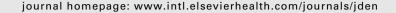


available at www.sciencedirect.com







Clinical study investigating abrasive effects of three toothpastes and water in an in situ model

E. Macdonald a , A. North a , B. Maggio b , F. Sufi b , S. Mason b , C. Moore a , M. Addy a , N.X. West a,*

ARTICLE INFO

Article history: Received 23 October 2009 Received in revised form 12 March 2010 Accepted 14 March 2010

Keywords:
Dental abrasion
Relative dentine abrasion (RDA)
Dentine
Toothpaste
Clinical study in situ

ABSTRACT

Objectives: This in situ study compared the abrasive effect of repeated brushings (over 10 days) of a low relative abrasive dentine (RDA) toothpaste with moderate and high relative abrasive dentine (RDA) toothpastes, on human dentine in situ.

Materials and methods: The study design was single centre, single blind, randomized, split mouth, two period, four-treatment cross-over, in situ study in 20 healthy subjects. Subjects wore bi-lateral lower buccal appliances each fitted with four dentine sections with treatment applied with a power toothbrush, during each 10 day study period. Samples were measured at baseline, day 5 and day 10 by contact profilometry, and baseline and day 10 with non-contact profilometry.

Results: Nineteen subjects were included in the efficacy analysis. Results as measured by contact and non-contact profilometry from brushing with the moderate RDA paste and high RDA paste showed significantly (p < 0.0001) more abrasion to dentine than brushing with the low RDA paste or water after 10 days. Dentine loss following tooth brushing with the low RDA paste was not significantly different from brushing with water, after 10 days.

Conclusions: The methodology successfully showed clear differentiation between the amount of dentine lost following toothbrushing with the low RDA paste compared to the moderate or high RDA pastes. Dentine loss following brushing with the low RDA paste showed a comparable degree of abrasion to brushing with water.

© 2010 Elsevier Ltd. All rights reserved.

1. Introduction

Toothbrushing with a toothpaste is the most common form of oral hygiene habit practiced by people in developed countries. Indeed, mechanical oral hygiene procedures are thought to be essential for proper plaque control and maintenance of periodontal health. ^{1–5} As well as plaque removal, an important feature of a toothpaste is its ability to reduce other surface deposits on the teeth during the brushing cycle such as calculus and stain. This cleaning efficacy is achieved with the incorporation of abrasives in the toothpaste formulation.

Toothpaste abrasives vary greatly in composition, some formulations being far more abrasive than others. A wide variety of abrasive systems of various particle size are thus present in commercially available toothpastes today, including precipitated silica of various sized particles, alumina, dicalcium phosphate dihydrate, insoluble metaphosphate, calcium carbonate and other polishing substances.

To obtain good cleaning properties and stain removal, toothpastes may abrade tooth structure to an unacceptable degree.⁶ It is therefore essential to be mindful of this thought when selecting an abrasive or mixture of abrasives for

^a Restorative Dentistry, Department of Oral and Dental Science, University of Bristol, UK

^b GlaxoSmithKline Consumer Healthcare, St. George's Avenue, Weybridge, Surrey KT13 ODE, UK

^{*} Corresponding author at: Department of Oral and Dental Science, Bristol Dental Hospital, Lower Maudlin Street, Bristol BS1 2LY, UK. Tel.: +44 0117 342 4505; fax: +44 0117 342 4100.

E-mail address: N.X.West@bristol.ac.uk (N.X. West). 0300-5712/\$ – see front matter @ 2010 Elsevier Ltd. All rights reserved. doi:10.1016/j.jdent.2010.03.007

inclusion in products, ⁷ and also remembering actual cleansing requirements will vary widely from person to person. Davis and Winter⁸ considered abrasives had a minimal effect on enamel, the effect being more pronounced on dentine, and this is supported by recent review.9 As a rule, toothpaste abrasives with reasonable efficacy, demonstrate some abrasivity for the dentine, which is five times softer than enamel. 10 A considerable amount of circumstantial evidence, supported by laboratory experiments, indicate toothbrushing with a toothpaste as a consistent factor in dentine loss.9 As a result, much of the recent research has concentrated on the abrasivity of toothpastes, as a toothbrush alone has been demonstrated to have little effect on dentine in a typical twice daily regimen (non abuse regimen).9,11-13 In an over zealous regimen of brushing of 3 or more times a day however the toothbrush may have an effect and this is often the case in dentine hypersensitivity sufferers.

The role of the toothbrush with toothpaste together have been implicated in gingival recession and hence exposure of dentine. This is predominantly based on circumstantial and/or epidemiological association data. Once dentine is exposed it can easily be abraded and this has led to concerns around toothpaste abrasivity regarding soft tissue changes and changes to the dentine surface. Manufacturers therefore continue to search for abrasive materials which maximize stain control whilst minimizing hard and soft tissue wear.

Methodologies have been established in vitro to determine the relative safety of abrasives including standard tests to measure dentine and enamel wear. A British Standard for toothpastes (BSI)14 was drawn up in 1974 and documentation subsequently revised in 1995 (ISO), where the relative dentine abrasion (RDA) and relative enamel abrasion (REA), define abrasive potential on a normalized scale with an accepted standard material serving as a reference. 15,16 The reasoning behind the introduction of this standard was to prevent toothpastes being manufactured which could conceivably produce harmful effects, not easily recognized by the public. For abrasivity, the values are expressed as the ratio of the paste to that of the reference paste. For dentine the test paste must not exceed $2\times$ the abrasivity of the BSI paste and for enamel $4\times$. The RDA scale thus starts at 0 and is open ended. There are no rules or recommendations which researchers and experts accept for abrasively standards for toothpastes but it would be reasonable to suggest that a toothpaste which scores above 200 on this scale should not be recommended for daily use. Other UK authors have investigated enamel and dentine wear with a range of RDA pastes.¹⁷ The same system operates in the USA, with most toothpastes having a relative radioactive dentine abrasivity (RDA), between 50 and 150 when tested in 1988. 18 Independent testing confirmed that most marketed toothpaste formulations in the past fell into the range of 50-150 and any product that falls below 250 is considered safe for everyday use by the American Dental Association. 18,19 Whilst regulations therefore safeguarded tooth tissue abrasion to a certain extent, there is no other standard accepted by the profession above or below which there could be an unacceptable level of enamel or dentine wear or an accepted sub classification of low, moderate, high, although many have been proposed.²⁰ It must be said that the historical toothpaste abrasives were far more abrasive than nowadays. In vitro work conducted by Miller back in the early

1900s, demonstrated that abrasive effects of early toothpastes could cause damage to the enamel and dentine but little research has been conducted in vivo to explore the relationship with tooth wear. 18 Since the 1990s general toothpaste abrasivity appears to be increasing again perhaps due to consumer desire for whitening or high cleaning of teeth. Accepted that toothpaste causes dentine loss through abrasion probably correlates directly with the RDA value of the paste. Reviews on the subject, based primarily on laboratory studies, have concluded that toothpastes generally cause insignificant amounts of dentine abrasion in a life time's use in non-abuse circumstances.²¹ However, very abrasive toothpastes (e.g. those containing alumina) or overzealous use of toothpastes, appear to cause more significant amounts of wear and in these cases a low abrasivity paste may preferable. There have to date, however, been few systematic studies and clinical trials conducted using more robust in situ models these studies have shown a correlation between the rate of tooth wear and RDA value. 9,22-25

Recently, laboratory (in vitro) experiments conducted by GlaxoSmithKline Consumer Healthcare (St George's Avenue, Weybridge, Surrey KT13 0DE, UK), indicate it may be possible to reduce the level of conventional abrasive in a toothpaste to a low level and yet still achieve stain control similar to that of a more conventional toothpaste. For consumers with gingival recession and exposed dentine, this approach, if successful, would provide a product which would be much gentler to both the hard and soft tissues than currently available toothpaste products.

In recent years, various alternative methods have been developed in order to quantify toothpaste abrasivity such as weight-loss techniques, shadow-graphic methods, radiotracer methods, microscopy, and diffusion of laser light and surface profilometry. 20 Surface contact profilometric method has been one of the most widely used techniques to measure loss of dentine. 24,26,27 It gives an accurate and reproducible measurement but only in a two-dimensional field. 27-29 With a surface non-contact profilometric method a 3D topographical image of the dentine surface loss is produced giving a far more informative representation of the surface changes. The aim of this clinical trial was to investigate the abrasive dentine effects of a low abrasive experimental formulation (relative dentine abrasion (RDA) value \sim 15) to a marketed moderate abrasive toothpaste (RDA value \sim 70), a marketed high abrasive toothpaste (RDA ~240) and water on dentine, in an in situ model after 10 days treatment, as assessed by contacta and non-contact^b profilometry.

The details of the toothpastes are tabulated in Table 1.

2. Materials and methods

2.1. Study design

The clinical study was a single centre, single blind (blinded to the person responsible for performing the profilometry measurements), randomized, split mouth, two period, fourtreatment cross-over, in situ clinical study in healthy subjects.

^a Surfometer SF200 Planer Products, Windmill Road, Sunbury-On-Thames, Middlesex TW167HD.

^b Proscan UK Ltd, 30 Regent Street, Nottingham NG1 5BT.

Table 1 – Details of toothpastes.					
Formulation	Manufacturer	Product Type	\sim RDA value		
Low RDA experimental formulation toothpaste (Sident 22S)	Supplied by GlaxoSmithKline	Test toothpaste	15		
Moderate RDA marketed toothpaste Colgate® cavity protection (great regular flavor) (US)	Registered trademark of Colgate Palmolive, Guilford GU2 8JZ	Reference control toothpaste	70		
High RDA marketed toothpaste Colgate® luminous (US)	Registered trademark of Colgate Palmolive, Guilford GU2 8JZ	Reference control toothpaste	240		
Volvic [®] water	Registered trademark of the Danone group of companies, Danone, 2nd Floor International House, 7 High St, London W5 5DW	Negative control	8		

The study was conducted in the Clinical Trials Unit at the Bristol Dental Hospital and School according to GCP³⁰ with ethical approval awarded by Central and South Bristol Research Ethics Committee.

Sufficient healthy subjects were recruited and screened from the Bristol Dental Hospital and School, so that a maximum of 20 who fulfilled all the entry criteria were randomized. There were no previous data/parameters available to guide calculation of the sample size for this type of study. Therefore sample size was estimated using previous in vitro work in this area^{4,27} suggesting randomizing 20 subjects in a two period cross-over design would be sufficient to yield enough data and accurate parameters (difference in treatment means and SD).

Subjects were screened up to 15 calendar days prior to the start of the first treatment period and eligible subjects randomly allocated to receive two study products during each of the two treatment periods. During each 10 day treatment period, subjects wore bi-lateral lower buccal intraoral appliances, each fitted with four dentine samples (eight samples in total) (Fig. 1).

2.2. Preparation of samples

Caries free human third molar teeth that had recently been extracted, intact, from patients aged between 18 and 30 years, of either gender were used for the dentine samples. Consent was obtained and documented in accordance with the Human



Fig. 1 – Lower buccal intra-oral appliance with 4 dentine samples in situ.

Tissue Act 2004. 31 Following extraction, the teeth were soaked in 20,000 ppm sodium hypochlorite to water solution for at least 24 h, and then scraped clean of any remaining tissue with a scalpel. The teeth were cut at the cemento-enamel junction to reveal root dentine, which was then sectioned to produce the dentine samples. Each sample was placed in a polyure-thane vacuum packed mould 6 mm \times 8 mm \times 2 mm (width, length and depth, respectively) filled with epoxy resin.

Twenty-four hours after the epoxy resin had cured, the test face of the dentine sample was ground with an automatic lapping and polishing machine using 1200 grit paper to produce a smooth, flat, polished area of dentine with a baseline reading for each sample, as measured by contact profilometry, of a maximum of ± 0.10 from $0.00~\mu m$. Samples were then masked with PVC tape on either side of a 5 mm wide window of dentine.

Each dentine sample was identified with a unique number on the reverse side of the dentine sample, so that when they were temporarily removed from the appliance for contact profilometry, they could be replaced back into the appliance in the identical position from which they were removed. Two readings were taken for each of the samples and a mean of the 8 readings was used for analysis. Readings were taken at baseline and on day 5 and day 10 for contact profilometry and day 10 for non-contact profilometry.

Attempts were made to try and reduce variability between tooth samples by only using unerputed third molar teeth, which have no topical fluoride experience.

2.3. Each treatment day

During every treatment day, each subject wore the lower intraoral appliances from 08:30 \pm 30 min to 15:00 \pm 30 min, ensuring appliances were worn a minimum of 5 h daily. The appliances were removed from the mouth for a 1 h period over lunch. Subjects were not allowed to eat or drink at other times, apart from water, whilst wearing the appliances.

Subjects attended the site three times a day for treatment application at $08:30\pm30$ min, $11:00\pm30$ min and $14:00\pm30$ min. The appliances were worn for a minimum of 60 min following the last treatment of the day.

Study treatment involved a member of the site study applying 1.1 g (± 0.1 g) of toothpaste to the brush head of an electric toothbrush (Oral B vitality precision clean power tooth brush) and brushing the four dentine samples in the appliance ex vivo for 60 s for each appliance. For water the brush head

was soaked in water prior to treatment. Following treatment the appliance was then rinsed with cold tap water for 60 s and returned to the subject's mouth.

From the completion of the screening visit through until the end of the final treatment period, subjects were asked to use a standard toothpaste (Crest® decay prevention) as well as a standard toothbrush (Oral B® 35) for home use. No other oral hygiene procedures were to be used.

Subjects were free to withdraw from the study at any time giving no reason.

2.4. Measurement of dentine samples

Measurement of the samples utilized two methodologies, contact and non-contact profilometry.

The contact profilometer was calibrated at the start of each contact profilometry assessment day using standard (control) dentine samples. A number of control samples were used periodically throughout the trial to ensure that the machine was producing accurate readings of the subjects' dentine samples. Two baseline readings of each sample were taken, measuring across the area to be exposed to the study treatment. The readings needed to be a maximum of ± 0.10 from $0.00\,\mu m$ in deflection. The designated treatment area was marked on the dentine sample with indelible ink, and PVC tape placed over the samples leaving approximately a 5 mm width zone of dentine exposed for treatment.

Day 5 and day 10 contact profilometry readings from this exposed area were carried out after the PVC tape was removed. Two values (measuring dentine loss) per dentine sample were obtained for each of the four samples using contact profilometry to give a representative value of tissue change in the treatment area after day 5. The samples were then replaced into the appliances for the remaining 5 days of the treatment period and measured again. The primary measure of efficacy was mean dentine tissue loss (μ m) taken as the mean of all values from all four samples at day 10.

Following contact profilometry measurements at day 10 an additional non-contact profilometer measurement was taken using the Proscan® which captured a 3D topographical image of the dentine surface loss of each dentine specimen. The dentine samples were baselined by placing each into the right angled guide on the X, Y axis computer controlled traversing sample stage of a white light non-contacting Proscan® profilometer and the window of dentine aligned into the centre of the field. A fibre optic camera positioned just behind the sensor transmitted the sample image to a monitor. The image displayed on screen represented what the monochromatic sensor will see once scanning begins and allows the user to position the sample accurately to determine where a scan will start.

The size of the zone to be scanned is keyed in as X=2 mm, Y=2 mm. The Z range of the scanner was then set at $150\pm 1\,\mu m$. All co-ordinates of the specimen position and scan start are recorded to permit exact repositioning of samples on the scan table for the day 10 measurement.

Scanning occurred in the X-direction, and upon completion, a 3D topographical image was returned to the computer terminal in the Proscan® software. This software has various

functions, most notably modification of the image in terms of leveling the scan and removing any noise points manually.

The amount of dentine tissue loss was calculated by way of exporting every Z-value (height) into a Microsoft Excel $^{\circledR}$ file and determining the mean of that data. The number returned was a single value in micrometers that represented the average peak height across the entire sample surface (in excess of 25,000 individual points). This reading was calculated for each sample. During baseline evaluation of the samples for use in a study, an average peak height (dentine loss) of $<0.3~\mu m$ was deemed acceptable.

2.5. Statistical methods

Efficacy analysis was conducted on the per-protocol (PP) population, defined as those subjects, who were randomized into the study, received at least one dose of study product and who had at least one post-baseline efficacy assessment and who did not violate the protocol in a major way. The primary efficacy variable was analysed using ANOVA based on a mixed model with factors of subject, treatment, period and side of mouth treated (left/right). Mean differences between treatments, 95% confidence intervals and p-values of the treatment difference were calculated.

2.6. Criteria for assessing efficacy

The low RDA toothpaste was expected to show a decreased (lower) amount of dentine lost as assessed by contact profilometry after 10 days of treatment in comparison to the moderate and high RDA toothpastes. Similar effects were expected with non-contact profilometry.

2.6.1. Primary efficacy variables

The primary efficacy variable was the mean dentine loss (μm) measured by contact profilometry at day 10 for the PP population. Whether the overall treatment effect was significant or not, the following principal paired comparisons were be made:

- low abrasive toothpaste vs. moderate abrasive toothpaste
- low abrasive toothpaste vs. high abrasive toothpaste

Mean differences between treatments, 95% confidence intervals and p-values of the treatment difference are presented. In addition the following secondary comparisons of the primary efficacy variable were made:

- low abrasive toothpaste vs. moderate abrasive toothpaste, at day 5
- low abrasive toothpaste vs. high abrasive toothpaste, at day 5
- low abrasive toothpaste vs. water, at day 10
- moderate abrasive toothpaste vs. water, at day 10
- high abrasive toothpaste vs. water, at day 10

2.6.2. Secondary efficacy variables

The secondary efficacy variable was the mean dentine loss (μm) obtained by non-contact profilometry at day 10. The secondary efficacy parameter was analysed in a similar

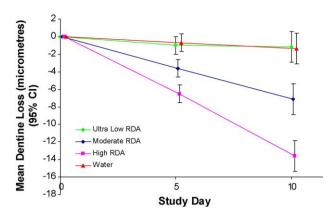


Fig. 2 - Mean dentine loss (contact profilometry).

manner to the primary efficacy variable and all similar treatment comparisons were made.

3. Results

Of the 19 evaluable subjects receiving treatment, 11 were male and 8 female, all Caucasian, with a mean age of 40 years (range 25–62 years). One volunteer withdrew for personal reasons. The mean dentine loss, using the contact profilometry method, for each of the treatment groups is presented in Fig. 2. Treatment comparisons for the contact and non-contact profilometry methods are presented in Table 2.

Results demonstrate that the low RDA paste was significantly (p < 0.0001) less abrasive to dentine than the moderate RDA paste at day 10 for both contact and non-contact profilometry, and significantly (p < 0.001) less abrasive to dentine than the moderate RDA paste at day 5 for contact profilometry.

When comparing the low RDA paste to the high RDA paste, again the former is significantly (p < 0.0001) less abrasive to dentine at both day 5 and day 10 for contact profilometry, and significantly (p < 0.0001) less abrasive to dentine at day 10 for non-contact profilometry.

Further results demonstrate that the moderate RDA and high RDA pastes are significantly (p < 0.0001) more abrasive to dentine than water at day 10 for both contact and non-contact profilometry. The low RDA paste is not significantly more

abrasive to dentine than water at day 10 for both contact and non-contact profilometry.

4. Discussion

There is a paucity of literature on clinically based studies to assess the abrasive nature of brushing tooth tissue with different toothpastes. The abrasivity of the toothbrush alone to enamel is almost certainly negligible, 11-13 although features of the toothbrush head can modify the abrasivity of the toothpaste. The in vitro measurement of toothpaste abrasivity, however, are well documented, 14,15 with a number of studies measuring abrasion of dentine and other substrates over time, with brushing times varying between months and years of twice daily normal oral hygiene practices. There are also a number of methodologies to measure abrasion using a number of substrates and techniques. Unfortunately, there are no studies comparing the different in vitro methodologies, pastes are ranked in comparison to the reference paste with each method using qualitative or semi-quantitative data.

Data derived from in vitro sources can be extremely informative and meaningful often giving "the worst case scenario type of effect" and allowing a multitude of variables to be investigated, aiding researchers regarding the design and conduct of expensive clinical studies. *In vitro* data must not, however, be used as a substitute for clinical data and findings should be interpreted with care and in the context they were conducted.

Observing the clinical environment, wear is a complex interaction in that it is rarely one process, but of multifactoral aetiology. 34,35 Further, clinically significant wear often occurs over a considerable period of time, and not necessarily in linear distribution. This leads to difficulties not only in measuring a specific wear process clinically but measuring the wear process generally due to a number of reasons; lack of instrumentation sensitive enough to detect minute wear of teeth, lack of reference points critical for comparison as the mouth is not a static environment, unless for example a dental implant is used, and thirdly the length of time needed. It is therefore extremely difficult to accurately measure abrasion of dentine clinically. In order to overcome these factors an in situ model can be employed as in this study. This methodology not only has the advantage of accurate measurement but also standardization of many variables, e.g. time, force of brushing.

Table 2 – Treatment comparisons for contact and non-contact profilometry (μm).					
Treatment comparison	Contact profilometry		Non-contact profilometry		
	Day 5	Day 10	Day 10		
Low RDA vs. moderate RDA	2.61*	5.97**	6.48**		
Low RDA vs. high RDA	5.53 ^{**}	12.43**	10.74**		
Low RDA vs. water		0.17	0.64		
Moderate RDA vs. water		-5.81 ^{**}	-5.84 ^{**}		
High RDA vs. water		-12.26 ^{**}	-10.10 ^{**}		

Positive differences favour the first named treatment.

p < 0.001.

p < 0.0001.

The study design was single centre, two period, fourtreatment cross-over, split mouth evaluating the abrasive effect of three different toothpastes compared to a negative control, water. The cross-over design allowed each subject to act as their own control thus reducing experimental variability in the treatment groups. Whilst no carryover effect was expected between treatments fresh dentine samples were used for each study period, therefore no wash-out period was included. There are many advantages of conducting a study of this type. An environment was provided similar to the in vivo environment for 5 h each treatment day allowing pellicle formation and flushing with saliva. This design also allowed good control of the abrasion wear process of the dentine with standardization of the amount of paste, brushing times and forces. The brushing time was based on brushing four samples, three times a day for 60 s over a 10 day period, which is about 450 s per dentine sample. This is not an unrealistic time period (approx a year) considering the brushing cycle is 2 min with the most time spend on the initial teeth brushed36 and many dentine hypersensitivity patients brushing up to five times a day.³⁷ In this study extracted dentine human was used. This is an ideal medium to study in an in situ study as it is as close to the natural living tooth as possible and can be withdrawn and measured during the study period. This in situ study successfully showed it was possible to clearly differentiate between the dentine wear of a low RDA toothpaste brushed on the dentine surface compared to a moderate and a high RDA paste after 10 days. Indeed a significant degree of dentine loss could be detected after as little as 5 days of three times a day brushing. Not only was the low abrasive paste significantly less abrasive than the other two marketed pastes, there was also no significant difference between the low RDA paste and water at day 10 which confirms the low abrasive nature of this paste and its possible use clinically for individuals who are susceptible to dentine wear, namely the dentine hypersensitivity suffers, of which there are believed to be approximately 15% in our population.38

The amount of abrasion of the dentine samples which were placed in subjects' mouths varied with the same treatment as shown in the standard variations in Fig. 2. This is to be expected in trials of this nature,9 due to subject variables such as the nature and composition of pellicle and saliva³⁹ and biological differences in tooth structure, confirming the accuracy of methodology, giving a spectrum of possibilities of abrasive results as in the in vivo situation. Wulknitz⁴⁰ evaluated 41 toothpastes available to European consumers in 1995 for cleaning efficacy in comparison with relative dentine abrasivity values. In order to assess cleaning efficacy, a modified pellicle cleaning ratio (PCR) measurement method was developed. No product exceeded an RDA value of 200, the majority (80%) having an RDA value below 100. Some major trends could be shown on the basis of abrasive types. Most of the hydrated silica-based toothpastes had good or very good cleaning values combined with low to moderate dentine abrasivity. A lower ratio was found in some products containing calcium carbonate or aluminium trihydrate as the only abrasive. The addition of other abrasives, such as aluminium oxide (polishing alumina), showed improved

cleaning power. Sequestrants such as sodium tripolyphosphate can also improve the PCR:RDA ratio without significantly changing abrasivity. It is encouraging to note that in Europe, over the last 30 years, there has been a general trend toward reduced abrasivity without loss of cleaning efficacy. However, it should be borne in mind that dentine abrasivity should not be regarded as the sole safety criterion for the abrasivity of toothpastes. Also comparison of data shows that enamel abrasivity values can differ substantially, without major changes in abrasion on dentine.⁴⁰

Abrasives still constitute the major anti-stain effects of toothpastes on the European market today and hence their inclusion in toothpastes. This benefit must be weighed against the possible loss of dentine and gingival recession due to toothbrushing with toothpaste. Bleaching by peroxides, an alternative method of stain removal, is restricted for consumer products in the EU due to the regulations of the European Cosmetics Directive. The particular toothpastes chosen for study were known to vary in their abrasive components and there predicted abrasive nature in vivo as determined with in vitro methodology. The low relative dentine abrasive toothpaste contained a 'thickening' silica which is known to have little abrasivity and a polyphosphonate/detergent/humectant combination. The RDA had been measured around a value of about 15. Whereas the moderate abrasive paste contained normal abrasive grade silica and the RDA was measured around a value of 70. Silica is an abrasive ubiquitously used in many of todays' toothpastes due to its excellent technical characteristics and cleaning properties and can vary in abrasive characteristics with the size of the silica particles employed. This paste would be classified as a moderate RDA paste, and was chosen as the benchmark for a family toothpaste. The high abrasive paste is believed to contain the abrasive alumina, and appears to be one of the more abrasive pastes on the market today, whilst still falling in line with the recommended abrasive values for toothpastes, with a tested RDA value of about 240.

Reassuringly the abrasion of dentine by these pastes with this in situ methodology produced the same trend in data value as the in vitro RDA measurements with the two different measuring methodologies, contact and non-contact profilometry.

In this study no attempt was made to measure the reduction in stain potential on dentine of the low relative dentine abrasive paste. This will be investigated in a stain model in further in situ studies utilising this paste.

In summary this study demonstrates that toothpaste abrasion, as a single wear process, can be modelled in situ and the model allows clear differentiation between a low abrasive paste and a moderate or high abrasive paste. And the measurement of abrasion on dentine of the low abrasive paste gives similar results to water. The stain removal properties of the low relative abrasive dentine paste needs to be investigated next.

Conflict of interest statement

The authors declare they have no conflict of interest.

Source of funding statement

This study was supported by a grant from GlaxoSmithKline, Consumer Healthcare, St. George's Avenue, Weybridge, Surrey KT13 ODE, UK.

Acknowledgement

The authors thank John Ward for his support on this work.

REFERENCES

- Anneroth G, Poppleman A. Histological evaluation of gingival damage by toothbrushing. An experimental study in the dog. Acta Odontologica Scandinavica 1975;33: 119–27.
- Sangnes G. Traumatization of teeth and gingivae related to habitual tooth cleaning. Review article. *Journal Clinical Periodontology* 1976;3:94–103.
- Sangnes G, Gjermo P. Prevalence of oral soft and hard tissue lesions related to mechanical tooth cleaning procedures. Community Dentistry and Oral Epidemiology 1976;4:77–83.
- Sandholm L, Niemi ML, Ainamo J. Identification of soft tissue brushing lesion. A clinical and scanning electron microscopic study. *Journal of Clinical Periodontology* 1982;9:397–401.
- Niemi ML, Sandholm L, Ainamo J. Frequency of gingival lesions after standardized brushing as related to stiffness of toothbrush and abrasiveness of toothpaste. *Journal of Clinical Periodontology* 1984;11:254–61.
- Hirschfeld I. The toothbrush. Its use and abuse. Dental Items of Interest. Kimpton; 1939. p. 1–27, 262–7, 358–465, 484–95.
- Bull WH, Callender RM, Pugh BR, Wood GD. The abrasion and cleaning properties of toothpastes. British Dental Journal 1968;125:331–7.
- Davis WB, Winter PJ. The effect of abrasion on enamel and dentine after exposure to dietary acid. British Dental Journal 1980:148:253-6.
- Addy M. Dentine hypersensitivity: new perspectives on an old problem. *International Dental Journal* 2002;5: 367–75.
- White DJ. Development of an improved whitening toothpaste based upon 'stain-specific soft silica' technology. *Journal of Clinical Dentistry* 2001;12:25–9.
- Phaneuf EA, Harrington JH, Dale PP, Stellar G. Automatic toothbrush: a new reciprocating action. *Journal of the* American Dental Association 1962;65:12–25.
- Absi EG, Addy M, Adams D. Dentine hypersensitivity. The effects of toothbrushing and dietary compounds on dentine in vitro: a SEM study. *Journal of Oral Rehabilitation* 1992:19:101–10.
- Dyer D, Addy M, Newcombe RG. Studies in vitro of abrasion by different manual toothbrush heads and a standard toothpaste. Journal of Clinical Periodontology 2000;27:99–103.
- British Standards Institution. Specification for toothpastes.
 Park Street, London W1A 2BS: British Standards Institution; 1981.
- ISO11609. ISO 1995 international standard: dentistrytoothpaste requirements, test methods and marking. Switzerland: ISO; 1995.
- Hefferren JJ. A laboratory method for assessment of toothpaste abrasivity. *Journal of Dental Research* 1976;55: 563–73.

- Pickles MJ, Joiner, A, Weader E, Cooper YL, Cox TF. Abrasion of human enamel and dentine caused by toothpastes of differing abrasivity determined using an in situ wear model International Dental Journal 55, 188–93.
- 18. Pader M. Oral hygiene products and practice. New York: Mercel Dekker; 1988. p. 141–516.
- American Dental Association. Home-use tooth stain removal products. Chicago, IL: Council on Scientific Affairs; 2007.
- Barbakov F, Lutz F, Imfeld T. A review of methods to determine the relative abrasion of dentifirces and prophylaxis pastes. Quintessence International 1987;18:23–8.
- 21. Addy M. Oral hygiene products: potential for harm to oral systemic health? *Periodontology* 2000 2008;**48**:54–65.
- 22. Miller WG. Experiments and observations on the washing of tooth tissue variously designated as erosion, abrasion, chemical abrasion, denudation etc.. *Dental Cosmos* 1907;49. p. 1–23,109–24, 225–47.
- 23. Hunter ML, Addy M, Pickles MJ, Joiner A. The role of toothpaste and toothbrushes in the aetiology of tooth wear. *International Dental Journal* 2002;**52**:399–405.
- 24. Hooper S, West NX, Pickles M, Joiner A, Newcombe RG, Addy M. Investigation of erosion and abrasion of enamel and dentine: a model in situ using toothpastes of different abrasivity. *Journal of Clinical Periodontology* 2003;30:802–8.
- 25. Addy M. Toothbrushing, tooth wear and dentine hypersensitivity—are they associated. *International Dental Journal* 2005;**55**:261–7.
- Addy M, Hughes J, Pickles M, Joiner A, Huntington E. Development of a method in situ to study toothpaste abrasion of dentine: comparison of 2 products. *Journal of Clinical Periodontology* 2002;29:896–900.
- Hooper SM, Newcombe RG, Faller R, Eversole S, Addy M, West NX. The protective effects of toothpaste against erosion by orange juice: studies in situ and in vitro. *Journal of Dentistry* 2007;35(6):476–81.
- Noordmans J, Pluim LJ, Hummel J, Arends J, Busscher HJ. A
 new profilometric method for determination of enamel and
 dentinal abrasion in vivo using computer comparisons: a
 pilot study. Quintessence International 1991;22(8):653–7.
- 29. Addy M, Embery G, Edgar WM, Orchardson R. Tooth wear and sensitivity. London: Martin Duntiz Ltd.; 2000. p. 106.
- ICH Topic 6 Guideline for Good Clinical Practice CPMP/ICH/135/ 95, 17th July, 1996.
- 31. Human Tissue Act 2004. Office of public sector information, HMSO official publications, UK Parliament Act.
- West NX, Jandt K. Tooth wear and sensitivity. Proceedings from the Council of Europe 1998. 2000:105–20. [This book has 30 chapters and 378 pages].
- Addy M. Clinical aspects of dentine hypersensitivity. Clinical Materials 1991;7:219–25.
- 34. Mair LH. Wear in the mouth: the tribology dimensions. In: Addy M, Embery G, Edgar WM, Orchardson R, editors. Tooth wear and sensitivity: clinical advances in restorative dentistry. London: Martin Dunitz; 2000. p. 181–8.
- 35. Meurman JH, Sovari R. Interplay of erosion, attrition and abrasion in toothwear and possible approaches to prevention. In: Addy M, Embery G, Edgar WM, Orchardson R, editors. Tooth wear and sensitivity: clinical advances in restorative dentistry. London: Martin Dunitz; 2000. p. 171–80.
- Addy M, Moran J. Evaluation of oral hygiene products: science is true; don't be misled by the facts. Toothpaste, mouthrinse and other topical remedies in Periodontics. Periodontology 2000 1997;15:40–51.
- West NX. Dentine hypersensitivity; clinical and laboratory studies of toothpastes, their ingredients and acids. PhD University of Wales; 1995.
- 38. Fischer C, Fischer RG, Wennberg A. Prevalence and distribution of cervical dentine hypersensitivity in a

- population in Rio de Janeiro, Brazil. *Journal of Dentistry* 1992;**20**:272–6.
- 39. Wetton S, Hughes J, West NX, Addy M. Exposure time of enamel and dentine to saliva for protection
- against erosion. A study in vitro. Caries Research 2006;40: 213–7.
- 40. Wulknitz P. Cleaning power and abrasivity of European toothpastes. Advances in Dental Research 1997;11:576–9.