the present study, all the various types of malocclusions hypothetically correlated to poor oral habits were summarized together in a unique variable (i.e. "malocclusions"). The logistic regression failed to evidence any correlation between orthodontic pacifier sucking and the presence of malocclusions in the present sample, as only the gender and the breastfeeding resulted significantly associated to the prevalence of malocclusion (**Table 2**). Neither the duration of orthodontic pacifier sucking resulted associated to the prevalence

of malocclusions. This could be considered a good and interesting finding, as malocclusion in the deciduous dentition represents a risk factor for orthodontic treatment need in the permanent dentition [26].

In the present sample, 36 children over 198 (18.18% of the sample) showed a posterior crossbite (28 children showed unilateral crossbite, and 6 children showed bilateral crossbite). The prevalence of posterior crossbite in children using conventional pacifiers varies between 12.8% and 88.9%, as assessed in a recent systematic review [12]. But in a sample of 55 children using orthodontic pacifiers, Lima et al. [10] reported only 4 cases over 55 of posterior crossbite (7.27%). To explain the difference with the present sample, we should consider that Lima et al. recorded a very low prevalence of crossbite (6 children over 55, i.s. less than 10% of the sample) also among children using conventional pacifiers. Thus, the results observed from Lima et al. [10] could be associated not only to the type of pacifier, but probably to the lower mean age of children, that was 28.2 ± 1.9 months (with an initial age range for selection of subjects indicated as 12-24 months) in their sample, while in the present sample the age of the children ranged between 3 and 5 years. Furthermore, Lima et al. excluded subjects with enlarged adenoids or respiratory problems, with history of finger sucking, lip sucking, lip biting or lingual interposition, while in the present sample these exclusion criteria were not adopted. Thus, the percentage observed in the present sample appear more generalizable to the population of children adopting orthodontic pacifiers.

From the present data, no significant correlation was reported between the beginning of orthodontic pacifier sucking, its duration, and the frequency of crossbite. Previous literature based on conventional pacifiers, strongly correlates the posterior crossbite with the duration of the habit, until 4-6 years of age [27], and with a use of the pacifier for more than 36 months [28], more than 2 years [2], more than 15.5 months [6], or more than 1 year [1]. The present observation suggests that the design of the orthodontic pacifier doesn't promote the occurrence of posterior crossbite, even when used for more than 2 years.

Most of the previous literature state that with a long duration and high frequency of conventional pacifier usage, there is a tendency to hyperfunction of the buccinator muscle, which causes a deficiency in transverse growth of the maxilla and increased frequency of crossbites. Differently, orthodontic pacifiers are designed to avoid hyperfunction of the buccinator muscle. However, some previous studies on conventional pacifiers failed to evidence an association between posterior crossbite and pacifier sucking. For example, Moimaz et al. could not find any statistically significant difference concerning posterior crossbites between the patients with or without previous usage of a pacifier at 12, 18, and 30 months, except when the posterior crossbite was associated with fingersucking [29]. The present data did not evidence any relationship between the orthodontic pacifier sucking and the posterior crossbite, even when associated with fingersucking/thumbsucking. The present findings suggest that the use of an orthodontic pacifier should be not correlated to the prevalence of malocclusions in primary dentition, differently from what reported in literature for conventional pacifiers.

Limitations of the study

This observational study presents some limitations. A longitudinal design with an additional follow-up would be useful, especially for monitoring those children that used the pacifier for more than two years. Anyway, it should be noted that the present report didn't evidence any higher risk of malocclusion for children with more than 2 years of pacifier usage respect to those children with less prolonged usage, that confounders were reported, and adjustments for non-nutritive sucking habits were performed, trying to avoid biased results. It should also be considered that owing to its design, this study could be susceptible to recall bias. Finally, as parents are unable to monitor their children for 24 h a day, there may be an underestimation of poor oral habits.

Conclusions

The use of orthodontic pacifiers does not promote the development of poor oral habits in children with primary dentition, even if the usage is prolonged over two years. An early orthodontic pacifiers usage beginning (0-3 months) seems to be associated with a reduced risk of developing

fingersucking/thumbsucking. The use of an orthodontic pacifier seems to be not associated with the development of malocclusions in primary dentition differently from what previously reported in literature for conventional pacifiers. Further prospective controlled studies are encouraged to confirm what reported in the present study about the relationship between the use of orthodontic pacifiers and the development of malocclusions and poor oral habits.

List of Abbreviations

95% CI: 95% Confidence interval

CI: Confidence interval

OR: Odds ratio

SPSS: Statistical Package for Social Science

Declarations

Ethics approval and consent to participate

Informed consent was obtained for participants from their legal representatives, as appropriate, in written form. This study was approved by the ethical committee of the University of L'Aquila.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are available from the University of L'Aquila, but restrictions are applied to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the University of L'Aquila.

Competing Interests

None of the authors have any competing interests.

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Author's contribution

SC: concept, design, clinical procedures, data collection, methodology, approval of the article.

AN: concept, design, writing of the article, methodology, critical revisions, approval of the article.

MS: data collection, article revision, approval of the article.

RG: concept and direction of clinical procedures, critical revision of the manuscript, accountability for research integrity and accuracy, final approval of the article.

ST: concept, design, writing of the article, methodology, critical revisions, approval of the article.

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Table 1. Descriptive characteristics of the sample

Variable	n (%)
Gender	
Male	96 (48.48)
Female	102 (51.52)
Age	
(in years)	3 - 5 years
What age did your baby start to use pacifiers at?	
0-3 months	156 (78.79)
4-6 months	26 (13.13)
7-12 months	16 (8.08)
How long did your baby use pacifiers?	
6 months	26 (13.13)
1 years	22 (11.11)
2 years	63 (31.82)
> 2 years	87 (43.94)
Did your baby start to use pacifiers gladly?	
No	43 (21.72)
Yes	155 (78.28)
Did your baby use the pacifier during sleep during the first year of life?	
No	21 (10.61)
Yes	177 (89.39)
Have you been informed at baby's birth about how to make your baby sleep safely?	
Yes	181 (91.41)
No	17 (8.59)
Did your baby suffer recurrent otitis complaints?	
No	178 (89.90)
Yes	20 (10.10)
Was your baby exclusively breastfed for the first six months of life?	
Yes	132 (66.67)
No	66 (33.33)

Have you been informed at birth about benefits and not using pacifiers?	
Yes	111 (56.06)
No	87 (43.94)
Did your baby suffer gastro-oesophageal reflux problems (frequent regurgitation, vomiting after meals)?	
No	
Yes	161 (81.31)
	37 (18.69)
Does your child sleep with open mouth?	
No	126 (63.96)
Yes	71 (36.04)
Does your child suck his/her finger/thumb?	
No	187 (94.44)
Yes	11 (5.56)
Did your baby suffer with weaning?	
No	191 (97.46)
Yes	5 (2.54)
Does the child bite his/her lip?	
No	187 (94.44)
Yes	11 (5.56)
Does the child bite his/her nails?	
No	168 (84.85)
Yes	30 (15.15)
Clinical examination: presence of malocclusion	
No	127 (64.14)
Yes	71 (35.86)
Clinical examination: presence of crossbite	
No	162(81.82)
Unilateral	28 (14.14)
Bilateral	8 (4.04)
Clinical examination: presence of tongue thrust swallow	
No	166 (83.84)
Yes	32 (16.16)
Clinical examination: tongue interposition between dental arches at rest	
No	173 (87.37)
Yes	25 (12.63)

Table 2. Multivariate logistic regression analysis for the association between development of malocclusion and the explanatory variables (gender, breastfeeding)

Risk factor	OR°	95% CI
Gender		
Males[#]	1	
Females	2.74	(1.42–5.31) *
Was your baby exclusively breastfed for the first six months of life?		
Yes[#]	1	(1.17–4.37) *
No	2.26	

[#]Reference category.
*Statistically significant association.
° adjusted ORs for the other factors in the model
95% CI: 95% confidence interval.

Table 3. Multivariate logistic regression analysis for the association between development of fingersucking/thumbsucking and the associated variable (age of beginning of orthodontic pacifier sucking)

Risk factor	OR°	95% CI
Age of beginning of orthodontic pacifier use:		
>3 months[#]	1	
0-3 months	0.13	(0.04–0.47) *

[#]Reference category.
*Statistically significant association.
° adjusted ORs for the other factors in the model
95% CI: 95% confidence interval.