COMPARATIVE CLINICAL EVALUATION OF OCTENIDINE DIHYDROCHLORIDE, CHLORHEXIDINE, POVIDONE-IODINE AND CETYLPYRIDINIUM CHLORIDE ON DENTAL PLAQUE, GINGIVITIS AND TASTE PERCEPTION IN PATIENTS WITH PERIODONTAL DISEASE

DISSERTATION

Submitted to

BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfilment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

In

PERIODONTOLOGY

By

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I hereby declare that this dissertation entitled "COMPARATIVE CLINICAL EVALUATION OF OCTENIDINE DIHYDROCHLORIDE, CHLORHEXIDINE, POVIDONE-IODINE AND CETYLPYRIDINIUM CHLORIDE ON DENTAL PLAQUE, GINGIVITIS AND TASTE PERCEPTION IN PATIENTS WITH PERIODONTAL DISEASE" is a bonafide and genuine research work carried out by me under the guidance of Dr. Sunil C Verma, Professor, and co-guide Dr. Suraj Pandey, Reader, Department of Periodontology, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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गुरु बिन ज्ञान न होत है, गुरु बिन दिशा अजान,

गुरु बिन इन्द्रिय न सधैं, गुरु बिन बढ़े न शान ।

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LIST OF ABBREVIATIONS

OCT	octenidine dihydrochloride
CHX	chlorhexidine gluconate
S. mutans	Streptococcus mutans
PVP-I	polyvinylpyrrolidone-iodine
CPC	cetylpyridinium chloride
HIV	Human immunodeficiency virus
PPD	Probing pocket depth
SR	Systematic review
PI	Plaque Index
GI	Gingival index
AEs	Adverse Events

ABSTRACT

INTRODUCTION: Antiseptic mouthwashes are used in many clinical situations for various preventive and therapeutic purposes. Due to the different antimicrobial effects and kinetics of solutions, it is difficult to determine which product is suitable for a particular purpose. The main indications are either the improvement of dental health (particularly the removal of plaque and gingivitis) or the prevention of infections caused by bacteria present in the oral cavity. Thus, the present study aims to compare the efficacy of 0.1% octenidine dihydrochloride, 0.2% chlorhexidine, 1% povidone-iodine and 0.07% cetylpiridinium chloride on dental plaque, gingivitis and taste perception in patients with periodontal disease.

MATERIAL AND METHODOLOGY: A total of 120 patients were included and were randomly divided into 4 equal groups: Group A (n=30): patients, who had undergone oral prophylaxis, were advised to regularly use 0.1% octeinidine dihydrochloride mouthwash (twice daily) and brush (twice daily), and Group B (n=30): patients who had undergone oral prophylaxis, were advised to regularly use 0.2% chlorhexidine mouthwash (twice daily) and brush (twice daily), Group C (n=30): patients who had undergone oral prophylaxis, were advised to regularly use 1% povidone-iodine mouthwash (twice daily) and brush (twice daily), Group D (n=30): patients who had undergone oral prophylaxis, were advised to regularly use 0.07% cetylpyridinium chloride mouthwash (twice daily) and brush (twice daily). The gingival status was assessed by the using Loe and Silness index , and dental plaque by using Silness and Loe index. Plaque index and gingival index was recorded at baseline and after 21 days whereas Modified Lobene index was used to record staining of tooth. The staining of tooth was recorded at baseline and after 21 days. A 5 item questionnaire was also used to assess patients self – assessment regarding the taste perception of prescribed mouthwashes.

RESULTS: On comparing the mean plaque index and mean gingival Index at baseline all the Groups showed statistically non-significant results, whereas after 21 days significant difference was observed in all the groups. On comparison among all 4 mouthwashes, Octenidine mouthwash significantly reduced plaque (p=0.001) and gingival index (p=0.001) and showed better patient acceptability.

The results of taste perception rating included questions on taste perception, duration of taste, alteration in taste perception, and duration of rinsing time which was found to be statistically significant in all the groups while the convenience in using shows statistically significant results.

CONCLUSION: From the above results, it can be concluded that 0.1% octeinidine dihydrochloride is a better mouth rinse than chlorhexidine, povidone-iodine and cetylpyridinium chloride.

Keywords: Octeinidine dihydrochloride, Chlorhexidine, Povidone-Iodine, Cetylpyridinium chloride, Gingivitis,

INTRODUCTION

Antiseptic mouthwashes are used in many clinical situations for preventive and therapeutic purposes. The main indications are to improve dental health (particularly the removal of plaque and gingivitis) or to be caused by bacteria in the oral cavity in certain situations such as tooth extraction, oral surgery, immunosuppression due to cancer treatment or transplantation.[1]

Dental plaque is considered the main cause of gingival inflammation and is associated with the onset and progression of periodontal disease. The amount of plaque is directly related to the severity of periodontal disease. Plaque control is central to the primary and secondary prevention of periodontal disease. Mechanical measures such as tooth brushing and interdental cleaning aids are the focus of plaque control. However, its effectiveness depends primarily on the technique and skill of the individual, so it is often difficult to perform successfully by most people. Chemical treatment is the next best option when mechanical plaque control is compromised. Therefore, mouthwash can be an important part of oral hygiene.[2]

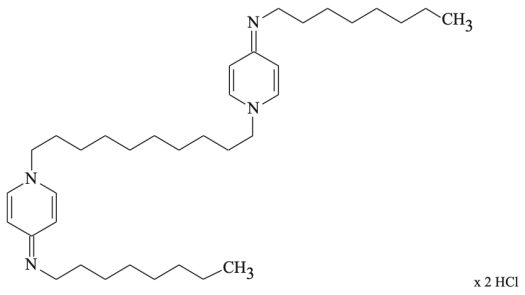


Figure 1: Octenidine dihydrochloride

Octenidine dihydrochloride (OCT), a second-generation bispyridinamine is one such novel agent that was developed in the 1980s. Since 1995, it has been approved as a disinfectant in 20 European countries. Octenidine dihydrochloride is a disinfectant with two active cation centres within the molecule. They do not interact with each other because long aliphatic hydrocarbon chains separate them. This makes octenidine toxicologically harmless as 4-chloroaniline is not released. OCT appears to be more effective than chlorhexidine (CHX) because

of its sustained bacterial antiadhesion activity. Data also supports the positive effects of mouthwash containing 0.1% OCT on plaque buildup and gingivitis. Most importantly, OCT has a high affinity for cardiolipin, which is specific to bacterial cell membranes, making it lethal only to bacterial cells and not to human tissues or epithelia. [2]

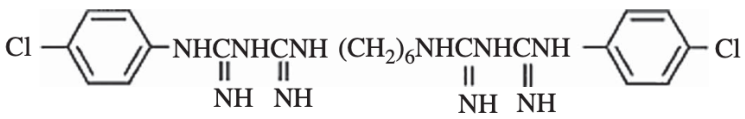


Figure 2: Chlorhexidine

Chlorhexidine is a second-generation cationic biguanide introduced by G.E. Davies in 1954 as an antibacterial agent. Due to its antibacterial spectrum and presumed residual efficacy, chlorhexidine digluconate is considered the "gold standard" for oral hygiene in the United States.[3]

Chlorhexidine is a broad-spectrum antibacterial agent. In dentistry, chlorhexidine reduces S. mutans levels in the oral cavity and is incorporated into mouthwash solutions. In addition to inhibiting plaque formation, chlorhexidine has been shown to reduce gum inflammation and prevent tooth decay. [4]

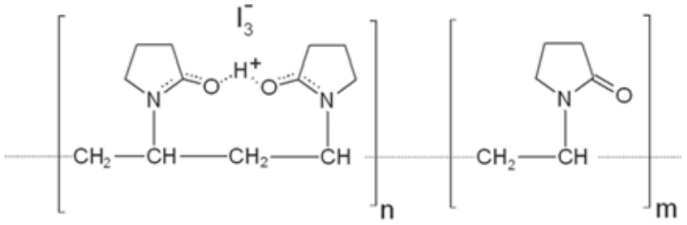


Figure 3: Povidone-Iodine

Povidone-iodine POV-I (polyvinylpyrrolidone-iodine) is one of the most commonly used disinfectants in the medical field. It is used as a disinfectant for skin, hands, and mucous membrane surfaces. It can also be used to treat wounds, and clean body cavities, joints, and eyes. It is made from a combination of water-soluble polymers, povidone, and iodine. This polymer prolongs the activity of iodine. It was found to kill microorganisms in vitro within 15 seconds. However,

it requires 5 minutes of contact with the microorganism to be clinically effective. It has broad antibacterial activity against bacteria, fungi, mycobacteria, and viruses. It is safe, easy to use, widely available, and inexpensive. Additionally, it has minimal side effects and little or no chance of inducing bacterial resistance.[5]

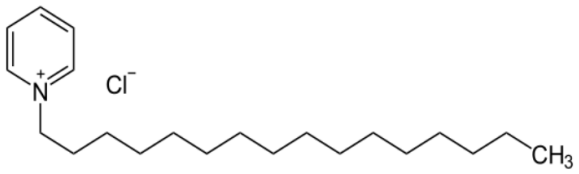


Figure 4: Cetylpyridinium chloride

CPC (cetylpyridinium chloride) is a quaternary ammonium compound with broad-spectrum antibacterial activity. It is a cationic surfactant (surfactant) that easily adsorbs to the surface of the oral cavity. This molecule has both hydrophilic and hydrophobic groups, allowing ionic and hydrophobic interactions. The positively charged hydrophilic region of the CPC molecule plays an important role in its antimicrobial activity, conferring high binding affinity to bacterial cells whose outermost surface carries a net negative charge. The strong positive charge and hydrophobic regions of CPC allow the compound to interact with the microbial cell surface and integrate into the cytoplasmic membrane. This interaction results in disruption of membrane integrity, leading to leakage of cytoplasmic components, disruption of cell metabolism, inhibition of cell proliferation, and cell death. The ability of CPC to adsorb to pellicle-covered enamel lends substance to the molecule. It remains in the mouth and maintains its antibacterial effect for a certain period of time even after rinsing. [6]

Various researches have been conducted to assess and compare the efficacy of Octenidine dihydrochloride, Chlorhexidine, Povidone-Iodine and Cetylpyridinium chloride mouthwashes in reducing the microorganisms in oral cavity after phase I therapy. As per review of literature there is scarcely few studies to assess the effect of these four chemical mouthwashes i.e. Octenidine dihydrochloride, Chlorhexidine, Povidone-Iodine and Cetylpyridinium on

dental plaque, gingivitis and taste perception. Therefore the present study was undertaken to assess and compare 0.1% Octenidine dihydrochloride, 0.2% chlorhexidine, 1% povidone-iodine and 0.07% cetylpyridinium chloride on dental plaque, gingivitis and taste perception in patients with periodontal disease.

AIM AND OBJECTIVES

AIM: To compare the efficacy of 0.1% octenidine dihydrochloride, 0.2% chlorhexidine, 1% povidone-iodine and 0.07% cetylpiridinium chloride on dental plaque, gingivitis and taste perception in patients with periodontal disease.

OBJECTIVES: To assess and compare the efficacy of 4 different mouthwashes:

i. On dental plaque.

ii. On gingivitis.

iii. Of taste perception.

REVIEW OF LITERATURE

Slee AM, O'Connor JR (1983)[7] performed a study on the antibacterial activity of octenidine dihydrochloride (WIN 41464-2) against intact preformed in vitro plaques of four indigenous oral plaque-forming microorganisms, Streptococcus mutans, Streptococcus sanguis, Actinomyces viscosus, and Actinomyces naeslundii. Both absolute (plaque bactericidal index) and relative (chlorhexidine coefficient) indices of antiplaque efficacy were established. Octenidine dihydrochloride was compared favourably with chlorhexidine digluconate concerning overall antiplaque potency in this in vitro plaque bactericidal model.

Patters M R et al (1986)[8] conducted a study to determine the effects of octenidine on plaque and gingivitis development in humans using a 21-day experimental gingivitis model. Eighty-eight subjects with a Plaque Index (PI) and Gingival Index (GI) < 0.4 were randomly assigned to 4 coded formulations: 1) 0.1% octenidine in mouthwash vehicle used 3 times a day (TID), 2) 0.1 % octenidine in mouthwash vehicle used twice a day (BID), placebo rinse once a day, 3) 0.1% octenidine in water used 3 times a day, and 4) mouthwash vehicle alone used 3 times a day (VEH). Each subject refrained from all mechanical plaque control and rinsed morning, noon, and evening under supervision with 15 ml of assigned formulation for 60 s. At 0, 7, 14, and 21 days, PI, GI, and mucosal tolerance were assessed. Tooth stain was measured at day 0 and twice at day 21 (prior to and immediately following a single toothbrushing). These results demonstrate that octenidine, when used as the only means of oral hygiene for 21 days, will significantly inhibit the development of plaque and gingivitis.

Beiswanger BB, Mallatt ME, Mau MS, Jackson RD, Hennon DK (1990)[9] evaluated the effects of a 0.1% octenidine mouth rinse on plaque, gingivitis, extrinsic dental stain, and the oral soft tissues in 3 months clinical trial. A total of 451 adult volunteer subjects were initiated into the study and given baseline dental examinations. The subjects were stratified into two balanced groups according to gender, plaque, and gingivitis scores. The subjects then received a dental prophylaxis and were provided with dentifrice, toothbrushes, and either a mouth rinse containing 0.1% octenidine dihydrochloride as the active

ingredient or a similar placebo mouth rinse. Subjects were instructed to rinse with their assigned product for 30 s twice each day. Examinations were repeated at six weeks (soft-tissue assessment, gingivitis) and three months (soft tissues, plaque, gingivitis, dental stain). The results showed that the group rinsing with 0.1% octenidine had significantly less plaque (39%), gingivitis (50%), and bleeding sites (60%) than the group using the control product, but had significantly higher stain formation and experienced longer prophylaxis times to remove the stain.

Smith RN, Andersen RN, Kolenbrander PE (1991)[10] presented a study to determine the potential inhibitory effect of chlorhexidine digluconate on the intergeneric coaggregation of 11 pairs of Gram-positive organisms was compared to its ability to inhibit coaggregation of 14 pairs comprised of both a Gram-positive and a Gram-negative cell type. Dramatic differences in the inhibitory effectiveness of the antimicrobial compound on the two kinds of coaggregating pairs were found, Gram-positive pairs were not inhibited at a concentration of 0.25%, whereas the coaggregations involving a Gram-negative partner were usually completely blocked at concentrations as low as 0.01%. Similar effects to chlorhexidine digluconate were found with octenidine dihydrochloride and cetylpyridinium chloride, while sodium dodecylsulfate was inhibitory only at 10- to 50-fold higher concentrations. These results suggested that chlorhexidine digluconate, octenidine dihydrochloride, and cetylpyridinium chloride may be effective inhibitors of later microbial colonizers of dental plaque but may not disturb a normal healthy indigenous flora.

Renton-Harper P, Addy M, Moran J, Doherty F.M and Newcombe R G (1996)[11] conducted a study to compare 4 mouth rinse products containing cetylpyridinium chloride (CPC), Chlorhexidine, C31G, or triclosan with saline rinse included as a placebo control. Twenty dentate volunteers took part in this 4-day plaque regrowth study which is a single-blind randomized cross-over design balanced for residual effects. All the differences in favour of the Chlorhexidine product were highly significant as were those in favour of the other rinses compared to saine. They concluded that the findings of this study

reflect the actual chemical benefits of the products divorced from the indeterminate variable of toothbrushing.

Arweiler NB, Boehnke N, Sculean A, Hellwig E, Auschill TM (2006)[12] presented a clinical cross over study to examine the antibacterial and plaque-inhibiting properties of two chlorhexidine solutions compared with a negative control. Twenty-one volunteers refrained from all oral hygiene measures but rinsed instead twice daily with 10 ml of a conventional chlorhexidine solution (0.2%; CHX), a chlorhexidine solution with anti-discolouration system (ADS) (0.2%, alcohol-free chlorhexidine solution (CSP)) or a placebo solution. Plaque index, plaque area and bacterial vitality were assessed after 24 h and 96 h. After a 10-day wash-out period, a new test cycle was started. The result suggested that the 0.2% alcohol-containing solution showed superiority in inhibiting plaque re-growth and reducing bacterial vitality compared with the solution with ADS.

Dogan AA et al (2008)[13] evaluated the efficacy of common antiseptic mouth rinses and octenidine dihydrochloride (OCT). The antibacterial activities of antiseptics against total and cariogenic bacteria (Streptococcus mutans and Lactobacillus species) in saliva were studied in vitro and in vivo. After unstimulated saliva was collected, one of the mouth rinse solutions was applied for 30 seconds. Saliva samples were collected 15, 30, 60, and 120 min later and evaluated for their bacterial count. In conclusion, OCT compared favourably with CHX and PVP—I in its antibacterial effects, both in vitro and in vivo ($p < 0.01$).

Dogan AA, Cetin E S, Hüssein E, Adiloglu A K (2009)[14] conducted a study to determine the absolute and relative antibacterial activity of octenidine dihydrochloride (OCT) against total and cariogenic bacteria in saliva samples of patients with fixed orthodontic appliances during 5 days of usage on 5 male and 13 female subjects. Each patient was given physiologic saline (PS), chlorhexidine gluconate (CHX), polyvinylpyrrolidone-iodine complex (PVP-I), and OCT every morning for 5 days, each separated by a 2-week interval. Cariogenic bacteria in saliva samples of orthodontically treated patients with

fixed appliances were collected during 5 days of usage. Unstimulated saliva was collected as a baseline sample. Saliva samples were collected at 15 minutes, and on the second, third, and fifth day after rinsing the mouth with any of the solutions for 30 seconds, bacterial counts were detected. They concluded that OCT compared favourably to CHX and PVP-I complex in orthodontically treated patients with fixed appliances.

Kocak M M, Ozcan S, Kocak S, Topuz O, Erten H (2009)[4] evaluated the effectiveness of three different antiseptic mouth rinse solutions on the saliva samples obtained from the individuals, who had high caries activity rates. The three antiseptic solutions used in this study were 0.1% octenidine dihydrochloride, 0.12% chlorhexidine digluconate and an antimicrobial enzymatic rinse on a total of 27 adult volunteer subjects who participated in the study. The subjects were stratified into three balanced groups. Then the mouth rinses were used by each group according to the manufacturer's directions. The subjects were restricted for 60 minutes for food intake after using the prescribed mouth rinse. The saliva samples were collected from the volunteers at 1, 10 and 60 minutes after their usage in tubes. Results showed that Octenisept was found to be more effective over *S. mutans* than the other mouthrinse solutions (P<.05). They concluded that all mouth rinse solutions except Biotene were effective on oral microorganisms.

Koburger T, Hübner NO, Braun M, Siebert J, Kramer A (2010)[15] presented a comparative investigation of the antimicrobial efficacy of the antiseptics PVP –iodine, triclosan, chlorhexidine, octenidine and polyhexanide used for pre-surgical antisepsis and antiseptic treatment of skin, wounds and mucous membranes based on internationally accepted standards. They concluded that when a prolonged contact time is feasible, the ranking of agents would be polyhexanide=octenidine>chlorhexidine>triclosan>PVP–iodine. Polyhexanide seems to be preferable for chronic wounds due to its higher tolerability. If an immediate effect is required, the ranking would be octenidine=PVP –iodine≫ polyhexanide>chlorhexidine>triclosan.

Charles CA, McGuire JA, Sharma NC, Qaqish J (2011)[16] performed a study to determine the comparative effectiveness of these two mouth rinses Listerine Antiseptic and Crest Pro-Health in which two antimicrobial agents, a fixed combination of essential oils (EOs) and 0.07% cetylpyridinium chloride (CPC) are found. The study was done on a 2-week experimental gingivitis model. Qualified subjects were randomly assigned to one of three mouth rinse groups: a fixed combination of EOs, 0.07% CPC, or negative control (C) rinse. This study concluded that the essential oil-containing mouth rinse has superior antiplaque/antigingivitis effectiveness compared to the 0.07% CPC-containing mouth rinse without mechanical oral hygiene influence.

Van Strydonck DAC, Slot DE, Van der Velden U, Van der Weijden F (2012)[17] presented a systemic review to evaluate the efficacy of chlorhexidine (CHX) mouth rinses on plaque, gingival inflammation and staining in gingivitis patients. Medline, EMBASE and Cochrane Central Register of Controlled Trials were searched through April 2011. Randomized controlled clinical trials comparing CHX to placebo/control mouth rinses or oral hygiene (OH) 4 weeks were included. It was concluded that in gingivitis patients, CHX mouth rinses together with OH versus placebo- or control mouth rinses provide significant reductions in plaque and gingivitis scores, but a significant increase in staining scores.

Raangs GC, Winkel EG, van Winkelhoff AJ (2013)[18] carried out a study to compare the antimicrobial activity of a mouth rinse containing chlorhexidine and cetylpyridinium chloride (MR1) with a stannous fluoride-based mouth rinse (MR2) in vitro. Samples of the tongues from 10 subjects with and 10 subjects without halitosis were inoculated on blood agar plates. The agar was perforated, and the cylindrical holes were filled either with mouth rinse MR1 or with mouth rinse MR2. After incubation, inhibition zones of the whole tongue microbiota and Fusobacterium nucleatum were measured. In addition, MR1 and MR2 were applied in a short interval killing test (SIKT) on four oral pathogens Porphyromonas gingivalis, Prevotella intermedia, F. nucleatum and Aggregatibacter actinomycetemcomitans. Total viable cell counts were made

after two minutes of incubation with increasing concentrations of MR1 and MR2. They concluded that their in vitro observation supports the use of chlorhexidine and cetylpyridinium chloride in the treatment of oral halitosis.

Costa X, Laguna E, Herrera D, Serrano J, Alonso B, Sanz M. (2013)[19] presented a study to assess the efficacy of a 0.07% cetylpyridinium chloride (CPC) mouth rinse in the control of plaque and gingival inflammation during a 6-month period. : Adult subjects with moderate gingivitis were selected [≥40% bleeding on marginal probing (BOMP)]. After retrieving microbiological samples and evaluating the clinical parameters (plaque, BOMP and stain indexes), a professional prophylaxis was performed and subjects were randomly assigned to the test (CPC mouth rinse) or to the placebo group. Subjects were re-assessed after 3 and 6 months. They concluded that 0.07% CPC-based mouth rinse, used three times per day adjunctively to mechanical tooth cleaning, prevents plaque accumulation and gingival inflammation, as compared to the placebo, for at least 6 months.

Osso D, Kanani N (2013)[20] performed a literature review to compare the effectiveness of selected antiseptic mouth rinses in controlling plaque and gingivitis, as well as risks associated with daily exposure, including salivary low rate, oral cancer and wear of composite restorations. Electronic database searches were conducted using Google Scholar and PubMed to identify articles comparing the effectiveness of 4 commercially marketed antiseptic mouth rinses differing in active ingredients (0.12% chlorhexidine gluconate, essential oils (menthol, thymol and eucalyptol) and methyl salicylate, 0.7% cetylpyridinium chloride and 20% aloe vera gel) for controlling plaque and gingivitis. Research supported the effectiveness of antiseptic mouth rinses in reducing plaque and gingivitis as an adjunct to home care. Insufficient evidence is available to support the claim that oral antiseptics can reduce the risk of developing periodontitis or the rate of progression of periodontitis.

Tirali RE, Bodur H, Sipahi B, Sungurtekin E. (2013)[21] The objective of this study was to compare the antimicrobial activity of sodium hypochlorite

(NaOCl), chlorhexidine gluconate (CHX) and octenidine hydrochloride (OCT) in different concentrations against endodontic pathogens in vitro. Agar diffusion procedure was used to determine the antimicrobial activity of the tested materials. Enterococcus faecalis, Candida albicans and a mixture of these were used. They concluded that various concentrations of octenidine dihydrochloride were as effective as 5.25% NaOCl solution on the tested microorganisms. From the results of their study, it seemed that OCT solution might be an effective endodontic irrigant.

Al-Sebaie D (2014)[22] study to assess the antibacterial effect of 0.1% octenidole solution on Streptococcus salivarius biofilms when using live/dead staining and standard CFU (colony forming units) counting for determination of the bacterial survival rate. Streptococcus salivarius biofilms were grown in vitro for 42h on 12 mm titanium discs in a flow chamber system. Formed Biofilms were exposed to 0,1% octenidine solution for 30s, 60s, 120s or 300s. The bacterial kill rate was determined by plating on TSB agar and CFU counting as well as live/dead viability staining (BacLight Viability Kit, Invitrogen,) and confocal laser scanning microscopy (CLSM) analyses. Using the plating method and CFU counting, complete killing of adherent could be observed after 30s treatment. Live/dead staining showed the complete killing of bacteria even after 5 minutes immersion of biofilms in octenidine solution. According to this study, significant differences of bacterial survival rates were observed with the two methods used. Therefore, it was concluded that special care should be taken when choosing a laboratory method for the evaluation of antibacterial effects.

Welk A, Zahedani M, Beyer C, Kramer A, Müller G (2015)[23] presented a clinical study to determine the antibacterial and antiplaque efficacy of a recently introduced octenidine-containing mouth rinse (Octenidol®) in comparison with established antiseptic mouthrinses. In a 4-day plaque-regrowth study employing a four-replicate cross-over design, a 0.1 % octenidine mouth rinse (Octenidol®/OCT-MR) was compared with a 0.12 % chlorhexidine mouth rinse (Paroex®/CHXMR), an essential oil mouth rinse (Listerine®/EO-MR), and a placebo mouth rinse/P-MR. Plaque regrowth was assessed with a modified Quigley-Hein plaque index. The antibacterial effect was assessed by taking

bacterial counts from the tooth surface and oral mucosa after professional tooth cleaning and after first rinsing with the allocated mouth rinse on days 1 and 5. They concluded that the recently introduced 0.1 % OCT-containing mouth rinse Octenidol® revealed antibacterial and antiplaque efficacy comparable to that of the 0.12 % CHX-containing mouth rinse Paroex® in the human oral cavity. Thus, Octenidol® may become an alternative to commercially available 0.12 % CHX-containing mouth rinses such as Paroex®.

Malhotra A, Bali A and Bareja R (2016)[24] conducted a study to evaluate the antimicrobial activity of Octenidine (OCT) 0.1%, Chlorhexidine (CHX) 0.2% against bacterial strains of Enterococcus faecalis and Staphylococcus aureus. The strains were inoculated in 7ml of brain heart infusion broth and diluted to reach the concentration equivalent (0.5 McFarland standard). 1ml of organism suspension was contacted with 1ml of each mouthwash and was removed at time intervals of 3,5 and 10 minutes and plated on Brain Heart Infusion agar. After 72 hours of incubation, colony counts were measured using stereomicroscope. Kruskal Wallis test was conducted on the mean number of CFU. Post-hoc tests were conducted by using the Mann-Whitney U test and Duncan's-test of multiple comparisons. The results showed that OCT 0.1% was found to be the most effective in substantially reducing total bacterial counts after 3, 5 and 10 min time intervals. They concluded that OCT 0.1% was found to be the most effective in substantially reducing total bacterial counts.

Decker E M, Bartha V, Kopunic A, Von Ohle C (2017)[25] conducted a study to compare the antibacterial efficacy of different antiseptic mouth rinses, of a conventional and a new, modified PDTplus as well as of the different antiseptic mouth rinses combined with either the conventional or the modified PDTplus against periopathogens. Six representative periodontitis-associated bacterial strains were grown for 24 h under anaerobic conditions. After mixing the individual cell pellets they were exposed to 10 different antiseptic mouth rinse formulations: chlorhexidine, CHX + cetylpyridinium chloride, sodium hypochlorite, polyhexanide, octenidine dihydrochloride; fluoride; essential oils; povidone-iodine and saline as control. They concluded that combination therapy

of preceding chemotherapeutical exposure and subsequent photo disinfection may be a more effective and promising antibacterial treatment than single applications of the antiseptic methods. The modified PDTplus using oxygen-enriched toluidine showed a superior antibacterial effect on periodontal pathogens to conventional PDT and the majority of the investigated mouth rinses.

Lorenz K et al (2018)[26] conducted a bi-centric, placebo-controlled, randomized, evaluator-blinded, incomplete cross-over clinical phase II trial to identify the most appropriate concentration of octenidine dihydrochloride (OCT) in mouth rinses. Rinses of 0.10, 0.15, and 0.20% OCT were compared to a saline placebo rinse regarding the reduction of salivary bacterial counts (SBCs) in 90 gingivitis patients over 4 days. Changes in plaque (PI) and gingival index (GI), taste perception, and safety issues were evaluated. They concluded that considering antibacterial efficacy, frequency of adverse events, and user acceptance, 0.10% OCT was identified as the preferred concentration to be used in future clinical trials. Due to its low toxicity and pronounced antibacterial properties, octenidine dihydrochloride (OCT) is a promising candidate for use in antiseptic mouth rinses. OCT concentrations of 0.10% are recommended for future clinical trials evaluating the plaque-reducing properties of OCT mouth rinses.

Goel A, Mishra N, Tikku A, and Chandra A (2018)[27] conducted a study to compare the antimicrobial efficacy of 0.2% Octenidine, 2% Chlorhexidine Digluconate, 3% Sodium Hypochlorite and the control (Distilled Water) using the Minimum Inhibitory Concentration(MIC) Test. MIC was performed using 10-fold dilution in 96 U-Well Micro Test plates. The results were tabulated and statistically analyzed using binary statistics. They concluded that 0.2% Octenidine was the most effective in inhibiting E. fecalis, followed by Sodium Hypochlorite, and Chlorhexidine Digluconate was the least successful. Distilled water showed no effect on the gram positive organisms.

Schmidt J et al (2018)[28] conducted a study to compare the cytotoxicity of a new octenidine mouth rinse (MR) on gingival fibroblasts and epithelial cells using

different established MRs. Octenidol (OCT), Chlorhexidine 0.2% (CHX), Meridol (MER), Oral B (OB), and control (PBS only) were used. Human primary gingival fibroblasts (HGFIBs) and human primary nasal epithelial cells (HNEPCs) were cultivated in cell-specific media and treated with an MR or PBS for 1, 5, and 15 min. All tests were performed in duplicate and repeated 12 times. They concluded that the slightly negative effect of OCT considering apoptosis and necrosis of HGFIBs and HNEPCs is nearly the same or even lower compared to the established MRs included in this study. The results confirm that OCT is a potential alternative to CHX.

Tandon V et al (2020)[1] conducted a study to compare the efficacy of 0.1% octenidine dihydrochloride with 0.2% chlorhexidine on dental plaque, gingivitis, stains and taste perception among young adults. A total of 60 were included and randomly divided into two equal groups: Group A was advised to regularly use 0.1% octenidine dihydrochloride mouthwash (twice daily) and brush (twice daily), Group B were advised to regularly use 0.2% chlorhexidine mouthwash (twice daily) and brush (twice daily). He concluded that 0.1% octenidine dihydrochloride is a better mouth rinse than Chlorhexidine.

Jockel-Schneider Y et al. (2021)[29] conducted a study to investigate plaque inhibition of 0.1% octenidine mouthwash (OCT) vs. placebo over 5 days in the absence of mechanical plaque control. For this randomized, placebo-controlled, double-blind, parallel-group, multi-centre phase 3 study, 201 healthy adults were recruited. After baseline recording of plaque index (PI) and gingival index (GI), collection of salivary samples, and dental prophylaxis, subjects were randomly assigned to OCT or placebo mouthwash in a 3:1 ratio. Rinsing was performed twice daily for 30 seconds. Colony-forming units in saliva were determined before and after the first rinse. At day 5, PI, GI, and tooth discolouration index (DI) were assessed. Non-parametric van Elteren tests were applied with a significance level of $p < 0.05$. They concluded that OCT 0.1% mouthwash inhibits plaque formation over 5 days. It therefore can be recommended when regular oral hygiene is temporarily compromised.

Razi M. A. et al (2021)[30] conducted a study to compare two commercially available mouth rinses, 0.2% chlorhexidine gluconate and 0.1% octenidine dihydrochloride for assessing their efficacy as an anti-plaque agent in patients with plaque-induced gingivitis on 45 patients with dental plaque-induced gingivitis, divided into 3 groups of 15 patients each. Clinical parameters viz, Plaque Index, Modified Gingival Index and Gingival Bleeding Index were assessed (day 0,5,10 and 15). He concluded that the antimicrobial and antiplaque efficacy of 0.1% octenidine dihydrochloride containing mouth rinse was comparatively higher than that containing 0.2% chlorhexidine gluconate thereby demonstrating the former's potential usefulness in controlling plaque and gingivitis.

Sadanandan S et al (2021)[2] conducted a study to assess the efficacy of 0.1% octenidine mouthwash as an antiplaque agent and to assess its effect on gingival inflammation and staining of teeth when compared to 0.2% chlorhexidine gluconate by evaluating the impact on plaque and gingival inflammation as well as on microbial load on 69 subjects, aged 20-50 years with moderate to severe gingivitis. Clinical and microbiological parameters were recorded at baseline, on 14th day and on 21st day. Subjective and objective criteria were assessed on the 14th day and 21st day. They concluded that octenidine can be a promising candidate for the use in antiseptic mouthwashes.

MATERIALS AND METHODS

Place of the study where it is conducted: -

A clinical prospective study was carried out in the Department of Periodontics, Babu Banarasi Das College of Dental Sciences (BBDCODS), Lucknow India. Ethical clearance was obtained from the ethical committee of BBDCODS (IEC Code 33); patients fulfilling the following inclusion and exclusion criteria were selected from the OPD of the Periodontology department of BBDCODS.

Study subjects

Systematically healthy individuals based on the inclusion and exclusion criteria to be selected for this study.

Study sample size

A total of 120 patients

- Group I – (Octenidine dihydrochloride) – 30 patients
- Group II – (Chlorhexidine) – 30 patients
- Group III – (Povidone-iodine) – 30 patients
- Group IV – (Cetylpyridinium chloride) – 30 patients

Eligibility criteria

Inclusion criteria

- Age range: ≥ 18 years
- More than 16 natural teeth are present.
- Systemically healthy patients.
- Non-smokers and non-tobacco chewers.
- No history of hypersensitivity to any drugs used in the study.

Exclusion criteria

- Pregnant and lactating females.
- Patients with a history of trauma in the past 6 months.
- Patients wearing orthodontic appliances or removable dentures.

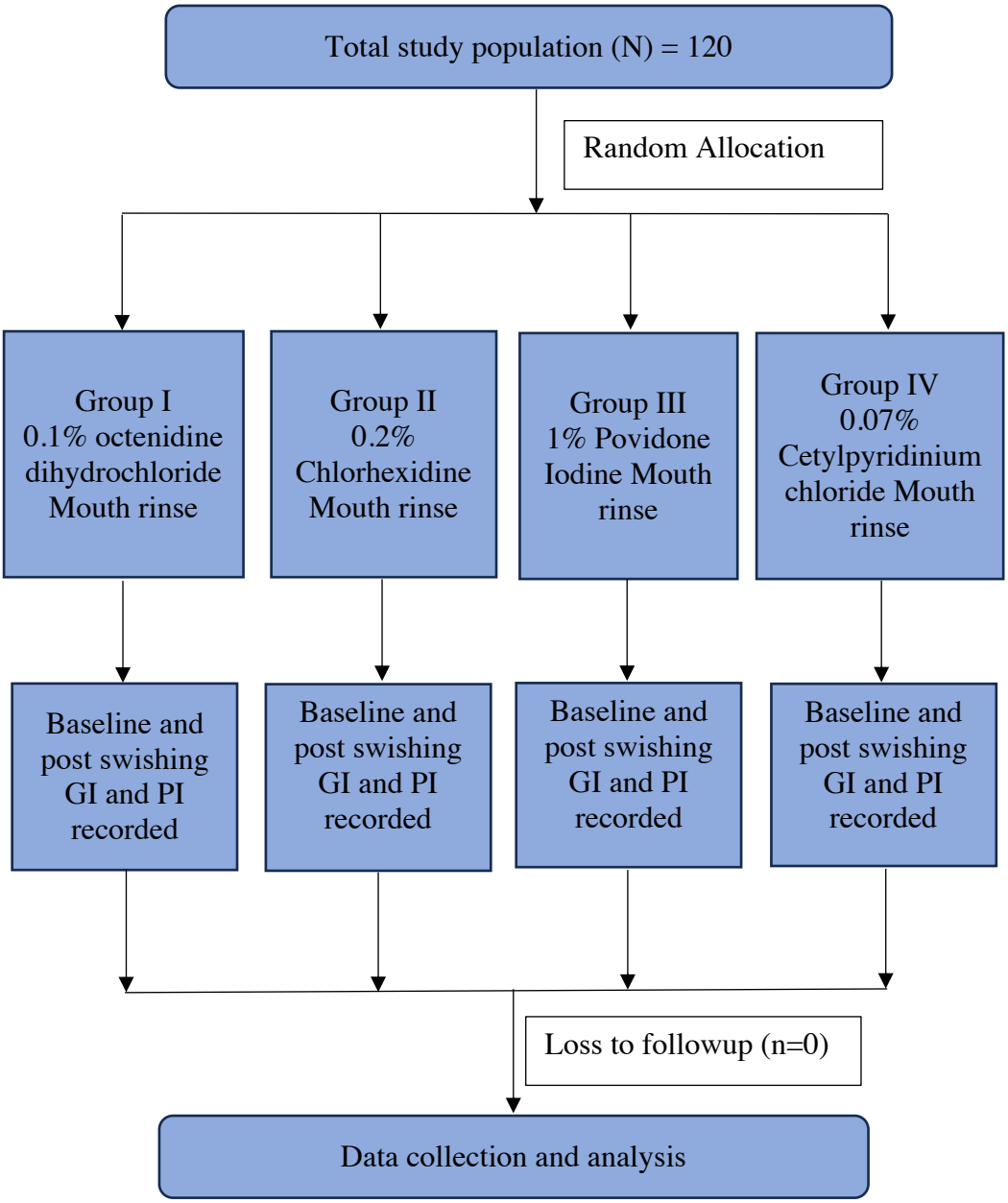
- Patients on antibiotic therapy for the past six months.

Armamentarium:

- Mouth mirror
- UNC-15 Probe (Hu-Friedy®)
- Tweezers
- Explorer
- Pezoelectronic Ultrasonic scaler (Woodpecker).
- High vacuum suction
- Disclosing agent (Alphaplac)
- 0.1% Octenidine dihydrochloride mouthwash (Ora-Hex)
- 0.2% Chlorhexidine mouthwash (Hexidine)
- 1% Povidone-Iodine (Betadine)
- 0.07% Cetylpyridinium chloride (Crest Pro-Health)

Study design

Preparation and formulation:



METHODOLOGY

This clinical prospective study was conducted in the Department of Periodontology, Babu Banarasi Das College of Dental Sciences, Lucknow. A sample size of 120 subjects was selected from the Outpatient Department (OPD) of the Periodontology. The patients were selected based on the inclusion and exclusion criteria. 120 subjects, age-matched, will be randomly divided into four groups:

- Group I – n=30 (patients, who had undergone oral prophylaxis, were advised to regularly use 0.1% octeinidine dihydrochloride mouthwash (twice daily) and brush (twice daily)
- Group II – patients, who had undergone oral prophylaxis, were advised to regularly 0.2% chlorhexidine (CHX) mouthwash (twice daily) and brush (twice daily)
- Group III – patients, who had undergone oral prophylaxis, were advised to regularly 1% povidone-iodine mouthwash (twice daily) and brush (twice daily)
- Group IV – patients, who had undergone oral prophylaxis, were advised to regularly use 0.07% cetylpyridinium chloride mouthwash (twice daily) and brush (twice daily)

On the first day (day 0), plaques were disclosed using a two-tone disclosing solution (Alpha Plac, DPI, Mumbai). For standardization, all participants received a thorough supragingival scaling and root planing using hand instruments and ultrasonic scalers. Subjects were instructed to brush their teeth with a uniform brand of toothpaste and toothbrush by modified Bass technique twice a day and use 10 ml of the provided mouth rinse for one minute (after 30 minutes before brushing) every 12 hours (twice daily) for 21 days. At appropriate time intervals, (day 21) plaque was assessed by disclosing agents. The gingival status was assessed by using Loe and Silness index, Dental Plaque was assessed by using Silness and Loe Index. Plaque index and gingival index were recorded at baseline and after 21 days whereas Modified Lobene stain was

used to record staining of tooth Index at 21 days. A 5-item questionnaire was also used to assess patients self–assessment regarding the taste perception of prescribed mouthwashes.

1. All the clinical parameters (PI, GI and tooth stain) were recorded at the baseline (after scaling and root planing) and after 21 days.

Plaque Index (Silness and Loe)[31]

The Plaque Index (PI) is fundamentally based on the same principle as the Gingival Index, namely the desirability of distinguishing clearly between the severity and the location of the soft debris aggregates. The purpose of introducing this system (Silness and Loe, 1964) was also to create a plaque index which would match the Gingival Index completely.

Criteria for the plaque index system

0 = No plaque in the gingival area.
1 = A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may only be recognized by running a probe across the tooth surface.
2 = Moderate accumulation of soft deposits within the gingival pocket, on the gingival margin and/or adjacent tooth surface, which can be seen by the naked eye.
3 = Abundance of soft matter within the gingival pocket and/or on the gingival margin and adjacent tooth surface.

Each of the four gingival areas of the tooth is given a score from 0-3; this is the PI for the area. The scores from the four areas of the tooth may be added and divided by four to give the PI for the tooth. The scores for individual teeth (incisors, premolars and molars) may be grouped to designate the PI for the groups of teeth. Finally, by adding the indices for the teeth and dividing by the number of teeth examined, the PI for the individual is obtained. PI I = 0 is the score given when the gingival area of the tooth surface is literally free of plaque.

PI I = 1 represents the situation where the gingival area is covered with a thin film of plaque which is not visible, but which is made visible. PI I = 2 is the score given when the deposit is visible in situ PI I = 3 is reserved for the heavy (1-2 mm. thick) accumulation of soft matter.

- **Gingival Index (Loe and Silness)**[31]

The gingival index (GI), a tool for evaluating the intensity and scope of gingival inflammation in both individuals and subjects within sizable demographic groupings, was first proposed in 1963. The GI just evaluates the gingival tissues. Each of the four gingival regions of the tooth—the face, mesial, distal, and lingual—is examined for inflammation using this procedure, and the degree of inflammation is quantified by assigning each area a score between 0 and 3. A periodontal probe is used to examine bleeding by moving it over the gingival crevice's soft tissue wall. To determine the tooth score, add the scores for the four tooth locations and divide the result by 4. By adding the tooth scores together and dividing by the number of teeth examined, an individual's GI score can be obtained.

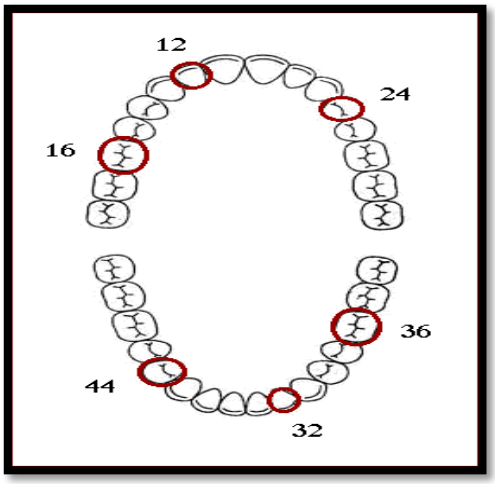


Figure- 5 Index Teeth

Surfaces examined on each Tooth: -Four gingival areas, i.e. distofacial, facial, mesiofacial and lingual surfaces are examined.

Scores and Criteria for Gingival Index (GI)

0 = Normal gingiva.

1 = Mild inflammation: slight change in color and slight edema; no bleeding on probing.

2 = Moderate inflammation: redness, edema, and glazing; bleeding on probing.

3=Severe inflammation: marked redness and edema; ulceration; tendency to spontaneous bleeding.

Interpretation: 0.1 - 1.0: Mild gingivitis
1.1 – 2.0: Moderate gingivitis
2.1 – 3.0: Severe gingivitis

Modified Lobene stain Index[32]

Stain was recorded using 2 separate characteristics, namely intensity and area (extent) as suggested by Lobene (1968). The criteria for these 2 parameters were also slightly modified to provide better discrimination at the lower end of the scale and to take account of anatomical differences between the different sites.

The criteria and codes for intensity were:

0 = no stain present, natural tooth colouration

1 = faint stain

2 = clearly visible stain, orange and brown

3 = dark stain, deep brown to black

The area (extent) of the stain was recorded only if an intensity score of 2 or 3 was given.

The area criteria and codes for approximal and gingival sites were:

1 = thin line, can be continuous

2 = thick line or band

3 = covering total area

The area criteria and codes for the body of the tooth are shown below and differed between the buccal/labial and lingual/palatal surfaces due to the normal difference in surface distribution of stain between these sites.

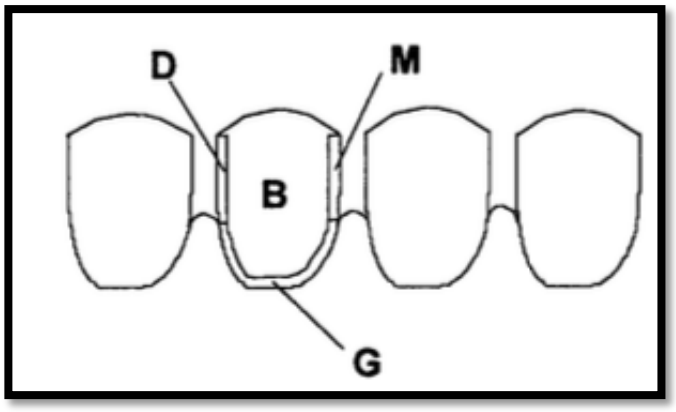
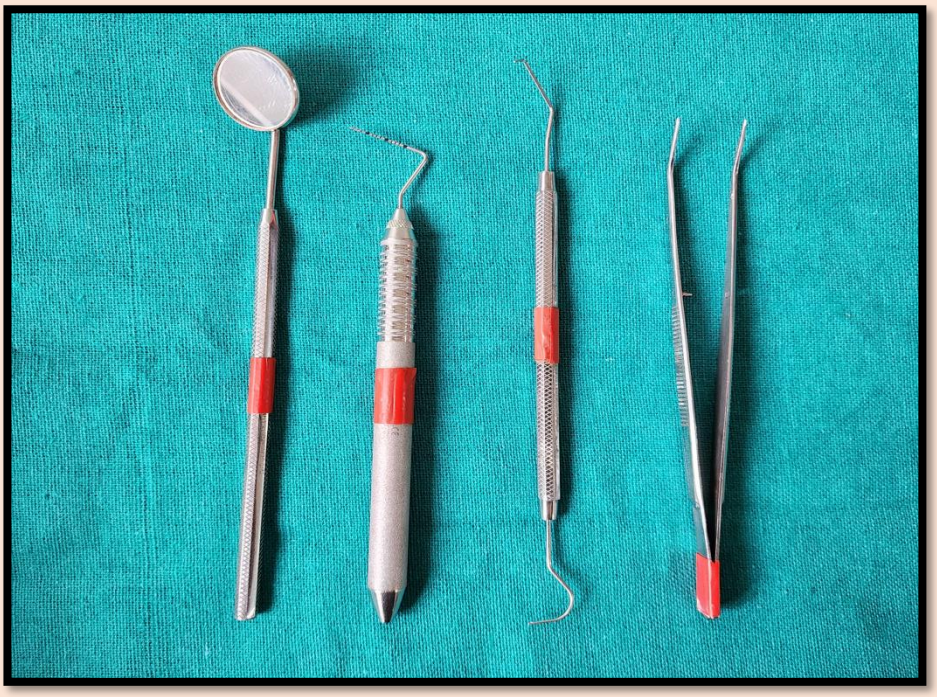


Figure 6: The Stain Sites of a Lower Anterior Tooth: Body (B), Gingival (G), Mesial (M) and Distal (D).

CODE	Buccal/labial surfaces	Lingual/palatal surfaces
1	stain limited to pits/grooves	up to 1/3 of area affected
2	stain outside pits/ grooves, up to 10% of area affected	between 1/3 and 2/3 of area affected
3	stain outside pits/ grooves, more than 10% of area affected	more than 2/3 of area affected

Before scoring, the examiner cleaned the index teeth with a soft toothbrush and water to remove any plaque and food debris. The index teeth were then dried using a chair-side air syringe and kept dry throughout the examination. A stain assessment was made without the aid of a magnifying glass. Only stain on natural tooth surfaces was recorded and staining in or adjacent to restoration margins was ignored.



PHOTOGRAPH 1: DIAGNOSTIC INSTRUMENTS

PHOTOGRAPH 2: DISCLOSING AGENTS

PHOTOGRAPH 3: 0.1% OCTENIDINE DIHYDROCHLORIDE (ORAHEX PRO)

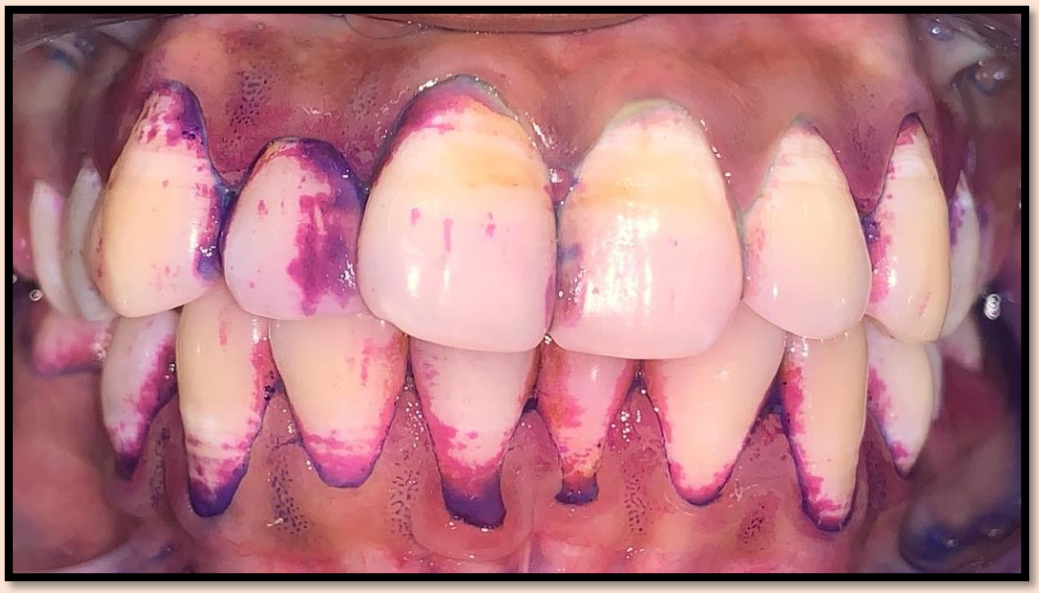
PHOTOGRAPH 4: 0.2% CHLORHEXIDINE (HEXIDINE)

PHOTOGRAPH 5: 1% POVIDONE-IODINE

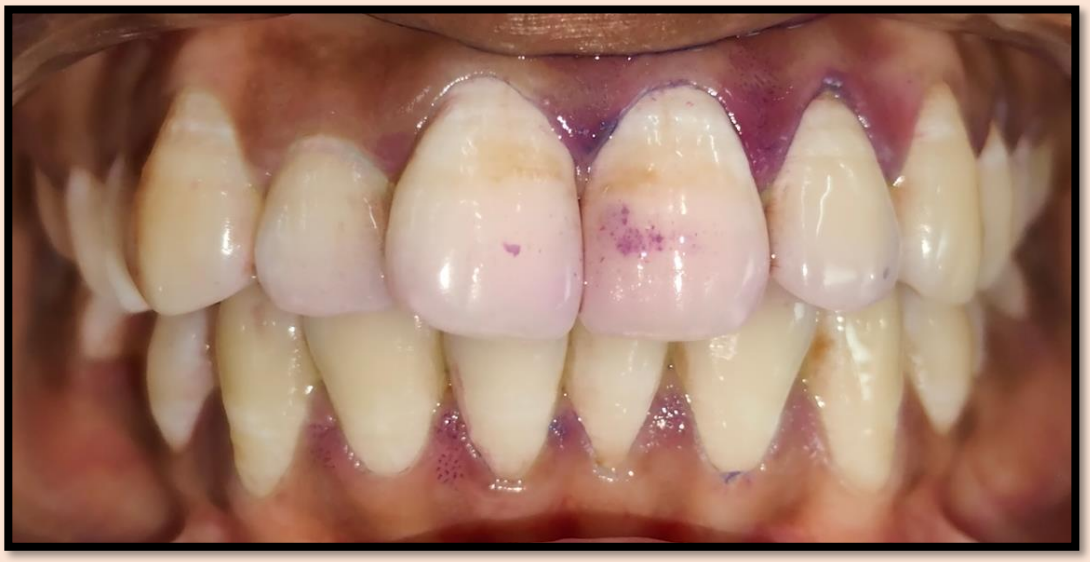
PHOTOGRAPH 6: 0.07% CETYLPYRIDINIUM CHLORIDE

PHOTOGRAPH 7: PEZOELECTRONIC ULTRASONIC SCALER (WOODPECKER)

GROUP I: 0.1% OCTENIDINE DIHYDROCHLORIDE MOUTHWASH

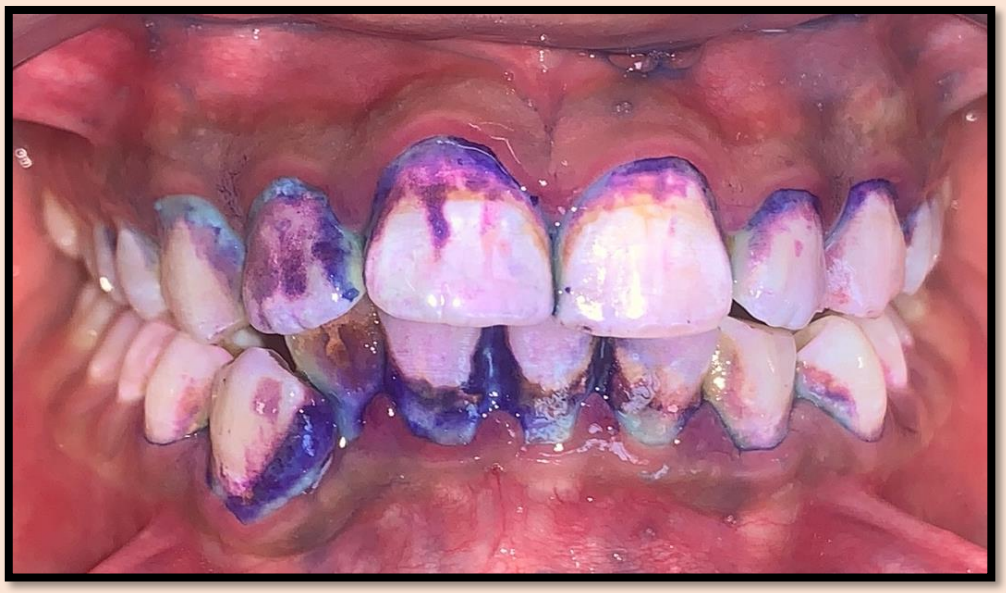


Photograph 8: Application of disclosing agent before phase I therapy (at baseline)

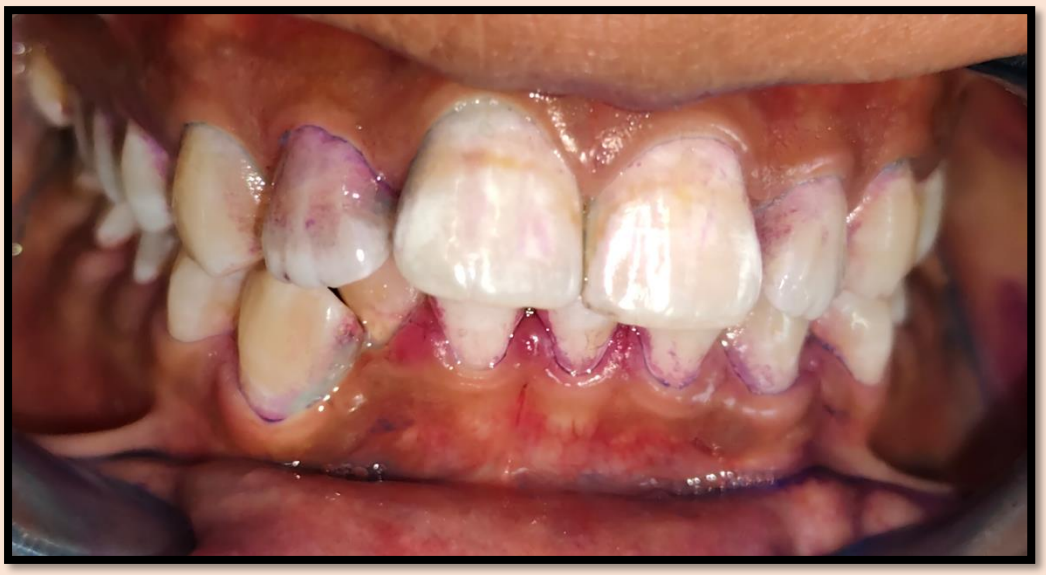


Photograph 9: Application of disclosing agent after 21 days

GROUP II: 0.2% CHLORHEXIDINE MOUTHWASH

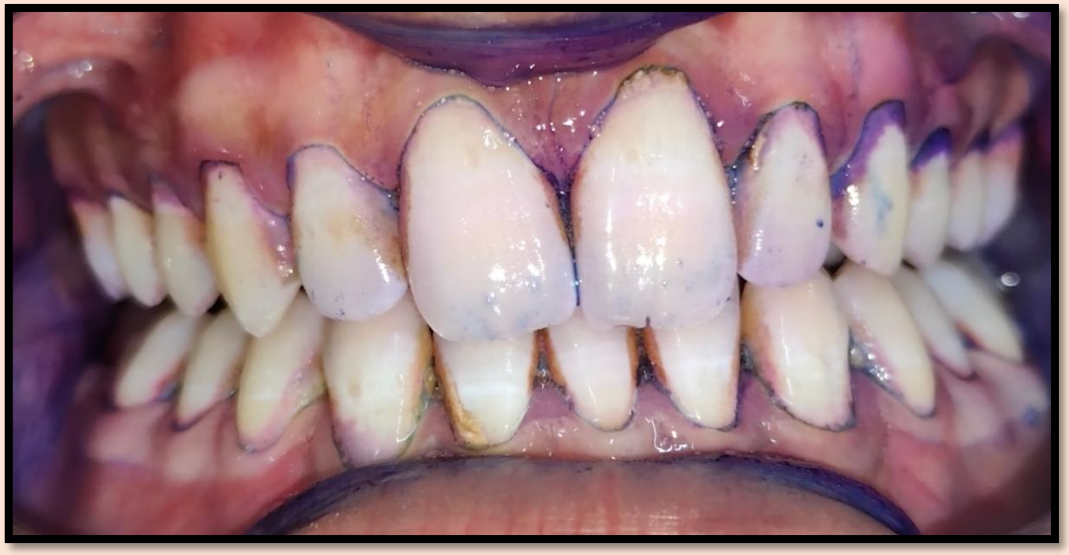


Photograph 10: Application of disclosing agent before phase I therapy (at baseline)

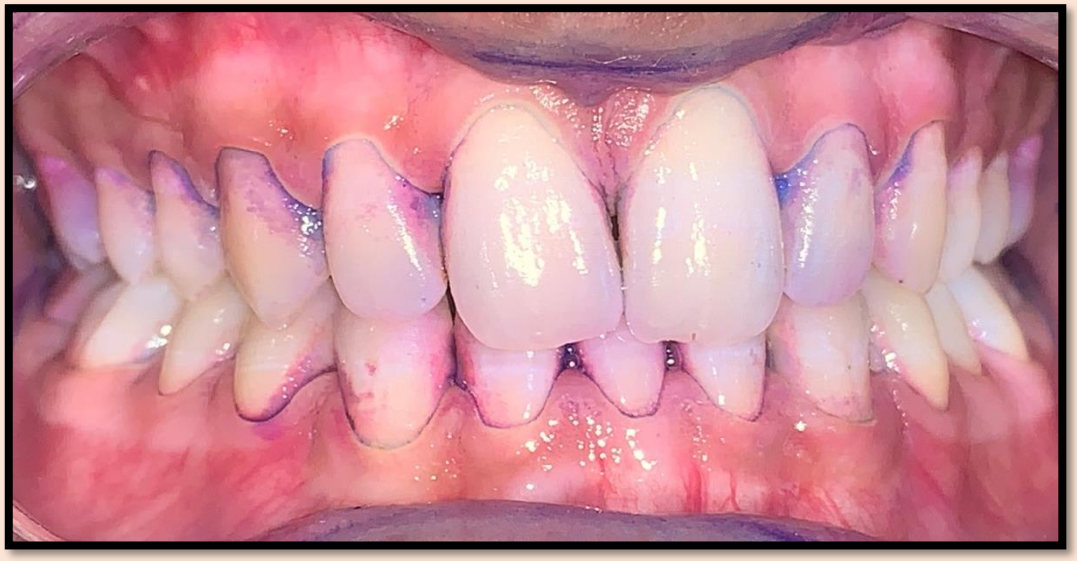


Photograph 11: Application of disclosing agent after 21 days

GROUP III: 1% POVIDONE-IODINE MOUTHWASH

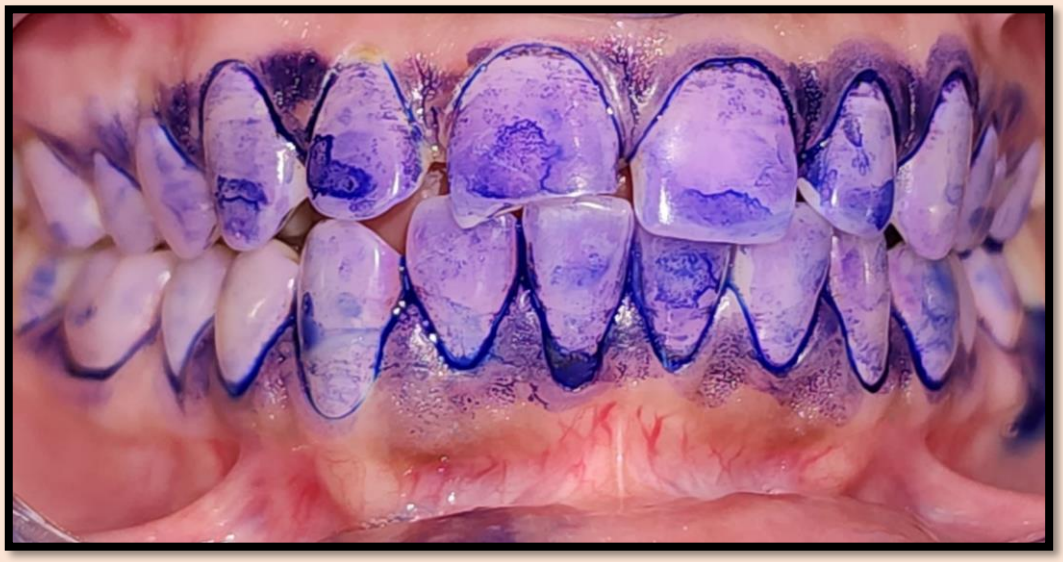


Photograph 12: Application of disclosing agent before phase I therapy (at baseline)

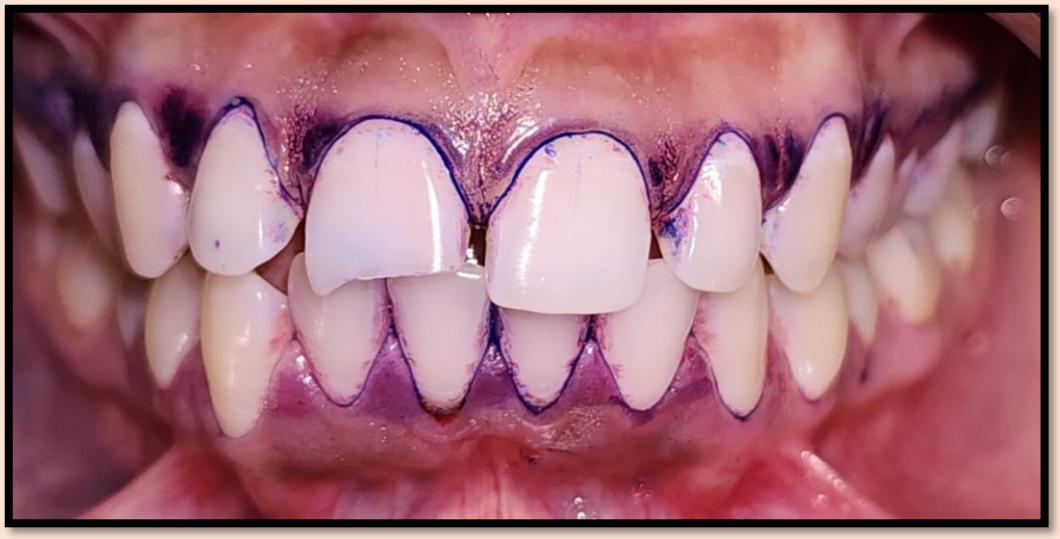


Photograph 13: Application of disclosing agent after 21 days

GROUP IV: 0.07% CETYLPYRIDINIUM CHLORIDE MOUTHWASH



Photograph 14: Application of disclosing agent before phase I therapy (at baseline)



Photograph 15: Application of disclosing agent after 21 days

OBSERVATIONS AND RESULTS

INTERGROUP COMPARISON OF PLAQUE INDEX BETWEEN THE GROUPS AT BASELINE AND 21 DAYS

The mean plaque score in Group I at the baseline was 2.430, in Group II was 2.156, in Group III was 2.163 and in Group IV was 2.086. The intergroup comparison between the four groups was statistically non-significant at baseline when analysed using One-way ANOVA (p=0.065). The post hoc analysis revealed a non-significant difference in the plaque scores between all four groups.

At 21-day time intervals, the mean plaque score was highest in Group IV (0.363), followed by Group III (0.216) and least in Group I (0.140). The intergroup comparison between the four groups was statistically significant at 21 days when analysed using One-way ANOVA (p=0.001). The post hoc analysis revealed a significant difference in the plaque scores between all four groups.

		Mean	Std. Deviation	Std. Error	Minimum	Maximum	P value
Baseline	Group I	2.430	.27687	.05055	2.00	2.90	0.065 (Non-Sig)
	Group II	2.156	.28246	.05157	1.60	2.70	
	Group III	2.163	.47233	.08623	1.30	2.90	
	Group IV	2.086	.37300	.06810	1.50	2.80	
21 Days	Group I	0.140	0.049	0.009	.10	.20	0.001 (Sig)
	Group II	0.186	0.050	0.009	.10	.30	
	Group III	0.216	0.087	0.015	.10	.40	
	Group IV	0.363	0.088	0.016	.20	.50	

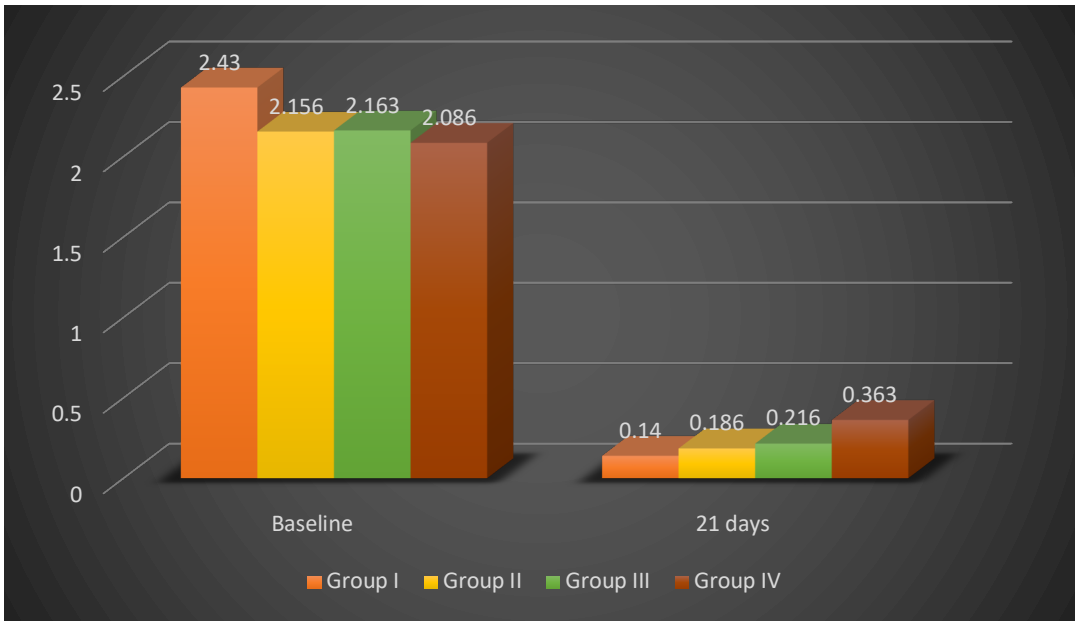
Table 1: Intergroup comparison of plaque index between the groups at baseline and 21 day

Post Hoc Intergroup comparison of Plaque Index scores

		Mean Diff	Std Error	P value	Significance
Baseline	Group I vs Group II	.27333*	.09297	.064	Non-Significant
	Group I vs Group III	.26667*	.09297	.065	Non-Significant
	Group I vs Group IV	.34333*	.09297	0.056	Non-Significant
	Group II vs Group III	-.00667	.09297	.943	Non-Significant
	Group II vs Group IV	.07000	.09297	.453	Non-Significant
	Group III vs Group IV	.07667	.09297	.411	Non-Significant
21 Days	Group I vs Group II	-.04667*	.01854	.013	Significant
	Group I vs Group III	-.07667*	.01854	.000	Significant
	Group I vs Group IV	-.22333*	.01854	.000	Significant

	Group II vs Group III	-.03000	.01854	.018	Significant
	Group II vs Group IV	-.17667*	.01854	.000	Significant
	Group III vs Group IV	-.14667*	.01854	.000	Significant

Table 2: Post Hoc Intergroup comparison of Plaque Index scores



Graph 1: Intergroup comparison of plaque index between the groups at baseline and 21 days.

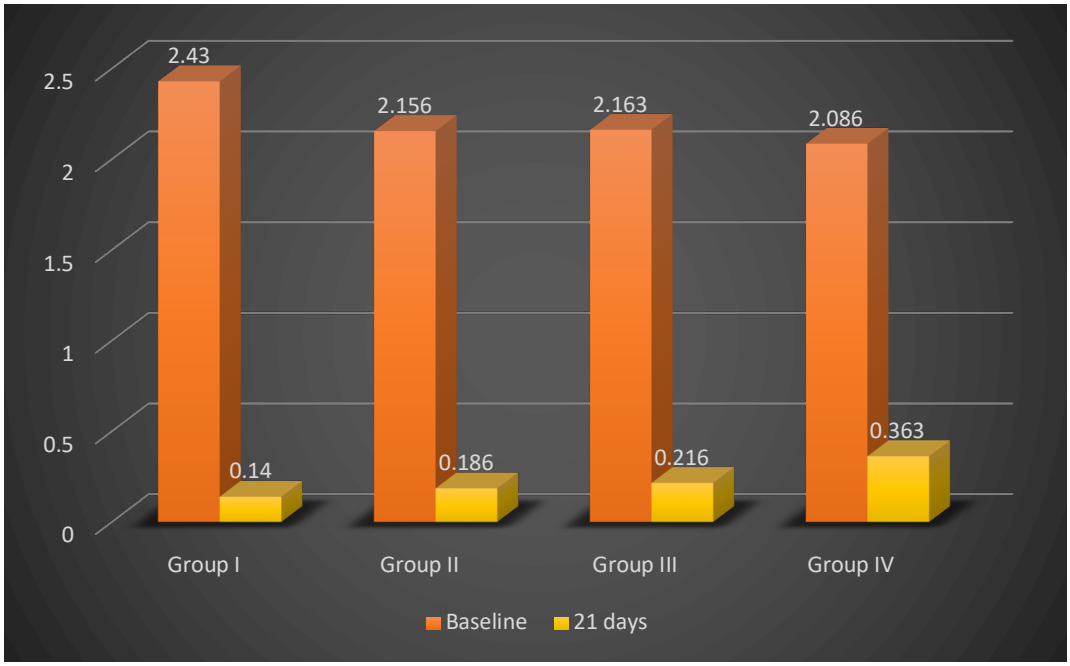
INTRAGROUP COMPARISON OF PLAQUE SCORES BETWEEN BASELINE AND 21 DAYS IN ALL THE GROUPS

The mean plaque score in Group I at the baseline was 2.430, in Group II was 2.156, in Group III was 2.163 and in Group IV was 2.086. At 21 days' time interval, the mean plaque score was highest in Group IV (0.363), followed by Group III (0.216) and least in Group I (0.140). The intragroup comparison between baseline and 21 days was statistically significant in all four groups.

		Baseline		21 Day		
		Mean	Std. Deviation	Mean	Std. Deviation	P value
Groups	Group I	2.430	0.276	0.140	0.049	0.001 (Sig)
	Group II	2.156	0.282	0.186	0.050	0.001 (Sig)
	Group III	2.163	0.472	0.216	0.087	0.001 (Sig)
	Group IV	2.086	0.373	0.363	0.088	0.001 (Sig)

Paired t-test with p value less than 0.05 is significant.

Table 3: Intragroup comparison of plaque scores between baseline and 21 days in all the groups



Graph 2: Intragroup comparison of plaque scores between baseline and 21 days in all the groups.

INTERGROUP COMPARISON OF GINGIVAL INDEX BETWEEN THE GROUPS AT BASELINE AND 21 DAYS

The mean gingival score in Group I at the baseline was 1.993, in Group II was 1.866, in Group III was 1.973 and in Group IV was 1.870. The intergroup comparison between the four groups was statistically non-significant at baseline when analysed using One-way ANOVA (p=0.622). The post hoc analysis revealed a non-significant difference in the gingival scores between all four groups.

At 21-day time intervals, the mean gingival score was highest in Group IV (0.343), followed by Group III (0.240) and least in Group I (0.146). The intergroup comparison between the four groups was statistically significant at 21 days when analysed using One Way ANOVA (p=0.001). The post hoc

analysis revealed a significant difference in the gingival scores between all four groups.

		Mean	Std. Deviation	Std. Error	Minimum	Maximum	P value
Baseline	Group I	1.993	0.514	0.093	1.30	2.90	0.622 (Non-Sig)
	Group II	1.866	0.433	0.079	1.10	2.60	
	Group III	1.973	0.477	0.087	1.10	2.80	
	Group IV	1.870	0.477	0.087	1.10	2.90	
21 Days	Group I	0.146	0.050	0.009	0.10	0.20	0.001 (Sig)
	Group II	0.180	0.071	0.013	0.10	0.30	
	Group III	0.240	0.077	0.014	0.10	0.40	
	Group IV	0.343	0.100	0.018	0.20	0.50	

One Way ANOVA with p value less than 0.05 is significant.

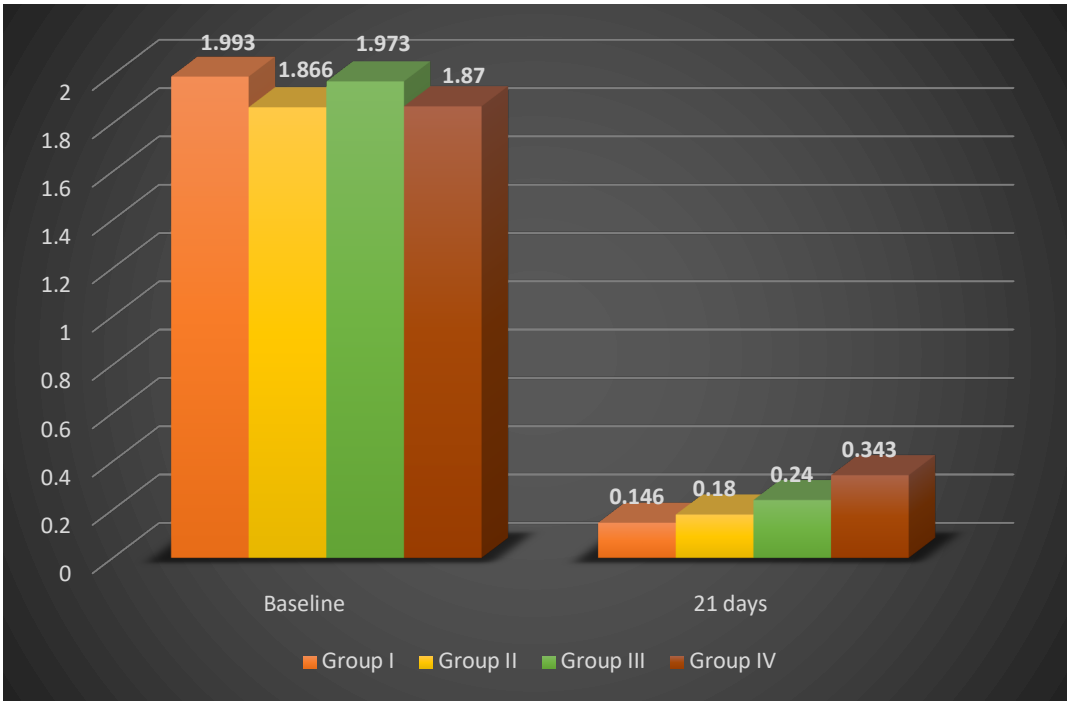
Table 4: Intergroup comparison of gingival index between the groups at baseline and 21 days.

Post Hoc Intergroup comparison of Gingival Index scores

		Mean Diff	Std Error	P value	Significance
Baseline	Group I vs Group II	.12667	.12310	.306	Non-Significant
	Group I vs Group III	.02000	.12310	.871	Non-Significant
	Group I vs Group IV	.12333	.12310	.318	Non-Significant
	Group II vs Group III	-.10667	.12310	.388	Non-Significant
	Group II vs Group IV	-.00333	.12310	.978	Non-Significant
	Group III vs Group IV	.10333	.12310	.403	Non-Significant
21 Days	Group I vs Group II	-.03333	.01989	.046	Significant
	Group I vs Group III	-.09333*	.01989	.000	Significant
	Group I vs Group IV	-.19667*	.01989	.000	Significant

	Group II vs Group III	-.06000*	.01989	.003	Significant
	Group II vs Group IV	-.16333*	.01989	.000	Significant
	Group III vs Group IV	-.10333*	.01989	.000	Significant

Table 5: Post Hoc Intergroup comparison of Gingival Index scores.



Graph 3: Intergroup comparison of gingival index between the groups at baseline and 21 days

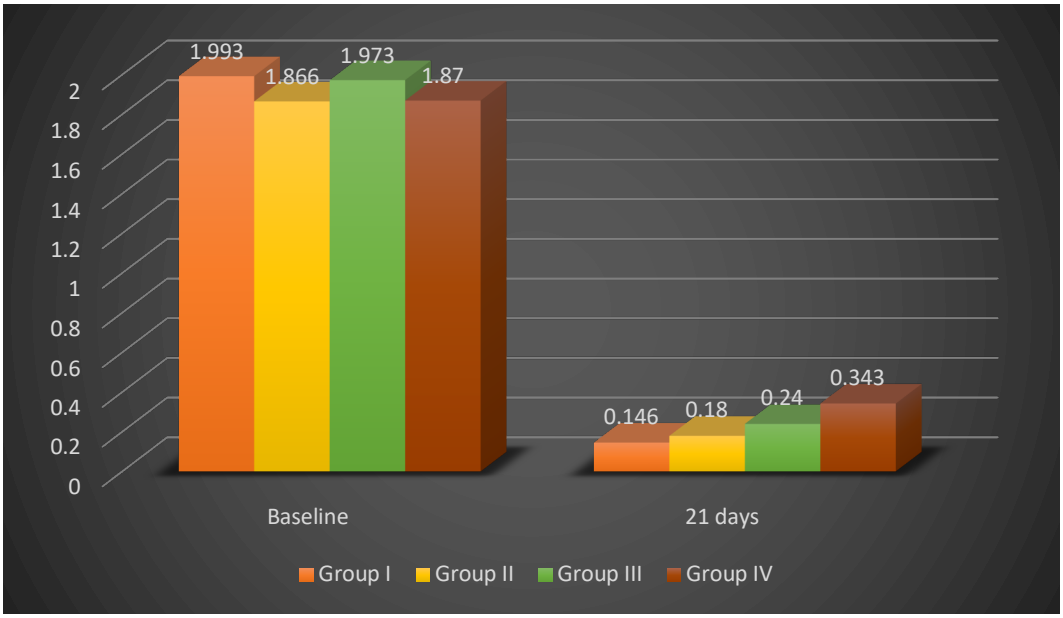
INTRAGROUP COMPARISON OF GINGIVAL SCORES BETWEEN BASELINE AND 21 DAYS IN ALL THE GROUPS

The mean gingival score in Group I at the baseline was 1.993, in Group II was 1.866, in Group III was 1.973 and in Group IV was 1.870. At 21-day time intervals, the mean gingival score was highest in Group IV (0.343), followed by Group III (0.240) and least in Group I (0.146). The intragroup comparison between baseline and 21 days was statistically significant in all four groups.

		Baseline		21 Day		
		Mean	Std. Deviation	Mean	Std. Deviation	P value
Baseline	Group I	1.993	0.514	0.146	0.050	0.001 (Sig)
	Group II	1.866	0.433	0.180	0.071	0.001 (Sig)
	Group III	1.973	0.477	0.240	0.077	0.001 (Sig)
	Group IV	1.870	0.477	0.343	0.100	0.001 (Sig)

Paired t-test with p value less than 0.05 is significant.

Table 6: Intragroup comparison of gingival scores between baseline and 21 days in all the groups.



Graph 4: Intragroup comparison of gingival scores between baseline and 21 days in all the groups

INTERGROUP COMPARISON OF MODIFIED LOBENE STAIN INDEX BETWEEN THE GROUPS AT BASELINE AND 21 DAYS

The mean Modified Lobene Stain Index score in Group I, Group II, Group III and Group IV at the baseline was 0.00 The intergroup comparison between the four groups was statistically non-significant at baseline when analysed using One Way ANOVA (p=0.622). The post hoc analysis revealed a non-significant difference in the plaque scores between all four groups.

At 21-day time intervals, the mean Modified Lobene Stain Index score was highest in Group IV (1.133), followed by Group III (0.866) and least in Group I (0.066). The intergroup comparison between the four groups was statistically significant at 21 days when analysed using One-way ANOVA (p=0.001). The post hoc analysis revealed significant differences in the Modified Lobene Stain Index score scores between all four groups except for Group II and Group III where the difference was statistically non-significant.

		Mean	Std. Deviation	Std. Error	Minimum	Maximum	P value
Baseline	Group I	0.000	0.000	0.000	0.000	0.000	1.000 (Non-Sig)
	Group II	0.000	0.000	0.000	0.000	0.000	
	Group III	0.000	0.000	0.000	0.000	0.000	
	Group IV	0.000	0.000	0.000	0.000	0.000	
21 Days	Group I	0.066	0.253	0.046	.00	1.00	0.001 (Sig)
	Group II	0.866	0.571	0.104	.00	2.00	
	Group III	0.866	0.681	0.124	.00	2.00	
	Group IV	1.133	0.681	0.124	.00	2.00	

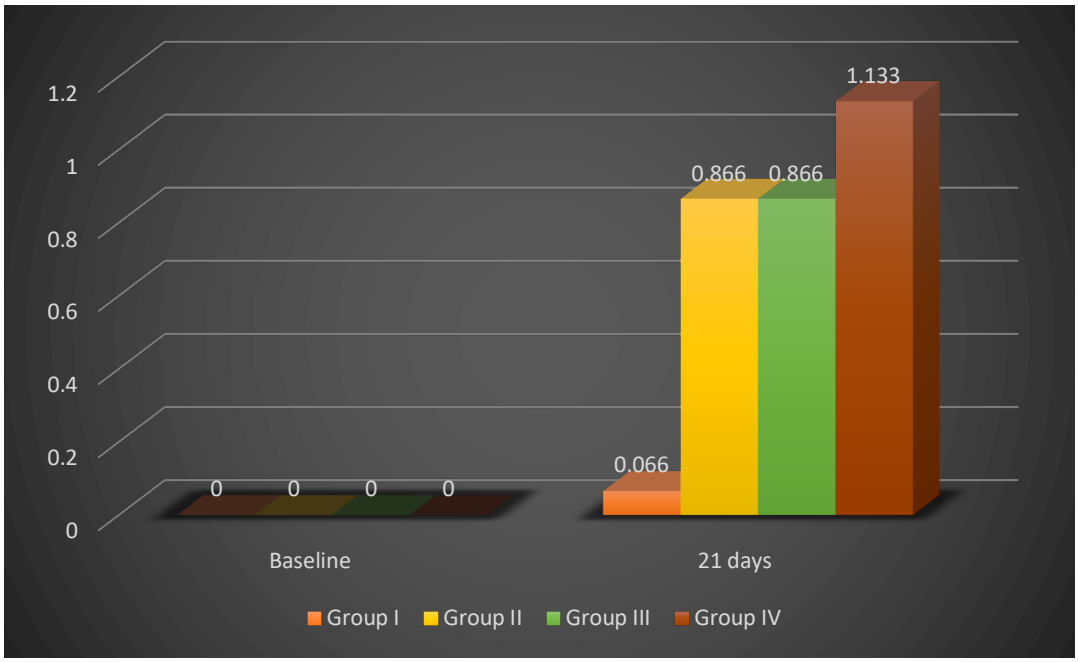
One Way ANOVA with p value less than 0.05 is significant.

Table 7: Intergroup comparison of Modified Lobene stain index between the groups at baseline and 21 days.

Post Hoc Intergroup comparison of Modified Lobene Stain Index scores

		Mean Diff	Std Error	P value	Significance
21 Days	Group I vs Group II	-.80000*	.14830	.000	Significant
	Group I vs Group III	-.80000*	.14830	.000	Significant
	Group I vs Group IV	-1.06667*	.14830	.000	Significant
	Group II vs Group III	.00000	.14830	1.000	Non-Significant
	Group II vs Group IV	-.26667	.14830	0.045	Significant
	Group III vs Group IV	-.26667	.14830	0.045	Significant

Table 8: Post Hoc Intergroup comparison of Modified Lobene Stain Index scores.



Graph 5: Intergroup comparison of Modified Lobene stain index between the groups at baseline and 21 days

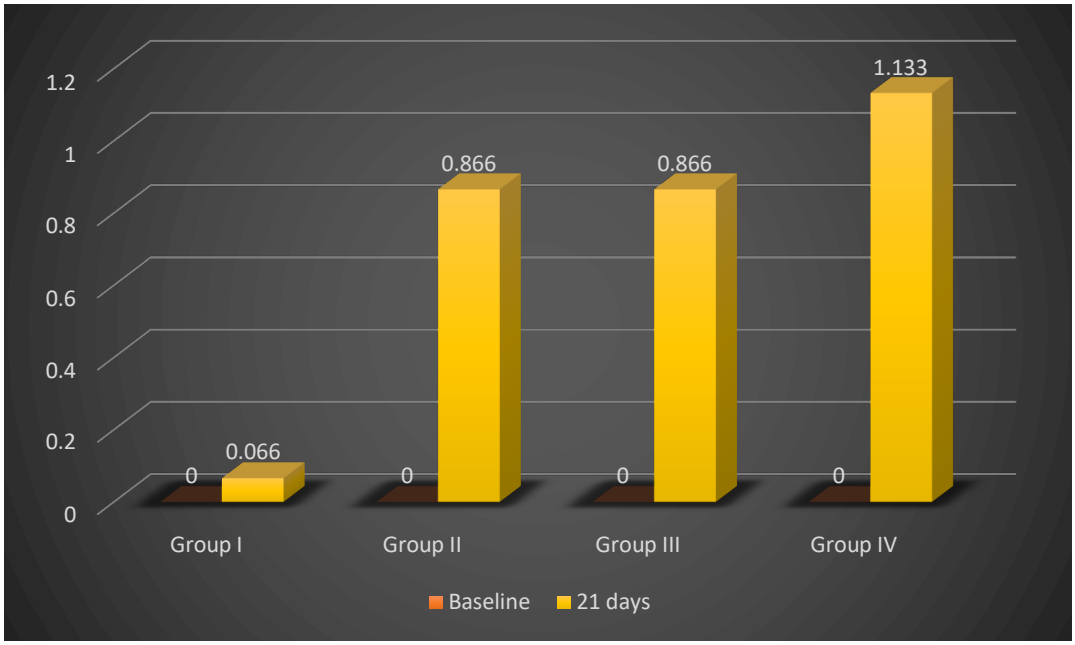
INTRAGROUP COMPARISON OF MODIFIED LOBENE STAIN BETWEEN BASELINE AND 21 DAYS IN ALL THE GROUPS

The mean Modified Lobene Stain Index score in Group I, Group II, Group III and Group IV at the baseline was 0.00 At a 21-days time interval, the mean Modified Lobene Stain Index score was highest in Group IV (1.133), followed by Group III (0.866) and least in the Group I (0.066). The intragroup comparison between baseline and 21 days was statistically significant in all four groups.

		Baseline		21 Day		
		Mean	Std. Deviation	Mean	Std. Deviation	P value
Baseline	Group I	0.000	0.000	0.066	0.253	0.001 (Sig)
	Group II	0.000	0.000	0.866	0.571	0.001 (Sig)
	Group III	0.000	0.000	0.866	0.681	0.001 (Sig)
	Group IV	0.000	0.000	1.133	0.681	0.001 (Sig)

Paired t-test with p value less than 0.05 is significant.

Table 9: Intragroup comparison of Modified Lobene stain between baseline and 21 days in all the groups.



Graph 6: Intragroup comparison of Modified Lobene stain between baseline and 21 days in all the groups

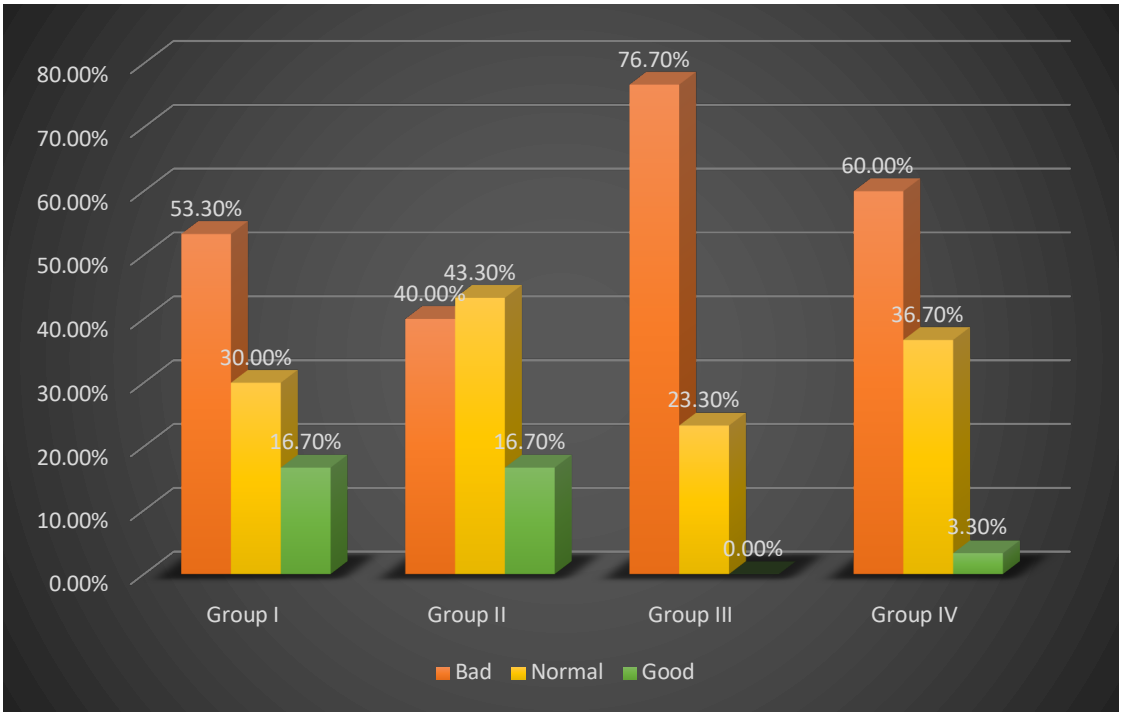
INTERGROUP COMPARISON OF TASTE OF PRODUCT BETWEEN THE GROUPS AT BASELINE AND 21 DAYS

In Group I (0.1% Octenidine Dihydrochloride) 53.3% experienced bad taste, 30% experienced normal taste and 16.7% experienced good taste. In Group II (0.2% chlorhexidine) 40% experienced bad taste, 43.3% experienced normal taste and 16.7% experienced good taste. In Group III (1% Povidone-Iodine) 76.7% experienced bad taste, 23.3% experienced normal taste and none of the subjects experienced good taste. In Group IV (0.07% Cetylpyridinium Chloride), 60.0% experienced bad taste, 36.7% experienced normal taste and 3.3% of the subjects experienced good taste. The intergroup comparison between the groups was statistically significant with a p-value of 0.001.

	Bad	Normal	Good	Chi Square value	P value
Group I	16	9	5	351.73	0.001 (Sig)
	53.3%	30.0%	16.7%		
Group II	12	13	5		
	40.0%	43.3%	16.7%		
Group III	23	7	0		
	76.7%	23.3%	.0%		
Group IV	18	11	1		
	60.0%	36.7%	3.3%		

Chi-Square test with p value less than 0.05 is significant.

Table 10: Intergroup comparison of taste of product between the groups at baseline and 21 days



Graph 7: Intergroup comparison of taste of product between the groups at baseline and 21 days

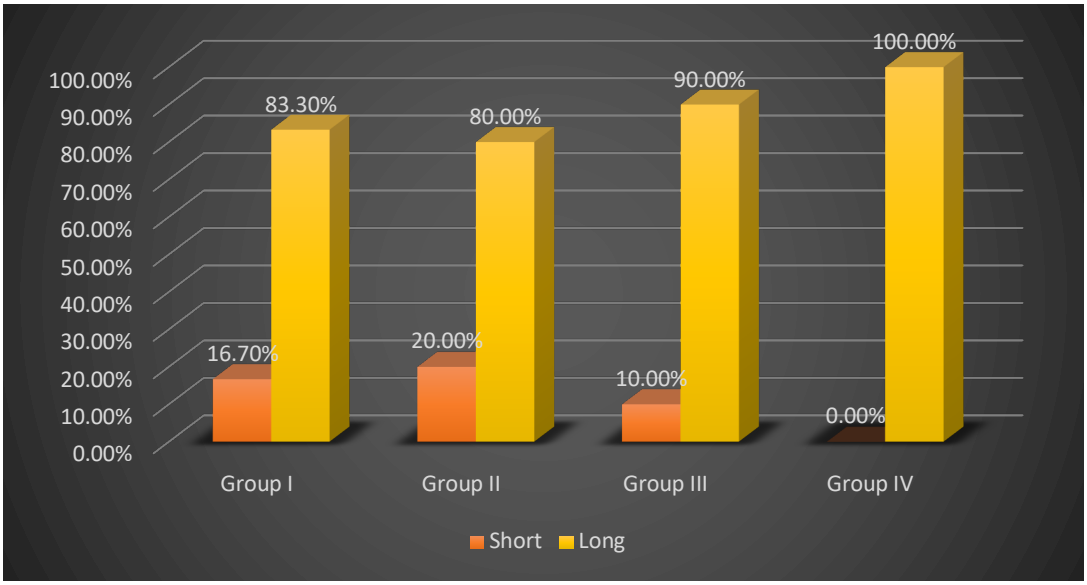
INTERGROUP COMPARISON OF DURATION OF THE TASTE BETWEEN THE GROUPS AT BASELINE AND 21 DAYS

In Group I (0.1% Octenidine Dihydrochloride) 83.3% experienced a bad taste for a long duration, In Group II (0.2% chlorhexidine) 80% experienced a bad taste for a long duration In Group III (1% Povidone-Iodine) 90.0% experienced bad taste for long duration In the Group IV (0.07% Cetylpyridinium Chloride), 100.0% experienced bad taste, for long duration. The intergroup comparison between the groups was statistically significant with a p-value of 0.043.

	Short	Long	Chi Square value	P value
Group I	5	25	6.782	0.043 (Sig)
	16.7%	83.3%		
Group II	6	24		
	20.0%	80.0%		
Group III	3	27		
	10.0%	90.0%		
Group IV	0	30		
	.0%	100.0%		

Chi-Square test with p value less than 0.05 is significant.

Table 11: Intergroup comparison of duration of the taste between the groups at baseline and 21 days



Graph 8: Intergroup comparison of duration of the taste between the groups at baseline and 21 days.

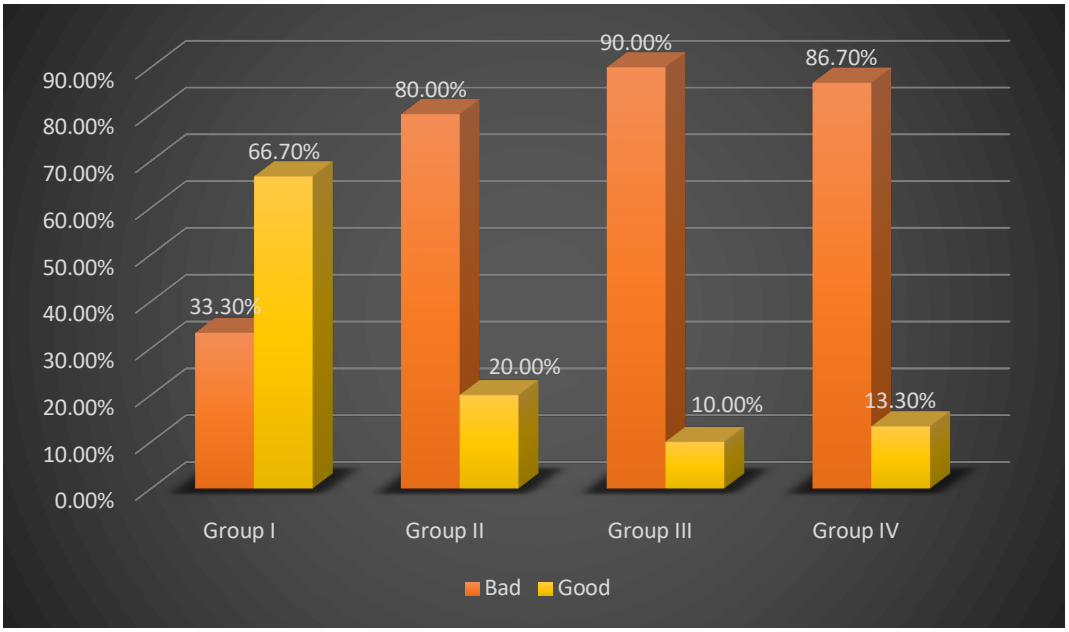
INTERGROUP COMPARISON OF EFFECT OF TASTE ON FOOD AND DRINK BETWEEN THE GROUPS

The effect of taste on the food was bad in 33.3% of the subjects in Group I (0.1% Octenidine Dihydrochloride), in 80% of the subjects in Group II (0.2% chlorhexidine), in 90% of the subjects in Group III (1% Povidone-Iodine) and 86.7% of the subjects in the Group IV (0.07% Cetylpyridinium Chloride). The difference between the groups was statistically significant between Group I and all other groups.

	Bad	Good	Chi Square value	P value
Group I	10	20	31.782	0.001 (Sig)
	33.3%	66.7%		
Group II	24	6		
	80.0%	20.0%		
Group III	27	3		
	90.0%	10.0%		
Group IV	26	4		
	86.7%	13.3%		

Chi-Square test with p value less than 0.05 is significant.

Table 12: Intergroup comparison of effect of taste on food and drink between the groups



Graph 9: Intergroup comparison of effect of taste on food and drink between the groups.

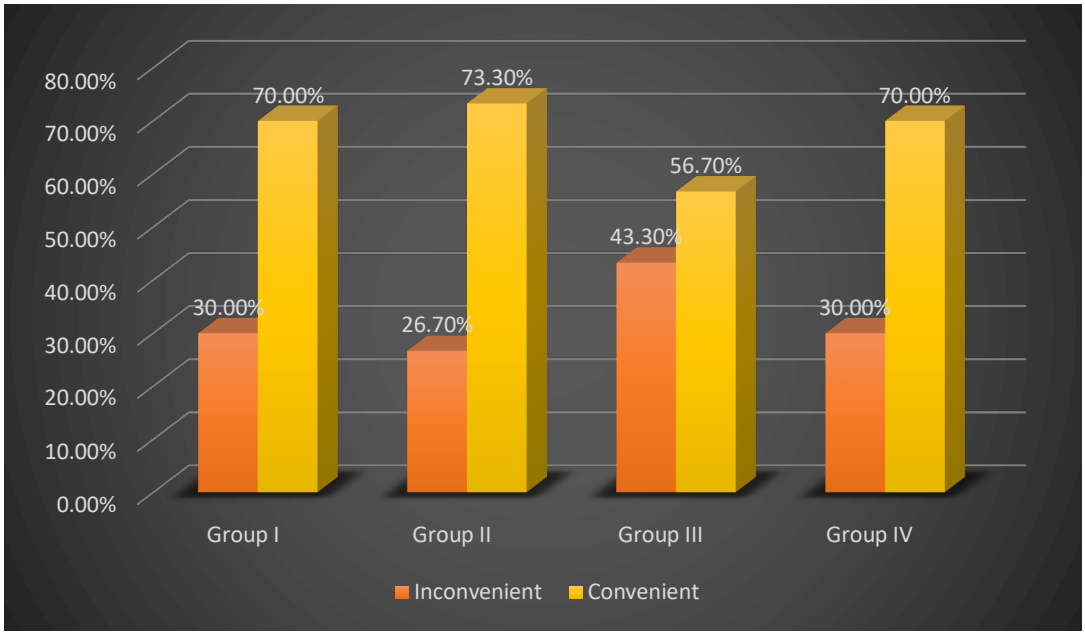
INTERGROUP COMPARISON OF CONVENIENCE BETWEEN THE GROUPS

In Group I -30% of the subjects felt inconvenienced while using, in Group II, 26.7% of the subjects felt inconvenienced, in Group III-43.3% of the subjects felt inconvenient and in Group IV 30% of the subjects felt inconvenienced in usage. The difference between the groups was statistically non-significant when analysed using the Chi-Square test with a p-value of 0.542.

	Inconvenient	Convenient	Chi Square value	P value
Group I	9	21	2.241	0.542 (Non-Sig)
	30.0%	70.0%		
Group II	8	22		
	26.7%	73.3%		
Group III	13	17		
	43.3%	56.7%		
Group IV	9	21		
	30.0%	70.0%		

Chi-Square test with p value less than 0.05 is significant.

Table 13: Intergroup comparison of convenience between the groups



Graph 10: Intergroup comparison of convenience between the groups

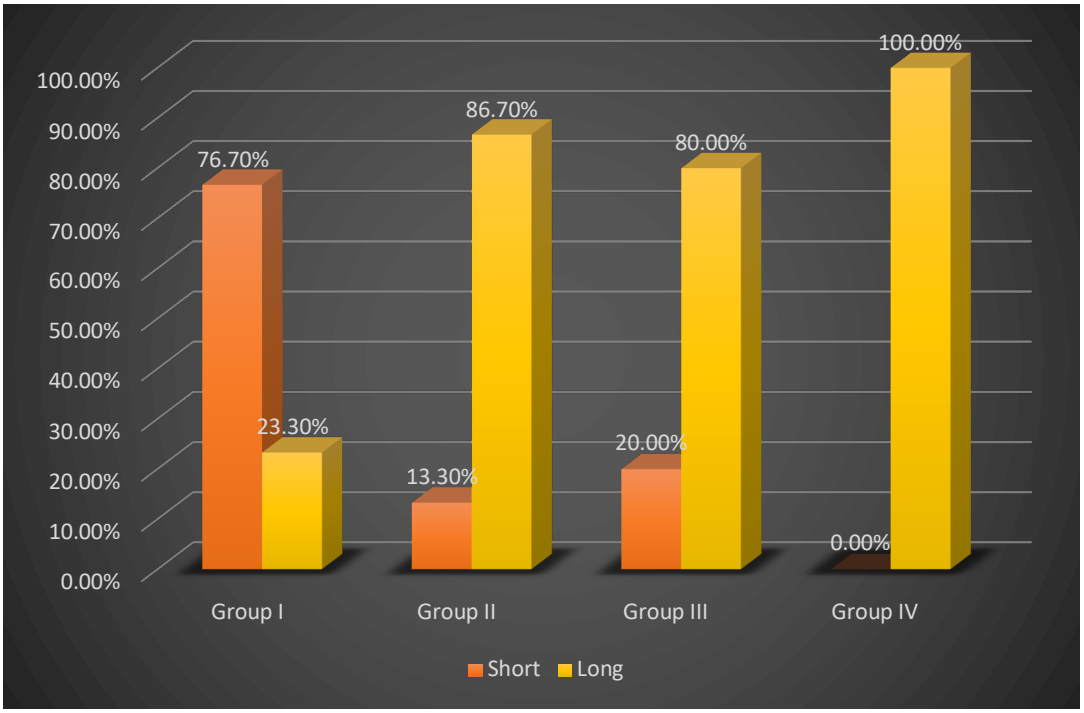
INTERGROUP COMPARISON OF RINSING TIME BETWEEN THE GROUPS

The rinsing time for Group I was short in 76.7% of the subjects and long in Group II (86.7%), Group III (80%) and Group IV (100%). The difference between the groups was statistically significant when analysed using Chi-square test.

	Short	Long	Chi Square value	P value
Group I	23	7	51.624	0.001 (Sig)
	76.7%	23.3%		
Group II	4	26		
	13.3%	86.7%		
Group III	6	24		
	20.0%	80.0%		
Group IV	0	30		
	.0%	100.0%		

Chi-square test with p value less than 0.05 is significant.

Table 14: Intergroup comparison of convenience between the groups



Graph 11: Intergroup comparison of rinsing time between the groups.

DISCUSSION

This clinical prospective study was designed to evaluate and compare the efficacy of dental plaque, gingivitis and taste perception with different mouthwashes like octenidine dihydrochloride, chlorhexidine, povidone iodine and cetylpyridium chloride.

Since the oral cavity is a dynamic ecosystem, it wouldn't be ideal to eradicate all of the oral microflora in an effort to control infections caused by dental plaque. Rather, it very well might be more ideal to eliminate just most cariogenic and periodontopathic components of the dental plaque microflora while allowing the more harmless components to remain. For a variety of purposes, including the control of dental plaque, the elimination of oral pathogens, and the prevention of malodor, a relatively large number of chemical agents, most of which are synthetic compounds, have been utilized.[4]

An optimal specialist to control the beginning or movement of periodontal illness might be one that upsets the amassing of potential periodontopathogens yet leaves undisturbed the typical sound or native flora. Various reports have recorded that the verdure change from fundamentally Gram-positive to Gram-negative microorganisms in conditions prompting gum disease. At the point when mechanical plaque control is hampered, the substance methodology stays the following most ideal decision. Clearly, bacterial growth cannot cause this change. A few components of adherence might be engaged with growth of another flora, and one of these is probably going to be acknowledgment between particles on the outer layer of free microorganisms and reciprocal surface atoms on the general disciple microbes.[32-38]

In the 1980s, the Sterling-Winthrop Research Institute in Rensselaer, New York, developed octenidine dihydrochloride (OCT), a novel antimicrobial cationic surfactant (Al-Doori et al., 2007; Slee and O'Connor, 1983).[39,40]

OCT is a mouthwash equipped for applying gainful clinical impacts upon plaque gathering and gum disease improvement. This inference is supported by the fact that octenidine is an effective mouth rinse that kills bacteria. Even though OCT has a lot of antibacterial power, more research is needed to find out if it's safe, biocompatible, and doesn't have bad cosmetic or organoleptic properties.

Octenidine dihydrochloride responds with polysaccharides in the cell mass of microorganisms, goes after the enzymatic frameworks there, obliterates cell capability and prompts spillage of the cytoplasmic membrane.[24] Octenidine diminished plaque by 33% and gum disease by one-half contrasted with the fake treatment. One of the new examinations showed that a 0.1% octenidine mouth flush gave measurably huge decreases of 39% less plaque, half less gum disease, and 60% less gingival draining destinations.[4,9]

All reviews evaluating the impacts of a 0.1% OCT mouthwash detailed a critical diminishing in plaque development versus control mouthwash. Additionally, the impact of two times day to day swishing was noticed even after momentary use for 4 days in certain examinations, and long haul use for as long as 90 days in others. A critical decrease in GI following the utilization of 0.1% OCT-based mouthwash versus control mouthwash was accounted for in all reviews, with the exception of one; furthermore, 10 examinations detailed a critical decrease in the all-out oral microbial development. The viability of 0.1% OCT-based mouthwashes in HIV-positive patients recommends that this detailing can be well utilized in patients with comorbid sicknesses notwithstanding persistent periodontitis.[39]

Chlorhexidine (CHX) as a highest quality level gives off an impression of being the best antimicrobial specialist for decrease of both plaque and gum disease. Its bactericidal and bacteriostatic effects as well as its substantivity within the oral cavity (8 hours after rinsing) account for its effectiveness.[1] However, the adverse effects of CHX restrict its long-term use and include changes in taste, excessive supragingival calculus formation, soft-tissue lesions in young patients, allergic reactions, and staining of teeth and soft tissues. This sort of staining particularly in the interproximal regions and tongue is much of the time brought about by a precipitation response between tooth-bound chlorhexidine and chromogens from food or refreshments.[13,41-43]

Chlorhexidine gluconate (CHX) is a well-known and tried-and-true ingredient in mouthwashes that prevents plaque formation, gingivitis, and the growth of oral microorganisms (Van Strydonck et al., 2012).58 In the selected studies, the

effect of CHX as an addition to oral hygiene procedures is fairly consistent. 23 of 28 examinations with information on plaque report a critical plaque decrease for the CHX bunch, 19 of 20 investigations with GI information report a decrease of gum disease for the CHX gathering, and 15 of 21 investigations with draining scores exhibit diminished draining scores for the CHX group. [39]

Another normal substance-based mouth rinse is povidone-iodine (betadine). In 1955, H. A. Shelanski and M. V. Shelanski at the Industrial Toxicology Laboratories in Philadelphia made the initial discovery of povidone-iodine (PVP-I). PVP-I was developed to produce a less harmful antimicrobial iodine complex than the tincture of iodine, which causes burns.[44] It is relatively well tolerated in comparison to other commonly used gargled antiseptics. When free iodine (I2) separates from the polymer complex, PVP-I takes action. At the point when iodine gets in free structure, it quickly enters microorganisms breaks proteins and oxidizes nucleic corrosive design prompting microbial death.[45] PVP-I 1% can be utilized as a mouth flush after each 2-4 hours.[46] The specific powerful grouping of PVP-I for mucins and spit was not known however two times the fixation will have areas of strength for be productive for the weakening from saliva.[47,48] With many years sensitivity to PVP-I is extremely uncommon [49] while some are delicate to PVP-I50 and some expectational sensitivity is type I allergy.[51]

The determination of the povidone-iodine as an adjunctive treatment during ultrasonic scaling and root planing depended on the microbial etiology of the periodontal sicknesses. Povidone–iodine is probably the antiseptic that is used the most in medical practice because of its low cost, broad-spectrum antiseptic action, and impeccable safety record (Reimer et al., 2002). [59] PVP-iodine as a clean adjunctive during non-careful periodontitis treatment has been utilized in different examinations - yet with conflicting results.[60-66] Looking at six examinations in a meta-examination, this efficient survey showed a little however genuinely massive impact of extra PVP-iodine washing during profound scaling and root planing concerning a decrease in PPD in patients with constant periodontitis. In the three-month meta-examination, the impact was less articulated. [67]

Cetylpyridinium chloride is a quaternary ammonium compound with an aliphatic chain and is named a cationic surface dynamic specialist. It has shown antimicrobial movement against a wide range of oral bacteria.[52-54] It can cooperate with the bacterial cell film, bringing about spillage of cell parts, disturbance of cell digestion, hindrance of cell development and cell death.[55-57] Cetylpyridinium chloride-containing mouthwashes have been showcased in the US starting around 1940. Since the decidedly charged hydrophilic locale of cetylpyridinium chloride is basic to antimicrobial movement, mouth flush plans shouldn't contain fixings that reduce or contend with the action of this cationic gathering. The cetylpyridinium chloride content in formulations must be sufficient to demonstrate biological activity and availability to support an antigingivitis claim. [56]

Versteeg et al.[68] showed that the 0.07% CPC mouthwash, which was indistinguishable from the test item, was fit for decreasing plaque arrangement by roughly 47%. Comparing the experimental 0.07 percent mouth rinse to a placebo, **Costa et al.**[19] recently demonstrated a distinct benefit. **Garcia et al.**[69] tried a lower-fixation 0.05% CPC mouthwash and found 25% plaque hindrance in a once more plaque development model. Be that as it may, **Rioboo et al.**[70] assessed a 0.05% CPC mouth wash more than a 4-week review and neglected to lay out a distinction between the test and control items as for gum disease, in spite of the fact that they detailed a pattern for contrasts in plaque scores. **Haps et al.**[71] methodically assessed the impacts of CPC-containing mouthwashes when utilized as assistants to either managed or solo oral cleanliness regimens in a deliberate survey (SR) and showed, given a meta-examination, a little yet critical extra advantage of CPC in decrease of plaque and gingival file scores.

It was first proposed in 1970 by **Gibbons and Nygaard**[72] that intergeneric coaggregation might assume a fundamental part in the improvement of dental plaque.

Hughes et al. [73] have shown that microbes detached from the equivalent econiches coaggregate with one another yet don't typically coaggregate with microorganisms from other econiches.

McBride and van der Hoeven [74] demonstrated the importance of coaggregation in vivo by demonstrating that coaggregating bacteria colonize the teeth of gnotobiotic animals while non-coaggregating bacteria do not.

Van der Hoeven et al.[75] expanded that perception by showing that coaggregation-flawed freaks neglect to colonize and that coaggregations that are lactose-repressed in vitro are likewise modified in vivo by expansion of lactose to the drinking water of the gnotobiotic creatures. Taken together, these information firmly embroil coaggregation as a significant system in dental plaque growth. 1991

In one more in vitro investigation of **Pitten et al.,**[76] PVP — I, OCT, and CHX made a 10 a few crease decline in the quantity of all out microscopic organisms with various disinfectant focuses and with various time stretches. The microorganisms examined included S. aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus faecium, and Candida albicans. Albeit the underlying antimicrobial exercises of OCT and CHX are tantamount, on account of the better constant antimicrobial movement of octenidine, it was proposed that OCT affects Mutans streptococci and Lactobacilli. They viewed cetylpyridinium-based items as less powerful and utilized hydrogen peroxide as a control.

Dogan et al[13] correlated the transient relative antibacterial impacts of OCT and CHX. Both in vitro and in vivo, OCT was found to be more effective than CHX in killing bacteria.

Even though the ongoing study is totally an in vivo examination of the inhibitory properties of antimicrobial specialists on plaque decrease, gingival decrease, tooth stain, and taste change; It is clear that these findings can be applied to the aforementioned in vitro-relevant, non-clinical studies.

As a result, changes in the plaque index (PI) and gingival index (GI), taste perception, and safety concerns were evaluated in the present clinical study. OCT is a mouthwash that can help prevent plaque buildup and the development of gingivitis in the clinic.

In the current study, on the correlation between the groups, the mean Plaque score at baseline was viewed as measurably non-significant (p-value=0.065), though following 21 days tremendous contrast was found (p-value=0.001). While comparing the mean Plaque score following 21 days, a tremendous distinction was found (p-value=0.001) within the groups. (Table 1.) The mean plaque score was highest in 0.07 percent CPC (0.363), followed by 0.216 in 1% POV-I, and lowest in 0.1% OCT at 21-day intervals. (Graph 1.)

Throughout 21 days while swishing with octenidine was utilized as the main method for oral cleanliness, plaque arrangement was totally forestalled. Information looking at the efficacies of 0.1% OCT and 0.2% CHX mouthwashes, were acquired from eight examinations **Dogan et al., 2008, 2009;[13,14] Jain et al., 2017;[77] Kocak et al., Kramer et al., 2009;[4] 1998;[78] Murmurs et al., Welk et al., 1995;[79] Pitten & Kramer, 1999;[80] 2016).[23]** Two examinations thought about the viability of OCT and CHX on plaque development **Hemanth et al., 2017;[81] Welk et al., 2016.[23]**

In one study by **Welk et al., 2016** washing two times every day, after breakfast/evening for 4 days created comparable plaque development restraint with 0.1% OCT versus 0.12% CHX (47.66% versus 57.87%, p = 0.682;

Hemanth et al., 2017 conducted a different study, 1 ml of 0.1% OCT/0.2% CHX was infused into the periodontal pocket of the impacted tooth to treat confined periodontitis (not at all like different examinations requiring flushing with mouthwash). On day 7, 0.1% OCT inhibited more plaque than 0.2% CHX (51.08% vs. 33.46%, p = 0.001), despite the fact that both were equally effective on days 14 and 21.

Beiswanger et al. (1990)[9] Following 3 months of treatment with 0.1% OCT, there was a 38.7% decrease in the PI contrasted with fake treatment mouth flush.

Gušic et al. (2016)[82] 0.1% OCT (periodontal treatment + OCT mouthwash for 7 days) showed 48.61% and 47.22% decrease in the PI at 1 and 90 days, separately, compared with standard ($p < 0.01$)

Lorenz et al., 2018[26] With 0.1%, 0.15 percent, and 0.2% OCT mouthwashes, PI was reduced by 67.09%, 72.78%, and 73.42%, respectively, when compared to placebo (0.9% saline solution). Examinations were statistically significant ($p < 0.001$) contrasted with all OCT concentrations (ANOVA).

Patters et al. (1983)[83] Seven days of swishing with 0.1% OCT mouthwash decreased PI by 70.29% compared with placebo treatment mouthwash (vehicle without OCT; $p < 0.01$). The 0.05% OCT mouthwash likewise decreased PI yet the decrease was lower than 0.1% OCT.

Patters et al., 1986[8] Contrasted with placebo mouthwash (vehicle without OCT), 0.1% OCT mouthwash (two times every day) decreased PI by 79.63%, 88.49%, and 90.53% at days 7, 14, and 21 ($p < 0.000001$). At the point when utilized threefold every day, they diminished PI by 83.33%, 89.21%, and 92.9% ($p < 0.000001$).

According to **Robrish et al.**[84] OCT had a longer-lasting antimicrobial effect on the organisms in the plaque than CHX did.

During the rinse phase of our study, the octenidine group's mean plaque index never exceeded 0.140, indicating that octenidine rinsing was as effective as mechanical plaque control in this highly motivated population. It was in agreement to every one of the previously mentioned examinations.

A fundamentally more grounded effect of OCT in lessening oral microbial burden than CHX, right away and 10 min after application was found in a study by **Kramer et al.,1998**. It was seen that 0.1% OCT was more viable than 0.12% CHX in lessening S. mutans development at 1, 10, and 60 min subsequent to flushing **Kocak et al., 2009**. These examinations correspond with our study in hindering plaque regrowth and diminishing bacterial imperativeness compared with other three mouth rinse arrangements.

On correlating the mean gingival Index at baseline all the Groups showed statistically non-significant results (p-value=0.066)(table 4.), whereas after 21 days significant difference was observed in all the groups (p-value=0.001)

(Graph 3). The effect of OCT on GI was evaluated in six studies. **Beiswanger et al., 1990;[9] Koertge et al., 1986;[90] Lobene et al., 1985;[91] Lorenz et al., 2018;[26] Patters et al., 1986;[8] Gusic et al., 2016**;[82] all studies reported a significant reduction in GI with OCT versus control mouthwash.

Beiswanger et al. (1990)[9] After 3 months of treatment 0.1% OCT reduced GI by 50% compared to placebo mouth rinse.

Gusic et al. (2016)[82] 0.1% OCT (periodontal therapy + OCT mouthwash for 7 days) showed 65.27% and 67.07% reduction in GI at 1 and 3 months, respectively compared to the baseline ($p < 0.01$).

Lorenz et al. (2018)[26] Compared to placebo (0.9% saline solution), GI was reduced by 41.07%, 64.4%, 59.25% with 0.1%, 0.15% and 0.2% OCT mouthwashes.

Patters et al. (1986)[8] Compared to placebo mouthwash (vehicle without OCT), 0.1% OCT mouthwash twice a day could reduce GI by 58.63%, 67.86%, 68.37% at days 7, 14, and 21, respectively. When used thrice daily, it could reduce GI by 63.79%, 65.48% and 67.35% ($p < 0.000001$)

In the present study, at a 21-day time interval, the mean gingival score was highest in 0.07% CPC (0.343), followed by 1% PVP-I (0.240) and least in 0.1% OCT (0.146). As a result, OCT appears to have promising effects and may be a better mouth rinse than the other mouthwashes that are utilized. In comparison to the previous studies on the reduction of the gingival index, our study produced results that were comparable.

Kramer et al[78] revealed that OCT and cetylpyridinium chloride were altogether more viable than other mouth-washing arrangements including Corsodyl (which contains chlorhexidine gluconate) in their nearby worth. These researchers revealed that the main disadvantage of OCT use was its unpleasant taste. Notwithstanding, in the current study, cetylpyridinium chloride was less viable against each of the three groups.

On examination of the mean staining score at baseline, each of the 4 Groups showed genuinely non-critical outcomes (p-value=0.622) (Table 7.), while following 21 days tremendous distinction was seen in each one of the groups (p-value=0.000). At 21-day time period, the mean Modified Lobene Stain Record score was highest in 0.07% CPC (1.133), followed by 1% PVP-I (0.866) and least in 0.1% OCT (0.066) (Graph 5.). **Beiswanger et al, Koertge et al., 1990;[9] Lobene et al., 1986;[90] 1985;[91] Lorenz et al., 2018;[26] Patters et al**., Six studies from 1983, 1986, and 1983 revealed that tooth stain was a common, non-serious AE linked to OCT use. In five examinations they additionally revealed that subjects ceased oral cleanliness measures, including tooth brushing during the trial. Tooth staining was reversible following single tooth brushing with a dentifrice or cleaning with an elastic cup or pumice. Only mild adverse events occurred when using the OCT rinse. In the OCT groups, tooth and tongue staining were among the 29 AEs that were definitely related and 17 that were probably related. As the concentration of OCT increased, so did the number of staining cases. Previous research on OCT and CHX has demonstrated a staining propensity. In most of cases, tooth staining was gentle and just identified by the investigator.[9,91] However in this study 0.1% OCT showed extremely gentle stains when contrasted with the other three mouthwashes for example CHX, PVP-I and CPC. As a result, it can be concluded that the OCT mouth rinses were safe to use and well-received.

A higher extent of subjects involving OCT in aqueous solution experienced mucosal intolerance in the examinations by **Koertge et al., 1986;[90] Patters et al., [8] Patters et al., 1983[83]** However, the oral mucosa tolerated the OCT formulation in the vehicle well and did not experience any significant adverse events in 1986 or 1983. However, there was no such evidence in our study.

Lang et al., 1982[92] Siegrist et al., 1986[93] Gross et al., 1987[94] detailed in their review that the improvement of questionable outward dental stain and taste/persistent flavour has been noted in past examinations including the utilization of other antimicrobial specialists. The questions on taste perception, duration of taste, alteration in taste perception, and rinsing time were found to be statistically significant (p-value=0.001) in the current study's taste perception

rating results. in each of the four groups, while the result regarding the ease of use is statistically insignificant.

When used for 21 days in conjunction with mechanical oral hygiene, the present study's findings suggested that octenidine mouth rinse is well tolerated and extremely effective at preventing plaque accumulation and gingivitis. Studies lasting longer than 21 days and a determination of octenidine's ability to reverse existing gingivitis are required for further evaluation of its efficacy as a treatment option.

CONCLUSION

Gingivitis and periodontitis are among the most prevalent infections afflicting humans, making it essential for dental professionals to include risk assessment and disease management in patients' treatment plans to ensure a favourable outcome. Strong evidence exists supporting the effectiveness of daily antiseptic mouth rinse used as an adjunct to mechanical plaque control to reduce or control plaque and gingivitis.

Based on the findings of the present study, it can be validated that mouthwashes when used as an adjunctive to scaling have positive benefits in patients with severe gingivitis.

1. Octenidine, introduced more than 20 years back is an effective antiseptic agent that is used in different fields and has the potential to replace various well-known antiseptics like CHX, PVP-I or CPC.
2. Its popularity among clinicians is increasing, as it is chemically stable with no reported resistant development, has low toxicity and is comparatively safe.
3. OCT was efficacious, and substantially reduced plaque formation, gingivitis and oral microbial growth.
4. OCT was either superior or comparable to CHX-based mouthwashes in controlling dental plaque.
5. OCT was well-perceived, tolerable, safe, and an effective alternative to CHX and other contemporary antibacterial mouthwashes.

However, further studies assessing the long-term effects of a 0.1% OCT-based mouthwash, involving a larger sample size, are required to confirm the results.

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ANNEXURES

ANNEXURE I

BABU BANARASI DAS UNIVERSITY

BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Clinical Evaluation Of Octenidine Dihydrochloride, Chlorhexidine, Povidone-Iodine And Cetylpyridinium Chloride On Dental Plaque, Gingivitis And Taste Perception In Patients With Periodontal Disease"** submitted by **Dr Dikshita Das** Postgraduate student in the **Department of Periodontology** for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on **14th September, 2022** 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. Dr. Puneet Ahuja
Chairperson

Dr. Mona Sharma
Co-Chairperson

ANNEXURE II

BABU BANARASI DAS UNIVERSITY
BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBD UNIVERSITY

BBDCODS/IEC/09/2022 **Dated: 16th September, 2022**

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 33

Title of the Project: Comparative Clinical Evaluation Of Octenidine Dihydrochloride, Chlorhexidine, Povidone-Iodine And Cetylpyridinium Chloride On Dental Plaque, Gingivitis And Taste Perception In Patients With Periodontal Disease.

Principal Investigator: Dr Dikshita Das **Department:** Periodontology

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

Type of Submission: New, MDS Project Protocol

Dear Dr Dikshita Das,

The Institutional Ethics Sub-Committee meeting comprising following members was held on 15th September, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry
2.	Dr. Praveen Singh Samant Member	Prof. & Head, Department of Conservative Dentistry & Endodontics
3.	Dr. Jiji George Member	Prof. & Head, Department of Oral Pathology & Microbilogy
4.	Dr. Amrit Tandan Member	Professor, Department of Prosthodontics and Crown & Bridge
5.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopaedics

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:

Prof. Dr. Puneet Ahuja
Principal
BBD College of Dental Sciences
BBD University, Lucknow

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

16/09/22

Dr. Lakshmi Bala
Member-Secretary
Institutional Ethics Sub-Committee (IEC)
BBD College of Dental Sciences
BBD University, Lucknow

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

ANNEXURE III

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

Consent Form (English)

Title of the Study: Comparative clinical evaluation of octenidine dihydrochloride, chlorhexidine, povidone-iodine and cetylpyridinium chloride on dental plaque, gingivitis and taste perception in patients with periodontal disease.

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 beenexplained 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 sucha 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 andside 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 ANNEXURE 3

ANNEXURE IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

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

Consent Form (Hindi)

अध्ययन का शीर्षक: ऑक्टेनिडाइन डाइहाइड्रोक्लोराइड, क्लोरहेक्सिडिन, पोविडोन आयोडीन और सेटिलपाइरिडिनियम क्लोराइड का दंत पट्टिका, मसूड़े की सूजन और पीरियोडोंटल बीमारी के रोगियों में स्वाद धारणा का तुलनात्मक नैदानिक मूल्यांकन।

स्टडी नंबर.....

विषय का पूरा नाम .....

जन्म तिथि/आयु .....

विषय का पता.....

फोन नंबर। और ई-मेल पता .....

योग्यता .....

व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)

विषय की वार्षिक आय.....

नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए) मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक ..... को पढ़ और समझ लिया है । उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएग

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।

5. मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं।

हाँ [ ] नही [ ] लागू नहीं [ ]

6. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):……..

हस्ताक्षरकर्ता का नाम…… तारीख ……।

अन्वेषक के हस्ताक्षर …… तारीख…….

अध्ययन अन्वेषक का नाम …… तारीख…….

गवाह के हस्ताक्षर…… तारीख…….

गवाह का नाम ……

पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से दिनांक…….

स्वीकार्य प्रतिनिधि

ANNEXURE V

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

Participant Information Document (PID)

1. Study Title

Comparative clinical evaluation of octenidine dihydrochloride, chlorhexidine, povidone-iodine and cetylpyridinium chloride on dental plaque, gingivitis and taste perception in patients with periodontal disease.

2. Invitation Paragraph

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

3. What is the purpose of the study?

The aim of the present study is to compare the efficacy of 0.1% octenidine dihydrochloride, 0.2% chlorhexidine, 1% povidone-iodine and 0.07% cetylpiridinium chloride on dental plaque, gingivitis, and taste perception in patients with periodontal disease.

4. Why have I been chosen?

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

5. 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 are still free to withdraw at any time and without giving a reason.

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

You will be one of the 30 participants in 120 patients enrolled in 4 groups in the study. All the participants diagnosed with Periodontal disease will be randomly prescribed with mouthwashes.

7. What do I have to do?

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

8. What is the procedure that is being tested?

The procedure will involve evaluating and comparing the effectiveness of 4 different types of mouthwashes in 4 different groups to assess and compare the efficacy on dental plaque, on gingivitis and of taste perception. The gingival status, Dental plaque will be assessed and recorded at the baseline and taste perception will be assessed after recall.

9. What are the interventions for the study?

4 different types of mouthwashes will be given to 4 different group of people to clinically evaluate and compare the better efficacy of mouthwashes on Dental plaque, Gingivitis and taste perception. All the participants will be instructed to rinse with mouthwash for 1 minute twice daily, 30 minutes after brushing. Group I with ocetenidine dihydrochloride, Group II with Chlorhexidine, Group III with povidone-iodine, Group IV with cetylpyridinium. The gingival status, dental plaque will be recorded at the baseline and taste perception will be assessed after 21 days.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

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

There are no risk or disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

This study will help us to know the clinical comparison between 4 different types of mouthwashes in assessing the efficacy on dental plaque, gingivitis and taste perception.

13. What if new information becomes available?

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

14. What happens when the research study stops?

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

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by the doctors expertising in the field at BBDCODS opd.

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

Yes, it will be kept confidential. Your name, address or any other personal information will not be shared outside the BBDCODS.

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

The results of the study will be used to evaluate and compare efficacy of the 4 different types of mouthwashes. Identity of the participants will not be disclosed in any result/ reports/ publications.

18. Who is organizing the research?

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

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

Yes. If the patient wishes, the result of the study will be made available to him/her.

20. Who has reviewed the study?

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

21. Contact for further information

Dr. DIKSHITA DAS
Department of Periodontology and Implantology
Babu Banarasi Das College of Dental Sciences.
Lucknow – 226028
Mob: 8638595059

Dr. Laxmi Bala,
Secretary and Member – Institutional Ethics Sub-committee
Babu Banarasi Das College of Dental Sciences.
Lucknow – 226028
bbdcods.iec@gmail.com

Signature of PI……

Name……..

Date……..

ANNEXURE VI

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

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

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

1. अध्ययन शीर्षक

ऑक्टेनिडाइन डाइहाइड्रोक्लोराइड, क्लोरहेक्सिडिन, पोविडोन आयोडीन और सेटिलपाइरिडिनियम क्लोराइड का दंत पट्टिका, मसूड़े की सूजन और पीरियोडोंटल बीमारी के रोगियों में स्वाद धारणा का तुलनात्मक नैदानिक मूल्यांकन।

2. आमंत्रण पैराग्राफ

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

3. अध्ययन का उद्देश्य क्या है?

वर्तमान अध्ययन का उद्देश्य पेरियोडोंटल रोग के रोगियों में दंत पट्टिका, मसूड़े की सूजन और स्वाद धारणा पर 0.1% ऑक्टेनिडाइन डाइहाइड्रोक्लोराइड, 0.2% क्लोरहेक्सिडिन, 1% पोविडोन-आयोडीन और 0.07% सेटिलपिरिडिनियम क्लोराइड की प्रभावकारिता की तुलना करना है।

4. मुझे क्यों चुना गया है?

आपको चुना जाता है क्योंकि आप अध्ययन के मानदंडों को पूरा करते हैं।

5. क्या मुझे भाग लेना है?

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

6. यदि मैं भाग लेता हूँ तो मेरा क्या होगा?

आप अध्ययन में 4 समूहों में नामांकित 120 रोगियों में से 30 प्रतिभागियों में से एक होंगे। पेरियोडोंटल रोग से पीड़ित सभी प्रतिभागियों को बेतरतीब ढंग से माउथवॉश निर्धारित किया जाएगा।

7. मुझे क्या करना होगा?

कुछ अन्य एहतियाती उपायों के साथ आहार सेवन में कुछ बदलाव किए जाएंगे और आपसे इसका पालन करने की अपेक्षा की जाएगी।

8. किस प्रक्रिया का परीक्षण किया जा रहा है?

इस प्रक्रिया में दंत पट्टिका, मसूड़े की सूजन और स्वाद धारणा पर प्रभावकारिता का आकलन और तुलना करने के लिए 4 अलग-अलग समूहों में 4 अलग-अलग प्रकार के माउथवॉश की प्रभावशीलता का मूल्यांकन और तुलना करना शामिल होगा। मसूड़ों की स्थिति, दंत पट्टिका का मूल्यांकन किया जाएगा और बेसलाइन पर दर्ज किया जाएगा और स्वाद धारणा का मूल्यांकन बाद में किया जाएगा।

9. अध्ययन के लिए क्या हस्तक्षेप हैं?

दंत पट्टिका, मसूड़े की सूजन और स्वाद धारणा पर माउथवॉश की बेहतर प्रभावकारिता का चिकित्सकीय मूल्यांकन और तुलना करने के लिए 4 अलग-अलग समूह के लोगों को 4 अलग-अलग प्रकार के माउथवॉश दिए जाएंगे। सभी प्रतिभागियों को ब्रश करने के 30 मिनट बाद दिन में दो बार 1 मिनट के लिए माउथवॉश से कुल्ला करने का निर्देश दिया जाएगा। समूह I ओसेटेनिडाइन डाइहाइड्रोक्लोराइड के साथ, समूह II क्लोरहेक्सिडिन के साथ, समूह III पोविडोन-आयोडीन के साथ, समूह IV सीटिलपाइरीडिनियम के साथ। मसूड़ों की स्थिति, दंत पट्टिका को बेसलाइन पर दर्ज किया जाएगा और 21 दिनों के बाद स्वाद धारणा का आकलन किया जाएगा।

10. भाग लेने के दुष्प्रभाव क्या हैं?

हालांकि प्रक्रिया के गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागियों को मतली और पोस्ट ऑपरेटिव उल्टी जैसी दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं। यदि प्रक्रिया के दौरान कुछ भी होता है तो हमारे पास किसी भी आपात स्थिति को प्रबंधित करने के लिए कुशल कार्मिक और विशेष उपकरण हैं।

यदि प्रतिभागियों को ऑपरेशन के बाद कोई अन्य लक्षण दिखाई देते हैं, तो अभिभावक को तुरंत डॉक्टर से बात करनी चाहिए।

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

अध्ययन में भाग लेने के कोई नुकसान नहीं हैं, दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं।

12. भाग लेने के संभावित लाभ क्या हैं?

यह अध्ययन हमें दंत पट्टिका, मसूड़े की सूजन और स्वाद धारणा पर प्रभावकारिता का आकलन करने में 4 विभिन्न प्रकार के माउथवॉश के बीच नैदानिक तुलना जानने में मदद करेगा।

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपको इसके बारे में सूचित किया जाएगा और अध्ययन में होने वाले परिवर्तनों के बारे में सूचित किया जाएगा। आप अध्ययन के बीच में हटने के लिए स्वतंत्र हैं। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

यदि अध्ययन निर्धारित समय से पहले समाप्त / बंद हो जाता है, तो इसका कारण रोगियों को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो बीबीडीसीओडीएस ओपीडी में क्षेत्र में विशेषज्ञता रखने वाले डॉक्टरों द्वारा शिकायतों का निपटारा किया जाएगा।

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

आपका नाम, पता या कोई व्यक्तिगत या अन्य जानकारी बीबीडीसीओडी के बाहर साझा नहीं की जाएगी।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणामों का उपयोग 4 विभिन्न प्रकार के माउथवॉश की प्रभावशीलता का मूल्यांकन और तुलना करने के लिए किया जाएगा। किसी भी परिणाम/रिपोर्ट/प्रकाशन में प्रतिभागियों की पहचान का खुलासा नहीं किया जाएगा।

18. शोध का आयोजन कौन कर रहा है?

यह शोध अध्ययन शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाता है।

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

यदि रोगी चाहे तो अध्ययन का परिणाम उसे उपलब्ध कराया जाएगा।

20. अध्ययन की समीक्षा किसने की है?

संस्थान के एचओडी/आईआरसी/आईईसी ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

21. अधिक जानकारी के लिए संपर्क करें

डॉ. दीक्षिता दास

पेरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज।
लखनऊ-226028
मोबाइल: 8638595059

डॉ लक्ष्मी बाला,
संस्था की आचार समिति के सदस्य सचिव,
पता: बाबू बनारसी दास विश्वविद्यालय, फैजाबाद रोड, आतिफ विहार,
लखनऊ, यूपी। 226028
ईमेल: bbdcods.iec@gmail.com

पीआई के हस्ताक्षर .....

नाम.....

तारीख.....

प्रतिभागी को सूचना पत्र की एक प्रति और हस्ताक्षरित सहमति प्रपत्र दिया जाएगा।

अध्ययन में भाग लेने के लिए धन्यवाद।

ANNEXURE VII

DEPARTMENT OF PERIODONTICS

PATIENT PROFORMA

OPD No:

Name :

Age :

Sex :

Chief complains:

History of Present Illness:

History of Past Illness:

A. Past Medical History:

B. Past Dental History:

History of Present Illness:

A. Present Medical History:

a. General Health:

b. Nutritional Status:

B. Present Dental History:

a. Oral Hygiene Maintainance:

b. Habits:

CLINICAL EXAMINATION

Extra oral examination

Face:

Lips: Competency

Skin: Color : Normal or Palor

Neck: Swellings: Unilateral or Bilateral

Jaws: Symmetry-

Antero-posterior relationships and movements

Tempero-Mandibular Joint

Intra oral Examination

A. Soft tissue:

B. Gingival Status:

1. Colour:
2. Contour:
3. Consistency:
4. Surface texture:
5. Position:
6. Size:
7. Exudate:

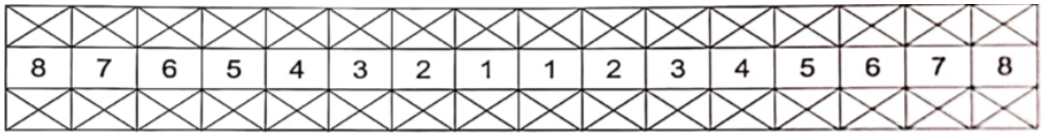
C. Hard tissue:

1. No. of teeth present:
2. Hypersensitivity:
3. Missing teeth (why, when):
4. Caries/Nonvital:
5. Supernumerary:
6. Proximal contact relationship:
7. Plunger cusp:
8. Crown size and colour:
9. Pathologic tooth migration:
10. Mobility: Grade I / II / III
11. Hypoplasia:
12. Occlusion: Angle's classification: Class I / II /III
13. Retained/Impacted:
14. Attrition/Erosion/Abrasion:
15. Furcation Involvement:
16. Trauma From Occlusion:
17. Halitosis:

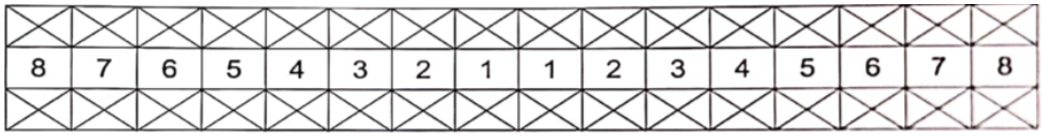
18. Any Dental anatomic factors:
19. Calculus: Mild / Moderate / Severe
20. Stains: Mild / Moderate / Severe

INDICES

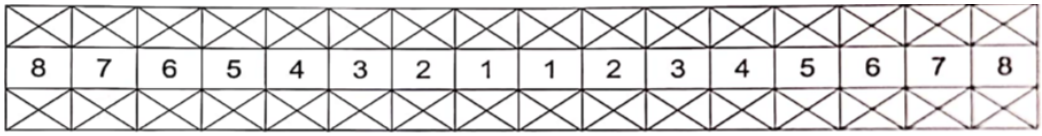
1. Plaque Index (Silnes and Loe / Turesky-Gilmore-Glickman Modification of Quigley-Hein) (at baseline)



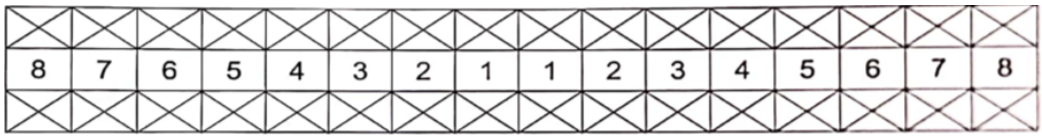
2. Gingival Index (Loe and Silnes / Modified Gingival Index) (at baseline)



3. Calculus Index (at baseline)

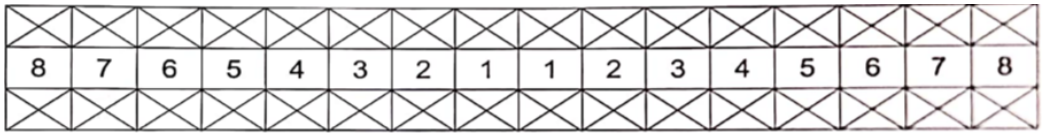


4. Modified lobene Stain Index (at baseline)

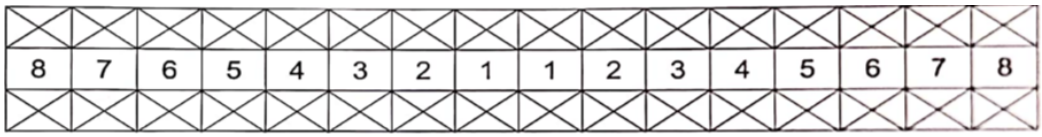


INDICES

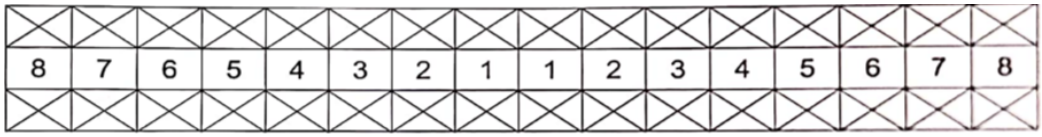
1. Plaque Index (Silnes and Loe / Turesky-Gilmore-Glickman Modification of Quigley-Hein) (at 21 days)



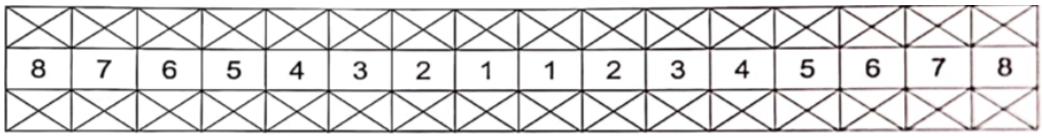
2. Gingival Index (Loe and Silnes / Modified Gingival Index) (at 21 days)



3. Calculus Index (at 21 days)



4. Modified lobene Stain Index (at 21 days)



DIAGNOSIS:

PROGNOSIS:

TREATMENT PLAN:

EMERGENCY:

PHASE I:

PHASE II:

PHASE III:

PHASE IV:

QUESTIONNAIRE FOR COMPARISON OF VARIABLES RELATED TO TASTE PERCEPTION

1. TASTE OF THE PRODUCT

a. Good

b. Normal

c. Bad

2. DURATION OF THE TASTE

a. Long

b. Short

3. EFFECT OF TASTE ON FOOD AND DRINK

a. Good

b. Bad

4. CONVENIENCE

a. Convenient

b. In-convenient

5. RINSING TIME

a. Long

b. Short

ANNEXURE VIII

STATISTICAL ANALYSIS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation frequency and percentage. The level of the significance for the present study was fixed at 5%.

The intergroup comparison will be done using the One Way ANOVA followed by post Hoc Analysis depending upon the normality of the data. The intergroup comparison of ordinal variables will be done using the Chi Square test The intragroup comparison will be done using the Paired t test depending upon the normality of the data. The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables.

Mean

$$\overline{X} = \frac{\Sigma X}{N}$$

Where:

$\overline{X}$ = the data set mean

$\sum$ = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$X_{highest}$ = largest score

X_{lowest} = smallest score

Variance

$$SD^2 = \frac{\Sigma(X - \overline{X})^2}{N}$$

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

SD^2 = the variance

Σ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Standard Deviation (N)

$$SD = \sqrt{\frac{\Sigma(X - \overline{X})^2}{N}}$$

The simplified standard deviation formula

$$SD = \sqrt{\frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}}$$

Where:

SD = the standard deviation

Σ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

One Way ANOVA

The formula for the one-way **ANOVA** *F*-test statistic is

$$F = \frac{\text{between-group variability}}{\text{within-group variability}}.$$

The between-group variability" is

$$\sum_{i=1}^{K} n_i (\bar{Y}_{i\cdot} - \bar{Y})^2 / (K-1)$$

where Y_i denotes the sample mean in the i^{th} group, n_i is the number of observations in the i^{th} group, $\bar{Y}$ denotes the overall mean of the data, and K denotes the number of groups.

The "within-group variability" is

$$\sum_{i=1}^{K} \sum_{j=1}^{n_i} (Y_{ij} - \bar{Y}_{i\cdot})^2 / (N-K),$$

where Y_{ij} is the j^{th} observation in the i^{th} out of K groups and N is the overall sample size.

Post Hoc Tukey Test

Tukey's range test, also known as the Tukey's test, Tukey method, Tukey's honest significance test, or Tukey's HSD (honestly significant difference) test,[1] is a single-step multiple comparison procedure and statistical test. It can be used on raw data or in conjunction with an ANOVA (post-hoc analysis) to find means that are significantly different from each other. Named after John Tukey, it compares all possible pairs of means, and is based on a studentized range distribution (q) (this distribution is similar to the distribution of t from the t-test. Tukey's test compares the means of every treatment to the means of every other treatment; that is, it applies simultaneously to the set of all pairwise comparisons $\mu i - \mu j$ and identifies any difference between two means that is greater than the expected standard error.Tukey's test is based on a formula very similar to that of the t-test. In fact, Tukey's test is essentially a t-test, except that it corrects for family-wise error rate.

The formula for Tukey's test is:

$$q_s = \frac{Y_A - Y_B}{SE},$$

where YA is the larger of the two means being compared, YB is the smaller of the two means being compared, and SE is the standard error of the sum of the means. This qs value can then be compared to a q value from the studentized range distribution. If the qs value is larger than the critical value obtained from the distribution, the two means are said to be significantly different at level

Paired t test

$$t = \frac{\bar{x} - 0}{SE(d)} = \frac{\bar{x}}{SD(x)/\sqrt{n}}$$

A paired t-test is used to compare two population means where you have two samples in which observations in one sample can be paired with observations in the other sample. Examples of where this might occur are: - Before-and-after observations on the same subjects (e.g. students' diagnostic test results before and after a particular module or course) or A comparison of two different methods of measurement or two different treatments where the measurements/treatments are applied to the same.

Chi Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test is commonly used to test association of variables in two-way tables, where the assumed model of independence is evaluated against the observed data. In general, the ***chi-square test statistic*** is of the form

$$X^2 = \sum \frac{(\text{observed} - \text{expected})^2}{\text{expected}}$$

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data

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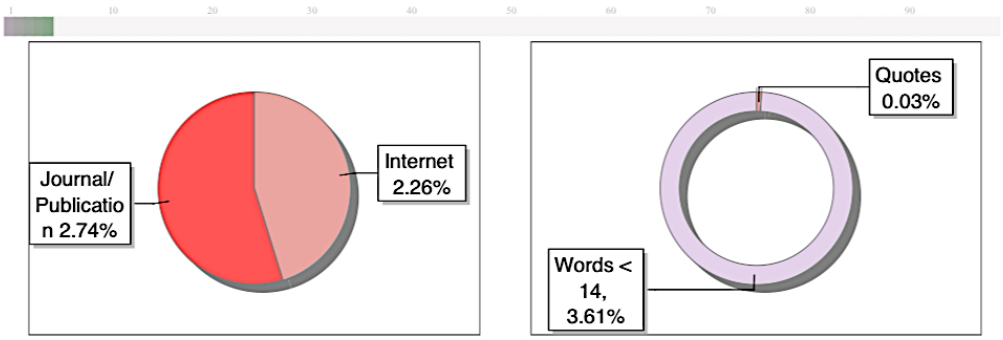

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