

**Prevalence of incipient malocclusion and orthodontic treatment  
needs in primary and mixed dentition period using Risk of  
Malocclusion Assessment (ROMA) index and Baby-ROMA index**

**Dissertation**

**Submitted to the**

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PRADESH**

**In the partial fulfillment of the requirement for the degree**

**O f**

**MASTER OF DENTAL SURGERY**

**In**

**PEDIATRIC AND PREVENTIVE DENTISTRY**

**By**

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**Under the guidance of**

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**BATCH- 2018- 2021**

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I hereby declare that this dissertation entitled “**Prevalence of incipient malocclusion and orthodontic treatment needs in primary and mixed dentition period using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index**” is a bonafide and genuine research work carried out by me under the guidance of **Dr. Monika Rathore, Professor**, Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 7/07/21

Place: LUCKNOW



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This is to certify that the dissertation entitled “**Prevalence of incipient malocclusion and orthodontic treatment needs in primary and mixed dentition period using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index**” is an original bonafide research work done by **Dr. SUMAIYA MUZAFFAR**, in partial fulfilment of the requirement for the degree of **MASTER OF DENTAL SURGERY (M.D.S)** in the speciality of **PEDIATRIC AND PREVENTIVE DENTISTRY** under our supervision.

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*In The Name of Allah Most Gracious and Most Merciful*

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***Dr. SUMAIYA MUZAFFAR***

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## LIST OF ABBREVIATIONS

<b>S. NO</b>	<b>ABBREVIATIONS</b>	<b>FULL FORM</b>
<b>1.</b>	ROMA	Risk Of Malocclusion Assessment
<b>2.</b>	Baby-ROMA	Baby-Risk Of Malocclusion Assessment
<b>3.</b>	IOTN-DHC	Index of Orthodontic Treatment Need- Dental Health Component

## **ABSTRACT**

### **Aim:**

To establish the prevalence of incipient malocclusion among 4-12 years old school going children in Lucknow city and to determine the need for early orthodontic treatment in primary and mixed dentition period using Baby-ROMA and Risk of Malocclusion Assessment (ROMA) index.

### **Methods:**

3600 children in primary and mixed dentition stage aged 4-12 years were clinically screened for indications of Early Orthodontic Treatment. The subjects were divided into two groups, on the basis of age and dentition: Group-I: 4-6 years- with primary dentition and Group-II: 7-12 years- with mixed dentition. The collected data was then clinical analyzed for occlusal deformities in Group-I using Baby-ROMA index and in Group-II using ROMA index. The Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index was recorded to assess the treatment needs.

### **Result:**

The overall prevalence of malocclusion was 47.9% in primary dentition and 50.9% in mixed dentition period. Based on the scoring criteria of Baby-ROMA index females were at a greater risk of developing malocclusion in primary dentition period (34.4%), (p value <0.001). However, on the basis of scoring criteria of ROMA index, males were at a greater risk of developing malocclusion in mixed dentition period (50.9%), (p value <0.001).

### **Conclusion:**

Early identification and assessment of malocclusion helps in reducing the length and the severity of the orthodontic treatments. Orthodontic treatment at an early stage of development utilizes the use of simple devices and offers the lower therapeutic cost besides playing an important role in terms of children oral health.

## **INTRODUCTION**

“*Timing is everything*” holds best for occlusal management in children indicating early orthodontic treatment need. Guidance of the eruption and development of the primary, mixed and permanent dentition is an essential part of Paediatric Dentistry. Such guidance should aid in the development of a permanent dentition which is, in a, harmonious, functional and aesthetically acceptable occlusion<sup>1-4</sup>.

There are primate spaces in a normal maxillary and mandibular arch. It has been well demonstrated that 1-2mm of lower incisor crowding is normal before closure of canine primate space, known as Incisor Liability. Incisors often use up these primate spaces in order to drift into better alignment. Leeway space in the mandibular arch is approximately 4.5-5mm, thereby, accounting for the difference in size between the second primary molars and the second premolars that replace them. When the Leeway space is closed, this brings about a natural loss in arch length during the transition from primary to permanent dentition<sup>5-7</sup>.

It is vital to understand the pattern of growth and development of the untreated arch as it transitions from primary to the permanent dentition<sup>5</sup>. One of the key function of primary dentition is the maintenance of the arch length, so that the permanent dentition, which replaces it has sufficient space to erupt. The three features of primary dentition that indicates good dental development are spacing, primate spaces and straight or mesial step primary second molar relationship<sup>8-10</sup>. Also, myofunctional habits like abnormal lip and tongue function, mouth breathing, thumb sucking etc. are reported to have an influence on craniofacial development. A correct timing when to start an orthodontic therapy is essential for treatment to be most effective in the shortest time and with the lowest cost possible. A number of orthodontic indices have been introduced for this purpose with an aim of recognizing the individuals with a greater need for therapy on the basis of potential damage that the detected malocclusion may cause (*Taylor, 1993*)<sup>11</sup>. These indices have been used to estimate the prevalence of malocclusion and the amount of individuals in need of orthodontic treatment in a population<sup>19</sup>. Many indices for this purpose have been used to evaluate the prevalence of malocclusion and the amount of individuals in need of orthodontic



treatment in a population (*Tausche et al, 2004; Soh e Sandham, 2004; Soh et al, 2005; Mandall et al, 2005; Richmond et al, 2005; Bernabe e Flores-Mir, 2006; Souames et al, 2006; Josefsson et al, 2007*)<sup>12-18</sup>.

The ROMA Index - Risk Of Malocclusion Assessment Index (*Russo et al, 1998*) - is a tool to evaluate the treatment need in young patients. It was developed reviewing and modifying the dental and occlusal parameters of DHC with the addition of items related to skeletal and functional problems, to identify the risk of worsening of the malocclusion during growth. The main difference between ROMA and IOTN - DHC indexes is that the ROMA index evaluates malocclusion problems in growing child, assuming that some aspects may change under the positive or negative effect of craniofacial development, while IOTN-DHC index classifies the treatment need on the basis of data that could not change instantaneously. Another difference among the ROMA and IOTN indexes is that the ROMA index evaluates the timing of intervention, which could be immediate or deferred to a different time of dentition and cranio-facial growth according to the estimated risk, whereas the IOTN-DHC index determines if a patient must undergo orthodontic therapy, according to the clinical relevance of the observed problems<sup>20</sup>. ROMA index was then modified by the authors and was targeted on the age of primary dentition, known as, Baby-ROMA index. The main objective of Baby-ROMA index is early diagnosis and treatment of malocclusion at an early stage of development<sup>21</sup>.

Hence preventive orthodontics aims at patient and parent education, supervision of growth and development of dentition and the cranio-facial structures, the diagnostic procedures undertaken to predict the appearance of malocclusion and the treatment procedures introduced to prevent the onset of malocclusion. Therefore, the purpose of this study is to find the the prevalence of incipient malocclusion among 4-12 years old school going children in Lucknow city and to determine the need for early orthodontic treatment using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index.

## **AIM & OBJECTIVES**

### **Aim:**

To establish the prevalence of incipient malocclusion among 4-12 years old school going children in Lucknow city and to determine the need for early orthodontic treatment in primary and mixed dentition period using Baby-ROMA and Risk of Malocclusion Assessment (ROMA) index.

### **Objectives:**

- To assess the prevalence of incipient malocclusion in primary and mixed dentition.
- To assess the prevalence of dental features that indicate a need for Early Orthodontic Treatment (EOT) in primary and mixed dentition period using Baby-ROMA and Risk of Malocclusion Assessment (ROMA) index.
- To assess the association between malocclusion and orofacial myofunctional problems arising from morphological changes among the school-going children in Lucknow city.

## **REVIEW OF LITERATURE**

**Thilander B, Myrberg N (1973)**<sup>22</sup> conducted a study on the prevalence of malocclusion on 6,398 Swedish schoolchildren. The subjects were divided into Group 1 consisting of 2,664 boys and 2,795 girls in the town of Umeå, examined at 7, 10 and 13 years of age. Group 2 consisted of 429 boys and 510 girls referred from the district of Västerbotten and were examined only once. Dental anomalies of the permanent teeth, and space and occlusal anomalies were recorded. In Group 1 73.8% had some form of anomaly, of these, 52.3% were occlusal anomalies, 32.6% space anomalies and 14.9% dental anomalies. Of the referred children (Group 2) 44.8% had occlusal anomalies, while space and dental anomalies were equally common (29.4% and 25.8%, respectively).

**Kohler Holst and Krebs (1973)**<sup>23</sup> studied malocclusion and sucking habits of 4 year old children from Lund and Dalby. They found that 66.4 % had malocclusion and 77.9 % had or present sucking habits. A strong statistical connection was found between sucking habits and malocclusion, which was more pronounced for dummy sucking. It was observed that frequency of finger suckers was more than those who used to suck both dummy and fingers.

**Foster TD (1974)**<sup>24</sup> conducted a study on occlusal features and the need for orthodontic treatment on 1000 children, aged 11 to 12 years. The population was found to have a high prevalence of dental arch crowding and of Class 2 dental arch relationship. No orthodontic treatment was found to be necessary in 40.1 per cent of the population. Treatment by planned extraction of teeth only was necessary in 22.0 per cent, and active tooth movement with appliances, either with or without extraction of teeth, in 37.9 per cent. Crowding of the dentition and Class 2 dental arch relationship were found to be the main cause of the need for orthodontic treatment. In this population, more than 50 per cent of the subjects required early orthodontic treatment for treating Class 2 Division 1 occlusion.

**Kisling and Krebs (1976)**<sup>25</sup> carried out a study on patterns of occlusion in 1624 Danish children of age 3 years. They found that 1396 children had normal transverse

relations, 214 had cross bite and 14 had scissor bite. Open bite was more frequent. They observed that the number of dummy suckers was high and was significantly higher among children with cross bite than among children with normal transversal relations. In relation to spacing, he found that it was more common in maxilla than mandible.

**Kerosuo H et al (1988)**<sup>26</sup> conducted a study on occlusion and its variations in a group of primary schoolchildren ( $n= 642$ , age 11–18 yr) in Dares Salaam. Most children (96%) had Angle's Class I occlusion. Distal and mesial molar occlusions were rare in the sample, representing 3% and 1%, respectively. Crowding was found to be the most common dental disorder (16%) and the frequency of moderate and severe crowding decreased with age. No clear differences in occlusion were found between boys and girls. The results of this study show smaller occlusal variation compared with Caucasian children, and also some differences compared with previous African studies.

**Viskovic R et al (1990)**<sup>27</sup> conducted a study to assess the prevalence of orthodontic anomalies and caries in pre-school children with exclusively deciduous dentition. The overall prevalence of orthodontic anomalies was 47.50%, among which premature loss of teeth was leading cause (13.28%) followed by open bite (12.62%), primary crowding (7.64%), cross-bite (4.98%), trauma (2.65%), overbite (2.32%), diastema (1.99%), other anomalies (1.32%) and progeny complex (0.66%). The frequency of caries in total sample was 68.8%. The percentage of intact teeth was higher in maxilla than in mandible, whereas the percentage of treated teeth was higher in mandible. There was no correlation found between the frequency of orthodontic anomalies and dental caries.

**Skrinjaric et al (1991)**<sup>28</sup> conducted a study on prevalence of anomalies of deciduous teeth on a sample of 2,987 children aged 3-6 years. They found that total prevalence of all anomalies was 1.0% out of which hypodontia was found in 0.47% and hyperdontia in 0.10%. Patients with hyperdontia of primary teeth displayed anomalies in permanent dentition in 85.7% while children with supernumerary teeth in primary dentition showed anomalies in permanent dentition in 61.1%. Missing deciduous teeth were found in both jaws in only 8.7% of cases and in 34.8% in permanent dentition.

They most frequently missing teeth were maxillary lateral incisors (48.8%) followed by mandibular central incisors (34.9%). It was concluded that anomalies of deciduous teeth show a high degree of association with the findings in the permanent dentition.

**Kabue MM, Moracha JK, Ng'ang' a PM (1995)<sup>29</sup>** studied prevalence of malocclusion in primary dentition of 221 children aged 3-6 years in Nairobi, Kenya. They found that 51 % of the children had some form of malocclusion. Maxillary overjet accounted for 13%, deep bite 13%, dental midline displacement 6%, frontal open bite 12% and anterior cross-bite 5%. Anthropoid spaces were observed in 85% of children, while over 60% had spacing in incisor region. Straight terminal plane was seen in 53% of subjects followed by mesial step 43% and distal step in 1% of subjects. They concluded that there was a need for interceptive orthodontic therapy in some children.

**Nik-Hussein NN et al (1996)<sup>30</sup>** did a study on analysis of all cases of anomalies in primary dentition. A total of 79 occurrences of anomalies was seen in 65 children. The anomalies detected were double teeth, hypodontia and supernumerary teeth. They concluded that anomalies of the permanent dentition were seen in 59% of subjects with primary double tooth and 50% of subjects with primary supernumerary tooth.

**Baccetti T, Franchi L, McNamara JA, Tollaro I (1997)<sup>31</sup>** conducted a longitudinal study by comparing 25 untreated subjects having Class II malocclusion with control group of 22 untreated subjects with ideal occlusion in primary dentition. They monitored for 2 and half period in the transition from primary to mixed dentition without any orthodontic treatment. They found that all occlusal Class II features were maintained or become exaggerated during this transition stage. They concluded that Class 2 problems can be initiated in all three planes of space (eg, RME, extra-oral traction, functional jaw orthopedics) and also other factors such as patient cooperation and management should be taken into consideration before early orthodontic treatment is started.

**Tschill P, Bacon W, Sonko A (1997)<sup>32</sup>** conducted a survey on occlusal characteristics of the deciduous dentition in a sample of young children. 407 boys and 382 girls aged 4-6 years participated in the epidemiological study. Lack of space (24%), lateral

cross-bites (16%), and excessive overjet of 6mm or more (6%) was frequently observed traits. Class 2 relationships (26%) and anterior open bites (37.4%) were also observed. The striking difference in primary dentition was much higher prevalence of anterior open bites which gradually tends to decrease in permanent dentition. They concluded that early attention may be given to malocclusion, but should mainly be focused on lateral cross-bites and sagittal mal-relationships.

**Carvalho JC, Vinker F, Declerck D (1998)**<sup>33</sup> studied the prevalence of malocclusion on a sample of 750 Belgian children aged 3-5 years. They found that open bite was more prevalent (32.0%) which decreased with age followed by posterior cross bite (10.1%) and overbite (2.0%). Boys showed tendency for a higher frequency of malocclusion than girls. They concluded that emphasis should be laid on early detection of these oral conditions in order to permit effective and long-term planning, according to the child's individual requirements.

**Alamoudi (1999)**<sup>34</sup> conducted a study to evaluate the prevalence of crowding, attrition, midline discrepancies and premature loss of primary molars in primary dentition. They examined 502 children of Saudi Arabia aged 4-6 years. Crowding was found in 14.7% of subject, crowding in maxilla was seen in 5.4% of the children whereas it was 13.4% in mandible. Midline shift was seen in 10% of the children with females showing significantly higher prevalence than males. Attrition was seen in 33.3% of children with attrition of enamel being most prevalent (31.9%). 0.5% of the children had missing teeth. It was found that overall, premature loss of 1<sup>st</sup> primary molars was found to be significantly higher than 2<sup>nd</sup> primary molars.

**Goel P, Sequeira P, Peer S (2000)**<sup>35</sup> conducted a survey among 200 subjects of 5-6 and 12-13 years of age in India to assess the prevalence of dental caries, malocclusion and dental calculus. They found the prevalence of malocclusion was less in 5-6 years old as compared to 12-13 years old, 0.45 % had mild malocclusion, while 1.34 % had moderate to severe malocclusion.

**Thialander B, Pena L, Infante C, Parad SS, de Mayorga C (2001)**<sup>36</sup> conducted an epidemiological study in 4724 children of age 5-17 years in Bogota, Colombia, to assess the prevalence of malocclusion. They observed that 88 % of the subjects had

some type of anomaly, half of them recorded as occlusal anomalies, one – third as space discrepancies and one- fifth as dental anomalies. Occlusal and space discrepancies varied in the different dental developmental periods.

**Chevitarese AB, Della Valle D, Moreira TC (2002)<sup>37</sup>** studied the prevalence of malocclusion and the relationship with oral habits in 112 children of Brazil with mean 6.67 months. The results demonstrated the presence of malocclusion in 75.8% of the subjects. They observed that open bite was the most prevalent malocclusion in the studied population and oral habits were the decisive etiological factor.

**Warren and Bishara (2002)<sup>38</sup>** conducted a study on 372 children to determine the association between the duration of nutritive and non-nutritive sucking behavior and various occlusal characteristics in the primary dentition. It was found that the prolonged pacifier habits resulted in changes to the dental arches and occlusal parameters. These were different from the effects of digit sucking. In addition, some changes like posterior cross bite and increased amount of overjet persisted well beyond the cessation of the pacifier or digit habit. Prevalence of anterior open bite was found to be significantly higher among children with pacifier habits of 48 months or longer.

**Tausche E et al (2004)<sup>39</sup>** conducted a study to determine specific factors for treatment need in the early mixed dentition period. 8768 children aged between 6 and 17 years were clinically screened for the features indicating early orthodontic treatment need. The results showed that deep overbite and overjet, both more than 3.5mm were the most frequent discrepancies, affecting 46.2 and 37.5 percent of subjects respectively. An anterior open bite was seen in 17.7 percent, cross-bite in 8.2 percent, and reverse over-jet in 3.2 percent. A tooth-width to arch length discrepancy was recorded in 12 percent of teeth in the upper arch and in 14.3 percent in the lower arch.

**Grippaudo C et al (2007)<sup>40</sup>** conducted a study for validation of ROMA (Risk Of Malocclusion Assessment) Index, verifying both its reproducibility as well as its ability to determine treatment priority. They found that the ROMA index is quick to apply, reproducible, reliable, and sensitive as a means for careful identification and

diagnosis of different dento-skeletal problems. It is also able to determine the priority of every risk grade and the corresponding timing of treatment.

**Grabowski R et al (2007)**<sup>41</sup> conducted a study on the prevalence of malocclusion and orofacial dysfunctions in the primary and early mixed dentition. Occlusal relationships and myofunctional status were evaluated in 766 children in the primary dentition and in 2,275 children in the early mixed dentition. They concluded that normal occlusal relationships were found in 25.3% of children in the primary dentition. Frequency of children with normal dentitions fell significantly in the mixed dentition (7.3%). Prevalence of bilateral distocclusion increased significantly from the primary to the mixed dentition. Increased maxillary overjet was diagnosed in 49.3% and 59.0% of the children in the primary and mixed dentition, respectively. Prevalence of lateral crossbites increased significantly from primary to mixed dentition (7.2% vs. 12.0%). Deep bites and edge-to-edge bites were found significantly more often in the early mixed dentition.

**Brito DI, Dias PF and Gleiser R (2009)**<sup>42</sup> conducted a study to assess the prevalence of malocclusion in 407 children aged 9-12 years. They found that the most prevalent malocclusion was crowding (45.5%) followed by, excessive overjet (29.7%), posterior cross-bite (19.2%), anterior diastema (16.2%), partially erupted teeth (12.0%), and excessive over-bite (10.8%). Class 1 molar relationship was seen in 76.7%. the presence of diastema was more in females and excessive over-bite was more prevalent in males. They concluded that evaluation of malocclusion prevalence does not reveal case severity or treatment need, both of which are important factors in public health planning.

**Grippaudo C, Pantanali F, Paolantonio E. G., Saulle R., La Torre G. and Deli R. (2011)**<sup>43</sup> conducted a cross-sectional study to estimate orthodontic treatment timing for occlusal problems in growing Italian children between 8 and 13 years of both the genders. They found that, early treatment of orthodontic problems which did not improve with age were helpful as to avoid worsening of the condition in permanent dentition.



**Carvalho AC et al (2011)**<sup>44</sup> carried out a cross-sectional survey to assess the prevalence of malocclusion in primary dentition involving 1069 children of either gender from 60-71 months of age. The prevalence of malocclusion was 46.2% with deep overbite being most prevalent feature (19.7%), followed by posterior cross-bite (13.1%), accentuated overjet (10.5%), open bite (7.9%) and anterior cross-bite (6.7%). They concluded that the prevalence of malocclusion in their study was high, especially vertical and transversal malocclusions.

**Gois EG et al (2012)**<sup>45</sup> conducted a five year longitudinal cohort study on incidence of malocclusion between primary and mixed dentitions. School children aged 8-11 years participated in this study. It was found that anterior open bite (RR=3.1[1.7-5.8]), posterior cross-bite (RR=7.5 [4.9-11.5]), and over-jet greater than 3mm (RR=5.2[3.4-8.0]) in the primary dentition are risk factors for malocclusion in early mixed dentition. Spontaneous correction of anterior open bite was confirmed in 70.1% of cases. Posterior cross-bite and over-jet greater than 3mm were persistent in 87.8% and 72.9% of children. It was concluded that the individuals with previous anterior open bite, greater over-jet and posterior cross-bite had greater risk of having the same characteristics in the mixed dentition.

**Zakirulla. M (2012)**<sup>46</sup> conducted a cross-sectional study aimed to record various primary dentition parameters in 700 Saudi children, aged 2-6 year. 55.6% of the children had a 'flush terminal plane' molar- relationship. The proportion of children with distal-step molar relationship was significantly lower 23 (3.2%). The degree of overbite was significantly less in the 5-year-olds than in the 3-year-olds. The majority of the children (80.7%) had spaced dentition. The prevalence of anterior cross bite was 0.7% and of open bite was 0.3%.

**C. Grippaudo, E. G. Pantanali, G. Antonini, R. Deli (2014)**<sup>47</sup> introduced a new index targeted on the risk of malocclusions in primary dentition called baby-ROMA (risk of malocclusion assessment) on a sample size of 200 children. They found that k test showed a high reproducibility of the index and revealed that 50 % of patients present with malocclusion and cross bite.

**De Sousa RV et al (2014)**<sup>48</sup> conducted a study on the prevalence of anterior open bite (AOB) and posterior cross-bite (PC) in the primary dentition and the association with sociodemographic factors, presence and duration of nutritive and non-nutritive habits. A cross-sectional study was carried out with 732 preschoolers in Campina Grande, PB, Brazil. A questionnaire addressing sociodemographic data as well as nutritive and non-nutritive sucking habits was administered to parents/caregivers. The prevalence of AOB and PC was 21.0% and 11.6%, respectively. AOB was significantly associated with the three-year-old age group with duration of pacifier sucking  $\geq 36$  months. PC was associated with pacifier use and duration of breastfeeding  $< 12$  months. Socioeconomic factors appear not to be related to AOB or PC in the primary dentition, except type of preschool.

**Karen Glazer Peres, Peres, William, Broadbent, Pedro, Ana (2014)**<sup>49</sup> conducted a study to validate whether malocclusion in primary dentition is a risk factor in the permanent dentition in a sample size of ages 6 (n = 359) and 12 (n = 339) years. They concluded that children with only open bite and those with concurrent open bite and canine malocclusion were more likely to have either highly desirable/mandatory orthodontic treatment or only mandatory orthodontic treatment needs by age 12. The combination of cross bite and open bite in the deciduous teeth was associated with the highest risk of need for mandatory orthodontic treatment.

**Kasparaviciene K (2014)**<sup>50</sup> conducted a study to verify the prevalence of different occlusal traits among 5-7 year old children and to assess their relationship with oral habits. 503 pre-school children (260 boys and 243 girls) with a mean age of 5.95 years were clinically screened for different occlusal traits. Oral habits were diagnosed using data gathered from clinical examination of occlusion and extra-oral assessment of the face, combined with a questionnaire for parents. The study demonstrated that 71.4% of the children presented with 1 or more attributes of malocclusion and 16.9% had oral habits. The incidence of anterior open bite (P=0.013) and posterior crossbite (P=0.05) was more prevalent with digit sucking habit while infantile type of swallowing demonstrated strong association (P=0.01) with anterior open bite.

**Oropeza LM et al (2014)**<sup>51</sup> conducted a study on the prevalence of malocclusions associated with pernicious oral habits in 147 children aged 2-15 year old. The prevalence of pernicious oral habits was 96.6% with the largest number of cases presented at age 4 and in the 6-11 years of age during mixed dentition. The habit with the highest prevalence was lingual interposition (66.2%), the second was lip sucking habit (49.3%) and mouth breathing (31.8%). The most prevalent malocclusion was open bite (35.1%) followed by lower anterior crowding (26.4%), upper anterior crowding (19.6%) and lastly, posterior cross-bite (12.8%). There was an association between tongue thrusting and open bite ( $P<0.000$ ), and with mouth breathing and posterior cross-bite ( $P<0.012$ ) and Angle's Class II ( $P<0.008$ ). It was concluded that child population presents greater susceptibility to develop malocclusions during growth so preventive measures should be adopted during this stage.

**Prabhakar RR et al (2014)**<sup>52</sup> conducted a study on the prevalence of dental feature that might result in malocclusion and need for early orthodontic treatment. Groups of 532 school going children were selected and complete case history was taken and were categorized based on the type of malocclusions, dental features that can predetermine need for early orthodontic treatment. Angle's Class I malocclusion is most commonly seen malocclusion followed by class II division 1 malocclusion followed by Angles class II division 2 malocclusion. In angle's class I malocclusion, incidence of crowding is more followed by proclination of anterior teeth. There is no significant difference between incidence of malocclusion in males and females.

**Dimberg L et al (2015)**<sup>53</sup> carried out a longitudinal study to determine the prevalence and change from primary to early permanent dentition on 277 children who were followed at 3, 7, and 11.5 years of age. Malocclusion was found prevalent in 71% of participants at 3 years of age, 56% at 7 years of age, and 71% at 11.5 years of age. Self correction was noted for anterior open bite, sagittal malocclusions, and posterior cross-bites. Severe or extreme orthodontic treatment need was apparent in 22% of subjects. They concluded that there was a significant percentage of malocclusions and orthodontic treatment need in the observed sample.

**Peres KG et al (2015)**<sup>54</sup> carried out a study to estimate orthodontic treatment need in the permanent dentition using information from the deciduous dentition malocclusion.

Two oral health studies nested in a birth cohort were carried out at ages 6 (n= 359) and 12 (n= 339) years assessing open bite, cross-bite and canine relationship in deciduous dentition. Children with only open bit and those with concurrent open bite and canine malocclusion were more likely to have either highly desirable/mandatory orthodontic treatment needs by age 12. The combination of cross-bite and open bite in the deciduous teeth was associated with the highest risk of need for orthodontic treatment. They concluded that malocclusion in deciduous teeth is a risk factor for orthodontic treatment need and should be monitored at regular intervals.

**DaCosta OO et al (2016)**<sup>55</sup> conducted a study on the prevalence of dental features that indicate a need for early intervention in 101 children in mixed dentition between ages 6 and 12 years. It was concluded that anterior tooth rotations (61.4%) and increased over-jet (44.6%) were the most prevalent occlusal anomalies. Others included deep-bite (31.7%), reverse over-jet (13.9%), and anterior open bite (14.8%). About a third (35.7%) of the subjects presented with cross-bite while lip incompetence was observed in 43.6% of the subjects. About 44% of the subjects also presented with various oral habits with digit sucking (15.8%) and lip sucking (9.9%) being the most prevalent.

**Zhifei Zhou et al (2016)**<sup>56</sup> conducted a study on the prevalence and associated factors of malocclusion among children with primary dentition in Xi'an, China. A total of 2,974 subjects with a mean age of 4.82 (SD, 1.76; range, 2.63–6.12) years were screened for malocclusion traits. It was found that the most common type of malocclusion was increased overjet (34.99 %) in the sagittal direction, deep overbite (37.58 %), and midline deviation (25.32 %) in the vertical and transverse directions, respectively. The prevalence of posterior crossbite, anterior crossbite, and anterior open bite was 7.56, 6.80 and 6.98 %, respectively. The prevalence of the anterior edge-to-edge occlusion was the lowest (2.46 %). It was concluded that the feeding methods (OR=3.614 with 95 % CI of 3.087–4.596) along with the method of delivery (OR=1.847 with 95 % CI of 1.323–2.451) have been observed to play an important role in the morbidity of malocclusion ( $P<0.05$ ).

**Grippaudo C et al (2016)**<sup>57</sup> conducted a cross-sectional study on 3017 children using the ROMA index, to verify if there was a significant correlation between bad

habits/mouth breathing and malocclusion. They found a significant association of bad habits with increased overjet and openbite, while no association was found with crossbite. Also, they found that mouth breathing is closely related to increased overjet, anterior or posterior crossbite, openbite and displacement of contact points. Therefore, it is necessary to intervene early on these aetiological factors of malocclusion to prevent its development or worsening and, if already developed, correct it by early orthodontic treatment to promote eugenic skeletal growth.

**Disha P et al (2017)**<sup>58</sup> conducted a study on the prevalence of malocclusion and its association with caries experience in 8–9-year-old children of Davangere city, South Indian region. A total of 800 children from 350 schools (both males and females) were randomly selected for the study. The overall prevalence of malocclusion among 8–9-year-old children was 40.9%. The most prevalent malocclusion was crowding (11.5%), followed by excessive overjet (9.4%), deep bite (6.8%), spacing (6.5%), crossbite (4.5%), and open bite (3.2%). Class I molar relationship prevailed in 95.5% of children. Although, correlation of malocclusion and dental caries in the primary dentition, was non-significant, but children who presented with malocclusion had higher caries experience than children without malocclusion.

**Zhou X, Zhang Y, and Liu Y (2017)**<sup>59</sup> conducted a cross-sectional study on the prevalence of malocclusions among 2335 children aged 3-5 years old in Shanghai, China. The prevalence of malocclusion in primary dentition in Shanghai was 83.9% and no significant difference was found in genders. The prevalence of deep overbite (63.7%) was highest in children followed by deep overjet (33.9%), midline deviation (26.6%), anterior cross-bite (8.0%) and anterior crowding (6.5%). They concluded that the need for preventive orthodontic therapy and oral health education about malocclusion should be strengthened.

**Lu Shen, Fang He Jinhua Wang (2018)**<sup>60</sup> carried out a meta-analysis to determine the epidemiological characteristics of malocclusion among pre-schoolers in China from 1998-2017. A total of 31 qualified papers describing 51,100 Chinese children aged 2-7 years were selected. The pooled malocclusion prevalence was 45.50% with 26.50% Class 1, 7.97% Class 2, and 12.60% Class 3. The most common type of malocclusion was over-bite (33.66%) and flush terminal type (47.10%) was the most

common in the terminal plane relationship. They concluded that the results provided by the sample evidence can aid clinicians and policy makers towards early prevention and timely treatment.

**E.G. Paolantonio et al (2019)<sup>61</sup>** carried out a study to evaluate the prevalence of malocclusion and associated factors in preschoolers assessing the existence of an association between bad habits and mouth breathing with the most severe malocclusions. A sample of 1616 children aged 3–6 years were clinically screened for the features indicating early orthodontic treatment need using Baby ROMA index. The data showed that 38% of the sample need orthodontic treatment and 46% have signs of malocclusion of less severe degree that require a close monitoring and the elimination of risk factors so that they can improve spontaneously with growth. Moreover the prevalence of bad habits and oral breathing increases with increasing severity of the malocclusion, and sucking habits and oral breathing are both closely related to anterior open bite, posterior crossbite and increased overjet.

**Reddy NV et al (2019)<sup>62</sup>** conducted a study to determine the prevalence of malocclusion among 2550 school-going children aged 10–12-years in Khammam district of Telangana state. The results revealed that the overall prevalence of malocclusion was 76.6%. Of this, 65.9% of the children had Angle's Class I malocclusion, 9.25% had Class II malocclusion, and 1.37% had Class III malocclusion. About 15.4% showed an increased overjet (>3 mm), 0.2% had reverse overjet, 43.6% had increased overbite (>3 mm), 2% had open bite, 14.01% had crossbite, 46.23% had deviation of midline, 2.07% had midline diastema, and 2.98% had rotated tooth.

**Sirate R et al (2019)<sup>63</sup>** conducted a cross-sectional study on etiology of malocclusion and dominant orthodontic problems in mixed dentition among 8–9 years old Thai children. Etiology of malocclusion was detected in both congenital and acquired etiology (64.3%), followed by acquired etiology only (29.7%). The top three dominant orthodontic problems were caries (22.5%), early loss of primary tooth (15.6%), and tendency of crowding in permanent dentition (14.6%). Nearly all the children needed restoration (86.4%) and interceptive orthodontic treatment (69.3%), whereas severe malocclusion level was found in one-fourth of the children (26.0%).

Statistical significance was found between type of early treatment and malocclusion severity ( $P < 0.001$ ).

**Zeyad AA (2019)**<sup>64</sup> conducted a study to assess the prevalence of malocclusion traits among male school-children aged 6-9 years in Rass, Saudi Arabia. Randomly selected 304 male children were clinically screened for the features indicating early orthodontic treatment needs. The molar relationships were recorded using Angle's classification system and other occlusal traits, such as overjet, overbite, and crossbite, based on the methods of Bjoerk et al. for registration of malocclusion in centric occlusion. The frequencies of Angle's Class I, Class II, and Class III molar relationships were 81.91%, 11.18%, and 6.91%, respectively. A total of 85.86% cases had normal overjet, whereas 90.13% of cases had normal overbite. The most prevalent malocclusion of the participants was increased overjet in 9.21%, followed by deep bite in 5.92%, deficient overjet in 4.93%, posterior crossbite in 3.95%, anterior open bite in 3.95%, and an anterior crossbite in 2.96%. No statistically significant difference was found age wise.

**Priede D et al (2020)**<sup>65</sup> conducted a study on association between malocclusion and orofacial myofunctional disorders of pre-school children in Latvia. The study sample comprised of 141 children-mothers' pairs of pre-school children aged 4-7 years. Children myofunctional situation, occlusal and speech defects were assessed during an examination and children's mothers were interviewed on their socio-demographic situation, feeding and habits of the child. It was found that the types of occlusion associated with OMD characteristics were: normal occlusion with prolonged respiratory disease (odds ratio, OR= 0.345 [95% confidence interval, CI 0.16; 0.75]); combined type with tongue thrust habits (OR= 3.11 [0.99;9.90]), lip closing strength (OR= 0.99 [0,98; 0.99]); and cross-bite (OR= 3.55 [1.07; 11.78]).

**Grippaudo C et al (2020)**<sup>66</sup> conducted a cross-sectional and multicenter study in a population of 4,422 patients aged between 2 and 13 years (2,078 males and 2,341 females). The prevalence data were classified according to the items of the Baby ROMA (first group, deciduous/early mixed dentition) and ROMA Index (second group, late mixed/permanent dentition). The result showed that the need for orthodontic treatment among Italian children was high. In the sample aged between 2

and 7 years, the most frequent malocclusions are the moderate and severe open bite (23%), moderate and severe Class II (21.2%), deep bite (18.8%), cross bite (16.5%), Class III (7.7%), and crowding (5.1%). In the sample aged between 8 and 13 years the most frequent malocclusions are crowding (50.8 %), Class II (33.1%), deep bite (19.2%) crossbite (18.1%), Class III (9.1%), open bite (6.6%), facial or mandibular asymmetries (3.3%), and functional asymmetries (3.2%). It was found a statistically significant variation of the different malocclusion conditions according to age.



## **MATERIALS AND METHODS**

### **Ethical Approval:**

The study proposal was submitted to the Research Ethics Committee, Babu Banarasi Das University, and ethical approval was obtained (Annexure-I & II). All the children were invited to participate after obtaining the informed consent from various schools and parents of children through consent letters (Annexure-III). Assent letters (Annexure-IV) were obtained from the older children.

### **Study Area:**

The present study was conducted on a sample of 3600 children with primary and mixed dentition, including both males and females. The subjects were randomly selected from the Out Patient Department of Paediatric and Preventive Dentistry and from various schools in Lucknow city.

### **Formalised Hypothesis:**

The current descriptive cross-sectional study was based on the clinical diagnosis using the malocclusion index that revealed the actual picture of malocclusion and their treatment needs. It was hypothesized that early diagnosis and improvement of occlusal interference that promotes malocclusion, could be prevented from becoming more severe in growing subjects.

### **Sampling Method:**

The study was a cross-sectional survey, which was performed during October 2018 to November 2020. Data collection was carried out in the schools and those reporting in the Out Patient Department of Paediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, BBDU, Lucknow. 3600 subjects aged 4-12 years were clinically examined for the features indicating early orthodontic treatment need using one stage cluster sampling.

### **Sample Size:**

The sample size was calculated using the following formula (Charan and Biswas, 2013):  $n = 4pq/d^2$  (Annexure VII).

Where, n=required sample size.

p= prevalence of cause

q= 1-p

d= precision

Taking 80% power, 5% significance level with 0.01 precision, the calculated sample size was 3600

$$n = 4 * 0.10 * 0.90 / (0.01 * 0.01) = 3600$$

### **Aramamentarium:**

- Mouth mirror (Microlux Lighted mirror ADentCE Marked and ISO 9001:2008 Registered)
- Probe (LMERgoSens Dent Diag)
- Tweezers (FASA Group 2500)
- Gloves (PROFEEL NR)
- Cotton (TRO ORTHOSOFT-TROGE)
- Kidney tray (KR Dent)
- Digital caliper (0-150mm Precision)

### **Study design and subjects:**

Research Ethics Committee, Babu Banarasi Das University, approved this descriptive cross-sectional study design. 3600 school going children and those reporting in the OPD of Department of Paediatric and Preventive Dentistry within the age group of 4-12 years were clinically screened for the features indicating early orthodontic treatment need. The data collected was later analysed for occlusal deformities using Baby-ROMA and ROMA index for primary and mixed dentition respectively. The design of the study followed the guidelines published by Strengthening the Reporting of Observational Studies in Epidemiology (STROBE). Before commencement of the study all the study procedures were explained to every child and parents or guardians. Both consent and assent letters were obtained.

**Eligibility Criteria:**

***Inclusion Criteria:***

- Healthy subjects (ASA I) of either gender aged 4-12 years.
- Subjects with no history of previous orthodontic treatment and,
- Subjects free from any systemic diseases or serious health problems.

***Exclusion criteria:***

- Children with special health care needs.
- Uncooperative subjects.

**Study Procedure:**

After, obtaining ethical approval, consent was taken from various schools and parents of the children through consent letters explaining the aim and benefits of the study. 3600 school going children and those reporting in the OPD of Department of Paediatric and Preventive Dentistry within the age group of 4-12 years were clinically screened for the features indicating early orthodontic treatment need. To avoid any bias, single investigator monitored the total evaluation system.

The sample size of 3600 subjects was divided into two groups, on the basis of age groups and dentition.

Group-I: Aged between 4-6 years- with primary dentition

Group-II: Aged between 7-12 years- with mixed dentition

A self-designed case history preforma (Annexure-VIII) was filled for each examinee, based on clinical examination and questioning, which included information on the molar and canine relationships, over-jet and over-bite, Angle's classification, upper and lower midlines, anterior and posterior cross-bite, crowding, ectopic eruption, oral habits, and facial symmetry. A group of randomly selected children were then examined in a bright day light with the help of mouth mirror, fine explorer and a half millimetre ruler while using disposable gloves. Average number of 10-15 children were examined per day to avoid the effects of tiredness.

The collected data was then clinical analyzed for occlusal deformities in Group-I using Baby-ROMA index (Annexure-IX) and in Group-II using ROMA index

(Annexure-X). The Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index was recorded to assess the treatment needs.

The ROMA Index is considered as a guide to clinical signs of malocclusion in paediatric patients. Depending upon how many signs are detected there is a greater or lesser risk for orthodontic intervention<sup>40</sup>. It was specifically designed for examining young patients during the first visit in an attempt to grade functional parameters besides malocclusions. After calculating the prevalence of malocclusion on the basis of the degrees of orthodontic risk determined by the indexes, the prevalence of dental features that indicate a need for Early Orthodontic Treatment (EOT) in primary and mixed dentition period was evaluated using Baby-ROMA and ROMA index respectively. Also the prevalence with which orofacial myofunctional problems arising from morphological changes found in association with malocclusion among the children was evaluated.

During examination each patient was categorized on the basis of index risk factor scale, thus indicating the level of urgency with which orthodontic diagnosis/treatment is required.

### **Baby-ROMA Index:**

This index was used to evaluate the risk of malocclusion in subjects aged 4-6 years. The index is classified as a five problem scale: 1. Systemic problems, 2. Craniofacial problems, 3. Dental problems, 4. Functional problems and, 5. None of the problems. Only the dental and the functional parameters were recorded through intraoral examination. The recording was done according to the points in the indices and the recorded data was then subjected to the statistical analysis.

### **ROMA Index:**

The index was used to evaluate the risk of malocclusion in subjects aged 7-12 years. The Risk of Malocclusion Index (Russo et al, 1998), is a tool to assess treatment need in young patients. It was developed analysing and modifying the dental and occlusal parameters of Dental Health Component (DHC) of IOTN index with addition of items related to skeletal and functional problems, in order to identify the risk of worsening

of the malocclusion during growth. The ROMA index was then modified to Baby-ROMA index for its age specific application on primary dentition. The index is classified same as Baby-ROMA index on a five problem scale: 1. Systemic problems, 2. Craniofacial problems, 3. Dental problems, 4. Functional problems and, 5. None of the problems. Only the dental and the functional parameters were recorded through intraoral examination. The recording was done according to the points in the indices and the recorded data was then subjected to the statistical analysis.

### **Study procedure (Calibration):**

The study was carried out by applying the ROMA and Baby ROMA index on a sample of 3600 school going children and those reporting in the OPD of Department of Paediatric and Preventive Dentistry within the age group of 4-12 years. The visits were provided by a single investigator who was trained and calibrated on how to use the ROMA and Baby ROMA index. The prevalence of each risk factor was then calculated. Also, the prevalence of treatment need for each degree of risk and for each index value was calculated for both the indices.

### **Data collection from the children:**

Demographic and dental variables were collected from 3600 school-going children and those reporting in the department of Paediatric and Preventive Dentistry. A self-designed case history preforma was filled for each examinee, based on clinical examination and questioning, which included information on the molar and canine relationships, over-jet and over-bite, Angle's classification, upper and lower midlines, anterior and posterior cross-bite, crowding, ectopic eruption, oral habits, and facial symmetry.

### **Data analysis:**

All the data was entered into the excel sheet and was then subjected for statistical analysis. The analysis was carried out using SPSS 20.0 version (Chicago, Inc., USA). The results are presented in frequencies, percentage and mean $\pm$ SD. The Chi-square test was used to compare categorical variables. P values below 0.05 were considered as statistically significant.



Diagnostic Instruments



## **RESULTS**

The present was conducted in the department of pediatric and preventive dentistry with an aim to evaluate the prevalence of features

All the statistical analysis was carried out using SPSS 20.0 version (Chicago, Inc., USA). The results are presented in frequencies, pie charts, percentages and mean  $\pm$ SD. The Chi-square test (Annexure-VII) was used to compare the categorical variables. P values  $\leq$  0.05 were considered as statistically significant.

**Table 1. and Graph 1.** depicts the gender-wise frequency distribution of subjects in primary dentition. Out of total 752 examined subjects 349 (46.6%) were girls and 403 (53.6%) were boys.

**Table 2. and Graph 2.** shows the prevalence of features indicating early orthodontic treatment need in primary dentition on the basis of sexual dimorphism. Sexual dimorphism was statistically significant for overjet, molar relationship, canine relationship, dental caries, habits and swallowing patterns (p value  $>$ 0.001). Increased overjet of  $\geq$ 4mm was seen in 33.3% of total examined subjects and was found to be more prevalent feature in girls (42.2%) than in boys. Distal step molar relationship (47.9%) was the most prevalent occlusal relationship observed in the examined subjects and was seen to be more prevalent in boys (65.3%), whereas, mesial step (33.5%) and flush terminal plane (33.7%) occlusal relationship were found to be more prevalent in girls.

A total of 37.5% of examined subjects were found to be affected by dental caries, out of which, 49.6% of girls were found to be more affected by dental caries than boys (23.5%). 62.5% of the subjects examined were found to be free from dental caries in primary dentition.

Clinical evidence to the practice of oral habits, supported by affirmative answer to questioning was found in 22.1% of total sample and the most prevalent habit was found to be tongue thrust (21.5%) followed by thumb sucking (0.4%). Tongue Thrust habit was seen to be more prevalent feature in boys (36.7%) in the primary dentition.



Position of tongue while swallowing was found to be infantile in 21.6% of the total examined subjects, which was found to be more prevalent in boys (36.6%) than in girls (8.5%).

**Table 3. and Graph 3.** depicts the comparison between caries free and caries affected sub-groups for distribution of the relevant parameters in primary dentition. Out of total 752 examined subjects 470 (62.5%) were caries free and 282 (37.5%) were affected by dental caries. Results were found to be statistically significant with respect to molar relationship, canine relationship and over-jet (p value >0.001).

Distal step (47.9%) was the most prevalent occlusal relationship found followed by the flush terminal plane (29.1%). Mesial step was the most prevalent occlusal relationship observed (50.7%) in caries affected subgroup followed by the flush terminal plane (28.4%) and distal step (20.9%).

Overjet was within the normal limits (0.5-4 mm) for 66.6% examinees. Increased overjet of  $\geq 4$ mm was seen in 33.4% of the examined subjects and was found more prevalent in caries affected sub-group (50.4%).

**Table 4. and Graph 4.** illustrates the frequency distribution of molar relationship and orofacial myofunctional problems arising from morphological changes in primary dentition. Tongue Thrust habit was found to be commonly associated with the Distal step molar relationship (44.7%) in the primary dentition. Mesial step (98.8%) and flush terminal plane (98.6%) molar relationships were found to be predominant in the subjects who did not have any of the habits.

**Table 5. and Graph 5.** depicts the gender-wise frequency distribution of subjects in mixed dentition. Out of total 2848 examined subjects 1495 (52.5%) were girls and 1353 (47.5%) were boys.

**Table 6. and Graph 6.** depicts the prevalence of features indicating early orthodontic treatment need in mixed dentition period. Sexual dimorphism was statistically significant for molar relationship, canine relationship, crowding, dental caries, habits and swallowing patterns (p value >0.001).

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Statistically significant gender difference was observed in the distribution of various categories of Angles classification (p value < 0.001). The most prevalent angles classification was found to be Angles Class II (50.9%). Angles Class II malocclusion was found to be more prevalent in boys (57.3%) than in girls (45.2%).

Class II canine relationship (50.9%) was found to be more prevalent than Class I and III. Class II canine relationship was seen to be more prevalent in boys (57.3%) than in girls (45.2%).

No significant gender difference (p value= 0.825) was found for the distribution of overjet and cross-bite (p value= 0.042). Anterior Cross-bite (1.6%) was more prevalent than posterior cross-bite with a greater predilection in girls (2.1%) than in boys.

A total of 66.3% of examined subjects were found to be affected by dental caries, out of which, 73.2% of girls were found to be more affected by dental caries than boys (58.7%). 33.7% of the subjects examined were found to be free from dental caries in mixed dentition.

Clinical evidence to the practice of oral habits, supported by affirmative answer to questioning was found in 53.5% of total sample and the most prevalent habit was found to be tongue thrust (33.2%) followed by tongue thrusting associated with mouth breathing habit (14.4%) with a statistically significant gender difference (P value <0.001). Tongue Thrust habit was seen to be more prevalent feature in girls (33.2%) in the mixed dentition. Position of tongue while swallowing was found to be infantile in 49.8% of the total examined subjects, which was found to be more prevalent in girls (52.2%) than in boys (47.1%).

**Table 7. and Graph 7.** shows the comparison between caries free and caries affected sub-groups for distribution of the relevant parameters in mixed dentition. Out of total 2848 examined subjects 959 (33.7%) were caries free and 1889 (66.3%) were affected by dental caries.

Results were found to be statistically significant with respect to molar relationship, canine relationship, mid-line shift and crowding (p value >0.001).

Angles Class II malocclusion (50.9%) was the most common type of occlusal relationship found in mixed dentition. The most prevalent malocclusion found in caries-affected sub-group was Angles Class II (57.1%) followed by Class I and III. Class II canine relationship (57.1%) was more frequently observed in caries affected sub-group.

Overjet >4mm was found in 11.6% of examined subjects, while overjet was within the normal limits (0.5-4mm) in 88.4% subjects in caries affected sub-group. No significant difference was between the two groups (p value= 0.825).

Out of total 2848 subjects dental midline shift was seen to be absent in 2128 of the examined subjects. The frequency of dental midline shift was found to be more prevalent on the left side (17.3%) than on left side (12.8%) in caries affected subjects, whereas, the frequency of midline shift was seen to more on right side (15.7%) in caries-free subjects.

Statistically significant difference (P value <0.001) between the two groups was found for the distribution of crowding in the examined subjects. Lower anterior crowding was found to be a prevalent feature (68.8%) as compared to upper crowding associated with lower crowding as well. Lower anterior crowding was found to be more prevalent in caries-affected (70.2%) subjects.

**Table 8 illustrates and Graph 8.** Distribution of the various Angle Classes in the caries free subgroup in mixed dentition period. Normocclusion was seen in 49.9% of examined subjects in caries free sub-group, whereas disto-occlusion and mesio-occlusion was seen in 38.8% and 11.3% of subjects in caries-free sub-group respectively.

**Table 9. and Graph 9.** depicts the frequency distribution of various Angles malocclusion categories and orofacial myofunctional problems arising from morphological changes in mixed dentition. Tongue Thrust habit was found to be

commonly associated with angles Class II malocclusion (56.4%). Out of total examined subjects 46.6% did not had any habits.

**Table 10. and Graph 10.** illustrates the distribution of Baby-ROMA and ROMA index risk score in the sample. Out of the total examined subjects 34.5% subjects in primary dentition, 47.0% subjects in early mixed dentition period and 53.6% in late mixed dentition period were found to be at great risk indicating immediate need for orthodontic treatment.

**Table 11. and graph 11.** depicts Frequency distribution of Baby-ROMA index risk scores in the sample. Based on the scoring criteria of Baby-ROMA index 34.4% of the examined subjects were at the great risk of developing malocclusion, among which girls (44.4%) were at a higher risk than boys (22.9%) (p value < 0.001).

**Table 12. and graph 12.** illustrates frequency distribution of ROMA index risk scores in the sample. Based on the scoring criteria of ROMA index 50.9% subjects were at a greater risk of developing a malocclusion with a statistically significant gender difference (P value <0.001). Boys (57.4%) were found to be at a greater risk to develop malocclusion then girls in mixed dentition period.

**Table 1. Frequency distribution based on demographic analysis in primary dentition period**

		<u>Frequency (N)</u>	<u>Percent (%)</u>
Gender	Male	349	46.4
	Female	403	53.6
	<b>Total</b>	<b>752</b>	<b>100.0</b>

**Table 2. Prevalence of features indicating early orthodontic treatment need in primary dentition**

		<u>Gender</u>				<b>Total (N=752)</b>		<b>p value</b>
		<b>Male (N=349)</b>		<b>Female (N=403)</b>				
Cross-bite Present/ Absent	Absent	348	99.70%	399	99.00%	747	99.30%	0.235
	Present wrt anterior teeth	1	0.30%	4	1.00%	5	0.70%	
Overjet	>4mm	81	23.20%	170	42.20%	251	33.40%	0.000*
	<=4mm	268	76.80%	233	57.80%	501	66.60%	
Molar relationship in primary dentition	Distal Step	228	65.30%	132	32.80%	360	47.90%	0.000*
	Mesial Step	38	10.90%	135	33.50%	173	23.00%	
	Flush Terminal	83	23.80%	136	33.70%	219	29.10%	

**Results**

	Plane							
Canine relationship	Class I	83	23.90%	136	33.70%	219	29.20%	0.000*
	Class II	227	65.20%	132	32.80%	359	47.80%	
	Class III	38	10.90%	135	33.50%	173	23.00%	
Crowding Present/ Absent	wrt lower anterior	0	0.00%	0	0.00%	0	0.00%	-
	wrt lower anterior and upper anterior	0	0.00%	0	0.00%	0	0.00%	
	Absent	349	100.00%	403	100.00%	752	100.00%	
Caries Free	Caries free	267	76.50%	203	50.40%	470	62.50%	0.000*
	Caries affected	82	23.50%	200	49.60%	282	37.50%	
Ectopic Eruption pattern present/ Absent	Absent	349	100.00%	403	100.00%	752	100.00%	-
	Present	0	0.00%	0	0.00%	0	0.00%	
Habits	Absent	219	62.80%	367	91.10%	586	77.90%	0.000*
	Tongue thrust	128	36.70%	34	8.40%	162	21.50%	
	Mouth	0	0.00%	1	0.20%	1	0.10%	

	breathing							
	Thumb sucking	2	0.60%	1	0.20%	3	0.40%	
Position of tongue while swallowing	Mature	218	63.40%	364	91.50%	582	78.40%	0.000*
	Infantile	126	36.60%	34	8.50%	160	21.60%	

**Table 3. Comparison of distribution of relevant parameters in the caries free and caries affected subgroups in primary dentition period**

<u>Dental Parameters</u>		<u>Dental Caries</u>				Total (N=752)		p value
		Caries free (N=470)		Caries affected (N=282)				
Molar relationship in primary dentition	Distal Step	301	64.00%	59	20.90%	360	47.90%	0.000*
	Mesial Step	30	6.40%	143	50.70%	173	23.00%	
	Flush Terminal Plane	139	29.60%	80	28.40%	219	29.10%	
Canine relationship	Class I	139	29.60%	80	28.40%	219	29.20%	0.000*
	Class II	300	64.00%	59	20.90%	359	47.80%	
	Class III	30	6.40%	143	50.70%	173	23.00%	
Overjet	>4mm	109	23.20%	142	50.40%	251	33.40%	0.000*
	≤4mm	361	76.80%	140	49.60%	501	66.60%	

**Results**

Midline Shift- right/left/absent	Absent	470	100.00%	282	100.00%	752	100.00%	-
	Left	0	0.00%	0	0.00%	0	0.00%	
	Right	0	0.00%	0	0.00%	0	0.00%	
Crowding Present/ Absent	wrt lower anteriors	0	0.00%	0	0.00%	0	0.00%	-
	wrt lower anteriors and upper anteriors	0	0.00%	0	0.00%	0	0.00%	
	Absent	470	100.00%	282	100.00%	752	100.00%	
Cross-bite Present/ Absent	Absent	466	99.10%	281	99.60%	747	99.30%	0.417
	Present wrt anterior teeth	4	0.90%	1	0.40%	5	0.70%	
	Present wrt posterior teeth	0	0.00%	0	0.00%	0	0.00%	



**Table 4. Distribution of molar relationship and orofacial myofunctional problems arising from morphological changes in primary dentition**

<b><u>Parameters</u></b>		<b><u>Molar relationship in primary dentition</u></b>						<b>Total</b>		<b>p value</b>
		<b>Distal Step</b>		<b>Mesial Step</b>		<b>Flush Terminal Plane</b>				
<b>Habits</b>	Absent	199	55.30%	171	98.80%	216	98.60%	586	77.90%	<b>0.000*</b>
	Tongue thrust	161	44.70%	0	0.00%	1	0.50%	162	21.50%	
	Mouth breathing	0	0.00%	1	0.60%	0	0.00%	1	0.10%	
	Thumb sucking	0	0.00%	1	0.60%	2	0.90%	3	0.40%	
<b>Total</b>		360	100.00%	173	100.00%	219	100.00%	752	100.00%	

**Table 5. Frequency distribution based on demographic analysis in mixed dentition period**

		Frequency (N)	Percent (%)
<b>Gender</b>	Male	1353	47.5
	Female	1495	52.5
	Total	2848	100.0

**Table 6. Prevalence of features indicating early orthodontic treatment need in mixed dentition period**

		<u>Gender</u>				Total (N=2848)		p value
		Male (N=1353)		Female (N=1495)				
Cross-bite Present/ Absent	Absent	1338	98.90%	1461	97.70%	2799	98.30%	0.042
	Present wrt anterior teeth	13	1.00%	32	2.10%	45	1.60%	
	Present wrt posterior teeth	2	0.10%	2	0.10%	4	0.10%	
Overjet	>4mm	150	11.10%	179	12.00%	329	11.60%	0.460
	<=4mm	1203	88.90%	1316	88.00%	2519	88.40%	

**Results**

Molar Relationship in mixed dentition	Class I	442	32.70%	642	42.90%	1084	38.10%	0.000*
	Class II	775	57.30%	676	45.20%	1451	50.90%	
	Class III	136	10.10%	177	11.80%	313	11.00%	
Canine relationship	Class I	442	32.70%	642	42.90%	1084	38.10%	0.000*
	Class II	775	57.30%	676	45.20%	1451	50.90%	
	Class III	136	10.10%	177	11.80%	313	11.00%	
Crowding Present/ Absent	wrt lower anterior	914	67.60%	1044	69.80%	1958	68.80%	0.000*
	wrt lower anterior and upper anterior	44	3.30%	4	0.30%	48	1.70%	
	Absent	395	29.20%	447	29.90%	842	29.60%	
Caries Free	Caries free	559	41.30%	400	26.80%	959	33.70%	0.000*
	Caries affected	794	58.70%	1095	73.20%	1889	66.30%	
Ectopic Eruption pattern present/ Absent	Absent	1353	100.00%	1495	100.00%	2848	100.00%	-
	Present	0	0.00%	0	0.00%	0	0.00%	
Habits	Absent	585	43.20%	741	49.60%	1326	46.60%	0.000*

	Tongue thrust	438	32.40%	496	33.20%	934	32.80%	
	Mouth breathing	168	12.40%	42	2.80%	210	7.40%	
	Tongue thrust, Mouth breathing	162	12.00%	216	14.40%	378	13.30%	
Position of tongue while swallowing	Mature	710	52.90%	708	47.80%	1418	50.20%	0.006*
	Infantile	631	47.10%	773	52.20%	1404	49.80%	

**Table 7. Comparison of distribution of relevant parameters in the caries free and caries affected subgroups in mixed dentition period**

		<u>Dental Caries</u>				Total (N=2848)		p value
		Caries free (N=959)		Caries affected (N=1889)				
Molar Relationship in mixed dentition	Class I	479	49.90%	605	32.00%	1084	38.10%	0.000*
	Class II	372	38.80%	1079	57.10%	1451	50.90%	
	Class III	108	11.30%	205	10.90%	313	11.00%	
Canine relationship	Class I	479	49.90%	605	32.00%	1084	38.10%	0.000*

**Results**

	Class II	372	38.80%	1079	57.10%	1451	50.90%	
	Class III	108	11.30%	205	10.90%	313	11.00%	
Overjet	>4mm	109	11.40%	220	11.60%	329	11.60%	0.825
	<=4mm	850	88.60%	1669	88.40%	2519	88.40%	
Midline Shift- right/left/absent	Absent	808	84.30%	1320	69.90%	2128	74.70%	0.000*
	Left	0	0.00%	327	17.30%	327	11.50%	
	Right	151	15.70%	242	12.80%	393	13.80%	
Crowding Present/ absent	wrt lower anterior	631	65.80%	1327	70.20%	1958	68.80%	0.000*
	wrt lower anterior and upper anterior	0	0.00%	48	2.50%	48	1.70%	
	Absent	328	34.20%	514	27.20%	842	29.60%	
Cross-bite Present/Absent	Absent	939	97.90%	1860	98.50%	2799	98.30%	0.521
	Present wrt anterior teeth	18	1.90%	27	1.40%	45	1.60%	
	Present wrt posterior teeth	2	0.20%	2	0.10%	4	0.10%	

**Table 8. Distribution of the various Angle Classes in the caries free subgroup in mixed dentition period**

<u>Angle Class</u>	<u>Percentage in the caries free subgroup (N=959)</u>
Class I	49.9%
Class II	38.8%
Class III	11.3%
<b>Total</b>	100.0%

**Table 9. Distribution of malocclusion and orofacial myofunctional problems arising from morphological changes in mixed dentition**

		<u>Malocclusion in mixed dentition</u>						<b>Total</b>		<b>p value</b>
		<b>Class I</b>		<b>Class II</b>		<b>Class III</b>				
Habits	Absent	858	79.20%	155	10.70%	313	100.00%	1326	46.60%	0.000*
	Tongue thrust	115	10.60%	819	56.40%	0	0.00%	934	32.80%	
	Mouth breathing	0	0.00%	210	14.50%	0	0.00%	210	7.40%	
	Tongue thrust,	111	10.20%	267	18.40%	0	0.00%	378	13.30%	

	Mouth breathing								
<b>Total</b>		1084	100.00%	1451	100.00%	313	100.00%	2848	100.00%

**Table 10. Frequency distribution of Baby-ROMA and ROMA index risk score in the sample**

		<u>Age</u>						<b>Total</b>		<b>p value</b>
		<b>Primary Dentition</b>		<b>Early Mixed Dentition</b>		<b>Late Mixed Dentition</b>				
Baby-ROMA & ROMA Index score	Minimum Risk	71	9.40%	70	6.00%	62	3.70%	203	5.60%	0.000*
	Mild Risk	198	26.30%	485	41.70%	452	26.80%	1135	31.50%	
	Moderate Risk	224	29.70%	61	5.20%	267	15.90%	552	15.30%	
	Great Risk	260	34.50%	547	47.00%	903	53.60%	1710	47.50%	
<b>Total</b>		753	100.00%	1163	100.00%	1684	100.00%	3600	100.00%	

**Table 11. Frequency distribution of Baby-ROMA index risk scores in the sample**

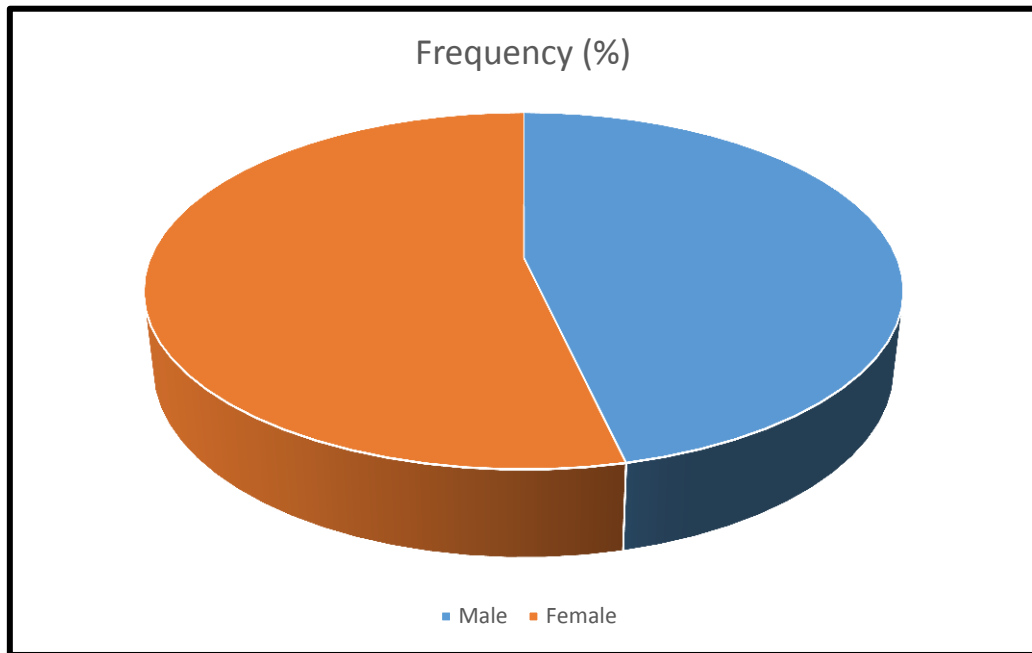
		<u>Gender</u>				Total (752)		p value
		Male (349)		Female (403)				
Baby-ROMA Index score	Minimum Risk	50	14.30%	21	5.20%	71	9.40%	0.000*
	Mild Risk	124	35.50%	74	18.40%	198	26.30%	
	Moderate Risk	95	27.20%	129	32.00%	224	29.80%	
	Great Risk	80	22.90%	179	44.40%	259	34.40%	

**Table 12. Frequency distribution of ROMA index risk scores in the sample**

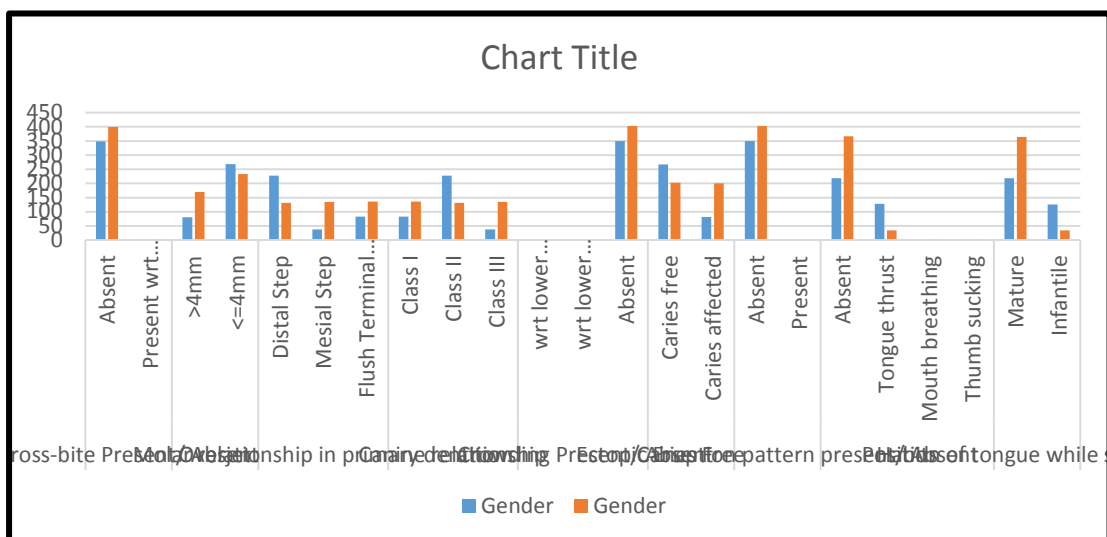
		<u>Gender</u>				Total (2848)		p value
		Male (1353)		Female (1495)				
ROMA index score	Minimum Risk	49	3.60%	83	5.60%	132	4.60%	0.000*
	Mild Risk	383	28.30%	554	37.10%	937	32.90%	
	Moderate Risk	145	10.70%	183	12.20%	328	11.50%	
	Great Risk	776	57.40%	675	45.20%	1451	50.90%	



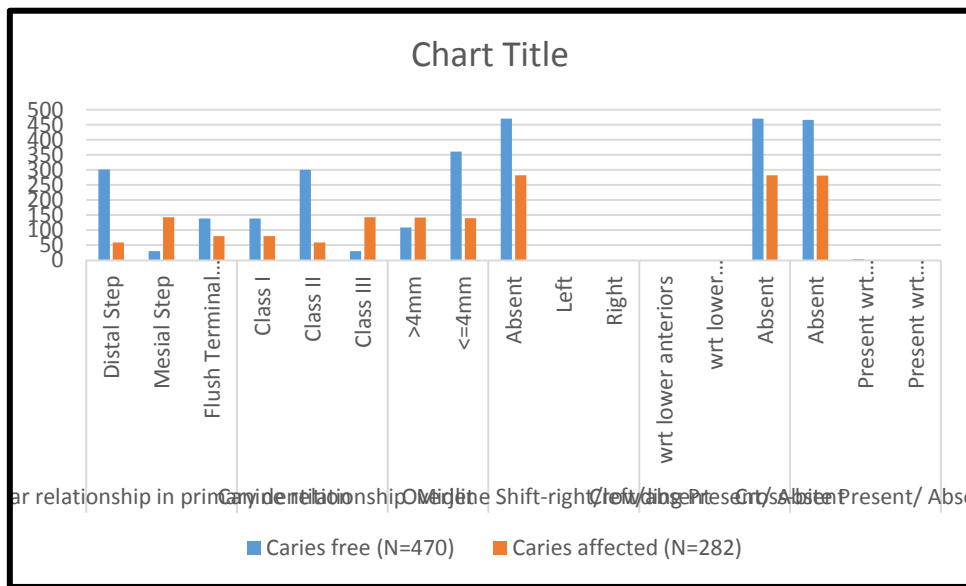
**Graph 1. Frequency distribution based on demographic analysis in primary dentition period**



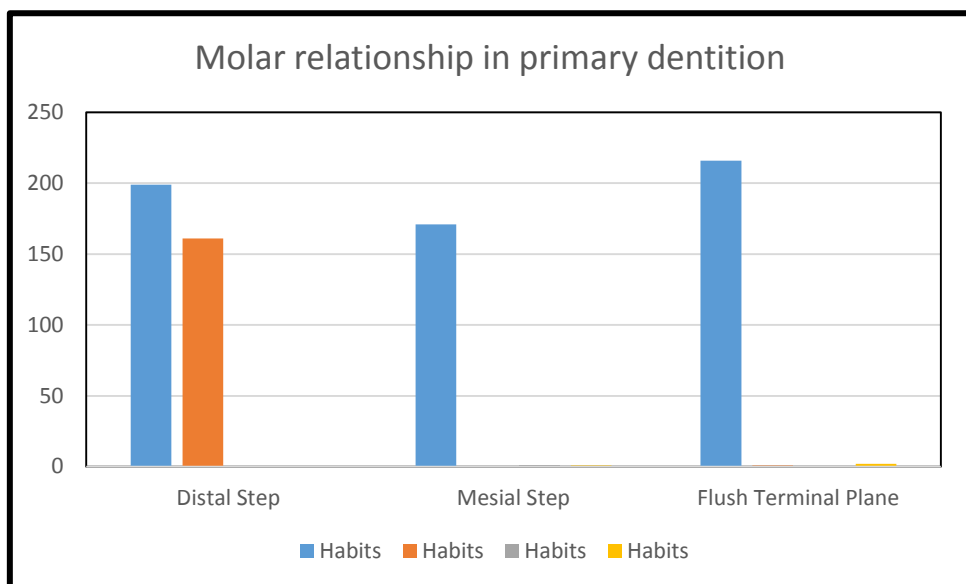
**Graph 2. Prevalence of features indicating early orthodontic treatment need in primary dentition**



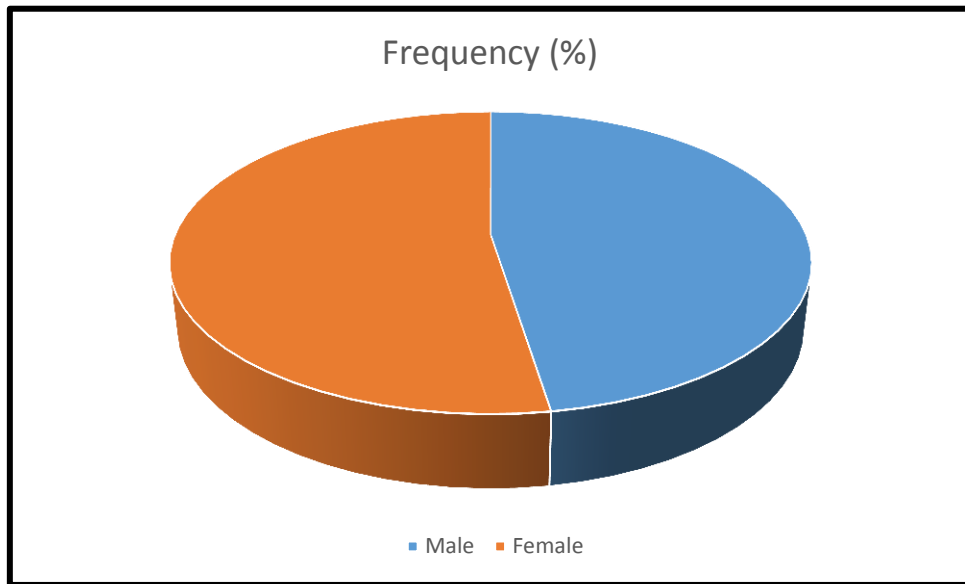
**Graph 3. Comparison of distribution of relevant parameters in the caries free and caries affected subgroups in primary dentition period**



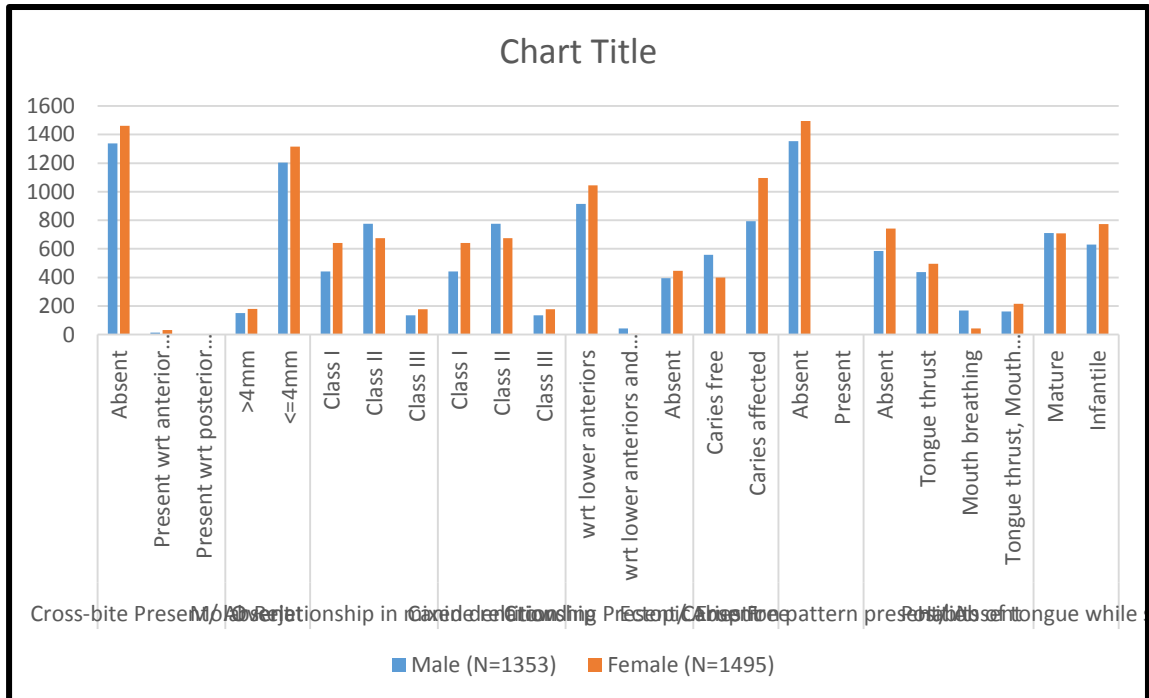
**Graph 4. Distribution of molar relationship and orofacial myofunctional problems arising from morphological changes in primary dentition**



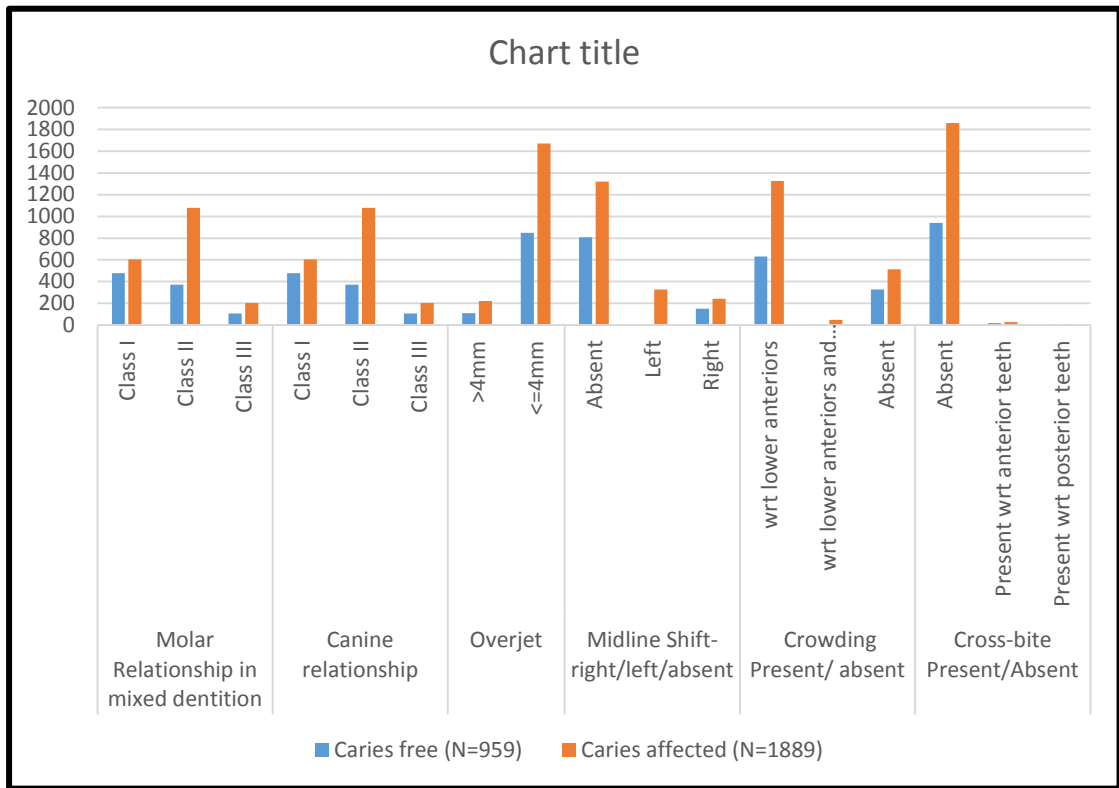
**Graph 5. Frequency distribution based on demographic analysis in mixed dentition period**



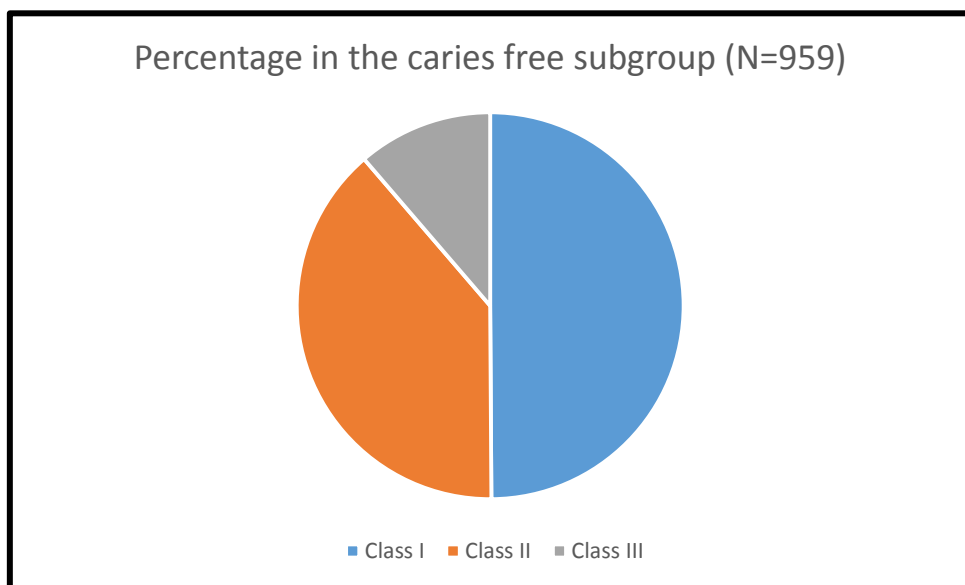
**Graph 6. Prevalence of features indicating early orthodontic treatment need in mixed dentition period**



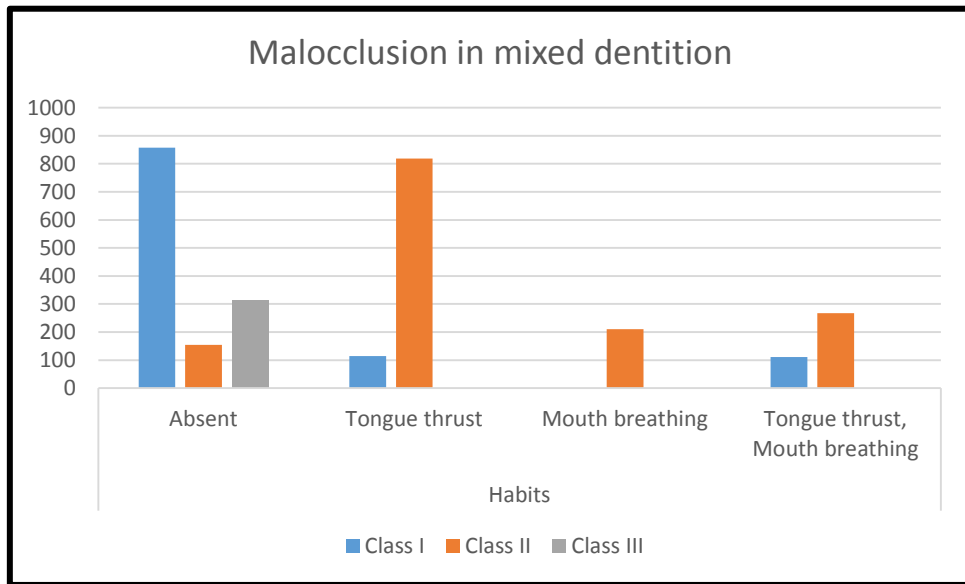
**Graph 7. Comparison of distribution of relevant parameters in the caries free and caries affected subgroups in mixed dentition period**



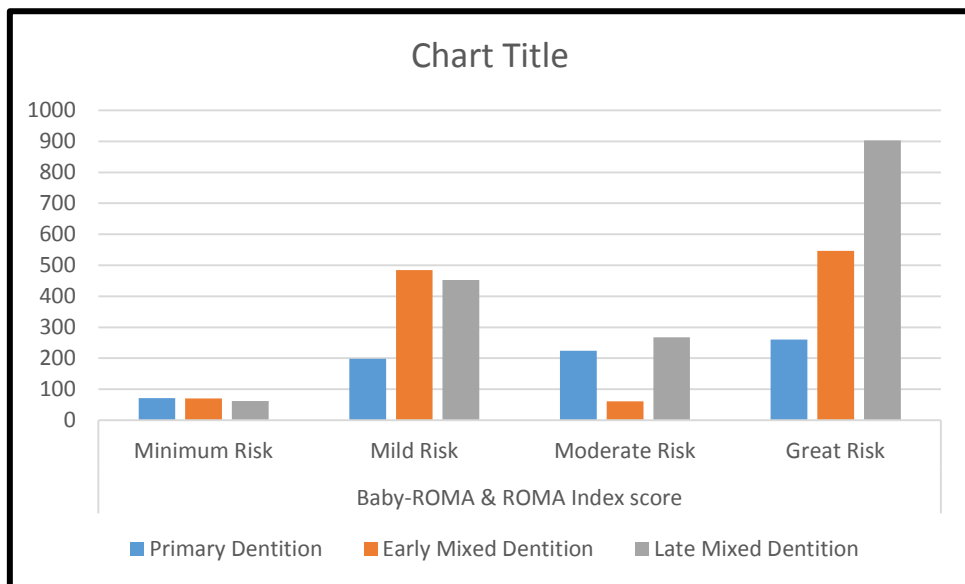
**Graph 8. Distribution of the various Angle Classes in the caries free subgroup in mixed dentition period**



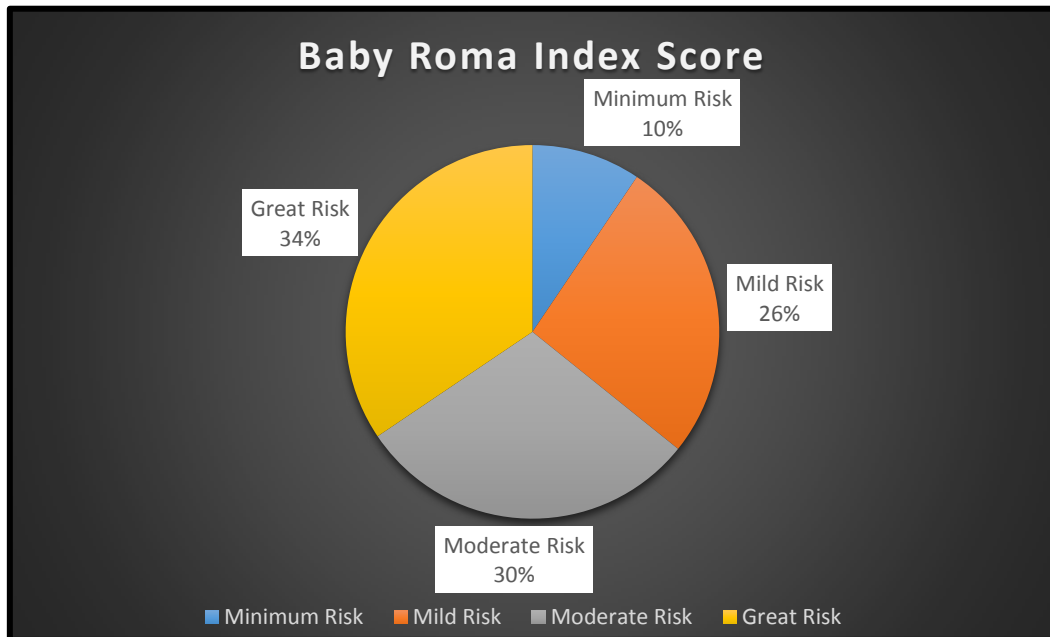
**Graph 9. Distribution of malocclusion and orofacial myofunctional problems arising from morphological changes in mixed dentition**



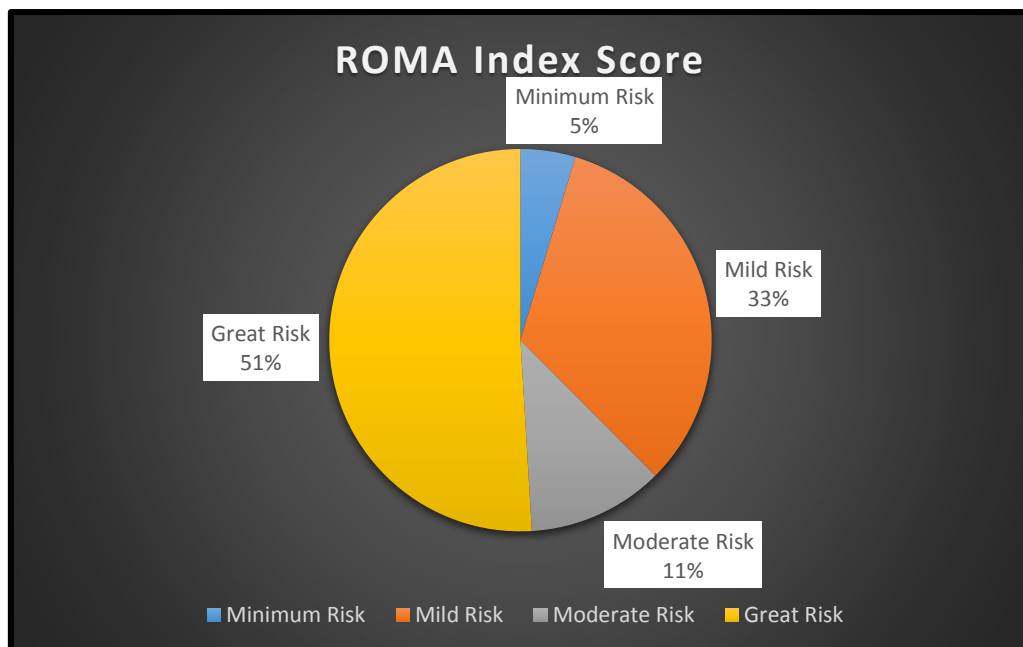
**Graph 10. Frequency distribution of Baby-ROMA and ROMA index risk score in the sample**



Graph 11. Frequency distribution of Baby-ROMA index risk scores in the sample



Graph 12. Frequency distribution of ROMA index risk scores in the sample



## **DISCUSSION**

This descriptive cross-sectional study was planned to offer a knowledge about the early diagnosis of the features that indicate early orthodontic treatment need, thereby preventing the complexity of malocclusion in growing children. The overall prevalence of malocclusion was 47.9% in primary dentition and 50.9% in mixed dentition. Studies done by *Usha Mohan Das et al, 2008; Kristina et al, 2014 and Eloisa et al,<sup>67, 68, 69</sup> 2012* have shown a higher prevalence of malocclusion. Our results were in accordance with the study done by *Disha Patil et al (2017)<sup>58</sup>*, in which they had obtained overall prevalence of 40.9% in 8-9-year old children.

Subjects were segregated based on the gender and the effect of caries both in primary and mixed dentition. We found that the cross-bite was more prevalent in females than in males in mixed dentition which was in accordance to the data reported by *Miriam Shalish et al (2012)* and *Celikoglu et al (2010)<sup>70, 71</sup>*. Whereas no significant difference in relation to cross-bite was found between the two genders in both primary dentition and mixed dentition.

Another predominant feature to affect occlusal relationships was Caries (**Table 3 and 7**). Out of total 752 examined subjects 470 (62.5%) were caries free and 282 (37.5%) were affected by dental caries in primary dentition and out of total 2848 examined subjects 959 (33.7%) were caries free and 1889 (66.3%) were affected by dental caries in mixed dentition period. The most prevalent molar relationship found in both caries-free and caries- affected sub-groups in primary dentition was distal step (47.9%) followed by flush terminal plane and mesial step. Distocclusion, registered as Angles Class II was recorded as 38.8% where as mesioocclusion registered as Angles Class III was found to be 11.3% which is much higher than the data recorded previously by (*Thilander et al, 2001 and Schopf, 2003<sup>72, 73</sup>*). The reason for this difference could be due ethnic diversity, living environment and eating habits. The distribution of various malocclusion types found in this study (**table 8**) is similar to the findings of previous surveys in Israel (*Rosenzweig, 1961; Krzypow et al, 1975; Shano, 1986; Ben-Bassat et al, 1997; Perillo et al, 2010<sup>74-77</sup>; Prabhakar RR et al, 2014<sup>52</sup>; Grippaudo C et al, 2020<sup>66</sup>*).

The higher prevalence of Class II canine relationship in the caries affected sub-groups (**Table 7**) of mixed dentition period could be attributed to the unilateral extractions or interproximal carious lesions, affecting the canine relationship. Also, the midline deviations were seen associated with caries, which were more prevalent on the right side than on left side.

Increased overjet of  $\geq 4$ mm was seen in 33.3% of the examined subjects in primary dentition whereas it was 11.6% in mixed dentition which was found to be more prevalent in late mixed dentition period (16.8%) than in early mixed dentition (4.0%) with more predilection in girls than in boys. Studies (*Bastone et al, 2000; Brin et al, 2000; Ben-Bassat et al, 2001; Sgan-Cohen et al, 2005*)<sup>78-81</sup> have shown a positive association between increased overjet and the risk of trauma to the upper incisors, hence this fraction of population needs orthodontic attention at an early age.

Cross-bite (**Table 2**) was present in 0.7% of the examined subjects in primary dentition which was much less than found in Sweden (*Kurol and Berglund, 1992*)<sup>82</sup>. Cross-bite was found to be more prevalent in girls (1%) than in boys (0.3%) but no significant gender difference was found as demonstrated by *Lindsten et al (2001)*<sup>83</sup>. In mixed dentition period (**Table 6**) anterior cross-bite (1.6%) was more prevalent than posterior cross-bite with a greater predilection in girls (2.1%) than in boys.

Anterior open bite is said to exist when there is an absolute vertical gap between the upper and lower incisors with teeth in centric occlusion. Anterior open bite as defined by *Subtelny and Sakuda* is deviation in the vertical relationship of the maxillary and mandibular dental arches with a definite lack of contact in the vertical direction between opposing segments of the teeth. Open-bite  $>4$ mm was found to be present in 0.1% of the population in primary dentition which was similar (2.8%) to that demonstrated by *I N Ize-Iyamu and M C Isiekwe (2012)*<sup>84</sup> in 2-5 year old children but lower than 8% and 7.9% found in other studies. Open-bite  $>4$ mm was found more prevalent in late mixed dentition (53.3%) whereas, open-bite  $>1$ mm was more prevalent feature in the early mixed dentition period. Open-bite  $>1$ mm was seen more in girls (54.8%) and open-bite  $>4$ mm was more prevalent feature in boys (57.3%). Statistically significant (P value  $<0.001$ ) gender difference was observed for the distribution of open-bite in the examined subjects.



In this study the overall prevalence of habits was found to be 22.1% in primary dentition (**Table 2**) with most prevalent habit being tongue thrust (21.6%) followed by thumb sucking (0.4%).

While overall prevalence of habits in mixed dentition (**Table 6**) was 53.5% with tongue thrust (33.2%) being most prevalent habit followed by tongue thrusting associated with mouth breathing habit (14.4%) with a statistically significant gender difference (p value <0.001). When compared with different categories of angles classification a statistically significant difference was found (p value <0.001). Angles Class II malocclusion was commonly seen associated with tongue thrust habit (56.4%) followed by tongue thrust in association with mouth breathing habit (18.4%).

The information regarding crowding relates to possible need for early orthodontic treatment need as it is one of the indications for arch length preservation (*Gianelly, 2002; AAO website*) or in severe cases serial extraction is recommended in the mixed dentition period.

Ideally, the process of identifying and assessing the severity of malocclusion within national health care services should require a simple and reliable method. Several indices on occlusal parameters are being used to assess priority of orthodontic care. Indices of orthodontic treatment are used in screening and in epidemiological studies with the purpose to identify the priority of treatment, specifically in countries where the cost of the orthodontic therapies are funded wholly or partly by Health Care Services or private insurances by *Jarvinen (2001)*. After thorough examination and review of indices Baby-ROMA and ROMA index for primary and mixed dentition were selected to assess the prevalence of need for early orthodontic treatment in primary and mixed dentition.

The ROMA Index - Risk Of Malocclusion Assessment Index [*Russo et al, 1998*]<sup>40</sup> - is a tool to assess treatment need in young patients. It was developed reviewing and modifying the dental and occlusal parameters of DHC with the addition of items related to skeletal and functional problems, to identify the risk of worsening of the malocclusion during growth. The main difference between ROMA and IOTN - DHC indexes is that the ROMA index evaluates malocclusion problems in growing child,

assuming that some aspects may change under the positive or negative effect of craniofacial development, while IOTN-DHC index classifies the treatment need on the basis of data that could not change instantaneously. Another difference is that the ROMA index evaluates the timing of intervention, which could be immediate or deferred to a different time of dentition and cranio-facial growth according to the estimated risk, whereas, the IOTN-DHC index is to simply determine if a patient must undergo orthodontic therapy, according to the clinical relevance of the observed problems. The authors have now modified the ROMA index and targeted on the age of primary dentition in order to provide early diagnosis and treatment at an early stage of development.

The evaluation of the need for early orthodontic treatment using Baby-ROMA and ROMA index (**Table 11 and 12; Graph 11 and 12**) in primary and mixed dentition respectively indicated 34.4% of the examined children in primary dentition and 50.9% of children in mixed dentition were in need for immediate orthodontic treatment which was in accordance with results demonstrated by *Grippaudo et al (2007)*. The most prevalent feature indicating early orthodontic treatment need was found to be dental caries (60.3%) followed by open-bite (40.3%). Boys (57.4%) were found to be at a greater risk to develop malocclusion than girls in mixed dentition period, whereas, girls were at a higher risk than boys (P value < 0.001) in primary dentition.

Early identification and assessment of malocclusion helps in reducing the length and the severity of the orthodontic treatments. Orthodontic treatment at an early stage of development utilizes the use of simple devices and offers the lower therapeutic cost besides playing an important role in terms of children oral health. Since a significant portion of population depends exclusively upon the public systems, therefore many patients with malocclusion are likely not to receive proper guidance. Hence, it should be emphasized that epidemiological surveys like this are extremely important so that a proper provision of interceptive and corrective treatment to this undeserved portion of the population is encouraged.

## **CONCLUSIONS**

The present descriptive cross-sectional study consisting of 3600 children both in primary and mixed dentition period, was conducted at the Department of Paediatric and Preventive Dentistry, Lucknow, Uttar Pradesh, to establish the prevalence of incipient malocclusion among 4-12 years old school going children and also to determine the need for early orthodontic treatment in primary and mixed dentition period using Baby-ROMA and Risk of Malocclusion Assessment (ROMA) index.

On the basis of observations made during the course of study and their analysis the following conclusions have been drawn:

- The overall prevalence of incipient malocclusion was 47.9% in primary dentition and 50.9% in mixed dentition period.
- In primary dentition 34.4% of the population were in need of immediate orthodontic treatment, 56.1% needed periodic follow-ups and orthodontic therapy at a later stage if required and 9.4% required routine monitoring of occlusion.
- In mixed dentition, 50.9% of the population were in need of immediate orthodontic treatment, while, in 44.4% required periodic assessment until growth acceleration phase in the affected region and 4.6% required routine monitoring of the normal course of development.
- The most common finding in primary dentition by using Baby-ROMA index was dental caries (37.6%) followed by overjet >4mm (33.3%).
- In mixed dentition period dental caries (60.3%) was found to be more prevalent feature indicating early orthodontic treatment need. It was found to be more prevalent in early mixed dentition period (78.2%) with females (73.2%) being more affected than males.
- Open-bite >4mm was another prevalent feature seen in mixed dentition period, being more prevalent in late mixed dentition period (53.3%) with significantly higher prevalence in boys (57.3%).
- The association between malocclusion and orofacial myofunctional problems arising from morphological changes was found to be more with tongue thrust habit (30.4%). Tongue Thrust habit was found to be commonly associated with the Distal step molar relationship (44.7%) in the primary dentition and Class II malocclusion (56.4%) in mixed dentition period.

**BIBLIOGRAPHY**

1. **Kanellis MJ.** Orthodontic treatment in the primary dentition. *In: Bishara SE, ed. Textbook of Orthodontics. Philadelphia, Pa: WB Saunders Co; 2001:248-56.*
2. **Woodside DG.** The significance of late developmental crowding to early treatment planning for incisor crowding. *Am J Orthod Dentofacial Orthop* 2000;117(5):559-61.
3. **Kurol J.** Early treatment of tooth-eruption disturbances. *Am J Orthod Dentofacial Orthop* 2002;121(6):588-91.
4. **Sankey WL, Buschang PH, English J, Owen AH III.** Early treatment of vertical skeletal dysplasia: The hyper-divergent phenotype. *Am J Orthod Dentofacial Orthop* 2000;118(3):317-27.
5. **Profitt WR, Fields HW, Sarver DM.** Contemporary Orthodontics, 4<sup>th</sup> Edition. 2007.
6. Brennan MM, Gianelly AA. The use of the lingual arch in the mixed dentition to resolve incisor crowding. *Am J Orthod Dentofacial Orthop* 2000; 117: 81-5
7. **Sinclair P, Little R.** Maturation of untreated normal occlusions. *Am J Orthod* 1983; 83: 114-23.
8. **Ravn JJ.** Occlusion in the primary dentition in three-year-old children. *Journal of the American Dental Association* 1975; 89: 599-606.
9. **Andlaw RJ and Rock WP** (1996) *A manual of paediatric dentistry 4th edn.* Churchill Livingstone, Edinburgh (a) pp 130-131, (b) 163-164, (c) 166-167.
10. **Moyers RE** (1980) *Handbook of orthodontics*, 4th edn. Year Book Medical Publishers, Inc. Chicago p 361-383.
11. **Taylor NG.** Orthodontic in the Netherlands. *Br Dent J* 1993; 175:333-335.
12. **Tausche E, Luck O, Harzer W.** Prevalence of malocclusions in the early mixed dentition and orthodontic treatment need. *Eur J Orthod.* 2004 Jun; 26:237-44.
13. **Soh J, Sandham A, Chan YH.** Malocclusion severity in Asian men in relation to malocclusion type and orthodontic treatment need, *Am J Orthod Dentofacial Orthop.* 2005 Nov;128(5):648-52.
14. **Soh J, Sandham A.** Orthodontic treatment need in Asian adult males. *Angle Orthod.* 2004 Dec;74(6):769-73.
15. **Souames M, Bassigny F, Zenati N, Riordan PJ, Boy-Lefevre ML.** Orthodontic treatment need in French schoolchildren: an epidemiological study using the Index

- of Orthodontic Treatment Need. *Eur J Orthod.* 2006 Dec;28(6):605-9. Epub 2006 Nov 9.
- 16. Mandall NA, Wright J, Conboy F, Kay E, Harvey L, O'Brien KD.** Index of orthodontic treatment need as a predictor of orthodontic treatment uptake, *Am J Orthod Dentofacial Orthop.* 2005 Dec; 128:703-7.
- 17. Josefsson E, Bjerklin K, Lindsten R.** Malocclusion frequency in Swedish and immigrant adolescents-influence of origin on orthodontic treatment need. *Eur J Orthod.* 2007 Feb;29(1):79-87.
- 18. Richmond S, Ngom PI, Diagne F.** Orthodontic treatment need: the IOTN, or Index of Orthodontic Treatment Need (part 2). *Orthod Fr.* 2005 Dec;76:303-8.
- 19. Brook PH, Shaw WC.** The development of an index of orthodontic treatment priority. *Eur J Orthod* 1989;11:309-320.
- 20. Grippaudo C, Russo E, Marchionni P, Deli R.** ROMA index come metronomo della terapia ortodontica nel paziente in crescita. Proceedings National Congress of SIDO, Firenze, 28-31 oct. 1998.
- 21. Grippaudo C et al.** Early orthodontic treatment: a new index to assess the risk of malocclusion in primary dentition. *Eur J Paediatr Dent* 2014; 15(4): 401-6.
- 22. Thilander B, Myrberg N.** The prevalence of malocclusion in Swedish schoolchildren, *Scand J Dent Res.* 1973;81(1):12-21. doi: 10.1111/j.1600-0722.1973.tb01489.
- 23. Kohler Holst and Krebs.** Malocclusion and sucking habits of four-year-old children, *Acta Paediatr Scand* 1973 Jul;62(4):373-9. doi: 10.1111/j.1651-2227.1973.tb08122.
- 24. Foster TD.** A survey of malocclusion and the need for orthodontic treatment in a Shropshire school population, *Br J Orthod* 1974 Apr;1(3):73-8. doi: 10.1179/bjo.1.3.73.
- 25. Kisling and Krebs.** Patterns of occlusion in 3-year-old Danish children, *Community Dent Oral Epidemiol* 1976 Jul;4(4):152-9. doi: 10.1111/j.1600-0528.1976.tb00974.
- 26. Kerosuo H et al.** Occlusion among a group of Tanzanian urban schoolchildren, *Community Dentistry and Oral Epidemiology* 1988; 16(5): 306-309.
- 27. Viskovic R et al.** Prevalence of orthodontic anomalies, analysis and evaluation of dental health in three groups of pre-school children in Zadar, *Acta Stomatol Croat* 1990;24(4):271-80.
-

28. **Skrinjaric et al.** Anomalies of deciduous teeth and findings in permanent dentition, *Acta Stomatol Croat* 1991;25(3):151-6.
29. **Kabue MM, Moracha JK, Ng'ang' a PM.** Malocclusion in children aged 3-6 years in Nairobi, Kenya, *East Afr Med J* 1995 Apr;72(4):210-2.
30. **Nik-Hussein NN et al.** Dental anomalies in the primary dentition: distribution and correlation with the permanent dentition, *J Clin Pediatr Dent Fall* 1996;21(1):15-9.
31. **Baccetti T, Franchi L, McNamara JA, Tollaro I.** Early dentofacial features of Class II malocclusion: a longitudinal study from the deciduous through the mixed dentition, *Am J Orthod Dentofacial Orthop* 1997 May;111(5):502-9. doi: 10.1016/s0889-5406(97)70287-7.
32. **Tschill P, Bacon W, Sonko A.** Malocclusion in the deciduous dentition of Caucasian children, *Eur J Orthod* 1997; 19:361-367.
33. **Carvalho JC, Vinker F, Declerck D.** Malocclusion, dental injuries and dental anomalies in the primary dentition of Belgian children, *Int J Paediatr Dent* 1998 Jun;8(2): 137-41.doi: 10.1046/j.1365-263x.1998.00070.
34. **Alamoudi.** The prevalence of crowding, attrition, midline discrepancies and premature tooth loss in the primary dentition of children in Jeddah, Saudi Arabia, *J Clin Pediatr Dent Fall* 1999;24(1):53-8.
35. **Goel P, Sequeira P, Peer S.** Prevalence of dental disease amongst 5-6 and 12-13 year old school children of Puttur municipality, Karnataka State-India, *J Indian Soc Pedod Prev Dent.* 2000 Mar;18(1):11-7.
36. **Thialander B, Pena L, Infante C, Parad SS, de Mayorga C.** Prevalence of malocclusion and orthodontic treatment need in children and adolescents in Bogota, Colombia. An epidemiological study related to different stages of dental development, *Eur J Orthod.* 2001 Apr;23(2):153-67.doi: 10.1093/ejo/23.2.153.
37. **Chevitarese AB, Della Valle D, Moreira TC.** Prevalence of malocclusion in 4-6 year old Brazilian children, *J Clin Pediatr Dent. Fall* 2002;27(1):81-5.doi: 10.17796/jcpd.27.1.an436m284201571p.
38. **Warren and Bishara.** Duration of nutritive and nonnutritive sucking behaviors and their effects on the dental arches in the primary dentition, *Am J Orthod Dentofacial Orthop.* 2002 Apr;121(4):347-56.doi: 10.1067/mod.2002.121445.

39. **Tausche E et al.** Prevalence of malocclusions in the early mixed dentition and orthodontic treatment need, *Eur J Orthod.* 2004 Jun;26(3):237-44.doi: 10.1093/ejo/26.3.237.
  40. **Grippaudo C et al.** Validation of the Risk Of Malocclusion Assessment (ROMA) index, *Eur J Paediatr Dent* 2007;3:136-42.
  41. **Grabowski R et al.** Relationship between occlusal findings and orofacial myofunctional status in primary and mixed dentition. Part I: Prevalence of malocclusions, *J Orofacial Orthop.* 2007 Jan;68(1):26-37.doi: 10.1007/s00056-007-1606-0.
  42. **Brito DI, Dias PF and Gleiser R.** Prevalence of malocclusion in children aged 9 to 12 years old in the city of Nova Friburgo, Rio de Janeiro State, Brazil, *R Dental Press Ortodon Ortop Facial* 2009; 14(6): 118-124.
  43. **Grippaudo C et al.** Orthodontic treatment timing in growing patients, *Eur J Paediatr Dent.* 2011 Sep;14(3):231-6.
  44. **Carvalho AC et al.** Prevalence of malocclusion in primary dentition in a population-based sample of Brazilian preschool children, *Eur J Paediatr Dent.* 2011 Jun;12(2):107-11.
  45. **Gois EG et al.** Incidence of malocclusion between primary and mixed dentitions among Brazilian children. A 5-year longitudinal study, *Angle Orthod.* 2012 May;82(3):495-500. doi: 10.2319/033011-230.1. Epub 2011 Oct 10.
  46. **Zakirulla. M.** Malocclusion in deciduous dentition of Saudi children: A cross-sectional study 2012, DOI: <https://doi.org/10.3329/bjms.v11i4.12608>.
  47. **C.Grippaudo, E. G. Pantanali, G. Antonini, R. Deli.** Early orthodontic treatment: a new index to assess the risk of malocclusion in primary dentition, *Eur J Paediatr Dent.* 2014 Dec;15(4):401-6.
  48. **De Sousa RV et al.** Prevalence and associated factors for the development of anterior open bite and posterior crossbite in the primary dentition, *Braz Dent J.* 2014;25(4):336-42.doi: 10.1590/0103-6440201300003.
  49. **Karen Glazer Peres, Peres, William, Broadbent, Pedro, Ana.** Deciduous-dentition malocclusion predicts orthodontic treatment needs later: Findings from a population-based birth cohort study 2014, *Am J Ortho Dentofacial Orthopaed* 2014; 147(4): 492-98.
  50. **Kasparaviciene K.** The Prevalence of Malocclusion and Oral Habits among 5–7-Year-Old Children, 2014 Oct 24. doi: [10.12659/MSM.890885](https://doi.org/10.12659/MSM.890885).
-

- 51. Oropeza LM et al.** Prevalence of malocclusions associated with pernicious oral habits in a Mexican sample, *Revista Mexicana de Ortodoncia* 2014; 2(4): 216-223.
- 52. Prabhakar RR et al.** Prevalence of Malocclusion and Need for Early Orthodontic Treatment in Children, *J Clin Diagn Res.* 2014; doi: [10.7860/JCDR/2014/8604.4394](https://doi.org/10.7860/JCDR/2014/8604.4394).
- 53. Dimberg L et al.** Prevalence and change of malocclusions from primary to early permanent dentition: a longitudinal study, *Angle Orthod.* 2015 Sep;85(5):728-34.doi: [10.2319/080414-542.1](https://doi.org/10.2319/080414-542.1).
- 54. Peres KG et al.** Deciduous-dentition malocclusion predicts orthodontic treatment needs later: findings from a population-based birth cohort study, *Am J Orthod Dentofacial Orthop.* 2015 Apr;147(4):492-8.doi: [10.1016/j.ajodo.2014.12.019](https://doi.org/10.1016/j.ajodo.2014.12.019).
- 55. DaCosta OO et al.** Epidemiology of malocclusions in primary dentition and associated factors, *FO UPF* [online]. 2016, vol.21, n.3, pp. 343-348. ISSN 1413-4012.
- 56. Zhifei Zhou et al.** Prevalence of and factors affecting malocclusion in primary dentition among children in Xi'an, China, *BMC Oral Health.* 2016 Sep 2;16(1):91.doi: [10.1186/s12903-016-0285-x](https://doi.org/10.1186/s12903-016-0285-x).
- 57. Grippaudo C et al.** Association between oral habits, mouth breathing and malocclusion, *Acta Otorhinolaryngol Ital.* 2016 Oct;36(5):386-394.doi: [10.14639/0392-100X-770](https://doi.org/10.14639/0392-100X-770).
- 58. Disha P et al.** Malocclusion and dental caries experience among 8–9-year-old children in a city of South Indian region: A cross-sectional survey, *J Educ Health Promot.* 2017; 6: 98. doi: [10.4103/jehp.jehp\\_24\\_17](https://doi.org/10.4103/jehp.jehp_24_17).
- 59. Zhou X, Zhang Y, and Liu Y.** Prevalence of malocclusion and occlusal traits in the early mixed dentition in Shanghai, China, 2019 Apr 2. doi: [10.7717/peerj.6630](https://doi.org/10.7717/peerj.6630).
- 60. Lu Shen, Fang He Jinhua Wang.** Prevalence of malocclusion in primary dentition in mainland China, 1988–2017: a systematic review and meta-analysis, *Sci Rep* 8, 4716 (2018). <https://doi.org/10.1038/s41598-018-22900-x>.
- 61. E.G. Paolantonio et al.** Association between oral habits, mouth breathing and malocclusion in Italian pre-schoolers, *Eur J Paediatr Dent.* 2019 Sep;20(3):204-208.doi: [10.23804/ejpd.2019.20.03.07](https://doi.org/10.23804/ejpd.2019.20.03.07).



- 62. Reddy NV et al.** The prevalence of malocclusion among 10–12-year-old schoolchildren in Khammam district, Telangana: An epidemiological study, DOI: 10.4103/ijpr.ijpr\_5\_19.
- 63. Sirate R et al.** Etiology of Malocclusion and Dominant Orthodontic Problems in Mixed Dentition: A Cross-sectional Study in a Group of Thai Children Aged 8-9 Years, *J Int Soc Prev Community Dent.* 2019 Jul 5;9(4):383-389. doi: 10.4103/jispcd.JISPCD\_120\_19. eCollection Jul-Aug 2019.
- 64. Zeyad AA.** Prevalence of malocclusal traits among 6–9-year-old male schoolchildren in Rass, Saudi Arabia, DOI: 10.4103/jioh.jioh\_44\_19.
- 65. Priede D et al.** Association between malocclusion and orofacial myofunctional disorders of pre-school children in Latvia, *Orthod Craniofac Res.* 2020 Aug;23(3):277-283. doi: 10.1111/ocr.12367. Epub 2020 Feb 11.
- 66. Grippaudo C et al.** Orthodontic treatment need and timing: Assessment of evolutive malocclusion conditions and associated risk factors, DOI 10.23804/ejpd.2020.21.03.09.
- 67. Mohan Das U et al.** Prevalence of Malocclusion Among School Children in Bangalore, India, *Int J Clin Pediatr Dent.* September-December 2008;1(1):10-12.
- 68. Kristina A, Bondemark L.** The impact of malocclusion on the quality of life among children and adolescents: A systematic review of quantitative studies, *Eur J Orthod.* 2014; 37(3):238-47.
- 69. Boeckl E M et al.** Prevalence of malocclusion in children between 5 and 12 years-old in municipal schools Araraquara. *Rev. CEFAC*[online]. 2013; 13(5):1270-1280.
- 70. Miriam Shalish et al.** Prevalence of dental features that indicate a need for early orthodontic treatment, *Eur J Orthod.* 2013; 35:454–459. doi:10.1093/ejo/cjs011
- 71. Celikoglu M, Akpınar S, Yavuz I.** The pattern of malocclusion in a sample of orthodontic patients from Turkey. *Med Oral Patol Oral Cir Bucal* 2010;15:e 791-6.
- 72. Thilander B , Pena L , Infante C , Parada S S , de Mayorga C.** Prevalence of malocclusion and orthodontic treatment need in children and adolescents in Bogota, Columbia. An epidemiological study related to different stages of dental development . *Eur J Orthod.* 2001; 23 : 153 – 167.
- 73. Schopf P.** Indication for and frequency of early orthodontic therapy or interceptive measures. *J Orofacial Orthop.* 2003; 64 : 186 – 200.
-

- 74. Rosenzweig K A.** Malocclusion in different ethnic groups in Israel . *Am J Ortho* 1961;47 : 858 – 864.
- 75. Krzypow A B , Lieberman M A , Modan M.** Prevalence of malocclusion in young adults of various ethnic backgrounds in Israel . *J Dent Res.* 1975;54 : 605 – 608.
- 76. Shano B.** The need for preventive and interceptive orthodontic treatment: a survey among 7-year old children in Jerusalem suburb Faculty of Dentistry, The Hebrew University of Jerusalem (DMD thesis) Hebrew University Medical Library, Jerusalem, Israel (1986).
- 77. Perillo L , Masucci C , Ferro F , Apicella D , Baccetti T.** Prevalence of orthodontic treatment need in southern Italian school children . *Eur J Orthod.* 2010;32 : 49 – 53.
- 78. Bastone E B , Freer T J , McNamara J R.** Epidemiology of dental trauma: a review of the literature . *Austr Dent J.* 2000;45 : 2 – 9.
- 79. Bastone E B , Freer T J , McNamara J R.** Epidemiology of dental trauma: a review of the literature . *Austr Dent J.* 2000;45 : 2 – 9.
- 80. Ben-Bassat Y , Brin I , Brezniak N.** Can maxillary incisor trauma be predicted from cephalometric measurements? *Am J Orthod Dentofacial Orthop.* 2001;120 : 186 – 189.
- 81. Sgan-Cohen H D , Megnagi G , Jacobi Y.** Dental trauma and its association with anatomic, behavioral and social variables among fifth and sixth grade schoolchildren in Jerusalem . *Community Dentistry and Oral Epidemiology* 2005;3 : 174 – 180.
- 82. Kurol J , Berglund L.** Longitudinal study and cost-benefit analysis of the effect of early treatment of posterior crossbites in the primary dentition . *Eur J Orthod* 1992;14 : 173 – 179.
- 83. Lindsten R , Ogaard B , Larsson E.** Transversal dental arch dimensions in 9 years old children born in the 1960s and the 1980s . *Am J Orthod and Dentofacial Orthop.* 2001;120 : 576 – 584.
- 84. I N Ize-Iyamu and M C Isiekwe.** Prevalence and factors associated with anterior open bite in 2 to 5 year old children in Benin city, Nigeria, *Afr Health Sci.* 2012 Dec;12(4):446-51.doi: 10.4314/ahs.v12i4.8.

- 85. PROFFIT, W. R.** A etiologia dos problemas ortodônticos. In: \_\_\_\_\_.  
*Ortodontia contemporânea*. 3. ed. Rio de Janeiro: Guanabara Koogan, 2002. p.  
105-34.
- 86. ORGANIZAÇÃO MUNDIAL DA SAÚDE.** *Levantamento epidemiológico  
básico de saúde bucal: manual de instruções*. 3. ed. São Paulo: Ed. Santos, 1991.

**ANNEXURE - I**

**INSTITUTIONAL RESEARCH COMMITTEE APPROVAL**

**BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES  
(FACULTY OF BBD UNIVERSITY), LUCKNOW**

**INSTITUTIONAL RESEARCH COMMITTEE APPROVAL**

The project titled "Prevalence Of Incipient Malocclusion And Orthodontic Treatment Needs In Primary And Mixed Dentition Period Using Risk Of Malocclusion Assessment (Roma) Index And Baby-ROMA Index." submitted by Dr Sumaiya Post graduate student from the Department of Paedodontics & Preventive Dentistry as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on 19<sup>th</sup> January, 2021 at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

**Prof. Vandana A Pant**  
Co-Chairperson

**Prof. B. Rajkumar**  
Chairperson

**ANNEXURE - II****INSTITUTIONAL ETHICAL COMMITTEE APPROVAL**

**Babu Banarasi Das University**  
**Babu Banarasi Das College of Dental Sciences,**  
**BBD City, Faizabad Road, Lucknow – 226028 (INDIA)**

**Dr. Lakshmi Bala**  
 Professor and Head Biochemistry and  
 Member-Secretary, Institutional Ethics Committee

**Communication of the Decision of the VII<sup>th</sup> Institutional Ethics Sub-Committee**

IFC Code: 18 (Revised)

BBDCODS/01/2021

**Title of the Project:** Prevalence of Incipient Malocclusion and Orthodontic Treatment needs in Primary and Mixed Dentition Period using Risk of Malocclusion Assessment (ROMA) Index and Baby-ROMA Index.

**Principal Investigator:** Dr. Sumaiya **Department:** Paedodontics & Preventive Dentistry

**Name and Address of the Institution:** BBD College of Dental Sciences Lucknow.

**Type of Submission:** Revised, MDS Project Protocol

Dear Dr. Sumaiya,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07 January, 2021.


1. Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry & Nutrition, BBDCODS, Lucknow
2. Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3. Dr. Sumalatha M.N. Member	Reader, Department of Oral Medicine & Radiology, BBDCODS, Lucknow
4. Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

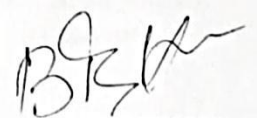
The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.

The comments were communicated to PI thereafter it was revised.

**Decisions:** The committee approved the above protocol from ethics point of view.

Forwarded by:

  
 (Dr. Lakshmi Bala)  
 Member Secretary  
 Institutional Ethic Committee  
 BBD College of Dental Sciences  
 BBD University  
 Faizabad Road, Lucknow-226028

  
 (Dr. B. Rajkumar)  
 Principal  
 BBDCODS  
**PRINCIPAL**  
 Babu Banarasi Das College of Dental Science  
 (Babu Banarasi Das University)  
 BRD City, Faizabad Road, Lucknow-226028

**ANNEXURE – III**

**Babu Banarasi Das College of Dental Sciences**

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

**Consent Form (English)**

Title of the Study: **“Prevalence of incipient malocclusion and orthodontic treatment needs in primary and mixed dentition period using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index”**

Study Number.....

Subject’s Full

Name..... Date of

Birth/Age .....

Address of the Subject.....

Phone no. and e-mail address.....

Qualification .....

Occupation: Student / Self Employed / Service / Housewife/

Other (Please tick as appropriate)

Annual income of the Subject.....

Name and of the nominees(s) and his relation to the subject..... (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated .....for the above study and have had the opportunity to ask questions.  
**OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor’s behalf, the Ethics Committee and the regulatory authorities will not need my

permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes** [  ] **No** [  ] **Not Applicable** [  ]
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me. Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:.....

Signatory's Name.....	Date .....
Signature of the Investigator.....	Date.....
Study Investigator's Name.....	Date.....
Signature of the witness.....	Date.....
Name of the witness.....	
Received a signed copy of the PID and duly filled consent form	
Signature/thumb impression of the subject or legally Acceptable representative	Date.....

**ANNEXURE – IV**

**Babu Banarasi Das College of Dental Sciences**

**(Babu Banarasi Das University)**

**BBD City, Faizabad Road, Lucknow – 227105 (INDIA)**

**Child Assent Form**

Study Title **“Prevalence of incipient malocclusion and orthodontic treatment needs in primary and mixed dentition period using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index”**

Study Number \_\_\_\_\_

Subject’s Full Name \_\_\_\_\_

Date of Birth/Age \_\_\_\_\_

Address \_\_\_\_\_

I \_\_\_\_\_, exercising my free power of choice, hereby give my consent for participation in the study entitled:

“.....”

I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant

\_\_\_\_\_ Date: \_\_\_\_\_ Name of the study participant \_\_\_\_\_

Signature of the Witness

\_\_\_\_\_ Date \_\_\_\_\_ Name of the Witness

Signature of the attending

Physician \_\_\_\_\_ Date: \_\_\_\_\_ Name of the attending Physician





**Babu Banarasi Das College of Dental Sciences**  
 (A Constituent Institution of Babu Banarasi Das University)  
 BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

शिशु सहमति पत्र

में \_\_\_\_\_ में भाग लेने के लिए

आपनी सहमति प्रदान करता हूँ। मुझे इस अध्ययन के हेतु और उसमें की जाने वाली प्रक्रिया के बारे में चिकिस्तक द्वारा बता दिया गया है। मुझे पता है कि अध्ययन सम्बन्धी किसी हानि जिसका अध्ययन की दवा से सम्बन्ध है उसका खर्च मेरे माता पिता अथवा अभिवाहक को नहीं करना है। मुझे यह भी पता है कि मैं इस अध्ययन से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ।

अध्ययन में भाग लेने वाले का नाम और हस्ताक्षर

दिनांक \_\_\_\_\_

माताह के हस्ताक्षर \_\_\_\_\_ दिनांक \_\_\_\_\_

माताह का नाम \_\_\_\_\_

चिकिस्तक का नाम और हस्ताक्षर \_\_\_\_\_ दिनांक \_\_\_\_\_

## **ANNEXURE – V**

**Babu Banarasi Das College of Dental Sciences**

**(Babu Banarasi Das University)**

**BBD City, Faizabad Road, Lucknow – 227105 (INDIA)**

**Guidelines for Devising a Participant / Legally Acceptable Representative  
Information  
Document (PID) in English**

### **1. Study Title**

**Prevalence of incipient malocclusion and orthodontic treatment needs in primary and mixed dentition period using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index**

### **2. Invitation Paragraph**

You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **3. What is the purpose of the study?**

The aim of the study is to establish the prevalence of incipient malocclusion among 4-12 years old school going children in Lucknow city and to determine the need for early orthodontic treatment using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index.

### **4. Why have I been chosen?**

Aesthetic alterations in the face can be self-perceived and can affect the quality of life as for young children physical attractiveness is an important factor affecting social relationships. Malocclusion is a misalignment or incorrect relation between the teeth of the two dental arches. Treating the developing malocclusion at an

early stage of life reduces the complexity of treatment in the permanent dentition thereby improving the quality of life.

**5. Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

**6. What will happen to me if I take part?**

Subjects between 4-12 years of age will be clinically screened for the features indicating early orthodontic treatment need. A group of randomly selected children will be examined in a bright day light with the help of mouth mirror, fine explorer and a half millimetre ruler while using disposable gloves. The Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index will be recorded to assess the treatment needs.

**7. What do I have to do?**

No lifestyle/dietary restrictions.

**8. What is the procedure that is being tested?**

To assess the prevalence of incipient malocclusion among 4-12 years old school going children in Lucknow city and to determine the need for early orthodontic treatment using Risk of Malocclusion Assessment (ROMA) index and Baby-ROMA index.

**9. What are the interventions for the study?**

There are no interventions to be performed in the study.

**10. What are the side effects of taking part?**

No possible side-effects.

**11. What are the possible disadvantages and risks of taking part?**

No possible disadvantages/risks.

**12. What are the possible benefits of taking part?**

As the demand for orthodontic treatment increases, the importance of performing epidemiological studies in order to obtain knowledge about both the prevalence of different types of malocclusions and the need for orthodontic treatment among the population is also required. These estimations are crucial for planning an orthodontic care services with regards to human and financial resources and also for monitoring the oral health programs offered.

**13. What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

**14. What happens when the research study stops?**

If the study finishes/stops before the stipulated time, this will be explained to the patient/volunteer.

**15. What if something goes wrong?**

Patients/volunteers will be informed regarding how complaints will be handled and what addresses may be available.

**16. Will my taking part in this study be kept confidential?**

If you consent to take part in the research any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities/IEC to check that

the study is being carried out correctly. Your name, however, will not be disclosed outside the laboratory/centre.

All information collected about you during the course of the research will be kept strictly confidential. Any information which leaves the laboratory will have your name and address removed so that you cannot be recognized from it.

**17. What will happen to the results of the research study?**

In result of the research patient information will be kept confidential and patients will not be identified in any report/publication.

**18. Who is organizing the research?**

Department Of Pedodontics And Preventive Dentistry, Babu Banarasi Das College Of Dental Sciences, BBD University, Lucknow, UP.

**19. Will the results of the study be made available after study is over?**

Results will be made available on requests.

**20. Who has reviewed the study?**

The study is reviewed by the head of the department of pedodontics and preventive dentistry and Institutional Research Committee, babu banarasi das college of dental science, babu banarasi das university, lucknow, UP.

**21. Contact for further information**

Name : Dr. Sumaiya

Adress: Department of Pediatric and Preventive Dentistry

BBDCODS, BBDU, Lucknow

Email Address: sumaiyamuzaffar07@gmail.com

Member secretary of Ethical Institution

Name- Dr. Lakshmi Bala

Email Address- bbdcos.iec@gmail.com

**Signature of PI.....**

Name.....

**Date.....**

## ANNEXURE – VI

### Participation Information Document (PID)- Hindi

#### 1. अध्ययन शीर्षक

मैलोकलूजन असेसमेंट (ROMA) इंडेक्स और बेबी-रोमा इंडेक्स के जोखिम का उपयोग करके प्राथमिक और मिश्रित दंत चिकित्सा अवधि में प्रारंभिक कुरूपता और रूढ़िवादी उपचार की आवश्यकता

#### 2. निमंत्रण पैराग्राफ

आपको एक शोध/परीक्षण अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि शोध/अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो मित्रों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक से इस पर चर्चा करें। हमसे पूछें कि क्या कुछ ऐसा है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं। यह तय करने के लिए समय निकालें कि आप भाग लेना चाहते हैं या नहीं।

#### 3. अध्ययन का उद्देश्य क्या है?

अध्ययन का उद्देश्य लखनऊ शहर में 4-12 साल के स्कूल जाने वाले बच्चों के बीच प्रारंभिक कुरूपता की व्यापकता को स्थापित करना और जोखिम के जोखिम मूल्यांकन (रोमा) सूचकांक और बेबी-रोमा इंडेक्स का उपयोग करके प्रारंभिक रूढ़िवादी उपचार की आवश्यकता का निर्धारण करना है।

#### 4. मुझे क्यों चुना गया है?

चेहरे में सौंदर्य परिवर्तन आत्म-कथित हो सकते हैं और जीवन की गुणवत्ता को

प्रभावित कर सकते हैं क्योंकि छोटे बच्चों के लिए शारीरिक आकर्षण सामाजिक संबंधों को प्रभावित करने वाला एक महत्वपूर्ण कारक है। मैलोकलूजन दो दंत मेहराब के दांतों के बीच एक गलत संरेखण या गलत संबंध है। जीवन के प्रारंभिक चरण में विकासशील कुरूपता का इलाज करने से स्थायी दंत चिकित्सा में उपचार की जटिलता कम हो जाती है जिससे जीवन की गुणवत्ता में सुधार होता है।

5. क्या मुझे भाग लेना है?

यह आपको तय करना है कि भाग लेना है या नहीं। यदि आप भाग लेने का निर्णय लेते हैं तो आपको यह सूचना पत्र अपने पास रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं तब भी आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. अगर मैं भाग लूंगा तो मेरा क्या होगा?

4-12 वर्ष की आयु के बीच के विषयों की चिकित्सकीय जांच की जाएगी ताकि उन लक्षणों की पहचान की जा सके जो प्रारंभिक ओर्थोडॉंटिक उपचार की आवश्यकता को दर्शाते हैं। बेतरतीब ढंग से चुने गए बच्चों के एक समूह की जांच दिन के उजाले में माउथ मिरर, फाइन एक्सप्लोरर और आधा मिलीमीटर रूलर की मदद से डिस्पोजेबल दस्तानों का उपयोग करते हुए की जाएगी। उपचार की जरूरतों का आकलन करने के लिए मैलोकलूजन असेसमेंट (ROMA) इंडेक्स और बेबी-रोमा इनेक्स का जोखिम दर्ज किया जाएगा।

7. मुझे क्या करना है?

कोई जीवनशैली / आहार प्रतिबंध नहीं।



8. वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है?

लखनऊ शहर में 4-12 साल के स्कूल जाने वाले बच्चों के बीच प्रारंभिक कुरूपता की व्यापकता का आकलन करने के लिए और मैलोकलूजन असेसमेंट (ROMA) इंडेक्स और बेबी-रोमा इंडेक्स के जोखिम का उपयोग करके प्रारंभिक रूढ़िवादी उपचार की आवश्यकता का निर्धारण करना।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?

अध्ययन में कोई हस्तक्षेप नहीं किया जाना है।

10. भाग लेने के दुष्प्रभाव क्या हैं?

कोई संभावित दुष्प्रभाव नहीं।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

कोई संभावित नुकसान/जोखिम नहीं।

12. भाग लेने के संभावित लाभ क्या हैं?

जैसे-जैसे ओर्थोडॉंटिक उपचार की मांग बढ़ती है, विभिन्न प्रकार के कुरूपता के प्रसार और आबादी के बीच रूढ़िवादी उपचार की आवश्यकता दोनों के बारे में ज्ञान प्राप्त करने के लिए महामारी विज्ञान के अध्ययन करने का महत्व भी आवश्यक है। मानव और वित्तीय संसाधनों के संबंध में ऑर्थोडॉंटिक देखभाल सेवाओं की योजना बनाने और मौखिक स्वास्थ्य कार्यक्रमों की निगरानी के लिए भी ये अनुमान महत्वपूर्ण हैं।

13. यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपका शोधकर्ता आपको इसके बारे में बताएगा और आपसे चर्चा करेगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता/अन्वेषक आपके लिए व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है

14. जब शोध अध्ययन रुक जाता है तो क्या होता है?

यदि अध्ययन निर्धारित समय से पहले समाप्त/बंद हो जाता है, तो यह रोगी/स्वयंसेवक को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

मरीजों/स्वयंसेवकों को सूचित किया जाएगा कि शिकायतों को कैसे संभाला जाएगा और कौन से पते उपलब्ध हो सकते हैं।

16. क्या इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा?

यदि आप अनुसंधान में भाग लेने के लिए सहमति देते हैं तो परिणामों का विश्लेषण करने के उद्देश्य से आपके किसी भी मेडिकल रिकॉर्ड का निरीक्षण कंपनी द्वारा प्रायोजित (और/या कंपनी द्वारा आयोजित) किया जा सकता है। अध्ययन को सही ढंग से किया जा रहा है या नहीं, यह जांचने के लिए कंपनी और नियामक प्राधिकरणों/आईईसी के लोगों द्वारा भी उन्हें देखा जा सकता है। तथापि, आपका नाम प्रयोगशाला/केंद्र के बाहर प्रकट नहीं किया जाएगा।

शोध के दौरान आपके बारे में एकत्र की गई सभी सूचनाओं को पूरी तरह गोपनीय रखा जाएगा। प्रयोगशाला से निकलने वाली किसी भी जानकारी से आपका नाम और पता हटा दिया जाएगा ताकि आपको इससे पहचाना न जा सके।

17. शोध अध्ययन के परिणामों का क्या होगा?

अनुसंधान के परिणामस्वरूप रोगी की जानकारी गोपनीय रखी जाएगी और किसी भी रिपोर्ट/प्रकाशन में रोगियों की पहचान नहीं की जाएगी।

18. शोध का आयोजन कौन कर रहा है?

पेडोडॉटिक्स एंड प्रिवेंटिव डेंटिस्ट्री विभाग, बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज, बीबीडी यूनिवर्सिटी, लखनऊ, यूपी।

19. क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?

अनुरोध पर परिणाम उपलब्ध कराए जाएंगे।

20. अध्ययन की समीक्षा कसने की?

अध्ययन की समीक्षा पेडोडॉटिक्स विभाग के प्रमुख और निवारक दंत चिकित्सा और संस्थागत अनुसंधान समिति, बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंस, बाबू बनारसी दास विश्वविद्यालय, लखनऊ, यूपी द्वारा की जाती है।

21. अधिक जानकारी के लिए संपर्क करें

नाम : डॉ सुमैया

पता: पेडोडॉटिक्स और निवारक दंत चिकित्सा विभाग बीबीडीसीओडीएस, बीबीडीयू,  
लखनऊ

ईमेल पता: sumaiyamuzaffar07@gmail.com

संस्था की आचार समिति के सदस्य सचिव

(डॉ. लक्ष्मी बाला, सदस्य सचिव, bbdcods.iec@gmail.com)

पते के साथ, टेलीफोन नंबरों के साथ ई-मेल पता (विस्तार संख्या 1291)।

दस्तावेजों को पढ़ने और अध्ययन में भाग लेने के लिए अपना कीमती समय

निकालने के लिए धन्यवाद।

पीआई का हस्ताक्षर .....

नाम .....

तारीख .....

## ANNEXURE – VII

### Formula used for the analysis

#### Arithmetic Mean

The most widely used measure of central tendency is arithmetic mean, usually referred to simply as the mean, calculated as

$$\bar{X} = \frac{\sum_{i=1}^n X_i}{n}$$

#### Standard deviation and standard error

The standard deviation (SD) is the positive square root of the variance, and calculated as

$$SD = \sqrt{\frac{\sum X_i^2 - \frac{(\sum X_i)^2}{n}}{n-1}}$$

and SE (standard error of the mean) is calculated as

$$SE = \frac{SD}{\sqrt{n}}$$

where, n= no. of observations

#### Minimum and Maximum

Minimum and maximum are the minimum and maximum values respectively in the measure data and range may be denoted as below

$$\text{Range} = \text{Min to Max}$$

and also evaluated by subtracting minimum value from maximum value as below

$$\text{Range} = \text{Maximum value} - \text{Minimum value}$$

**Median**

The median is generally defined as the apical measurement in an ordered set of data. That is, there are just as many observations larger than the median as there are smaller. The median (M) of a sample of data may be found by first arranging the measurements in order of magnitude (preferably ascending). For even and odd number of measurements, the median is evaluated as

$$M = [(n+1)/2]\text{th observation - odd number}$$

$$M = [n(n+1)/2]\text{th observation - even number}$$

**Chi-square test**

The chi-square ( $\chi^2$ ) test is used to compare the categorical data as

$$\chi^2 = \sum \frac{(F_{ij} - f_{ij})^2}{f_{ij}}$$

where,  $F_{ij}$  is the observed frequency while  $f_{ij}$  the expected frequency. The degrees of freedom (DF) is calculated as

$$DF = (r-1)(c-1)$$

**Statistical significance**

Level of significance " $P$ " is the probability signifies level of significance. The mentioned  $P$  in the text indicates the following:

$P > 0.05$ - not significant (ns)

$P < 0.05$ - just significant (\*)

$P < 0.01$ - moderate significant (\*\*)

$P < 0.001$ - highly significant (\*\*\*)

**ANNEXURE – VIII**  
**QUESTIONNAIRE**

NAME-

AGE-

GENDER-

ADRESS-

CONTACT NUMBER-

PAST MEDICAL/DENTAL HISTORY-

**EXTRA-ORAL EXAMINATION:**

1. SHAPE OF HEAD-

MESOCEPHALIC (average shape of head)

(75.0-79.9)

- DOLICOCEPHALIC (long and narrow head)

(70.0-74.9)

- BRACHYCEPHALIC (broad and short head)

(80.0-84.9)

CEPHALIC INDEX- maximum skull width/maximum skull length × 100

2. FACIAL FORM-

- MESOPROSOPIC(average or normal face form)

(85.0-89.9)

- EURYPROSOPIC(broad and short face)

(80.0-84.9)

- LEPTOPROSOPIC(long and narrow face)

(90.0-94.9)

FACIAL INDEX- nasio-mental length/bizygomatic width  $\times$  100

3. FACIAL PROFILE-

- STRAIGHT
- CONVEX
- CONCAVE

4. FACIAL DIVERGENCE-

- ANTERIOR DIVERGENT
- POSTERIOR DIVERGENT
- STRAIGHT OR ORTHOGNATHIC

5. LIP COMPETENCY-

- Competent lips-
- Potentially competent-
- Incompetent-

INTRA-ORAL EXAMINATION:

ORAL HYGIENE-

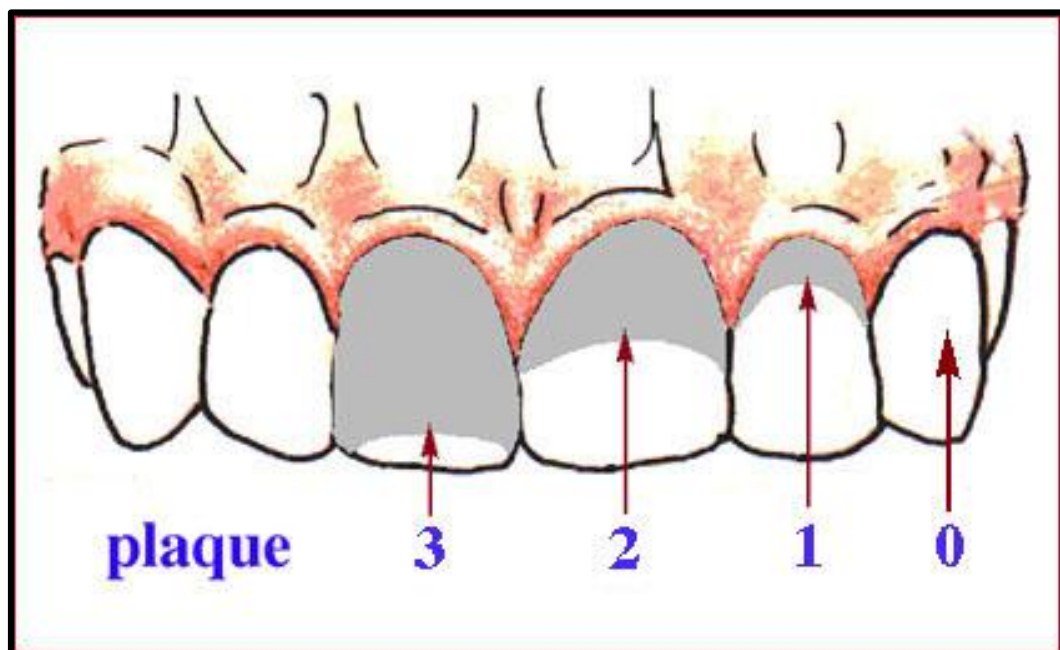
❖ OHI-S INDEX-

- GOOD- 0.0-1.2
- FAIR- 1.3-3.0
- POOR- 3.0-6.0



**CRITERIA FOR CLASSIFYING DEBRIS**

Scores	Criteria
0	No debris or stain present
1	Soft debris covering not more than one third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered
2	Soft debris covering more than one third, but not more than two thirds, of the exposed tooth surface.
3	Soft debris covering more than two thirds of the exposed tooth surface.



## CRITERIA FOR CLASSIFYING CALCULUS

Scores	Criteria
0	No calculus present
1	Supragingival calculus covering not more than third of the exposed tooth surface.
2	Supragingival calculus covering more than one third but not more than two thirds of the exposed tooth surface or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth or both.
3	Supragingival calculus covering more than two third of the exposed tooth surface or a continuous heavy band of subgingival calculus around the cervical portion of the tooth or both.

## DEBRIS

	Right		Anterior		Left		Total	
	Buccal (16)	Lingual (16)	Labial (11)	Lingual (11)	Buccal (26)	Lingual (26)	Buccal/Labial	Lingual
Upper								
Lower								
<b>Total</b>								

**Debris Index** = (The total of the upper and lower buccal-scores) + (The total of the upper and lower lingual-scores) / (The number of segments scored).

<b>Debris Index =</b>
-----------------------

## CALCULUS

	Right		Anterior		Left		Totals	
	Buccal (16)	Lingual (16)	Labial (11)	Lingual (11)	Buccal (26)	Lingual (26)	Buccal/Labial	Lingual
Upper								
Lower								
<b>Total</b>								

**Calculus Index** = (The total of the upper and lower buccal-scores) + (The total of the upper and lower lingual-scores) / (The number of segments scored).

<b>Calculus Index =</b>
-------------------------

<b>Oral Hygiene Index</b>	=	<b>Debris Index + Calculus Index</b>
---------------------------	---	--------------------------------------

### 1. MALOCCLUSION:

- Angle's Class I-

Class II-

- ❖ Div. 1-
- ❖ Div. 2-
- ❖ Subdivision –

Class III-

- ❖ Pseudo Class III-
- ❖ Subdivision-

2. MOLAR RELATIONSHIP IN PRIMARY DENTITION-

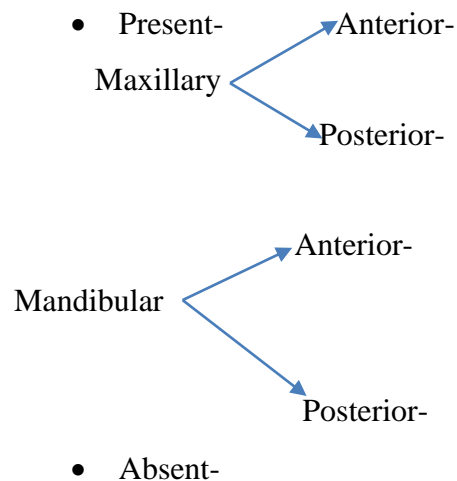
Flush terminal plane-

- a) Mesial step-
- b) Distal step-

3. CANINE RELATIONSHIP-

- CLASS I-
- CLASS II-
- CLASS III-

4. Crowding-



5. Tooth Eruption Disturbances-

- Whether Ectopic Eruption Pattern is:

PRESENT- w.r.t.

ABSENT-

- MISSING TEETH:

PRESENT- w.r.t.

ABSENT-

- SUPERNUMARARY TEETH:

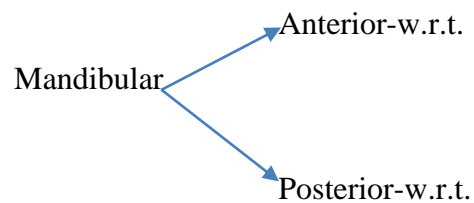
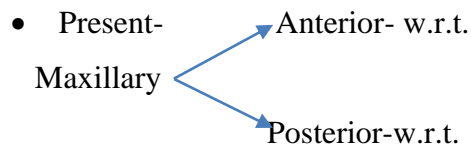
PRESENT- w.r.t.

ABSENT-

6. OVERJET-

- NORMAL- 2-3mm
- 3.5 -  $\leq$  6mm
- $>$  6mm -  $\leq$  9mm
- $>$  9mm

7. CROSS-BITE-



- Absent-

8. MIDLINE SHIFT-

- RIGHT/LEFT/ABSENT

9. LABIAL FRENIUM-

- MUCOSAL- fibres attached up to mucogingival junction
- GINGIVAL- fibres inserted within attached gingiva
- PALLARY- fibres extend into interdental papilla
- PAPILLA PENETRATING- fibres extend up to palatine papilla

10. DENTAL CARIES-

- CARIES FREE-
- CARIES-

❖ INTERPROXIMAL CARIES-

❖ OCCLUSAL CARIES-

**FUNCTIONAL ANALYSIS:**

1. HABITS-

- THUMB SUCKING-
- MOUTH BREATHING-
- TONGUE THRUSTING-
- TONGUE TIE-

❖ KOTLOW'S CLASSIFICATION:

- CLASS I- Mild Ankyloglossia (12-16mm)
- CLASS II- Moderate Ankyloglossia (8-11mm)
- CLASS III- Severe Ankyloglossia (3-7mm)
- CLASS IV- Complete Ankyloglossia (<3mm)

2. PATH OF CLOSURE OF MANDIBLE:

- NORMAL/DEVIATED TO RIGHT/LEFT

3. MENTALIS ACTION WHILE SWALLOWING-

- HYPERACTIVE
- NORMAL

4. POSITION OF TONGUE WHILE SWALLOWING-

- INFANTILE
- MATURE

**ANNEXURE – IX****Baby-ROMA INDEX**

SYSTEMIC PROBLEMS	Maxillo-facial Trauma	with condylar fracture	5a
		without condylar fracture	2a
	Congenital Syndromes/ Malformations		5b
	Postural/ Orthopaedic Problems		2c
	Medical or Auxological Conditions		2d
	Inheritance of malocclusion		2e
CRANIOFACIAL PROBLEMS	Facial or Mandibular Asymmetries		4f
	TMJ dysfunctions		4g
	Outcomes of trauma or Surgery of the cranio-facial district		5j
	Maxillary Hypoplasia / Mandibular Hyperplasia	OVJ<0	4k
		OVJ>0	2k

DENTAL PROBLEMS	Maxillary Hyperplasia / Mandibular Hypoplasia	OVJ>6mm	3h
		3mm<OVJ<6mm	2h
	Caries and Early Loss of Deciduous Teeth		4l
	Scissor bite		4m
	Crossbite	>2mm or lateral shift	4n
		<2mm or no lateral shift	2n
	Displacement	>2mm displacement	3o
		>1mm - absence of diastema	2o
	Open bite	>4mm	3p
		>2mm	2p
	Hypodontia	up to 2 teeth	3q
		more than 2 teeth	4q
	Supernumerary teeth		4q
	OVB>5mm		2r
	Poor oral hygiene		2t
FUNCTIONAL PROBLEMS	Parafunctions (bruxism, jaw clenching)		2v
	Thumb/finger Sucking Habit		2w
	Oral breathing / OSAS		2x
NONE OF THE PROBLEMS LISTED ABOVE			N



**ANNEXURE –X****ROMA INDEX**

<b>Grade 5</b>	
<i>Systemic problems</i>	
Malformation syndromes	5a
Congenital malformations	5b
<b>Grade 4</b>	
<i>Systemic problems</i>	
Postural/orthopaedic problems	4c
Medical/auxological problems	4d
Familial tendency for malocclusion	4e
<i>Cranio-facial problems</i>	
Facial or mandibular asymmetries	4f
Articular dysfunctions	4g
Sequelae of traumas or surgery of cranio-facial district	4j
Maxillary hypodevelopment or mandibular hyperdevelopment (OVJ <0 mm)	4k
Maxillary hyperdevelopment or mandibular hypodevelopment (OVJ >6 mm)	4h
Mandibular hypo- or hyperdivergence	4i
<i>Dental problems</i>	
Scissor bite	4m
Anterior or posterior cross-bite >2mm	4n
Displacement >4 mm	4o
Open-bite >4 mm	4p
Hypodontia of permanent dentition	4q

**ROMA INDEX**

<b>Grade 3</b>	
<b><i>Cranio-facial problems</i></b>	
Maxillary hypodevelopment or mandibular hyperdevelopment (OVJ >0 mm)	3k
Maxillary hyper- or mandibular hypodevelopment (3 mm<OVJ<6 mm)	3h
<b><i>Dental problems</i></b>	
Caries and early loss of deciduous dentition	3l
Anterior or posterior cross-bite >1 mm	3n
Displacement >2 mm	3o
Open-bite >2 mm	3p
OVB >5 mm	3r
<b>Grade 2</b>	
<b><i>Cranio-facial problems</i></b>	
Maxillary hyper- or mandibular hypodevelopment (0 mm<OVJ<3 mm)	2h
<b><i>Dental problems</i></b>	
Anterior or posterior cross-bite <1 mm	2n
Displacement >1 mm	2o
Open-bite >1 mm	2p
Permutation abnormalities	2s
Poor oral hygiene	2t
Normal mesial or distal occlusion (up to a cuspid)	2u
<b><i>Functional problems</i></b>	
Functional asymmetries	2v
Bad habits	2w
Oral respiration	2x
<b>Grade 1</b>	
None of the problems listed above	N

**ANNEXURE – XI****Document Information**

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**Sources included in the report**

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