International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 17s, 2025
https://www.theaspd.com/ijes.php

"Comparative evaluation of chlorhexidine mouthwash with and without an anti-discoloration system - a randomized controlled trial"

Dr. Ruparani Bodduru[1], Dr. Phani Yasaswini.kanakagiri[2*], Dr. Koineni Rajender[3], Dr. Katkam.Chandana[4], Dr. Manne Harish Kumar[5], Dr Venkat Ram Reddy Gurrala[6]

[1]Professor and HOD, Dept of Periodontics, MNR Dental College and Hospital, Sangareddy, dr.rupaprakash@gmail.com

[2]Senior Lecturer, Dept of Periodontics, MNR Dental College and Hospital, Sangareddy, phanikanakagiri@gmail.com

[3]Senior Lecturer, HKE's. S. Nijalingappa Institute of Dental Sciences & Research. drrkoineni@gmail.com

[4]Iyr Post Graduate, Dept of Periodontics, MNR Dental College and Hospital, Sangareddy, chandanakatkam2510@gmail.com

[5]Private practitioner, Dept of Prosthodontics, Sangareddy, harishkumar7143@gmail.com.

[6]Private practitioner, Dept of Oral Medicine and Radiology, Sangareddy, venkyfreaky1024@gmail.com

Abstract

Objective: This research seeks to determine if a formulation combining chlorhexidine with an agent to counteract discoloration (ADS)lowers the risk of external tooth staining while maintaining clinical efficacy comparable to standard 0.2% chlorhexidine mouthwash. Secondary aim includes evaluating patient adherence to prescribed usage protocols and identifying and characterizing any adverse effects associated with either mouthwash.

Procedure: A trial conducted using a single-blind format and randomized group distribution was performed on 40 non-smoking patients who had been diagnosed with chronic gingivitis. Participants were assigned to use either a conventional mouthwash (control group; Bottle B) or a chlorhexidine-based mouthwash enhanced with an anti-discoloration system (ADS) (test group; Bottle A) over a 15-day period. A complete dental cleaning was conducted before the beginning of each treatment phase. Prior to the start of each intervention phase, a full dental prophylaxis was performed. Clinical evaluations were conducted using the indices assessing dental plaque (plaque index), gum health (gingival index), bleeding response during probing (bleeding on probing index) and the Modified Staining Index to assess both oral hygiene status and tooth discoloration

Keywords: *Oral hygiene, Dental plaque, Gingivitis, Mouthwashes, Chlorhexidine, Staining and Labelling.*

INTRODUCTION

The two most widespread oral health problems, dental cavities and gum disease, are primarily caused by dental plaque.[1] Evidence indicates that regular and effective plaque control significantly reduces the risk of periodontal disease progression.[2,3] However, despite the demonstrated benefits of mechanical oral hygiene measures, such as toothbrushing and flossing, these practices are often performed inconsistently and inadequately, limiting their effectiveness in maintaining optimal oral health.

Mechanical plaque control requires time, motivation, and manual dexterity—factors that may not be consistently achievable by all individuals.[4] As a result, adjunctive strategies are necessary to enhance plaque control.[5,6] Various chemotherapeutic agents employed in oral hygiene include Bisguanides (such as chlorhexidine), essential oils, metal salts (including stannous fluoride, zinc, and copper), triclosan,[12] and quaternary ammonium compounds like cetylpyridiniumchloride[15] and phenols oxygenating[17] , have all been suggested as helpful additions to mechanical cleaning.[7-9]

During initial periodontal therapy (Phase I therapy), clinicians frequently recommend the use of antimicrobial mouthwashes to reduce plaque accumulation and gingival inflammation. Research has demonstrated that many of these agents possess significant anti-plaque and anti-gingivitis properties compared to placebo, especially in the absence of mechanical cleaning.[9,18] However, when used alongside toothbrushing, not all agents show a consistent or enhanced effect, underscoring the need to identify the most effective adjunctive agents.[19]

Chlorhexidine is widely considered the gold standard in chemical plaque control, owing to its well-established clinical efficacy[19-23]. It stands out due to its ability to combat a wide range of bacteria, its low toxicity, and its strong adherence to mucosal and epithelial surfaces.[21] In addition to its potent antiplaque properties, chlorhexidine demonstrates strong substantivity, maintaining up to a 90% reduction in salivary microorganisms for several hours following use.[19,21,22-24]

The downside of chlorhexidine is that it can lead to certain side effects, most notably dental staining, potentially impacting how consistently patients use it.[27] The most prominent among these is dental staining.[26,28] Other less

frequent adverse effects include altered taste sensation and mucosal erosions.[24,29] Research has identified several methods to mitigate or eliminate enamel and cementum staining.[26,30,31]

To address the issue of staining, chlorhexidine mouthwashes have been reformulated with **anti-discoloration systems (ADS)**. This study evaluates the clinical efficacy, stain-reduction potential, and overall oral health benefits of chlorhexidine-based mouthwash designed to reduce tooth discoloration (ADS) containing sodium fluoride (NaF) and zinc chloride ($ZnCl_2$), in comparison to a conventional chlorhexidine formulation.

Zinc chloride, a trace metal with bacteriostatic properties, plays a crucial role in minimizing chlorhexidine-induced staining This is achieved by inhibiting the Maillard reaction, thereby preventing the formation of pigmented compounds, and by reducing the adhesion of dietary chromogens to dental surfaces.[32] Additionally, zinc ions exhibit anti-halitosis activity and contribute to reduced plaque accumulation.[33]

Sodium fluoride, a well-established anti-caries agent, provides complementary benefits by enhancing enamel remineralization and reducing acid solubility. [34]Its inclusion in chlorhexidine mouthwash formulations offers an added protective effect against caries, especially in patients with high caries risk or exposed root surfaces.

This study examines the clinical efficacy, Anti discolouration properties, and overall oral health benefits of a chlorhexidine mouthwash formulated with an anti-discoloration system (ADS) containing sodium fluoride (NaF) and zinc chloride ($ZnCl_2$)., in comparison with a standard chlorhexidine formulation. This investigation seeks to determine whether the modified formulation can offer improved tolerability and patient satisfaction without sacrificing antimicrobial efficacy.

RESEARCH MATERIALS AND STUDY PROTOCOL:

A clinical trial was performed using randomization and a single-blind protocol with parallel groups conducted over a period of 15 days. A total of 40 systemically healthy individuals with mild to moderate gingivitis with 20 in each group are randomly grouped into following two groups.

- **Group A (Test Group):** Participants received a 0.2% chlorhexidine mouthwash formulated with ADS.
- **Group B (Control Group):** Participants received a 0.2% chlorhexidine mouthwash without ADS
- Patients were advised to abstain from consuming tea, coffee, and wine for one hour both before and after applying the mouthwash. A thorough cleaning of supragingival areas was completed, and intraoral photographs were taken as part of the procedure.

The instructions for participants were to rinse with 10 mL of the given mouthwash for 30 seconds, morning and night following tooth brushing, and to refrain from eating or drinking for 30 minutes afterward. No other oral hygiene modifications were introduced during the study period.

INCLUSION CRITERIA:

1. Participants must possess a minimum of 20 teeth within the oral cavity.
2. Patient diagnosed with gingivitis.

EXCLUSION CRITERIA:

1. Smokers
2. Presence of any uncontrolled systemic diseases (Diabetes, cardiovascular disorders and infectious diseases), that may effect study outcome and wound healing.
3. History of allergies to Chlorhexidine.
4. Pregnant and lactating women.
5. Patients using antibiotics and anti-inflammatory drugs.

Patients in all the groups are evaluated for the following clinical parameters at baseline and 15 days.

CLINICAL PARAMETERS

1. Gingival index[35,37]
2. Plaque index[36,37]
3. Bleeding on probing[40]
4. Modified stain index[38,39]

RESULTS

Table 1: Analysis of the mean plaque index within each individual group

Group	Timeline	n	Mean	SD	t value	P value
Test group	Baseline	20	2.2300	0.38947	27.599	**<0.001***
	15 days	20	1.1800	0.33182		
Control group	Baseline	20	2.1850	0.38970	37.994	**<0.001***
	15 days	20	1.1950	0.37902		

Statistical analysis was conducted using a paired t-test, with a p-value of ≤ 0.05 indicating significance.

Table 2: Displays the comparison of mean plaque index values across the groups

Timeline	Group	n	Mean	SD	t value	P value

Baseline	Test group	20	2.2300	0.38947	0.365	0.717
	Control group	20	2.1850	0.38970		
15 days	Test group	20	1.1800	0.33182	-0.133	0.895
	Control group	20	1.1950	0.37902		

The independent t-test was used for analysis, considering $p \leq 0.05$ as the threshold for statistical significance.

Table 3: Shows the intra-group comparison of mean Gingival Index values

Group	Timeline	n	Mean	SD	t value	P value
Test group	Baseline	20	2.1400	0.36476	13.620	**<0.001***
	15 days	20	1.6600	0.40445		
Control group	Baseline	20	2.1250	0.36256	13.770	**<0.001***
	15 days	20	1.6850	0.40298		

A paired t-test was performed, with $p \leq 0.05$ set as the criterion for statistical significance.

Table 4: Presents a comparison of mean Gingival Index scores between the two groups.

Timeline	Group	n	Mean	SD	t value	P value
Baseline	Test group	20	2.1400	0.36476	0.130	0.897
	Control group	20	2.1250	0.36256		
15 days	Test group	20	1.6600	0.40445	-0.196	0.846
	Control group	20	1.6850	0.40298		

An independent t-test was conducted, with statistical significance defined as $p \leq 0.05$.

Table 5: Displays the comparison of mean Bleeding on Probing (BOP) index values within the groups.

Group	Timeline	n	Mean	SD	t value	P value
Test group	Baseline	20	1.6900	0.37543	3.119	**0.006***
	15 days	20	1.2050	0.52863		
Control group	Baseline	20	1.5800	0.46634	1.723	0.101
	15 days	20	1.3200	0.35482		

A paired t-test was utilized for analysis, with $p \leq 0.05$ regarded as the threshold for statistical significance.

Table 6: Presents the comparison of mean Bleeding on Probing (BOP) index scores between the groups

Timeline	Group	n	Mean	SD	t value	P value
Baseline	Test group	20	1.6900	0.37543	0.822	0.416
	Control group	20	1.5800	0.46634		
15 days	Test group	20	1.2050	0.52863	-0.808	0.424
	Control group	20	1.3200	0.35482		

An independent t-test was applied, with $p \leq 0.05$ considered indicative of statistical significance.

Table 7: Shows the intra-group comparison of mean values for the Modified Stain Index

Group	Timeline	n	Mean	SD	t value	P value
Test group	Baseline	20	2.2650	0.60024	17.351	**<0.001***
	15 days	20	1.8900	0.56652		
Control group	Baseline	20	2.4200	0.63875	-5.994	**<0.001***
	15 days	20	2.8650	0.62178		

A paired t-test was used for statistical analysis, with significance defined as $p \leq 0.05$.

Table 8: Displays the comparison of average Modified Stain Index scores between the two groups.

Timeline	Group	n	Mean	SD	t value	P value
Baseline	Test group	20	2.2650	0.60024	-0.791	0.434
	Control group	20	2.4200	0.63875		
15 days	Test group	20	1.8900	0.56652	-5.184	**<0.001***
	Control group	20	2.8650	0.62178		

An independent t-test was employed, with a p-value of ≤ 0.05 regarded as statistically significant.

Table 1 Both test and control groups showed plaque and gingival inflammation (GI) scores showed a significant decrease from baseline to day 15 (all $p < 0.001$). The groups remained comparable, with no significant changes detected at day 0 or day 15.

The group A demonstrated a significant reduction in bleeding on probing (BOP) .A statistically significant improvement was observed in the group A scores ($p = 0.006$), while the group B remained unchanged. Still, BOP scores showed no significant variation between the groups at baseline or after 15 days.

Notably, the group A showed a marked reduction in stain index ($p < 0.001$), in contrast to the control group, which demonstrated a significant rise in stain accumulation ($p < 0.001$). This led to statistically significant difference in stain index favouring the test group at 15 days ($p < 0.001$).

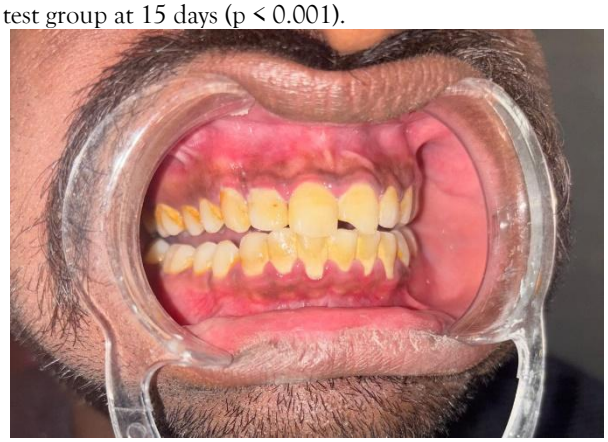

Fig 1 : Preoperative view of patient with gingivitis

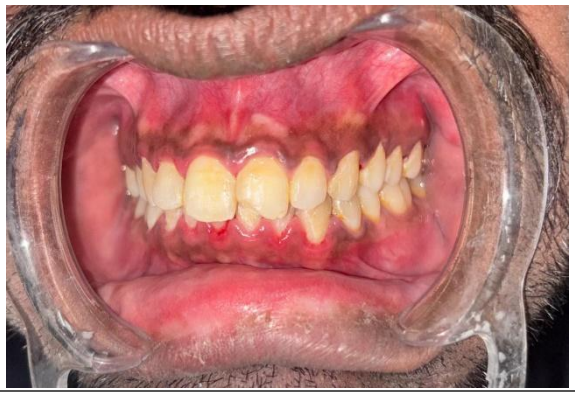

Fig 2 : Post-operative view of patient with gingivitis

DISCUSSION

This work focuses on exploring the efficacy and potential side effects of a 0.2% chlorhexidine (CHX) mouthwash with an Anti-Discoloration System (ADS) to those of a standard 0.2% CHX mouthwash in patients suffering from chronic periodontitis. Our key measures were the indices assessing dental plaque (plaque index), gum health (gingival index), bleeding response during probing (bleeding on probing index), and Modified Stain Index (MSI). (fig 1 and 2).

In contrast to the group B, a significant decline in bleeding on probing was observed in the group. Although inter-group differences in BOP were not statistically significant, this finding suggests a potential clinical advantage of the test intervention in reducing gingival bleeding.

Most notably, the test group showed a marked reduction in stain accumulation, while the control group demonstrated an increase. There was a statistically meaningful variation between the groups at the 15-day mark in the Modified Stain Index strongly supports the efficacy of the test intervention in stain prevention or reduction, an important aesthetic consideration in oral hygiene compliance.These findings align with prior studies indicating the benefits of targeted interventions in oral hygiene routines. Nevertheless, the lack of significant differences in most inter-group comparisons suggests that longer observation periods or larger sample sizes may be needed to further elucidate the comparative advantages of the test product.

The purpose behind this study was to evaluate the clinical effectiveness and potential side effects of a 0.2% chlorhexidine (CHX) mouthwash formulated with an Anti-Discoloration System (ADS), in comparison to a conventional 0.2% CHX mouthwash, in individuals diagnosed with chronic periodontitis. Key clinical parameters assessed included the Plaque Index (PI), Gingival Index (GI), Bleeding on Probing (BoP), and the Modified Stain Index (MSI).Both mouthwashes demonstrated comparable effectiveness in reducing plaque accumulation. Analysis revealed no meaningful statistical difference in PI values between the group A and B. This finding aligns with previous studies, such as **Solís et al. (2011)**[41], which reported comparable antiplaque effects between CHX with and

without ADS. Both mouthwash formulations demonstrated a comparable ability to reduce gingival inflammation, as no significant differences in GI scores were observed between the groups. This indicates that the inclusion of an Anti-Discoloration System (ADS) does not affect the anti-gingivitis properties of chlorhexidine. Similar results were reported by Solís et al. (2011), who also found no significant difference in GI scores between CHX with and without anti-stain mechanism.Both mouthwashes were effective in reducing BOP, indicating a reduction in gingival inflammation. The comparison revealed no statistically significant variation between These results align with the study by Solís et al. (2011), who also reported no significant variation in Bleeding on Probing (BOP) between chlorhexidine with and without the anti-stain mechanism.Compared to the group B, group A showed a significant decrease in tooth discolouration. The addition of ADS, which includes components like sodium metabisulfite and ascorbic acid, likely contributed to this reduction by neutralizing reactive intermediates responsible for staining. This finding corroborates previous studies, such as **Solís et al. (2011)**[41], which showed reduced staining with CHX containing ADS.Patient compliance was high, with 88% adherence to the prescribed mouthwash regimen. With respect to side effects, both mouthwash types were associated with complaints of an unpleasant taste from two patients. This is consistent with previous studies that have noted adverse effects like a bad taste, mucosal injury, and burning sensation associated with CHX use.

CONCLUSION

This study showed that both the test and control interventions effectively reduced plaque and gingival inflammation after 15 days. However, the test group offered additional advantages, significantly reducing both bleeding on probing and stain accumulation. These results suggest the test intervention is beneficial not only for improving oral health but also for maintaining a better aesthetic appearance.

It is important for future research to assess the effects over an extended period.

REFERENCES

1. Page RC, Offenbacher S, Schroeder HE, Seymour GJ, Kornman KS. Advances in the pathogenesis of peri odontitis: Summary of developments, clinical implica tions and future directions. Periodontol 2000 1997;14: 216-248.
2. Axelsson P, Lindhe J. Efficacy of mouthrinses in inhibiting dental plaque and gingivitis in man. J Clin Periodontol 1987;14:205-212.
3. Axelsson P, Nystro¨ m B, Lindhe J. The long-term effect of a plaque control program on tooth mortality, caries and periodontal disease in adults. Results after 30 years of maintenance. J Clin Periodontol 2004;31:749-757.
4. DePaola LG, Overholser CD, Meiller TF, Minah GE, Niehaus C. Chemotherapeutic inhibition of supragin gival dental plaque and gingivitis development. J Clin Periodontol 1989;16:311-315.
5. Bouwsma OJ. The status, future, and problems of oral antiseptics. Curr Opin Periodontol 1996;3:78-84.
6. Wolff LF. Chemotherapeutic agents in the prevention and treatment of periodontal disease. Northwest Dent 1985;64:15-24.
7. Nishihara T, Koseki T. Microbial etiology of peri odontitis. Periodontol 2000 2004;36:14-26.
8. Addy M, Moran JM. Clinical indications for the use of chemical adjuncts to plaque control: Chlorhexidine formulations. Periodontol 2000 1997;15:52-54.
9. Ciancio SG. Chemical agents: Plaque control, calculus reduction and treatment of dentinal hypersensitivity. Periodontol 2000 1995;8:75-86.
10. Stephen KW, Burchell CK, Huntington E, Baker AG, Russell JI, Creanor SL. In vivo anticalculus effect of a dentifrice containing 0.5% zinc citrate trihydrate. Caries Res 1987;21:380-384.
11. Lusk SS, Bowers GM, Tow HD, Watson WJ, Moffitt WC. Effects of an oral rinse on experimental gingivitis plaque formation, and formed plaque. J Am Soc Prev Dent 1974;4:31-33, passim.
12. Jenkins S, Addy M, Newcombe RJ. A dose-response study of triclosan mouthrinses on plaque regrowth. J Clin Periodontol 1993;20:609-612.59) Nordbo H. Discolouration of dental pellicle by tannic acid. Acta Odontol Scand 1977; 35: 305-310
13. Beiswanger BB, Doyle PM, Jackson RD, et al. The clinical effect of dentifrices containing stabilized stan nous fluoride on plaque formation and gingivitis — A six-month study with ad libitum brushing. J Clin Dent 1995;6(Spec. No.):46-53.
14. Addy M. Chlorhexidine compared with other locally delivered antimicrobials. A short review. J Clin Peri odontol 1986;13:957-964.
15. Wolff LF, Pihlstrom BL, Bakdash MB, Schaffer EM, Aeppli DM, Bandt CL. Four-year investigation of salt and peroxide regimen compared with conventional oral hygiene. J Am Dent Assoc 1989;118:67-72.
16. Wennstro¨ m J, Lindhe J. Some effects of a sanguinar ine-containing mouthrinse on developing plaque and gingivitis. J Clin Periodontol 1985;12:867-872.
17. Jones CM,Blinkhorn AS, White E. Hydrogen peroxide, the effect on plaque and gingivitis when used in an oral irrigator. Clin Prev Dent 1990;12:15-18.
18. Jackson RJ. Metal salts, essential oils and phenols — Old or new? Periodontol 2000 1997;15:63-73.
19. Addy M, Sharif N, Moran J. A non-staining chlorhex idine mouthwash? Probably not: A study in vitro. Int J Dent Hyg 2005;3:59-63.
20. Segreto VA, Collins EM, Beiwanger BB, et al. A com parison of mouthwashes containing two concentrations of chlorhexidine. J Periodontal Res 1986;21:23-32.

21. Jones CG. Chlorhexidine: Is it still the gold standard? Periodontol 2000 1997;15:55-62.
22. Moran J, AddyM, Kohut B, Hovliaras CA, Newcombe RG. Efficacy of mouthwashs in inhibiting the de velopment of supragingival plaque over a 4-day period of no oral hygiene. J Periodontol 1994;65: 904-907.
23. Ellingsen JE, Rølla G, Eriksen HM. Extrinsic dental stain caused by chlorhexidine and other denaturing agents. J Clin Periodontol 1982;9:317-322.
24. Arweiler NB, Boehnke N, Sculean A, Hellwig E, Auschill TM. Differences in efficacy of two commercial 0.2% chlorhexidine mouthrinse solutions: A 4-day plaque re-growth study. J Clin Periodontol 2006;33: 334-339.
25. Jenkins S, Addy M, Newcombe RG. Dose response of chlorhexidine against plaque and comparison with triclosan. J Clin Periodontol 1994;21:250-255.
26. Santos A. Evidence-based control of plaque and gingivitis. J Clin Periodontol 2003;30(Suppl. 5):13 16.
27. Ciancio SG. Antiseptics and antibiotics as chemothera peutic agents for periodontitis management. Compend Contin Educ Dent 2000;21:59-62, 64, 66 passim, quiz 78.
28. Eriksen HM, Nordbø H, Kantanen H, Ellingsen JE. Chemical plaque control and extrinsic tooth discolor ation. A review of possible mechanisms. JClinPeri odontol 1985;12:345-350.
29. Bernardi F, Pincelli MR, Carloni S, Gatto MR, Montebugnoli L. Chlorhexidine with an anti discolor ation system. A comparative study. Int J Dent Hyg 2004;2:122-126.
30. Armitage GC. Development of a classification system for periodontal diseases and conditions. Ann Peri odontol 1999;4:1-6.
31. Lo¨e H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. Acta Odontol Scand 1963; 21:533-551.
32)Li W, Wang RE, Finger M, Lang NP. Evaluation of the antigingivitis effect of a chlorhexidine mouthwash with or without an antidiscol- oration system compared to placebo during experimental gingivitis. J Investig Clin Dent. 2014;5:15-22.
33) Nao SUZUKI1 Yoshio NAKANO2 .Two mechanism of oral malodour inhibition by zinc ions.
34) De Amorim RG, Leal SC. Association of chlorhexidine and fluoride for plaque control and white spot lesion remineralization in primary dentition. Int J Paediatr Dent 2008 Nov;18(6): 446-451.
35). Lo¨e H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. Acta Odontol Scand 1963; 21:533-551.
36) Silness J, Loe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. Acta Odontol Scand 1964;22:121-135.
37) Lo ¨e H. The gingival index, the plaque index and the retention index systems. J Periodontol 1967;38:610-616.
38) Lobene, R. R. Effect of dentifrices on tooth stains with controlled brushing. J Am. Dent. Assoc. 77(4), 849–855 (1968).
39) Macpherson, L. et al. Comparison of a conventional and modified tooth stain index. J. Clin. Periodontol. 27(11), 854–859 (2000).
40) Ainamo, J. & Bay, I. Problems and proposals for recording gingivitis and plaque. Int. Dent. J. 25, 229–235 (1975).
41) 0.2% Chlorhexidine Mouthwash With an Antidiscoloration System Versus 0.2% Chlorhexidine Mouthwash: A Prospective Clinical Comparative Study.