Original Research Article

Chlorhexidine mouth rinse with a plasdone based anti-discolouration system for maintenance after periodontal flap surgery: A comparative clinical study

Huda Hussain[1*], Suhail Majid Jan[2], Roobal Behal[3]

[1]Postgraduate Scholar, Department of Periodontics, Government Dental College and Hospital, Srinagar, J&K, India
2Professor and Head, Department of Periodontics, Government Dental College and Hospital, Srinagar, J&K, India
[3]Assistant Professor, Department of Periodontics, Government Dental College and Hospital, Srinagar, J&K, India
[*]Corresponding author email: **dr.huda.hussain@gmail.com**

International Archives of Integrated Medicine, Vol. 6, Issue 5, May, 2019.

Available online at http://iaimjournal.com/
ISSN: 2394-0026 (P) **ISSN: 2394-0034 (O)**
Received on: 25-04-2019 **Accepted on:** 08-05-2019
Source of support: Nil **Conflict of interest:** None declared.
How to cite this article: Huda Hussain, Suhail Majid Jan, Roobal Behal. Chlorhexidine mouth rinse with a plasdone based anti-discolouration system for maintenance after periodontal flap surgery: A comparative clinical study. IAIM, 2019; 6(5): 124-131.

Abstract

Background: A number of chlorhexidine mouth rinse preparations have been developed with 'anti-discoloration' additives, in an attempt to counteract the undesirable tooth discoloration that accompanies the clinical activity of this 'gold-standard' plaque control agent. However, the efficacy of such formulations for periodontal maintenance remains yet to be elucidated.

Aim: To evaluate the feasibility and efficacy of 0.2% chlorhexidine mouthwash with a plasdone (polyvinylpyrrolidone) anti-discoloration system for maintenance after flap surgery, as compared to conventional 0.2% chlorhexidine mouthwash.

Methods and Material: The investigation was carried out at the Department of Periodontology, Government Dental College and Hospital, Srinagar, and was designed as a randomized parallel group, triple blind study. Forty patients with chronic periodontal disease, with at least one sextant (with the presence of at least two teeth) scheduled for flap surgery were included and randomly divided into two groups. After preparation, open flap debridement was carried out and the patients were provided pre-calibrated color masked bottles, containing either 0.2% chlorhexidine, or 0.2% chlorhexidine with an anti-discoloration system, which they were instructed to use twice a day (10 ml for 1 minute) for 3

months. Tooth brushing was reinstituted one week after surgery and the patients were recalled every 15 days. Gingival index, Plaque index and Discoloration index were recorded immediately before, 1 month and 3 months after surgery and compared in the two groups. The quantitative data was evaluated as means and standard deviations (SD). Paired t-test was used to evaluate the intragroup differences; intergroup comparisons of post-treatment changes were analyzed by unpaired t-test. P-values <0.05 were considered to statistically significant.

Results: Post-operative healing and patient compliance were satisfactory with either mouth rinse. After 3 months of use, a statistically non-significant difference ($p<0.05$) between the two treatments was found for all indices, with the values being marginally higher for the CHX-ADS mouthwash. Over time, plaque index and discoloration were significantly increased over baseline in both the treatments, however, inter-treatment variation was non-significant.

Conclusions: The statistical analysis of the present data reveals that PVP neither significantly reduced the efficacy of 0.2% chlorhexidine nor significantly reduced the staining side effect.

Key words

Chlorhexidine, Anti-discoloration, Flap surgery, Maintenance.

Introduction

The results of periodontal surgery can be effectively maintained if a proper standard of hygiene is sustained during the early healing phase [1, 2, 3]. Though ideal plaque control can be achieved by sequenced bimonthly professional debridement through the first six months of maintenance, these procedures are quite demanding, not only for the dentist and auxiliaries, but also for patients; making them largely impractical. Moreover, as self-performed oral hygiene is compromised during the post-operative period, contemporary research efforts have focussed on supplementing plaque control with the use of antiseptics and antibiotics in the treatment and subsequent maintenance care of patients with advanced periodontal disease [4].

Sanz, et al. [5] showed that the post-operative use of 0.12% CHX mouthwash after flap surgery was found to enhance healing as compared to periodontal dressing. Thereafter, it was demonstrated that the use of 0.2% CHX mouth-rinse is an effective alternative to conventional professional debridement during the first six months after open flap debridement [6]. However, the prolonged use of chlorhexidine was soon found to be associated with brown pigmentation of the dental surfaces, prosthesis and tongue [7], which was a bothersome & common side effect, postulated to occur, among other mechanisms, by the precipitation of ionic complexes of tooth-adsorbed CHX and dietary chromogens [8].

To overcome this adverse effect, anti-discoloration additives like peroxiborate, and ascorbic acid have been incorporated in the traditional CHX mouth rinse, with reported efficacy in preventing tooth discoloration when after flap surgery [9]. However, more recently, polyvinyl pyrrolidone (PVP), a surface binder has been tested for this purpose [10]. Commonly known as Plasdone, PVP, is a medical grade binder which forms complexes with catechins and other chromogens and is the active component in “whitening” chewing gums and toothpastes, where it delivers non-abrasive and non-oxidative tooth whitening. When evaluated in a crossover randomized trial [11], chlorhexidine with a plasdone based anti-discoloration system was found to prevent plaque formation and dental stains as compared to chlorhexidine alone, when used for a period of 15 days after oral prophylaxis. However, the effect of this system on plaque control and tooth discoloration in the long term has not been evaluated and remains elusive. This elucidation is even more relevant to maintenance after flap surgery, where chlorhexidine may be used for

extended periods in the setting of compromised mechanical plaque control.

Therefore, the present study was designed to evaluate the feasibility and efficacy of 0.2% CHX mouthwash with a PVP anti-discoloration system for use during maintenance after flap surgery, as compared to conventional 0.2% CHX mouthwash.

Materials and methods

The study was designed as a single-centre, triple-blind randomized clinical trial on 40 consecutive patients scheduled for periodontal flap surgery, comparing a 0.2% CHX mouthwash containing an ADS (plasdone K 19/32) with a mouthwash containing 0.2% CHX. Prior to commencement of the study, ethical clearance was obtained from the institutional ethical committee, and informed written consent was obtained from all participants. Patients with advanced periodontal disease, in general good health, presenting with at least one sextant scheduled for periodontal flap surgery, were considered to be eligible for this study. They were recruited after completion of cause-related therapy consisting of scaling and root planing, motivation and oral hygiene instructions.

The inclusion criteria were as follows:

- Patients with chronic periodontal disease, with at least one sextant, with at least two teeth scheduled for flap surgery.
- Systemically healthy patients.
- Good oral hygiene--full-mouth plaque score≤ 25%.
- Bleeding Points score ≤25%.
- Patients willing to participate in the study.

Patients were excluded based on the presence of:

- Allergy to chlorhexidine.
- Smoking
- Use of any oral medications known to cause staining of teeth.
- Systemic diseases.

The study was designed to have 80% power to detect an odds ratio (OR): 0.25 for pigmentation of the test CHX versus control CHX. The α level was set at 0.05. The proportion of pigmentation in the control group was set at 0.6 and the correlation coefficient for staining between paired data was set at 0.1 [12]. The required number of patients was 39. The final number of patients recruited was 40.

At baseline, patients were surgically treated with periodontal flap surgery by a single operator. Immediately before surgery Gingival Index [13], Plaque Index [14] and Discoloration Index [15] were recorded and full-mouth prophylaxis was performed with a low speed rubber cup. Periodontal surgery was performed according to clinical indications. Interrupted passing or external mattress sutures (4-0) were applied to close the flaps. At the end of surgery, all patients received an anonymous bottle containing a mouthwash along with a 10 ml calibrated glass. The bottles were coded as either A or B and allotted randomly by coin toss method. The test mouthwash (A) was a commercially available 0.2% CHX with ADS (plasdone K 29/32 also known as crospolyvinylpyrrolidone) (Chlohex-ADS ®, Dr.Reddy's Laboratories, India) and the control (B) was commercially available 0.2% CHX (Chlohex®, Dr. Reddy's Laboratories, India) mouthwash. Patients were prescribed to rinse two times per day with 10 ml of the mouthwash for 1 min and the amount of product per bottle was calibrated as per recall interval to satisfy this prescription. Brushing and interdental cleaning of the surgical area were not allowed for the first post-surgical week. At week 1, patients were examined and sutures were removed. Thereafter, tooth brushing (twice daily) was re-instituted and the patients were recalled every 15 days. At the end of 1 month and 3 months, the gingival index, plaque index and discoloration index were recorded. The patients were asked to bring back the bottles to directly check for compliance with the rinsing prescription. All patients were instructed in the bass method of tooth-brushing (twice daily) and prescribed the same brand of toothbrush (soft) and toothpaste (of which the patients were instructed to use a pea sized amount). Subjects were asked not to eat

or drink for 30 minutes after using the mouthwash and to allow a gap of 10 minutes between tooth-brushing and mouth-washing. They were also asked to maintain a dairy to record their diet (intake of tea/coffee per day) which was checked at each recall.

The quantitative data was evaluated as means and standard deviations (SD). Paired t-test was used to evaluate the intragroup differences; intergroup comparisons of post-treatment changes were analyzed by unpaired t-test. P-values <0.05 were considered to statistically significant. The interaction between time and treatment was also considered, exploring in particular a potential difference in the effect of the two tested products in month 1 or in month 3.

Results

All recruited patients completed the study. The mean age was 45.6± 10.7 years (minimum: 30; maximum: 62 years). All patients reportedly used the mouthwashes according to prescriptions, as evaluated by the periodic appraisal of the used bottles; none reported any complication or unexpected complaint. From the diet records, it was found that patients consumed an average of 3.4, and maximum 4 cups of tea per day.

Figure - 1 shows the changes in gingival, plaque and discoloration index for the two groups at 1 month recall. A statistically non-significant difference (P<0.05) between the two treatments was found for these indices, with the values being marginally higher for the CHX-ADS mouthwash. Similar changes were noted at the 3 month recall, where gingival, plaque and discoloration indices differed between the two treatments non-significantly.

Figure - 1: Gingival index, Plaque index and Discoloration index with the use of test (CHX-ADS) and control (CHX) mouthwash after a) 1 month and (b) 3 months.

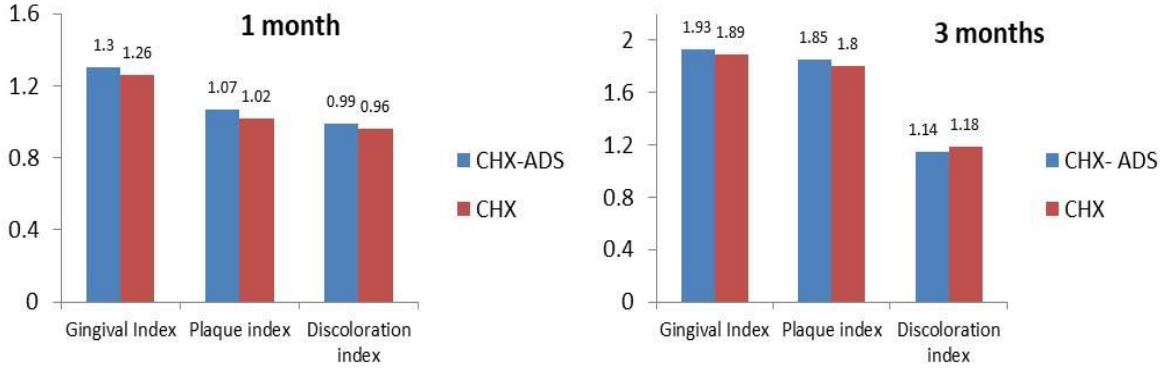
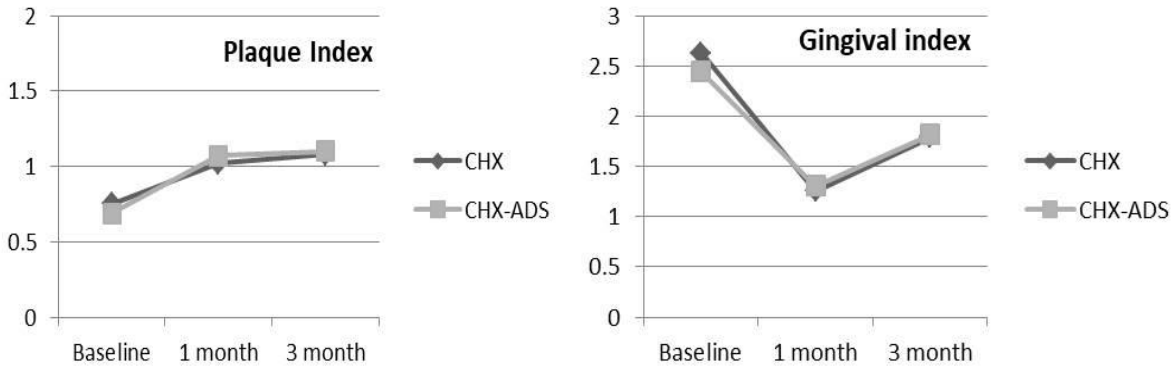
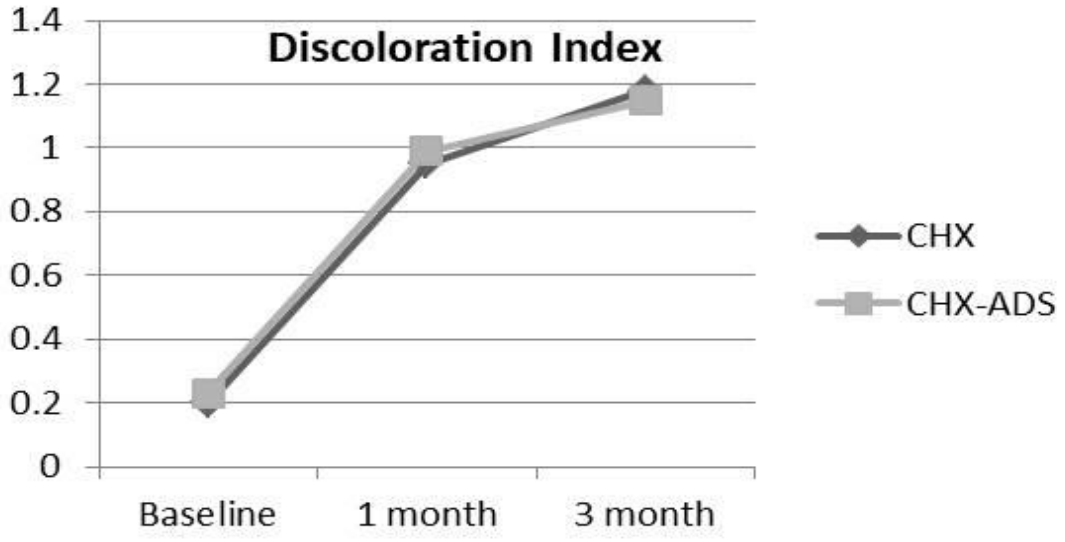


Figure - 2: Changes in (a) Plaque index, (b) Gingival index and (c) Discoloration index over time with the use of test (CHX-ADS) and control (CHX) mouthwash.





Changes over time with the use of either treatment are depicted in **Figure - 2**. As is evident plaque index, and discoloration were significantly increased over baseline in both the treatments, however, inter-treatment variation was non-significant. Gingival index decreased during the first month after flap surgery, thereafter a minimal elevation was noted during the next two months of maintenance for both the treatments. Nevertheless, GI remained below 2 for the entire duration of the study. In this case again, the two mouth rinses differed non-significantly in maintaining gingival health.

Discussion

The present study evaluated plaque control efficacy, maintenance of gingival health and potential for tooth discoloration following the use of CHX mouthwash with an anti-discoloration system consisting of plasdone K29/32 (crospolyvinylpyrrollidone) during maintenance after periodontal flap surgery.

With regard to plaque control, both mouth rinses were found to perform equally, with there being a statistically non-significant difference between the two. Similar results have been reported for CHX-ADS system containing plasdone by Periera and Phad [11]. In concomitance, gingival health was maintained equally by both the treatments, with mean GI remaining less than 2 throughout the study. Similar observations have been made by Claydon, et al. [16]. It has been shown in vitro that, though the inhibition of colony forming units of bacteria by CHX-ADS is sufficient for a long term prophylactic application, it is significantly less than that of CHX without ADS [17]. Pertinently, for effective plaque control, a formulation should contain at least 4mg of active chlorhexidine; there are only relatively small gains in effect with doses greater than 6–10 mg X2 per day [18, 19]. Hence, in the present study, 0.2% chlorhexidine was used, which independent of PVP would have delivered an effective dose of 14-20 mg CHX, which would place the effect on the flat part of the dose-response curve, and hence account for the statistically non-significant difference between the two formulations. Clinically however, differences in the efficiency of either mouthwash were apparent, and may be of consequence in the long term. A numerical trend for higher PI and GI was observed with CHX-ADS, as plaque control and maintenance of gingival health were clinically better with traditional CHX, as compared to CHX-ADS (**Figure - 1**, **Figure - 2**). As plaque inhibition is derived only from the cationic CHX adsorbed to the tooth surface, and anionic surfactants may inhibit this activity by binding to the active site on the CHX molecule [19]; hence, it may be likely that plasdone, which is also a surface

active agent may occupy binding sites in a competition for tooth surfaces or may overly the adsorbed chlorhexidine thereby reducing the surface area for binding of CHX [16]. A chemical interaction between the two is unlikely, as no precipitation occurs on mixing. Elucidation of the physicochemical interactions between CHX and plasdone on the tooth surface milieu need to be elucidated to be able to justify these findings with confidence.

In accordance with the observations on plaque control, gingival health was also better maintained clinically in the CHX group as compared to CHX-ADS group. Cortinelli, et al. [9] studied the effect of CHX-ADS on early healing (15 days) after flap surgery, in comparison with CHX without ADS; it was found that either mouthwash did not have any adverse effect on gingival changes during healing. Similar conclusions were made in the present study, where the use of CHX-ADS and CHX without ADS was monitored for 3 months after flap surgery, and post-op healing was not found to be affected by either mouth rinse; all surgical sites responded well to flap debridement, which was evident from the improvement in mean GI over time (**Figure - 2**). Minor differences observed in GI could be attributed to the corresponding plaque control efficacy of each mouthwash.

With regard to the staining potential of CHX, it was found that addition of plasdone did not prevent the occurrence of stains, rather, it modified the pattern and intensity of staining over the tooth surface. At the end of 3 months, brown stains were observed in case of control (CHX) mouthwash which were more pronounced in the interproximal areas, whereas the test (CHX-ADS) mouth rinse resulted in deeper yellowish film over the entire tooth surface, with slight concentration along the interproximal areas. As both features received a similar score in the stain index, statistically significant difference between the two could not be established. These results are in agreement with those of Claydon, et al. [16], who showed that area of tooth stain did not differ significantly for CHX/PVP mouthwash as compared to CHX alone; difference was only reported in the intensity of tooth stain along the gingival margin. The staining associated with chlorhexidine appears to result largely from an interaction on surfaces of the cationic antiseptic with anionic dietary. In the present study, it was apparent that the PVP did not block this reaction to a clinically meaningful extent. Taken with the plaque data, the suggestion of a temporary sandwiching of chlorhexidine between pellicle coated tooth surface and PVP is an attractive explanation for the findings. Thus, it is possible that chlorhexidine being highly polar is more rapidly absorbed to surfaces than PVP: the PVP therefore adsorbing on top of the chlorhexidine. But given that PVP is relatively non-polar, once the concentration of PVP in the oral environment falls, desorption would occur re-exposing the reactive chlorhexidine [16]. Alternatively, from the staining pattern observed herein, it appears that plasdone does complex with dietary chromogens, however due to the surface active properties of PVP and ionic nature of CHX, the plasdone-chromogen complex is unable to release from the tooth surface and remains adsorbed there, possibly attached to CHX. In any event, molecular interactions between the two molecules need to be elucidated to validate these hypotheses.

Conclusion

In conclusion, the statistical analyses of the present data reveal that PVP neither significantly reduced the efficacy of 0.2% chlorhexidine nor significantly reduced the staining side effect. Nevertheless, there was a numerical pattern for greater plaque accumulation, more gingivitis and diffuse staining with the CHX-ADS rinse compared to chorhexidine alone and hence equivalence for the two rinses therefore cannot be justified. This study presents pioneer evidence for the clinical effect of 0.2% CHX with a plasdone based anti-discoloration system when used for maintenance after periodontal flap surgery, and amid strongly marketed commercial “anti-discoloration” mouth rinses, provides

valuable information to base further research and clinical decisions and indicates the need to review such combinations with regard to appropriate concentration for long term use.

References

1. Ramfjord SP, Knowles JW, Nissle RR, Shick RA, Burgett FG. Longitudinal study of periodontal therapy. Journal of Periodontology, 1973 Feb; 44(2): 66-77.
2. Ramfjord SP, Knowles JW, Nissle RR, Burgett FG, Shick RA. Results following three modalities of periodontal therapy. Journal of Periodontology, 1975 Sep; 46(9): 522-6.
3. Lindhe J, Westfelt E, Nyman S, Socransky SS, Heijl L, Bratthall G. Healing following surgical non-surgical treatment of periodontal disease: A clinical study. Journal of clinical periodontology, 1982 Apr; 9(2): 115-28.
4. Loesche WJ. Chemotherapy of dental plaque infections. Oral Sci Rev., 1976; 9: 65-107.
5. Sanz M, Newman MG, Anderson L, Matoska W, Otomo-Corgel J, Saltini C. Clinical enhancement of post-periodontal surgical therapy by a 0.12% chlorhexidine gluconate mouthrinse. Journal of periodontology, 1989 Oct; 60(10): 570-6.
6. Westfelt E, Nyman S, Lindhe J, Socransky S. Use of chlorhexidine as a plaque control measure following surgical treatment of periodontal disease. Journal of clinical periodontology, 1983 Feb; 10(1): 22-36.
7. Löe H, Schiött CR, Karring G, Karring T. Two years oral use of chlorhexidine in man. I. General design and clinical effects. Journal of periodontal research, 1976 Jun; 11(3): 135-44.
8. Watts A, Addy M. Tooth discolouration and staining: Tooth discolouration and staining: a review of the literature. British dental journal, 2001 Mar 24; 190(6): 309.
9. Cortellini P, Labriola A, Zambelli R, Pini Prato G, Nieri M, Tonetti MS. Chlorhexidine with an anti discoloration system after periodontal flap surgery: a cross-over, randomized, triple-blind clinical trial. J Clin Periodontol., 2008; 35: 614-620.
10. Claydon N, Addy M, Jackson R, Smith S, Newcombe RG. Studies on the effect of polyvinyl pyrrolidone on the activity of chlorhexidine mouthrinses: plaque and stain. Journal of clinical periodontology, 2001 Jun; 28(6): 558-64.
11. Pariera R, Phad SG. Comparative evaluation of 0.2% chlorhexidine mouthrinse with and without an antidiscoloration system: A clinical study. J Contemp Dent., 2017; 7(1): 53-56.
12. Dupont WD, Plummer Jr WD. Power and sample size calculations: a review and computer program. Controlled clinical trials, 1990 Apr 1; 11(2): 116-28.
13. Löe H, Silness J. Periodontal disease in pregnancy I. Prevalence and severity. Acta odontologica scandinavica., 1963 Jan 1; 21(6): 533-51.
14. Silness J, Löe H. Periodontal disease in pregnancy II. Correlation between oral hygiene and periodontal condition. Acta odontologica scandinavica. 1964 Jan 1;22(1):121-35.
15. Li W, Wang RE, Finger M, Lang NP. Evaluation of the antigingivitis effect of a chlorhexidine mouthwash with or without an antidiscoloration system compared to placebo during experimental gingivitis. Journal of investigative and clinical dentistry, 2014 Feb; 5(1): 15-22.
16. Claydon N, Manning CM, Darby-Dowman A, Ridge D, Smith S, Addy M. The effect of polyvinyl pyrrolidone on the clinical activity of 0.09% and 0.2% chlorhexidine mouthrinses. Journal of clinical periodontology, 2001 Nov; 28(11): 1037-44.

17. Guggenheim B, Meier A. In vitro effect of chlorhexidine mouth rinses on polyspecies biofilms. Schweiz Monatsschr Zahnmed., 2011; 121: 432–41.
18. Cancro LP, Paulovich DB, Bolton S, Picozzi A. Dose response of chlorhexidine gluconate in a model in vivo plaque system. Journal of Dental Research, 1974 May; 53(3): 765.
19. Jenkins S, Addy M, Newcombe RG. Dose response of chlorhexidine against plaque and comparison with triclosan. Journal of clinical periodontology, 1994 Apr; 21(4): 250-5.