COMPARATIVE EVALUATION OF THE ANTI-PLAQUE AND ANTI-GINGIVITIS EFFECTS OF CHLORINE DIOXIDE AND CHLORHEXIDINE MOUTHRINSES: A CLINICAL STUDY

Dissertation

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MASTER OF DENTAL SURGERY

In

PERIODONTOLOGY

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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I hereby declare that this dissertation entitled "**COMPARATIVE EVALUATION OF THE ANTI-PLAQUE AND ANTI-GINGIVITIS EFFECTS OF CHLORINE DIOXIDE AND CHLORHEXIDINE MOUTHRINSES : A CLINICAL STUDY"** is a bonafide and genuine research work carried out by me under the guidance of ***Dr Suraj Pandey,*** Reader , Department of Periodontology and Implantology, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 5 July 2021

Place: Lucknow

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-Dr. Nidhi Chaudhary

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S. NO	ABBREVIATIONS	FULL FORM
1.	CHX	Chlorhexidine
2.	ClO_2	Chlorine Dioxide
3.	PI	Plaque Index
4.	GI	Gingival Index
5.	SBI	Mombelli and Outson modified sulcular bleeding index - SBI
6.	TCI	Tongue Coating Index
7.	TDI	Tongue Discoloration Index

ABSTRACT

Plaque removal by mechanical means seems to be a common way of controlling plaque. Chlorhexidine (CHX) is the most effective chemical agent in short- and long term use. Because of its established use and efficacy, CHX is the gold standard against with which other chemical factors should be compared when claims of efficacy are attempted. Most common side effects are staining of the tooth surfaces and taste alteration and increase in calculus formation. Chlorine dioxide (ClO_2) is a chemical agent with known antimicrobial properties. It is an oxidizing biocide, implicating that microorganisms are killed by disrupting nutrition transport across the cell membrane. The aim of the present study is to assess the anti-plaque and anti-gingivitis of ClO_2 containing mouthwash compared to a CHX-containing mouthwash. Forty systemically healthy patients, fulfilling the inclusion and exclusion criteria were randomly divided into two groups. Supragingival scaling was performed on all patients to remove all plaque, stain and calculus. Following this patients in both the groups were prescribed ClO_2 and CHX mouthwash accordingly and were kept under recalled program of 2 weeks and 4 weeks post- operately. All the clinical parameters were assessed at baseline, 2 weeks and 4 weeks. Within the limits of this clinical longitudinal prospective study, it may be concluded that Group A containing ClO_2 had anti-plaque and anti-gingivitis property which was clinically superior to Group B having CHX. However this difference between the two groups was found to be statistically not significant.

INTRODUCTION

Dental plaque is an adherent bacterial biofilm that forms on hard and soft tissues intra-orally. It is the main etiologic agent in the development and progression of gingival and periodontal diseases.[1] Plaque is a biofilm with layers of microorganisms accommodated in a matrix that forms on oral surfaces and is continuously cleaned by saliva. Plaque control and prevention of gingivitis and periodontitis is the main goal of periodontal therapy, affecting more than 90% of the population, regardless of age, sex, or race.[2,3] Plaque removal by mechanical means (mostly a toothbrush combined with dentifrice) seems to be a common way of controlling plaque. Mouthrinses generally considered as adjuncts to oral hygiene and widely used in delivery of active agents to the teeth and gums. They obstruct the production of mature biofilms at biochemical and ecological levels[4] by impeding bacterial colonisation, growth, and metabolism. Such medicines are widely prescribed as adjuvants in the prevention and treatment of oral illnesses. A chemical approach to deal with the potential deficiencies of daily self-performed mechanical oral hygiene procedures has been introduced. The aim of chemical plaque control is to develop an active anti -plaque agent that does not disturb the natural flora of the oral cavity.

The hurdles such as plaque retentive factors, inaccessibility, and tissue-born bacteria limit the efficiacy of self performed oral hygiene procedures. Therefore, chemical plaque control agents have been recommended to prevent dental plaque and gingivitis. There are various chemical plaque control measures which includes sprays, irrigators, varnishes, chewing gums, and mouthwash. Mouthwashes provide a method for depositing an active drug for slow release in mouth. An effective concentration of the drug in the mouth over a considerable period of time following its use is thus maintained.

Chlorhexidine (CHX), a broad spectrum antibiotic with notable antibacterial action on both gram-positive and gram-negative bacteria, as well as fungi and some viruses, is used for chemical plaque control.[5] It the most effective chemical agent in short and long term use[6]. Because of its established use and efficacy, CHX is the gold standard against which other chemical agents should be compared when claims of efficacy are endeavoured. The most common side effects of CHX are staining of the tooth surfaces

and taste variation and increase in calculus formation. The brownish discolouration of teeth is due to disintegration of the bacterial membrane leading to denaturation of bacterial protein. It should not be used for more than 2 weeks because of its side effects. The use of CHX mouthrinse may also induce an increase in supragingival calculus formation because CHX causes salivary protein precipitation on the tooth surface, which causes pellicle thickness, to rise and in orgranic salts to precipitate on the pellicle layer. Parotid swelling is also a rare unwanted effect of CHX mouthrinse. Cases of burning feeling and painful desquammative lesion on the oral mucosa have been recorded occasionally. Because of the side effects reported, new chemical agents that would exert the same efficacy as CHX without its side effects are being researched[7].

Chlorine dioxide (ClO_2) is a chemical agent with known antimicrobial properties. It is used in different industries, including the dairy, beverage, and food industries, to control microbiologic growth and for the removal of biofilms[8]. It is an oxidizing biocide, implicating that it kills microorganisms by via interfering with food transport through the cell wall. ClO2 is a gas at room temperature. The relatively stable free radical species ClO_2 is a chemical oxidant with powerful bactericidal, viricidal, sporicidal, cysticidal, algicidal, and fungicidal properties. The oxidative consumption of critical biomolecules by ClO_2 is primarily responsible for its wide range of biocidal activity, and its single electron reduction product can also act as a reactive oxidant toward many electron-donating biomolecules (e.g., methionine, pyruvate, urate, and endogenous thiols, such as cysteine).[9] Thus chlorine dioxide appears to be a promising agent in chemical plaque control measures.

Since very few studies have been reported in literature, the aim of the present study is to compare and assess the anti-plaque and anti-gingivitis of ClO_2 containing mouthwash compared to a CHX-containing mouthwash.

AIM AND OBJECTIVES

AIM :- To compare the efficacy of chlorine dioxide mouthwash and chlorhexidine mouthwash as an anti plaque and anti gingivitis agent.

OBJECTIVES :-

- To determine the efficacy of chlorine dioxide mouthwash as an anti- plaque and anti- gingivitis agent.
- To determine the efficacy of chlorhexidine mouthwash as an anti-plaque and anti-bacterial agent and anti- gingivitis agent.
- To compare the difference in efficacy between the two agents.

REVIEW OF LITERATURE

Goldschmidt P et al (1977)[10] CHX's cytopathologic effects on human cells were investigated. The researchers found that exposing human cells in culture to CHX at concentrations of 0.004 percent or higher resulted in decreased cellular activity and/or cell death**.** Release of membrane bound 51 Cr, inhibition of protein synthesis as measured by incorporation of 3H- leucine into protein-like material, and staining by trypan blue were seen as sequellae to exposure to 0.006% CHX for 3 hours. Lower doses were capable of inhibiting protein synthesis and releasing 51Cr, but did not result in staining of cells by trypan blue. Exposure of cells to 0.2% CHX for 30 seconds produced maximal suppression of protein synthesis and release of 51Cr.

Bassetti C et al (1980)[11] conducted a study on influence of CHX rinsing on the healing of oral mucosa and osseous lesions. This study was done using standarised open mucosal-osseous wounds in the left side of palate in Wister rats. In five test groups each containing 10 rats, rinsing was performed twice daily for 30 seconds with 0.1, 0.2 and 0.5 CHX solution, CHX solution vehicle, and Ringer solution. A sixth test group (control) was not rinsed at all. Seven days postoperatively, wound healing was evaluated clinically (size of the defect) and histomorphometrically (percent comparision of mature connective tissue, immature connective tissue, granulation tissue, fibrin with granulocytic infiltrate). Clinically it was clear that wound healing was best in those animal that rinsed with Ringer solution, and worst in those and worst in those that rinsed with 0.5% CHX solution. Increasing concentration of CHX caused in delayed in wound healing, which in the following cases resulted in significant differences: rinsing with Ringer solution and vehicle versus all concentrations of CHX, no rinsing versus 0.5% CHX. Intensive rinsing with high concentrations of CHX may, after oral surgical operations, especially surgery in which bone is exposed, result in delay and disturbance of wound healing in humans.

Hefti AF et al (1987)[12]conducted a study to investigated the effectiveness of mouthwashes containing hexetidine/zinc (HZA) or tin (ASF) in inhibiting plaque formation and gingivitis in human. 24 dental students and assistant participated in the study, they rinsed twice daily for 1 minute with formulations: HZA = 750 ppm hexetidine/750 ppm zinc acetate, ASF= 100 ppm aminefluorid/310 ppm stannous

fluoride, CHX = 0.1% and M = negative control. Plaque accumulation was determined planimetrically and gravimetrically. Gingivitis was evaluated with the papillary bleeding index. The result showed that HZA and CHX completely inhibited plaque accumulation and gingivitis. ASF was left effective than HZA and CHX.

Brightman JL et al (1991)[13] conducted a study to analysis the effects of 0.12% CHX mouthrinse on orthodontic patients aged 11 to 17 with established gingivitis. In this study 34 subjects were divided into 2 groups (CHX and Placebo) 17 students in each group, they were evaluated at baseline, 6 weeks, and 12 weeks. GI, PI, Eastman interproximal bleeding index was recorded. That result showed that a significant reduction in plaque accumulation, gingival inflammation, and gingival bleeding could be attained with CHX mouthrinse was being used. Staining caused with CHX was mild to moderate and were removed with oral prophylaxis.

Joystone SB et al (1993)[14] conducted a study in which 47 adults with > 20 teeth and a CPTIN score > 1 but 4 were randomised into test and control groups to see how mouthrinses containing CHX and fluoride affected plaque and gingival bleeding. After baseline assessments for plaque bleeding and stain, teeth were professionally cleaned. Subjects were asked to rinse for 30s with 10 ml of the respective test or placebo rinse after normal oral hygiene for 8 weeks. 39 subjects completed the study. Study concluded that, as an adjunct to normal oral hygiene, the CHX/fluoride rinse has a significant inhibitory effect on plaque and bleeding but its effect on staining is uncertain.

Charles CH et al (2004)[15] A 6-months clinical experiment was conducted to examine the antiplaque and antigingivitis effects of a CHX and an essential oil mouthrinse**.** In the study 108 subjects age 20-57 were randomly allocated in 3 groups: essential oil mouthrinse(Listerine antiseptic), 0.12% CHX (peridex) or 5% hydroalcoholnegative control. Oral soft tissue examination at baseline, GI index, PI index, Volpe-Manhold calculus index and Lohene extrinsic tooth stain index following scaling was done. Rinsing twice daily with the mouthwash adjunct to mechanical oral hygiene were told. Clinical variables were tested at 3 and 6 months. The study concluded the essential mouthrinse and CHX had comparable antiplaque and antigingivitis effect.

Paraskevas S et al (2008)[16] study investigated the inhibiting effect of a chlorine dioxide mouthrinse as opposed to a mouthrinse containing chlorhexidine (0.20%) during 3 days of plaque accumulation. At baseline, all participants (N = 77) received a professional prophylaxis and were randomly assigned to the test (chlorine dioxide) or (positive) control (chlorhexidine) group. On the following 3 days, both groups rinsed twice daily for 1 minute with 10 ml test or control solution. At the end of the experimental period, plaque was assessed, and the panellists filled out a questionnaire. This study concluded that chlorine dioxide mouthrinse seems to be a less potent plaque inhibitor than chlorhexidine.

Haps S et al (2008)[17] conducted a literature study on mouth rinses containing cetylpyridinium chloride (CPC) as useful adjuncts to tooth brushing in the prevention of plaque formation and gingival irritation. Medline and the Cochrane Central Register of Controlled Trials were searched up to January 2008 to identify appropriate studies. The primary outcome measurements were plaque accumulation and gingivitis. Resulted that independent screening of titles and abstracts of 3250 papers resulted in eight publications that met the criteria of eligibility. Mean values and standard deviations were obtained by data extraction. Descriptive comparisons are presented for brushing only or brushing and rinsing. Meta-analyses were performed when possible. Further concluded that the existing evidence supports that CPC containing mouth rinses, when used as adjuncts to either supervised or unsupervised oral hygiene, provide a small but significant additional benefit in reducing plaque accumulation and gingival inflammation.

Kayoko Shinada et al (2010)[18] did a study to see if mouthwash containing ClO2 has any inhibitory effects on morning oral malodor and salivary periodontal and malodorous bacteria after 7 days of use. Study was conducted among 15 healthy male volunteers, who were divided into 2 groups. Subjects were instructed to rinse with the experimental mouthwash containg ClO_2 or the placebo mouthwash, without ClO_2, twice per day for 7 days. After a one week washout period, each group then used the opposite mouthwash for 7 days. At baseline and after 7 days, oral malodor was evaluated with Organoleptic measurement and analyzed the concentrations of hydrogen sulfide, methyl mercaptan and dimethyl sulfide, the main VSCs of human oral malodor, were assessed by gas chromatography. Clinical outcome variables

included plaque and gingival indices, and tongue coating index. The samples of saliva were microbiologically investigated. Study concluded that the baseline oral condition in healthy subjects in the 2 groups did not differ significantly. After rinsing with ClO_2 mouthwash used over a 7 day period appeared effective in reducing plaque, tongue coating accumulation and the count of Fusobacterium nucleatum in saliva.

Li W et al (2012)[19] conducted a study to evaluate the anti-gingivitis effect of CHX mouthwash with or without an Anti-discolouration system. In this study 26 healthy dental students were included assigned to 3 groups: grou P (placebo), group T1(0.12%CHX), group T2 (0.12% CHX with ADS). Particioants were asked to rinse 10ml of sample twice daily. The clinical parameters, taken are discolouration index (DI), plaque index(PI), gingival index (GI) were assessed on day 0, 7, 14, 21. Study concluded that CHX with ADS appeared to be effective in preventing stains on the teeth. The ability of CHX mouthwash of preventing plaque accumulation and gingivitis was also greatly hampered by the addittion of ADS. Infact the CHX mouthwash with ADS showed no superior effect over water on maintenance of oral hygiene or prevention of gingivitis.

Kandwal A et al (2014)[20] conducted a study to evaluate clinical effects of chlorine dioxide mouthrinse on plaque induced gingivitis and oral malodor. 30 patients were included in the study and they were divided into three groups.Group-I:10 patients using ClO2 mouthrinse only, Group-II: 10 patients using ClO2 +SRP(scaling and root planning) and Group-III-10 Ptients with SRP only.Gingival index (Silness & Loe 1964),Plaque Index (Loe & Silness 1963) and Organoleptic measurements were recorded at baseline,7 and 14 days. Clinical parameters of gingivitis reduced with the experimental mouthwash used for 14 days which concluded that mouthwash containing ClO2 improved halitosis.

Parashar A (2015)[21] reviewed a study in which mouthwashes were medicated solutions used for gargling and rinsing the mouth. Many oral conditions require the use of a mouthwash, which can vary from oral malodour to periodontal disease to treatment of secondary infections like oral mucositis. A mouthwash may be recommended as an antimicrobial, a topical anti-inflammatory agent, a topical analgesic or for caries prevention. Many different mouthwashes are available now a

day. Selection of an appropriate mouthwash depends on patient's oral condition, disease risk and efficiency and safety of mouthwash. The main objective was to help the oral health care professionals to make the correct selection of mouthwash while dealing with different conditions of oral cavity.

Acharya S et al (2015)[22] study conducted to evaluate the effect of Aloe vera, chlorine dioxide, and chlorhexidine mouth rinses on plaque and gingivitis in orthodontic treatment. A randomized single-center, single-blind, parallel group, controlled trial was conducted among 90 subjects undergoing fixed orthodontic treatment. The subjects were randomly divided into one of the three study groups (Aloe vera, chlorhexidine, chlorine dioxide). Plaque and gingivitis were assessed using modified Silness and Loe Plaque Index and Gingival Index at baseline and at follow-up after 15 days. Paired t-test and ANOVA with post hoc Dunnett test were used. A p-value of <0.05 was considered statistically significant., which concluded that Chlorine dioxide can be a suitable and economical alternative for chlorhexidine. Further long-term studies are recommended for evaluating their effectiveness.

Prasad KA et al (2015)[23] conducted a study on anti-plaque efficacy of herbal and 0.2% chlorhexidinegluconate mouthwash. 100 preclinical dental students were randomized into three groups (0.2% chlorhexidine, Saline and herbal mouthwash). All the groups were made to refrain from their regular mechanical oral hygiene measures and were asked to rinse with given respective mouthwashs for 4 days. The gingival and plaque scores were evaluated on 1 and 5 day, and differences were compared statistically. Concluded that within the limitations of this study chlorhexidinegluconate and herbal mouthwash (Hiora) showed similar anti-plaque activity with later showing no side effects.

Nadkerny PV et al (2015)[24] conducted a comparative evaluation of the efficacy of probiotic and chlorhexidine mouthrinses on clinical inflammatory parameters of gingivitis. The study was designed for a period of 4 week on 45 systemically healthy subjects between 20 and 30 years having chronic gingivitis. The study population was divided into three groups. Group A- 15 subjects were advised experimental (probiotic) mouthwash. Group B- 15 subjects were advised positive control (chlorhexidine) mouthwash and Group C- 15 subjects into a negative control group

(normal saline). Oral prophylaxis was done for all groups at baseline. After the proper oral hygiene instructions all the three groups were instructed to rinse their mouth with 10 ml of their respective mouthrinse, undiluted for 1 minute twice daily, 30 min after brushing. Clinical parameters such as PI, GI, and OHI-S were assessed at baseline, 2 weeks and 4 weeks, respectively. The study concluded probiotic mouthrinses tested was effectively used as an adjunct to mechanical plaque control in the prevention of plaque and gingivitis. Thus, the probiotic mouthrinse has a great therapeutic potential.

Yadav SR et al (2015)[25] study conducted to evaluate the efficacy of stabilized chlorine dioxide containing mouthrinse and CHX containing mouthrinse in inhibition of tongue coat accumulation and dental plaque formation using a four day plaque regrowth model clinically and microbiologically in healthy dental cohort. Study concluded that clinical antiplaque efficiacy of CHX and ClO_2 mouthwash is comparable and so was the efficacy in reducing the oral bacteria load.

Deshmukh MA et al (2017)[26] conducted a comperative evaluation of the efficiacy of probiotic, herbal and chlorhexidine mouthwash on gingival health. A group of 45 healthy subjects in the age group of 18-21 years received complete supragingival scaling at baseline and study variables OHI-S, PI and GI were recorded. Subjects were then randomly divided into three groups (15 in each group) and were randomly intervened with three different mouthwashes i.e., HiOra mouthwash, CHX mouthwash and Probiotic mouthwash. Variables were again recorded on the seventh and 14^{th} day after use of mouthwashes and data obtained was subjected to statistical analysis. The study concluded that herbal and probiotic mouthwashes can prove to be effective alternatives to CHX with minimal side effects.

Pathan MM et al (2017)[27] study aimed to look at the antimicrobial effect of herbal mouthwash and CHX mouthwash on select organism in in –vitro test and an ex – vivo model. The antimicrobial effects were determined against standard strains of bacteria that are involve in different stages of periodontal diseases. The in – vitro test included determination of minimam inhibitory concentration (MIC) using broth diluation and agar diffusion. In the ex-vivo part of the study supragingival dental plaque were obtained from 20 periodontally healthy adult volunteers. Descriptive analysis found no statistically significant difference between the mouthwashes. Study concluded that

CHX showed higher levels of antimicrobial action than the herbal mouthwash against bacterial species.

Rathore K K et al (2018)[28] purpose of the study was to determine the efficacy of three different mouthwashes in patients undergoing fixed orthodontic treatment for prevention of white spot lesions. study was conducted on 30 patients undergoing fixed orthodontic treatment between the ages of 15-25years. Patients were divided into 3groups - Group 1 control group, Group 2 using freshclor for 30 seconds twice daily and group 3 using HiOra mouth wash for 30sec twice daily. Samples from tooth surfaces were collected at 1st day, 30th day and 90th day interval and were incubated for 48 hours. Colonies were counted using digital colony counter. Study resulted that Freshclor and HiOra mouthwashes showed the maximum potential for the control of pathogenic organisms, and prevention of gingivitis and b acterial plaque inhibition than patients those were not using mouthwash.

Avhad SK et al (2020)[29] study compared the effectiveness of ClO_2 mouthwash and chlorhexidine gluconate mouthwash in reduction of oral viral load in patients with covid -19. 40 patients were provided with chlorhexidine gluconate(0.2%) mouthwash and chlorine dioxide (0.1%) mouthwash to rinse and gargle thrice a day for a week. Study concluded that regular use of ClO_2 could effectively reduce the symptoms and oral viral load, thereby reducing the symptoms and risk of transmission of COVID-19.

MATERIALS AND METHODS

Place of the study where it is conducted:-

This clinical, experimental prospective study was carried out in the Department of Periodontology, Babu Banarasi Das College of Dental Sciences (BBDCODS), Babu Banarsi Das University (BBDU) Lucknow.

Study subjects

40 patients were selected from the OPD, department of periodontology, BBDCODS based upon the inclusion and exclusion criteria mention below. They were randomly divided into two groups.

Study Sample and size

40 sites

- Group A- 20 Patients were given chlorine dioxide mouthwash.
- Group B- 20 Patients were given chlorhexidene mouthwash.

Eligibility Criteria:

- **Inclusion criteria:-**
- Patients in the age group of 20-50 years.
- Systemically healthy patients.
- Minimum of 20 teeth present in the dentition with no visible signs of untreated caries.
- Mild to moderate gingivitis.
- Bleeding on probing present.
- No periodontal therapy for last 6 months.

Exclusion Criteria:-

- Patients who have been taking antibiotics within last 6 months.
- Pregnant and lactating women.
- Smokers and tobacco chewers.
- Patients wearing partial dentures or having clinically unacceptable restorations or bridges.
- Patients wearing orthodontic appliances.

- Non co-operative patients.
- Patients who are sero-positive for COVID-19 virus

Materials

1. Mouth mirrors, UNC-15 Probe, Twezzer, Explorer.
2. Chlorine dioxide mouthwash (Guard-OR®)
3. Chlorhexidene mouthwash (Freshclor®)
4. Anterior and posterior jaquette group of supragingival scalers.(Hu- Friedy®)

Methodology:

The following clinical parameters were recorded at baseline, 2 weeks and 4 weeks post operatively.

Clinical parameters

- Plaque Index - PI (Silness and Loe, 1964)[30].
- Gingival Index - GI (Loe and Silness, 1963)[31]
- Mombelli and Outson modified sulcular bleeding index - SBI (1987)[32].
- Tongue Coating index – TCI.[33]
- Tongue discoloration index – TDI[34].

Study Design: (procedure)

The study was carried out in the department of Periodontology , Babu Banarsi Das College of dental sciences. Forty systemically healthy patients, fulfilling the inclusion and exclusion criteria were be randomly divided into two groups. All the patients who were to participate in the study were instructed to undergo mandatory RT-PCR for covid -19 prior to the procedure.

The treatment procedure was fully explained to all the patients and a signed written consent form was obtained from each patient before initiation of the procedure. The patients were randomly divided into 2 groups: Group A (chlorine dioxide mouthwash) and Group B (chlorhexidine mouthwash). At baseline, clinical parameters were recorded (PI, GI, SBI, TCI,TDI)[30,31,32,33,34]. Supragingival scaling was performed on all patients to remove all plaque, stains and calculus. This was performed using hand

instruments as well as ultrasonic scalers and oral hygiene instructions were given to the patients. The patients were educated and motivated regarding the importance of maintaining oral hygiene. They were also taught Modified Bass brushing technique.

Following this the patients in both the groups were prescribed ClO2 and CHX mouthwash accordingly. Patients were instructed to rinse with their assigned mouthwash (10ml), undiluted twice daily for 30 seconds over a period of 28 days. Patients in both the groups were completely blinded regarding the type of mouthrinse. They were recalled for re-evaulation after 2 weeks and 2 weeks and all clinical parameters were recorded and plaque control measures were reinforced.

At the end of the study, the entire data thus collected was subjected to statistical analysis by a qualified statistician and the results thus obtained were interpreted.

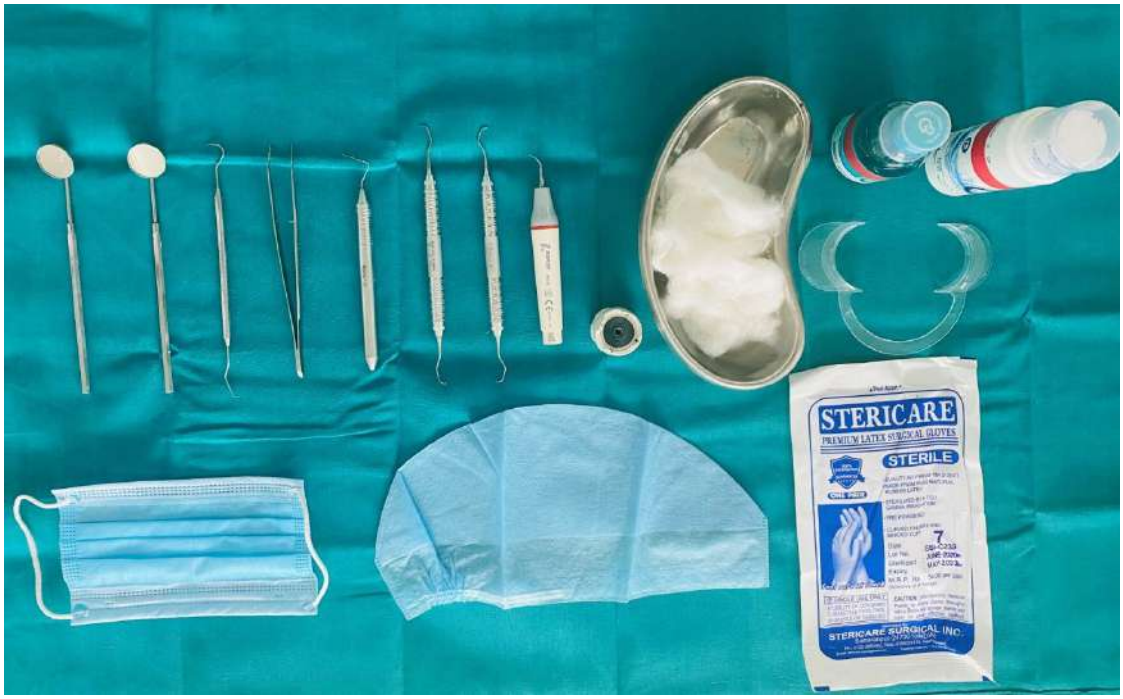


Fig. 1: Armamentarium for the study

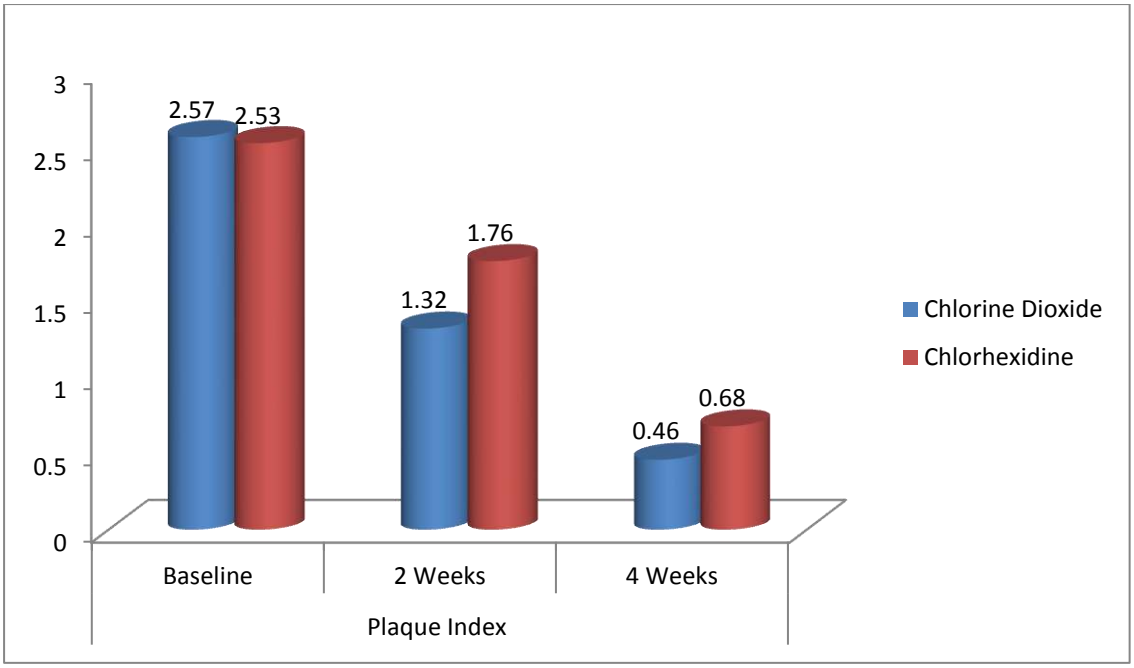
Fig. 2: ClO_2 and CHX mouthwashes

RESULTS AND OBSERVATIONS

Table 1: Plaque index at different intervals among the study groups

Intervals	Chlorine Dioxide		Chlorhexidine		t test	p value
	Mean	SD	Mean	SD		
Baseline	2.57	.39	2.53	.36	0.32	0.76
2 Weeks	1.32	.69	1.76	.54	1.79	0.09
4 Weeks	.46	.59	0.68	.57	1.88	0.07

Table 1, graph 1 shows the comparison of plaque index at different intervals among the study groups. The study comprised of two groups i.e. Group A (20 Patients were given chlorine dioxide mouthwash) and Group B (20 Patients were given chlorhexidene mouthwash). Mean±SD plaque index at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group was 2.57±.39, 1.32±.69, .46±.59 and 2.53±.36, 1.76±.54 and 0.68±.57 respectively. When mean plaque score was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant, though plaque score reduction was found more in chlorine dioxide group.

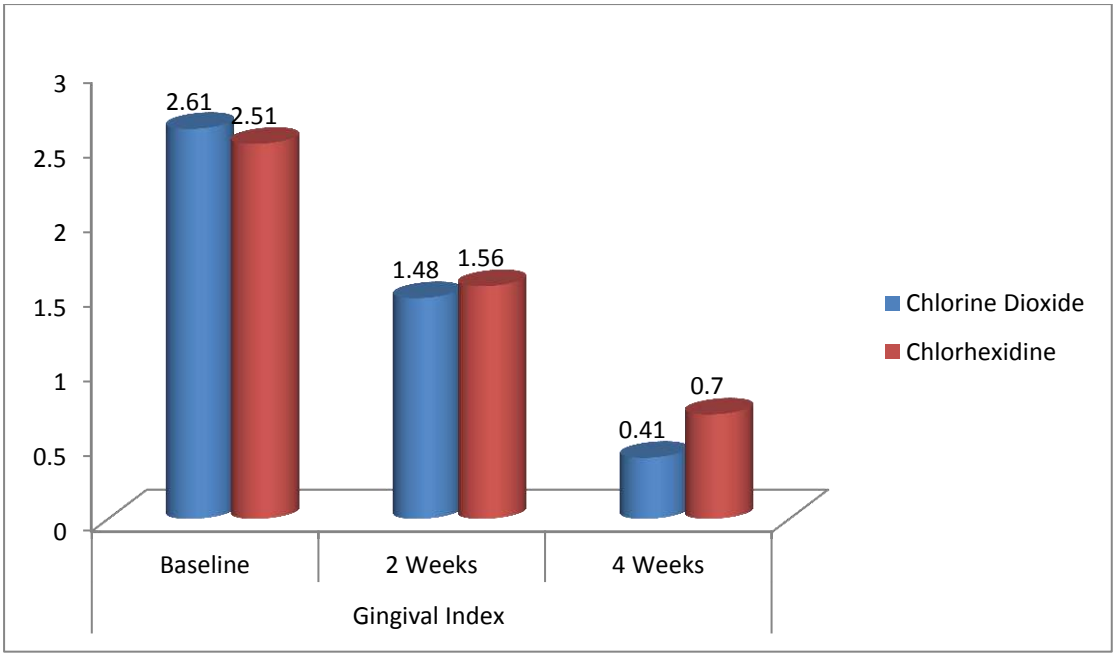


Graph 1: Plaque index at different intervals among the study groups

Table 2: Gingival index at different intervals among the study groups

Intervals	Chlorine Dioxide		Chlorhexidine		t test	p value
	Mean	SD	Mean	SD		
Baseline	2.61	.38	2.51	.36	0.86	0.41
2 Weeks	1.48	.73	1.56	.45	0.37	0.71
4 Weeks	.41	.47	.70	.49	2.03	0.06

Table 2, graph 2 shows the comparison of gingival index at different intervals among the study groups. Mean±SD gingival index at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group was 2.61±.38, 1.48±.73, .41±.47 and 2.51±.36, 1.56±.45 and 0.70±.49 respectively. When mean gingival score was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant, though gingival score reduction was found more in chlorine dioxide group.

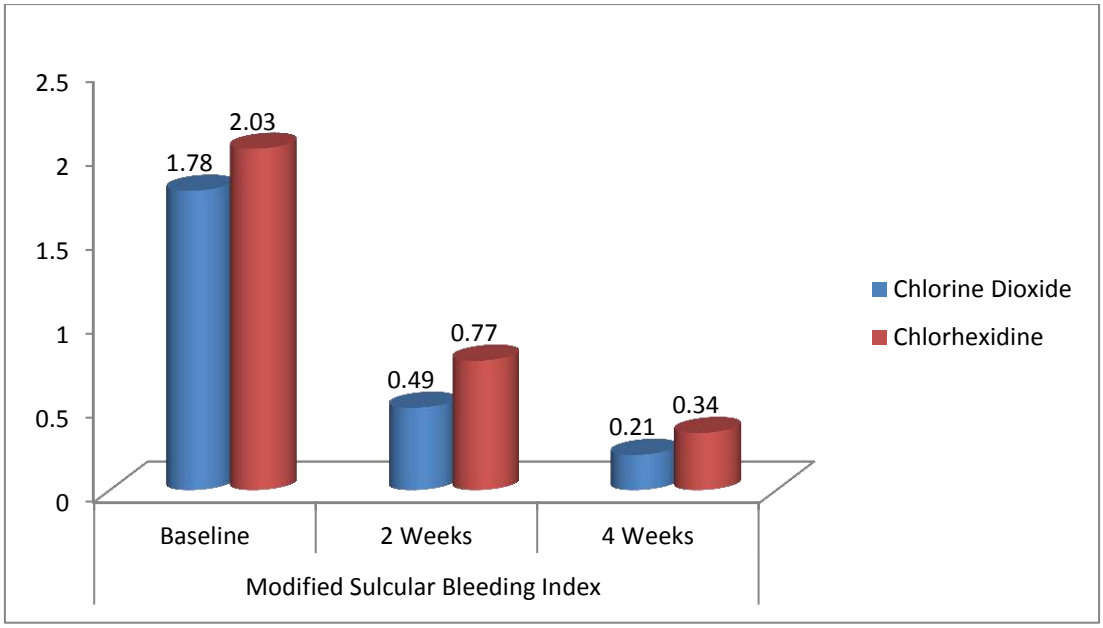


Graph 2: Gingival index at different intervals among the study groups

Table 3: Modified sulcular bleeding index at different intervals among the study groups

Intervals	Chlorine Dioxide		Chlorhexidine		t test	p value
	Mean	SD	Mean	SD		
Baseline	1.78	.62	2.03	.54	1.22	0.24
2 Weeks	.49	.69	.77	.74	0.89	0.39
4 Weeks	.21	0.38	.34	0.47	1.09	0.58

Table 3, graph 3 shows the comparison of modified sulcular bleeding index at different intervals among the study groups. Mean±SD modified sulcular bleeding index at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group was 1.78±.62, .49±.69, .21±.38 and 2.03±.54, .77±.74 and .34±.47 respectively. When mean modified sulcular bleeding index was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant.

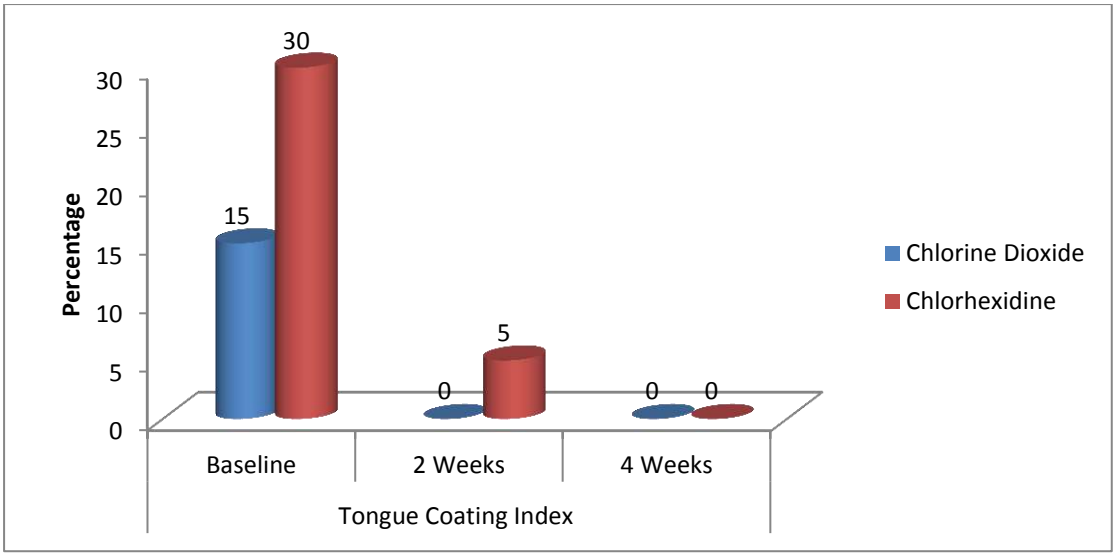


Graph 3: Modified sulcular bleeding index at different intervals among the study groups

Table 4: Comparison of tongue coating index (present) at different intervals among the study groups

Intervals	Chlorine Dioxide		Chlorhexidine		Chi Square test	p value
	N	%	N	%		
Baseline	3	15	6	30	3.89	0.16
2 Weeks	0	0	1	5	0.18	0.83
4 Weeks	0	0	0	0	0	1

Table 4, graph 4 shows the comparison of tongue coating index at different intervals among the study groups. Tongue coating was present in 15%, 0%, 0% and 30%, 5%, 0% of the subjects at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group. When tongue coating index was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant.

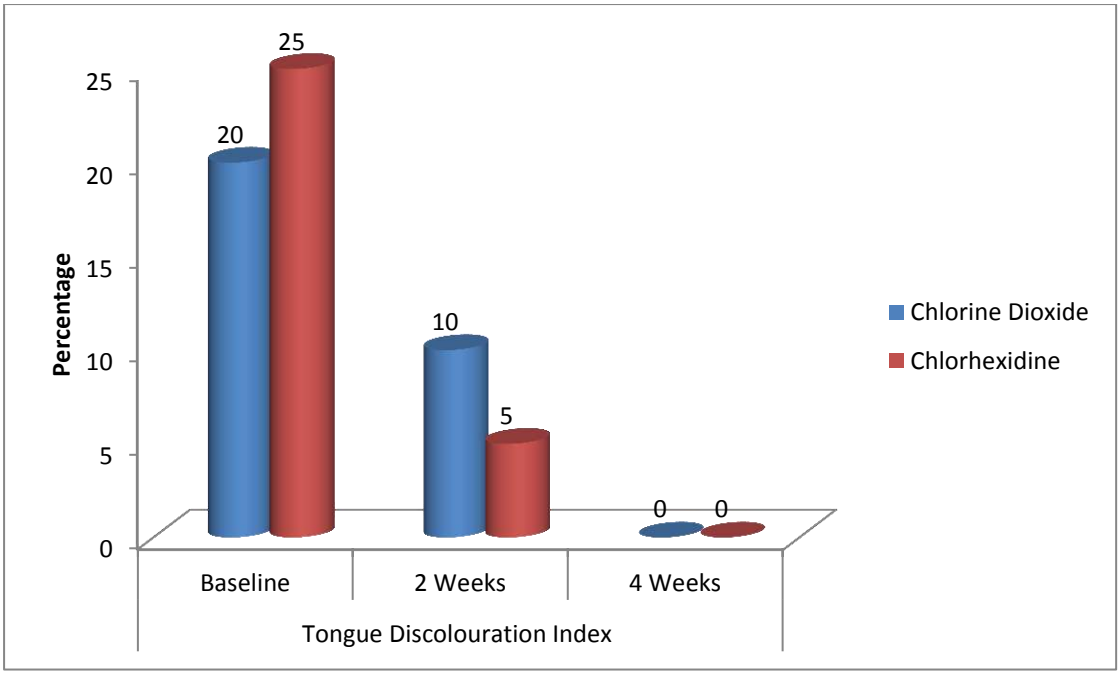


Graph 4: Tongue coating index (present) at different intervals among the study groups

Table 5: Comparison of tongue discolouration index (present) at different intervals among the study groups

Intervals	Chlorine Dioxide		Chlorhexidine		Chi Square test	p value
	N	%	N	%		
Baseline	4	20	5	25	3.89	0.51
2 Weeks	2	10	1	5	0.32	0.73
4 Weeks	0	0	0	0	0	1

Table 5, graph 5 shows the comparison of tongue discolouration index at different intervals among the study groups. Tongue discolouration was present in 20%, 10%, 0% and 25%, 5%, 0% of the subjects at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group. When tongue discolouration index was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant.



Graph 5: Comparison of tongue discolouration index (present) at different intervals among the study group

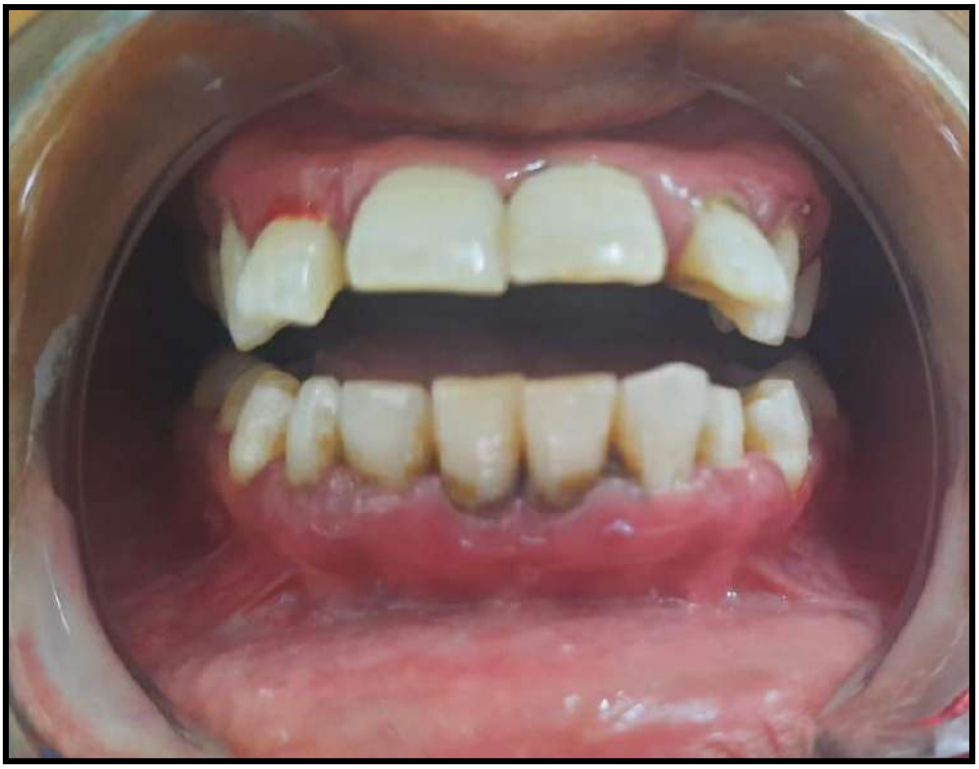


Fig. 3: Group A ClO_2 at baseline

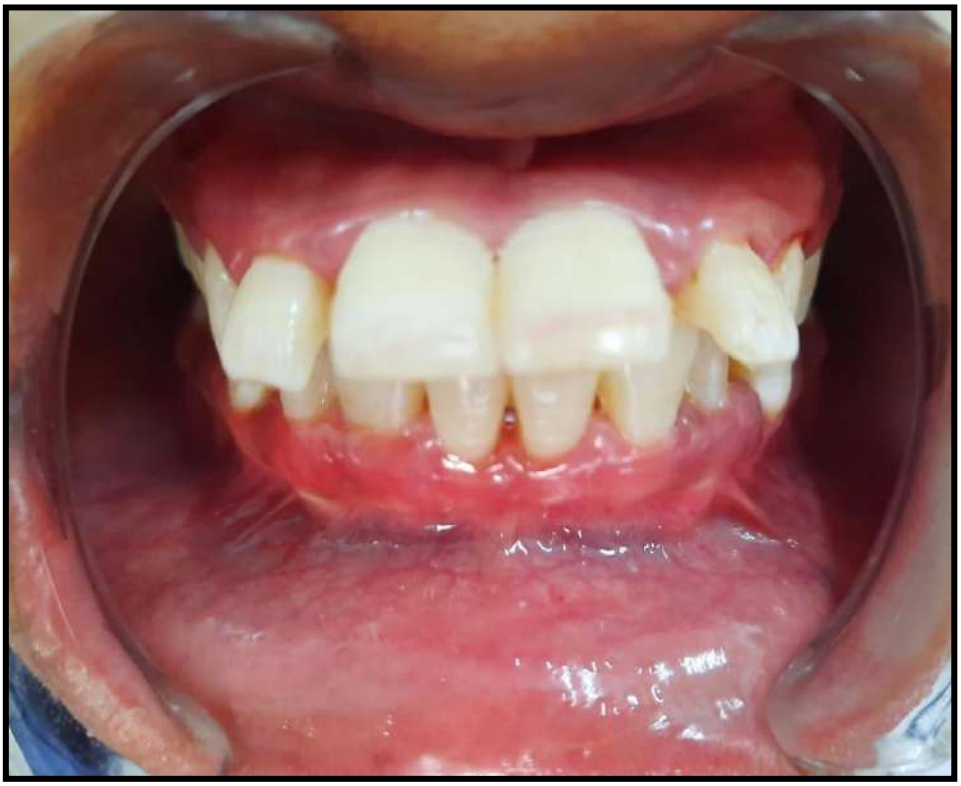


Fig. 4: Group A ClO_2 at 28 day

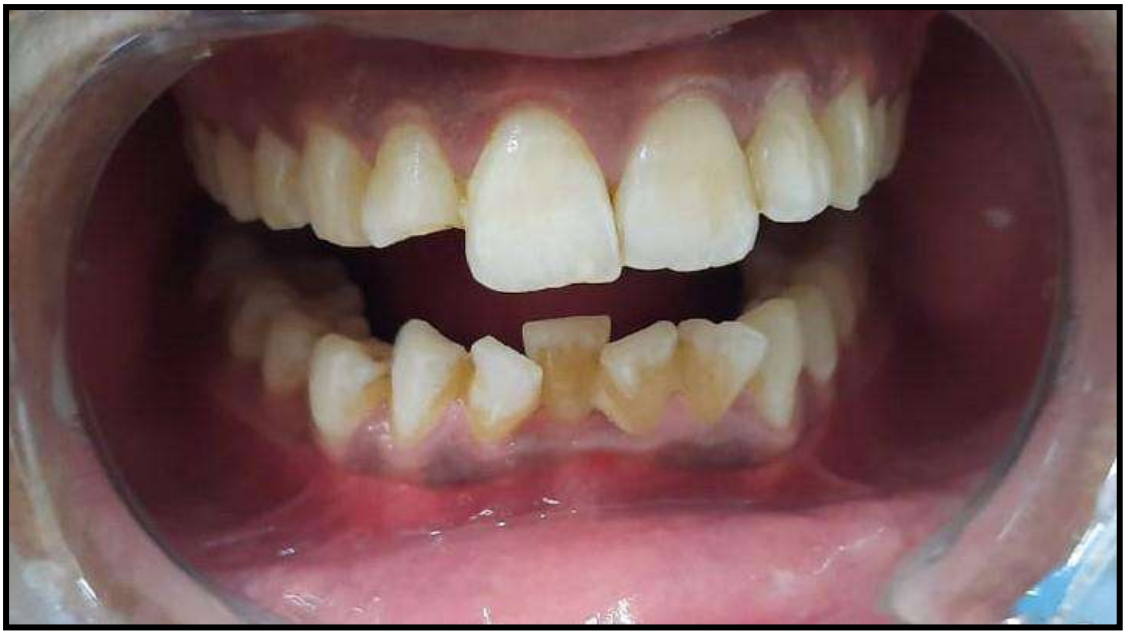


Fig. 5: Group B CHX at baseline

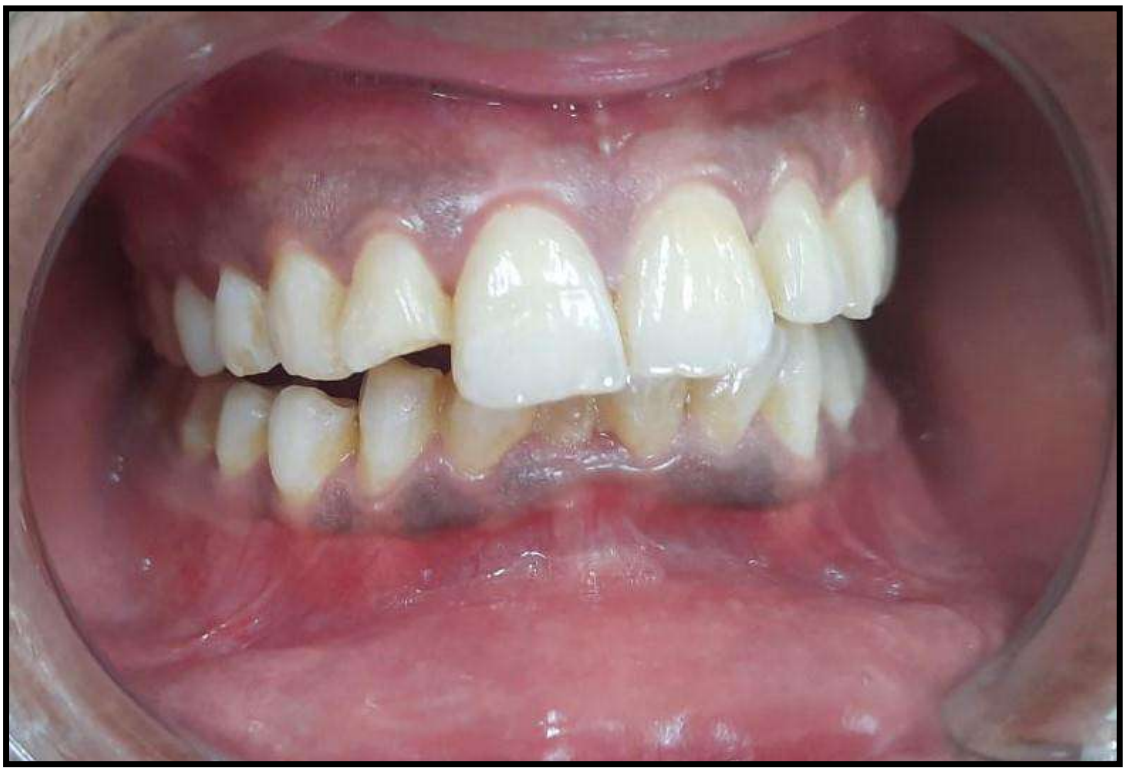


Fig. 6: Group B CHX at 28 day

DISCUSSION

This clinical longitudinal prospective study was done to compare two mouthwashes; ClO_2 and CHX and to evaluate the efficacy of their anti-plaque and anti-gingivitis effects.

Dental plaque formed on the gingival margin and adjacent tooth surface causes inflammation of gingiva. The bacteria in the plaque release toxins which cause swelling, redness and bleeding of gingival. Bacteria in the dental plaque are the main factors causing gingival inflammation; therefore plaque control is very important. As it is impossible to eliminate oral bacteria causing dental plaque, it is important to achieve plaque control by limiting growth of harmful bacteria. However, mechanical plaque removal is inadequately performed by host members of the population.[35] The necessity for further assistance in managing bacteria plaque provides patients with justification to use antimicrobial mouthwash in addition to their mechanical oral hygiene regiments. In the recent years, use of mouthwash has been on the increase as it is relatively easy to use for maintaining oral hygiene.[36]

Imperial Chemical Industries in England created chlorhexidine in the 1940s. It was first sold as a general antiseptic in 1950. In 1957, chlorhexidine was approved for human use as a skin antiseptic in the United Kingdom. It was frequently utilised in surgery and medicine. Inhibition of plaque by CHX Schroeder looked at it for the first time in 1969[37]. Loe and Schiott 1972[38] conducted a conclusive investigation on caries control by inhibiting dental plaque. Chlorhexidine is a broad spectrum bis-biguanide antiseptic, with two positive charges, it is a strong base and dicationic at pH values above 3.5.[39] It is an antiplaque and antigingivitis agent because it prevents plaque accumulation[40]. Depending on the dose, it can be bacteriostatic [0.02-0.06] or bactericidal [0.2-0.12].[41] The American Dental Association's Council on Dental Therapeutics [42] has accepted. CHX use for chemical plaque control. This family of rinses is mainly indicated for use as adjuncts to mechanical cleaning, in specific clinical situations where mechanical oral hygiene is difficult, such as post surgery, in individuals with intermaxillary fixation, in fixed appliance orthodontic therapy and in individuals with intellectual and physical disabilities.[43] CHX mouthwash is mainly available in concentrations of 0.1 %, 0.12%, or 0.2 %. The effect of CHX on the

microbial biofilm is dose-dependent.[44] The optimum dose of CHX in a mouthwash is considered to be 20 mg twice daily equivalent to 10 ml of 0.2% CHX mouthwash (20mg) or 15 ml of 0.12% CHX mouthwash (18mg)[45]. A rinse time of 30 seconds appears to be effective and acceptable all those 60 second rinse times are also advocated. But its long term usage may result in various adverse effects most common being the formation of brown staining on the teeth and oral tissues, particularly the tongue.[43] Other less common local adverse effects have also been reported including supragingival calculus accumulation oral mucosal lesions and altered taste sensation. Parotid gland swelling has been reported following CHX mouthwash use. There have been where reports of Type 1 hypersensitivity reactions to CHX use in the mouth or on the lips[46]. These local adverse effects limit the use of CHX to short or moderate term used in specific clean clinical circumstances, the adverse effects are transient and resolve once CHX mouthwash use has ceased. The occurrence of side-effects tends to be reduced with lower CHX concentrations. Hence, search for an effective and safe alternative to CHX mouthwash has lead to introduction of various other antimicrobial mouthwash in dentistry which are without any major side effects, can be used for longer duration are cheap and locally available. Considering the limitations in present assessment, an attempt was made to evaluate the efficacy of ClO_2 as an anti-plaque and anti-gingivitis agents.

Chlorine dioxide (ClO_2) is a chemical compound is a free radical that is stable. It easily dissolves in water, forming a pale yellow solution that can be kept intact for long periods of time. ClO_2 oral rinses are now used as a topical antiseptic for the oral cavity or dentures[47] in dental offices. ClO_2 and H_2O_2 have been linked in previous research. ClO_2 are oxidants that are chemically reactive. According to Lynch et al., the reaction of L-cystein, a thiol molecule that contributes significantly to oral malodor[48], with ClO_2. and/or ClO_2, which contained 0.10 percent (w/v) ClO2 (the same as the experimental mouthwash used in this investigation), produced the disulfide cystine as a main product. The processes for the oxidation of thiols through the consecutive, two-step reaction sequence involving $ClO_2^{\cdot}$ and/or $ClO_2^{\cdot -}$ are shown as the following equations: (1) RSH (e.g. CH_3SH) + $ClO_2^{\cdot} \rightarrow RS^{\cdot} + ClO_2^{\cdot -} + H^+$; (2) $2RS^{\cdot} \rightarrow$ RSSR (e.g. CH_3SSCH_3); (3) $4RSH + ClO_2^{\cdot -} \rightarrow 2RSSR + Cl^- + 2H_2O$[49]. Grootveld et al. found that an oral rinse containing ClO_2 reduced the amount of Streptococcus mutans and lactobacilli in saliva in vivo, indicating that the

bacteriocidal activity of the current oxohalogen oxidants[50]. Despite the fact that a few respondents complained about a chloric odour, chlorite anion is a potent antibacterial to malodorous bacterial microorganisms.[51] Chlorine dioxide enters bacterial cells and kills the organism by reacting with essential amino acids in the cytoplasm. Its bactericidal effects are said to be achieved by fixing cellular membrane proteins as a result of its oxidising potential, as similar as penicillin[47].

ClO_2 is frequently employed in a variety of industries due to its safe and effective antibacterial properties.[48] The standard element in practically all oxygen supplementation today, sodium chlorite (NaClO2), is a non-toxic chemical designated by the US Food and Drug Administration (FDA) as an antibacterial agent.[52] According to Shinada et al ClO_2 was found to be effective at reducing oral malodor, and none of the volunteers reported tongue stimulation or discoloration after using the mouthwash containing 0.10 percent ClO_2 (0.16 percent $NaClO_2$). The flavour and odour of this mouthwash were unappealing to several participants. This could be solved by developing new formulations that hide these flaws[18].

Kimoto et al evaluated the antibacterial properties of a mouthwash containing ClO_2 and its cytotoxicity on human oral cells. For the objective of employing ClO_2 as a bactericidal agent for natural teeth, dental implants, and the oral cavity. The findings imply that mouthwash containing ClO2 is safe for human cells and could be used as a bactericidal agent for dental implant.[53] The emission of irritating gases, the majority of which are VSCs, is caused by a multiplication of oral bacteria during sleep. This is sometimes referred to as "morning foul breath," and it can occur in otherwise healthy persons[54]. This type of oral malodor affects a large percentage of healthy persons.
Individuals that are healthy but are afflicted with a disease are likely to use mouthwashes having various masking or antimicrobial ingredients. Therefore, recent study had emphasised the need of comparative research in determining the efficacy of mouthwashes on accumulation of plaque and calculus in gingivitis patients. Long-term effects, as well as consequences on periodontal diseases and plaque accumulation in a well-defined sample of halitosis patients, will need to be investigated further. Comparative efficacy tests versus CHX[55]containing mouthwashes that have been shown to be effective and acknowledged as necessary.

This study was designed to evaluate the efficiacy of Group A ClO_2 (Test Group) to compare with Group B CHX (Control group) on clinical parameters GI, PI, TCI, TDI, SBI. The means and standard deviations of the measurements were used for statistical analysis. Difference between the two groups was determined using student t-test as well as chi square test and the level of significance was set at $p < 0.05$. After being statiscally analysed, results revealed that reduction was seen in all the clinical parameters in both the groups but reduction was found more in chlorine dioxide group.

Mean±SD plaque index at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group was 2.57±.39, 1.32±.69, .46±.59 and 2.53±.36, 1.76±.54 and 0.68±.57 respectively. When mean plaque score was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant, though plaque score reduction was found more in chlorine dioxide group. (Table1, Graph 1).

Mean±SD gingival index at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group was 2.61±.38, 1.48±.73, .41±.47 and 2.51±.36, 1.56±.45 and 0.70±.49 respectively. When mean gingival score was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant, though gingival score reduction was found more in chlorine dioxide group. (Table2, Graph 2).

Mean±SD modified sulcular bleeding index at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group was 1.78±.62, .49±.69, .21±.38 and 2.03±.54, 77±.74 and .34±.47 respectively. When mean modified sulcular bleeding index was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant.(Table 3, Graph 3).

Tongue coating was present in 15%, 0%, 0% and 30%, 5%, 0% of the subjects at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group. When tongue coating index was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant. (Table 4, Graph 4).

Tongue discolouration was present in 20%, 10%, 0% and 25%, 5%, 0% of the subjects at baseline, 2 weeks and 4 weeks among chlorine dioxide and chlorhexidine group. When tongue discolouration index was compared statistically among chlorine dioxide and chlorhexidine group using t test, it was found to be statistically insignificant. (Table 5 Graph 5).

Joystone SB et al (1993)[14] reported the study which concluded that, as an adjunct to normal oral hygiene, the CHX/fluoride rinse has a significant inhibitory effect on plaque and bleeding but its effect on staining is uncertain.

Paraskevas S et al (2008)[16] reported a study which concluded that Chlorine dioxide mouthrinse appears to be less effective than chlorhexidine at preventing plaque formation.

Acharya S et al (2015)[22] reported a study in which the participants were randomly allocated to one of three study groups (Aloe vera, chlorhexidine, chlorine dioxide), in which Chlorine dioxide mouthwash was found to be an acceptable and cost-effective alternative to chlorhexidine.

Rathore K K et al (2018)[28] reported a study which concluded that determine the Freshclor and HiOra mouthwashes exhibited the greatest potential for pathogen management, gingivitis prevention, and bacterial plaque inhibition when compared to those who did not use mouthwash.

Kandwal A et al (2014)[20] reported a study which resulted in reduction of clinical parameters of gingivitis experimental mouthwash used for 14 days which concluded that mouthwash containing ClO2 improved halitosis.

This study emphasises the importance of adjunctive chemical plaque control in mild to moderate gingivitis patients. The aim of the study was to compare CHX and ClO_2 mouthrinses as in anti- plaque and anti-gingivitis agents. The study demonstrated that ClO_2 appears to be clinically superior as compare to CHX mouthrinse. Also it was demonstrated that ClO_2 mouthrinse circumvented many of the adverse effects when

compared to CHX. Thus, ClO_2 appears to be a promising substitute for CHX as in adjunctive chemical plaque control therapy along with standard mechanical plaque control measures.

CONCLUSION

Within the limits of this clinical longitudinal prospective study, it may be concluded that Group A containing Chlorine dioxide had anti-plaque and anti-gingivitis property which was clinically superior to Group B having CHX. However this difference between the two groups was found to be statistically not significant.

Group A showed clinically significant reduction in PI, GI, SBI, TCI and TDI with Group B at 2 weeks and at 4 weeks.

The findings of the present study suggested that both ClO_2 and CHX were effective in controlling the plaque and maintaining a healthy gingival status. In the study however,the ClO_2 demonstrated clinically better results with respect to the anti-plaque and anti-gingivitis effects. As compared to CHX group the use of ClO_2 mouthrinse demonstrated minimal adverse effects.

Within the perspective of this study, it can be concluded that ClO_2 appears to be a promising substitute for CHX.

The limitations of this study is a smaller sample size and short follow up period.
Therefore further clinical and microbiological studies with larger sample size and a longer follow up period are required to further substantiate the results of the present study.

BIBLIOGRAPHY

1. Adams D, Addy M; Mouthrinses. *Adv Dent Res*., 1994; 8: 291-301.
2. Wu CD, Savitt ED. Evaluation of the safety and efficacy of over-the counter oral hygiene products for the reduction and control of plaque and gingivitis. *Periodontal* 2000 2002;28:91-105.
3. Axelsson P, Lindhe J. Effects of controlled oral hygiene procedures on caries and periodontal diseases in adults. *J.Clin.Periodontol* 1981;8:239-48.
4. Zhan L, Featherstone JD. Antimicrobial treatment needed for severe childhood caries. *J. Public Health Dent* 2006;66:174-79.
5. Sekino S, Ramberg P, Guzain U. The effect of Chlorhexidine regimen on de novo plaque formation. *J Clin Periodontal* 2004;21:296-300.
6. Jones CG. Chlorhexidine: Is it still the gold standard? *Periodontol* 2000 1997;15:55-62.
7. Rahmani ME, Radvar M. The antiplaque effects of Salvadora persica and Padina essential oil solution in comparison to chlorhexidine in human gingival disease; a randomized placebo- controlled clinical trial . *Int J Pharmacol*. 2005;14:311-5.
8. Grootveld M, Silwood C, Gill D, Lynch E. Evidence for the microbicidal activity of a chlorine dioxide containing oral rinse formulation in vivo. *J Clin Dent* 2001;12:67-70
9. Goldschmidt P, Cogen R, Tauban S. Cytopathologic effects of chlorhexidine on human cells. *J Periodontal* 1977;48:212-5.
10. Bassetti C, Kallenberger A. Influence of chlorhexidine rinsing on the healing of the oral mucosa and osseous lesions. *J Periodontal* 1980;7:443-56.
11. Hefti AF, Huber B. The effect on early plaque formation, gingivitis and salivary bacterial counts of mouthwashes containing hexetidine /zinc, amine fluoride / tin or chlorhexidine. *J Clin Periodontal* 1987;14:515-8.
12. Brightman LJ, Terezhalmy GT, Greenwall H, Jacobs M, Enblow DH. The effects of a 0.12%chlorhexidine gluconate mouthrinse on orthodontic patients aged 11 through 17 with established gingivitis. *Am J OrthodDentofacialOrthop* 1991;100:324-9.
13. Joyston SB, Hernaman N. The effect of a mouthrinse containing chlorhexidine and fluoride on plaque and gingival bleeding. *J Clin Periodontal* 1993;20:49-53.

14. Charles CH, Mostler KM, Bartels LL, Mankodi SM. Comparative antiplaque and antigingivitis effectiveness of chlorhexidine and an essential mouthrinses: 6 months clinical trial. *J Clin Periodontol* 2004;31:878-84.

15. Paraskevas S, Nanning A.M. Rosema, Versteeg P Chlorine Dioxide and Chlorhexidine Mouthrinses Compared in a 3-DayPlaque Accumulation Model. *J Periodontol* 2008;79:1395-1400.

16. Haps S, Slot D E, Berchier C E, Van der Weijden G A. The effect of cetylpyridinium chloride-containing mouth rinses as adjuncts to toothbrushing on plaque and parameters of gingival inflammation: a systematic review. *Int J Dent Hyg* 2008; 6(4): 290-303.

17. Shinada K, Ueno M, Konishi C. Effects of a mouthwash with chlorine dioxide on oral malodor and salivary bacteria : A randomized placebo-controlled 7- day trial. *Clinical Trials* 2010;11:14.

18. Li W, Wang RE, Finger M, Lang LP. Evaluation of the anti-gingivitis effects of a chlorhexidine mouthwash with or without the Anti- Discoloration System (ADS) compared to placebo during experimental gingivitis. *Swiss Dent* 2012;33:51-56.

19. Kandwal A, Ghani B. A comprative evaluation of effect of chlorine dioxide mouthrinse on plaque induced gingivitis and oral malodor: a clinical study *Int J Dent Health Sci* 2014; 1(1): 24-33

20. Parashar A. Mouthwashes and Their Use in Different Oral Conditions *Sch. J. Dent*. Sci.,2015; 2:186-191

21. Yeturu SK, Acharya S, Urala AS Pentapati AC. Effect of Aloe vera, chlorine dioxide, and chlorhexidine mouthrinses on plaque and gingivitis: A randomized controlled trial. *J Oral Biol Craniofac Res*. 2015

22. Prasad KA, John S, Deeoika V. Anti- Plaque efficacy of herbal and and 0.2% chlorhexidinegluconate mouthwash: A comparative study. *J Int Oral Health* 2015;7:98-102.

23. Nadkemy PV, Ravishankar PL, Pramod V, Agarwal LA, Bhandari S. A comparative evaluation of the efficacy of probiotic and chlorhexidine mouthrinses on clinical inflammatory parameters of gingivitis: A ramdomized controlled clinical study. *J Indian SocPeriodontol* 2015;19:633-9

24. Yadav SR. Inhibition of tongue coat and dental plaque formation by stabilized chlorine dioxide vs chlorhexidine mouthrinse: A randomized, triple blinded study. *J Clin Diagn Res*.2015.

25. Deshmukh MA. Comparative evaluation of probiotic, herbal and chlorhexidine mouthwash on gingival health: A randomized clinical trial. *J ClinDiag Res* 2017;11:13-16.

26. Pathan MM , Bhat GK, Joshi VM. Comparative evaluation of the efficacy of a herbal mouthwash and chlorhexidine mouthwash on select periodontal pathogens: An in vitro and ex vitro study. *J Indian Soc Periodontol* 2017;21:270-275.

27. Rathore KK, Reddy HG, Johar RS. Antimicrobial effect of mouthwashes in patient undergoing orthodontic treatment. *Indian J Dent Oral Health* 2018;2.

28. Avhad SK, Bhanushali M, Sachdev SS. Comparison of effectiveness of Chlorine dioxide mouthwash and Chlorhexidine Gluconate mouthwash in reduction of oral viral load in patients with COVID-19. *Indian J Public Health Res Dev* 2020;11:11

29. Silness J, Loe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontol Scand*. 1964;22:121-135.

30. Loe H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odontol Scand.* 1963;21:533-51.

31. Newbrun E. Indices to measure gingival bleeding. *J Periodontol* 1996;67:555-61.

32. Gomez SM, Danser MM, Sipos PM, Rowshani B. Tongue coating and salivary bacterial counts in healthy / gingivitis subjects and periodontal patients. *J Clin Periodontol.* 2001;28:97078.

33. Winkel EG, Roldan S, van Winkelhoff AJ, Sanz M. The clinical effects of a new mouthrinse containing chlorhexidine, cetylpridinium chloride and zinc-lactate on oral halitosis. A dual- center, double-blind placebo-controlled study. *J Clin Periodontol.* 2003;30:300-06.

34. Phatak AA, Patankar DR, Galgatte CU. Antimicrobial activity of a poly-herbal extract against dental micro flora. *Res J Pharma Bio ChemSci* 2011;2:533-39.

35. Kauzimma E, Yanuschevitch O, Lapatina A. A pilot study into the effectiveness of two anti-microbial mouthrinses in a group of Russian adults wirh gingivitis. *OHDMBSC* 2010;9:131-39

36. Schroeder H E. Formation and Inhibition of Dental Calculus. *Hans Huber*, Berlin 1969; 145-172.

37. Löe H, Von der Fehr FR, Schiött CR. Inhibition of experimental caries by plaque prevention. The effect of chlorhexidine mouthrinses. *Scand JDent Res*. 1972;80(1):1-9.

38. Wade WG, Addy M. In vitro activity of a chlorhexidine containing mouthwash against subgingival bacteria. *J Periodontal* 1989;60:521-25.

39. Corbet EF, Tam JO, Zee KY, Wong MC, Lo EC, Mombelli AW. Therapeutic effects of supervised Chlorhexidine mouthrinses on untreated gingivitis. *Oral Dis.* 1997; 3:9– 18.

40. Jenkins S , Addy M Wade W .The mechanism of action of Chlorhexidine .A study of plaque growth on enamel inserts in vivo . *J Clin Periodontol*1988;15: 415- 24.http://www.ncbi.nlm.nih.gov/pubmed 3183067 8. Council on Dental Therapeutics. *J Am Dent Assoc* 1986;112:529-532.

41. Council on Dental Therapeutics. *J Am Dent Assoc* 1986;112:529-532.

42. Addy M. Chlorhexidine compared with other locally delivered antimicrobials. A short review. *J Clin Periodontal* 1986;13:957-64.

43. Keijser JA, Verkade H. Comparison of two commericially available chlorhexidine mouthrinses. J Periodontal 2003;74:214-8.

44. Eley BM. Antibacterial agents in the control of supragingival plaque- A review. *Br Dent J* 1999;186:286-96.

45. Pemberton MN, Gibson J. Chlorhexidine and hypersensitivity reactions in dentistry. *Br Dent J* 2012;213:547-50.

46. Silwood CJ, Grootveld M, Lynch E. A multifactorial investigation of the ability of oral health care products (OHCPs) to alleviate oral malodour. *J Clin Periodontol.* 2001;28:634–641.

47. Lynch E, Sheerin A, Claxson AWD, Atherton MD, Rhodes CJ, Silwood CJL, Naughton DP, Grootveld M. Multicomponent spectroscopic investigations of salivary antioxidant consumption by an oral rinse preparation containing the stable free radical species chlorine dioxide (ClO_2) *Free Radical Res.* 1997;26:209–234.

48. Yates R, Moran J, Addy M, Mullan PJ, Wade WG, Newcombe R. The comparative effect of acidified sodium chlorite and chlorhexidine mouthrinses on

plaque regrowth and salivary bacterial counts. *J Clin Periodontol.* 1997;24:603–609

49. Grootveld M, Silwood CJ, Gill D, Lynch E. Evidence for the microbicidal activity of a chlorine dioxide-containing oral rinse formulation *in vivo*. *J Clin Dent.* 2001;12:67–70.

50. Frascella J, Gilbert R, Fernandez P. Odor reduction potential of a chlorine dioxide mouthrinse. *J Clin Dent.* 1998;9:39–42.

51. Food and Drug Administration. FDA 21 CFR 173.325 (e) *Acidified sodium chlorite solutions.*

52. Kimoto K, Hamada N, Ohno M, Furuya M, Kushida M, Usui S, Toda S, Kawamura K, Okudera H, Hirata Y, Umemoto T, Arakawa H. Study on the bactericidal effects of chlorine dioxide gas. *Bull Kanagawa Dent College.* 2004;32:77–82.

53. Suarez FL, Furne JK, Springfield J, Levitt MD. Morning breath odor: influence of treatments on sulfur gases. *J Dent Res.* 2000;79:1773–1777.

54. De Boever EH, Loesche WJ. Assessing the contribution of anaerobic microflora of the tongue to oral malodour. *J A D A.* 1995;126:1384-93.

ANNEXURES - I

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Evaluation of the Anti-Plaque and Anti-Gingivitis Effects of Chlorine Dioxide and Chlor hexidine Mouthrinses: A Clinical Study."** submitted by **Dr Nidhi Chaudhary** Post graduate student from the **Department of Periodontology** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **04th 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

ANNEXURES - II

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 VIIth Institutional Ethics Sub-Committee

IEC Code: 28 (Revised) **BBDCODS/01/2021**

Title of the Project: Comparative Evaluation of the Anti-Plaque and Anti-Gingivitis Effects of Chlorine Dioxide and Chlor hexidine Mouthrinses: A Clinical Study.

Principal Investigator: Dr. Nidhi Chaudhary **Department:** Periodontology

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

Type of Submission: Revised, MDS Project Protocol

Dear Dr. Nidhi Chaudhary,

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

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, 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:

Lakshmi Bala 07/01/21

(Dr. Lakshmi Bala)
Member-Secretary,
IEC

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 Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURES - 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 ……..

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 Date……..

ANNEXURES – IV

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

सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन संख्या.....
प्रतिभागी के पूर्ण नाम.....
जन्म तिथि / आयु.....
प्रतिभागी का पता .....
फोन नं. और ई-मेल पता .....
योग्यता .....
व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....
अन्य (उचित रुप मे टिक करें) .....
प्रतिभागी की वार्षिक आय .....
प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले मे मुआवजे के प्रयोजन के लिए)

1. मेरी पुष्टि है कि मैने अध्ययन हेतु सुचना पत्र दिनांक ..... को पढ व समझ लिया तथा मुझे प्रश्न पुछने या मुझे अध्ययन अन्वेषक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पुछने के समान अवसर प्रदान किए गये।

2. मैंने यहाँ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णत: स्वैच्छिक है और किसी भी दबाव के बिना स्वतंत्र इच्छा के साथ दिया है किसी भी समय किसी भी कारण के बिना , मेरे इलाज या कानूनी अधिकारो को प्रभावित किए बिना , अध्ययन में भाग न लेने के लिए स्वतंत्र हुँ ।

3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक , प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नही है, चाहे मैने इस अध्ययन से नाम वापस ले लिया है। हॉलाकि मै यह समझता हुँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नही दी जायेगी।

4. मै इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नही है।
5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ।

हॉ [ ] नही [ ] अनउपयुक्त [ ]

6. मै परीक्षण की अनुमति देता हुँ। मुझे इसके द्वारा यदि कोई परेशानी होती है, इसके बारे में जानकारी दे दी गई है। मैने रोगी जानकारी सूचना पत्र को पढ तथा समझ लिया है।

प्रतिभागी / कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अंगूठे का निशान.....

हस्ताक्षरकर्ता का नाम..... दिनांक .....अन्वेषक के हस्ताक्षर ..... दिनांक .....

अध्ययन अन्वेषक का नाम .....

गवाह के हस्ताक्षर ..... दिनांक .....गवाह के नाम .....

मैनें पीआईडी और विधिवत भरे सहमति फार्म का एक हस्ताक्षर की नकल प्राप्त की.

प्रतिभागी कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/ अंगूठे का निशान ..... दिनांक.....

ANNEXURES – V

Babu Banarasi Das College of Dental Sciences

(A constituent institution of Babu Banarasi Das University) BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Participant Information Document (PID)

Study title: COMPARATIVE EVALUATION OF THE ANTI-PLAQUE AND ANTI-GINGIVITIS EFFECTS OF CHLORINE DIOXIDE AND CHLORHEXIDINE MOUTHRINSES : A CLINICAL STUDY

1. **Invitation paragraph**

   You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

2. **What is the purpose of the study?**

   To compare the efficacy of chlorine dioxide mouthwash and chlorhexidine as an anti plaque and anti- gingivitis agent

3. **Why have I been chosen?**

   You have been chosen for this study as you are fulfilling the required criteria for this study.

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

   Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

5. What will happen to me if I take part?

You will be one of the subjects, enrolled in the study. To assess the efficacy of chlorine dioxide and chlorhexidine mouthwash as an anti- plaque and anti-gingivitis agent and to compare the difference in efficacy between the two agents.

6. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study.

7. What is the procedure that is being tested?

The procedure will involve to assess the Plaque index, Gingival index, Mombelli and Outson modified sulcular bleeding index ,Tongue Coating index ,Tongue discoloration index.

8. What are the interventions for the study?

Patient with mild to moderate type of gingivitis will be selected for the study.

9. What are the side effects of taking part?

There are no side effects on patients of this study.

10. What are the possible disadvantages and risks of taking part? There are no risks or disadvantages of taking part in this study.

11. What are the possible benefits of taking part?

This study will help us to compare the efficacy of both Chlorine dioxide and Chlorhexidine mouthwash. It will reduce plaque index, gingival index, and bleeding index.

12. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your

withdrawal. If you decide to continue in the study, you may be asked to sign an updated consentform.

13. What happens when the research study stops?

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

14. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and Institutional ethical community.

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

Yes it will be kept confidential.

16. What will happen to the results of the research study?

The results of the study will be to assess plaque index, gingival index, bleeding index, tongue coating index.

17. Who is organizing theresearch?

This research study is organized by the academic institution (BBDCODS).

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

Yes.

19. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Dept, and the IEC/IRC of the institution.

20. Contact for further information

Dr Nidhi Chaudhary
Department of Periodontology
Babu Banarasi College of Dental Sciences.
Lucknow-227105 Mob.9759649402

Dr Vandana A Pant (HOD)
Department of Periodontology
Babu Banarasi College of Dental Sciences.
Lucknow-227105 Mob- 9935957775

Dr. Laxmi Bala, Member Secretary,
Babu Banarasi College of Dental Sciences.
Lucknow
bbdcods.iec
@gmail.com

ANNEXURES – VI

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

;बाबू बनारसी दास वश्व वद्यालय का एक घटक संस्थान)

बीबीडी सटी फैजाबाद रोड लखनऊ - 227105 ;भारत)

प्रतिभागी सूचना दस्तावेज (पीआईडी)

1- अध्ययन शीर्षक

चीलेटीन डायोक्साइड और क्लोरोक्साइडिन पदार्थों के एंटी.प्लेट और एंटी.जिंजिविटस यौगिकों का यौगिक विकासरू एक नैदानिक अध्ययन

2. आमंत्रण अनुच्छेद

आपको एक शोध अध्ययन में भाग लेने के लए आमंत्रित कया जा रहा हैए इस लए यह समझना आपके लए महत्वपूर्ण है क अध्ययन क्यों कया जा रहा है और इसमें क्या शा मल होगा। कृपया निम्न ल खत जानकारी को ध्यान से पढ़ने के लए समय दें। कसी भी स्पष्टीकरण या आगे की जानकारी के लए हमसे पूछें। चाहे आप भाग लेना चाहते हैं या नहींए आपका निर्णय है।

3. अध्ययन का उद्देश्य क्या हैः

एंटी-प्लाक और एंटी-जिंजिवाइटिस एजेंट के रूप में क्लोरीन डाइऑक्साइड माउथवॉश और क्लोरहेक्सि डन की प्रभावकारिता की तुलना करने के लए

4. मुझे क्यों चुना गया हैः

इस अध्ययन के लए आपको चुना गया है क्यों क आप इस अध्ययन के लए आवश्यक मानदंडों को पूरा कर रहे हैं।

5. क्या मुझे भाग लेना हैः

शोध में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैंए तो आपको यह जानकारी पत्र दिया

जाएगा और सहमति फॉर्म पर हस्ताक्षर करने के लए कहा जाएगा। अध्ययन के दौरान आप अभी भी कसी भी समय बिना कसी कारण के वापस लेने के लए स्वतंत्र हैं।

6.अगर मैं भाग लेता हूं तो मेरे साथ क्या होगा

आप अध्ययन में नामांकित एक विषय होंगे। क्लोरीन डाइऑक्साइड और क्लोरहेक्सिडाइन माउथवॉश की प्रभावकारिता का आकलन करने के लिए एंटी.प्लाक और एंटी.जिंजिवाइटिस एजेंट के रूप में और दो एजेंटों के बीच प्रभावकारिता के अंतर की तुलना करने के लिए।

7. मुझे क्या करना हैः

अध्ययन की जांच के लए आपको अपने निय मत जीवन शैली को बदलने की ज़रूरत नहीं है।

8. परीक्षण की जा रही प्र क्रया क्या हैः

इस प्र क्रया में प्लाक इंडेक्स, गं गवल इंडेक्स, मोम्बेली और आउटसन संशो धत सुल्ड्रन ब्ली डंग इंडेक्स, टंग्यू कोटिंग इंडेक्स और टंग्यू डस्कोलेशन इंडेक्स का आकलन शा मल होगा।

9. अध्ययन के लए हस्तक्षेप क्या हैं

अध्ययन के लिए हल्के से मध्यम प्रकार के मसूड़े की सूजन वाले रोगी को चुना जाएगा।

10. भाग लेने के दुष्प्रभाव क्या हैं

इस अध्ययन के कोई दुष्प्रभाव नहीं हैं।

11. भाग लेने के संभा वत नुकसान और जो खम क्या हैं

इस अध्ययन में कोई जो खम शा मल नहीं है।

12. भाग लेने के संभा वत लाभ क्या हैं

यह अध्ययन हमें क्लोरीन डाइऑक्साइड और क्लोरहेक्सिडाइन माउथवॉश दोनों की प्रभावकारिता की तुलना करने में मदद करेगा। यह पट्टिका सूचकांकए मसूड़े के सूचकांक और रक्तस्राव सूचकांक को कम करेगा।

13. क्या होगा अगर नई जानकारी उपलब्ध हो जाए

यदि शोध के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है तो आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ चर्चा करने के लए स्वतंत्र हैंए आपका शोधकर्ता आपको बताएगा क आप अध्ययन में जारी रखना चाहते हैं या नहीं। यदि आप वापस लेने का निर्णय लेते हैंए तो आपका शोधकर्ता आपके वापसी के लए व्यवस्था करेगा। यदि आप अध्ययन में जारी रखने का निर्णय लेते हैंए तो आपको एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लए कहा जा सकता है।

14. शोध अध्ययन बंद होने पर क्या होता है

यदि अध्ययन निर्धारित समय से पहले समाप्त / खत्म हो जाता हैए तो यह रोगी / स्वयंसेवक को समझाया जाएगा।

15. क्या होगा अगर कुछ गलत हो जाए

यदि कोई गंभीर प्रतिकूल घटना होती है या अध्ययन के दौरान कुछ गलत हो जाता है तो शकायतों को संस्था (ओं)ए और संस्थागत नैतिक समुदाय को रिपोर्ट करके संभाला जाएगा।

16. क्या इस अध्ययन में मेरा हिस्सा गोपनीय रखा जाएगा

हां इसे गोपनीय रखा जाएगा।

17. शोध अध्ययन के नतीजों का क्या होगा

। अध्ययन के परिणाम पि का सूचकांक, मसूड़े के सूचकांक, रक्तस्राव सूचकांक, जीभ कोटिंग सूचकांक का आकलन करने के लए होंगे।

18. शोध का आयोजन कौन कर रहा है

यह शोध अध्ययन अकाद मक संस्थान द्वारा आयोजित कया जाता है। आपको शा मल कसी भी प्र क्रया के लए भुगतान नहीं करना है।

20. अध्ययन की समीक्षा कसने की है

इस अध्ययन की समीक्षा वभाग के प्रमुख और संस्थान के आईईसी / आईआरसी द्वारा की गई और अनुमोदित की गई है।

21. अ धक जानकारी के लए संपर्क करें

डॉ निधि चौधरी

पीरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ.227105

मो. 9759649402

डॉ वंदना ए पंत ;

पीरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ.227105

मोब. 9935957775

डॉ लक्ष्मी बाला

सदस्य स चव

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज लखनऊ

bbdcods.iec@gmail.com

पीआई का हस्ताक्षर .....

नाम .....

दिनांक .....

ANNEXURES – VII

CASE HISTORY PROFORMA

DATE: OPD NO.

NAME: AGE: SEX:

ADDRESS: MOBILE NO.:

OCCUPATION:

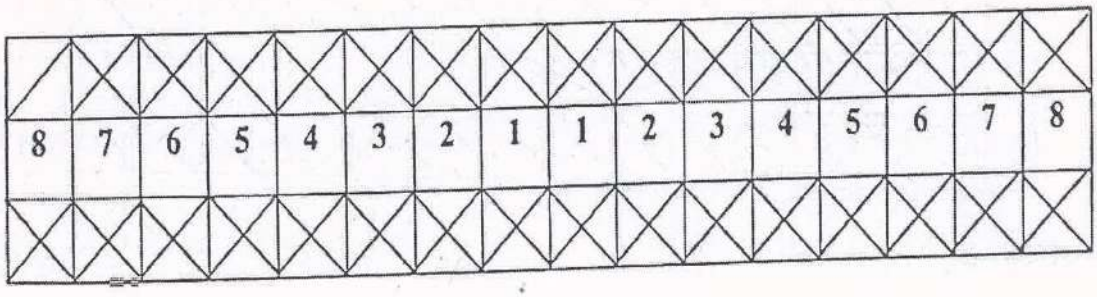
CHIEF COMPLAINT (S) :

PAST MEDICAL AND DENTAL HISTORY:

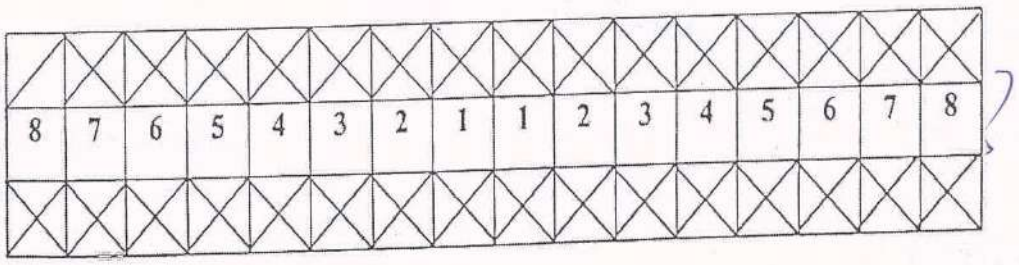
INDICES

PLAQUE INDEX

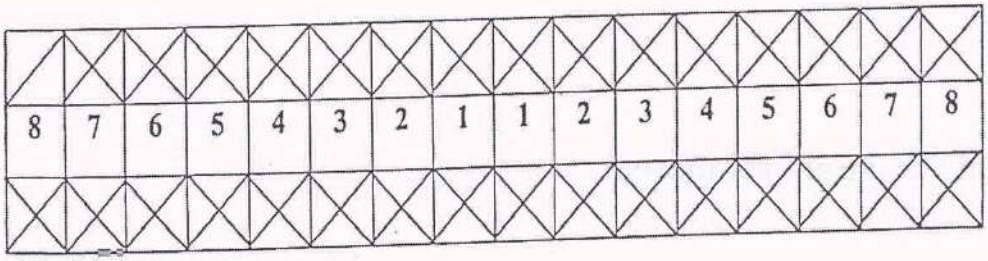
AT BASELINE



AFTER 2 WEEKS

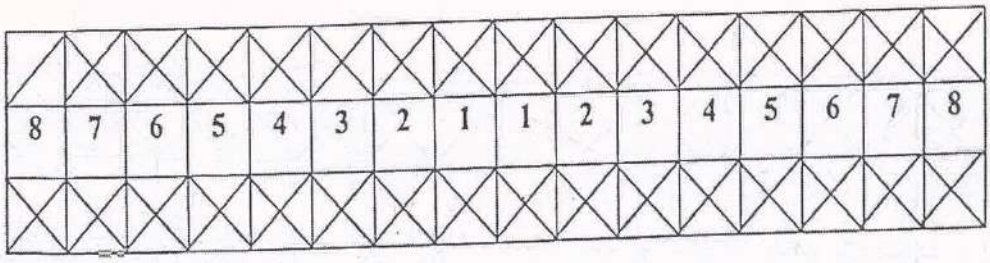


AFTER 1 MONTH



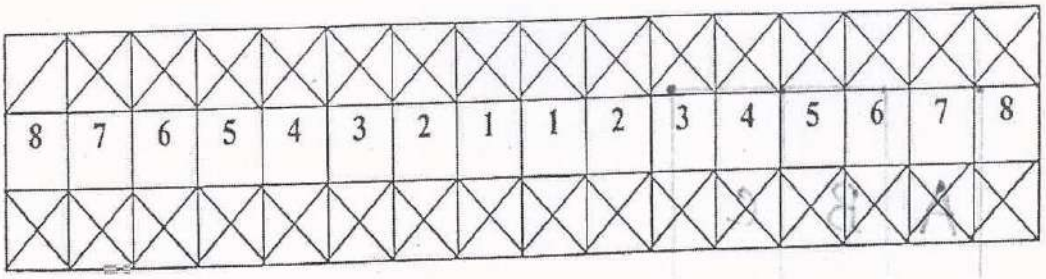
PI scoring

GINGIVAL INDEX: (AT BASELINE)



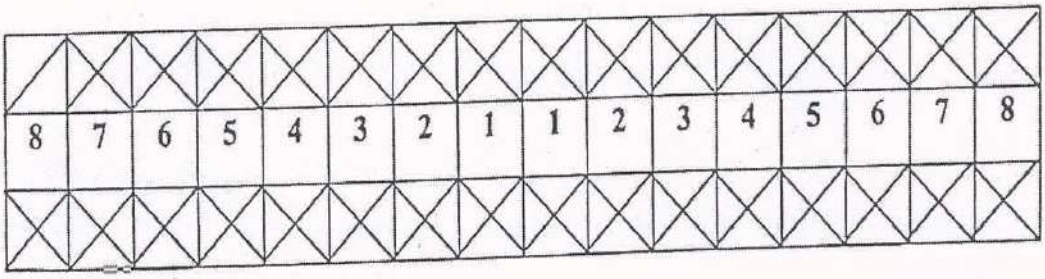
GI scoring:

AT 2 WEEKS



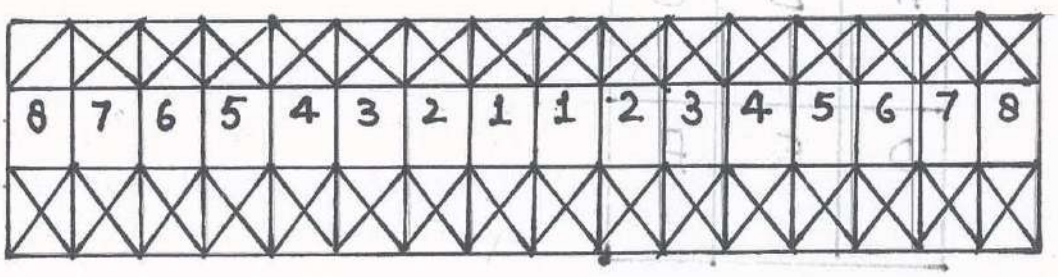
GI scoring

AFTER 1 MONTH

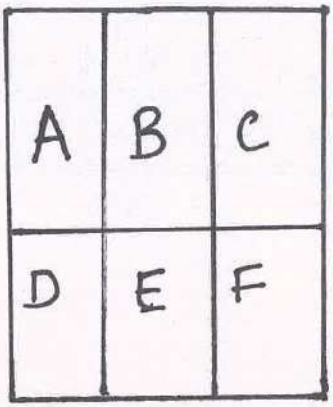


GI scoring

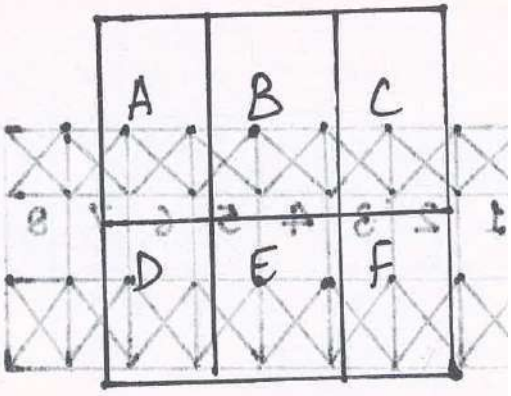
MODIFIED SULCULAR BLEEDING INDEX



TONGUE COATING INDEX



TONGUE DISCOLORATION INDEX



ANNEXURES – VIII

Statistical analysis: Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). Difference between two groups was determined using student t-test as well as chi square test and the level of significance was set at $p < 0.05$.

The statistical analysis for the present study was done by applying the following formulae:

1. **Mean**: The mean (or average) is the most popular and well known measure of central tendency. It can be used with both discrete and continuous data, although its use is most often with continuous data. The mean is equal to the sum of all the values in the data set divided by the number of values in the data set. So, if we have n values in a data set and they have values x_1, x_2, ..., x_n, the sample mean, usually denoted by $\bar{x}$ (pronounced x bar), is:

$$\bar{x} = \frac{(x_1 + x_2 + \cdots + x_n)}{n}$$

This formula is usually written in a slightly different manner using the Greek capitol i.e.:

Sample Mean	Population Mean
$\bar{x} = \frac{\Sigma x}{n}$	$\mu = \frac{\Sigma x}{N}$

where Σx is sum of all data values

N is number of data items in population

n is number of data items in sample

2. **Standard deviation**: the standard deviation (SD, also represented by the lower case Greek letter sigma σ or the Latin letter s) is a measure that is used to quantify the amount of variation or dispersion of a set of data values. A low standard deviation indicates that the data points tend to be close to the mean (also called the expected value) of the set, while a high standard deviation indicates that the data points are spread out over a wider range of values.

$$\sigma = \sqrt{\frac{\sum (x - \bar{x})^2}{n}}$$

σ = lower case sigma
$\sum$ = capital sigma
$\bar{x}$ = x bar

3. **Chi-square test**: A chi-squared test, also written as $\chi 2$ test, is any statistical hypothesis test where the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. The chi-squared test is used to determine whether there is a significant difference between the expected frequencies and the observed frequencies in one or more categories.
4. **Student T test**: A student *t*-test is any statistical hypothesis test in which the test statistic follows a Student *t*-distribution under the null hypothesis. It can be used to determine if two sets of data are significantly different from each other. It is most commonly applied when the test statistic would follow a normal distribution if the value of a scaling term in the test statistic were known. When the scaling term is unknown and is replaced by an estimate based on the data, the test statistics (under certain conditions) follow a Student's *t* distribution.

ANNEXURES – IX

Curiginal

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