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EFFECTIVENESS OF CHLORHEXIDINE VARNISH IN PREVENTING DENTAL CARIES IN PATIENTS WITH CLEFT LIP AND PALATE

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ABSTRACT

Aims: This research aimed to evaluate the effect of chlorhexidine varnish in preventing dental caries in patients with cleft lip and palate**.**

Settings and Design: The study was conducted as a clinical trial. The clinical part was carried out at Pediatric Dentistry Department, Faculty of Dentistry, Tanta University and the laboratory work was carried out at Medical Microbiology and Immunology Department, Faculty of Medicine.

Subjects and Methods: 60 children with (CL/P) with an age range from 8-12 years were included in the study. The selected children were divided into three equal groups; Group (I) topical chlorohexidine varnish was applied, group (II) topical fluoride varnish, while in group (III) included children received oral health education only. Salivary samples were collected from each child at baseline, one day, three months, six months and twelve months intervals. Salivary samples were prepared for measuring salivary pH and streptococcus mutants counts and scheduled immediately before and after varnish application.

Results: Group I where chlorohexidine varnish was applied shown an improvement in dental caries prevention during follow up period until one year.

Conclusions: Chlorohexidine varnish is better than fluoride varnish for cleft children.

KEY-WORDS: cleft lip and palate**,** chlorhexidine varnish**,** dental caries

INTRODUCTION

Worldwide, the Cleft lip and/or palate (CL/P) are among the most prevalent congenital deformities in newly born infants and are influenced by complicated environmental and genetic factors. The international literatures reported that the prevalence rate of CL/P vary between 0.87 to 1.2 per 1000 births. These prevalence rates are like those observed in studies conducted in Egypt[1].

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The incidence of CL/P has been associated with numerous environmental and dietary risk factors[2]. These risk factors include advanced maternal age, smoking, alcohol consumption, type I diabetes mellitus, deficiency of vitamins such as folic acid, and intrauterine irritation. Moreover, maternal use of various drugs known to be teratogenic, such as valproate acid, anticonvulsants, retinoic acid derivatives, thalidomide, and phenytoin contribute to the incidence of CL/P[3].

In general, patients with CL/P need intensive care from a multidisciplinary team of medical and dental specialists to correct their cosmetic, speech, psychosocial, and dental problems. Since managing of one health component will affect the outcome of the other, coordination within the CL/P management team is crucial[4].

Preventing dental decay and maintaining excellent oral health are crucial from the perspective of oral health care. Moreover, early tooth loss could delay and complicate the suggested surgical or orthodontic therapy, which could be carried out at various stages from birth to adulthood [5].

Following the systematic review with the meta-analysis by Worth et al (2017)[6], this patient had numerous dental cavities, as the authors concluded that CL/P patients have a higher prevalence of dental caries than the overall population.

Meanwhile, a study made by Weraarchakul W et al., 2017[7], observed that children with oral clefts have 3.5 times more decayed surfaces in comparison with noncleft control group. Moreover Stec-Slonicz et al., 2007[8], found that there was an increase in the prevalence of dental caries when comparing patients with cleft lip and/or palate to their non-cleft counterparts. This higher caries susceptibility was attributed to many factors such as insufficient parental dietary counseling, enamel hypoplasia, deterioration of their oral hygiene, and early colonization of microorganisms associated with caries[8].

The oral hygiene in CL/P patients was affected due to the higher incidences of supernumerary teeth and the limited dental arch space attributed to the underdeveloped maxilla may lead to malalignment of teeth in the CL/P patients. Also crowding causes restricted access for the toothbrush and the natural cleansing of the teeth by the tongue and saliva[9].

Likewise, parents tend to overindulge their children with CL(P) and offer them sucrose containing food and snacks as a compensation for their medical condition. Also prolonged oral clearance time in children with oral clefts can contribute to a cariogenic environment[9].

According to numerous studies, chlorhexidine is the most potent antibacterial agent due to its inhibitory effect against Streptococcus mutans which considered the main cause of dental caries. Chlorhexidine can be found in a variety of products, including varnish, mouthwash, and paste. The mode of action of chlorhexidine depends on inhibition of acid production. This preserves the neutrality of salivary PH and gives better chance for repairing of any initial demineralized lesion[10,11,12]. Also using of fluoride varnish could reduce streptococcus count in saliva and preserves the neutrality of salivary PH as discussed by Badjatia S et al.,2017[13].

Consequently, some authors recommended the frequent application of fluoride varnish to CL/P patients not only to improve their oral hygiene and reduce risk of dental caries but also during necessary orthodontic treatment at mixed dentition period to avoid the increase in caries incidence. Therefore, the present study aimed to evaluate the potential of chlorhexidine varnish in preventing dental caries in children with CL/P[14].

SUBJECTS AND METHODS

Study design

A randomized controlled clinical trial design was adopted in the present research.

Study setting

Children were recruited from Oral & Maxillofacial department, Faculty of Dentistry, Tanta University. Laboratory procedures were performed at Medical Microbiology and Immunology Department, Faculty of Medicine, Tanta University.

Ethical considerations

Approval for this research was obtained from Research Ethics Committee, Faculty of Dentistry, Tanta University. The aim of the current study was clarified to children and their parents and informed consents, assents were obtained according to the guidelines on human research.

Sample size calculation

The sample size was calculated by using Epi Info computer software version7[15]. Assuming that confidence level at 95% with 5% margin of error and design defect in the power analysis is 2, the calculated sample was 53 patients. A sample inflation of 10% was added to compensate for sample attrition.

Study sample and group assignment

The study sample consisted of 60 children. The age group ranged from 8-12 years. All children received oral hygiene instructions and randomly divided into three equal groups comprising 20 children each.

Study groups

- ***Group (I):*** Twenty children received oral health education and topical chlorohexidine (varnish (Cervitec Plus)
- ***Group (II):*** Twenty children received oral health education and topical fluoride (varnish (NaF. Nova Bright)
- ***Group III:*** Twenty children received oral health education only. (control group)

Exclusion criteria:

- Children with any systemic diseases.
- Children receiving any medications.
- Children receiving any oral or dental preventive program.
- Uncooperative children or children not willing to participate in the study.

Preventive regimens

Oral health education

Dental health education for children was presented as a small group discussion. Each group was composed of 5-10 children. Audio-visual aids in the form of animation video, models, posters and educational films were used for demonstration.

The topics of oral health exams, regular checkup, healthy diet and home care were discussed. The educational sessions were implemented every three months. Monthly, all children were phone-called to re-emphasize the health educational message.

Varnishes application

- Chlorhexidine and fluoride varnishes were applied at the start of the study, three months and six months later. Fig(1,2)
- Before application of the varnishes, teeth were cleaned using non fluoridated pumice with rotary rubber cup.
- Teeth were partially isolated using cotton rolls and saliva ejector followed by dryness using ship syringe.
- Chlorhexidine and fluoride varnishes were applied with a small brush using paint on technique.
- Interproximal application of the varnishes was accomplished by non-waxed dental floss. Children were instructed not to eat or drink for one hour after application according to manufacturer's instruction.

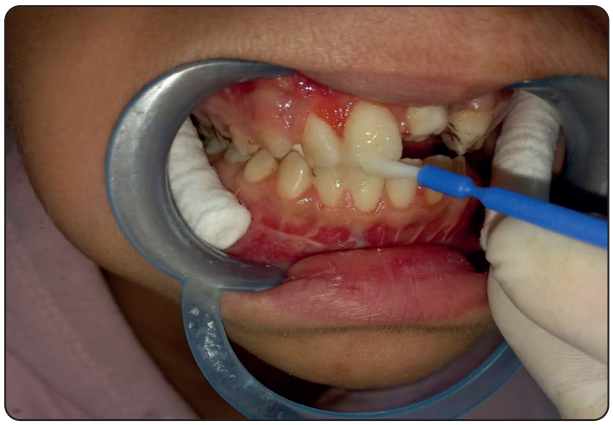


Fig. (1)

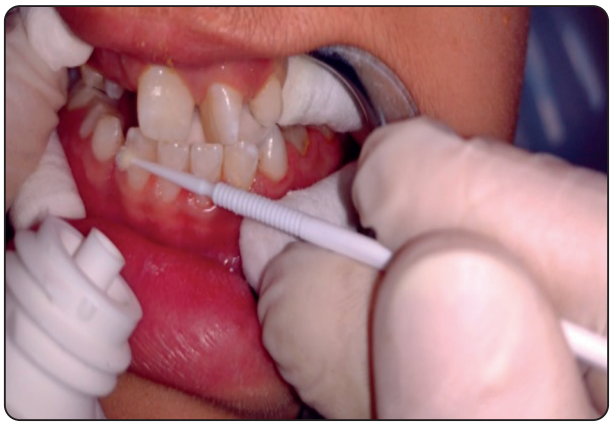


Fig. (2)

Saliva collection and assessment of salivary parameters

Saliva sampling:

Saliva was collected in the morning and children were informed not to eat or drink for one hour prior to collection of saliva to diminish possible food debris[16]. Saliva samples were obtained with the children sitting, swallowing and allowing saliva to pool in the mouth for 2 minutes. All saliva samples were taken from underneath the tongue by means of a sterile plastic syringe [16]. Salivary samples were collected from each child at (baseline, one day, three months, six months and twelve months). At the start of the study, three months and six months later, salivary samples were scheduled immediately before and after varnish application. Collected saliva was transferred to sterile screw capped tubes to be transported immediately to the laboratory.

Assessment of salivary pH[16]

Salivary pH was measured by single electrode digital pH meter. The calibration of the digital pH meter done by attaching the automatic temperature compensation (ATC) to the electrode. The pH buffer was freshly prepared and present in the same temperature of the experimented salivary samples. Also, the pH electrode was washed with distilled water with pH 7, dipped in neutral buffers and stirred with magnetic bar. Finally, calibration was performed when the reading is stable.

pH measurements:

The pH meter was adjusted at the measurement mode. After that, the pH electrode was dipped in the testing solution and stirred with magnetic bar for getting best results. Then, the pH reading is registered when it became stable, and The MEMORY button was pressed to record and store the measured value.

Preparation of culture medium[17]

A mixture of 90 gm of agar was suspended in 1 L distilled water was boiled to allow for complete dissolving of the medium. Mitis Salivaris Agar media was modified by adding 0,2 units of bacitracin/L to ensure maximum inhibition of normal salivary flora. The medium was placed in autoclave at 15 Ibs pressure, 121˚C for 15 minutes to be sterilized and dispensed. Then, the medium was cooled to 50-55˚C and, 1ml of sterile 1% Potassium Tellurite Solution (FD052) was added. Finally, the medium was mixed well and poured in sterile Petri plates.

Culture of salivary Streptococcus mutans:

Serial dilutions were made from saliva sample. 0,1 ml of each dilution was spread on Mitis Salivaris (MS) Agar as selective media for streptococcus mutants. Next, the plates were incubated in 5% carbon dioxide environment at 37˚C for 48 hours. The streptococcus mutants were identified based

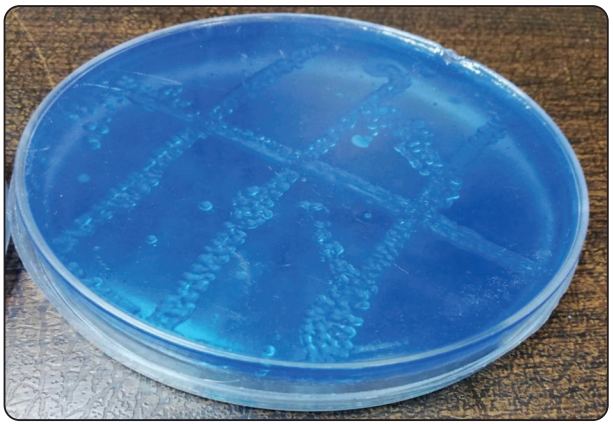


Fig. (3)

on the distinct appearance of the colonies as hard, dark blue, coherent, berry-like and raised colonies varying in size from 0.5 to 1 mm in diameter. Fig (3)

Data analysis

Statistical analysis of all data was done using SPSS package system V.22[18]after they were collected and tabulated. Descriptive and inferential statistics including ANOVA and paired-t-test were used.

RESULTS

The present study was done on sixty children with CL/P. There was dropout of three cases from group (III) at six months and four cases from group (I) and group (II) at twelve months.(Illustrated in patient flow chart)

Patient flow chart

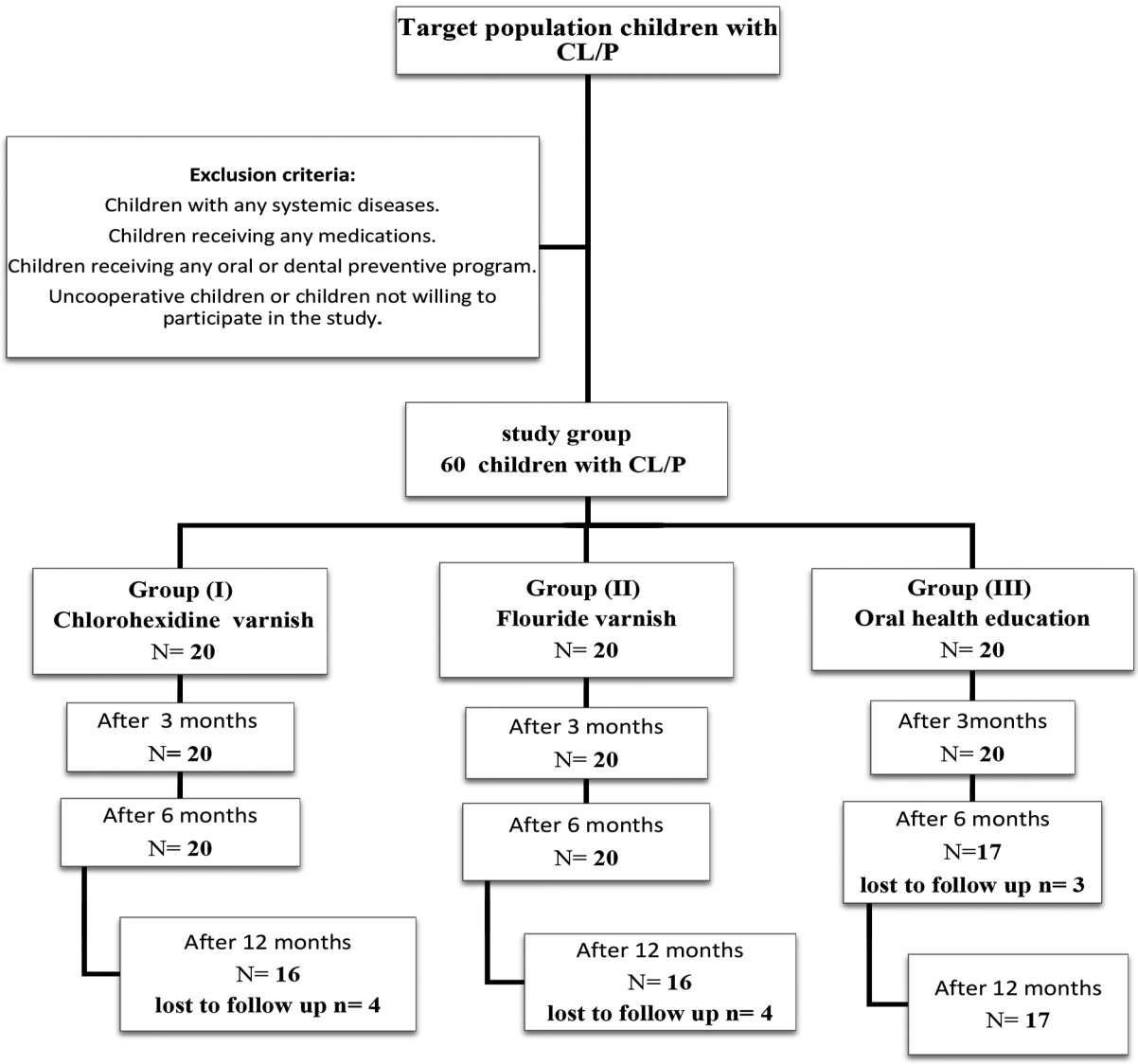
n relation to Salivary pH:

The Results of salivary pH in group (I) chlorohexidine varnish at different follow up periods demonstrated that the mean salivary pH at baseline, one day after 1st application, three months and one day after 2nd application were 6.41, 7.15, 7.05 and 7.07 respectively. Whereas the mean salivary pH at six months, one day after 3rd application and at twelve months were 7.38, 7.38 and 6.84 respectively. Paired t test reveals a statistically significant differences of the mean salivary pH between baseline and different follow up periods ($p < 0,05$) as shown in table (V-1)

While, in group (II) fluoride varnish the mean salivary pH in different follow up periods were 6.46, 6.97, 6.59 and 7.01 at baseline, one day after 1st application, at three months and one day after 2nd application respectively. Additionally, salivary samples display pH values of 6.49, 7.05 and 6.37six months, one day after 3rd application and twelve months respectively. Statistically significant differences were reported only between the mean baseline salivary pH and the mean salivary pH at one day after 1st, 2nd, and 3rd applications ($p < 0,05$)

Table (V-1) demonstrates the salivary pH at different follow up periods among control group (III). The mean salivary pH at baseline, three months, six months, and twelve months were 6.32, 5.67, 5.81 and 5.67 respectively. Paired t test reveals a statistically significant differences between the mean salivary pH at baseline and the mean salivary pH at three months, six months, and twelve months ($p < 0,05$)

Regarding to the comparison of salivary pH among different groups at different follow up periods the results indicated that, at baseline there was no statistically significant difference of the mean salivary pH among different groups ($p>0.05$). One day after 1st application, the mean salivary pH of group (I) and group (II) were significantly higher than that of control group ($p = 0.001$). Similarly, at one day after 2nd application, the mean salivary pH of group III was significantly lower than the corresponding values of group I and group II ($p = 0.001$). While, at three months, six months, one day after 3rd application and twelve months, there were statistically significant differences between all groups ($p = 0.001$) as presented in table (V-2).



Streptococcus mutans count

The mean salivary streptococcus mutans count in group (I) at different follow up periods demonstrate that salivary streptococcus mutans count at baseline, one day after 1st application, at three months and one day after 2nd application are 2.97 x 10^6 , 10^4, 2.9 x 10^5 and 9.8 x 10^3 CFU/ml respectively. Whereas the mean salivary streptococcus mutans count at six months, one day after 3rd application and at twelve months were 9.45 x 10^3, 9.45 x 10^3 and 2.74 x 10^5CFU/ml respectively. Paired t test reveals a statistically significant difference of the mean salivary streptococcus mutans count between baseline and different follow up periods ($p < 0,05$)

In group (II), results demonstrated that the mean salivary streptococcus mutans count at baseline, one day after 1st application, at three months and one day after 2nd application are 3.1 x 10^6, 2.88 x 10^5, 3 x 10^6 and 2.78 x 10^5 CFU/ml respectively. While, at six months, one day after 3rd application and at twelve months the mean streptococcus mutans count were 2.98 x 10^6, 2.67 x 10^5 and 3.09 x 10^6CFU/ml respectively. Paired t test reveals a statistically significant difference only between the mean baseline salivary streptococcus mutans count

and the mean salivary streptococcus mutans count at one day after 1st, 2nd and 3rd applications ($p < 0.05$)

While in group (III), the mean salivary streptococcus mutans count at baseline, three months, six months and twelve months were 3.02 x 10^6, 3 x 10^6, 3.1 x 10^6 and 3.5 x 10^6 CFU/ml respectively. Paired t test reveals no statistically significant difference between the mean salivary streptococcus mutans count at different follow up periods. ($p < 0,05$)

The Comparison of salivary streptococcus mutans count among different groups at different follow up periods are illustrated in table (V-4). There was no statistically significant difference of the mean salivary streptococcus mutans count among different groups at baseline ($p>0.05$). One day after 1st application, the mean salivary streptococcus mutans count of group (I) and (II) were significantly lower than that of control group ($p = 0.008$).

Similarly, at one day after 2nd and 3rd applications, the mean salivary streptococcus mutans count of group (III) was significantly higher than the corresponding values of group (I) and group (II) ($p <0.05$). At three months, six months the mean salivary streptococcus mutans count of group (I) was statistically lower than the mean salivary streptococcus mutans count of group (II) and (III) ($p <0.05$). At twelve months, there were statistically significant differences of the mean salivary streptococcus mutans count between all groups ($p <0.05$).

TABLE (1) Evaluation of salivary pH at different follow up periods in different study groups

Groups	pH	Mean ± SD	Paired "t"	P
GROUP I	**Baseline**	6.41±0.45		
	One day after 1st application	7.15±0.36	**"t_1"** 6.918	0.001*
	Three months	7.05±0.19	**"t_2"** 5.384	0.001*
	One day after 2nd application	7.07±0.22	**"t_3"** 5.189	0.001*
	Six months	6.85±0.21	**"t_4"** 3.453	0.001*
	One day after 3rd application	7.38±0.16	**"t_5"** 8.025	0.001*
	Twelve months	6.84±0.26	**"t_6"** 2.692	0.001*
GROUP II	**Baseline**	6.46±0.42		
	One day after 1st application	6.97±0.22	**"t_1"** 4.764	0.001*
	Three months	6.59±0.74	**"t_2"** 1.184	0.323
	One day after 2nd application	7.01±0.22	**"t_3"** 4.737	0.001*
	Six months	6.49±0.45	**"t_4"** 1.122	0.848
	One day after 3rd application	7.05±0.20	**"t_5"** 5.385	0.001*
	Twelve months	6.37±0.17	**"t_6"** 1.471	0.155
GROUP III	**Baseline**	6.54±0.42		
	Three months	5.90±0.23	**"t_2"** 5.266	0.001*
	Six months	6.04±0.19	**"t_4"** 4.154	0.001*
	Twelve months	6 ±0.11	**"t_6"** 5.330	0.001*

**Significant at 0.05 level*
"t_2" : Baseline versus three months
"t_4" : Baseline versus six months
"t_6" : Baseline versus twelve months
"t_1" : Baseline versus one day after 1st application
"t_3" : Baseline versus one day after 2nd application
"t_5" : Baseline versus one day after 3rd application

TABLE (2): Comparison of salivary pH among different groups at different follow up periods

Ph	Group I	Group II	Group III	F (p)	Post hoc test	
	Mean ± SD	Mean ± SD	Mean ± SD			
Baseline	6.41±0.45	6.46±0.42	6.54±0.42	0.657 (0.569)		
One day after 1st application	7.15±0.36	6.97±0.22	6.54±0.42	24.3546 (0.001*)	P1 P2 P3	0.077 0.001* 0.001*
Three months	7.05±0.19	6.59±0.74	5.9±0.23	33.225 (0.001*)	P1 P2 P3	0.003* 0.001* 0.001*
One day after 2nd application	7.07±0.22	7.01±0.22	5.9 ±0.23	127.270 (0.001*)	P1 P2 P3	0.365 0.001* 0.001*
Six months	6.85±0.21	6.49±0.45	6.04±0.19	35.415 (0.001*)	P1 P2 P3	0.001* 0.001* 0.001*
One day after 3rd application	7.38±0.16	7.05±0.20	6.04±0.19	193.567 (0.001*)	P1 P2 P3	0.001* 0.001* 0.001*
Twelve months	6.84±0.26	6.37±0.17	6 ±0.11	89.476 (0.001*)	P1 P2 P3	0.001* 0.001* 0.001*

Significant at 0.05 level; P1: Group I vs Group II; P2: Group I vs Group III; P3: Group II vs Group III

Table (3): Evaluation of salivary streptococcus mutans at different follow up periods in different study groups

Groups	streptococcus mutans CFU/ml	Mean ± SD	Paired "t"		P
GROUP I	**Baseline**	$2.97 \times 10^6 \pm 1.01947 \times 10^5$	**"t_1"**		0.001*
	One day after 1st application	$10^4 \pm 94.6$	2.167		
	Three months	$2.9 \times 10^5 \pm 3.01 \times 10^3$	**"t_2"**	2.166	0.001*
	One day after 2nd application	$9.8 \times 10^3 \pm 109.4$	**"t_3"**	2.176	0.001*
	Six months	$2.65x\ 10^5 \pm 2.94 \times 10^3$	**"t_4"**	2.185	0.001*
	One day after 3rd application	$9.45 \times 10^3 \pm 112.5$	**"t_5"**	2.192	0.001*
	Twelve months	$2.74 \times 10^5 \pm 2.76 \times 10^3$	**"t_6"**	2.186	0.001*
GROUP II	**Baseline**	$3.1 \times 10^6 \pm 9.77338 \times 10^5$	**"t_1"**	2.235	0.027*
	One day after 1st application	$2.88 \times 10^5 \pm 3x\ 10^3$			
	Three months	$3 \times 10^6 \pm 9.672386 \times 10^5$	**"t_2"**	1.009	0.476
	One day after 2nd application	$2.78 \times 10^5 \pm 4.23 \times 10^3$	**"t_3"**	2.425	0.023*
	Six months	$2.98 \times 10^6 \pm 2.67x\ 10^5$	**"t_4"**	1.022	0.478
	One day after 3rd application	$2.67 \times 10^5 \pm 3.767\ x10^3$	**"t_5"**	4.115	0.020*
	Twelve months	$3.09 \times 10^6 \pm 8.9798x\ 10^5$	**"t_6"**	0.362	0.433
GROUP III	**Baseline**	$3.02 \times 10^6 \pm 8.30020 \times 10^5$	**"t_1"**	1.687	0.965
	Three months	$3 \times 10^6 \pm 9.65743 \times 10^5$			
	Six months	$3.1 \times 10^6 \pm 8.54638 \times 10^5$	**"t_2"**	1.774	0.306
	Twelve months	$3.5 \times 10^6 \pm 7.65746x\ 10^5$	**"t_3"**	2.768	0.384

Significant at 0.05 level

"t1" : Baseline versus one day after 1st application; "t2" : Baseline versus three months

"t3" : Baseline versus one day after 2nd application; "t4" : Baseline versus six months

"t5" : Baseline versus one day after 3rd application; "t6" : Baseline versus twelve months

TABLE (4): Comparison of salivary streptococcus mutans among different groups at different follow up periods

streptococcus mutans CFU/ml	Group I	Group II	Group III	F (p)	Post hoc test	
	Mean ± SD	Mean ± SD	Mean ± SD			
Baseline	$2.97 \times 10^6 \pm 1.01947 \times 10^5$	$3.1 \times 10^6 \pm 9.77338 \times 10^5$	$3.02 \times 10^6 \pm 8.30020 \times 10^5$	1.729 (0.421)		
One day after 1st application	$10^4 \pm 94.6$	$2.88 \times 10^5 \pm 3 \times 10^3$	$3.02 \times 10^6 \pm 8.30020 \times 10^5$	12.354 (0.01*)	P1 P2 P3	0.543 0.005* 0.013*
Three months	$2.9 \times 10^5 \pm 3.01 \times 10^3$	$3 \times 10^6 \pm 9.672386 \times 10^5$	$3 \times 10^6 \pm 9.65743 \times 10^5$	9.431 (0.02*)	P1 P2 P3	0.03* 0.03* 0.327
One day after 2nd application	$9.8 \times 10^3 \pm 109.4$	$2.78 \times 10^5 \pm 4.23 \times 10^3$	$3 \times 10^6 \pm 9.65743 \times 10^5$	1117.2 (0.001*)	P1 P2 P3	0.03* 0.001* 0.001*
Six months	$2.65 \times 10^5 \pm 2.94 \times 10^3$	$2.98 \times 10^6 \pm 2.67 \times 10^5$	$3.1 \times 10^6 \pm 8.54638 \times 10^5$	8.332 (0.01*)	P1 P2 P3	0.023* 0.003* 0.1
One day after 3rd application	$9.45 \times 10^3 \pm 112.5$	$2.67 \times 10^5 \pm 3.767 \times 10^3$	$3.1 \times 10^6 \pm 8.54638 \times 10^5$	123.567 (0.001*)	P1 P2 P3	0.001* 0.001* 0.001*
Twelve months	$2.74 \times 10^5 \pm 2.76 \times 10^3$	$3.09 \times 10^6 \pm 8.9798 \times 10^5$	$3.5 \times 10^6 \pm 7.65746 \times 10^5$	17.174 (0.01*)	P1 P2 P3	0.02* 0.01* 0.1*

Significant at 0.05 level; P1: Group I vs Group II; P2: Group I vs Group III; P3: Group II vs Group III

DISCUSSION

Orofacial clefts (OFC) are very common worldwide congenital deformity. A multidisciplinary team of dental and medical specialists is frequently required to treat patients with cleft lip and palate who typically need considerable care to restore their cosmetic, speech, hearing, psychosocial, and dento-orthopedic problems.

A healthy dentition in cleft children is crucial for the successful outcomes of speech development, orthodontic treatment, oral function, and space maintenance for permanent teeth. Nevertheless, obtaining ideal oral health in children with cleft lip and palate may be challenging due to the anatomy of the cleft area, scarring, malposed teeth, and the outcomes of surgical repair that cause immobility of the lip.

The present study aimed to apply two different prophylactic agents (chlorhexidine & fluoride) in the form of varnish to improve oral health of cleft children and reduce the risk of dental caries. The rationale for using these agents as a varnish not solution as it acts as slow-releasing reservoirs because it can adhere to teeth surfaces for a longer period and prevent its immediate loss.

The age range of the selected children in this study were 8-12 years because dental caries is highly prevalent in this mixed dentition period as observed by Caufield PW et al., 2000 [19].

Unstimulated saliva was used in this study due to the ease of sampling and processing. It has a lower concentration of bicarbonate ions, which reduces the bias caused by the buffering action of saliva. This is in an agreement with a study made by Seeman R etal., 2004, who recommended the use of unstimulated saliva during salivary sample collection and processing[20].In the current study, saliva was collected from floor of the mouth using

a suction method by sterile disposable syringe to prevent any contamination [21].

Oral health education was applied to all children to develop desirable dental health attitude and habits in the form of a small group discussion to ensure face to face contact and proper motivation thus provide mutual trust, instructions were followed by all children.

The principal action of fluoride is to enhance remineralization and retard demineralization of enamel by attracting calcium and phosphates ions from saliva. As well, it restricts transport, storage of carbohydrate, and creation of extracellular polysaccharide by intervening with enolase enzyme in streptococcus mutans bacteria[22].

On contrary, the chlorhexidine was supposed to be appropriate antimicrobial gent against streptococcus mutans bacteria as it sticks to the glycoproteins by reverse electrostatic binding, therefore become preserved into the oral surfaces[23].

The effect these prophylactic agents on salivary PH and oral streptococcus mutans of cleft children were evaluated as an indicator of caries activity. Moreover, salivary pH can also determine the properties of saliva and assessment of caries risk[24].

In relation to current study, the mean salivary pH in group (I) is significantly increased throughout follow up periods in comparison with control group. This was in agreement with Hassan SM et al.,2008[25] who found that salivary pH was 7.67±0.14 for the initial salivary pH and 7.14±0.54 for the final salivary pH after the use of different CHX regimens that inhibited acid produced by streptococcus mutans bacteria.

Justification of this result was illustrated by Prabhakar et al., 2017[26] who concluded that CHX varnish can remain in longer contact with teeth surfaces subsequently decreases the activity of acidogenic bacteria. Moreover, Khadra M etal., 2019[27] demonstrated that salivary pH increased for long period due to suppression of S.Mutans for extended period of time by CHX varnish thus decrease acid production by S.Mutans bacteria.

On the other hand, these results disagree with the outcomes of study made by Yalcin F etal.,2006[28] who concluded that there was no change in the pH values of saliva after application of CHX varnish. It was attributed to the method of application i.e., with disposable micro brushes in which the total duration of contact with teeth surfaces was too short.

The present study also illustrated a statistical significant increase of the mean pH in group of children treated with fluoride varnish in a short period of time, this is in agreement with Badjatia S etal.,2017[29] who found that fluoride varnish upon contact with saliva, it hardens on teeth surfaces thus allow high concentration of fluoride to be in contact with teeth enamel for a considerable amount of time (about 1–7 days). Moreover, it was believed that the effect of fluoride varnish on raising salivary pH attributed to its inhibitory effect on acidogenic microorganisms.

In group (III) children who did not receive any preventive agents, the mean pH was significantly decreased throughout follow up periods. This result coincides with the result of Cheng L etal., 2007[24] who found that pH level of the oral environment of cleft children may drop to around the critical pH of 5.5, which enables demineralization of tooth structure to occur. It was concluded that many predisposing factors could contribute to this result such as excessive consumption of carbohydrates as their parents tend to nurse them extremely.

Concerning streptococcus mutans, the present results showed significant decreased in the mean number of streptococcus mutans in group (I) in comparison with other groups and mean base line count. This result was consistent with Ekenbach SB et al.,2000[30] who compared the effect of chlorhexidine and fluoride varnishes on suppression of S. Mutans on exposed sound root surfaces and concluded that the treatment with Cervitec varnish had high effectivness up to one year as compared to

fluoride varnish and this was attributed to substantial bactericidal effect of chlorohexidine.

The present study also revealed a statistical significant reduction of S.Mutans bacteria in group (II) as children treated with topical fluoride varnish in comparison to control group. However, this reduction was only temporary and continued for short period of time. This result was in agreement with Zickert and Emilson 1982[31], who observed that topical fluoride varnish reduced S.Mutans bacteria in saliva just for twenty days after first application.

In group (III) it was noticed that the mean streptococcus mutans count was significantly decreased throughout follow up periods. This result was consistent with Antonarakis GS etal., 2013[32] who explained the higher caries incidence in cleft children as they subjected to multiple episodes of removable and fixed orthodontic therapies. These appliances allow early establishment of streptococcus mutans bacteria in the oral cavity. The earlier the colonization of streptococcus mutans bacteria, the higher the caries susceptibility and caries experience consequentially.

The limitation of this study presented as a number of these children had high amount of calculus and sever extrinsic stains in their teeth that required scaling and teeth polishing before application of varnish.

CONCLUSION

Chlorohexidine varnish showed better performance than fluoride varnish as it improved oral health of cleft patients by reducing streptococcus bacteria count, raising salivary pH and its efficacy could last for long period of time until one year

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