Antiplaque and Antigingivitis effect of a Dentifrice containing Bioactive Glass particulate-A Randomized Clinical Trial

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Abstract

Background: Maintenance of gingival health is critical in preventing gingivitis and its progression into periodontal disease. Bioactive glass has recently been formulated into a dentifrice and has demonstrated strong antimicrobial property.
Objectives: The objective of this clinical trial was to evaluate the antigingivitis and antiplaque effect of a dentifrice containing bioactive glass compared with a placebo control dentifrice in a four weeks clinical study.
Methodology: The Study design was a randomized triple blind parallel clinical trial. Sixty volunteers took part in the study and were matched for age and gender. Plaque index (Turesky et al modified Quigley Hein index, 1970) and Gingival bleeding index (Ainamo and Bay, 1975) was recorded at baseline for all selected subjects. Following the baseline assessments, all subjects received a supragingival prophylaxis and polishing to remove plaque, calculus and extrinsic stain. After prophylaxis the plaque levels were brought to uniform levels, ideally close to zero, which was assessed by plaque index. After which the subjects were instructed on the proper brushing technique with their assigned dentifrice and toothbrush. Gingiva and plaque was evaluated at the end of 4 weeks using same indices.
Results: A total of 60 subjects completed the study. Total number of participant (n) = 60 males (n) =50 females (n) =10. The results showed that the PLI (baseline 1.12, 4 weeks 0.65) and GBI (baseline 0.16, 4 weeks 0.08) were significantly reduced, respectively, over the 4 weeks period in the test group ($p<0.001$ for each measure). There was a 50% reduction in gingival bleeding and a 40%reduction in plaque growth. There was no difference of the PLI (baseline 1.34, 4 weeks 1.30) and GBI (baseline 0.13, 4 week 0.15) over the 4 week period in the control group.
Conclusion: The study demonstrated that the dentifrice containing Bioactive glass significantly improves gingival health as measured by a reduction in gingival bleeding and reduction in supragingival plaque compared with Placebo dentifrice over the 4 weeks study period.

KEYWORDS: Anti-gingivitis, Anti-plaque, Bioactive glass, Dentifrice.

Introduction

The prevention of dental caries and periodontal diseases is targeted at the control of dental plaque. In this context, chemical agents could represent a valuable complement to mechanical plaque control. The active agents should prevent biofilm formation without affecting the biological equilibrium within the oral cavity. Toothpaste formulations containing antimicrobial agents in addition to fluoride are designed to reduce the levels of plaque and its pathogenic bacteria whilst maintaining the healthy balance of the oral cavity. Reductions in pathogenic bacteria have been associated, in particular, with reductions in periodontal diseases such as gingivitis.

Maintenance of gingival health is critical in preventing gingivitis and its progression into periodontal disease. A recent survey of periodontal health reported that as many as 62% of the adult population in the United States suffers from gingivitis as determined by gingival bleeding.[1] A similar study conducted in the United Kingdom reported that over 70% of adults had visible plaque on examination.[2]The control of plaque in the maintenance of gingival health has been well established in the literature .The role of plaque-associated bacteria in the development of gingivitis has also been studied extensively [3.] This study demonstrated that professional plaque control had a significant influence on subgingival bacterial levels. McNabb et al. (1992) [4]and Hellstrom et al. (1996) [5]showed that rigorous self performed plaque control over long periods of time reduced the levels and composition of subgingival bacteria and reduced the frequency of deep periodontal pockets.

Owing to the established relationship between bacteria, plaque and gingivitis, major focus in the treatment of gingivitis in recent years has been the development and use of various antimicrobial therapies. Chlorhexidine [6], triclosan/co-polymer and hexetidine) [7] have all, been shown to reduce plaque and gingivitis in various clinical studies. Essential oil-containing mouthrinses have also demonstrated reductions in plaque and gingivitis in clinical studies [7,8].

Many of these clinical studies have demonstrated improvements in indices of gingival health, which have been ascribed to the anti-microbial properties of the various compounds.There has also been a significant body of in vitro research that has demonstrated anti-microbial properties of these compounds. In a study comparing the anti-microbial efficacy of a triclosan/zinc dentifrice, Finney et al. (2003) found a broad spectrum of anti-microbial activity against a mixed biofilm.[9]

Bioactive glasses have been used in bone and tissue regeneration for over 15 years Recently, anti-microbial properties inherent in these materials have been described.[10] one of these compositions has recently been formulated into a dentifrice and has demonstrated strong anti-microbial behaviour in vitro[11,12]. There is also in vivo report of an anti-gingivitis effect which, in one Chinese study, showed a 16% reduction in plaque and a 59% reduction in gingival bleeding.[13] Although a variety of antiplaque, antigingivitis agents have been evaluated in randomized trials, this is the first time that a dentifrice that does not contain antibiotics and/or fluoride has been shown to have a therapeutic effect on gingival health.

Hence this study was undertaken to test the hypothesis that antigingivitis effect of Bioglass when incorporated into a daily use dentifrice could improve the indices of gingival health in adult population with no periodontitis.

Material and methods

A sample size of 60 students was recruited into the study through simple random sampling. Study design was a randomised triple blind parallel clinical trial comparing experimental dentifrice containing Bioactive glass to a placebo formulation. All subjects provided written informed consent for participation in the study. Subjects were above 18 years of age from V.V. Puram Arts and Commerce Degree College, Bangalore .Sample size calculations were based on detecting a difference of 0.2 in plaque score between the test group and the control group using a significance level of 5% with 80% power.

The inclusion criteria required study subjects to be aged 18 years and above, in good general health, minimum of 20 scorable teeth, no visible signs of untreated caries. Exclusion criteria included patients who received antibiotics or anti-inflammatory therapy within 14 days of the baseline examination or were on long-term antibiotic or anti-inflammatory therapy, patients who had periodontal pockets in excess of 4mm, no partial dentures or clinically unacceptable restorations or bridges, pregnant or lactating women and patients with removable dentures (partial or full).

A single Investigator conducted the study. The Investigator, Subjects and the Analyser were all blinded in the study. A complete clinical oral assessment of all the subjects was carried out based on inclusion and exclusion criteria for selection of study subjects. Plaque index[14] Gingival bleeding index[15]were recorded at baseline for all selected subjects. After assessment subjects underwent oral prophylaxis to bring the plaque levels to uniformly low state, ideally close to zero. After oral prophylaxis subjects were instructed on the proper brushing technique (Modified Bass) and were given either the test dentifrice or placebo formulation. The dentifrices were packed in plain white tubes (50 g each) labeled only as sample A and sample B to insure proper blinding of the product from the subjects and the examiner. The test and control dentifrices were dispensed to subjects along with a diary to record product usage and daily oral hygiene activity. The two Dentifrices were similar in terms of their texture and colour. Subjects were assigned and consorted to one of the toothpastes randomly by an assistant. Based on the dentifrice received (A or B) the group was divided as group A and group B. All the subjects in both the groups were given a soft bristled toothbrush for use during the study. The study groups were asked to refrain from all other unassigned forms of oral hygiene, including non study toothbrushes or toothpastes, dental floss, chewing gum or oral rinses during the study. After 4 weeks, subjects were recalled. Subjects abstained from all oral hygiene procedures for 8 hours prior to the visit. Study subjects were asked to return the paste and toothbrush. Gingiva and Plaque were evaluated at the end of 4 weeks using same indices by same investigator. The Dentifrices

were decoded after the data was analysed. Sample A: Experimental dentifrice containing active ingredient Bioglass Sample B: Control dentifrice

Statistical analysis

Data was analysed by Paired and unpaired Student t test to determine if there were any significant differences within the group or between groups. Data was analysed with statistical SPSS 13 software package.

Results

A total of 60 subjects completed the study among them 50 were males and females were 10. Mean age of the subjects in both the groups were 19.6 years (SD 1.4)

Test Group recorded higher mean PI at baseline compared to control and the difference in mean PI at baseline between the two groups was not statistically significant (P>0.05).

Control group recorded higher mean PI at 4 weeks compared to test Group after 4 weeks and the difference in mean PI at 4 weeks between the two groups was found to be statistically significant (P<0.001).

Test Group recorded higher mean GI at baseline compared to control Group but the difference in mean GI at baseline between the two groups was not statistically significant (P>0.05).

Control Group recorded higher mean GI at 4 weeks compared to test Group and the difference in mean GI at 4 weeks between the two groups was found to be statistically significant (P<0.05).

Group	Mean	Std dev	Median	Min	Max
Test Group	19.63	1.40	19.5	17	22
Control Group	19.60	1.43	19.0	18	23

Table 1: Mean age of the samples in both the groups

Sex	n	%
Male	50	83%
Female	10	17%
Total	60	100%

Table2: Sex distribution in the sample

Parameter	Group	Mean	Std dev	Mean difference	t	P-Value
PI – Baseline	Test group	1.12	0.33	-0.221	-2.147	0.056
	control	1.34	0.46			
PI - 4 Weeks	Test group	0.65	0.24	-0.644	-5.957	<0.001*
	control	1.30	0.54			
GI – Baseline	Test group	0.16	0.18	0.023	0.690	0.493
	control	0.13	0.05			
GI - 4 Weeks	test	0.08	0.04	-0.071	-2.550	0.016*
	control	0.15	0.15			

**denotes significant difference*

Table3: Comparison of PI and GI at different time intervals between the two groups

Discussion

The purpose of this clinical study was to evaluate the effect of a new bioactive glass-containing dentifrice on the gingival health of an adult population with moderate gingivitis. The material was incorporated into a non-aqueous dentifrice formulation without fluoride and contained 5% by weight of the bioactive glass. The results demonstrated a significant reduction in GBI (50%) over a 4-week period of twice daily use, and a statistically significant reduction in PLI (40%) over that same period. In both cases, there was a statistically significant difference in both the PLI ($p<0.001$) and GBI ($p<0.05$) between the (Bioactiveglass Dentifrice) test group and the control group at the 4-week time period.
The results of the current study demonstrated a significant reduction in gingivitis in a relatively short period of time**.** There were no adverse effects reported with the use of the Bioglass dentifrice The data in this study compares favorably with those from a clinical study performed at the university of Wuhan in 2005, Tai Bj et al, where there was a 58.8% reduction in gingival bleeding and a 16.4% reduction in plaque growth formulation. The results were consistent in demonstrating a significant effect in reducing plaque and gingivitis with bioactive glass dentifrice.

Limitations

Since this study was short term clinical study, further clinical studies are required to determine the long-term effectiveness of this new compound. Additional studies should also be undertaken to determine, if there will be any build-up of microbial resistance and to determine whether the reductions seen in the bleeding index in this study are due to a modification of the plaque composition either in amount or species of bacteria, or merely a reduction in the overall plaque level.

Conclusion

The study demonstrated that the dentifrice containing Bioactive glass significantly improves gingival health as measured by a reduction in gingival bleeding and reduction in supragingival plaque compared with Placebo dentifrice over the 4 weeks study period.

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