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Randomized Controlled Trial (rct)

The effect of early childhood non-nutritive sucking behavior including pacifiers on malocclusion: a randomized controlled trial#

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Abstract

Background/rationale: Systematic reviews on the effects of pacifiers on occlusion have highlighted the need for quality RCTs.

Trial design: Single region, three parallel-armed, prospective, randomized controlled trial.

Objectives: To investigate the correlations between early childhood non-nutritive sucking habits and malocclusion. Specifically to test whether the use of a study pacifier has differing effects compared to other pacifiers and control, and whether the duration of pacifier use or digit sucking influence the occlusion.

Participants: The subjects were firstborn children, born in 2008 in Vantaa, Finland.

Intervention: One-third of participants were offered study pacifiers, free of charge, from birth up to 2 years of age. The history of the subjects' sucking habits, including pacifier use was screened in a questionnaire at the age of 2 years, and clinical examinations were performed at the age of 7 years. In addition, the subjects were divided into groups that were equally matched regarding their mother's level of education.

Outcomes: Posterior crossbite, anterior crossbite, overjet, deep bite, open bite, and crowding.

Randomization method: Three districts were randomly allocated to three study groups by drawing lots.

Blinding: It was not possible to blind the clinicians or parents from the intervention. Blinding during data analysis was performed.

Results: From the original cohort of 2715 children born in the town of Vantaa, 1911 were excluded and 353 were lost to follow-up. The remaining 451 children were divided into three groups according to the use of pacifiers. The prevalence of posterior crossbite at the age of 7 years was higher if a non-study pacifier had been used ($P = .005$) even when matched for the mother's level of education ($P = .029$). The prevalence of posterior crossbite was higher if the pacifier habit had continued for 12 months or more compared to 11 months or less, 7% and 1%, respectively, ($P = .003$). Digit sucking for 12 months or more was associated with crowding ($P = .016$). The prevalence of crossbite in the study pacifier group was less than in control pacifiers.

Harms: No adverse harms were reported other than effects on the dentition.

Conclusion: The use of pacifiers is associated with the posterior crossbite, especially if their use continues for a year or more. Parents/guardians should be advised to stop the use or reduce the use of pacifiers to a minimum after their child's first birthday.

Trial registration: ClinicalTrials.gov NCT01854502.

Keywords: non-nutritive sucking habit; pacifier sucking; digit sucking; malocclusion

Introduction

Non-nutritive sucking habits (NNSH) are very common among young children and with age their incidence reduces [1–5]. NNSHs include sucking pacifiers or digits and are most prevalent from birth up to the age of 1 or 2 years with Larsson reporting an incidence of 82% at 5 months [6]. For some children, NNSHs can continue for many years and have been reported to affect the developing occlusion, with an increased risk correlated to prolonged use [6–11]. In some studies, pacifier sucking has been found to have more adverse effects than digit sucking [9, 10]. While others have recommended that the habit of digit sucking should be finished as soon as possible and changed to a pacifier (Bishara et al.).

Interestingly co-sleeping, that is to say, mother and child, sharing the bed or sleeping in close proximity to each other, for less than 6 months compared to more than 6 months, has

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been associated with increased anxiety and an increased incidence of pacifier use, digit sucking, atypical swallowing and malocclusion in the deciduous dentition [12].

Pacifier use can influence the shape and growth of the maxillary arch even before the eruption of the teeth in the first six months after birth [13]. *In vitro* studies, using the finite element method have been performed to compare different pacifiers and their resultant contact area and force on the palate when subjected to the tongue and oral forces of NNSHs. Some, so-called orthodontic, pacifiers result in a more uniform and wider transverse stress distribution with less load on the palate compared to other pacifiers [14]. Clearly, pacifiers may interact with the palate differently based on their shape and size regardless of whether they are labeled conventional or orthodontic [15].

The duration, frequency, intensity, and manner of digit or pacifier sucking has an effect on the type and severity of the resulting malocclusion. It has been reported that in individuals with pacifier sucking, anterior open bite (negative overbite) can develop and that this is usually symmetrical and of elliptical form. In contrast, in individuals who have a digit-sucking habit, the open bite is asymmetric [9]. Prolonged pacifier use has also been associated with posterior cross bites [16]. Digit-sucking habits have been found to persist for last much longer than pacifier-sucking habits [8].

Following the cessation of NNSHs, self-correction of the malocclusion can occur in anterior open bite, sagittal malocclusions, and unilateral crossbite [17, 18]. However, even if the NNSHs stop in the primary dentition phase, they may still result in malocclusion in the mixed dentition. Prolonged pacifier habits for more than 4 years have been found to correlate with anterior open bite and bilateral Class II malocclusion, and digit habits of 5 years or more with anterior open bite [8].

While knowledge of the detrimental effects of prolonged pacifier use seems to be commonplace and is even highlighted in many dental textbooks, two systematic reviews on this subject have revealed that the level of evidence is weak [10, 19]. In their review, Schmid et al. included nine cross-sectional studies, seven prospective cohort studies, and only one RCT. No meta-analysis was able to be carried out [19]. Both systematic reviews highlighted the need for better quality evidence and particularly for RCTs, hence the rationale for the current investigation.

The aim of this clinical trial was to test the effect of pacifiers on dental occlusion. Specifically 1. Does the use of a study pacifier (DentoBon) versus other pacifiers affect the occlusion at 7 years of age? 2. Does the duration of pacifier use or digit sucking influence the occlusion at 7 years of age? The study was started at birth, there was a questionnaire completed at 2 years of age and a clinical examination at 7 years of age. The results suggest that the use of pacifiers, particularly after the age of one year, may contribute to posterior crossbite.

Materials and methods

Trial design and ethical approval

Single region, three parallel-armed, prospective, and randomized controlled trials. The guidelines of the CONSORT Statement for RCTs were followed. The present trial was part of clinical study 'Organizing Family-based Health Promotion for Young Children in Public Dental Service' of firstborn children born in the municipality of Vantaa, Finland in 2008 [20]. The identifier in ClinicalTrials.gov is NCT01854502. It should be noted that pacifier use/intervention, questionnaire, and dental occlusal assessment were not mentioned in the trial registration.

The trial was conducted according to the declaration of Helsinki and was approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa, §289/2007.

Participants, inclusion criteria, and interventions

All firstborn children, whose parents/guardians accepted the informed consent, were included (Fig. 1). One-third of participants were offered study pacifiers, free of charge, from birth up to 2 years of age (District F, Northern Vantaa). The study pacifier (DentoBon) was designed at the University of Turku and made by Plastone OY, Finland (Plastone.com). The teat was wider and flatter than other comparable pacifiers in an attempt to conform to the anatomy of an infant's palate and possibly reduce the negative effects of pacifier use on the development of dental occlusion. The parents were offered pacifiers up to the age of 2 years, and delivered on request. During the first 12 months, they were sent small pacifiers and after that, a larger size was used (Fig. 2). The parents of the children were given oral health promotion advice, including oral hygiene instruction and fluoride intake when their children were 6–24 months old. As a routine, all children in the town of Vantaa (study districts F, X, and C) were offered a dental examination at least three times before starting school at the age of 7 years. For this study, follow-up assessment was performed at the age of 2 years (questionnaire and clinical examination) and at 7 years (during the 1st school year, clinical examination). In the 2-year questionnaire, parents were asked about the child's oral health, sucking habits, and the parents' own level of education (Supplementary Table S1). Study groups were formed according to those who had used only study pacifiers (group 1), other pacifiers (group 2), or no pacifiers at all (group 3). Information regarding specifically which other pacifiers were used by children was not asked in the questionnaire only asked whether a pacifier had been used or not, and whether it was the study pacifier or another pacifier. In an attempt to reduce the influence of one possible confounder, the groups were matched according to the mothers' level of education in group 1. The matched groups were named groups 4, 5, and 6.

Exclusion criteria

Children excluded from the study were those with craniofacial abnormalities, a history of dental or maxillofacial trauma, one of each pair of twins, if the parent/guardian failed to complete the 2-year questionnaire, or if the child failed to attend the follow-up at 7 years.

Outcomes

The main outcome of the present study was a posterior crossbite. Additional outcomes were overjet, overbite, and crowding, use, and duration of use of pacifier/digit sucking habits (study pacifier or other pacifier) (Fig. 3).

Confounder

Larsson has suggested a relationship between the education of parents and non-nutritive sucking habits [21] therefore the level of the mother's education was asked in the questionnaire and incorporated in the analysis.

Sample size calculation

To obtain statistical significance the effect size was assessed so that the proportion of posterior crossbites should decrease from an average of 15% to 4 % [17]. The present sample size analysis was done using the Newcombe-Wilson Hybrid Score [22].

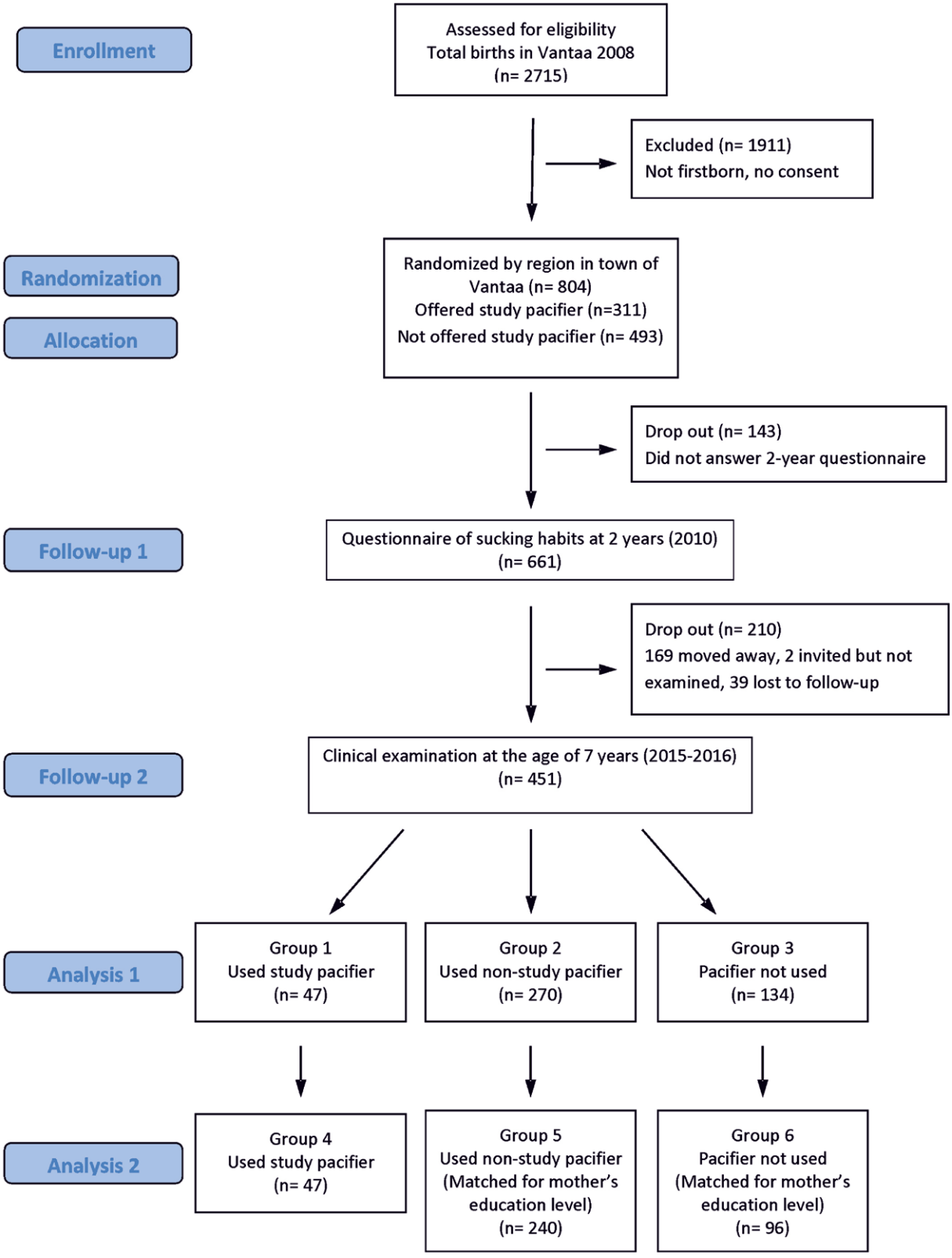

Figure 1. Participant flow.

Clinical examinations

Practically all children were examined by dentists during the first year of school (7 years of age). Findings were recorded in the electric patient database. Overjet, the horizontal distance between upper and lower incisors, was recorded from the most protruding maxillary central incisor. Overbite, the overlap of lower incisors by the upper incisors, which is negative in open bite, was recorded. Both overjet and overbite were recorded in millimeters. Transverse relations (posterior crossbite, scissor bite), anterior crossbite, and crowding were recorded in the

Figure 2. DentoBon study pacifiers.

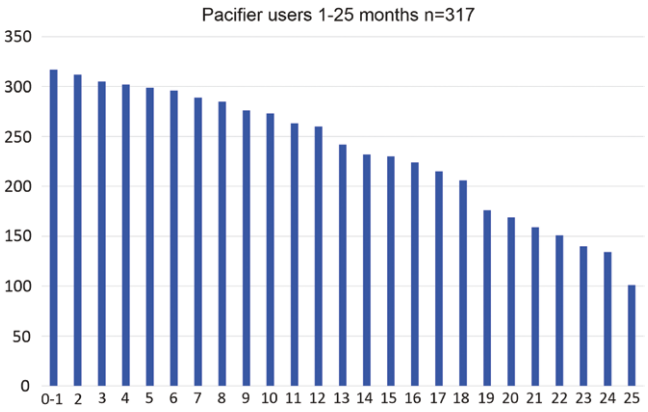

Figure 3. Pacifier usage over time. Parent-reporting at the child's age of 2 years.

patient records. Posterior crossbite was recorded if all molars (deciduous and permanent) on one side were involved and anterior crossbite if at least one tooth was involved.

Questionnaire

In the 2-year questionnaire, parents/guardians were asked about the child's oral health, sucking habits, and the parents' own level of education [20]. The questions of oral health concerned the frequency of brushing teeth and having meals, as well as the use of fluoride, xylitol, or probiotic products. Questions were asked about the child's sucking habits, breastfeeding, the use of feeding bottle, pacifier, digit sucking, or other sucking habits were inquired. The choice of parents' education category were basic, vocational, secondary school graduation, college, or university education. Parents' age and the age and number of other children living in the same household were also inquired. The questionnaire was validated in a pilot study [20].

Randomization method

The study population was divided according to geographical district: Northern Vantaa (District F), Southern Vantaa (District X), and the Central Vantaa (District C). Residents in these three districts had similar socio-economic levels. They were randomly allocated into the 3 study districts by the drawing lots by a blinded assessor. Parents in District F, Northern Vantaa were offered the study pacifier. In total 311 subjects were offered the study pacifier and 493 were not offered the study pacifier (Fig. 1). The parents answered the questionnaire when their child was 2 years old. Only after the questionnaires had been completed was it possible to construct the three study groups according to reported pacifier use: group 1 (intervention with study pacifier), group 2 (Control, child used another pacifier), and group 3 (Control, no pacifier used).

Data handling and blinding

The children who had moved away from Vantaa before school age, those who had not answered 2-year questionnaire, and those who did not attend the 7-year examination, were excluded. The level of mother's education was dichotomized as lower (basic, vocational, or high school) and advanced (college or university), the length of using pacifiers was dichotomized as 0-11 months and 12–33 months, and digit-sucking was dichotomized as 1–6 months and at least 12 months. The exclusive use of the study pacifier only was recorded as 1 (group 1), the use of pacifiers other than the study pacifier as 2 (group 2), and no pacifiers used as 0 (group 3). Those who tried the study pacifier for some time but changed to use other pacifiers were also recorded as 2 (other pacifiers). The children in group 2 were selected according to the questionnaire, from all districts. The information of the 7-year-old dental examinations was searched individually from the children's electric patient records by two authors (I.A. and K.H.) and added to the data of the original study. Posterior crossbite and anterior crossbite were recorded if those were mentioned in the written patient records. An overjet of 4 mm or more was classified as increased and an overbite of 4 mm or more was classified as a deep bite. The dental arch was classified as crowded or the bite as open if those were mentioned in the written patient records.

It was not possible to blind the clinicians or parents from the intervention. Blinding during data analysis was performed.

Statistical methods

The effects of the study pacifier, other pacifiers, or no pacifiers at all (group 1 study pacifier, group 2 nonstudy pacifier and group 3 no pacifier) were analyzed by cross-tabulating the reported use of them with malocclusions. The associations between the groups matched for the mother's level of education (group 4 study pacifier matched, group 5 nonstudy pacifier matched, group 6 no pacifier matched) were analyzed by cross-tabulating them with malocclusions posterior crossbite, anterior crossbite, increased overjet, deep bite, open bite, and crowding. The tests used were Pearson Chi-Square. Fisher's exact test, and Likelihood Ratio.

The main outcome of the present study, the posterior cross bite was analyzed using multivariable logistic regression analysis with manual backward elimination. The initial statistical model included the use of pacifiers (for 0–11 or 12–33 months), the use of a sucking bottle (for 0–11 or 12–33 months), digit sucking (for 0–6 or at least 12 months), breastfeeding (for 0-11 or 12–24 months), and the level of mother's education (lower or advanced), as independent variables, and their first order interactions. Independent variables for which

the regression coefficient did not reach statistical significance were eliminated one by one if the regression coefficient did not reach statistical significance and eliminating them did not worsen the model fit. The statistical software used was PASW Statistics 20.0 and the level of statistical significance was set at $P < .05$.

Intention to treat analysis

This study was planned 2006/2007 and started 2008. At that time, intention-to-treat analyses (ITT) were not commonplace. The subjects were treated, that is given oral health counseling, in each study district as it was intended in the study plan. If subjects moved away from the original study district or from the city of Vantaa, they were dropped out of the study as is prone to happen in long-term studies [20]. Since the data from time points after exclusion were not available, a per-protocol analysis was used [23]. In the first analysis of the present study, all groups of the previous studies were joined, and the analysis was based on both the questionnaires of oral habits at the age of 2 years and oral examinations at the age of 7 years. The intervention was to voluntarily order study pacifiers from birth to 2 years of age in one study area (Group 1), which is not considered equal to treatment. In this case, the data was analyzed according to those who reported that they had received the intervention assigned by the protocol. In the second analysis of the present study, the subjects, who had reported having used study pacifiers with intention to use them were analyzed. All other subjects were analyzed based on their reported pacifier usage of other kinds of pacifier or no pacifier at all. In this analysis, the per protocol analysis was also used, so to reduce bias and increase transparency, the protocol was not changed throughout the whole study.

Results

Participant flow and subject numbers

A total of 2715 births in Vantaa, Finland in 2008 were assessed for eligibility. From this, the study cohort consisted of 804 firstborn children whose parents had given consent. Study pacifiers were offered to the parents of 311 children. Parents of 56 children ordered the test pacifier with the intention to use it. From the initial study cohort of 804 children, during their first school year (2015–2016), 451 children (230 males and 221 females) underwent dental examination. At the 7 year examination, 36 children were already receiving orthodontic treatment. Groups for analysis 1 were: 1 (study pacifier) consisted of 47 children, group 2 (nonstudy pacifier) 270 children, and group 3 (no pacifier) 134 children.

After matching groups 2 and 3 to the mother's educational level in group 1 the following groups for analysis 2 resulted: group 4 (study pacifier) consisted of 47, group 5 (nonstudy pacifier, matched for mother's educational level) 240 subjects, and group 6 (no pacifier, matched for mother's educational level) 96 subjects (Fig. 1).

Outcomes

Non-nutritive sucking habits (Questionnaire at 2 years of age)

From 451 participants, 317 children reported using a pacifier (47 children (11%) used the study pacifier only; 270 children (60%) used other, nonstudy pacifiers). A total of 134 children (30%), 65 males and 69 females, reported not to have used any pacifiers. The parents reported that 260 (58%) children used the pacifier at 12 months, and 134 (30%) children up to the age of two years (Fig. 3).

Effect of pacifier sucking habits on malocclusion at 7 years

The prevalence of posterior crossbite in children whose parents reported them to have used study pacifiers, nonstudy pacifiers, or no pacifiers at all, between 0 and 2 years of age, was 4%, 7%, and 1%, respectively ($P = 0029$) (Table 1). The statistical significance was $P = .002$ when comparing children, who had used no pacifier with those who had used nonstudy pacifiers (group 2 vs 3), but in comparison between those who had used study pacifiers and those who had used nonstudy pacifiers, the result did not reach statistical significance ($P = .510$) (group 1 vs 2). Interestingly, there was no statistical difference between the use of the study pacifier and not using a pacifier ($P = 0.136$). Results for malocclusions other than posterior crossbite did not reach statistical significance.

Effect of duration of pacifier use on malocclusion at 7 years

The prevalence of posterior cross bite and the duration of a pacifier habit had a positive correlation; if any kind of pacifier was used for 12 months or more. The prevalence of posterior cross bite was increased to 7% compared to 1% for less than 11 months ($P = .003$) (Table 2). Anterior cross bite was slightly less prevalent with a longer duration of pacifier habit, yet the result did not reach statistical significance (Table 2). In the multivariable logistic regression analysis on the posterior crossbite, the final model included only the use of pacifiers as an independent variable. Based on these results, the crossbite was more common if the child had used a pacifier for more than 11 months (R2 = 0.087, OR 6.77, and $P = .013$).

Effect of digit sucking on malocclusion at 7 years

The length of digit sucking for at least 12 months was found to increase the prevalence of crowding compared to digit sucking for less than 6 months, 36% and 16%, respectively ($P = 0.016$) (Table 3). Together with an increase in crowding at 7 years, overjet, deep bite, and open bite were all increased with a longer digit-sucking habit but did not reach statistical significance (Table 3).

Matching the study groups for the mother's level of education

In group 1, the proportion of children with mothers' with lower levels of education was 38.3% ($n = 18$) and advanced 61.7% ($n = 29$). Groups 2 and 3 were matched according to these proportions resulting in 240 participants in group 2, and 96 participants in group 3 (Fig. 1).

The prevalence of malocclusions between study groups matched the mother's level of education

The proportions of different malocclusions were compared between the children in groups that were equally matched regarding their mother's level of education (Table 4). The prevalence of posterior crossbite was 4%, 6%, and 1% in groups 4 (study pacifier), 5 (non-study pacifier), and 6 (no pacifier), respectively, ($P = .093$). Statistical significance was found comparing groups 5 (6%) and 6 (1%) ($P = .029$), but if the prevalence was compared between those who had used study pacifiers (group 4) and those who had used nonstudy pacifiers (group 5) the result did not reach statistical significance ($P = .656$) (group 4 vs 5). Similar to the unmatched

Table 1. The prevalence of malocclusions among 7-year-old children, whose parents reported them to have used the study pacifier, a non-study-pacifier, or no pacifier between the ages of 0 and 2 years.

	Group 1 study pacifier %	Group 2 non-study pacifier* %	Group 3 no pacifier %	*P*	*P* Group 1 vs 3	*P* Group 2 vs 3	*P* Group 1 vs 2
n	47	270	134				
Posterior cross bite	4	7	1	***.029***[2]	.136	***.002***	.510
Anterior cross bite	0	4	5	.155[1]	.055	.710	.071
Increased overjet	11	13	12	.926[2]			
Deep bite	19	19	22	.702[2]			
Open bite	0	0	2	.354[1]			
Crowding	17	16	20	.513[1]			

Analyzed using likelihood ratio chi-square[1] and Pearson chi-square[2].
*Including also those who tried the test pacifier for some time but changed to using other pacifiers.
Italic font indicates significance of .05.

data, there was no statistical difference between the use of the study pacifier and not using a pacifier ($P = .227$) (group 1 vs 3). Results for malocclusions other than posterior crossbite did not reach statistical significance. The prevalence of anterior crossbite was highest in group 6, but the result did not reach statistical significance either ($P = .084$) (Table 4).

Harms

No adverse harms were reported during the present study.

Discussion

Effects of orthodontic pacifiers versus conventional pacifiers

In this randomized controlled trial, which started at birth (prior to tooth eruption) and continued until participants were in the mixed dentition stage, we found that the prevalence of crossbite in the study pacifier group was less than in other pacifiers but that this was not statistically significant (4% vs 7%) ($P = .656$). This result was similar whether adjusted for the mother's level of education or not. However, the use of nonstudy pacifiers was associated with crossbite ($P = .002$) and interestingly the use of the study pacifier showed no statistical difference from not using a pacifier ($P = .227$). Systematic reviews comparing the effects of conventional and orthodontic pacifiers on the developing dentition have not been able to draw conclusions on the occlusal effects of different types of pacifiers [24, 25]. However, only a small number of studies have been included in these reviews. In the Medeiros review, three studies that assessed children in the primary dentition (24–60 months) were identified as being at moderate risk of bias: two cross-sectional and 1 cohort study, and these were analyzed further [25]. This risk of bias was attributed to the uncertainty of the sample randomization technique as they were all samples of convenience and open to selection bias [26–28]. In relation to confounding factors, the authors of these studies excluded: children with other NNSHs; mouth breathers, and children with a lingual interposition. Adair et al. found a reduction of anterior open bite prevalence in the orthodontic pacifier group [26],. Both del Zardetto et al. and Lima et al. found a reduction of anterior overjet, and posterior cross-bite prevalence in the orthodontic pacifier sample [27, 28]. Lima et al. detected a significant difference in orthodontic and conventional pacifiers with respect to anterior open bite ($P = .027$) and posterior crossbite ($P = .040$) [28]. However, these findings should be treated with caution as sample sizes were relatively small and the duration of use was slightly longer in the conventional pacifier groups.

Table 2. The prevalence of malocclusions among seven-year-old children, whose parents reported them to have used pacifiers for 0–11 months or 12 months or more.

Pacifier ($n = 451$)	0–11 months *n*/ %	12 months + *n*/ %	*P*
n	191	260	
Posterior cross bite	2/ 1	19/ 7	***.003***
Anterior cross bite	9/ 5	7/ 3	0.270
Increased overjet	23/ 12	33/ 13	0.855
Deep bite	37/ 19	54/ 21	0.766
Open bite	2/ 1	1/ 0	0.999[1]
Crowding	36/ 19	42/ 16	0.531

Analyzed using Fisher's exact test[1] and Pearson Chi-Square[2].
Italic font indicates significance of .05.

Impact of pacifier use duration on malocclusion development

We found that the use of a pacifier for 12 months or longer increased the risk of posterior cross-bite. This is in line with several previous studies reviewed systematically by Dogramaci and Rossi-Fedele in 2016 [10]. That said, most of the studies looking into the relation between pacifier use and malocclusion have been cross-sectional surveys not longitudinal, with relatively few being prospective in design. Of note were the investigations by Larsson (1975) and by Duncan et al (2008) which were large sample, longitudinal studies from birth until 4 years and 5 years of age, respectively [9, 21]. Both these

studies examined children in the primary dentition and concluded that persistent pacifier use was associated with anterior open bite, and posterior cross-bite. Larsson found that the prevalence of posterior cross bite was five times higher in pacifier users compared to those with no previous sucking-habit. In addition, Duncan et al. also found an association between pacifier use with a lack of spacing in upper labial segments at several observation time points [9].

Long-term prospective studies, similar to the current study, which investigate the effects of pacifier use on the mixed dentition or permanent dentition are rare. Interestingly, in the longest prospective, longitudinal study from birth to 16 years of age, it was not been possible to establish a significant correlation between previous pacifier use and the development of crossbite in the permanent dentition [29].

In a large sample prospective, longitudinal study from birth to 8 years of age, prolonged pacifier use (≥ 48 months) was associated with anterior open bite ($P = .004$) and Class II molar relationships ($P = .017$) [8]. It should be noted that the sample of children using a pacifier at ≥48 months was small, only 13 out of 444 children. In the current study, the anterior open bite was only observed in one subject. However, the prevalence of posterior crossbite was higher in the pacifier group ($P = .003$) and this prevalence increased if the pacifier habit had continued for 12 months or more compared to 11 months or less, 7% and 1%, respectively, ($P = .003$). In the Warren study, the percentage of children with posterior crossbite increased with increased duration of use (<24 months v s≥48 months) from 9% to 23% but did not reach statistical significance ($P = .266$) [8].

What should also be noted in the Warren study is that all children who had started or completed orthodontic treatment, $n = 28$ of the original sample of 580 children, were excluded from the analysis [8]. Exclusion clearly may affect the results as some of the malocclusions that were treated may have resulted from pacifier usage. In addition, during treatment sessions advice may have been given to stop non-nutritive sucking habits. Strictly applied, children who had orthodontic treatment were not excluded from the current study. However, if a child had a clear malocclusion and treatment need, an occlusal assessment for the current study was performed prior to treatment.

Differences in the results of the current study and Warren et al. can be attributable to several factors. Warren et al. studied the development of malocclusion in children with prolonged pacifier use (<36 months vs ≥48 months), they did not compare the prevalence of malocclusion in a pacifier use group vs no NNSH control group, with only 7% of the sample reporting no or short duration NNSH [8].

Factors that may affect results may include the environmental setting, the study time period (1991 vs 2008), and the location (Iowa, USA vs Vantaa, Finland). One confounder, i.e. variable that may influence both the exposure (NNSH) and the outcome of interest (malocclusion) is the education level of the parents [21]. Interestingly, we found that the prevalence of malocclusions studied was similar whether the level of mother's education was taken into account or not (Table 1 compared to Table 4).

Seventy percent of the children in the present study had used pacifiers, but at the age of 2 years, the habit had decreased to 24%. This finding is less than in previous studies. Duncan found in her study that 35% of children were still using pacifiers at

Table 3. The prevalence of malocclusions among seven-year-old children, whose parents reported them not digit sucking or sucking for up to 6 months compared to sucking digit for 12 months or more.

Sample total $n = 447$	Non digit sucking plus + digit sucking for ≤ 6 months %	Digit sucking for 12 months + %	*P*
n	422	25	
Posterior crossbite	5	4	0.999[1]
Anterior crossbite	4	4	0.909[1]
Increased overjet	12	20	0.245[2]
Deep bite	19	32	0.128[2]
Open bite	1	4	0.137[1]
Crowding	16	36	***0.016***[2]

Analyzed using likelihood ratio[1] and Pearson chi-square[2].

Table 4. The prevalence of malocclusions among 7-year-old children, whose parents reported them to have used study pacifiers, non-study pacifiers, or used no pacifier at the age of 0–2 years. The groups were equally matched regarding their mother's level of education.

	Group 4 Study pacifier matched %	Group 5 Non-study pacifier matched %	Group 6 No pacifier matched %	*P*	*P*: Group 4 vs 6	*P*: Group 5 vs 6	*P*: Group 4 vs 5
n	47	240	96				
Posterior cross bite	4	6	1	.093[1]	.227	.029	.656
Anterior cross bite	0	4	6	.084[1]	.027	.331	.070
Increased overjet	11	13	13	.911[2]			
Deep bite	19	20	20	.996[2]			
Open bite	0	0	1	.627[1]			
Crowding	17	16	20	.689[2]			

Analysed using likelihood ratio chi-square[1] and Pearson chi-square[2].

the age of two [9]. Bishara et al. found out that 25% of the 2-year-old children were pacifier users in their longitudinal study of sucking habits [30]. And Paunio found that 23% of the 3-year-old Finnish children of her study used pacifiers [7].

Influence of digit sucking on the occlusion

According to the questionnaire data from the present study, parents reported that 4.6% of their 2-year-old children had a digit-sucking habit. This was similar to previous Finnish studies which reported relatively prevalence of digit sucking of 6.8% at 2 years and 7.2% at 3 years in 1969, and 1.7% among 3-year-olds in 1989 [2, 7]. However, there is a marked difference from other studies elsewhere in the world which have reported that 20%–21% of children have a digit-sucking habit at 2 years [9, 30]. Interestingly Bishara et al. reported that the prevalence of digit suckers was still 4% at the age of eight years [30].

The acceptance of non-nutritive sucking habits may have differences between cultures and the awareness of the adverse effects of occlusion vary. Clearly, there are many psychological and social factors which might influence non-nutritive sucking habits. Of note, is the comprehensive system of postnatal infant and mother health checks that are carried out under the universal health care system, which is free of charge. During these health checks, non-nutritive sucking habits are actively discouraged at the age of approximately 1 year. As it is by dental professionals during population dental health screening which starts at the age of 1 year. However, these factors are not the sole influence. Interestingly, the prevalence and duration of non-nutritive sucking habits in neighboring Sweden, which has similarities in having a public health care system, have been reported to be higher than those found in this study and also to have increased over the past decades [31–34].

Bishara et al. in their longitudinal study of non-nutritive sucking habits; concluded that the habit of digit sucking should be changed for a pacifier as early as possible, and then pacifier use subsequently reduced [30]. However, there are researchers that have a differing opinion and state that pacifiers have more profound effects on the occlusion of children than digit sucking [9].

Limitations of the study

The subjects were examined by several dentists, who were working in Vantaa Public Dental Service, and thus the data on occlusal features was collected afterwards from dental records. Ideally, dental examinations could have been conducted by one or two researchers after inter-examiner calibration, or alternatively, the occlusal features could have been studied from dental casts. The original study plan included a dental hygienist's visit where occlusal records, including impressions for dental casts, would have been taken. However, this visit could not be carried out due to limited resources. The dental examinations in the present study were conducted at about 7 years of age that is to say in the late deciduous or early mixed dentition stage. Some malocclusions identified at this age might still self-correct and thus it may be too early to evaluate orthodontic treatment needs.

Apart from sucking habits, other possible etiological factors or anatomical findings including abnormal orofacial functions which could contribute to malocclusion were not considered in this study. Upper airway obstruction and a mouth-breathing habit has been associated with various malocclusions and this may be a confounding factor in our results [35, 36]. The adenotonsillar status, history of adenotonsillectomy, and breathing pattern of our study subjects were not assessed and were not taken into account in the study design and analysis and this can be regarded as a limitation.

Strengths of the study

This study raises the level of evidence when compared to many previous studies. This prospective, randomized controlled trial has a large sample, and as this population-based screening including all firstborns in a town is utilized, selection bias is kept to a minimum.

Generalizability

The study was performed by population screening in the public dental service. In Finland, most dentistry for children is provided for in the public sector. Results may be transferable to other similar clinical settings.

Conclusions

In this study:

We found that the use of pacifiers, including the study pacifier, is associated with a higher incidence of posterior crossbite at the age of 7 years.

The prevalence of crossbite in the study pacifier group was less than in other pacifiers but this was not statistically significant (4% vs 7%) ($P = .656$).

The risk of developing a posterior cross bite is higher if the pacifier use continues for a year or more after birth.

To avoid the development of posterior crossbite and its possible need for treatment, the cessation of pacifier use after the age of one year can be recommended.

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Conflict of interest

The study pacifier (DentoBon) was designed at the University of Turku.

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Data availability

The data underlying this article may be shared on a reasonable request to the corresponding author.

Supplementary data

Supplementary material is available at *European Journal of Orthodontics* online.

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