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Full Length Article

A randomised clinical *in situ* study to evaluate the effects of novel low abrasivity anti-sensitivity dentifrices on dentine wear

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ABSTRACT

Objectives: To compare the abrasive wear on human dentine in an *in situ* model associated with use of an experimental low abrasivity anti-sensitivity dentifrice containing 1% alumina and 5% sodium tripolyphosphate (STP) with an experimental ultra-low abrasivity non-alumina 5% STP dentifrice, a higher abrasivity daily-use whitening dentifrice, and water as controls.
Methods: This was a single-centre, single-blind, randomised, split-mouth, four-treatment, two-period, crossover *in situ* study in 29 healthy subjects. Subjects wore bilateral lower buccal appliances, each fitted with four dentine specimens. Study treatments were applied *ex vivo* (three times daily). Dentine loss was measured by non-contact profilometry after 5, 10 and 15 days' treatment.
Results: All 29 subjects were included in the efficacy analysis. Significantly less dentine loss was associated with brushing with the low and ultra-low abrasivity dentifrices than with the higher abrasivity dentifrice at all timepoints ($p < 0.01$). Brushing with ultra-low abrasivity dentifrice or water resulted in statistically significantly less dentine loss compared with brushing with the low abrasivity dentifrice at all timepoints ($p < 0.05$). Dentine loss after brushing with ultra-low abrasivity dentifrice was not significantly different from brushing with water.
Conclusions: The degree of dentine loss observed in this *in situ* model reflected the abrasivity of the study dentifrices. Brushing with low or ultra-low abrasivity STP-containing anti-sensitivity dentifrices resulted in significantly less dentine loss (equating to dentine wear) than with a higher abrasivity daily-use whitening dentifrice.

1. Introduction

Dentifrices – particularly daily-use whitening pastes – are typically formulated with dental abrasives, such as hydrated silica, chalk, dicalcium phosphate or alumina [1–3], or with a combination of abrasive and chemical cleaning agents, such as sodium tripolyphosphate (STP), to help control the build-up of stain on the surface of the teeth whilst helping to achieve good hygiene. Polyphosphates, such as STP, are often utilised in dentifrices to supplement the physical mode of action of stain removal offered by abrasives [4].

Particle hardness, shape, size, size distribution and concentration have all been reported to affect the stain-removal properties of dental-grade abrasives [1,2]. These same parameters also influence the rate of abrasive wear, which increases as abrasive particle size increases up to a critical point, after which it becomes independent of size [5,6]. Dentine is considerably softer than enamel [7], making it more vulnerable to abrasive wear from over-brushing or use of higher abrasivity dentifrices. The effect of abrasivity on dentine should be considered when formulating a dentifrice as most abrasives have a hardness similar to or greater than dentine [8]. Abrasive wear is of particular concern in people with dentine hypersensitivity, where the dentine is exposed, notably at the cervical margin of the tooth [9]. Use of a lower abrasivity dentifrice may be more appropriate for this population to help minimise wear of exposed dentine.

Relative dentine abrasivity (RDA) is a quantitative *in vitro* measure used to assess the abrasiveness of a dentifrice formulation on dentine [10]. It is included in the International Organization for Standardization specification for a dentifrice [11] and is the most widely accepted standardised measure of dentifrice abrasion [12]. Dentifrices with an RDA value up to 250 are considered suitable for normal daily use [11]. Effective extrinsic stain removal has long been associated with higher RDA formulations; indeed, a review of

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commercially available dentifrices noted that whitening dentifrices were generally more abrasive than other dentifrice products [2]. However, dentifrice formulations containing a low calcined, small particle size alumina abrasive in combination with STP have also been reported to exhibit highly effective stain removal *in vitro* with low dentine abrasivity [13]. More recently, the combination of a small particle size alumina and STP in a low abrasive anti-sensitivity dentifrice has also been shown to be clinically effective at removing extrinsic dental stain compared with a dentifrice containing abrasive dental silica alone [14].

Polyphosphates such as STP have been shown to strongly bind to the surface of the tooth, desorbing protein and chromogens from hydroxyapatite *in vitro* and desorbing the acquired enamel pellicle *in vivo* [15–18]. It is understood that binding of polyphosphates to the surface of the tooth can cause changes to the surface charge that disrupt protein adsorption [5], thus enhancing the removal of protein-based stain offered from tooth brushing with a dentifrice containing dental-grade abrasive.

In vitro and *in situ* methodologies have been established to evaluate the long-term wear potential of abrasives and dentifrices on human dentine and enamel using a number of substrates and techniques [19–21]. An *in situ* clinical study demonstrated significantly less dentine loss following use of an ultra-low abrasivity dentifrice (RDA ~15) compared with brushing with moderate (RDA ~70) or higher (RDA ~240) abrasivity formulations, and no significant difference from brushing with water alone [22], i.e. it showed increased dentine loss (equating to wear) with increasing dentifrice abrasivity.

The aim of this study was to compare the abrasive wear on human dentine of an experimental, low abrasivity anti-sensitivity dentifrice containing 1% w/w alumina abrasive and 5% w/w STP, developed to provide relief from dentinal hypersensitivity and stain removal benefits, with that of an experimental ultra-low abrasivity anti-sensitivity dentifrice containing no alumina and 5% w/w STP, a daily-use whitening dentifrice, and mineral water as reference controls. The null hypothesis was that there would be no significant difference in the abrasion of dentine from tooth brushing with the three toothpastes of different RDA values. Further, all three pastes would be significantly more abrasive to dentine than water.

2. Methods

2.1. Study design

This was a single-centre, single-blind (specimen analyst), randomised, split-mouth, four-treatment, two-period, crossover, exploratory *in situ* study in healthy subjects. The study was conducted in accordance with the Declaration of Helsinki at the Clinical Trials Unit of the Bristol Dental Hospital and School, with ethical review by an independent ethics committee (South West – Exeter, IRB number 14/SW/0044).

The *in situ* method used in the current study was based on a previously published *in situ* abrasion methodology [19,22]. The model employs removable acrylic mandibular appliances that hold the dentine specimens buccally in the oral cavity. Subjects wear the intra-oral appliances for 5–7 h on a treatment day; they are removed for *ex vivo* treatment of the dentine specimens. Dentine loss is measured by surface profilometry at intervals over the treatment period.

2.2. Subjects

Subjects were recruited by the Clinical Trials Unit. The eligible study population comprised healthy adults aged ≥18 years with good general and oral health and the ability to accommodate lower bilateral buccal intra-oral appliances. Exclusion criteria included pregnancy; breastfeeding; current or recurrent disease or dental pathology that could have affected the study assessments; any oral appliance/restorations that could have interfered with study procedures; recurrent aphthous ulcers; susceptibility to acid regurgitation; severe gingivitis, carious lesions or periodontal disease; signs/history of dental erosion; and daily doses of medication that was causing xerostomia.

2.3. Preparation of dentine specimens and appliances

Dentine specimens were obtained from recently extracted caries-free human third molars. Slices of coronal root dentine with a surface area of 3 mm × 3 mm were sectioned from buccal and palatal areas of the teeth and set in composite (QuiXfil®; Dentsply IH Ltd, Weybridge, UK), polished with 1200 grit silica powder and 0.3 μm alumina powder to produce flat specimens (1 μm tolerance) with parallel sides, and ultrasonicated in deionised water after each polishing stage. Before use, a 3 mm × 1 mm area was scanned by non-contact profilometry (Proscan 2100; Scantron Industrial Products Ltd, Taunton, UK) to confirm that the specimens were flat and within the 1 μm tolerance. This included the area of the dentine to be exposed to study treatment and two outer (reference) areas from which changes from baseline were calculated. Polyvinyl chloride (PVC) tape was applied over the reference areas to protect them from abrasion, leaving an approximately 2 mm wide zone of exposed dentine along the length of the specimen for treatment.

During the study, subjects wore lower left and right buccal appliances, each fitted with four dentine specimens (Fig. 1). At the start and end of each treatment day the buccal appliances including the dentine specimens were disinfected in chlorhexidine mouthwash (Corsodyl®; GSK Consumer Healthcare, Weybridge, UK) for approximately 3 min and rinsed with tap water before either placing in the mouth or storing overnight. At the end of each treatment day and during the profilometry analysis period, appliances were stored at the study site in moist conditions to ensure the dentine specimens remained hydrated. Before and after profilometry, the PVC tape was removed from the specimens and the appliances were disinfected for at least 20 min in a mixture of 0.5% chlorhexidine and 70% ethanol, then rinsed with tap water. After analysis, the PVC tape was re-applied and the specimen re-inserted into the appliance.

2.4. Study products

Four study products were tested over two separate treatment periods: two during the first treatment period and two during the second.

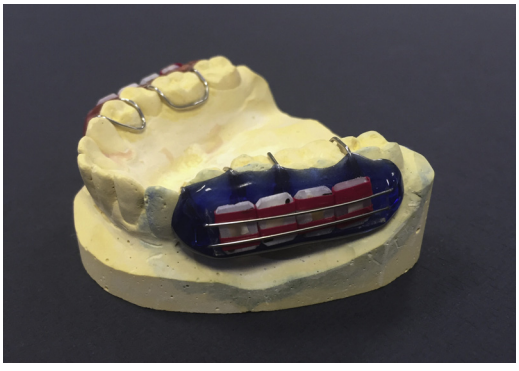

Fig. 1. Intra-oral lower buccal appliance showing four dentine specimens *in situ*.