DENTAL MATERIALS XXX (2015) XXX–XXX

Available online at www.sciencedirect.com

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Randomized, placebo-controlled study of the efficacy of a calcium phosphate containing paste on dentin hypersensitivity

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ARTICLE INFO

Article history:
Received 26 March 2015
Received in revised form
24 July 2015
Accepted 17 August 2015
Available online xxx

Keywords:
Biomaterial
Hypersensitive dentin
Desensitization
Calcium-phosphate
Randomized controlled trial

ABSTRACT

Objective. Hypersensitivity of non-carious cervical lesions (DH) is a frequently encountered disease. This randomized, controlled, single-blind crossover study evaluated the effectiveness of a calcium phosphate containing desensitizer paste (TAP) on DH in comparison to water as placebo (PLA).

Methods. In this clinical trial 35 patients were randomly assigned to the test and the negative control group. Using a 10 cm long VAS (visual analog scale) patients should respond with DH score >6 on one tooth in each of two quadrants for allocation. Pain stimuli were a 2-seconds air blast (AB) and probe scratching (PS) of the exposed dentin. VAS scores were determined pre-operatively (PRE), immediately after treatment (POST), at 1 week, 1, 3 and finally after 6 months.

Results. Both TAP and PLA applications decreased DH significantly at POST and throughout the 6-months recalls ($p < 0.001$). Pain reductions upon AB stimulation of TAP treated teeth, assessed at POST and 6 months were 35 and 55%, upon PS stimuli 21 and 54%, respectively. PLA treated lesions responded to AB at POST and after 6 months with 20 and 36% pain reduction, to PS with 11 and 30% pain reduction, respectively. Differences between TAP and PLA pain scores were statistically significant at all recalls ($p < 0.05$).

Significance. TAP paste reduced DH successfully during this 6-months trial. The calcium phosphate crystallites included in the paste and the presumed hydroxyapatite precipitates upon exposure to saliva were hypothetically able to occlude open dentinal tubules, at least to some extent. TAP is considered a biocompatible desensitizer paste.

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http://dx.doi.org/10.1016/j.dental.2015.08.162
0109-5641/

1. Introduction

The definition of dentin hypersensitivity as accepted by the Canadian Advisory Board as "short, sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dental defect or disease" is globally acknowledged [1]. This description emphasizes careful differential diagnostics as an important first step before treatment options should be considered.

Hypersensitive dentin is mostly diagnosed at the buccal surfaces of teeth, where enamel is missing due to erosion, abrasion and attrition. Only when exposed dental tubuli are patent at both ends hypersensitivity can occur. According to Brännström's hydrodynamic theory [2] external stimuli, mostly thermal, evaporative or osmotic, lead to inward or outward fluid shifts in the dentinal tubules that would trigger pain due to stimulation of A-δ fibers around odontoblasts. A logical treatment would therefore be based on total or partial occlusion of the orally open tubular entrances, a concept that is widely used with different desensitizing agents.

Dentin hypersensitivity is a frequently reported oral pain condition. Prevalence reports from around the world show wide variations, ranging from 3 to 98% [3]. This tremendous heterogeneity may be explained by the different study samples, type of practice where the study was performed, and the different therapeutic approaches. A number of recent regional evaluations show prevalence rates between 34.5% in China [4], 46% in Brazil [5], 32% in India [6], and 41.9% in seven European countries [7].

Considering such high prevalence rates diagnosing and selection of correct treatment options is a daily challenge for dental practitioners. A vast array of methods and compounds is available for blockage of dentin tubules. According to a survey of therapeutic choices made in the USA 45% of dentists use regularly oxalates, and approximately 60% prefer glutaraldehyde/HEMA compounds. However, when asked for their preferred strategy 45% of practitioners mentioned "observation/no treatment" as their most frequent option [8]. This indicates that individual experience with desensitizing agents is not always satisfactory, and that natural re-mineralization of patent dentin tubuli in the oral environment is sometimes considered an adequate option [9]. If however the patient's pain reaction on daily occurring stimuli is severe, in-office intervention is the method of choice for pain relief.

Among the different topical in-office treatment options, calcium phosphate containing dentin desensitizers have gained considerable interest, mainly because of their excellent biocompatibility [10–12]. In a recently published clinical study a calcium phosphate containing desensitizer material proved highly effective after one single in-office application, both immediately and throughout the six-months control appointments [13]. At this time, another calcium phosphate desensitizer paste for topical application on hypersensitive dentin lesions is introduced in Japan. This paste is basically a mixture of two calcium phosphate crystallites and sodium fluoride suspended in a water-free carrier medium (Teethmate AP Desensitizer, Kuraray Noritake Dental Inc., Okayama, Japan). Upon application in the mouth and exposure to saliva hydroxyapatite may be precipitated that is expected to close the orifices of open dental tubules.

Aim of this study was to evaluate the effect of Teethmate AP on elimination or reduction of dentin hypersensitivity in a randomized controlled clinical trial. The null hypothesis was that there was no difference in pain reduction compared with placebo.

2. Materials and methods

This trial was designed as a randomized, placebo-controlled, single-masked, split-mouth study, to evaluate the effects of Teethmate AP (TAP; Kuraray Noritake, Dental Inc. Okayama, Japan. Batch #: T13605; expiry: 2015-07) and placebo (PLA; distilled water) on desensitization of non-carious buccal cervical lesions of teeth. The 'Guidelines for the design and conduct of clinical trials on dentin hypersensitivity' were adopted and followed during planning and execution of the study [14]. Approval for this clinical investigation was obtained from the ethics committee of the local University Review Board (VokkaligaraSangha Dental College and Hospital, Bangalore, India. Approval: VSDC/EC-16, 11/07/2013).

The study was conducted in agreement with the principles of the Declaration of Helsinki (World Medical Association Declaration of Helsinki, 2008). Before signing the informed consent form all patients eligible for this trial received verbal and written information regarding possible benefits and risks of the treatments. Patients were informed that one of the compounds tested is a placebo.

2.1. *Materials*

Teethmate AP Paste (TAP) is a desensitizing compound consisting of tertracalcium phosphate (TTCP), dicalcium phosphate anhydrous (DCPA), sodium fluoride, glycerol and polyethylene glycol. The placebo (PLA) is distilled water.

2.2. *Method*

Patients for this study were recruited from the Department of Conservative Dentistry and Endodontics, Vokkaligara Sangha Dental College and Hospital, Bangalore, India. The main inclusion criterion was the presence of one hypersensitive tooth with a sensitive buccal cervical dentin site in each of two quadrants responding with score ≥6 on a 10 cm long visual analog scale (VAS). Forty-eight patients were screened for eligibility to this trial. Exclusion criteria were systemic diseases, pulpitis, carious lesions, defective restorations, cracked enamel, active periodontal disease, medication with analgesic drugs, pregnant or lactating women and professional desensitizing treatment received during the preceding three months. Most of the lesions were exposed dentin due to gingival retraction. All patients included in this study self-reported cervical sensitivity, in particular upon cold stimuli and mechanical irritation during tooth brushing.

Two proficient dentists examined potential candidates for inclusion into the trial. Possible teeth for inclusion were selected for determination of the pretreatment sensitivity

Please cite this article in press as: Mehta D, et al. Randomized, placebo-controlled study of the efficacy of a calcium phosphate containing paste on dentin hypersensitivity. Dent Mater (2015), http://dx.doi.org/10.1016/j.dental.2015.08.162