Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.intl.elsevierhealth.com/journals/jden

A 3-day randomised clinical study investigating the efficacy of two toothpastes, designed to occlude dentine tubules, for the treatment of dentine hypersensitivity

N. West [a,*], R.G. Newcombe [c], N. Hughes [b], S. Mason [b], B. Maggio [b], F. Sufi [b], N. Claydon [a]

[a] Applied Clinical Research Group, Department of Oral and Dental Science University of Bristol, UK
[b] GlaxoSmithKline Consumer Healthcare, St. George's Avenue, Weybridge, Surrey, KT13 ODE, UK
[c] Department of Primary Care and Public Health, Clinical Epidemiology Interdisciplinary Research Group, Cardiff University, Cardiff, Wales, UK

ARTICLE INFO

Article history:
Received 20 April 2012
Received in revised form
22 October 2012
Accepted 6 November 2012

Keywords:
Dentine hypersensitivity
Strontium
Arginine
Pain

ABSTRACT

Objectives: A product comparison study to compare the short term clinical efficacy of a strontium acetate/silica toothpaste with an arginine/calcium carbonate paste for pain reduction in dentine hypersensitivity.

Methods: The study was examiner blind of two arm parallel design. Eighty healthy adult subjects from general dental practice with ≥2 sensitive teeth but otherwise good oral health, were enrolled and randomised to 1 of 2 toothpaste treatments, schedule provided by the sponsor. Almost equal numbers received each treatment. Tooth sensitivity was measured in three ways; evaporative (Schiff score; Visual Analogue Scale) and tactile stimuli (Yeaple probe), prior to and immediately after subjects' self application of a single pea sized dose of toothpaste, and following subsequent twice daily brushing for three days with the paste.

Results: All 80 subjects completed the study. Results confirm that for both treatments, pain was reduced immediately and relief was sustained after 3 days use. For all 3 measures, benefit was similar between the two pastes, with no statistical or clinical difference demonstrated, apart from response to evaporative stimulus at 3 days, where Schiff scores were significantly lower in the arginine group, $p = 0.02$.

Conclusions: It can be concluded that both desensitising, occluding toothpastes provided reduction of pain from dentine hypersensitivity on a short term basis: toothpastes appearing to be clinically similarly effective both after a single subject dab on application and post twice daily brushing for three days.

National Research Ethics Service register number 09/H020/57.

1. Introduction

The oral pain condition of dentine hypersensitivity is experienced by millions of people throughout the world.[2,3] As the short, shooting pain is transient in nature, more often than not, individuals accept the discomfort, guarding and protecting the dentition as necessary to avoid experiencing pain. Indeed, they commonly fail to inform and seek help from their general dental practitioner.[4] The first documented diagnosis of dentine hypersensitivity was in the 1530 by Blum.[5] Since this time countless treatment modalities have been suggested and implemented, however a definitive treatment for all, eludes us.[6–9]

* Corresponding author at: Clinical Trials Unit, Department of Oral and Dental Sciences, University of Bristol, UK. Tel.: +44 1173424314; fax: +44 1173424404.
E-mail address: N.X.West@bristol.ac.uk (N. West).
0300-5712/$ – see front matter
http://dx.doi.org/10.1016/j.jdent.2012.11.007

Management of dentine hypersensitivity is primarily based on twice daily home use of over the counter toothpaste products, utilising one of two treatment approaches, based on either nerve depolarization or dentinal tubule occlusion.[10] Potassium therapy is weakly supported by a Cochrane review[11] on potassium nitrate, studies by Gillam et al.[12] and West et al.,[13] failing to show improvement in symptoms of dentine hypersensitivity after prolonged use of the products. Patients can however, achieve meaningful reductions in their day to day sensitivity, within about a two week period following application of potassium based dentifrices according to studies such as Ayad et al.[14] and Schiff et al.[15]

The second treatment approach of tubule occlusion, physically addresses the concept that dentine tubules need to be patent throughout their length in order to provoke the pain response associated with dentine hypersensitivity.[16] The hydrodynamic theory proposed by Gysi in 1900[17] and reinforced by Brännström in 1963,[18] suggests that external stimuli such as thermal, evaporative, tactile or osmotic pressure, when applied to an exposed dentine surface with patent dentine tubules, can result in shifts of dentinal fluid within the tubule. This fluid movement stimulates mechanoreceptors near the base of the tubule and may, if certain physiological parameters are met, trigger a pain response. Reducing dentine tubule diameter, changes the rate of flow and subsequent pain response. Absi et al.[19] documented the necessity of the tubule diameter being in the order of about 1 μm for the individual to experience pain and that a number of dentine tubules of these dimensions need to be present on the dentine surface.[16,19] Dentinal tubule occlusion, therefore describes the action of depositing material on the dentine surface, or within the dentine tubules, thereby reducing or minimising dentinal tubule diameter, reducing fluid movement and subsequent stimulation of the mechanoreceptors. Logically, occlusion techniques offer far superior benefits over and above nerve depolarisation potassium treatment, due to the their speed of action, which in theory could be immediate.

The ability of occluding agents to adhere to and resist removal from the dentine surface has always proven to be a very credible treatment option for sensitivity and indeed has been the concept of most treatments for 40 years.[20–23] The concept of tubule occlusion or partial occlusion, seems an eminently sensible solution for the condition however, there are a number of oral challenges which come into play to dislodge or remove tubule occlusion, to compound effective, efficient treatment.

Over recent years, toothpastes have been specifically developed to meet these challenges, namely a strontium based paste and an arginine based paste. Strontium has been demonstrated[24] to form a compact continuous layer on the surface, and within the tubule. This formation can be attributed to ion exchange between the strontium and calcium in the dental tissue, followed by reprecipitation of calcium and finally the formation of a higher density strontium substituted calcium hydroxyapatite. The deposition of a granular surface layer (inter- and intra- tubular) has also been reported elsewhere for products containing strontium,[25] the stability of which has been reported to be dependent on the presence of particles such as silica.[26,27] Silica incorporated in the abrasive system of this strontium toothpaste has been demonstrated to have excellent tubule occlusion and surface coverage properties[28,29] and further proves very resistant to acid challenge.[25,27,29,30] Another paste incorporates arginine, a positively charged amino acid. This compound binds to the negatively charged dentine surface, whilst attracting calcium to form an occlusive layer.[31] In vitro studies confirm this occlusive effect.[30]

Clinically, both treatments have been shown to provide significant reductions in dentine hypersensitivity. This is either after one minute, with a dab-on application of the toothpaste directly onto cervical dentine by the patient with pre-determined sensitivity, and massaging the paste on the dentine for one minute;[32–34] or prolonged relief by twice daily brushing for periods up to eight weeks.[35,36] Mason et al.[32] reported strontium acetate paste was superior to a minus active paste over a rapid time frame. With regards to the arginine paste, this demonstrated superiority compared to a potassium paste,[33,34] and showed superiority to a minus active and benchmark paste.[34] The strontium acetate and arginine pastes have also been compared in the same clinical study, the participants being evaluated after stimulation at 2, 4 and 8 weeks home usage,[35] however no significant difference in the reduction of sensitivity was found between the two products over these time intervals.

Not only has the ability of each paste been demonstrated to alleviate pain in clinical studies, both have been documented to occlude dentine tubules. Petrou et al.[31] showed an arginine paste occluded tubules and resisted a 2 min cola challenge, whilst Parkinson et al.[27] demonstrated both arginine and strontium pastes were able to provide significant levels of occlusion compared to water, with the strontium based dentifrice providing significantly better occlusion to dietary acidic challenge. This is supported by other researchers.[30] Seong et al.[37] conducted an in situ study showing that the occluding properties of the strontium acetate toothpaste were significantly more robust after acid challenge than those of the arginine toothpaste over a 4-day period of evaluation. This may have clinical implications.

The objective of this product comparison study, was to evaluate the short term efficacy for pain reduction of two marketed occlusion based toothpastes, one containing strontium acetate (8% Strontium Acetate/Silica/1040 ppm sodium fluoride in a silica dentifrice base, Sensodyne Rapid Relief, GlaxoSmithKline Consumer Healthcare, UK) and the other arginine (8% arginine/calcium carbonate/1450 ppm sodium monofluorophosphate in a calcium carbonate dentifrice base, Colgate Sensitive Pro-Relief, Colgate-Palmolive, UK). The short term ability of these pastes to control and reduce the pain experienced from dentine hypersensitivity was evaluated immediately following a single topical 'dab on' application, and shortly after commencing treatment following twice daily use of the products for three days in healthy participants with a known history of dentine hypersensitivity.

2. Materials and methods

2.1. *Study design*

The clinical study design was parallel, stratified and randomised, with a single blind examiner performing the clinical