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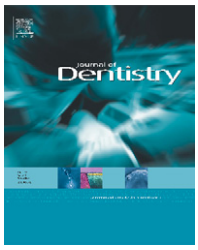

A double blind randomised controlled clinical trial comparing a novel anti-stain and calculus reducing dentifrice with a standard fluoride dentifrice

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ARTICLE INFO

Article history:
Received 9 November 2011
Received in revised form
1 November 2012
Accepted 10 December 2012

Keywords:
Toothpaste
Sodium polyaspartate
Dental calculus
Gingivitis

ABSTRACT

Objectives: This clinical trial tested the anti-stain efficacy at 3 and 6 months of a novel, sodium polyaspartate-containing, anti-stain dentifrice. In addition, the efficacy of the new dentifrice in controlling gingival inflammation and inhibition of calculus deposition was tested.

Methods: Participants were recruited to this double blind randomised control clinical trial, and allocated to either test or control groups. The presence of stain and calculus were entry criteria. Measurements of stain, calculus and gingival inflammation were recorded using the Shaw and Murray Stain score, Volpe-Manhold Calculus score and the Modified Gingival Index respectively. Measurements were made at baseline, prior to the removal of stain and calculus, and after 3 and 6 months. Missing data were imputed by and the outcomes were analysed using univariate analysis.

Results: At three months, toothpaste containing sodium polyaspartate was better (difference of mean 1.13 with SEM 0.57) than control for the control of dental stain ($p < 0.05$). Stain scores also showed a trend in favour of the test product (difference of mean 1.03 with SEM 0.78) at six months ($p > 0.05$). There was no difference between toothpastes with respect to calculus deposition or gingival inflammation.

Conclusions: Toothpaste containing sodium polyaspartate was more effective than a control toothpaste at preventing deposition of dental stain for 3 months after professional tooth cleaning but showed no significant effect at 6 months.

Clinical relevance: Sodium polyaspartate toothpaste was more effective than a control toothpaste at preventing dental stain formation and maybe helpful in controlling staining between episodes of scaling and polishing.

1. Introduction

Dental stain and the formation of calculus are of clinical and economic importance. Dental stain can be unsightly, and calculus, typically forming around the necks of teeth, becomes a rough, hard surface which retains the dental plaque biofilm. This leads to further calculus formation and plaque directly affects the gingival tissues inducing gingivitis that may lead to more serious periodontitis,[1] which may ultimately lead to tooth loss. Once dental calculus becomes hard, it may require professional removal. The cost of scaling and polishing teeth

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0300-5712/$ – see front matter
http://dx.doi.org/10.1016/j.jdent.2012.12.005

to remove dental stain and calculus was at least £140 million to the UK NHS general dental services alone,[2] excluding treatment in hospitals and by private contract. Dentifrices reducing stain and calculus formation may therefore lead to improvements in oral health and reduce the demand and cost of dental care.

Tooth staining is a common dental complaint and may be controlled to varying degrees by the home use of a dentifrice or by a dental professional undertaking scaling and polishing. In a review of the literature, Watts and Addy[3] found the extrinsic staining of teeth to be caused by either the basic colour of compounds incorporated into the dental pellicle (direct staining) or as a result of chemical interaction at the tooth surface (indirect staining). Examples of the former include direct staining from tobacco, tea and coffee, though these and other substances including mouthrinses, medicaments and chromogenic bacteria may also indirectly cause tooth staining. Indirect extrinsic staining can be associated with the use of chlorhexidine mouthrinse or metallic salts within dietary supplements, medications or from occupational exposure to metal salts.

Since the removal of stain by dental professionals is costly and labour intensive, there has been considerable interest in its control by the use of dentifrices formulated for this purpose. Whilst the results of some clinical studies are encouraging,[4–8] there continues to be a demand for new formulations of dentifrice that aim to improve the control of dental stain, control calculus formation and maintain tooth whiteness.

There has also been considerable clinical research on anti-calculus agents and the efficacy of these in dentifrices. Fairbrother and Heasman[13] reviewed these studies and concluded there was evidence for some formulations effectively reducing calculus formation. However, there was a lack of evidence from comparative studies to show that any one formulation was clearly better than the others tested. In their paper, the strategies for controlling calculus formation were also reviewed and included measures to alter the attachment of calculus to tooth surfaces, the prevention of plaque formation and also the inhibition of mineralisation. More recent studies have continued to report the efficacy of new formulations of toothpaste.[9–12] A wide variety of agents have been used to reduce calculus formation, including the use of heavy metals to inhibit mineralisation, bisphosphonates, pyrophosphates, polymers and co-polymers that are familiar ingredients in anticalculus dentifrices. Their efficacy in reducing calculus formation in clinical trials varied widely from as little as 9% to as much as 69% in the data they presented, when anticalculus dentifrices were compared with a sodium monofluorophosphate control dentifrice. However, in most studies, anticalculus agents reduced the amount of calculus by approximately 30–50%. The variability may in part be accounted for by different study designs. Sowinski et al.,[14] identified some of these variations, and recommended reporting the importance of ensuring participants' ability to form calculus during a pre-trial phase, scaling prior to the test phase, random assignment to test groups and for studies to be undertaken for periods of up to 6 months.

Further research on new agents is warranted to identify better anticalculus agents. One such new agent is sodium polyaspartate. Polyaspartate is an anionic polymer that is used industrially to inhibit crystal growth and which could be used to reduce dental calculus formation.[15,16] In addition, polyaspartate was effective in controlling the development of dental plaque and the formation of a bacterial biofilm when used in a dentifrice formulation *in vitro*.[15] The benefits of polyaspartate both in reducing the build-up, and in increasing the removal of, stain on extracted teeth and on artificial substrates, as well as in reducing calculus crystal growth have been shown in laboratory studies.

The aim of this study was to assess the efficacy of a sodium polyaspartate-containing toothpaste compared to a sodium monofluorophosphate control toothpaste in its ability to prevent deposition of dental stain and calculus in the medium term. The working hypothesis was that a sodium polyaspartate-containing toothpaste is more effective than a control in preventing deposition of dental stain for 3 and 6 months after professional tooth cleaning. Secondary outcomes of reduction in deposition of dental calculus and gingivitis were also assessed.

2. Methods

The research project was independently approved by the South Sheffield Research Ethics Committee (reference STH14105/SSREC 96/308) and conducted in accordance with the World Medical Association Declaration of Helsinki.

2.1. *Sample*

Using the data for a negative control dentifrice,[14] it was calculated that a sample size of 40 per group would be required to detect a 35% difference between test and control dentifrices, as might be anticipated since in most studies, anti-calculus agents reduce the amount of calculus by between 30 and 50%,[13] with an 80% power with respect to calculus formation. It was calculated that fewer participants would be required to detect differences in stain formation based on previous studies conducted within our group. Therefore a sample size of 40 per group was selected.

Participants were recruited from staff of the University of Sheffield and Sheffield Teaching Hospital NHS Foundation Trust, by use of email networks. Participants were screened according to the inclusion and exclusion criteria (Table 1). Screening and recruitment was undertaken by AKJ or AR.

2.2. *Toothpaste allocation*

Prior to recruitment an allocation sequence according to gender and smoking status, in accordance with a random permitted blocks with strata[17] was generated by Dr Robinson of the Statistical Services Unit, The University of Sheffield. Ninety-two participants were recruited to allow for over 10% drop-out, given a consecutive number and allocated by a dental nurse to the test or control group according to the predefined sequence.

The test and control toothpastes (composition summarised in Table 2) were packaged identically except for a coded identification number. The coding for the toothpaste was withheld from the clinicians until data analysis was complete.