Evaluation of Effect of Orthodontic Pacifiers in Prevention of Sudden Infant Death Syndrome: A Finite Element Method and Questionnaire Based Study

Raj K Maurya*/ Harpreet Singh**/ Deepak Malyala***/ Babita Niranjan****/ Ashutosh Dubey*****

Introduction: *Considering the morbidity associated with Sudden Infant Death Syndrome (SIDS) and limitations of absence of such syndrome in animals, a retrospective survey based human study and prospective Finite Element Method (FEM) study was planned to evaluate the effect of orthodontic pacifier in prevention of SIDS.* ***Study design:*** *Two groups, Group I (case) consisting of 48 people, who had lost their infant due to SIDS in past, and Group II (control) consisting of 200 participants with infant in the family, were established. The study was conducted in two parts. An online questionnaire-based survey consisting of 20 multiple choice questions was conducted to establish the correlation of pacifiers in families affected with SIDS. Thereafter, FEM evaluation was carried out in two age groups (up to six months, and between seven to 12 months) with two different pacifiers i.e. conventional and orthodontic, and one human nipples.* ***Results:****12 participants from case group and 170 in control group gave history of using pacifier for their infants between 2 to 6 months. The frequency and duration of use of pacifiers in case group generally increased while infant cried as high as 66 percent in frequency and 75 percent in duration in comparison to 90 percent in control group. FEM analysis showed significant stresses incurred with conventional pacifiers in relation to oral cavity and tongue. Orthodontic pacifiers exhibited human nipple like effect with more pronounced effects on posterior oral cavity and lesser strain on soft and hard tissues.* ***Conclusion****: Promising results obtained with survey and positive correlation of FEM data with orthodontic pacifiers indicates the superiority and advantages of orthodontic pacifiers in prevention of SIDS.*

Keywords: *SIDS, FEM, orthodontic, pacifiers*

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INTRODUCTION

Centre of Disease Control (CDC) defines Sudden Infant Death Syndrome (SIDS) as sudden, unexplained death of an infant younger than one year old. It has been classified as one of the subcategories of Sudden Unexpected Infant Death (SUID), which also includes homicides, accidental death and sudden natural death.[1]

There have been persistent disparities in SIDS deaths among different race and ethnicity peoples. As per census 2013, in North America, the SIDS reported incidence were 20.3 per 100,000 live births for Asian and Pacific Islander to 119.2 per 100,000 live births for American Indians and Alaska. Similarly, Indian subcontinent had a prevalence of 3.9/10000 in 2010. African American infants have a 24% greater risk of SIDS related death and prone to a 2.5 greater incidence of SIDS in comparison to Caucasians.[1,2] Literature also showed that New Zealand have reported the highest incidence of SIDS in the world. Further, epidemiological data have shown that SIDS is most likely to occur between 2 and 4 months of age and its prevalence is more often in male children mainly during winter months.[3,4]

The 'Back to Sleep' Campaign started in 1994 helped in reducing incidence of SIDS all over the world till 2000-01, which later saw a reversal of trend with a 2.9% increase in the SIDS rate from 2001 to 2002 till next decade plateau.[1]

The exact etiopathogenesis of SIDS is still unanswered. However, it has been proposed that the combination of factors including a specific underlying susceptibility, a specific time in development, and an environmental stressor could play an important role in precipitating the events. These variables could include sleeping on the stomach or side, co-sleeping, overheating and exposure to tobacco smoke. Other precipitating factors are birth before 39 weeks of gestation, infections, genetic disorders, and heart problems.[5]

The various preventive and therapeutic measures that have been suggested by Task force on SIDS in 2011, 2005 were related to control of environmental stressors which can further reduce the infant susceptibility towards the incident. One of the measures among them are pacifiers or teethers or soothers.[2] Though, there have been negative recommendations against the use of pacifiers in infants by various Paediatric associations including the Indian Paediatric Associations on the ground of inhibition of satiety centre, interference with breast feeding and development of orthodontic malocclusions, pacifiers have been still recommended in Netherlands and Germany to decrease SIDS risk. Use of pacifiers particularly after one month of age have also been boosted and encouraged by American Association of Paediatricians.[6,7]

The present-day pacifiers' designs are based on 'soothers' provided to infants and kids to comfort them especially while having bedtimes and during teeth eruptions. The etymology of word "pacifier" originates from the verb "to pacify," which means "to calm down." Although, the history of pacifiers dates back to thousands of years ago with the ancient text's writings of Sorano in 2nd century and Oribasius in 4th century, medical literature could be traced only as early as 15th century by writings of Metlinger (1473) and Rosslin (1513).[8]

The role of pacifiers and SIDS show a complex relationship with plethora of unexplored literature. Fern R. Hauck and co-workers[9] conducted a meta-analysis by searching the Medline database from January1966 to May 2004 to collect data on pacifier use and its association with SIDS, morbidity, or other adverse effects. The authors reported that encouraging pacifier use is likely to be beneficial and that 1 SIDS death could be prevented for every 2733 infants, who use a pacifier when placed for sleep. Pacifiers could also help the child from not spitting up and blocking the air supply, which has been a probable cause of SIDS.[10] A recent Cochrane Database Systematic Review by Jaafar *et al* [11] showed no significant effects of pacifier use on the prevalence or duration of exclusive and partial breastfeeding up to four months of age in healthy term breastfeeding infants. They also found lack of evidence regarding the short-term breastfeeding difficulties faced by mothers and long-term effect of pacifiers on infants' health.[11]

The finite element method (FEM) is an engineering resource applied to calculate the stress and deformation of complex structures and has been widely used in orthodontic research. With the advantage of being a non-invasive and accurate method that provides quantitative and detailed data on the physiological reactions possible to occur in tissues, applying the FEM can anticipate the visualization of these tissue responses through the observation of areas of stress created from applied orthodontic mechanics.[12,13]

Questionnaire based survey is a valuable tool for gathering important information in relation to various aspects of human health. The method is being used most commonly in field of psychology for data assessment. A questionnaire is an instrument for collecting quantitative data which involve asking open ended or closed questions on given subject to respond to a set of oral or written questions in a method. Especially online and mobile surveys have a very low cost and a generous reach.[14,15]

It was first postulated in 1979 that pacifiers might decrease the risk for SIDS at a time when SIDS was linked to sleep apnoea. Although, the association between SIDS and sleep apnoea is no longer considered plausible, there is strong and consistent evidence that fewer SIDS infants use a pacifier than their age-matched control. As mentioned above, some countries recommend pacifiers use as a risk-reduction measure for SIDS, others are more ambivalent requiring further evidence about the ground and mechanism of protection. A recent Cochrane review by Psaila *et al* [16] found no rand omised control trial evidence on which to support or refute the use of infant pacifiers for the prevention of SIDS.

Considering the difference in morphology of conventional and orthodontic pacifiers and long-term side effect of conventional pacifiers on dental arches and morphology, further exploration of the role of Orthodontic pacifiers is needed for not only as a preventive measure of SIDS but also for promoting better oro-facial hard and soft tissue growth and development.[5,6]

Considering the morbidity of SIDS and limitations of absence of such syndrome in animals, a retrospective survey based human study and a prospective FEM study was planned to evaluate the effect of different pacifiers on prevention of SIDS. Hence, present study was conducted in two parts. Firstly, questionnaire-based survey was conducted to establish the co-relation of pacifiers in families affected with SIDS in India; and secondly, FEM analysis was carried out to find out the stress distribution pattern of different types of pacifiers in relations to craniofacial region. Subsequently, combined null hypothesis was evaluated regarding the potential positive role of different pacifier in reducing potential SIDS incidents.

MATERIALS AND METHOD

Present study was conducted at Govt. Dental Centre and associated University Hospital in collaboration with Institute of Industrial Design, Dwarka, New Delhi, India vide permission letter number 'ADC/09/Pers/RKM/2017 dated 17 April 2017. Ethical committee approval was obtained from 'Institutional Research Ethics Committee' vide Appx 'A' to O/o DGAFMS/DG-3B letter No 15965/56th dated 03 May 2017 from Government Dental Hospital (Research & Referral), New Delhi.

Present study was conducted in two parts. The first part of the study had been carried out by conducting a questionnaire-based survey of 248 people. STROBE guidelines were adhered strictly to evaluate the result of questionnaire-based case control study. Participants were divided in two groups; Group I (case) group consisting of 48 people, who had lost their infants due to SIDS in past, and Group II (control) consisting of 200 participants with infants in the family. Survey was prepared online using Google Survey Forms consisting of 20 multiple choice questions (Annx's I and II). For validity and reliability, the questionnaire was first piloted on 15 subjects who were not part of the study. Based on the results of the pilot survey, the questionnaire was modified to make it simpler and more relevant. Study protocol was explained to the participants of

the study. The participants had given a written informed consent as part of the study. The questionnaire was completed and returned by the participants. Questions were given with answer choices that were easily understandable and brief in manner. Survey was conducted between Jun 2017 till March 2018. Records of the affected families were obtained from Stats section of Tertiary care hospitals of Indian Armed forces across the country. One investigator was available while filling the questions, and participants were encouraged to approach the investigator for any clarification. All answers were kept confidential. Families who refused to participate in the study were excluded from study. Questionnaire was completed by family members usually, and data collected included details of pregnancy and birth, infant health and well-being, parenting practices, knowledge about pacifiers and its user preferences (Annx's I and II). The Google Forms system was programmed to send out reminders every 7 days to the email addresses that had not answered.

The second part of the study was a finite element method (FEM) study. All the required ethical clearances were taken from the institutional ethics committee. The study was conducted in collaborations with the Institute of Industrial Design, Dwarka, New Delhi India.

FEM evaluation was carried out in two age groups using two different pacifiers i.e. conventional and Orthodontic, and one human nipples. The age groups were up to six months, and between seven to 12 months.

Steps Carried out to conduct FEM

1. Set type of analysis to be used
2. Fabrication of 3D Models
3. Defining Element types
4. Meshing procedure
5. Setting up material properties and boundary conditions
6. Deriving element matrices and equations
7. Assembling element equations
8. Solving unknown quantities at nodes
9. Interpretation of Results

ANSYS Workbench 15.0 Software (ANSYS Inc USA) package was used to perform the FEM Analysis in the present study. Hypermesh Software (ALTR™, USA was used for meshing the CAD model, which was then exported to ANSYS Software. Although ANSYS has the provision for meshing, meshing was done using Hypermesh software as it is much more detailed and accurate.

Present study was performed with static structural analysis as the load and field conditions remains static which allows gradual change to take place. Inertia and damping effects were ignored for analysis. The FEM software gave output for displacements, stresses, strains and reaction forces. FEM process were divided into three phases namely, pre-processing, solution & post-processing. Pre-processing was the phase, where input data was given to the software and used in the subsequent stages. The standard procedure of FEM was followed at pre-processing stage, which included geometric model fabrication, Meshing design, and their subsequent loading and cleaning. The subsequent step was the solution phase (a completely automatic stage) in which element matrices were generated, nodal values were computed, and subsequently result data was stored in result files in graphical and tabular format. Finally, post-processing was done to generate the results.

Construction of Geometric Model (Figure 1)

The skeletal model and the corresponding facial structures were developed using the Autodesk Maya software (Autodesk Inc, USA), which is a 3D computer graphics software. The use of such software was so chosen since, the CT Scans of infants were not available for 3D analysis. Hence the 3D model was created using average dimensions of a human infant. The 3D models were then exported in STL file format. The 3D Model of the different pacifiers were made using SolidWorks 3D Software. The dimensions of the pacifiers were obtained using Vernier calipers & Screw gauge.

Conversion of Geometric model into FEM Model (Figure 2)

After performing the general meshing, each of the two different pacifiers used in the study were meshed separately to achieve best results. The facial structure was meshed as a mechanical assembly. After meshing the file was exported to ANSYS Workbench Software wherein the material properties were defined, as well as loading and boundary conditions.

Although, it is impossible to obtain perfect quality meshes and parameters for the complex structures under study, special care has been taken to ensure the best levels of accuracy in the study. Care was taken to model the various contact points between structures, such as contact between lips and pacifier, contact between pacifier and palate & tongue, contact between teeth and alveolar bone. All contact points were defined using unique terminologies during the study.

The Finite Element details of the pacifier's model had 55190 Nodes and 32264 Elements.

Material Properties Data Representation (Tables 1 and 2)

Most of the material properties of the objects, both living and non-living were available through various material databases. For the following study, all material was assumed to be isotropic materials, which exhibit the same material property throughout the object under consideration. Hence all materials had been defined by using only two autonomous constants namely Young's Modulus & Poisson's Ratio. Young's Modulus (MPa), also known as modulus of elasticity is the measure of the stiffness of an elastic material. Poisson's Ratio is the ratio of the differential contraction to differential extension, when an object is subjected to loading conditions. The tendency of every material to expand in the opposite directions to the applied load, is called Poisson's phenomenon; and Poisson's Ratio is the measure of the same. Mechanical Properties of all the materials used have been taken from past available literature and have been tabulated below.

Defining Boundary Conditions

For the static structural analysis to be performed, certain constraints had to be applied and certain assumptions had to be made for defining boundary. The friction between the upper and lower jaw was ignored. Similarly, friction between the lips & pacifier, and pacifier and tongue were also ignored. The alveolar bone was

Figure 1. 3D Model and Mesh of tongue and upper-lower alveolus

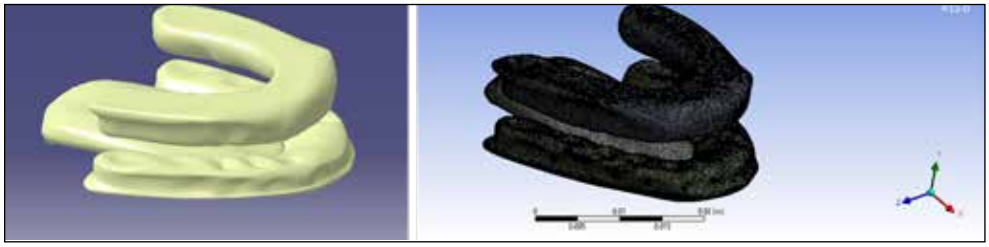


Figure 2. 3D mesh of Orthodontic pacifiers

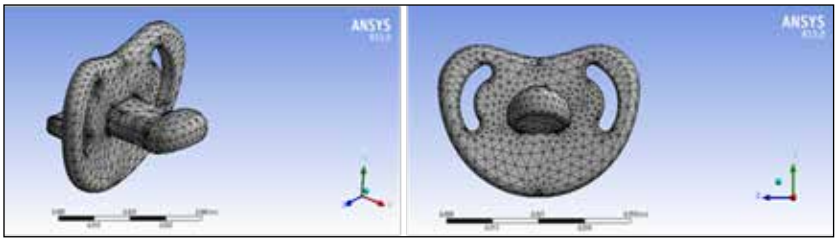


Table 1. Elastic Properties of material under study FEM analysis

Material	Young's Modulus	Poisson's Ratio
Periodontal Ligament	27.5Mpa	0.49
Bone (Alveolar & Mandibular)	1.5MPa	0.30
Tongue	15KPa	0.49
Lips (Rest)	6.2KPa	0.49
Lips (Contracted)	110KPa	0.49
Palate	6Mpa	0.42
Polyurethane & Rubber Pacifier	27.5MPa	0.49
Skin	15KPa	0.49
Muscles (Rest)	6.2KPa	0.50
Muscles (Contracted)	110KPa	0.50
Fat	6.2Kpa	0.49
Teeth	19.6Mpa	0.30

Table 2. Density used for FEM analysis

Muscle density	1.06 kg/ltr
Teeth Density	2.84 gm/ml
Polyurethane density	1.05 gm/ml

constrained to prevent it from free bodily motion. It was assumed that the pacifier was held at the same position throughout the entire duration under study. Facial structure above the mandibular condyle level was also ignored.

Application of Forces

Single point of force application was chosen for the present study. This was done to simulate the biting force applied by the Lower jaw in the upwards (+Y) direction. The value of load was gradually increased to study the effects of pacifiers use on the four different age groups under consideration. Table 3 depicts the magnitude of applied force for different pacifiers in two age groups. Intraoral pressure of 0.8688 Psi was also applied uniformly across the entire region under consideration.

Table 3. Load distribution during FEM analysis

Age Group	Load Distribution		
	Orthodontic pacifier	Conventional pacifier	Human nipple
0 Days to 6 Months	1N	1N	1N
6 Months to 1 Year	1.5N	1.5N	1.5N

Statistical Analysis

Statistical analysis of survey data as case and control group was performed using SPSS software for Windows (version 21; IBM Inc., USA). Shapiro-Wilk test showed that the data were normally distributed, and thus, parametric tests were used. Descriptive statistics of data calculated P value, Z value, 95 % Confidence Interval of Difference and Odds ratio. The chi-square test was used to assess inter-group comparison of case and control group. Student's t- test were used for intra-group comparison of each group. Tests of significance were two-tailed, and the minimum level of significance was set at $P < 0.05$.

RESULTS

Questionnaire Evaluation (Annx's I and II)

The survey data revealed that 48 participants of case group and 200 participants of control group responded the questionnaire. Data revealed that professions of both case and control group participants were majority of Defense personnel with average 60 percent in both groups, followed by health care professionals and other private jobs. 72 percent case group had lost their infant due to SIDS between 5 to 9 months of age.

Regarding the awareness about SIDS, as high as 90 percent of families in case group were not aware of SIDS, in comparison to 70 percent in control group. Among them, approximately 6 percent participants in case group reported with past family history of SIDS, in comparison of only 2 percent of control group. Male infant dominance as high as 68 percent in case group and 60 percent in control group was present in both groups. Average

percentage of mother and fathers with ages between 20 to 30 years were 40 and 44 percent in case and control group, respectively, followed by 30 and 35 percent in age group of 30-40 years. Around 70 percent participants in case and control groups reported infant sleeping positions as prone and supine, respectively. Around 80 percent had reported their infants with sleeping hours more than 15 hours. (Table 4)

As for the history of pacifiers either orthodontic or conventional, 90 percent participants provided consent of being aware about the pacifiers in both groups. In terms of use of pacifiers, 12 participants from case group and 170 in control group gave history of using pacifier for their infants; and average age of starting pacifiers were between 2 to 6 months. 66 percent i.e. only 8 families among 12 participants did use conventional pacifiers in comparison to 70 percent among 170 control participants.

The frequency and duration of use of pacifiers in case group generally increased while infant cried as high as 66 percent in frequency and 75 percent in duration compared to 90 percent in control group. None of the participants in case group responded regarding switching over from conventional pacifiers to orthodontic pacifiers; however, 27 percent participant in control group did change.

The major positive effect reported with conventional pacifiers were baby engagement and sleep as high as 87.50 percent, in comparison to 70 percent with orthodontic pacifiers. Control group for the conventional pacifiers showed as high as 54 percent

Table 4. Descriptive Statistics of Questionnaires of Survey

S.No.	Questions (20)	Case Group (P value) n=48	Control Group (P value) n=200	Inter Group (P value)	Odd Ratio	95 % CI	Z value
1	What is your Profession?	1.6731E-11	2.2324E-45	1.0000	1.0000	0.6405 to 1.5613	0.000
2	At what Age did you Lose your child?	2.81008E-13	0.0000	0	0	0	0
3	Have you heard about the SIDS before the incident?	1.42088E-15	1.98123-19	0.0032	0.1628	0.0486 to 0.5453	2.943
4	Do you Have History of SIDS in Family?	1.42088E-15	1.35650	0.0389	6.8023	1.1028 to 41.9596	2.065
5	What Was the gender of Infant?	0.009374768	0.0087775	0.2645	1.4667	0.7485 to 2.8740	1.116
6	What was the Age of the Mother during pregnancy?	0.006324314	5.88949E-19	0.048275	0.6706	0.3237 to 1.3893	1.075
7	What was the age of father during pregnancy?	0.002686849	1.06551E-08	0.014428167	1.0500	0.4998 to 2.2059	0.129
8	What was the sleeping position of baby most of the time?	7.36218E-11	2.00779E-47	0.100021393	1.0102	0.4083 to 2.4995	0.022*
9	How many hours baby use to sleep in a day?	1.59164E-16	1.17741E-71	0.1989560	1.1875	0.4615 to 3.0559	0.356
10	Have you heard about pacifiers?	4.13873E-08	1.12243E-29	0.9314	0.9556	0.3395 to 2.6898	0.086
11	When did you start pacifier for your baby?	0.881014843	7.29341E-09	0.172743625	0.6926	0.1478 to 3.2469	0.466
12	Was it Conventional or Orthodontic pacifier	0.018315639	6.13815E-27	0.7355	0.8067	0.2320 to 2.8049	0.338
13	What was the frequency of pacifier uses in a day?	0.007383161	1.07393E-83	0.170525633	0.4444	0.0872 to 2.2650	0.976
14	What was the duration of pacifier uses in a day?	0.00043985	1.07393E-83	0.218945	0.1103	0.0064 to 1.9017	1.518
15	Did you switch over between conventional to orthodontic pacifier?	6.14421E-06	1.91363E-31	0.1291	0.1103	0.0064 to 1.9017	1.518
16	Please select the positive noticed effect of conventional pacifier.	0.00081006	6.58687E-71	0.243627	0.0374	0.0043 to 0.3247	2.980
17	Please select the negative noticed effect of conventional pacifiers.	0.02517214	1.90836E-27	0.2134546	0.3034	0.0532 to 1.7301	1.343
18	Please select the positive noticed effect of orthodontic pacifiers.	0.052473896	3.54357E-19	0.53260	0.3030	0.0270 to 3.4072	0.967
19	Please select the negative noticed effect of Orthodontic pacifiers.	0.111610225	6.69353E-19	0.43269	2.5000	0.2237 to 27.9409	0.744
20	Do you recommend Orthodontic pacifier or Conventional design?	4.4134E-85	3.56171E-36	0.0001	12.333	5.1572 to 29.4950	5.647

CI, Confidence Interval of Difference; * P < 0.05 is significant

for baby engagement and 53 percent for sleep. However, control group reported various advantages of orthodontic pacifiers in terms of analgesic effect, substitute of feeding, engagement of baby and facilitation of sleeping equally around 20 to 38 percent each. The negative side effects of conventional and orthodontic pacifiers reported were mainly interference with breast feeding in case group. Likewise, control group showed interference with breast feeding as main problem with conventional pacifier as high as 75 percent, but only 25 percent responded same with orthodontic pacifiers.

At last, as high as 77 percent in case group recommended the use of orthodontic pacifiers, while 60 percent control participants recommended conventional design pacifiers.

FEM Analysis

ANSYS Workbench 15.0 Software (ANSYS Inc USA) was used for mathematical simulation, a model in which orthodontic and conventional design pacifier were studied in comparison to the human nipple about the effects on orofacial region starting from the age group of one month till 24 months. Equivalent Stress (Von-Mises) in MPa was analysed for these 3 variables among two different age group i.e. group 1, up to six months and group 2, 7 – 12 months. The stress distribution was studied on the palate and the tongue. Various stresses were observed in various directions due to interaction of the pacifier with the objects under study. A biting force of 2N was applied in all the 3 cases and the simulation was conducted for 3000 seconds.

Figure 3. FEM analysis with conventional pacifier up to six months

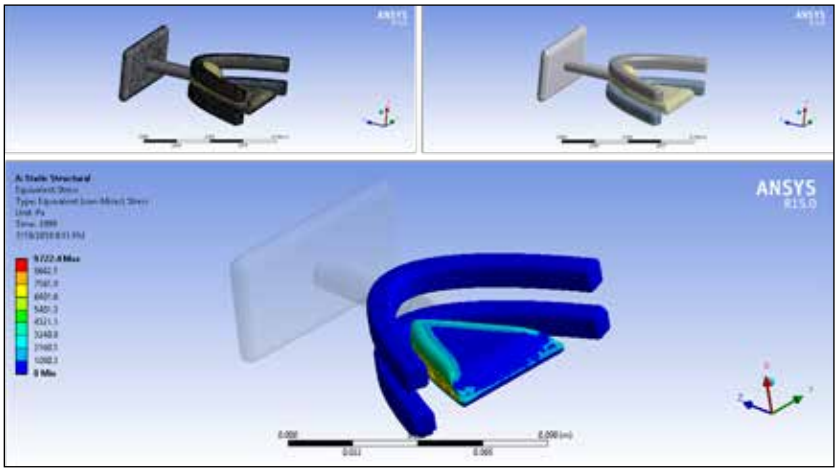
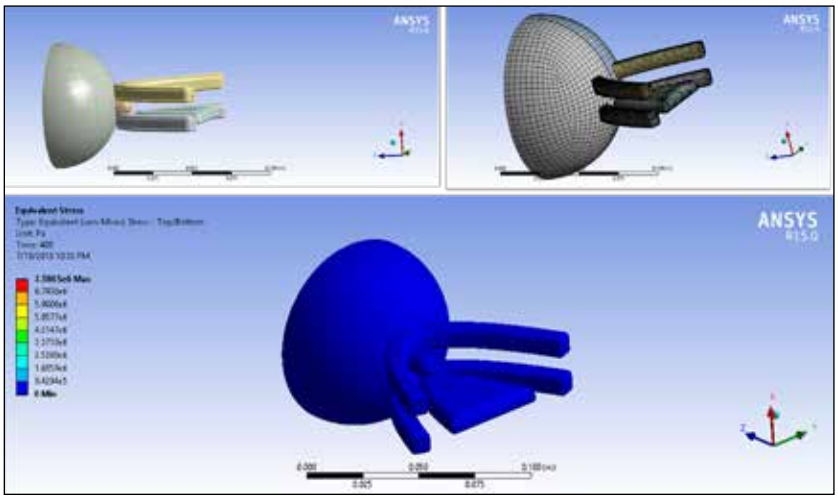


Figure 4. FEM analysis of Human nipple up to six months



Up to six-month analysis

The data up to six months showed that the stresses incurred with the use of a conventional pacifier were of the magnitude of 9.7224 MPa, leading to significant stress generation in relation to oral cavity and tongue (Fig 3) Similarly, the stress generated with human nipple was minimal, which implies that the facial structure does not experience any significant stress when sucking on the human nipple, even for prolonged periods of time (Fig 4). With orthodontic pacifier, it was observed that the stress generated was more uniformly distributed in oral cavity as compared to conventional design wherein greater stress was observed in the posterior region. The max stress due to orthodontic pacifier was 11.623 MPa, which was experienced at the end of the tongue, at the opening of the pharynx. Minimum stress measured was 0.008MPa, which was experienced at the point of interaction between the tongue and the lower jaw. It was also observed that the stress of the magnitude of 1.36Mpa was evenly distributed in the lower jaw (Fig 5).

6 months to one- year analysis

Conventional pacifiers showed maximum stress at lip level with point of contact of lower lip stress evenly distributed on tongue and reducing with the depth towards oral cavity. There was some indication of change in position of teeth with conventional pacifiers as intensity of sucking were increased (Fig 6). Human nipple stress evenly spreads around both upper and lower jaws with maximum stress at the centre of lower jaw and significant influence on posterior airway region (Fig 7). Orthodontic pacifiers also showed human nipple like effect with more pronounced effects on posterior oral cavity and lesser strain on soft and hard tissues. (Fig 8)

DISCUSSION

The present study was proposed to assess the effectiveness of orthodontic pacifiers in prevention of SIDS. The study had been planned in two phases. The first phase was a questionnaire-based survey among the case and control of families of SIDS, consisting of 248 participants. The second phase of the study was a FEM analysis of human nipple, conventional cherry top pacifier and orthodontic pacifiers on craniofacial region. It determined stress induced changes among cranio-facial region starting from lip junction till pharynx in sagittal direction, from buccal mucosa from left to right in transverse direction, and floor of the mouth till level of mandibular condyle cross section.

As per the SIDS task force 2011,[2] since the SIDS prevalence is defined with infant under one year of age, two age groups were constituted. The age groups were up to six months, and between seven to 12 months. The assessment up to six months was done to evaluate the difference of

Figure 5. FEM analysis of Orthodontic Pacifier up to six months

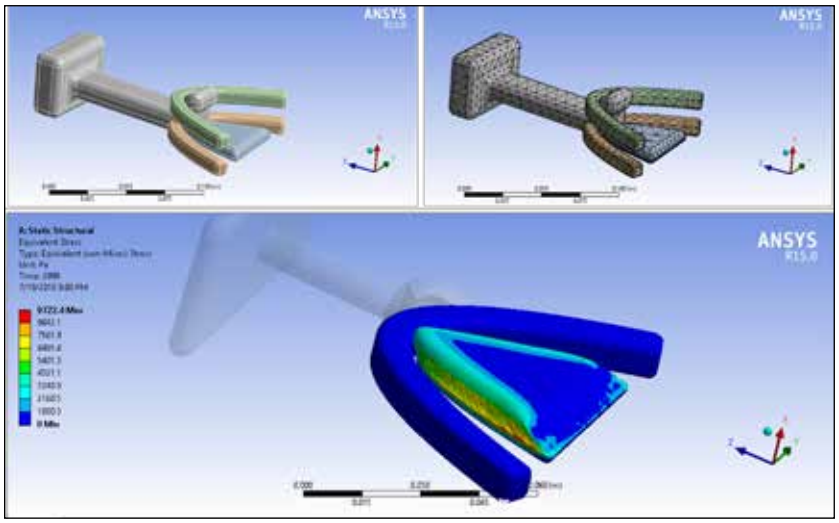


Figure 6. FEM analysis of conventional Pacifier from 6 to 12 months

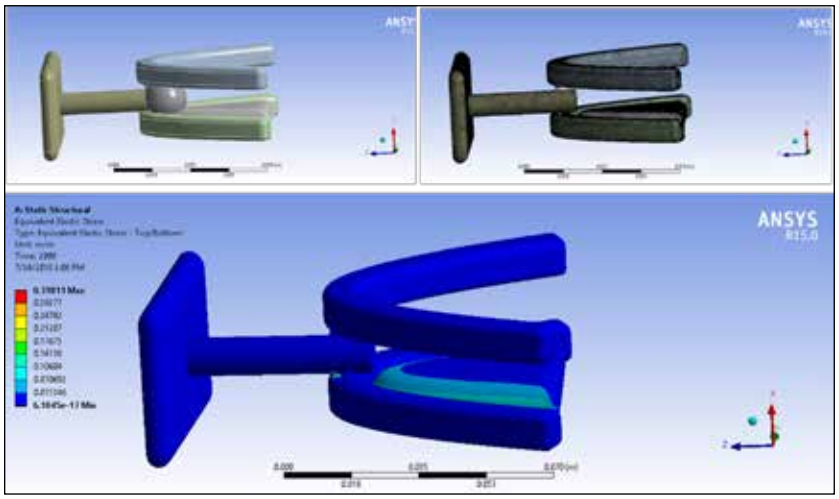
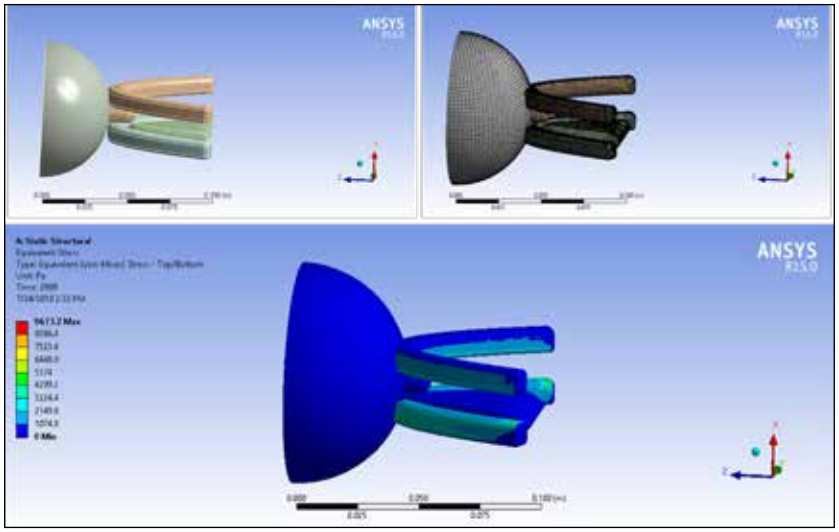


Figure 7. FEM analysis of Human Nipple from 6 to 12 months



impact of pacifiers among the dentate and edentulous gum pads.

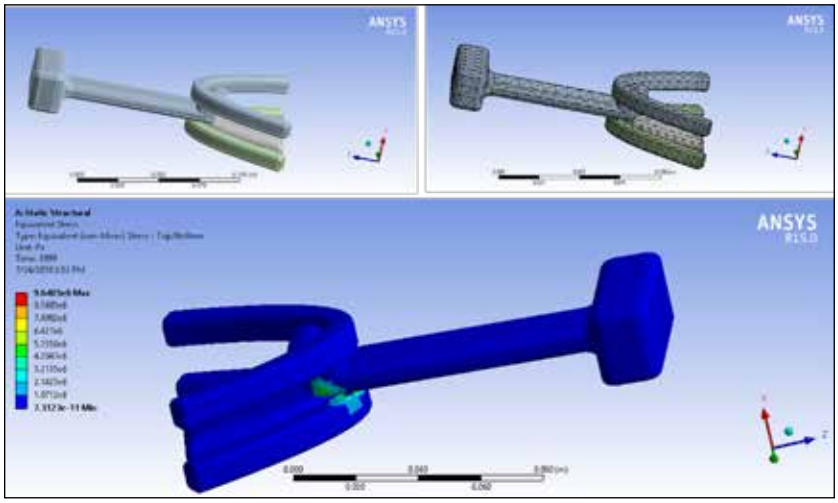
Since, the prospective clinical study on SIDS is ethically not feasible due to death as end point, the FEM evaluation were planned to assess the effects of pacifiers on SIDS. The results of this study are difficult to compare with previous investigations, as, to our knowledge, no other comprehensive study or RCT has examined/explored the association between pacifiers and SIDS. Present study, hence tried to convey the answer by using retrospective data of SIDS and its relationship with FEM generated findings, which might act as base line for future RCTs.

The FEM evaluation was done in two age groups with two different pacifiers i.e. conventional and Orthodontic and one human nipples. Two models of pacifiers, namely, conventional and orthodontic, are commercially available in the present-day market. The shield of the conventional pacifier has a convex curvature in relation to the oral structures of the child; while in the orthodontic pacifiers, it has a concave curvature that is more suitable to the infant's jaws. The nipple of the conventional pacifier has a "cherry-like" shape and is thicker than that of orthodontic pacifier. Few studies have shown that the shape of the orthodontic pacifier better fits the child's oral structures due to its anatomical resemblance to human nipple, which is assumed to promote an adequate lip seal. It is also believed that the use of orthodontic pacifiers not only induces patterns of muscle contraction, but also improves the tongue position and nasal breathing, hence, not interfering with the growth and development of dentofacial region and occlusion. This study demonstrated favorable and even stress distribution pattern with orthodontic pacifier which was able to maintain the patency of airway with minimal attrition effect on dentition. Similar findings were also reported in the study of Levrini *et al.*[17]

Additionally, the findings of this study further affirm the reports of the task force on SIDS which states that pacifiers when given to the child before bedtime can prevent the tongue from falling into the back of the pharynx, thereby reducing the risk of blockage to the air supply.

Li *et al* [18] theorized that the bulk design of pacifiers could change the airway dynamics due to their phenotypes which act as hindrance in accidental sleep associated hypoxia. Same authors also reported that pacifiers improve neural pathway development and help maintain the patency around the upper airway. Mitchell et al[19] and Weiss and Kerbl[20] independently reported that the forward positioning of tongue

Figure 8. FEM analysis of Orthodontic Pacifier from 6 to 12 months



facilitated due to sensory stimulations while using pacifiers can prevent the collapse of airway. Weese-Mayer *et al* [21] also reported similar findings by showing the co-relation between gene mutation and abnormal arousal mechanism due to receptor defect in autonomic nervous system.

A simple, economical and reliable questionnaire-based survey used in this study showed that in case group out of 48 patients, only 12 had used pacifiers, with eight conventional and four orthodontic design, thus increasing their odds ratio of SIDS in comparison to control of 180 patients out of 200 who used pacifiers. Our study also found significant difference in the sleeping position between both case and control groups.

Similar to earlier findings,[22,23,24] this study also found that interference with breast feeding were among one of the major side effects of conventional pacifiers mainly in case group and too some extent in control group. However, the effect was quite low with orthodontic pacifiers. Although, Kramer *et al* [25] reported a strong observational association between pacifier use and early weaning, however, no such association was observed during analysis of data by randomised allocation, indicating that pacifier use has a negative impact on breastfeeding, rather than being a true cause of early weaning.

In present study, one of the negative effects reported by participants were delayed eruption of dentition and mouth breathing. Present study concurs the finding of AM Nelson[26] who reported development of various malocclusion such as cross bite, delayed dentition eruption, anterior open bite with prolonged use of pacifiers. A systematic review by Pinelli and Symington[27] showed that non-nutritive sucking (NNS) significantly decreased the duration of hospital stay in preterm infants. The review also revealed no consistent benefit of NNS with respect to other major clinical variables.

Present study showed orthodontic pacifier design to be less detrimental in comparison to conventional pacifiers, especially in control group with Odd ratio as low as 0.3, hence, support the finding of the consensus which reported the prevalence and degree of malocclusion to be lower in the orthodontic pacifier group than in the conventional one. Adair et al[28] also found statistically significant difference between the orthodontic and conventional pacifier groups regarding open bite and overjet.

The American Association of Pediatricians (AAP) first published SIDS recommendation in 1992 and showed that prone positions for sleeping present a greater risk of dying from SIDS. Present study also found the high incidence of prone sleeping position babies in case group with odd ratio of 1.0102. The AAP re-confirmed their recommendation in the year 1994, 2000, and lately 2005.[6]

Considering the advantages of orthodontic pacifiers over conventional Pacifier in reducing the morbidities of SIDS and orthodontic malocclusions, present study tried to explore the mechanism, role and superiority of orthodontic pacifiers in SIDS prevention using FEM stress distributions model in craniofacial region.

CONCLUSION

This study was aimed to provide guidance to clinicians and parents as to whether orthodontic or conventional pacifier use is an effective and safe strategy in reducing SIDS. Promising results have been found with survey, and positive co-relation of FEM data towards Orthodontic pacifiers indicates the superiority and advantages of orthodontic pacifiers in prevention of SIDS. Moreover, longitudinal multi-centric randomized controlled trial can be conducted to further validate the finding at large scale.

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Conflict of interest

The authors received no financial support, and declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

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