J Clin Periodontol 2004; 31: 1088–1091 doi: 10.1111/j.1600-051X.2004.00611.x

Journal of Clinical Periodontology

Clinical study to compare the effectiveness of a test whitening toothpaste with a commercial whitening toothpaste at inhibiting dental stain

N. C. A. Claydon[1], J. Moran[1], M. L. Bosma[2], S. Shirodaria[3], M. Addy and R. Newcombe[4]

[1]Department of Oral & Dental Science, University of Bristol Dental School, UK; [2]GlaxoSmithKline Consumer Healthcare, Parsippany, NJ, USA; [3]GlaxoSmithKline Consumer Healthcare, Weybridge, Surrey, UK; [4]Department of Medical Computing & Statistics, University of Wales College of Medicine, UK

Claydon NCA, Moran J, Bosma ML, Shirodaria 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. J Clin Periodontol 2004; 31: 1088–1091. doi: 10.1111/j.1600-051X.2004.00611x. © Blackwell Munksgaard, 2004.

Abstract

Aims: A single centre, randomised single-blind, three-way crossover study was performed, to compare the effect of an experimental test toothpaste with a commercially available whitening toothpaste and water control at inhibiting extrinsic stain promoted by repeated chlorhexidine/tea rinses.

Methods: This study used 23 subjects. During the week before the study the subjects received a prophylaxis to remove all staining, plaque and calculus deposits. On the Monday of the following week subjects returned to the clinic to receive their rinses and to check their dentition was stain free. Under direct supervision at both 09:00 and 13:00 hours they rinsed with either a toothpaste slurry or water control that was repeated daily up to and including the following Thursday. Additionally from the Monday to the Thursday each subject rinsed with a 0.2% chlorhexidine mouthrinse, immediately followed by a rinse with a warm black tea solution. This cycle was repeated hourly eight times throughout the day and on the following days until the Friday. Throughout this period volunteers omitted all other forms of oral hygiene except rinsing with the chlorhexidine mouthwash. On the Friday the level of stain on the teeth and dorsum of tongue was assessed using the Lobene stain index for both stain area and intensity. At the end of each trial period each subject received a thorough prophylaxis to remove all plaque, calculus and staining before starting the second and third period of the study.

Results: As expected appreciable amounts of extrinsic stain accumulated on the teeth over each study period. The amount of stain following use of the toothpastes and water control was least with the experimental toothpaste, followed by water control and lastly the commercial whitening paste. For all sites combined there was evidence that the experimental paste was significantly superior to both the commercial paste and water control at reducing stain area ($p<0.001$), a product of stain area and intensity ($p<0.001$ and 0.05, respectively) but not stain intensity ($p>0.05$).

Conclusions: In this stain-prevention model the use of an experimental paste showed a significant reduction in stain accumulation on the teeth compared with a (placebo) negative water control and a commercially available whitening paste. As such the experimental paste would be expected to be of benefit in controlling extrinsic dental staining.

Key words: chlorhexidine, clinical trial, dental stain, whitening toothpaste

Accepted for publication 12 March 2004

The potential value of toothpastes at reducing or removing extrinsic dental stain has recently been accentuated with the introduction of more and more whitening toothpastes onto the market. Many of these products will help to control dietary-induced stain by way of the abrasives incorporated into the product that remove both pellicle and extrinsic dental stain itself. It is also recognised that certain types of chemicals incorporated into the paste may also help to reduce stain by a chemical action through stain inhibition and or direct stain removal. These chemicals include enzymes, detergents and oxygenating agents (for reviews, see Pontefract et al. 2001, White 2001). One chemical that initially showed promise was polyvinyl pyrrolidone (PVP), which in vitro was shown to reduce staining of hydroxyapatite specimens exposed to tea and chlorhexidine (Barnett et al. 1994). The results of a clinical study using PVP with chlorhexidine rinses initially produced promising results in terms of a stain-reducing effect by the former but at the expense of reduced clinical activity for the chlorhexidine (Claydon et al. 2001a). However, the findings of a subsequent study by the same authors questioned the usefulness of PVP as an inhibitor of staining associated with chlorhexidine (Claydon et al. 2001b).

Irrespective of how a specific chemical may be of benefit when used in either a mouthrinse or indeed in a toothpaste, there is lack of evidence to suggest that one stain-reducing system or product is superior to another. This conclusion is compounded by the lack of clinical studies that aim to compare the efficacy of new and established products. Most studies would appear to be home usage studies in which large numbers of volunteers use a test product or a control over a period of weeks or months and naturally occurring stain is measured at predetermined intervals (Sharma et al. 1999, Gerlach et al. 2001, Ayad et al. 2000, 2002, Sielski et al. 2002, Singh et al. 2002). Other studies have used similar protocols in which extrinsic dental stain is promoted by the use of chlorhexidine rinses (Grossman et al. 1987, Emling et al. 1992, Koertge et al. 1993, Bollmer et al. 1995). The antiseptic chlorhexidine is particularly known to promote staining through an interaction with dietary chromogens such as those found in tea, coffee and red wine (Addy & Moran 1985, Addy et al. 1985). This interaction between chlorhexidine and tea can be exploited in clinical studies to force stain production in subjects over a period of a few days. This promotion of chlorhexidine staining can either be instituted prior to the start of the study, i.e. a stain removal study (Gerlach & White 2001) or actually during the study period itself, i.e. a stain inhibition study (Koertge et al. 1993). Thus the efficacy of whitening toothpastes at inhibiting or reducing the formation of chlorhexidine/tea-induced staining can be assessed over a few days instead of over a few weeks or months. In the present study the effectiveness of an experimental whitening toothpaste was compared with a commercially available whitening paste and water control. In order to exclude any activity because of the presence of abrasives in either of the toothpastes when applied by a toothbrush, both pastes were employed as slurry rinses used twice daily.

Material and Methods

A group of 24 healthy dentate volunteers were recruited to this study who fulfilled the necessary inclusion/exclusion criteria. Subsequently 23 subjects (10 male, 13 female, age range 21–58 years, mean 34 years) started the study as one volunteer dropped out before recovering any stain data. Prior to the study, approval from the Local Ethics Committee was sought and fully informed consent, both oral and written, was obtained from all participating subjects. Healthy subjects were included of either gender, aged between 18 and 65 years, with no medical or pharmacotherapy history that could have compromised the conduct of the study. The subjects were dentate with at least 24 natural teeth and with no fixed or removable orthodontic appliances or removable prostheses. The design of the study consisted of three cycles, comprising 4 days of stain formation. The study toothpastes consisted of a test paste with a novel whitening formulation, a commercially available whitening toothpaste (Rembrandt Whitening, Den-Mat Corporation, Santa Maria, CA, USA) and a negative control water rinse. The test toothpaste was a non-marketed experimental formulation that contained sodium fluoride and hydrated silica as the abrasive. In addition, the paste contained sodium tripolyphosphate that is associated with potential stain removal properties and PVP, which is associated with stain-prevention properties. Each subject was assigned to one of the toothpaste or water rinse according to a predetermined randomisation schedule supplied by the sponsor. Prior to each study period, each subject received a thorough prophylaxis to remove all staining, plaque and calculus from the dentition. On day 1 of the treatment phase (Monday) the teeth were examined to confirm that they were stain free. Any remaining stain required the subject to undergo a further oral prophylaxis. At this time and for the following 3 days, subjects were instructed under supervision to rinse with 10 ml of a 0.2% chlorhexidine mouthwash for 60 s eight times a day and then expectorate. Immediately after rinsing with the mouthwash subjects rinsed for 60 s with 10 ml of a warm tea solution and then expectorated. Throughout this period volunteers omitted all other forms of oral hygiene except rinsing with the chlorhexidine mouthwash. The toothpaste slurry rinses comprised 3 g of the paste dissolved in 10 ml of water rinsed for 60 s at 09:00 and 13:00 hours every day from the Monday to the Thursday. Alternatively and according to the randomisation schedule, subjects rinsed with 10 ml of water. This regimen continued each day until the Friday when the level of stain on teeth was assessed by an experienced assessor (N. C.) who was completely blinded as regard to which toothpaste was used by each subject at each study period.

Using the method described by Lobene (1968), the intensity of stain on the gingival crescent and body of the tooth on the buccal surfaces of each assessable incisor, canine and premolar teeth were observationally scored using the four-point scale:

0 = no stain
1 = light stain
2 = moderate stain
3 = heavy stain

Using the method described by Lobene (1968), the area of stain on the gingival crescent and body of the tooth on the buccal surfaces of each assessable incisor and premolar teeth were observationally scored using the four-point scale:

0 = no stain detected only tooth colour
1 = stain covering up to one-third of the tooth surface
2 = stain covering between one-third and two-thirds of the tooth surface
3 = stain covering more than two-thirds of the tooth

The dorsum of the tongue was also scored using similar scales. For both scoring of tongue and teeth a standardised light source for stain assessment was used (Color-i-dent II®, Waldmann GMBH, Villingen-Schwenningen, Germany).

Subjects were then told to brush at home over the weekend with a supplied washout toothpaste and toothbrush. Each subject also received a thorough prophylaxis to remove all plaque calculus and staining before the second and subsequent third study period.

These periods of the study employed the same regimen and on completion of both legs of the study, volunteers were seen again to remove any deposits of stain, plaque and calculus.

Statistical analysis

The primary outcome measures were the whole-mouth mean stain area score, stain intensity and the mean combined (product of area and intensity) dental stain scores on the assessment day. These outcome measures were summarised by calculating means and standard deviations for each of the two toothpastes. Means and standard deviations were also calculated where appropriate, for each tooth surface subset, i.e. gingival crescent and body of tooth.

The main analysis was analysis of variance (ANOVA) corresponding to the crossover design, modelling the stain score on three factors namely subject, period and treatment. Point estimates, 95% confidence intervals and *p*-values were calculated for differences between the three treatments. Preliminary examination of data did not suggest any serious departure from Gaussian distributional form and as such confirmatory non-parametric analyses were not performed.

Results

Of the 23 subjects, 21 fully completed the three test periods. None of the subjects were either suspected or known to have seriously violated the protocol. At the end of each of the periods considerable amounts of stain were evident irrespective of treatment with the toothpastes or water control (Table 1). For gingival and body sites combined, the least amount of stain measured as the product of stain intensity and area was seen following use of the test toothpaste, followed by the water control and finally the commercially available whitening paste. Similar findings were seen when considering gingival and body sites alone. Mean statistics and subsequent ANOVA showed that there were significant differences in the ability of the two toothpastes and water control to inhibit stain. This was evident whether assessing stain area, intensity or a product of the two measurements. Pairwise comparisons between the products and the water control demonstrated significantly less stain with the test paste than the commercial paste (Table 2). This was notable especially for combined gingival and body sites stain area ($p = <0.001$) and intensity × area ($p = <0.001$). This represented a difference of about 25% between the two pastes for stain intensity × area. No significant difference in stain intensity was noted, however, between the two pastes for combined gingival and body sites. Significant reductions in stain area ($p = <0.001$) and intensity × area ($p = <0.05$) were also seen for the test paste compared with the water control. This represented reductions of 16% and 14%, respectively, for combined gingival and body sites. Perhaps surprisingly the stain following use of the water control was also significantly less than that seen with the commercial paste. Thus for combined gingival and body sites, stain intensity and product of stain intensity × area were significantly greater than with the water rinses ($p < 0.05$). No significant differences between treatments for assessment of tongue staining were noted.

Table 1. Mean stain intensity and area after 4 days use of test and commercial toothpaste slurries and chlorhexidine/tea mouthrinses

	Mean stain intensity (*I*)	Mean stain area (*A*)	Mean stain product ($I \times A$)
Gingival and body sites combined			
test paste	1.70 (0.35)	1.89 (0.45)	3.34(1.26)
commercial paste	1.86 (0.40)	2.35 (0.33)	4.47(1.35)
water	1.69 (0.36)	2.26 (0.36)	3.89 (1.29)
Gingival sites			
test paste	2.21 (0.49)	2.08 (0.54)	4.63 (1.82)
commercial paste	2.31 (0.50)	2.50 (0.41)	5.77 (1.73)
water	2.15 (0.50)	2.43 (0.43)	5.19 (1.80)
Body sites			
test paste	1.20 (0.31)	1.69 (0.51)	2.06 (0.84)
commercial paste	1.42 (0.36)	2.20 (0.33)	3.16 (1.12)
water	1.23 (0.29)	2.10 (0.48)	2.60 (0.90)

Table 2. Comparison of stain accumulation following use of test (T) and commercial (C) toothpaste slurry rinses and water

	Point estimate	95% confidence interval	*p*-value
Intensity (*I*)			
paste T versus paste C	0.12	−0.03 to 0.27	0.104
paste T versus water	−0.04	−0.19 to 0.11	0.598
paste C versus water	0.16	0.01–0.31	0.032
Area (*A*)			
paste T versus paste C	0.45	0.33–0.57	<0.001
paste T versus water	0.38	0.26–0.50	<0.001
paste C versus water	0.07	−0.06 to 0.19	0.280
Product ($I \times A$)			
paste T versus paste C	1.03	0.61–1.46	<0.001
paste T versus water	0.50	0.08–0.92	0.020
paste C versus water	0.53	0.11–0.95	0.015

Contrasts between pairs of treatments for gingival and body sites combined.

Discussion

At present there would appear to be considerable demand for oral hygiene products that help to eliminate or reduce extrinsic dental staining. The incorporation of abrasives in particularly toothpastes may help to physically remove stain but since virtually all toothpastes contain abrasives some benefit may be expected even by conventional products. The concept of whitening formulations containing specific chemicals that reduce or inhibit stain independent of a physical effect would appear to be particularly attractive since reduced

staining may be apparent in sites of the dentition where the abrasive effects of the toothpaste would be less obvious. To date various types of chemicals have been suggested to be of potential value and work via the inclusion of surfactants, enzyme systems, calcium-chelating builders and calcium phosphate absorbants. These chemicals work either by lightening existing stain or by physical desorption of adherent stain. Sound clinical evidence of efficacy to support laboratory data overall remains patchy (Sharif et al. 2000). In the present study, a test whitening formulation containing PVP was evaluated to determine whether stain could be inhibited more effectively than a recognised commercial whitening paste and water control. The findings of the study showed evidence that the test whitening paste was superior to the commercial paste and water control. The mechanism whereby the test product inhibited stain formation is not known. It is possible, however, that either or both of the active ingredients, namely PVP and sodium tripolyphosphate interfered with the binding of dietary chromogen (tea) to chlorhexidine adsorbed to the tooth surface. Perhaps surprisingly, the recognised commercial whitening paste not only failed to reduce stain compared with the water control but was also found to promote stain in this model. This is more surprising since as part of its formulation it would contain the surfactant sodium lauryl sulphate that is known to have a reducing effect on stain in vitro (Swaminathan et al. 1996a). This relative lack of activity for the commercial paste has been demonstrated in vitro (Swaminathan et al. 1996b) and from a recent clinical study (Pontefract et al. 2004) would question previously reported clinical efficacy for this particular product (Emling et al. 1992). One possible reason for this variance in findings may be because of the reduced time frame and accumulated total exposure of the commercial paste in the present study. Thus any efficacy for the control commercially available product may take weeks or months to be obvious. It is also feasible that the stain-reducing capacity in the commercial paste was based primarily on reducing stain by an abrasive effect and as such rinsing with toothpaste slurries would not be expected to reduce stain to any appreciable degree.

In conclusion, using this stain-prevention model an experimental paste showed a significant reduction in stain accumulation on the teeth compared with a (placebo) negative water control and a commercial whitening paste. As such the experimental paste would be expected to be of benefit in controlling extrinsic dental staining.

References

Addy, M. & Moran, J. (1985) Extrinsic tooth discoloration by metals and chlorhexidine II. Clinical staining produced by chlorhexidine, iron and tea. *British Dental Journal* **159**, 331–334.

Addy, M., Moran, J. & Griffiths, A. et al. (1985) Extrinsic tooth discoloration by metals and chlorhexidine. I. Surface protein denaturation or dietary precipitation? *British Dental Journal* **159**, 281–285.

Ayad, F., Demarchi, B., Khalaf, A., Davies, R., Ellwood, R., Bradshaw, B., Petrone, M. E., Chaknis, P., De Vizio, W., Volpe, A. R. & Proskin, H. M. (2000) A six week clinical tooth whitening study of a new calculus-inhibiting dentifrice formulation. *Journal of Clinical Dentistry* **11**, 84–87.

Ayad, F., Khalaf, A., Chaknis, P., Petrone, M. E., De Vizio, W., Volpe, A. R. & Proskin, H. M. (2002) Clinical efficacy of a new tooth whitening dentifrice. *Journal of Clinical Dentistry* **13**, 82–85.

Barnett, P., Burgon-Lyon, K. & Smith, J. (1994) Use of polyvinyl pyrrolidone to prevent chlorhexidine stain formation in vitro. *Journal of Dental Research* **73**, 261 (abstract 1272).

Bollmer, B. W., Sturzenburger, O. P., Vick, V. & Grossman, E. (1995) Reduction of calculus and Peridex stain with tartar control Crest. *Journal of Clinical Dentistry* **6**, 185–187.

Claydon, N., Addy, M., Jackson, R., Smith, S. & Newcombe, R. G. (2001a) Studies on the effect of polyvinyl pyrrolidone on the activity of chlorhexidine mouthrinses: plaque and stain. *Journal of Clinical Periodontology* **28**, 558–564.

Claydon, N., Manning, C. M., Darby-Dowman, A., Ridge, D., Smith, S. & Addy, M. (2001b) The effect of polyvinyl pyrrolidone on the clinical activity of 0.09% and 0.2% chlorhexidine mouthrinses. *Journal of Clinical Periodontology* **28**, 1037–1044.

Emling, R. C., Shi, X. & Yankell, S. L. (1992) Rembrandt Toothpaste: stain removal following the use of Peridex. *Journal of Clinical Dentistry* **3**, 66–69.

Gerlach, R. W., Barker, M. L., Hyde, J. D., Jones, M. B. & Cordero, R. E. (2001) Effects of a tartar control whitening dentifrice on tooth shade in a population with long-standing natural stain. *Journal of Clinical Dentistry* **12**, 47–50.

Gerlach, R. W. & White, D. J. (2001) Removal of extrinsic stain using a tartar control whitening dentifrice: a randomized clinical trial. *Journal of Clinical Dentistry* **12**, 42–46.

Grossman, E., Sturzenburger, O. P., Bollmer, B. W., Moore, D. J., Manhart, M. D. & Huetter, T. E. (1987) Reduction of chlorhexidine associated stain with crest tartar control dentifrice. *Journal of Dental Research* **66**, 279.

Koertge, T. E., Gunsolley, J. C., Domke, T. W. & Nelson, B. J. (1993) Comparison of two dentifrices in the control of chlorhexidine induced stain. *Journal of Clinical Dentistry* **4**, 1–5.

Lobene, R. R. (1968) Effects of dentifrices on tooth stains with controlled brushing. *Journal of the American Dental Association* **77**, 849–855.

Pontefract, H., Courtney, M., Smith, S., Newcombe, R. G. & Addy, M. (2004) Development of methods to enhance extrinsic tooth discoloration for comparison of toothpastes. 2. Two product clinical study. *Journal of Clinical Periodontology* **31**, 7–11.

Pontefract, H., Sheen, S. & Moran, J. (2001) The benefits of toothpaste – real or imagined – tooth whitening products. *Dental Update* **28**, 67–70, 72, 74.

Sharif, N., MacDonald, E., Hughes, J., Newcombe, R. G. & Addy, M. (2000) The chemical stain removal properties of ''whitening'' toothpaste products: studies in vitro. *British Dental Journal* **188**, 620–624.

Sharma, N., Galustians, J., Qaquish, J., Rustogi, K. N., Petrone, M. E., Chaknis, P., De Vizio, W., Volpe, A. R. & Proskin, H. M. (1999) A six-week clinical efficacy study of three commercially available dentifrices for the removal of extrinsic tooth stain. *Journal of Clinical Dentistry* **10**, 111–114.

Sielski, C., Berta, R. L., Petrone, M. E., Chaknis, P. & Proskin, H. M. (2002) A study to assess the tooth whitening efficacy of a new dentifrice formulation variant containing a special grade of silica: a six-week study on adults. *Journal of Clinical Dentistry* **13**, 77–81.

Singh, S., Mankodi, S., Chaknis, P., Petrone, M. E. & 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**, 86–94.

Swaminathan, D., Moran, J. & Addy, M. (1996a) The efficacy of detergents on stain removal. *Asian Journal of Aesthetic Dentistry* **4**, 25–29.

Swaminathan, D., Moran, J. & Addy, M. (1996b) Inhibition of stain by some commercially available oral hygiene products. *Annals of the Dentistry University of Malaya* **3**, 19–22.

White, D. J. (2001) Development of an improved whitening dentifrice based upon ''Stain-Specific Soft Silica'' technology. *Journal of Clinical Dentistry* **12** (Special Issue No. 2), 25–29.

Address:
John Moran
Department of Oral & Dental Science
University of Bristol Dental School
Lower Maudlin Street
Bristol BS1 2LY
UK
E-mail: John.Moran@bristol.ac.uk