Short Term Clinical Effects of a Herbal Based Toothpaste

-A Randomized Clinical Trial

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Abstract : A randomized, double blind, pilot clinical study was performed to compare the effectiveness of a herbal –based test toothpaste at reduction of existing plaque, gingivitis and extrinsic dental stains with a placebo, over six weeks. 48 subjects were instructed to brush twice daily with the supplied toothpaste (test or placebo) and toothbrush using modified bass method of brushing and refrain from other unassigned forms of oral hygiene aids. No prophylaxis was undertaken prior to commencement of the study. Subjects were assessed at baseline, 2, 4 and 6 weeks using Turesky et al .modification of the Quigley and Hein plaque index, gingival index and Macpherson et al .modification of Lobene stain index. Immediately after completion of six weeks, subjects received a professional prophylaxis.

Both the toothpastes were found to be effective in reduction of existing plaque. Gingivitis and extrinsic dental stains. The test toothpaste resulted in a statistically significant improvement in all the parameters except the plaque index when compared with the placebo toothpaste at the end of 6 weeks. The findings of the present study would imply that the herbal –based test toothpaste may confer some additional gingivitis and extrinsic stain reduction properties beyond that of the placebo paste. However, further long term studies with larger sample size are suggested to test the product as an efficacious alternative to conventional dentifrices formulations.

Introduction:

Supragingival plaque control is an effective method of controlling gingivitis and is an important component of periodontal therapy. Undoubtedly, the most widely practiced form of oral hygiene is tooth brushing with with a dentifrice.(2) A wide range of toothpastes are commercially available and recently interest in naturally based products has increased. It has been estimated that less than one third of the population of developed nations can be expected to practice adequate mechanical plaque removal. Therefore it could be argued that supplementation of mechanical brushing with effective adjunctive chemotherapeutic agents would be beneficial to gingival health. (2,3)

Over the last few years there has been a considerable interest in the use of whitening toothpaste to reduce or remove extrinsic dental stains, with more and more products becoming commercially available. The mode of action of many of these products would appear to rely on the incorporation into the formulation of an effective abrasive system and /or chemicals that could help to inhibit or remove stain. The chemicals used centre around the use of surface active agents, whitening bleaches or oxidizing agents. (4) These chemicals work in a variety of ways but clinical evidence of efficacy to support laboratory data remains patchy. (5)

Certain plants used in folk medicine serve as a source of therapeutic agents having multi-potential effects in addition to their antimicrobial activity. Herbal formulations can provide an option for a safe and long term- use. (6) Thus, the present randomized, double blind, pilot clinical study was designed to evaluate the effectiveness of a herbal based test toothpaste at reduction of existing plaque, gingivitis and extrinsic dental stains in comparision to a placebo over a six weeks period.

Materials and methods:

After the ethical approval, 48 healthy dentate (26 males and 22 females, mean age 30-34 years) subjects who reported to the department of Periodontics, government dental college and research institute, Bangalore were recruited for the study. The inclusion criteria included subjects of either gender ,aged 18 years or older and having a minimum of 20 teeth including all the anterior teeth. Each subject had to have gingivitis as defined by bleeding on gentle on probing at more than 30 % and a gingival

index of > 1 at more than 60 %the sites examined. At baseline all subjects also have a plaque index > 2 as ,measured by the Turesky et al. modification of Quigley and Hein plaque index.(7,8) subjects having periodontal pockets greater than 3mm,dental defects, intrinsic discoloration of teeth, gross oral pathology, esthetic restorations which could become discolored ,those wearing orthodontics appliances or prostheses or full coverage restorations, those using tobacco products or chromogenic oral products such as chlorhexidine and those under medications that could stain the dentition were excluded from the study. Subjects who had a history of known sensitivity or oral mucosal tissue reaction to the ingredients of toothpaste and who had undergone oral prophylaxis in the four week period prior to the baseline examination were also excluded.

Each subject was assigned to group 1 (test toothpaste) or group 2 (placebo toothpaste) randomly by toss of a coin after obtaining the informed consent. To ensure blinding, the two products were similar in term s of taste ,texture and color. The toothpaste along with the soft bristled toothbrush were dispensed to subjects by a dental assistant not involved in the study.

Subjects were instructed to brush twice daily with the supplied toothpaste and toothbrush using modified bass method of brushing and refrain from all other unassigned forms of oral hygiene aids including non study toothbrush or toothpaste, dental floss, chewing gum or oral rinse during the study. No prophylaxis was undertaken prior to commencement of the study. The same clinician conducted all the examination and scorings. Subjects were assigned for plaque, gingivitis and extrinsic stains in the same dental unit under identical conditions at baseline,2 weeks and 6 weeks.

Plaque was disclosed with an trythrocine dye and assessed at the midbuccal, mesiobuccal, midpalatal/lingual and distopalatal/lingual surfaces of each index tooth using the Turesky et al modification of the Quigley and Hein plaque index.(7,8). The mean of these values was calculated as the plaque score for each subject. From the individual scores, mean group plaque index was calculated.

Gingival index according to the criteria of Loe and silness (9) was assessed at the midbuccal, mesiobuccal, midpalatal/lingual and distopalatal/lingual surfaces of each tooth index and the mean of these values calculated for each subject. From the

individual scores ,mean group gingival index scores were calculate

Using the Macpherson et al. modification of Lobene index(10,11) the intensity of stain on the gingival ,body and approximal surfaces of the tooth on the buccal and lingual surfaces of each assessable incisor teeth were obsertionally scored using four point scale. The area (extent) of the stain (A) was recorded for approximal ,intensity score of 2 0r 3 was given. An average stain score was calculated for each patient by the adding the product of stain intensity and area scores of labial and lingual surfaces and then dividing by total number of sites examined. From the individual scores , mean group stain index was calculated.

At each scoring visit, the examiner directly questioned as to the adverse events during individual periods before conducting the soft tissue examination. Immediately after completion of six weeks, subjects received a professional prophylaxis.

To check for compliance, the participants were asked to return their assigned toothpaste tubes,so that the investigators could verify the amount of dentifrice that was used.

Parameters were summarized as mean and standard deviation. Parameters were compared from baseline values in each group using paired t-test. Mean change in parameters from baseline to other time periods were compared between group 1 and 2 using paired t-test .In addition ,for non – Gaussian distribution of stain index ,intensity and area, confirmatory non – parametric Mann-Whitney tests were performed ,$P < 0.05$ was considered as the level of significance.

Results: Forty subjects completed the study. Eight did not complete the study because of personal and medical reasons unrelated to the use of study toothpastes. The results are depicted in table 1. There was no significant difference between group 1 and 2 with respect to all the three parameters at baseline. Over a period of 6 weeks ,both the test and the placebo toothpastes resulted in a statistically significant reduction in plaque index ,gingival index,stain intensity,area and index.(table 2)the test toothpaste resulted in a statistically significant improvement in all parameters except plaque index when compared with the placebo toothpaste at the end of 6 weeks.(table 3)Acceptability of the test toothpaste was found to be good except for a complaint of bitter taste in the test group.

Table 1 :Descriptive statistics of group 1 and 2 for all the parameters.

Parameter	Visits	Group 1	Group 2
Plaque index	Baseline	2.56	2.73
	2 wks	2.16	2.45
	4 wks	1.93	2.20
	6 wks	1.66	1.89
Gingival index	Baseline	0.78	0.69
	2 wks	0.65	0.54
	4 wks	0.62	0.46
	6 wks	0.54	0.37
Stain index	Baseline	25.15	28.20
	2 wks	20.28	26.38
	4 wks	18.77	25.64
	6 wks	17.91	24.20
Stain intensity	Baseline	48.95	51.95
	2 wks	45.35	50.60
	4 wks	41.90	50.10
	6 wks	39.45	48.60
Stain area	Baseline	32.40	34.05
	2 wks	26.85	32.45
	4 wks	25.90	31.30
	6 wks	25.00	29.80

Table 2 : Intra group comparison of mean values of parameter between baselines and other time intervals.

Parameter	Visits	Group 1			Group 2		
		Mean difference +SD	t value	P value	Mean difference	t value	P value
Plaque index	2 wks	0.40+0.06	6.69	<0.001*	0.28+0.06	4.70	<0.001*
	4 wks	0.63+0.07	8.45	<0.001*	0.53+0.07	7.13	<0.001*
	6 wks	0.89+0.07	12.27	<0.001*	0.84+0.07	11.49	<0.001*
Gingival index	2 wks	0.13 +0.02	5.92	<0.001*	0.15+0.02	6.93	<0.001*
	4 wks	0.16+0.03	5.52	<0.001*	0.23+0.03	7.82	<0.001*
	6 wks	0.24+0.03	7.67	<0.001*	0.32+0.03	9.91	<0.001*
Stain index	2 wks	4.87+0.91	5.35	<0.001*	1.83+0.91	2.01	0.052
	4 wks	6.38+1.13	5.67	<0.001*	2.56+1.13	2.28	0.029*
	6 wks	7.24+1.34	5.39	<0.001*	4.01+1.43	2.98	0.005*
Stain intensity	2 wks	3.60 +0.43	8.29	<0.001*	1.35+0.43	3.11	0.004*
	4 wks	7.05+0.61	11.50	<0.001*	1.85+0.61	3.02	0.005*
	6 wks	9.50 +0.70	13.62	<0.001*	3.35+0.70	4.80	<0.001*
Stain area	2 wks	5.55+0.69	8.04	<0.001*	1.60+0.69	2.32	0.026*
	4 wks	6.50 +7.90	7.90	<0.001*	2.75+0.82	3.34	0.002*
	6 wks	7.40+0.91	8.10	<0.001*	4.25+0.91	4.65	<0.001*

Table 3: Inter group comparison of mean values of parameter between baselines and other time intervals.

Parameter	Visits	Group 1			Group 2		
		Mean change from baseline values		Mean difference SD	t value	p value	P (Value Mann whitney test)
		Test	Control				
Plaque index	2 wks	0.40	0.27	0.13+0.08	1.49	0.144	NA
	4 wks	0.63	0.52	0.11+0.11	0.99	0.327	NA
	6 wks	0.90	0.83	0.07+0.11	0.61	0.543	NA
Gingival index	2 wks	0.12	0.16	0.03+0.03	1.26	0.217	NA
	4 wks	0.16	0.24	0.08+0.04	2.16	0.38*	NA
	6 wks	0.24	0.32	0.08 +0.04	2.17	0.038	NA
Stain index	2 wks	4.93	1.76	3.17+0.91	3.47	<0.003	0.037*
	4 wks	6.45	2.50	3.95+1.20	3.31	<0.004*	0.030*
	6 wks	7.31	3.94	3.37+1.47	2.29	<0.033*	0.129
Stain intensity	2 wks	3.65	1.30	2.34+0.52	4.48	<0.001*	<0.001*
	4 wks	7.10	1.80	5.29+0.73	7.26	<0.001*	<0.001*
	6 wks	9.54	3.30	6.24+0.85	7.37	<0.001*	<0.001*
Stain area	2 wks	5.60	1.55	4.05+0.72	5.66	<0.001*	<0.001*
	4 wks	6.55	2.70	3.85+0.84	4.58	<0.001*	0.003*
	6 wks	7.45	4.20	3.25+0.88	3.71	<0.001*	<0.031*

Discussion: It has been shown that mechanical tooth brushing is an effective method of removing plaque. Mandel suggested that antibacterial ingredients should be included in toothpaste to enhance plaque control (3). The concept of whitening formulations containing specific chemicals which reduce or inhibit stain independent of a physical effect would appear to be particularly attractive because reduced staining may be apparent in sites of the dentition where the abrasive effects of the toothpaste would be less obvious (12). Prophylaxis and scaling were not carried out previous to the experiment phase of the present clinical study, as in the previous

studies by Lindhe et al (13) and Triratana et al (14)

Toothpaste are by nature made up of various compound and it is sometimes the case that the effectiveness of one consitituent is influenced by the inclusion of another (15). Detergents and abrasives may alter the substantivity or the antimicrobial activity of active ingredients. The paste tested in this trial contained several different constituents like neem and miswak. With putative anti-inflammatory and anti-bacterial properties which theoretically could be useful in controlling plaque and gingivitis. The data presented in a study support the hypothesis that water soluble extracts of the neem (Azadirrachta indica)stick affect some bacterial properties which may alter bacterial adhesion and the ability of some streptococci to colonize tooth surfaces. The neem plant contains components like tannins which can inhibit some oral streptococci virulence factors which influence plaque formation (16). Streptococcus mutans and s. faecalis (17). Studies suggest several additional properties of miswak extracts from the Salvador persica tree including haemostatic, analgesic, anti-inflammatory antimicrobial and anticaries effects (18,19).

The test formulation also contains papain an extract of papaya, a proteolytic enzyme thought to whiten by dissolving the proteinaceous component of the stain (20). It is possible that the abrasive action of silica and perhaps a combination of abrasive and enzyme in the test toothpaste alter the physical nature of established stain. Subsequently reduction in intensity may be the result of thinning of stain layers by the abrasive action of the toothbrush and toothpaste or alteration of stain color characteristics eg brown to yellow by an enzymatic action.

Patients frequently appear to improve merelu from the effects of being place in a clinical trial. This often occurs because patients may improve oral hygiene or compliance with the treatment regimen as a result of the special attention or frequent examinations that often result from study participation . This phenomenon has been termed the Hawthorne effect (21). This may be the reason for improvement in the parameters assessed in the subjects using the placebo toothpaste.

Bitterness of the test toothpaste reported could be attributed to nimbin, a bitter compound isolated from neem oil (22).

Conclusion :

The finding s of the present study would imply that the herbal –based test toothpaste may confer some additional gingivitis and extrinsic stain reduction properties beyond that of the placebo toothpaste. However further long term studies with larger sample size are suggested to test the herbal based product as an efficacious alternative to conventional dentifrice formulations.

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References:

1.Loe H, Theilade E, Jensen S B, Experimental gingivitis in man .Journal of Periodontology 1965:36:177-187.

2. Frandsen A .Mechanical and hygiene practices. In dental plaque control measures and oral Hygiene Practices Eds. Loe Hand Kleintnan D V,1986:pp.93-116,Oxford:IRL Press.

3. Mandel ID chemotherapeutic agents for controlling plaque and gingivitis. Journal of clinical Periodotology 1988:15:488-498

4. white DJ development of an improved whitening dentifrice based upon stain –specific soft silica" Technology Journal of clinical Dentistry 2001:12 (spec Iss.2) :2529.

5. Pontefract H , Sheen S, Moran J. The benefits of toothpaste real or imagined tooth whitening products. Dental update 2001 :28;6774.

6. Takahashi K ,Fukazawa M, Motohira H, Ochiai K Nishikawa H, Miyata. A pilot study on antiplaque effects of mastic chewing gum in the oral cavity. J periodontal 2003 :74 :501-505.

7. Turesky S, Gilmore ND, Glickman I reduced plaque formation by the chloromethyl analogue of victamine . Journal of Periodontology 1970:41_43.

8. Quigley GA ,Hein JW comparative cleansing efficiency of manual and power "brushing .Journal of American dental association.1962 :65:26-29.

9. Loe H & silness .J periodontal disease in pregnancy (1) .Prevalence and severity. Acta odontologica scandinavica 1963 ; 21:533-551.

10. Macpherson LMD, Stephen K W ,Joiner A ,Schafer F,Huntington E .Comparison of a conventional and modified tooth stain index. Journal of clinical Periodontology. 2000:27 (11): 854 859.

11. Lobene R R .Effects of dentifrices on tooth stains with controlled brushing. Journal of the American Dental Association 1968:77: 849855.

12. Claydon NCA ,Moran J,Bosma ML, Shirodarai S, Addy M & Newcombe R. Clinical study to compare the effectiveness of a test whitening toothpaste with a commercial whitening toothpaste at inhibiting dental stain .Journal of clinical peridontology. 1993 :20:327-334.

13. Lindhe J .Rosling B ,Socransky S S,volpe A R .The effect of a triclosan containing dentifrice on established plaque and gingivitis. Journal of clinical Periodontology 1993:20:327-334.

14. Triratana T Rustogi KN , Volpe AR ,DeVizio W ,Petrone M, Giniger M. Clinical effects of a new liquid dentrifrice containing triclosan ? Copolymer on existing plaque and gingivitis. Journal of American Dental Association 2002 :133:219-225.

15. Mullally B H .James JA , Coulter W A ,Linden G J. The efficacy of a herbal based toothpaste on the control of plaque and gingivitis. Journal of clinical Periodontology. 1995:22; 686-689.

16. Wolinsky LE, Mania S, Nachnani S, Ling S . The inhibiting effect of aqueous Azadirachta indica (neem)extract upon bacterial properties influencing in vitro plaque formation .Journal of Dental Research 1996:75(2):816 -822.

17.Almas K. The antimicrobial effects of exracts of Azadirachta indica. Indian journal of dental research 1999:10 (1) ;2326.

18. Almas K.Al-Zeid Z.The immediate antimicrobial effect of a toothbrush and miswak on cariogenic bacteria. A clinical study , journal of contemporary Dental Practice 2004 ;1(5) : 105-114.

19. Darout IA ,Skaug N ,Albandar Jm . Subgingival microbiota levels and their associations with periodontal status at the sampled sites in an adult Sudanese population using miswak or toothbrush regularly. Acta Odontologica scandinavica 2003 : 61 :115122.

20. Whitening toothpastes. Journal of American Dental Association 2001; 132:1146.

21. Jeffcoat M K .Principles and pitfalls of clinical trials design. Journal of Periodontology. 1992:62; 1045-1051.