Anterior Open Bite In 27 Months Old Children after Use of a Novel Pacifier – A Cohort Study

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Objectives**: The aim of the present cohort study was to evaluate the influence of a novel pacifier on the first formation of malocclusion, the anterior open bite in children. **Study design:** 129 newborn children whose parents had decided to use pacifiers were randomly attributed to two experimental groups (D=Dentistar, n=56, Novatex, Pattensen, Germany; N=NUK, n=73, Mapa, Zeven, Germany). Children (n=42) who did not use a pacifier were not randomized and served as reference (C). Primary outcome was the presence of anterior open bite. It was hypothesized that D would result in lower incidence when compared to N. At the age of 27 months the children were examined with respect to anterior open bite. Fisher's exact test served to detect significant differences between groups D and N (SPSS 22.0). **Results:** 121 children with a mean age of 26.7 months were included in the final analysis (D: n=45; N: n=42; C: n=34). In group D three children (6.7%) showed an anterior open bite. The respective values were 21 (50.0%) for N and 0 for C. The results for group D compared to N were significantly different (chi²-test, p<0.001). **Conclusion:** **In comparison to a commonly used pacifier the novel one causes significantly less anterior open bites.

Key words : pacifier, malocclusion, open bite

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INTRODUCTION

Pacifiers are widely used to calm children during stressful episodes, to lull to sleep, and to alleviate teething discomfort. However, their use is controversially discussed in pediatrics and pediatric dentistry. In 1993 pacifiers were firstly identified as a protective factor against Sudden Infant Death Syndrome (SIDS)[1]. Accordingly, the American Academy of Pediatrics Task Force on Sudden Infant Death Syndrome (SIDS) recommends pacifier use because of a protective effect on the incidence of SIDS[2]. There is also evidence, that pacifier use alone or in combination with 30% sucrose or glucose show some analgesic effect in newborns undergoing minor procedures such as venipuncture[3]. As a result of this evidence, pacifier use alone or in combination with sucrose is recommended by the American Academy of Pediatrics as a pain-relieving tool in the emergency department[4]. However, evidence is contradictory with respect to preterm infants. While Liaw et al. have found a pain relief during heel stick procedure when non-nutritive sucking was performed[5], Carbajal et al. could not confirm this effect during subcutaneous injection[6]. In the first study, the gestational age of the preterm infants was between 28.9 and 37 weeks, in the latter one <32 weeks. It can be speculated that the different gestational age had an influence on the study outcome.

A negative effect of non-nutritive sucking (NNS) is a slight increase of the risk for otitis media (odds-ratios < 2)[7,8]. Joint guidelines of the American Academy of Pediatrics and the American Academy of Family Physicians recommend to reduce or stop pacifier use in the second six months of life as a preventive measure to reduce the risk of otitis media; however they admit that the usefulness of this measure is unclear[9].

Prevalence and duration of breast-feeding are negatively correlated with pacifier use[10,11], but there is evidence that the pacifier is only a risk indicator and not a risk factor for breast-feeding difficulties or reduced breast-feeding duration[7,12]. The reason for this finding may be the fact that mothers are using pacifiers to wean or to use the pacifier as a substitute if they decided not to breast-feed. In a retrospective study Lindsten and Larsson compared two groups of young children born 30 years apart with respect to pacifier-sucking and breast-feeding. They found that both, breast-feeding and pacifier use had largely increased over the 30 years. The authors concluded that pacifier use does not negatively affect the prevalence of breast-feeding[13]. As a result of discussing risks and benefits of pacifiers, Sexton and Natale state that "Pacifier use should not be actively discouraged"[14].

With respect to dental health, pacifier use is associated with several changes in dental occlusion such as open bites, an increase in overjet, and posterior crossbites[15,16]. In their study on 732 three to five years old children, de Sousa et al. found the highest prevalence of anterior open bite in the three-year-olds and a correlation to the duration of pacifier sucking[17]. Moimaz et al. performed a longitudinal study on children from birth to 30 months of age. They found a strong correlation between pacifier sucking and overjet as well as open bite at 12-, 18- and 30-months examinations[18].

In summary, pacifier use is associated with certain risks but predominantly with benefits. Therefore it seems reasonable to develop pacifiers with minimized risk potential. This in mind Novatex Company (Pattensen, Germany) has developed a novel pacifier with the aim to reduce or prevent orthodontic problems. This Dentistar pacifier is narrow and tapered in order to prevent palatal distension; the nipple is low and concave at the lingual side and the connector between nipple and shield is thin and shows a stepped form which allows the pacifier to fit between mandibular and maxillary incisors.

It was the aim of the present study to evaluate the influence of this pacifier on the early formation of anterior open bite. It was hypothesized that the use of the novel pacifier would result in a lower incidence of anterior open bite when compared to a commonly used one, the NUK pacifier (Mapa, Zeven, Germany).

MATERIALS AND METHOD

This was a single blind, parallel, two-arms, cohort study which was conducted in Germany. The trial was registered at the German Clinical Trials Register (https://drks-neu.uniklinik-freiburg.de/drks_web/; registration number DRKS 00003086). All mothers of the study participants signed an informed consent form. All experiments were performed in accordance with relevant guidelines and regulations. The study was institutionally approved by the ethics committee of the Heinrich-Heine-University, medical faculty, Duesseldorf, Germany (#2650).

Figure 1 shows the enrollment of the children in the study according to CONSORT[19]. Newborn children (n=129) whose parents had decided to use pacifiers were attributed to two experimental groups: D=Dentistar, n=56, Novatex, Pattensen, Germany; N=NUK, n=73, Mapa, Zeven, Germany (figures 2-5). While 112 children were attributed by randomization, 17 additional infants who already used a NUK-pacifier at the first contact, were included in Group N. This was caused by the fact that in the maternity clinic all newborns received a "welcome package" which included a NUK pacifier. Parents were advised to use only the allocated pacifier. Children (n=42) who did not use a pacifier served as reference group (C). Eligible participants were all children born between November 2005 and April 2007 at the gynecological hospital of the Heinrich-Heine-University Duesseldorf/Germany whose mothers stayed for at least two days in the hospital. This resulted in a total of about 1,500 children. The study took place at the Department of Operative Dentistry, Periodontology, and Endodontics of the Dental School of Duesseldorf/Germany between November 2005 and March 2009.

Sample size was determined on the basis of 80% power and a significance level of 0.05 (G-Power, Bonn, Germany). It was assumed that the incidence of open bite would be at least 30% less in the Dentistar group compared to the NUK group (chi²-test). This resulted in a minimum of 88 subjects in two groups. Due to an assumed maximum drop out of 20% over the observation period, higher group sizes were initiated.

Randomization was performed using prepared envelopes containing the group number. The sequence of the envelopes was randomly defined. According to group assignment, pacifiers were allocated by a nurse of the maternity clinic which was not involved in the study and had no contact to the study staff. Parents in group D and N were advised to use only the allocated pacifier; no further instructions about its use were given.

In order to ensure that lost pacifiers could be replaced immediately parents received three additional pacifiers and could request more when needed. At the screening examination, exclusion criteria were preterm birth (<8th month pregnancy), congenital maxillofacial anomalies such as cleft lip and/or palate, and systemic diseases of the infant. Recruitment started in November 2005 and ended in April 2007. At an age of 16 months, an intermediate examination was performed in 2007 to 2008. Results were reported earlier[20]. At an average age of 27 months, the final examination with respect to occlusion and anterior open bite was performed by the blinded operator (March 2008 to March 2009). By use of a questionnaire, the mothers were interviewed about pacifier use as well as breast- and bottle feeding. Screening and enrollment of the participants was performed by a dentist not involved in the final examination.

All examinations were performed by one single examiner (HZ) in the same dental office (University of Duesseldorf, Dental School) under artificial light. Due to the age of the children, no impressions were taken. A calibration of the blinded examiner was performed in ten infants by RL (Ruzi Ljubicic). Children were excluded from analysis if they did not follow the study regimen, for example if they switched to another pacifier or stopped using the attributed one. In the reference group only children who did not show any kind of NNS as stated by their mothers, e.g. digit sucking, were included. Any NNS in group C during the entire study period resulted in an exclusion. In total, 50 children were excluded from final analysis (N: 31, D: 11, C: 8).

Open bite was diagnosed if there was a gap between the incisal edge of at least one incisor of maxilla and mandible. The extent of open bite (=negative overbite) was measured at the largest distance to the nearest 0.5 mm using a ruler. For reproducibility, measurement was repeated once and if values were different, a mean value was built. Normocclusion was diagnosed if the mandible and maxilla were anteroposteriorly normal as reflected by the relationship of the first primary molars. Wearing time of the pacifier was recorded as reported by the mothers in hours with an accuracy of half an hour.

Primary study outcome was the presence of anterior open bite, secondary outcome the incidence of normocclusion. Mean values for overbite and overjet were calculated for those children only, were overbite or overjet was diagnosed.

Statistical analysis was performed per-protocol. Group C served as reference group and was not included into statistical analysis since it could not be randomized. Kolmogorov-Smirnov-test showed normal distribution for the results of age, feeding times and use time of the pacifiers. Therefore, t-test served for statistical analysis between group D and N. Frequencies were analyzed using Fisher's exact test. In addition to univariate analysis, a multiple logistic regression was performed for the potentially confounding variables using a stepwise backward selection based on the likelihood ratio statistics. The items bottle-feeding, bottle-feeding duration/day and pacifier use/day were introduced as dependent variables in the logistic regression model with open bite as target variable. For all included variables, adjusted odds ratios (AOR) and 95% confidence intervals (CI) were calculated. The Hosmer-Lemeshow goodness-of-fit test was used to assess how well the chosen model fitted the data (SPSS 22.0).

RESULTS

A total of 121 infants (64 female, 57 male) could be included in the final analysis (D: n=45; N: n=42; C: n=34). The mean age was 26.5 (SD 2.8; 95% CI: 26.0 – 27.0) months (D=26.8; N=26.0; C=26.7). T-test showed no statistically significant differences between groups D and N.

The mean number of teeth was as follows: D: 18.02 (SD 1.83; 95% CI: 17.5 to 18.6), N: 18.09 (SD 2.15; 95% CI: 17.4 to 18.8), C: 18.12 (SD 1.79; 95% CI: 17.5 to 18.7). That means that on average, the primary dentition was nearly completely erupted. No adverse effects were found or reported during the study period.

Three children from group D (6.7%) showed anterior open bite. The respective values were 21 (50%) for N and 0 for C. The incidence of open bites was significantly less in group D when compared to N (Fisher's exact test, $p<0.001$). The relative risk for group N to develop an anterior open bite in comparison to group D was 7.46 (95% CI 2.44 to 30.59) (table 1) This results in a risk-reduction of 86.6% for the Dentistar when compared to the NUK-pacifier.

Mean values for overbite and overjet were calculated for those children only, were overbite or overjet was diagnosed. For this

Figure 1 CONSORT 2010 Flow Diagram

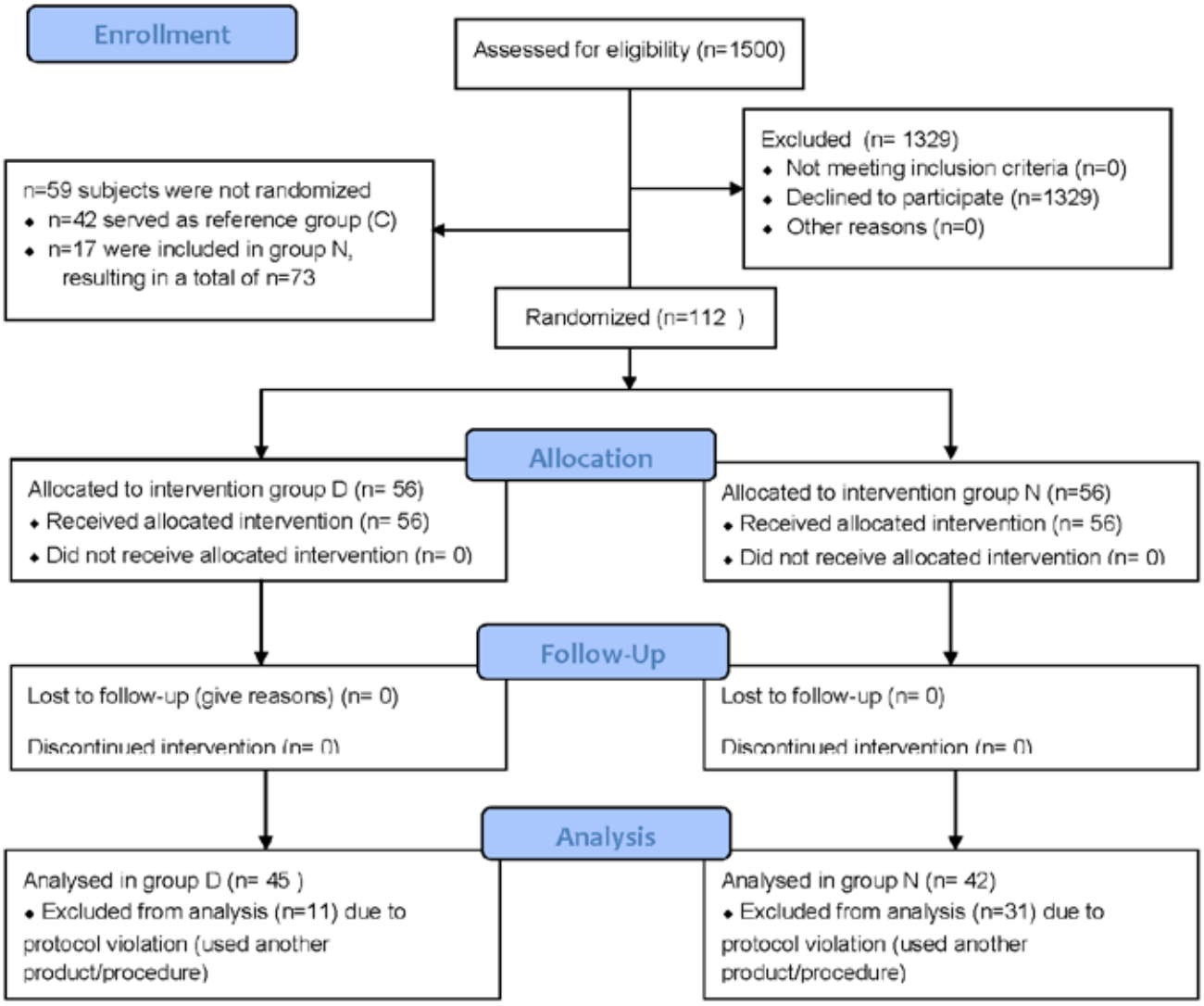

Figure 2 - Dentistar pacifier front view

In comparison to the NUK pacifier (fig. 4), the nipple is narrower and tapered in order to prevent palatal distension.

Figure 3 - Dentistar pacifier side view.

In comparison to the NUK pacifier (fig. 5), the 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 mandibular and maxillary incisors.

cases, the mean value of overbite was -1.3 mm (SD -0.6; 95% CI: -2.8 to -0.1; n=3) in group D and -1.9 mm (SD -1.1; 95% CI: -2.4 to -1.4; n=21) in group N. The respective values for overjet were 2.3 (SD 1.1; 95% CI: -0.5 to 5.2; n=3) in group D and 2.0 mm (SD 1.2; 95% CI:-1.4 to 2.5; n=21) in group N. It has to be pointed out that these values only refer to those children showing an anterior open bite in the two pacifier groups. Due to the low number of children with open bite in group D (n=3), no statistical testing was performed with respect to the differences between the two groups.

Normocclusion was found in 39 (88.6%) subjects in group D, 39 (95.1%) in N, and 33 (97.1%) in C. No statistically significant

Figure 4 - NUK pacifier front view

Figure 5 - NUK pacifier side view

difference between groups D and N was found with respect to regular occlusion (Fishers exact test, p>0.05) (table 1).

The reported mean use of the pacifier during the entire study period was 2.2 hours/day in group D (SD 2.1; 95% CI: 1.6 to 2.8) and 2.9 hours/day (SD 3.3; 95% CI: 1.9 to 4.4) in group N. This difference was not statistically significant different between these two groups (p>0.05, t-test).

At the time of the final examination, breastfeeding was performed in two cases of the reference group and in none of the cases in group D and N.

Bottle feeding was performed in 24 cases in group D (53.3%), 25 cases in group N (59.5%), and in 13 cases in the reference group (38.2%). There was no statistically significant difference between the two test groups (Fisher's exact test, p>0.05). The average bottle feeding times are presented in table 2. No statistically significant difference was found (p<0.05, t-test).

In the logistic regression model, adjusted odds ratios (AORs) for

Table 1: Incidence and relative risk of anterior open bite, and normocclusion.

	Group D (n=45)	Group N (n=42)	Group C (n=34)
anterior open bite cases (%)[1]	**3/45 (6.7) a**	**21/42 (50.0) a**	**0/34 (0)**
Relative risk (95% CI)[2]	**1**	**7.46 (2.44 to 30.59)**	**-**
Normocclusion cases (%)[3]	**39/45 (88.6)**	**39/42 (95.1)**	**33/34 (97.1)**

[1]Statistically significant difference between groups D and N at p<0.001 (Fisher's exact test). Group C was not included in statistical analysis.

[2]Statistically significant difference between groups D and N at p<0.001 according to confidence intervals. Group C was not included in statistical analysis.

[3]No statistically significant difference between groups

Table 2 Mean duration of bottle feeding *per* day.

	Group D (n=45)	Group N (n=42)	Group C (n=34)
mean bottle feeding duration in minutes/day (SD)[1]	**16.9 (20.2)**	**12.0 (8.8)**	**16.3 (15.5)**
95% CI[1]	**(8.4 to 25.4)**	**(8.4 to 15.7)**	**(6.9 to 25.7)**

[1]No statistically significant differences at p<0.05 between D and N (t-test). Group C was not included in statistical analysis.

the development of open bite were calculated. Multivariate analysis found only one significant result at p<0.05: AOR was significantly lower than 1 for pacifier use/day (AOR 0.704, 95% CI: 0.573 to 0.864). That means, that a short duration of pacifier use/day was reducing the risk of open bite. For both groups (D and N), the mean duration of pacifier use/day was 4.0 hrs (SD 2.6; 95% CI: 2.9 to 5.1) in the case of open bite (n=24) and 1.3 hrs (SD 2.3; 95% CI: 0.8 to 1.8) when no open bite was found.

DISCUSSION

One methodological limitation of the present study is the randomization process. From the 73 babies that were initially allocated to group N, only 56 were attributed by random. The remaining 17 newborn children which were included in this group had already used pacifier N when the first contact with the mother took place. This was caused by the fact that the NUK-pacifier was included in a standard-"welcome-package" that each newborn received immediately after birth. Nonetheless, the 17 not randomized babies were included in the analysis because of the not expected high drop-out-rate in group N. Otherwise, the study power would have been too low. Retrospectively, it would have been better to randomize more children. However, it was difficult at all to include children in the study since the mothers were not very motivated to give consent for their newborns to be part of a clinical study. Another methodological weakness is that the children from group (C) could not be randomized. These babies' parents had decided not to use any pacifier and could therefore not be exposed to the risk to be allocated to a pacifier-group (D or N). In the statistical analysis, group C could therefore not be treated as a real control, but only as a reference group.

These limitations in mind, the use of the Dentistar pacifier resulted in a risk-reduction of 86.6% when compared to the NUK-pacifier. The reason for this finding might be the special form of the Dentistar which can be seen in figures 2 and 3. In particular, in comparison to the NUK-pacifier, the connector between nipple and shield of the Dentistar is thinner and shows a stepped form which allows the pacifier to follow the natural incisal step of mandibular and maxillary incisors. Consequently, the upper incisors are less displaced when using the Dentistar in comparison to a pacifier with a thicker and straight connector between nipple and shield.

Pacifier use is known to cause harmful effects on the developing primary dentition. In his meta-analysis, Poyak showed that the most notable changes are an increase in the prevalence of anterior open bite, posterior cross bite, narrow intercuspid width of the maxillary arch, and a high narrow palate[15]. In the present study the average age of the children was 27 months. Until now, no data is available for such young children. With respect to the age of the probands, we did not take impressions and therefore had no plaster models for orthodontic analyses. Therefore, only clinical findings such as the presence of anterior open bite and normocclusion could be evaluated. The present data are in accordance with our preliminary data[20] and the findings of other authors from older children showing that pacifier use results in an elevated occurrence of open bites[16,18,21,22].

According to Poyak[15], it may be argued that the prevalence of an open bite at the age of about two years is not relevant since a spontaneous remission can be observed usually if pacifier use is stopped by the age of two to three years. On the other hand, if pacifier sucking is continued, it is important how early and how fast the alterations occur since the greater the longevity and duration of pacifier use, the greater the potential for harmful results[15].

There is some evidence that pacifier use time is positively correlated with incidence of open bites[21,23] and posterior cross-bites[24,25]. In the present study, multivariate analysis showed a significant correlation between the duration of pacifier use and the incidence of open bite. However, the reliability of the data concerning daily sucking time has to be questioned since they were based on mother's notations.

In the present study there was a higher frequency of bottle feeding in both test groups when compared to the reference. Other authors have found a negative correlation between breastfeeding and pacifier use[10,12] whilst Lindsten and Larsson have shown that an increased use of pacifiers over time did not result in negative effects in breast-feeding[13]. Charchut et al. demonstrated that predominant bottle-feeding between 0 and 6 months of age is associated with the development of a pacifier habit[26]. In the present study, the pacifier use was already decided immediately after birth (inclusion criteria). It may be speculated that the decision for pacifier and bottle feeding was made simultaneously.

CONCLUSIONS

Pacifier use may promote the incidence of open bites in 27 months old children. Within the limitations of this study, the use of the novel pacifier resulted in 86.6% risk reduction for anterior open bites in comparison to a commonly used pacifier. Therefore it might be recommended for children up to 27 months of age.

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