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Effect of a thin-neck pacifier on primary dentition: a randomized controlled trial

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Structured Abstract

Objectives – To evaluate changes in occlusal characteristics in the primary dentition that occur after introducing a thin-neck pacifier (TNP) to children with previously diagnosed pacifier-associated anterior open bite (AOB) and increased overjet.

Setting and Sample Population – Department of Preventive and Pediatric Dentistry, Jena University Hospital, Germany. Subjects were 86 children (mean age 20.3 months) with a pacifier-associated open bite or overjet ≥2 mm.

Material & Methods – Randomized controlled trial. Subjects were randomly assigned: group I (n = 28), intervention group using a TNP; group II (n = 30), control group, using a conventional or physiological pacifier; and group III (n = 28), intervention group, Gold standard, weaned off pacifier. Participants were re-examined after 3, 6, 9 and 12 months by an operator, blinded for the treatment.

Results – After 12 months data for 63 children (mean age 33.1 months) were analyzed (I: n = 24; II: n = 22; III: n = 17). There was a significant difference between the groups regarding mean overjet (group I: 2.7 ± 0.5 mm, group II: 3.2 ± 0.7 mm, group III: 2.4 ± 0.5 mm, Kruskal–Wallis, $p = 0.002$) and AOB (group I: −1.2 ± 0.3 mm, group II: −2.2 ± 0.3 mm, group III: −0.8 ± 0.8 mm, Kruskal–Wallis, $p < 0.001$). The differences between group I and II regarding increased overjet (3.1 ± 0.2 mm vs. 3.6 ± 0.3 mm, Mann–Whitney, $p < 0.001$) and extent of AOB (−1.2 ± 0.3 mm vs. −2.2 ± 0.3 mm, Mann–Whitney, $p < 0.001$) were statistically significant.

Conclusion – Use of TNP resulted in better clinical measurements for in overjet and overbite compared with the continuing use of conventional or physiological pacifiers.

Key words: child; malocclusion; open bite; overbite; pacifiers; preschool

Introduction

Nonnutritive sucking (NNS) is common and the prevalence of NNS in children varies from 60 to more than 80% (1, 2). A pacifier is used for comforting; as a sleeping aid; and to ameliorate uncomfortable, stressful or painful episodes (3–5). Use of a pacifier is considered socially normal in most cultures, and weaning may be difficult (1, 5). Ideally, NNS habits should be discontinued by 24–36 months of age to reduce the risk of developing malocclusion (4, 6). Nevertheless, more than twenty per cent of children that are 3 years and older continue this behavior (1).

Numerous studies have examined the effects of NNS habits on occlusal characteristics and found that NNS beyond age 3 may have detrimental consequences for dento- and maxillofacial development (1–15). Anterior open bite (AOB), increased overjet, posterior crossbite, narrow intercuspid width of the maxillary arch and a high narrow palate are the most notable changes in the developing dentition (5–15). Studies have also shown when NNS habits are stopped spontaneous resolution may occur (1, 12, 14–18). AOB tends to resolve, while posterior crossbite and increased overjet tend to persist after the cessation of the pacifier habit (1, 12, 14–18). The majority of children who use a pacifier beyond age 3 have a malocclusion (18, 19). Seventy-seven per cent of children with pacifier habits during 48 months or more had a malocclusion (19).

Two types of pacifiers are commercially available: physiological (also known as orthodontic) pacifiers and conventional ones. With the exception of one study (20), comparisons between these pacifiers have shown no significant advantages of physiological over conventional pacifiers with respect to development of AOB, increased overjet or reduced maxillary arch width (19–27). Longitudinal studies examining impact on dental development of these pacifiers are lacking. To date, only one longitudinal study has reported on the development of AOB with use of a newly designed physiological pacifier; the study population was a group of 121 children aged 16 months (20). The physiological pacifier exhibited advantages over the conventional model; the use of the pacifier resulted in a lower incidence of open bites (20).

In 2009, a pacifier was developed with a unique design: an extra thin and soft neck (MAM Perfect, Bamed AG, Wollerau, Switzerland) (Fig. 1). To date, there has been no longitudinal *in vivo* study investigating the effects of a TNP on dental development. Therefore, the aim of this study was to compare changes in occlusal characteristics in the primary dentition that occur after introducing a TNP to children with previously diagnosed AOB and increased overjet and those using a conventional or physiological pacifier or those weaned off a pacifier. The working hypothesis was that changing to a TNP would reduce pacifier-associated malocclusions in the primary dentition.

Materials and methods

Trial design

This was a prospective, parallel-assigned, randomized controlled trial with an equal allocation ratio (German Clinical Trials Register DRKS 00003533). The Ethics Committee of Jena University Hospital approved this study (3441-05/12). The study was conducted with informed consent of all parents and in full accordance with the ethical requirements of the World Medical Association Declaration of Helsinki (2008). The study also followed the principles of the CONSORT statement.

Participants

All new patients (n = 106) attending the Department of Preventive and Paediatric Dentistry at

Fig. 1. Front view and side view of the thin-neck pacifier (MAM Perfect).

Jena University Hospital in Germany for routine dental examinations between May 2012 and January 2014 were assessed for eligibility. The inclusion criteria were provision of written consent by the parents, age 16–24 months with previously diagnosed pacifier-associated AOB or increased overjet (AOB ≤0 mm and/or overjet ≥2 mm), current use of a pacifier, availability of data related to dental examinations and completed pacifier-usage questionnaire. According to the criteria of Foster et Hamilton (28) a measurement of ≥2 mm was considered as increased overjet (28). Exclusion criteria were lack of written consent; age above or below the acceptable range; congenital, genetic or trauma-related maldevelopment; preterm birth; dental caries or fillings; mouth breathing; thumb or finger sucking; use of a baby bottle for longer than 15 months and incomplete data. Eighty-six children with a mean age of 20.3 months met the inclusion criteria. They were randomly assigned to three groups: group I (intervention) switched to a TNP (n = 28), group II (control) (n = 30) continued to use their initial pacifier (conventional or physiological) and group III (intervention, Gold standard) were to be weaned off the pacifier during the study period (n = 28). No incentives were offered.

Group allocation was performed by a research assistant not involved in the study using prepared, sequentially numbered, opaque sealed envelopes containing group numbers. The SAS 9.2 computer program (SAS Software Institute, Cary, NC, USA) was used to generate a random allocation sequence (parallel assignment, equal allocation ratio, block randomization: block length 6, random seed 5834935). Randomization and statistical analysis of the study were carried out in collaboration with the Institute of Medical Statistics, Informatics and Documentation, Jena University Hospital.

Children were excluded from the final analysis if they did not follow the study regimen (e.g., if they switched to another pacifier or started sucking their thumb). In group III, only children who were successfully weaned off their pacifier during the study period were included in the final analysis. Cessation of pacifier use for at least 3 months was considered successful weaning.

Interventions

All parents received study instructions. To ensure that lost pacifiers in group I could be replaced immediately, parents received sufficient replacements of the experimental pacifier. Parents were instructed on completion of a diary of pacifier usage time to record the approximate hours of pacifier use by the child. Parents in group III were given guidance on how to wean their child off the pacifier. For example, a slow, gentle weaning process vs. stopping immediately; restricting the pacifier to certain times or certain places; take or give it away or lose it; or leave it for the binky fairy. It has to be mentioned that all parents received the same guidance to assist their child in ceasing the habit independently of their group allocation.

After 3, 6, 9 and 12 months, the children were re-examined by two calibrated dentists, one of them was blinded for the treatment. Participants, parents and one calibrated dentist were aware of the treatment intervention. Data analysis was conducted by the blinded dentist. The dentists had been trained and calibrated following WHO guidelines (29). Each examiner first practised the examination on a group of ten subjects. Afterwards, every examiner independently examined the same group of 20 pre-selected subjects to assess the consistency. All measurements were rechecked for accuracy. The intraclass correlation coefficients for intraobserver agreement regarding the measurements of overbite and overjet were 0.87–0.89. The intraclass correlation coefficients for interobserver reliability with regard to the measurements of overbite and overjet were 0.86–0.88. The average measuring difference between the dentists was 0.1 mm.

Examinations were conducted using a dental light, mirror and sterile gauze for removing debris and drying the teeth, and with the child sitting on their parent's lap in an upright position in a dental chair so that the Frankfort horizontal plane was parallel to the floor. No radiographs were taken. Sagittal and vertical measurements

were made with a vernier caliper (Münchner Modell 042-751-00, Germany) with an accuracy of 0.1 mm. Registration of the occlusal characteristics was carried out according to the principles developed by the Federation Dentaire Internationale (30). All measurements were rechecked for accuracy. The following occlusal parameters were recorded:

1. Overjet in millimeters between two antagonistic anterior teeth (lateral or central incisor) measured from the buccal surface of the most lingual mandibular tooth to the middle of the incisal edge of a more buccally positioned maxillary tooth.
2. Overbite, measured in millimeters and recorded as overlap of mandibular anterior teeth by maxillary anterior teeth. A pencil mark on the tooth (central mandibular incisor) indicating the extent of the overlap facilitated the measurement. Overbite was recorded as degree of overbite, recorded as per cent overlap of the mandibular incisors crown:
   - $\leq \frac{1}{3}$ one-third covering of lower incisors
   - $\frac{1}{3}$ to $\frac{2}{3}$ between one-third and two-thirds covering
   - $> \frac{2}{3}$ more than two-thirds covering
3. Open bite, when present, measured in millimeters between the incisal edges of maxillary and mandibular anterior teeth.

Sample size

The sample size calculation was based on a preliminary study with 17 patients using the same methods as in the main study. Primary outcome measure AOB/increased overjet was -1.0 ± 0.2 mm/2.8 ± 0.4 mm in group I and -2.3 ± 0.2 mm/3.1 ± 0.4 mm in group II. To detect the observed difference between groups with a two-tailed significance test, a 5% critical level and a power of 90%, a sample of three children per group were required for the primary outcome AOB and 21 children per group was required for the primary outcome increased overjet (calculated with the nQuery Advisor 7.0 computer program, Statistical Solutions Ltd, Cork, Ireland). The calculated sample size was adapted to at least 28 children per group to allow for dropout.

Statistical analysis

Data were recorded in Excel files and transferred to the Statistical Package for Social Sciences (SPSS version 20, IBM Corporation, Armonk, NY, USA). The data were analyzed using the Mann–Whitney *U*-test (for comparison of two groups), Kruskal–Wallis (for comparison of three groups) and Bonferroni intervals (for the difference between mean values of quantitative variables). A p-value ≤ 0.05 was used to indicate statistically significant differences.

Results

A total of 106 children met the inclusion criteria and 86 (81.1%) of them participated in the study (Fig. 2). Figure 2 is presenting the participant flow diagram for the entire study population. Eighty-six patients (mean age 20.3 ± 2.4 months, 48 males) were randomly assigned to three groups: 28 children in group I (TNP, intervention group), 30 in group II (initial pacifier, control group) and 28 in group III (weaning off, intervention group, Gold standard). Twelve children were lost to follow up due to relocation, non-appearance or start of thumbsucking. Seventy-four children were invited for the final examination. Eleven children were excluded from the final analysis due to dental trauma, mouth-breathing, and no weaning off. Ultimately, 63 subjects (mean age 33.1 ± 5.0 months, 40 males) met the inclusion criteria (group I: n = 24; group II: n = 22; group III: n = 17). None of the children in groups I and II had ceased the habit for longer than 3 months.

Baseline patient characteristics

Descriptions of all children according to group at baseline are presented in Table 1. All patients were drawn from the same population. There were no baseline differences between groups

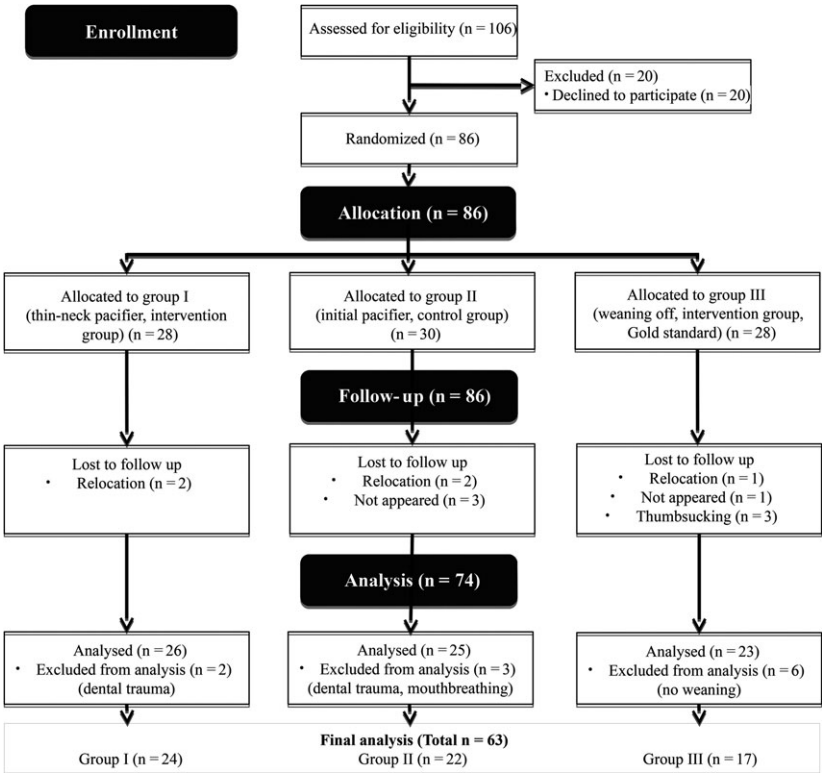

Fig. 2. Participant flow diagram for the entire study population.

regarding age, number of teeth, diet, pacifier type, duration and frequency of pacifier use, or occlusal characteristics (Kruskal–Wallis test, $p > 0.05$). Most of the children (82.0%) started the use of the pacifier in their first month of life. All children had an intense pacifier use throughout the day and night and engaged in the habit for more than 8 h a day.

Dental measurements at follow-up

Descriptions of all children according to group at the final examination are presented in Table 2. There were no differences between groups regarding age, gender, and number of teeth (Kruskal–Wallis test, $p > 0.05$). The total duration of pacifier use was lower in group III, who had ceased the habit (Kruskal–Wallis, $p = 0.010$). The differences between group I and II regarding duration of pacifier use and average pacifier use time were not statistically significant (Mann–Whitney *U*-test, $p_{Duration} = 0.712$, $p_{Time} = 0.613$). There was a statistically significant difference between the three groups regarding mean overjet (Kruskal–Wallis, $p = 0.002$) and mean overbite (Kruskal–Wallis, $p = 0.031$). Bonferroni reliance intervals demonstrated a statistically significant difference (overjet and overbite) between those who used a conventional or physiological pacifier (group II) and those who had been weaned off their pacifier or used TNP. The difference between the three groups regarding the prevalence of AOB, the prevalence of overjet ≥2 mm, or the prevalence of overjet ≥3 mm was not statistically significant (Kruskal–Wallis test, $p > 0.05$).

Change in dental measurements

Table 3 presents a comparison of the baseline and final outcome data of all groups regarding AOB, overjet ≥2 mm and overjet ≥3 mm. In group I, the only significant change in measurement between baseline and follow-up was the mean overjet ≥2 mm (Mann–Whitney *U*-test, $p = 0.001$). In group II, there was strong evidence to indicate a change in all measurements from baseline to final follow-up, with exception of AOB prevalence. In group III, there was strong evidence for a change from baseline to final follow-up in mean overjet ≥3 mm (Mann–Whitney *U*-test, $p = 0.002$), but little evidence of a change for other measurements.

Table 1. **Description of all participating children according to group at baseline**

	Group I (TNP) (thin-neck pacifier, intervention group)	Group II (initial pacifier, control group)	Group III (weaning off, intervention group, Gold standard)	Kruskal–Wallis *p*-value
N	28	30	28	
Male N (%)	14 (50.0)	17 (56.7)	17 (60.7)	0.720
Mean age ± SD (months)	20.8 ± 2.7	20.1 ± 2.1	20.1 ± 2.4	0.586
Mean number of teeth ± SD	15.2 ± 1.8	14.9 ± 1.8	15.0 ± 2.0	0.509
Diet N (%)				
Breastfeeding N (%)	19 (67.9)	26 (86.7)	20 (71.4)	0.209
Up to age (years)	0.8 ± 0.2	0.8 ± 0.2	0.8 ± 0.2	0.966
Bottle feeding N (%)	7 (25.0)	4 (13.3)	7 (25.0)	0.452
Up to age (years)	0.9 ± 0.2	1.0 ± 0.0	1.0 ± 0.2	0.368
Drink learn cup N (%)	18 (64.3)	14 (46.7)	12 (42.9)	0.233
From age (years)	0.7 ± 0.2	0.6 ± 0.2	0.8 ± 0.2	0.175
Cup N (%)	28 (100.0)	30 (100.0)	28 (100.0)	
From age (years)	1.0 ± 0.2	1.0 ± 0.2	0.9 ± 0.2	0.486
Pacifier type N (%)				
Physiological	22 (78.6)	20 (66.7)	20 (71.4)	0.601
Conventional	6 (21.4)	10 (33.3)	8 (28.6)	0.601
Duration pacifier use (months)	19.5 ± 2.4	19.0 ± 2.0	19.1 ± 2.2	0.368
Mean overjet ± SD (mm)	2.2 ± 0.4	2.1 ± 0.4	2.1 ± 0.5	0.896
Mean overbite ± SD (mm)	0.3 ± 1.3	0.4 ± 1.2	0.4 ± 1.3	0.889
≤⅓ overlap N (%)	13 (46.4)	12 (40.0)	13 (46.4)	0.851
⅓ to ⅔ overlap N (%)	2 (7.2)	4 (13.3)	3 (10.7)	0.745
Anterior open bite N (%)	13 (46.4)	14 (46.7)	12 (42.9)	0.950
Mean overbite ± SD (mm)	−1.0 ± 0.6	−1.0 ± 0.6	−1.0 ± 0.6	0.913
Overjet ≥2 mm N (%)	22 (78.6)	22 (73.3)	21 (75.0)	0.896
Mean overjet ± SD (mm)	2.3 ± 0.5	2.4 ± 0.5	2.4 ± 0.4	0.303
Overjet ≥3 mm N (%)	5 (17.9)	6 (20.0)	4 (14.3)	0.848
Mean overjet ± SD (mm)	3.1 ± 0.2	3.2 ± 0.1	3.2 ± 0.1	0.151

Comparison in final dental measurements between groups

Table 4 shows a comparison of groups regarding malocclusion at final examination. The difference between the groups regarding the prevalence of AOB, the prevalence of overjet ≥2 mm, or the prevalence of overjet ≥3 mm was not statistically significant (Mann–Whitney *U*-test, $p > 0.05$). Differences between groups I and II regarding the extent of malocclusion were statistically significant for the children with an AOB (Mann–Whitney *U*-test, $p < 0.001$), overjet ≥2 mm (Mann–Whitney *U*-test, $p = 0.015$), and overjet ≥3 mm (Mann–Whitney *U*-test, $p < 0.001$). The difference between group I and III was only statistically significant for the children with an overjet ≥2 mm (Mann–Whitney *U*-test, $p = 0.012$) but not for the children with an overjet ≥3 mm (Mann–Whitney *U*-test, $p = 0.277$) or AOB (Mann–Whitney *U*-test, $p = 0.185$). Differences between groups II and III regarding the extent of malocclusion were statistically significant for the children with an AOB (Mann–Whitney *U*-test, $p < 0.001$), overjet ≥2 mm (Mann–Whitney *U*-test, $p < 0.001$), and overjet ≥3 mm (Mann–Whitney *U*-test, $p < 0.001$).

Table 2. **Description of all children according to group at final examination**

	Group I (TNP) (thin-neck pacifier, intervention group)	Group II (initial pacifier, control group)	Group III (weaning off, intervention group, Gold standard)	Kruskal–Wallis *p*-value
N	24	22	17	
Male (%)	14 (58.3)	13 (59.1)	13 (76.5)	0.429
Mean age ± SD (months)	32.9 ± 4.3	32.4 ± 5.0	34.6 ± 5.3	0.260
Mean number of teeth ± SD	19.6 ± 1.3	19.6 ± 1.2	19.8 ± 0.7	0.752
Duration pacifier use (months)	**31.8 ± 4.1***	**31.3 ± 5.0***	28.0 ± 3.7	**0.010**
Frequency pacifier use N (%)				
For sleeping only	1	6	–	
Intermittently during day	13	6	–	
Throughout day and night	0 (0.0)	0 (0.0)	–	
Pacifier use time (hours per day)	**2.2 ± 1.1***	**2.2 ± 0.8***	–	
Mean overjet ± SD (mm)	2.7 ± 0.5	3.2 ± 0.7	2.4 ± 0.5	**0.002**
Mean overbite ± SD (mm)	0.2 ± 1.2	−0.8 ± 1.8	0.5 ± 1.3	**0.031**
≤⅓ overlap N (%)	13 (54.2)	8 (36.4)	7 (41.2)	0.461
⅓ to ⅔ overlap N (%)	1 (4.2)	1 (4.5)	3 (17.6)	0.228
Anterior open bite N (%)	10 (41.7)	13 (59.1)	7 (41.2)	0.461
Overjet ≥2 mm N (%)	21 (87.5)	21 (95.5)	15 (88.2)	0.618
Overjet ≥3 mm N (%)	10 (41.6)	14 (63.6)	6 (35.3)	0.167

Bold values indicate statistically significant, $p<0.05$.
*Comparison group I vs. II, Mann–Whitney *U*-test, $p_{Duration} = 0.712$, $p_{Time} = 0.613$.

Discussion

This study evaluated the impact of a newly designed TNP on pacifier-associated malocclusion. The outcome was that use of the TNP resulted in better clinical measurements regarding overjet and overbite compared to continuing use of conventional or physiological pacifiers but not in comparison to cessation of habit. These observations were supported by a clinical case report showing that changing from a conventional pacifier to a TNP closed a 6-mm AOB within 6 months in a 3-year-old child (31). There are very few contemporary studies comparing occlusions in children who used physiological vs. conventional pacifiers. With the exception of one study (20), no clinically significant differences were found regarding mean overjet, mean overbite, occurrence of AOB or posterior crossbite between physiological and conventional pacifiers (20–23). This study is the first to show advantages of the use of a TNP over a previously used physiological or conventional pacifier with respect to overjet and overbite. It has to be emphasized that even though the observed differences are small they are statistically significant. In addition the differences were noted after only a relatively short time of intervention. However the clinical relevance for the permanent dentition is yet unproven and requires further research. Discrepancies in occlusal characteristics of the primary dentition could lead to similar occlusal problems in permanent dentition (4–6, 32–34).

This study was unique in that children who already had a pacifier-associated malocclusion were recruited. It is important to note that even though the observation period was short, children, who were weaned off their pacifier, had significantly fewer and less severe occlusal alterations than those in the other two groups. These results confirm recent findings that if NNS is stopped by age two to three, spontaneous remission may occur (1, 12, 14–18, 35–38). Therefore,

Table 3. **Comparison of baseline and final data for all groups**

	Baseline examination	Final examination	95% CI	Mann–Whitney *p*-value
Group I (TNP) (thin-neck pacifier, intervention group)				
Anterior open bite N (%)	13 (46.4)	10 (41.7)	−0.24 to 0.33	0.737
Mean overbite ± SD (mm)	−1.0 ± 0.6	−1.2 ± 0.3	−0.07 to 0.47	0.145
Overjet ≥2 mm N (%)	22 (78.6)	21 (87.5)	−0.30 to 0.12	0.406
Mean overjet ± SD (mm)	2.3 ± 0.5	2.8 ± 0.4	−0.76 to −0.25	**0.001**
Overjet ≥3 mm N (%)	5 (17.9)	10 (41.6)	−0.49 to 0.01	0.061
Mean overjet ± SD (mm)	3.1 ± 0.2	3.1 ± 0.2	−0.11 to 0.11	1.0
Group II (initial pacifier, control group)				
Anterior open bite N (%)	14 (46.7)	13 (59.1)	−0.41 to 0.16	0.386
Mean overbite ± SD (mm)	−1.0 ± 0.6	−2.2 ± 0.3	0.92 to 1.48	**0.001**
Overjet ≥2 mm N (%)	22 (73.3)	21 (95.5)	−0.43 to −0.01	**0.038**
Mean overjet ± SD (mm)	2.4 ± 0.5	3.2 ± 0.6	−1.11 to −0.49	**0.001**
Overjet ≥3 mm N (%)	6 (20.0)	14 (63.6)	−0.69 to −0.19	**0.001**
Mean overjet ± SD (mm)	3.2 ± 0.1	3.6 ± 0.3	−0.52 to −0.28	**0.001**
Group III (weaning off, intervention group, Gold standard)				
Anterior open bite N (%)	12 (42.9)	7 (41.2)	−0.30 to 0.33	0.914
Mean overbite ± SD (mm)	−1.0 ± 0.6	−0.8 ± 0.8	−0.62 to 0.22	0.345
Overjet ≥2 mm N (%)	21 (75.0)	15 (88.2)	−0.39 to 0.12	0.293
Mean overjet ± SD (mm)	2.4 ± 0.4	2.4 ± 0.5	−0.27 to 0.27	1.0
Overjet ≥3 mm N (%)	4 (14.3)	6 (35.3)	−0.47 to 0.05	0.105
Mean overjet ± SD (mm)	3.2 ± 0.1	3.1 ± 0.1	0.04 to 0.16	**0.002**

Bold values indicate statistically significant, $p<0.05$.

pediatricians and pediatric dentists recommend stopping pacifier use by age two to three (1, 4–6). The present study showed that weaning off a pacifier is the best treatment option. However, it was also the most difficult option, consistent with findings of other studies (1, 4–7, 16, 23, 24, 38–40). Parents worry that the child will start using their thumb or finger instead. In our study, six children in group III could not be successfully weaned off their pacifier within the examination period, and three children started thumb sucking. Switching from the previously used pacifier to a TNP could be a compromise.

There are some limitations of this study. The first limitation was the procedure for recording pacifier-use time. Earlier studies had shown that, in retrospect, it is difficult for parents to give a precise estimation of hours per day or night (20–23). In our study parents were asked to keep a diary of usage times to approximate the children's pacifier use times. Another limitation of the study pertains to intra-oral measurements in toddlers <3 years of age due to their stage of development and the possible limited cooperation. To ensure comparable measurements and stabilize the toddler, a parent sat in the dental chair with the child in his or her lap. If there were cooperation problems the dental appointment was used to practice and a new date for the examination was set. To reduce sources of bias, all measurements were rechecked for accuracy, and follow-up examinations were verified by an operator, blinded for the group the patient belonged to. Nonetheless, the measurements might have been more accurate if we had impressions and photographs.

This study evaluated changes in occlusal characteristics in the primary dentition that may occur after introducing a TNP to children with previously diagnosed AOB and increased overjet. It was demonstrated that changing to a TNP can reduce pacifier-associated malocclusion in the primary

Table 4. **Comparison of groups regarding malocclusion at final examination**

	Groups		95% CI	Mann–Whitney *p*-value
	Group I	**Group II**		
Anterior open bite N (%)	10 (41.7)	13 (59.1)	−0.47 to 0.13	0.247
Mean overbite ± SD (mm)	−1.2 ± 0.3	−2.2 ± 0.3	0.74 to 1.26	**0.001**
Overjet ≥2 mm N (%)	21 (87.5)	21 (95.5)	−0.25 to 0.09	0.350
Mean overjet ± SD (mm)	2.8 ± 0.4	3.2 ± 0.6	−0.72 to −0.08	**0.015**
Overjet ≥3 mm N (%)	10 (41.6)	14 (63.6)	−0.52 to 0.08	0.142
Mean overjet ± SD (mm)	3.1 ± 0.2	3.6 ± 0.3	−0.73 to –0.27	**0.001**
	Group I	**Group III**		
Anterior open bite N (%)	10 (41.7)	7 (41.2)	−0.32 to 0.33	0.976
Mean overbite ± SD (mm)	−1.2 ± 0.3	−0.8 ± 0.8	−0.99 to 0.19	0.185
Overjet ≥2 mm N (%)	21 (87.5)	15 (88.2)	−0.22 to 0.21	0.945
Mean overjet ± SD (mm)	2.8 ± 0.4	2.4 ± 0.5	0.10 to 0.71	**0.012**
Overjet ≥3 mm N (%)	10 (41.6)	6 (35.3)	−0.26 to 0.38	0.689
Mean overjet ± SD (mm)	3.1 ± 0.2	3.1 ± 0.1	−0.29 to 0.09	0.277
	Group II	**Group III**		
Anterior open bite N (%)	13 (59.1)	7 (41.2)	−0.15 to 0.51	0.279
Mean overbite ± SD (mm)	−2.2 ± 0.3	−0.8 ± 0.8	−1.78 to −1.03	**0.001**
Overjet ≥2 mm N (%)	21 (95.5)	15 (88.2)	−0.11 to 0.25	0.415
Mean overjet ± SD (mm)	3.2 ± 0.6	2.4 ± 0.5	0.43 to 1.17	**0.001**
Overjet ≥3 mm N (%)	14 (63.6)	6 (35.3)	−0.04 to 0.61	0.083
Mean overjet ± SD (mm)	3.6 ± 0.3	3.1 ± 0.1	0.35 to 0.65	**0.001**

Group I = TNP thin-neck pacifier, intervention group.
Group II = initial pacifier, control group.
Group III = weaning off, intervention group, Gold standard.
Bold values indicate statistically significant, $p<0.05$.

dentition compared to conventional or physiological pacifiers. Given this remarkable finding and the limited number of other studies and data, further studies are warranted to investigate the clinical relevance for the permanent dentition.

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References

1. Warren JJ, Bishara SE. Duration of nutritive and non-nutritive sucking behaviors and their effects on the dental arches in the primary dentition. *Am J Orthod Dentofacial Orthop* 2002;121:347–56.
2. Wagner Y, Heinrich-Weltzien R. Occlusal characteristics in 3-year-old children – results of a birth cohort study. *BMC Oral Health* 2015;15:94.
3. Sexton S, Natale R. Risks and benefits of pacifiers. *Am Fam Physician* 2009;79:681–5.
4. American Academy of Paediatric Dentistry. Guideline on Management of the Developing Dentition and Occlusion in Paediatric Dentistry. www.aapd.org/media/Policies_Guidelines/G_DevelopDentition.pdf. 2014.
5. Silva M, Manton D. Oral Habits-Part 1: the dental effects and management of nutritive and non-nutritive sucking. *J Dent Child* 2014;81:133–9.
6. Poyak J. Effects of pacifiers on early oral development. *Int J Orthod Milwaukee* 2006;17:13–6.
7. Nihi VSC, Maciel SM, Jarrus ME, Nihi FM, Salles CLF, Pascotto RC et al. Pacifier-sucking habit duration and frequency on occlusal and myofunctional alterations in

preschool children. *Braz Oral Res* 2015;29:1–7. doi: 10.1590/1807-3107BOR-2015.vol29.0013. www.scielo.br/pdf/bor/v29n1/1807-3107-bor-29-1-1807-3107BOR-2015vol290013.pdf
8. Warren JJ, Bishara SE, Steinbock KL, Yonezu T, Nowak AJ. Effects of oral habits' duration on dental characteristics in the primary dentition. *J Am Dent Assoc* 2001;132:1685–93.
9. Viggiano D, Fasano D, Monaco G, Strohmenger L. Breastfeeding, bottle feeding, and non-nutritive sucking; effects on occlusion in the deciduous dentition. *Arch Dis Child* 2004;89:1121–3.
10. Duncan K, McNamara C, Ireland AJ, Sandy JR. Sucking habits in childhood and the effects on the primary dentition: findings of the Avon Longitudinal Study of Pregnancy and Childhood. *Int J Paediatr Dent* 2008;18:178–88.
11. Aznar T, Galan AF, Marin I, Dominguez A. Dental arch diameters and relationships to oral habits. *Angle Orthod* 2006;76:441–5.
12. Katz CRT, Rosenblatt A, Gondim PPC. Nonnutritive sucking habits in Brazilian children: effects on deciduous dentition and relationship with facial morphology. *Am J Orthod Dentofacial Orthop* 2004;126:53–7.
13. Farsi NMA, Salama FS, Pedo C. Sucking habits in Saudi children: prevalance, contributing factors, and effects on the primary dentition. *Pediatr Dent* 1997;19:28–33.
14. Gois EGO, Ribeiro HC, Vale MPP, Paiva SM, Serra-Negra JMC, Ramos-Jorge ML et al. Influence of nonnutritive sucking habits, breathing pattern and adenoid size on the development of malocclusion. *Angle Orthod* 2008;78:647–54.
15. Varas VF, Gil BG, Izquierdo FG. Prevalence of childhood oral habits and their influence in primary dentition. *Rev Pediatr Aten Primaria* 2012;14:13–20.
16. Bishara SE, Warren JJ, Broffit B, Levy SM. Changes in the prevalence of nonnutritive sucking patterns in the first 8 years of life. *Am J Orthod Dentofacial Orthop* 2006;130:31–6.
17. Dimberg L, Lennartsson B, Söderfeldt B, Bondemark L. Malocclusions in children at 3 and 7 years of age: a longitudinal study. *Eur J Orthod* 2013;35:131–7.
18. Kohler L, Holst K. Malocclusion and sucking habits of four year-old children. *Acta Paediatr Scand* 1973;62:373–9.
19. Warren JJ, Slayton RL, Bishara SE, Levy SM, Yonezu T, Kanellis MJ. Effects of non-nutritive sucking habits on occlusal characteristics in the mixed dentition. *Pediatr Dent* 2005;27:445–50.
20. Zimmer S, Barthel CR, Ljubicic R, Bizhang M, Raab WHM. Efficacy of a novel pacifier in the prevention of anterior open bite. *Pediatr Dent* 2011;33:52–5.
21. Zardetto CG, Rodrigues CRM, Stefani FM. Effects of different pacifiers on the primary dentition and oral myofunctional structures or preschool children. *Pediatr Dent* 2002;24:552–60.
22. Adair SM, Milano M, Lorenzo I, Russel C. Effects of current and former pacifier use on the dentition of 24- to 59-month-old children. *Pediatr Dent* 1995;17:437–44.
23. Adair SM, Milano M, Dushko JC. Evaluation of the effects of orthodontic pacifiers on the primary dentitions of 24- to 59-month-old children: preliminary study. *Pediatr Dent* 1992;14:13–8.
24. Turgeon-O'Brien H, Lachapelle D, Gagnon PF, Larocque I, Maheu-Robert LF. Groupe de Recherche en Nutrition Humaine. Nutritive and nonnutritive sucking habits: a review. *ASDC J Dent Child* 1996;63:321–7.
25. Proffit WR. The etiology of orthodontic problems. In: Proffit WR, Fields HW Jr, Sarver DM, editors. *Contemporary Orthodontics*, 5th edn. St. Louis, MO: Mosby; 2012. pp. 114–46.
26. Melsen B, Stensgaard K, Pederson J. Sucking habits and their influence on swallowing pattern and prevalence of malocclusion. *Eur J Orthod* 1979;1:271–80.
27. Nelson A. A comprehensive review of evidence and current recommendations related to pacifier usage. *J Pediatr Nurs* 2012;27:690–9.
28. Foster TD, Hamilton MC. Occlusion in the primary dentition-study of children at 2-1/2 and 3 years of age. *Br Dent J* 1969;26:76–9.
29. World Health Organization. *Oral Health Surveys, Basic Methods*, 4th edn. Geneva: World Health Organization; 1997.
30. Baume L, Horowitz H, Summers C, Backer D, Brown W, Carlos J et al. A method for measuring occlusal traits. *Int Dent J* 1973;23:530–7.
31. Birardi V. The morphology of the pacifier in the treatment of open bite for a three-year-old child. Clinical Case. *Italian Dent J* 2012;9:28.
32. Katri KN, Raija L, Vuokko L, Keski-Nisula L, Varrela J. Occurence of malocclusion and need of orthodontic treatment in early mixed dentition. *Am J Orthod Dentofacial Orthop* 2003;124:631–8.
33. Steegmayer G, Komposch G. Early orthodontic treatment of the deciduous dentition. The therapeutic potentials and indications. *Fortschr Kieferorthop* 1993;54:172–8.
34. Rankine CA. Orthodontic treatment in the mixed dentition for the general dentist. *Curr Opin Dent* 1992;2:14–8.
35. Heimer MV, Katz CRT, Rosenblatt A. Non-nutritive sucking habits, dental malocclusions, and facial morphology in Brazilian children: a longitudinal study. *Eur J Orthod* 2008;30:580–5.
36. Klocke A, Nanda RS, Kahl-Nieke B. Anterior open bite in the deciduous dentition: longitudinal follow up and craniofacial growth considerations. *Am J Orthod Dentofacial Orthop* 2002;122:353–8.
37. Ovsenik M, Farcnik FM, Korpar M, Verdenik I. Follow-up study of functional and morphological malocclusion trait from 3 to 12 years of age. *Eur J Orthod* 2007;29:523–9.
38. Verrastro AP, Stefani FM, Rodriguez CR, Wanderley MT. Occlusal and orofacial myofunctional evaluation in children with primary dentition, anterior open bite and pacifier sucking habit. *Int J Orofacial Myology* 2006;32:7–21.
39. Johnson ED, Larson BE. Thumbsucking: literature review. *ASDC J Dent Child* 1993;60:385–91.
40. Fukuta O, Braham RL, Yokoi K, Kurosu K. Damage to the primary dentition resulting from thumb and finger (digit) sucking. *ASDC J Dent Child* 1996;63:403–7.