

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

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

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

### **Abstract**

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

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

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

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

### **Key-words:**

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

## Background

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

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

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

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

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

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

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

### **Methods**

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

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

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

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

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

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

*Statistical analyses*

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

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

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

## Results

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

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

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

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



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

### **Discussion**

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

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

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

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

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

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

This finding appears to disagree with what is generally believed for conventional pacifiers, *i.e.* that if conventional pacifiers are given to infants in the early postpartum period, when they are learning to suck from their mothers' breasts, the use of the pacifier may interfere with proper sucking and cause nipple confusion, favouring a late fingersucking/thumbsucking habit [24]. In agreement with this statement, Ling et al. reported, from a sample of 1034 Asian children aged 2 to 5 years old, that

children who use conventional pacifiers "daily" have significantly higher chances of developing fingersucking/thumbsucking habits [1]. The present study doesn't confirm this association in case of orthodontic pacifiers, because fingersucking/thumbsucking resulted not correlated to the duration of orthodontic pacifier sucking. The present data states the opposite concept, *i.e.* that children who began to use orthodontic pacifier very early - between 0 and 3 months - are less likely to develop fingersucking/thumbsucking respect to children who had begun after 4 months (OR 0.13, 95% CI 0.04-0.47,  $p=0.0004$ ). It must be noted that Ling et al. report data on conventional pacifiers, and didn't analyze the beginning of the pacifier sucking, but only its frequency (a "daily" use or "not daily" use) (OR 2.136; 95% CI 1.11-4.10) [1]. These factors could explain the different conclusions between the two studies. Not many other studies in literature have focused on the relationship between pacifier sucking and fingersucking/thumbsucking, except for another study, published in

1977 that found an inverse association between the two habits, more in accordance to what is reported in the present sample [25]. Probably, the infants that early begin to use orthodontic pacifiers, obtain satisfaction from one habit, and this may reduce the urge for addiction to the sucking sensation, preventing them to develop other habits as fingersucking/thumbsucking to help them to fulfil their needs, and the same is for other poor habits.

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

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

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

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

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

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

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

#### *Limitations of the study*

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

#### **Conclusions**

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

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

#### **List of Abbreviations**

**95% CI:** 95% Confidence interval

**CI:** Confidence interval

**OR:** Odds ratio

**SPSS:** Statistical Package for Social Science

#### **Declarations**

##### **Ethics approval and consent to participate**

Informed consent was obtained for participants from their legal representatives, as appropriate, in written form.

This study was approved by the ethical committee of the University of L'Aquila.

##### **Consent for publication**

Not applicable.

##### **Availability of data and materials**

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

##### **Competing Interests**

None of the authors have any competing interests.

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No funding was received for this study. The study was spontaneous.

## **Author's contribution**

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

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

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

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

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

All authors have read and approved the manuscript.

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**Table 1.** Descriptive characteristics of the sample

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

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

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

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

<sup>#</sup>Reference category.

\*Statistically significant association.

<sup>o</sup> adjusted ORs for the other factors in the model

95% CI: 95% confidence interval.

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

Risk factor	OR <sup>o</sup>	95% CI
<b>Age of beginning of orthodontic pacifier use:</b>		
>3 months <sup>#</sup>	1	
0-3 months	0.13	(0.04–0.47) *

<sup>#</sup>Reference category.

\*Statistically significant association.

<sup>o</sup> adjusted ORs for the other factors in the model

95% CI: 95% confidence interval.

