The efficacy of dentifrices on extrinsic tooth stains among community dwelling adults in India – a randomised controlled trial

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Objective: To examine the effects of routine use of two dentifrices on tooth stain. ***Basic research design:*** Single centre, parallel design, double blind randomised clinical study with two treatment groups. ***Clinical setting:*** Department of Dental Public Health, SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India. ***Participants:*** 125 of the 140 study subjects aged 18-70 years completed the 8-week study period. ***Interventions:*** Subjects were randomly assigned to brush twice daily with fluoride toothpaste (control) or a dentifrice formulated with silicas (test) and recalled for tooth stain examinations after 4 and 8 weeks of dentifrice use. ***Main outcome measures:*** Modified Lobene tooth stain index. ***Results:*** Whereas statistical analyses indicate no significant differences between the treatment groups for baseline scores of tooth stain intensity, stain area and tooth stain composite scores (p>0.53), examinations demonstrate significant reductions in stain area, intensity and stain composite scores amongst subjects assigned the test dentifrice at both recall visits versus the control (p<0.05). ***Conclusions:*** Routine use of the test dentifrice demonstrated significant removal of tooth stain among individuals recruited from the community.

Key words: *Adults, clinical, dentifrice, fluoride, modified Lobene stain index, rural, toothbrush, silica, stain.*

Introduction

Teeth are commonly recognised among the facial features indicative of health and beauty (Jørnung and Fardal 2007). Teeth colour represents a critical factor in smile attractiveness and the aesthetics of smile (Van der Geld *et al.*, 2007). Research outcomes from quality of health analyses indicate that individuals with stained teeth often have by additional social and psychological burdens.

Tooth stains have been noted in previous civilizations, e.g., following analyses of skeletal remains from pre-Columbian Peruvian cultures (Elzay *et al.*, 1977). Furthermore, historical literature identifies the importance of teeth as a primary facial feature. Various treatments that reduce or remove extrinsic stains (Richardson *et al.*, 2001) including the Romans' use of herbs such as rose and myrrh to whiten teeth have earlier been recorded. Individuals' desire to maintain white teeth may have changed little over the centuries and recent research has identified the social consequences of stained teeth (Vallittu *et al.*, 1996).

A report from Ireland indicates that 34% of Irish adults were dissatisfied with their teeth and half of the adults had a stain score of 28 or higher according to the MacPherson Modification of the Lobene Stain Index (Kingston *et al.*, 2005). A similar level of dissatisfaction with tooth colour was observed in England (Walker and Cooper, 2000). Thus, these factors contribute to the burgeoning growth for consumer products designed to whiten teeth and the shifts observed in restorative dentistry from functional to aesthetic aspects.

A variety of reasons contribute to extrinsic tooth stain (Kihn, 2007). Common among these are dietary factors, metals in drinking water, habits such as tobacco and betel nut chewing and a lack of effective daily oral hygiene. In many regions of the world, professional dental care maybe infrequently accessed or may remain unavailable to many. Poor oral conditions amongst underserved populations remain a significant challenge. Tooth stains represent one of the most common conditions reported in underserved populations with higher risk reported among specific populations (Mariño *et al.*, 2007).

The objective of this study was to compare the removal of extrinsic tooth stains by two dentifrices among subjects in the region of Dharwad, India with an increased propensity for extrinsic tooth stain due to chewing habits, smoking, and dietary and other habits. It was hypothesised that there would be greater reductions in extrinsic tooth stains following the use of test dentifrice formulated with silicas as compared with the control dentifrice after 4 and 8 weeks of dentifrice use. The study included subjects with a range of tooth stain in an effort to examine the effects of these treatments on individuals with the widest range of stained teeth.

Materials and Methods

This was a single centre, parallel design, double blind clinical study with two treatment groups. An ethical committee approved the study protocol prior to the start of the study. Prior to the implementation of the actual study, an examiner was trained in recording the modified

Lobene tooth stain. A pilot study was later conducted with 20 study subjects in the Department of Public Health Dentistry, S.D.M. College of Dental Sciences and Hospital, Dharwad. These subjects were scored for stain on two occasions in the same day. The results were analysed for internal reliability of the examiner and it was found to be 92%.

The sample size was determined based on review of literature, aforementioned pilot study and also by consulting a biostatistician. A power of 90% was estimated for 110 study subjects, 55 in each arm. Considering attrition among subjects, 140 subjects were recruited from November 2007 to January 2008.

Key players in the community in Dharwad were first contacted and the nature of the study was explained to them. Other members of the community were also informed about the present study. Individuals who volunteered for the study were examined for the inclusion and exclusion criteria. Volunteers fulfilling these criteria were included in the present study. The purpose and nature of the present study was explained to the study subjects (age range 18-70 years) and informed consent was obtained from them. Subjects who were available for the duration of the study were scheduled for an oral examination. Subjects with more than 20 natural teeth and a propensity to form stains on the anterior teeth and with a composite Lobene stain index of 25 or more were enrolled. Individuals who were pregnant or lactating, those with chronic medical conditions or on prescription medications, those who had undergone any medical or dental procedures in the preceding month were excluded.

Enrolled subjects were examined by a dentist for oral health that included an assessment of both hard and soft tissues at the baseline clinical examination. During this exam, all subjects were scored by the modified Lobene tooth stain index for stain prior to stratification into two treatment groups. The subjects were allocated either to test or control arm based on their composite stain score and the two groups were balanced with respect to their composite stain score. An instructional program was provided to all subjects on study procedures along with written instructions on the study. Study participants, outcomes assessor and data-analysts were blinded regarding the allocation of study subjects into two groups. They were also blinded as to whether the dentifrices issued to study subjects were test or control products. Subjects were instructed to brush twice daily with a randomly issued test dentifrice which was over wrapped and marked with a unique code. To minimize bias, allocation was concealed to all the investigators involved in the study.

All the study subjects were provided an instructional program on tooth brushing during baseline and 1 month follow-up visit. They were directed to brush twice daily with the toothpaste and brush provided to them. Instructions were also provided to the study subjects to obtain additional tubes of dentifrices provided to them during their 1 month follow-up visit. As part of the study, subjects were instructed to discontinue the use of all other oral hygiene formulations including dentifrices, mouthwashes and chewing gums and not share the test articles with anyone. Dentifrices tested in this study were Colgate Ultrabrite (henceforth referred to as test) and Crest Regular (henceforth referred to as control).

Both toothpastes are commercially available and are formulated with fluoride.

The modified Lobene stain index was used to score extrinsic stain on the facial and lingual surfaces of six anterior teeth for all subjects. Facial and lingual surfaces for the mandibular teeth and facial surfaces for the maxillary teeth surfaces were scored under constant lighting conditions. Stain intensity and stain area were recorded for each formulation tested with the corresponding stain composite scores computed as described previously (MacPherson *et al.*, 2000; Singh *et al.*, 2002).

Statistical comparisons of subject demographics in the two treatment groups included t-test analysis for age and Chi-square analyses for all the other demographic parameters between the two treatment groups. Baseline scores between the two dentifrices were examined by One Way ANOVA for each stain parameter. Inter-group and intra-group differences were analysed by an analysis of covariance (ANCOVA) with the corresponding baseline scores as covariates analyses were conducted by Minitab (State College, PA) and results at $p<0.05$ reported as significant.

Results

Subjects recruited for this study were from the communities around Dharwad. Out of the 140 adults who were initially enrolled, 125 completed all phases of the study with evaluable results. Of the 15 drop outs, seven subjects had changed their jobs, three subjects had moved to different towns, three had reported the use of antimicrobial agents and two had undergone oral prophylaxis with the local dentist. Since these were unrelated to the use of the test articles, their results were excluded from analyses. No adverse experiences were reported among subjects provided with the test and control dentifrices.

More than 50% of the subjects in the enrolled population did not recall their last visit to a dentist and approximately 70% reported once daily oral hygiene (table 1). Between 10-20% of the subjects reported daily habits that involved tobacco or betel nut chewing and approximately 40% of the population indicated a specific diet. No differences were found in the age, gender and other routine habits including food among two groups, despite higher enrolment of males in the study population ($p>0.05$). Sixty four (91%) adults completed the study with the control paste and 61 (87%) subjects with the test formulation.

Baseline scores of stain area, intensity and composite scores for control and test dentifrices showed no statistically significant differences ($p>0.05$) by one way ANOVA (Table 2). No baseline adjustments were made for nominated baseline variables by using analysis of covariance. Results indicate that there were significant differences in stain area, intensity and composite scores for control and test dentifrices at 4 and 8 weeks ($p<0.05$). The test toothpaste also demonstrated a fourfold, 1.6 fold and 1.72 fold reductions in stain area, intensity and composite scores than the control formulation at the 8 week assessment.

Table 1. Demographic and baseline characteristics

Parameter	Treatment sequence			
	Control dentifrice	Test dentifrice	Total	p-value (test)
Age (in years)				
Mean	29.66	30.08	29.86	
Std. Dev.	8.94	7.97	8.45	
Median	28	30	29	0.7795, NS (t-test)
Minimum	18	18	18	
Maximum	55	50	55	
Gender				
Male	54 (84.38)	49 (80.33)	103 (82.40)	0.5526, NS (χ^2)
Female	10 (15.63)	12 (19.67)	22 (17.60)	
Visit to dentist				
Yes ($\geq$1)	31 (48.44)	25 (40.98)	56 (44.80)	0.4022, NS (χ^2)
No (never)	33 (51.56)	36 (59.02)	69 (55.20)	
Smoking habit				
Yes	7 (10.94)	7 (11.48)	14 (11.20)	0.9241, NS (χ^2)
No	57 (89.06)	54 (88.52)	111 (88.80)	
Chewing habit				
Yes	11 (17.19)	13 (21.31)	24 (19.20)	0.5585, NS (χ^2)
No	53 (82.81)	48 (78.69)	101 (80.80)	
Food habits				
Vegetarian	22 (34.38)	30 (49.18)	52 (41.60)	
Non-vegetarian	33 (51.56)	23 (37.70)	56 (44.80)	0.2226, NS (χ^2)
Mixed	9 (14.06)	8 (13.11)	17 (13.60)	
Frequency of brushing				
Once a day	45 (70.31)	46 (75.41)	91 (72.80)	
Twice a day	19 (29.69)	15 (24.59)	34 (27.20)	0.5221, NS (χ^2)
Total	64 (100.00)	61 (100.00)	125 (100.00)	

Table 2. Comparison of tooth stain area, intensity and composite scores and duration among the study subjects

		Control Group mean (sd) CI (n=64)	Test Group mean (sd) CI (n=61)	p-value
Tooth stain Area scores	Baseline	1.4 (sd 0.3) 1.3-1.5	1.4 (sd 0.3) 1.3-1.4	0.53 NS*
	4 week	1.5 (sd 0.3) 1.4-1.5	1.4 (sd 0.3) 1.3-1.4	0.05 S$
	8 week	1.4 (sd 0.3) 1.3-1.5	1.3 (sd 0.3) 1.2-1.4	0.02 S$
Tooth stain Intensity scores	Baseline	2.4 (sd 0.5) 2.3-2.5	2.5 (sd 0.5) 2.4-2.6	0.59 NS*
	4 week	2.2 (sd 0.5) 2.1-2.3	2.0 (sd 0.6) 1.9-2.1	0.00 S$
	8 week	2.0 (sd 0.5) 1.8-2.1	1.8 (sd 0.5) 1.6-1.9	0.00 S$
Tooth stain composite scores	Baseline	64.0 (sd17.3) 60.3-68.5	63.5 (sd17.2) 59.4-67.6	0.87 NS*
	4 week	61.4 (sd 16.6) 57.3-65.6	52.2 (sd 18.3) 47.5-56.8	0.00 S$
	8 week	52.9 (sd 16.7) 48.6-57.1	44.3 (sd16.8) 40.0-48.5	0.00 S$

NS = Notsignificant; S = Significant

* = One way ANOVA performed,

$ = ANCOVA test performed with baseline scores as covariates.

Discussion

This parallel design clinical study compared the efficacy of two fluoridated dentifrices on controlling tooth stain. Subjects selected for this study were from the general population with no experience in clinical studies and therefore these results can be considered reflective of a normal population. The stain scores of the study subjects in the present study are typically higher than the mean scores reported in previous studies that examined the effects of dentifrices on tooth stain (Mankodi *et al.*, 2002; Singh *et al.*, 2002).

The differences observed between the two treatment groups at each post-brushing time point is noteworthy. The test product showed greater reduction in stain area, intensity and composite scores at 4 and 8 weeks. A higher difference was observed between the baseline and the 4 week recalls than the differences between the 4 to 8 week recalls. It is likely that the higher baseline scores among these subjects may contribute to the results.

Multifunctional toothpastes with fluoride and stain removal attributes have witnessed significant advances in recent years (Singh *et al.*, 2002). These formulations comprise fluoride for its proven anti-caries effects and silicas that aid the physical scrubbing and removal of the stain on enamel. The silicas are engineered for stain removal while reducing their abrasivity. In this study, the effect of the test dentifrice formulated with these silicas was evident on reducing all parameters of tooth stain. If the primary role of the silicas were to remove the stains one would expect comparable performance by the two dentifrices tested. However, from the results, it is evident that test demonstrated better stain removal effects than the control and was evident at 2 post-brushing assessments. Stain inducing factors bind the salivary pellicle and the ability of the silicas to remove this stained pellicle comprises an efficient and simple approach to manage tooth staining that occurs daily. Another advantage of multifunction toothpastes includes its ability to manage distinct aspects of oral health following routine use.

Analyses of demographic data of the subjects included in the study reveal habits commonly found in the sub-continent that included variations in diet and habits. Although these dietary habits are diverse, herbs and spices comprise a prominent and common feature of these diets. Whereas, the effects of distinct dietary habits on tooth stain remain unknown, literature traces the use of these ingredients from antiquity and in the practice of Ayurveda, a health care system practiced in India for over 5000 years (Deocaris *et al.*, 2008). Investigations from different geographical areas including the province that formed the venue for this study report new ingredients and present their application for previously unreported oral indications (Hebbar *et al.*, 2004). While the gastronomic and medicinal attributes of these ingredients including unique pharmacological features and isolation of common medicines are available, their applications in the textile and other industries for dyeing or as colorants are not widely recognised (Hatcher *et al.*, 2008). An additional aspect of the demographics is the inclusion of subjects with specific dietary habits they maintain life-long. Subjects in this study were not instructed to change any of their routine habits including their diet. Although the influences of these diets on oral health remain unknown, a pilot study suggests specific differences in oral health due to differences in diet (Sherfudhin *et al.*, 1996). A sizable number of individuals recruited for this study included those who routinely used tobacco as a chew or in other forms. Together, the continuous influences of these components constitute fundamental factors that influence the wide range of tooth stains observed in this population.

As shown in Table 1, a majority of these subjects included in this study had not visited a dentist in the year prior to the start of the study, an observation similar to many previous reports (Kumar *et al.*, 2005). Although subjects selected for this study routinely used a toothbrush and toothpaste for their oral hygiene our observations indicate a significant lack of dental awareness. Although a multitude of factors including cultural or financial implications may contribute to these observations, it is interesting to note the sustainability of dental education in improving oral health amongst rural subjects. In a recent clinical investigation, the introduction of routine use of dentifrices and toothbrush to subjects from a rural region of India along with support and education demonstrated improvements in their oral health during the study period (Madden *et al.*, 2004). A follow up exam, conducted 1 year later on a subset of 150 subjects from the original population demonstrated sustained use of toothpaste and toothbrush along with improvements in oral health despite the lack of support in this period. In this study, all subjects were uniformly instructed on toothbrushing procedures and educated on study procedures. Study compliance was determined during the recall examination, routine visits scheduled for each patient along with occasional telephone follow-up indicate adherence to study procedures. At the conclusion of the study, all subjects were provided an instructional program on oral health developed by the investigators from this Dental College. It would be interesting to follow-up these subjects in the future to examine the influences of study participation and the educational program on sustained improvements in oral hygiene.

From the standpoint of improving community dental health, an effective oral hygiene regimen applicable to the general population is beneficial. In this regard, education and other services designed for the community including programs to promote effective oral hygiene habits have proven useful. This study was conducted with individuals from the local communities with no exposure to clinical studies and limited access to oral educational programs. Although not a component of this study, exit interviews with subjects at the conclusion of the study indicate that more subjects provided the test toothpaste observed visible improvements in their teeth. Thus, the results from this study support the role of a toothpaste such as Ultrabrite for the general population for inclusion in regional or national community dental health initiatives.

Conclusion

Routine oral hygiene with a dentifrice formulated with silicas demonstrates effective stain removal among subjects from an underserved region of India and with limited access to preventive oral care.

References

Deocaris, C.C., Widodo, N., Wadhwa, R. and Kaul, S.C. (2008): Merger of ayurveda and tissue culture-based functional genomics: inspirations from systems biology. *Journal of Translational Medicine* **18**, 6:14.

Elzay, R.P., Allison, M.J. and Pezzia, A (1977): A comparative study on the dental health status of five precolumbian Peruvian cultures. *American Journal of Physical Anthropology* **46**, 135-139.

Hatcher, H., Planalp, R., Cho, J., Torti, F.M. and Torti, S.V. (2008): Curcumin: from ancient medicine to current clinical trials. *Cellular and Molecular Life Sciences* **65**, 1631-1652.

Hebbar, S.S., Harsha, V.H., Shripathi, V. and Hegde, G.R. (2004): Ethnomedicine of Dharwad district in Karnataka, India--plants used in oral health care. *Journal of Ethnopharmacology* **94**, 261-266.

Jørnung, J. and Fardal, Ø. (2007): Perceptions of patients' smiles: a comparison of patients' and dentists' opinions. *Journal of American Dental Association* **138**, 1544-1553.

Kihn, P.W. (2007) Vital tooth whitening. *Dental clinics of North America* **51**, 319-331.

Kingston, R., Whelton, H., O'Mullane, D. and Flannery, E. (2005): Tooth colour satisfaction and prevalence of extrinsic stain in Ireland. *Journal of Dental Research* 84 A, (Abstract 2129).

Kumar, M.P., Joseph, T., Varma, R.B. and Jayanthi, M. (2005): Oral health status of 5 years and 12 years school going children in Chennai city - An epidemiological study. *Journal of Indian Society of Pedodontics and Preventive Denistrt* **23**, 17-22.MacPherson, L.M., Stephen, K.W., Joiner, A., Schäfer, F. and Huntington, E. (2000): Comparison of a conventional and modified tooth stain index. *Journal of Clinical Periodontology* **27**, 854-859.

Madden, I.M., Newman, H., Hall, C., Brading, M.G., Ketkar, V. and Bidinger, P.D. (2004): Sustained oral health improvement and use of toothbrushes and dentifrice by previous users of traditional materials in a rural population in Andhra Pradesh, India. *International Dental Journal* **54** (5 Suppl 1), 315-320.

Mankodi, S., Lopez, M., Smith, I., Petrone, D.M., Petrone, M.E., Chaknis, P. and Proskin, H.M. (2002): Comparison of two dentifrices with respect to efficacy for the control of plaque and gingivitis, and with respect to extrinsic tooth staining: a six-month clinical study on adults. *Journal of Clinical Dentistry* **13**, 228-233.

Mariño, R., Calache, H., Wright, C., Morgan, M., Schofield, S.M. and Minichiello, V. (2007): Profile of the oral health among ambulant older Greek and Italian migrants living in Melbourne. *Australian Dental Journal* **52**,198-204.

Richardson, M.E. (2001): By their teeth shall ye know them. *British Dental Journal* **191**, 459-464.

Sherfudhin, H., Abdullah, A., Shaik, H. and Johansson, A. (1996): Some aspects of dental health in young adult Indian vegetarians. A pilot study. *Acta Odontologica Scandinavia* **54**, 44-48.

Singh, S., Mankodi, S., Chaknis, P., Petrone, M.E., DeVizio, W., Volpe, A.R. and Proskin, H.M. (2002): The clinical efficacy of a new tooth whitening dentifrice formulation: a six-month study in adults. *Journal of Clinical Dentistry* **13**, 86-90.

Vallittu, P.K., Vallittu, A.S. and Lassila, V.P. (1996): Dental aesthetics - a survey of attitudes in different groups of patients. *Journal of Dentistry* **24**, 335-358.

Van der Geld, P., Oosterveld, P., Van Heck, G. and Kuijpers-Jagtman, AM. (2007): Smile attractiveness. Self-perception and influence on personality. *The Angle Orthodontist* **77**, 759-765.

Walker, A. and Cooper, I. (2000): *Adult Dental Health Survey: Oral Health in the United Kingdom 1998*. London: The Stationary Office.