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Original Research

Efficacy of a novel toothbrush in improving oral hygiene among children with cleft lip and palate: a randomized control trial.

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ABSTRACT

Background: Cleft lip and palate are the most prevalent orofacial congenital malformation as common as 1 in 500. These children are born with multiple problems and face multiple traumas physically and psychologically. There is a clear need to develop improved methods of accessing and cleaning areas of high retention of the biofilm, either by the cleft morphology or the sensitivity of the surrounding tissues due to frequent local inflammatory conditions.

Aim: To evaluate and compare the efficacy of a novel toothbrush in removing dental plaque in cleft lip and palate patients with a regular toothbrush.

Materials & method: A total of 44 children aged 8 to 12 years with CLP were clinically examined and pre-operative intraoral pictures were documented. The adapted PI uses 2% erythrosine to stain the bacterial plaque and cleaning conditions were evaluated by visual observation. Data were recorded in the WHO assessment for children in oral hygiene form. Group A and Group B intervened using the novel toothbrush & conventional toothbrush respectively with A follow-up of 3,6,9,12 and 15 months.

Results: Groups were analyzed using a chi-square test in which group A showed a significant reduction in plaque compared to group B.[P<0.034]

Conclusion: The study shows children using novel toothbrushes not only showed a reduction in plaque but also showed more patient compliance.

***Keywords:** Toothbrush; Cleft lip and palate; Oral health.*

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INTRODUCTION

Cleft lip and palate are the most prevalent orofacial congenital malformation that may occur alone or in combination with lip and alveolar cleft as common as 1 in 1000[1]. These are commonly associated with multiple problems such as congenital missing teeth, neonatal teeth, ectopic eruption, supernumerary teeth, enamel hypoplasia, deep bite crossbite, crowding or spacing of teeth, early feeding, and nutritional concerns. Various studies highlight the increased plaque accumulation in cleft lip and palate patients. due to several factors, such as the cleft anatomy, the local tissue characteristics as a result of surgical correction procedures, the potential for trauma and bleeding, and the difficulties of local accessibility, make it challenging to perform efficient tooth brushing.[2]

Especially poor oral hygiene favors local inflammatory processes that compromise the tooth in the cleft area, the bone, and the bone graft.[3] Difficulties in performing an appropriate brushing which include fear of soft tissue trauma during brushing, worries about bleeding from inflamed gingiva and difficult access to the teeth, and the deepest area of the cleft due to surgeries such as cheiloplasty which diminish the flexibility of the mucobuccal fold and alveoloplasty make the vestibular space shallower.[4,5] Regular toothbrushes are not equipped to tackle the challenges brought on by cleft lip and palate. Recognizing this therapeutic necessity, a design that can address all of these patients' oral hygiene needs is required as the typical brush used by other children won't be sufficient to address all of the aforementioned concerns.[6,7,8,9]

The innovative toothbrush has a flexible shaft and a double-sided head encircled by extra-soft bristles. The flexible shaft makes it easier to reach the difficult areas of the cleft, and the double-sided bristles help clean two quadrants at once, decreasing oral sensitivity. The angulation and flexibility of the shaft are advantageous design features that enable children to comfortably brush in many directions as needed. Therefore, the purpose of this study was to compare the Novel Toothbrush to a conventional toothbrush in terms of how effectively it removed bacterial plaque from cleft lip and palate children.

MATERIAL AND METHODS

In group 1 children were clinically examined and pre-operative intraoral pictures were taken. Baseline data was calculated using an adapted Plaque Index (aPI) which is designed especially for these patients. The adapted PI uses 2% erythrosine to stain the bacterial plaque and cleaning conditions were evaluated by visual observation. In detail, to reveal the bacterial plaque, two drops of erythrosine 2% were placed on the tongue of the child (Figure 1) so that the dye would be distributed on maxillary dental surfaces for 30 seconds. In children who have difficulty rinsing, the solution was applied with the aid of a swab. Then patients were asked to rinse twice with tap water and the presence or absence of bacterial plaque was ascertained by visual examination. Data was recorded as a baseline and then Novel toothbrushes were distributed to each of the participants, demonstrations, and instructions were given to the participants and caregivers about the brushing technique of novel toothbrushes. [Figure 2] Data were recorded in the WHO assessment for children in oral hygiene form formulated in the year 2013, for baseline, and follow-ups of 3 months, 6 months, 9 months, 12 months, and 15 months, and the same method followed for group 2 (Regular toothbrush) [Figure3]

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RESULTS

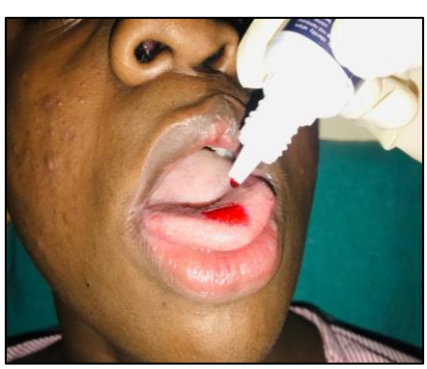
Data was entered into a Microsoft Excel data sheet and was analyzed using SPSS for Windows (Statistical Presentation System Software, SPSS Inc.) version 21.0. Shapiro Wilk test was done for testing normality and data was found to be normally distributed. Continuous data was represented as mean and standard deviation. An unpaired t-test was done. Graphical representation of data: MS Excel and MS Word were used to obtain various types of graphs such as bar diagrams and Pie diagrams. p-value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests. Statistical software: MS Excel, SPSS version 21.0 was used to analyze data. The adapted PI and two sub-measurements were performed in this study: Adapted PI (aPI) – evaluation of the buccal surfaces of all maxillary teeth, namely the teeth from 16 to 26 in children with mixed dentition, and the teeth from 55 to 65 in those with primary dentition; Adapted PI of the teeth near the Cleft (API-NC); and, Adapted PI of the teeth adjacent to the Cleft (aPI-C).

	GROUP 1: NOVEL TOOTH BRUSH	**GROUP 2: REGULAR TOOTHBRUSH**	**P value**
Adapted PI (aPI)	1.2±0.5	1.3±0.6	0.54
Adapted PI of the teeth near the Cleft (aPI-NC)	2.1±0.4	2.5±0.5	0.6
Adapted PI of the teeth adjacent to the Cleft (aPI-C)	2.5±0.2	2.1±0.4	0.92

Table 1: Baseline comparison between groups

	GROUP 1: NOVEL TOOTH BRUSH	**GROUP 2: REGULAR TOOTH BRUSH**	**P value**
Adapted PI (aPI)	1.2±0.5	1.3±0.6	<0.05*
Adapted PI of the teeth near the Cleft (aPI-NC)	0.5±0.4	1.6±0.5	<0.05*
Adapted PI of the teeth adjacent to the Cleft (aPI-C)	0.6±0.2	1.5±0.4	<0.05*

Table 2: 6th month comparison between groups



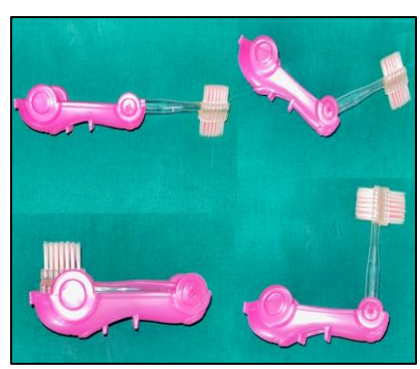


Figure 1: shows 2% erythrosine dye application to stain the bacterial plaque, **Figure 2:** shows the brush used for the study group, and **Figure 3**: shows the brush used for the control group.

	GROUP 1: NOVEL TOOTH BRUSH	GROUP 2: REGULAR TOOTH BRUSH	P value
Adapted PI (aPI)	1.2±0.5	1.3±0.6	<0.05*
Adapted PI of the teeth near the Cleft (aPI-NC)	0.6±0.4	1.9±0.5	<0.05*
Adapted PI of the teeth adjacent to the Cleft (aPI-C)	0.5±0.2	1.4±0.4	<0.05*

Table 3: 9th month comparison between groups

	GROUP 1: NOVEL TOOTH BRUSH	GROUP 2: REGULAR TOOTH BRUSH	P value
Adapted PI (aPI)	1.2±0.5	1.3±0.6	<0.05*
Adapted PI of the teeth near the Cleft (aPI-NC)	0.6±0.4	1.9±0.5	<0.05*
Adapted PI of the teeth adjacent to the Cleft (aPI-C)	0.5±0.2	1.9±0.4	<0.05*

Table 4: 12th month comparison between groups

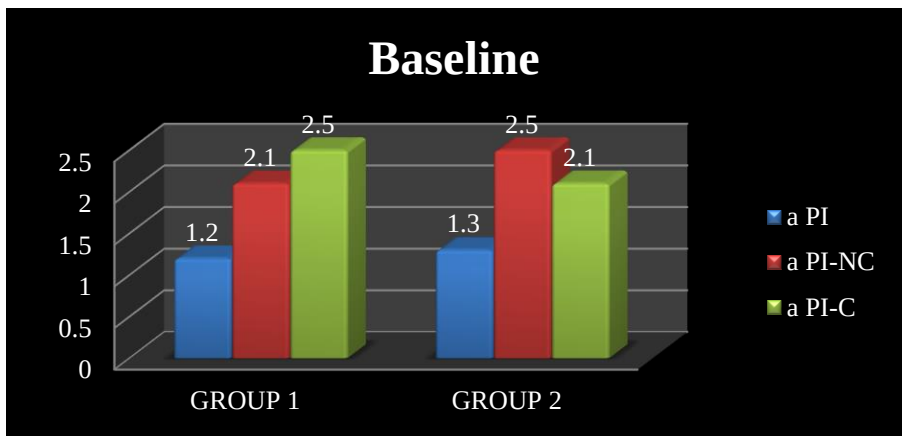
	GROUP 1: NOVEL TOOTH BRUSH	GROUP 2: REGULAR TOOTH BRUSH	P value
Adapted PI (aPI)	1.2±0.5	1.3±0.6	<0.05*
Adapted PI of the teeth near the Cleft (aPI-NC)	0.6±0.4	1.9±0.5	<0.05*
Adapted PI of the teeth adjacent to the Cleft (aPI-C)	0.4±0.2	2±0.4	<0.05*

Table 5: 15th month comparison between groups

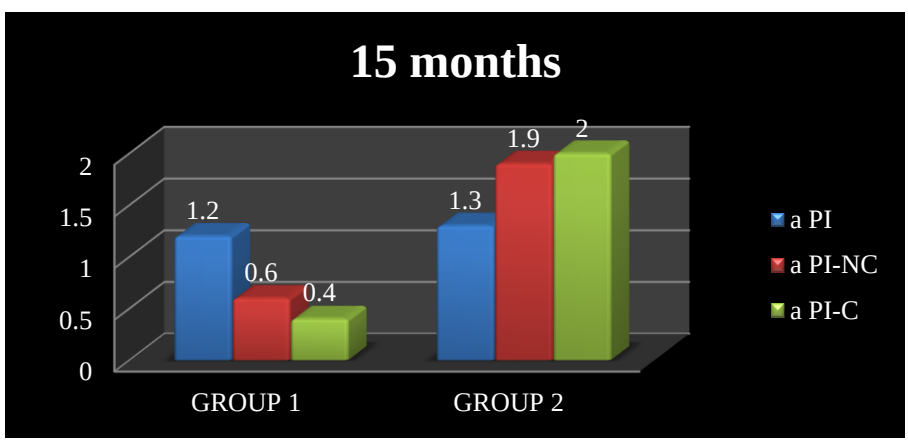
Figure 4: Preoperative baseline intra-oral photograph

Figure 5: Regular toothbrush

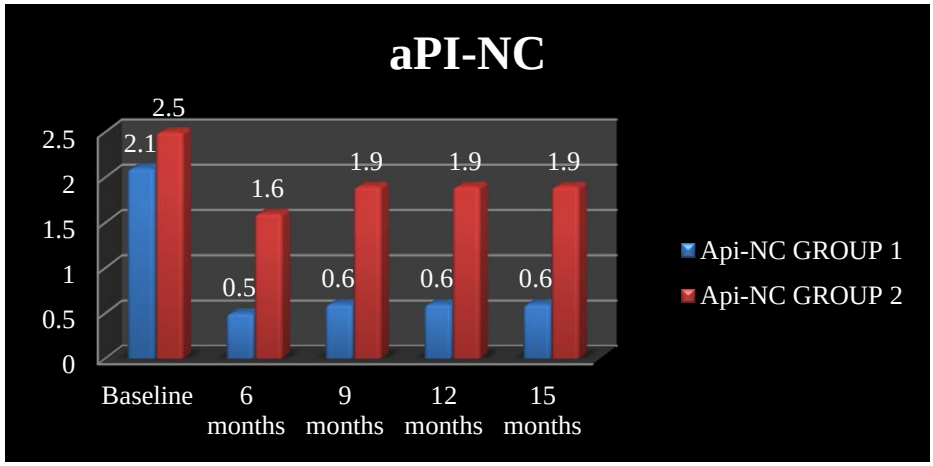
Figure 6: 15-month follow-up of a group1 patient



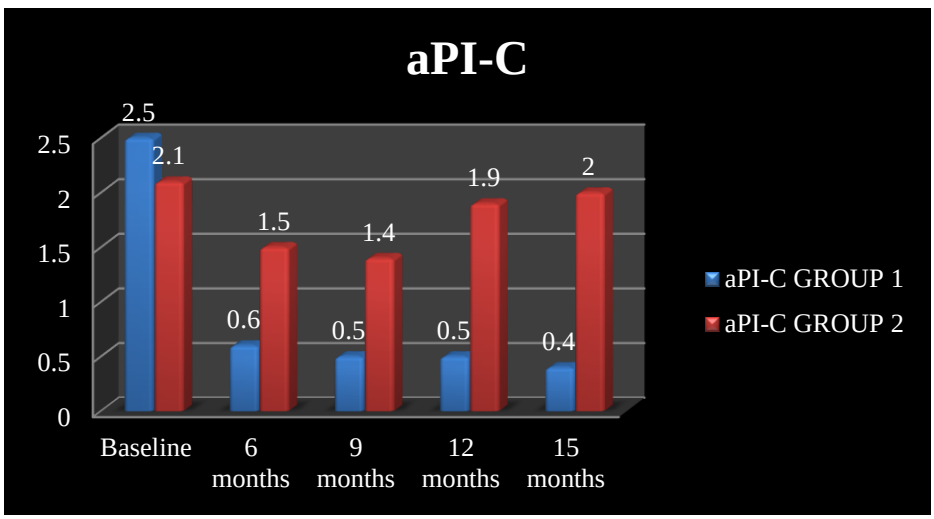
Graph 1: baseline descriptive comparison between the groups



Graph 2: 15th-month descriptive comparison between the group



Graph 3: Comparison of aPI-NC at different times (baseline to 15th month)



Graph 4: Comparison of aPI-C at different times (baseline to 15th month)

The adapted PI or adapted PI-C for each child was calculated by dividing the sum of the dental surface stained of each tooth by the number of observed teeth. The scores were 0 (no staining), 2 (staining < 1/3: 2), and 3 (staining between 1/3 and 2/3), as in the Greene Vermillion Index 18. The results can be interpreted as Excellent: 0; Good: 0.1 - 0.6; Reasonable: 0.7 - 1.8; and Bad: 1.9 – 3.19

An analysis of both the groups after intervention in 6th months, to assess the efficacy of novel toothbrushes and regular toothbrushes in removing plaque using adaptive plaque index. We found that group 1 (Novel toothbrush) and group 2 (Regular toothbrush) show a significant difference in P value (<0.05), Adapted plaque index of the teeth near the cleft (aPI -NC), and adapted plaque of the teeth adjacent to the cleft (aPI-C) showed high plaque level in group 2 (Regular toothbrush) compared to group 1 (Novel toothbrush)

And the 9th-month follow-up found that reduction in adaptive plaque index (aPI), Adapted plaque index of the teeth near the cleft (aPI-NC), and Adapted plaque index adjacent to the cleft (aPI-C) was statistically significant with P value (<0.05) which was similar to our 6th-month comparison. The higher plaque load in group 2 (regular toothbrush) especially near the cleft questions the efficacy of regular toothbrushes, it could be due to the fear of brushing in the cleft area, poor accessibility of regular

toothbrushes in these areas, and the results are by Gaggl et al[14] who found the vicinity of the cleft is responsible for the high gingival bleeding indicator in the anterior maxilla segment and higher loss of clinical gingival attachment. And reduction in plaque level near and adjacent to a cleft in group 1 (Novel toothbrush) proved the efficacy of the novel toothbrush in removing plaque, especially in these areas.

In this study, two groups at 12th month found a relative decrease in adaptive plaque index since the children with cleft lip and palate patients adapt themselves to the environment when trained with proper oral hygiene maintenance. And p-value (P<0.05) shows significant intergroup comparison in group 1(Novel toothbrush) and group 2 (Regular toothbrush) decreased from 0.6 to 0.5. This observation is by Rivkin et al,[5] who found poor efficacy of regular toothbrushes in the removal of plaque among cleft lip and palate patients.

Study comparison between the groups at the end of the 15th month shows a statistically significant p-value (<0.05) and clinically higher significant reduction of plaque shows in group 1 using a novel toothbrush compared to group 2 using a regular toothbrush.

DISCUSSION

The cariogenic microbiota is linked to the risk factors for dental caries in children with cleft lip and palate,[6] the type of cleft,[7] the gender[8] the mouth breathing[9], mother's knowledge[10] the fear of brushing the cleft area[11] and there is more worry about corrective procedures than about early detection or prevention of caries lesions8Moreover, the presence of the healing tissues after surgery complicates local hygiene efforts and favors the retention and/or obstruction of bacterial plaque control, leading to high plaque indexes[12] and an elevated risk of periodontal disease.[13] This is especially important for patients with oronasal communication and in the vicinity of clefts[14]. Despite the general agreement that CLP children have poor oral hygiene, no concrete solutions have been put up to improve the condition. For instance, brushing your teeth and getting rid of dental plaque are inextricably linked, but the toothbrush has received inadequate attention. As a result, such susceptible areas will not be effectively cleaned of plaque with a conventional brush. Thus, the implementation of measures that effectively ensure better oral hygiene is the need of the hour some modification that helps in removing the dental plaque in these areas would minimize the complications associated with poor oral hygiene and help the cleft child minimize oral problems.

This study primarily focused on children with cleft lip and palate between the ages of 8 and 12, when secondary bone grafting is undertaken to provide bone support for the teeth adjacent to the cleft and allow teeth to erupt, yet these teeth in the cleft area frequently have poor periodontal health (Eldeeb etal), chronic infections of the graft, minor wound dehiscence due to poor oral hygiene before and after the corrective surgery. It has been proven that building a systematic oral hygiene routine before adolescence is crucial because it is simple to make lifestyle changes in this age group. According to social cognitive theory, health behaviors and designing oral hygiene promotion self-efficacy and family environment are strongly associated with brushing among school children aged between 7 to 12 years and they should be considered in interventions. [Bashirian et al].[15]

At the end of the 15th month follow-up up adaptive plaque index near the cleft in group 1 compared with the baseline [Figure 4] shows an increase of plaque level initially followed by a gradual decrease in alternative follow-up from 2.1 to 0.4 which is an interpretation shows from bad ranges from 1.9 -3.19 to good where value ranges from 0.1- 0.6 while in group 2 using regular brush [Figure5] shows very mild improvement

Comparison in group 1 shows plaque level at cleft region decreases [Figure 6] from 2.5 (Interpreted as bad) to 0.4 (interpreted as good) at the end of the 15th month while group 2 shows less significance compared to group 1 where the novel toothbrush is used. This study evaluated the baseline plaque level of the cleft lip and palate children to evaluate the oral hygiene of non-syndromic cleft lip and palate patients while using a regular toothbrush by using an adapted plaque index (aPI), especially for these patients, developed by Rodrigues et al [16] where both plaque index and Green Vermillion index were associated.[17] In our study we did an innovative toothbrush that has a flexible shaft and a double-sided head encircled by extra-soft bristles which helps in preventing soft tissue trauma. The flexible shaft makes it easier to reach the difficult areas of the cleft, and the double-sided bristles help clean two quadrants at once, decreasing oral sensitivity among children with cleft lip and palate.

Our study showed that the Novel Toothbrush decreased a significant level of plaque load in the clef area, which represents the efficacy of this novel toothbrush in removing plaque from cleft lip and palate patients. This is of utmost relevance as stressed by a variety of studies. The dental health of the hard and soft tissues adjacent to the cleft is improved by better local hygiene. For bone grafts to successfully integrate and support subsequent surgical procedures, a non-inflamed area is crucial[18] for the multidisciplinary team committed to these children. So, a novel brush might be better for children with cleft lip and palate.

CONCLUSION

Children with CLP would benefit from improved oral health if devices were created specifically for the cleft area's hygiene and standardized preventative and control programs that focused on compliance, education, and motivation were implemented.[19,20] Because a typical toothbrush cannot go into the deepest parts of the gap and because individuals are afraid of causing soft tissue damage, cleaning the cleft area properly can be challenging. It is crucial to ensure that these children have better dental hygiene. The innovative toothbrush has a high level of effectiveness in eliminating dental plaque from the cleft region. The tool is simple for children to use, with or without adult assistance, and is anticipated to improve dental hygiene.

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Nil

CONFLICTS OF INTEREST

There are no conflicts of interest

ABBREVIATIONS : **CLAP**: Cleft lip and palate; **aPI**: Adapted plaque Index; **aPI-NC**: Adapted plaque index near to cleft; **aPI-C**: Adapted plaque adjacent to cleft; **NSCL± P**: Nonsyndromic cleft lip and Palate; **OIDP**: Oral impact of daily performance; **ICDAS**: International caries detection and assessment system; **OH**: Oral hygiene; **UCLAP**: Unilateral cleft lip and palate; **BCLAP**: Bilateral cleft lip and palate; **CLPA**: Cleft lip, palate, and Alveolus; **ADA**: American dental association**; PHP**: Patient hygiene performance

REFERENCES

1. Shkoukani MA, Chen M, Vong A. Cleft lip–a comprehensive review. Frontiers in pediatrics. 2013 Dec 27; 1:53.

2. Pisek A, Pitiphat W, Chowchuen B, Pradubwong S. Oral health status and oral impacts on quality of life in early adolescent cleft patients. J Med Assoc Thai. 2014;97(Suppl 10):S7‐16.

3. Quirynen M, De Soete M, Dierickx K, van Steenberghe D. The intraoral translocation of periodontopathogens jeopardizes the outcome of periodontal therapy. A review of the literature. J Clin Periodontol. 2001;28:499–507. [PubMed] [Google Scholar]

4. Gaggl A, Schultes G, Kärcher H, Mossböck R. Periodontal disease in patients with cleft palate and patients with unilateral and bilateral clefts of lip, palate, and alveolus. Journal of Periodontology. 1999 Feb;70(2):171-8.

5. Eldeeb ME, Hinrichs JE, Waite DE, Bandt CL, Bevis R. Repair of alveolar cleft defects with autogenous bone grafting: periodontal evaluation. Cleft Palate J. 1986 Apr 1;23(2):126-36.

6. deCastilho AR, Das Neves LT, de Carvalho Carrara CF. Evaluation of oral health knowledge and oral health status in mothers and their children with cleft lip and palate. The Cleft palate-craniofacial journal. 2006 Nov;43(6):726-30.

7. Ankola AV, Nagesh L, Hegde P, Karibasappa GN. Primary dentition status and treatment needs of children with cleft lip and/or palate. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2005 Apr 1;23(2):80.

8. Hazza'a AM, Rawashdeh MA, Al‐Nimri K, Al Habashneh R. Dental and oral hygiene status in Jordanian children with cleft lip and palate: a comparison between unilateral and bilateral clefts. Int J Dental Hygiene. 2011;9(1):30‐36.

9. Freitas AB, De Barros LM, Fiorini JE, Boriollo MF, Moreira AN, Magalhães CS. Caries experience in a sample of adolescents and young adults with cleft lip and palate in Brazil. The Cleft Palate-Craniofacial Journal. 2013 Mar;50(2):187-91.

10. Sundell AL, Ullbro C, Marcusson A, Twetman S. Comparing caries risk profiles between 5- and 10-year-old children with cleft lip and/or palate and non-cleft controls. BMC Oral Health. 2015 Jul 25;15:85. doi: 10.1186/s12903-015-0067-x. PMID: 26208495; PMCID: PMC4514989.

11. Bian Z, Du M, Bedi R, Holt R, Jin H, Fan M. Caries experience and oral health behavior in Chinese children with cleft lip and/or palate. Pediatr Dent. 2001 Sep-Oct;23(5):431-4. PMID: 11699170.

12. Parapanisiou V, Gizani S, Makou M, Papagiannoulis L. Oral health status and behaviour of Greek patients with cleft lip and palate. Eur Arch Paediatr Dent 2009;10:85-9.

13. Mutthineni RB, Nutalapati R, Kasagani SK. Comparison of oral hygiene and periodontal status in patients with clefts of palate and patients with unilateral cleft lip, palate and alveolus. Journal of Indian Society of Periodontology. 2010 Oct;14(4):236

14. Wyrębek B, Cudziło D, Plakwicz P. Evaluation of periodontal tissues in growing patients with bilateral cleft lip and palate. A pilot study. Journal of Mother and Child. 2017 Jan 1;21(2):154-63.

15. Bashirian S, Seyedzadeh-Sabounchi S, Shirahmadi S, Karimi-Shahanjarini A, Soltanian AR, Vahdatinia F. Predictors of oral health promotion behaviors among elementary school children: Examination of an extended social cognitive theory. Int J Paediatr Dent. 2021 Mar;31(2):191-203. doi: 10.1111/ipd.12659. Epub 2020 May 16. PMID: 32339312.

16. Rodrigues R, Chung AP, Mortensen MS, Fernandes MH, Monteiro AB, Furfuro R, Silva CC, Manso MC, Sørensen SJ, Morais PV. Temporal oral microbiome changes with brushing in children with cleft lip and palate. Heliyon. 2021 Mar 18;7(3):e06513. doi: 10.1016/j.heliyon.2021.e06513. PMID: 33817376; PMCID: PMC8005767.

17. Rivkin CJ, Keith O, Crawford PJ, Hathorn IS. Dental care for the patient with a cleft lip and palate. Part 1: From birth to the mixed dentition stage. British dental journal. 2000 Jan;188(2):78-83.
18. Ahluwalia M, Brailsford SR, Tarelli E, Gilbert SC, Clark DT, Barnard K, Beighton D. Dental caries, oral hygiene, and oral clearance in children with craniofacial disorders. Journal of dental research. 2004 Feb;83(2):175-9.
19. Ankola AV, Nagesh L, Hegde P, Karibasappa GN. Primary dentition status and treatment needs of children with cleft lip and/or palate. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2005 Apr 1;23(2):80.
20. ST SM. Prevalence of dental caries and oral hygiene practices in children with cleft lip and/or palate. International Journal of Contemporary Dentistry. 2010 Sep 1;1(3).

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