Scientific Article

Efficacy of a Novel Pacifier in the Prevention of Anterior Open Bite

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Abstract: ***Purpose:*** *The purpose of this study was to test a novel pacifier (Dentistar) regarding the development of anterior open bite in infants.* ***Methods:*** *One hundred twenty-nine newborn children were randomly assigned to 2 experimental groups: NUK (N; N=73); and Dentistar (D; N=56. Children (N=42) who did not use a pacifier served as the control (C). At 10- to 26-months old, the children were re-examined (via a blind operator) regarding the existence of an anterior open bite.* ***Results:*** *One hundred twenty-one toddlers (66 females, 55 males) were included in the final analysis (N: N=42; D: N=43; C: N=36). The mean age was 15.9 (±3.9 SD) months. In Group N, 16 children (38%) showed an anterior open bite, 2 (5%) in Group D, and 0 in Group C. The incidence of open bites was significantly less in Groups D and C vs N (chi-square test, P<.001). No significant difference was found between D and C.* ***Conclusion:*** *Pacifier use may promote open bites in 16-month-old infants. Compared to a commonly used pacifier, the Dentistar caused almost no anterior open bites and, therefore, can be recommended for children younger than 16 months old. (Pediatr Dent 2011;33:52-5) Received June 25, 2009 / Last Revision September 21, 2009 / Accepted September 22, 2009*

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In recent years, the discussion in pediatric journals on the use of pacifiers has mainly focused on their impact on the incidence of sudden infant death syndrome (SIDS), otitis media, and the duration of breast-feeding. Non-nutritive sucking (NNS) seems to reduce the incidence of SIDS,[1] and it was concluded that the use of pacifiers should no longer be discouraged. By contrast, pacifier use may slightly increase the risk for otitis media (odds ratios<2).[2,3] Breast-feeding duration and prevalence are negatively correlated with pacifier use.[4,5] There is strong evidence, however, that the pacifier is only a risk indicator, but not a risk factor, for breast-feeding difficulties or reduced breast-feeding duration.[2,6] The reason for this finding may be that mothers are using pacifiers to wean or as a substitute if they decide not to breast-feed. Overall there is an obvious trend in pediatrics to no longer ban the use of pacifiers.

From a dental viewpoint, however, the use of pacifiers has to be recommended with caution, since NNS via pacifier is known to cause several changes in dental occlusion, including open bites, an overjet increase, and posterior crossbites. On the other hand, it is not realistic to demand a renunciation of pacifiers since they are widely used to: calm children during stressful episodes; lull children to sleep; and alleviate teething discomfort. Therefore, it seems reasonable to develop pacifiers to reduce or prevent orthodontic problems. With this in mind, a novel pacifier was developed and introduced. It was the aim of the present study to evaluate the influence of this pacifier on the first formation of malocclusion—the anterior open bite in infants.

Methods

This study was institutionally approved by the Ethics Committee of Heinrich-Heine University, Medical Faculty, Düsseldorf, Germany. At the University Hospital of Düsseldorf, Düsseldorf, Germany, 129 newborn children whose parents decided to use pacifiers were randomly assigned to 2 experimental groups:

1. NUK (N; N=73; Mapa, Zeven, Germany [Figure 1 left]); and
2. Dentistar (D; N=56; Novatex, Pattensen, Germany [Figure 1 right], available in the United States as the Playtex Ortho-Pro Pacifier).

Group allocation was performed by a nurse not involved in the study using prepared envelopes containing the group number.

The front view of the 2 pacifiers (Figure 1a) shows that the nipple of the Dentistar is narrower and tapered in order to prevent palatal distension. From the side view (Figure 1b) the Dentistar nipple is lower and concave at the lingual side. The connector between nipple and shield is thinner and shows a stepped form, which allows the pacifier to better fit between mandibulary and maxillary incisors.

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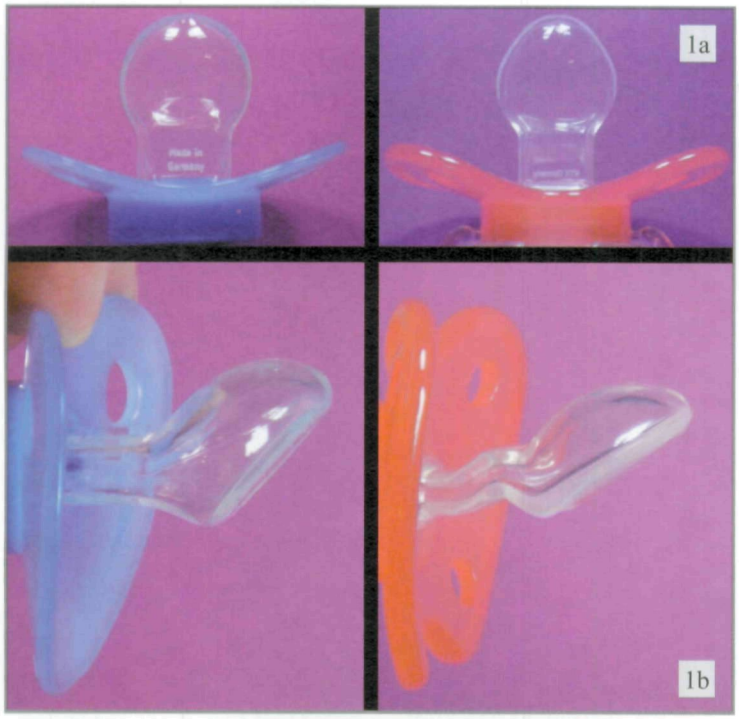

Figure 1. (a) Front view of NUK (left) and Dentistar (right); (b) Side view of NUK (left) and Dentistar (right).

Parents were advised to use only the allocated pacifier. Children (N=42) who did not use a pacifier served as control (C). To ensure that lost pacifiers could be replaced immediately, parents received a reserve. At the screening examination, exclusion criteria included: preterm birth (<eighth month pregnancy); congenital maxillofacial anomalies such as cleft lip and/or palate; and systemic diseases of the infant. Recruitment started November 2005 and ended in April 2007. At 10 and 26 months old, the children were re-examined via a blind operator (March 2007 to April 2008). The prevalence of anterior open bite was registered, and the overjet distance was measured. The mothers were interviewed via questionnaire about pacifier use, breast-feeding, and bottle-feeding.

Open bite was diagnosed if there was a gap between the incisal edges of the maxillary and mandibular incisors. The extent of open bite was measured using a ruler to the nearest 0.5 mm. In the same way, the extent of overjet was measured from the lingual surface of the mesial corners of the maxillary incisors to the facial surface of the mandibular incisors.[7] Wearing time of the pacifier was recorded in hours with an accuracy of half an hour.

All examinations were performed by a single examiner in the same dental office under artificial light. Children were excluded from analysis if they did not follow the study regimen (eg, if they switched to another pacifier or stopped using the attributed one). In group C, only children who did not show any kind of NNS (eg, digit sucking) during the entire study period were included. In total, 50 children were excluded from final analysis (N=31; D=13; C=6). The Kolmogorov-Smirnov-test showed normal distribution for the results of age, overjet, and overbite, but not for use time of the pacifiers. Therefore, this variable was calculated using the Mann-Whitney-U-test, whereas analysis of variance (ANOVA) served for statistical analysis in the other cases. Frequencies were analyzed using the chi-square test (SPSS 15.0, SPSS Inc, Chicago, Ill).

Results

A total of 121 infants (66 females, 55 males) were included in the final analysis (N: N=42; D: N=43; C: N=36). The mean age was 15.9 (±3.9 SD) months (N=15.3±3.96; D=17.0±4.15; C=15.4±3.53). No statistically significant difference between groups was found regarding age (ANOVA). The mean number of teeth was as follows: N=11±3; D=12±3; C±12±3. This means that, on average, the toddlers had all incisors fully erupted and primary molars at least in part. No adverse effects were found or reported during the study period.

In Group N, approximately 38% (16/42) of the children showed anterior open bites vs 5% (2/43) in Group D. This difference was statistically significant at $P<.001$ (chi-square test). No case of anterior open bite was found in Group C (Table 1). There was no significant difference between D and C. By contrast, Group N showed significantly more cases of anterior open bite than Group C ($P<.001$, chi-square test). The extent of open bite in Group N was 1.00 mm (±0.13) and 2.00 mm in both cases of Group D. Regarding extent of overjet, no statistically significant differences were found among groups (Table 1).

The reported average use of the pacifier was 3.0 hours per day in Group N (maximum=10.0; minimum=0.5) and 2.0

Table 1. INCIDENCE OF ANTERIOR OPEN BITES AND EXTENT OF OVERJET IN TEST AND CONTROL GROUPS*

	Group N (N=42)	Group D (N=43)	Group C (N=36)
Anterior open bite cases N (%)	16 (38)	2 (5)	0 (0)
Overjet (mm) Mean±SD	1.7±1.4	1.3±1.0	1.2±1.1

* Horizontal bars indicate statistically significant differences at $P<.001$ (chi-square test).

Table 2. AVERAGE DURATION OF BREAST- OR BOTTLE-FEEDING IN TEST AND CONTROL GROUPS*

	Group N (N=42)	Group D (N=43)	Group C (N=36)
	Median (min/max)		
Breast-feeding duration (hs/day)	0.0 (0.0,/1.0)	0.0 (0.0/0.5)	0.0 (0.0/2.0)
Bottle-feeding duration (mins/day)	10.0 (0.0/60.0)	20.0 (0.0/60.0)	0.0 (0.0/60.0)

* Horizontal bars indicate statistically significant differences at $P<.05$ (Kruskall-Wallis and Mann-Whitney U-test).

hours per day in Group D (maximum=5.0; minimum=0.5). This difference was statistically significantly different at $P<.01$ (Mann-Whitney U-test). Breast-feeding was performed significantly more often in Group C vs the 2 test groups (chi-square, $P<.05$): 2 children in Groups N (5%) and D (5%), but 8 children in Group C (22%). Bottle-feeding was performed in 32 children in Group N (76%), 33 children in Group D (77%), and 17 children in Group C (47%). Again, there was a statistically significant difference between Group C and the 2 test groups (chi-square, $P<.01$). The median feeding times are presented in Table 2. Regarding bottle-feeding times, the differences between the 2 pacifier-groups and Group C were statistically significant ($P<.05$, Kruskall-Wallis and Mann-Whitney U-tests).

Discussion

Pacifier use is known to cause harmful effects on the developing dentition. In his meta-analysis, Poyak[8] showed that the most notable changes are an increase in the prevalence of anterior open bite, posterior crossbite, narrow intercuspid width of the maxillary arch, and a high narrow palate. It was shown that pacifiers do not alter the dentition, however, if their use is stopped by 2- to 3-years-old.[8] In the present study, the average age of the children was 16-months-old. All incisors of the primary dentition were fully erupted, but first molars and canines were only partially erupted. Therefore, only the occurrence of an anterior open bite could be evaluated. The present study confirms the findings of other authors that children using a pacifier show a higher occurrence of open bites than children without NNS habits.[9-11] According to Poyak's findings,[8] it can be argued that the prevalence of an open bite at the age of 16 months is not relevant, since usually a spontaneous remission can be observed if NNS is stopped by 2- to 3-years-old. On the other hand, if the child continues with pacifier sucking, it is important to determine how early and fast the alterations occur, since the greater the longevity and duration of pacifier use, the greater the potential for harmful results.[8,12]

With respect to pacifier use, there are no published data for children at the same age as those in the present study. Adair et al[9] showed that children with an average age of 3½ years old had an average overjet of 2.4 mm when using pacifiers and 1.7 mm without pacifiers.[9] In the present study, with younger toddlers, the differences between Group N (conventional pacifier) and Group C were in the same range (1.69 mm vs 1.17 mm), whereas the novel pacifier (Group D) showed a smaller difference compared to Group C (1.31 vs 1.17). The differences, however, did not reach statistical significance.

There is some evidence that pacifier use time is positively correlated with incidence of open bites.[9,13] The lower incidence of open bites in infants using the novel pacifier (Group D) may be partly the result of the shorter daily use time that was reported by mothers in comparison to the standard pacifier (group N). On the other hand, the average daily bottle-feeding duration at the final examination time was 20 minutes in Group D vs 10 minutes in Group N. This longer feeding time may have promoted the development of an open bite, but evidence for such a correlation is not clearly shown.[14,15]

In the 2 test groups, bottle-feeding was predominant, whereas breast-feeding was performed more often in Group C. This agrees with other studies showing a negative correlation between breast-feeding and pacifier use.[4,5] Charchut et al demonstrated that predominant bottle-feeding between 0 and 6-months-old is associated with the development of a pacifier habit[16]. In the present study, an association between the frequency of bottle-feeding and the use of a pacifier was present. Since the pacifier use was already decided immediately after birth (inclusion criteria), however, it can not be promoted by bottle-feeding. By contrast, it may be speculated that pacifier use may have promoted bottle-feeding. It's also possible that there is a common reason for both pacifier use and bottle-feeding, such as socioeconomic factors. This may be true in our case, because mothers went back to work very quickly and their children, therefore, usually remained in day care.

Conclusions

1. The novel pacifier (Dentistar) caused almost no anterior open bites in 16-months-old children.
2. The novel pacifier caused statistically significantly fewer anterior open bites in 16-months-old children than a commonly used one (NUK) and was not statistically significant different from no pacifier use.
3. The novel pacifier can be recommended for children up to 16-months-old.

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Disclosure

The authors declare that they have no commercial, proprietary, or financial interest in the products or companies described in this article.

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