Journal of Dental Problems and Solutions

Peertechz

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Dates: **Received:** 23 June, 2016; **Accepted:** 30 November, 2016; **Published:** 01 December, 2016

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www.peertechz.com

ISSN: 2394-8418

Keywords: Dentin hypersensitivity; Paste containing 8% arginine and calcium carbonate; Dental scaling procedure

Research Article

Clinical Evaluation of the Desensitizing Efficacy of a Paste Containing 8% Arginine and Calcium Carbonate

Abstract

Background: To evaluate the clinical efficacy of an in-office desensitizing paste containing 8% arginine and calcium carbonate relative to that of a commercially-available pumice prophylaxis paste when applied pre-procedurally to a dental scaling procedure (dental prophylaxis).

Methods: This was a parallel group, randomized, double-blind, trial study conducted in 130 subjects who presented a tactile hypersensitivity score of 2 or 3 (Orchardson và Collins Tactile Sensitivity Scale) and an air blast hypersensitivity score of 2 or 3 (Schiff Cold Air Sensitivity Scale) and randomly assigned to one of two treatment groups. The two treatment groups were: (1) a Test paste, a desensitizing paste containing 8% arginine and calcium carbonate; and (2) a Control paste, Nupro pumice prophylaxis paste. Subjects had their assigned paste applied immediately before receiving dental scaling procedure. Record tactile and air blast hypersensitivity examinations score immediately after paste application and after the completion of the dental scaling procedure following the same methodology employed for the baseline hypersensitivity examinations.

Results: At the final hypersensitivity examinations, the Test Paste and Control Paste groups were not statistically significant differences from baseline scores. Immediately following product application and after the completion of the dental scaling procedure, subjects assigned to the Test Paste group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean air blast (38.9% and 37.4% respectively) and mean tactile hypersensitivity scores (40.2% and 42.4% respectively). At the same time points, subjects assigned to the Control Paste group exhibited statistically significant improvements from baseline with respect to baseline- adjusted mean air blast (16.0% and 17.8% respectively) and mean tactile hypersensitivity scores (14.6% and 16.4% respectively).

Conclusion: The desensitizing paste containing 8% arginine and calcium carbonate provides reduction in dentin hypersensitivity immediately following product application and after the completion of the dental scaling procedure when applied as a single treatment before dental prophylaxis.

Background

Dentin hypersensitivity is defined as a 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 pathology [1]. It is a clinically relevant and population-wide problem and it may affect about a quarter of the adult population. About 80% of the sensitivity lesions are associated with premolars and cuspids [2,3]. Affected are mainly the facial rather than the lingual surfaces of these teeth near the gingival margin[8] and women have a higher prevalence rate than men [4,5].

Dentin hypersensitivity can manifest when dentin is exposed by enamel loss (lesions of abrasion, erosion or corrosion) followed by the constant action of acids, which keep the tubules open on the dentin surface, or because the root surface has been denuded due to loss of structures such as cementum, which is easily removed [6,7].

The properties of dentine and pulp are closely related and from a functional standpoint these tissues are often referred to as the dentine-pulp complex. Pulp is integrally connected to dentine, i.e., physiologic and/or pathologic reactions in one of the tissues will also affect the other [8,9]. Based on the hydrodynamic theory for stimulus transmission across dentine, it would be logical to conclude that teeth exhibiting the clinical symptoms referred to as dentine hypersensitivity should have dentinal tubules open at the root surface and patent to the pulp. Hypersensitive teeth showed highly significantly increased numbers of tubules per unit area (approximately 8 X) compared with non-sensitive teeth. Tubule diameters were significantly wider (approximately 2 X) in hypersensitive compared to non-sensitive teeth [10].

Although dentin hypersensitivity is not considered a lethal problem, it affects the quality of life of patients and, therefore, it should be properly addressed in research, dental education, prevention, and treatment [4]. Densensitizing agents have been classified according to their mode of action [6]; whether they are applied by the patient or professional, according to their chemical or physical properties [6,11]; or by their reversible or irreversible characteristics [6,12]. They may be found in the form of gels, dentifrices, mouthwashes,

or agents to be applied topically, such as varnishes, resin composite, glass ionomer cement, dentinal adhesive, periodontal membranes and laser applications [6].

Kleinberg et al. has developed a simple and effective new approach to the plugging and sealing of dentinal tubules [2]. The method uses an arginine bicarbonate/calcium carbonate complex applied in a prophylaxis paste to plug and seal open dentinal tubules. This can be applied while polishing the teeth. The procedure is painless and reduction of tooth sensitivity is usually immediate [2].

This randomized clinical study evaluated the efficacy in reducing dentin hypersensitivity of an in-office desensitizing paste containing 8% arginine and calcium carbonate as compared to a prophylaxis paste control, when applied prior to a professional dental scaling in a group of patients with known dentin hypersensitivity.

Materials and Methods

This clinical study was a parallel-group, randomized, double-blind, and trial study design. The study protocol has been reviewed and approved by the Ethical Board and volunteers were asked to give an informed written consent to participate, after a thorough explanation of the safety and potential efficacy of 8% arginine and calcium carbonate paste and Nupro pumice prophylaxis paste. Volunteers were enrolled in the study based upon the following criteria:

Inclusion criteria

Eligible study subjects had to be greater than or equal to the age of 18 and were at least two vital hypersensitive teeth which were demonstrated cervical erosion/abrasion or gingival recession, had a tactile hypersensitivity stimuli score of 2 or 3 (Orchardson and Collins scale) and an air blast hypersensitivity stimuli score of 2 or 3 (Schiff Cold Air Sensitivity Scale). Individuals who were systemically healthy were ready to sign informed written consent and complete the study period

Exclusion criteria

Subjects were excluded from the study if they had gross oral pathology, chronic disease, advanced periodontal disease, treatment for periodontal disease (within the last 12 months); were current users of anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics. Pregnant or lactating women, individuals who were participating in any other clinical study or who had participated in a desensitizing dentifrice study or who used a desensitizing dentifrice within the last 3 months, were not allowed to participate in the study. Subjects with a history of allergy to the test products, or allergies to oral care/personal care consumer products or their ingredients, or subjects with existing medical conditions, which precluded them from not eating and drinking for periods up to 4 hours, were also excluded from the study.

Hypersensitive teeth had extensive/defective restorations (including prosthetic crowns), suspected pulpitis, caries, cracked enamel, mobility greater than one or that were used as abutments for removable partial dentures were also excluded from the study.

Clinical procedure

Prospective study subjects reported to the clinical facility having refrained from all oral hygiene procedures and chewing gum for 8 hours, and having refrained from eating and drinking for 4 hours prior to their baseline examination. All prospective subjects who met the inclusion/exclusion criteria and signed an informed consent form received a baseline tactile and air blast hypersensitivity evaluation along with an oral soft and hard tissue assessment.

Two hypersensitive teeth per study subject that satisfied the tactile and air blast sensitivity enrollment criteria were identified for evaluation throughout the study. Subjects were randomly assigned within strata to one of the following study treatments:

- Test paste: Desensitizing paste containing 8% arginine and calcium carbonate
- Control paste: Nupro pumice prophylaxis paste.

Subjects had their assigned paste applied immediately before receiving dental scaling procedure. Professional product application consisted of two consecutive 3-second applications of the paste using a rotating rubber cup. After that, they were re-examined for tactile and air blast dentin hypersensitivity. Then, subjects receive a professional scaling and tooth polishing using the control (prophylaxis) paste. Immediately after completion of tooth polishing, tactile and air blast dentin hypersensitivity examinations, as well as oral soft and hard tissue assessments, were performed by the same examiner and following the same methodology employed at the baseline examinations. Subjects were also interviewed with respect to the presence of adverse events.

Clinical scoring procedures

Tactile hypersensitivity: Tactile hypersensitivity was assessed by use of a sharp dental explorer. Teeth were lightly passed by a sharp dental explorer along the cementoenamel junction and graded the response of the patient on a severity scale, generally 0 to 3:

0 - no pain felt;

1 - Slight pain of discomfort;

2 - Severe pain;

3 - Severe pain that lasts.

Air blast hypersensitivity: Air blast hypersensitivity [13] was assessed in the following manner:

Each hypersensitive tooth was isolated from the adjacent teeth (mesial and distal) by the placement of the examiner's fingers over the adjacent teeth.

Air was delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F (± 3°F). The air was directed at the exposed buccal surface of the hypersensitive tooth for 1 second from a distance of approximately 1 cm.

The Schiff Cold Air Sensitivity Scale was used to assess subject response to this stimulus. This scale is scored as follows:

0 - subject does not respond to air stimulus;

1 - Subject responds to air stimulus but does not request discontinuation of stimulus;

2 - Subject responds to air stimulus and requests discontinuation or moves from stimulus;

3 - Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Scores for each subject were calculated by averaging the values obtained from the two baseline-designated study teeth.

Oral soft and hard tissue assessment: The dental examiner used a dental light and dental mirror to examined visually the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsilar and pharyngeal areas.

Statistical methods

Statistical analyses were performed separately for the tactile hypersensitivity assessments and air blast hypersensitivity assessments. Comparisons of the treatment groups with respect to baseline tactile scores and air blast scores were performed using an independent t-test. Within-treatment comparisons of the baseline versus final tactile sensitivity and air blast sensitivity scores were performed using paired t-tests. Comparisons of the treatment groups with respect to baseline-adjusted tactile hypersensitivity and air blast hypersensitivity scores at the follow-up examinations were performed using analyses of covariance (ANCOVAs). All statistical tests of hypotheses were two sided, and employed a level of significance of $\alpha = 0.05$.

Results

Subjects

One hundred and thirty subjects complied with the protocol, and completed the clinical study. A summary of the gender and age of the study population is presented in Table 1. The treatment groups did not differ significantly with respect to either of these characteristics. Throughout the study, there were no adverse effects on the soft or hard tissues of the oral cavity which were observed by the examiner, or reported by the subjects when questioned.

Baseline data

Table 2 presents a summary of the mean tactile and air blast scores measured at the baseline examination. For air blast-induced hypersensitivity, the mean baseline scores were 2.37 for the test group and 2.41 for the control group. For tactile induced hypersensitivity, the mean baseline scores were 2.36 the test group and 2.26 for the control group. No statistically significant differences were indicated between the treatment baselines tactile and air blast hypersensitivity scores.

Immediate after topical application data

Air blast hypersensitivity: Table 3 presents a summary of the mean air blast hypersensitivity scores measured immediately after topical application. The mean air blast hypersensitivity scores recorded immediately after topical application of the product were 1.45 for the Test group, 2.00 for the Control group. The mean percent reductions from baseline were 38.9% for the Test group, 16.0% for the Control group; both of which were statistically significant. Relative to the Test group and the Control groups exhibited statistically significant improvements in mean air blast hypersensitivity scores immediately after topical product application (22.9%).

Tactile hypersensitivity: Table 4 presents a summary of the mean tactile hypersensitivity scores measured immediately after topical application. The mean tactile hypersensitivity scores were 1.42 for the Test group, 1.93 for the Control group. The mean percent reductions from baseline were 40.2% for the Test group, 14.6% for the Control group; both of which were statistically significant. Relative to the

Table 1: Summary of age and gender for subjects who completed the clinical study.

Treatment	Number of subjects (N)			Age		
	Male	Female	Total	Mean±SD	Range	Sig[3].
Test paste[1]	31	34	65	31.72±8.01	21-51	NS
Control paste[2]	31	34	65	32.05±8.19	19-48	
Total	62	68	130	31.88±8.08	19-51	

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] No statistically significant difference was indicated between the two treatment groups at baseline with respect to either tactile or air blast hypersensitivity.

Table 2: Summary of the baseline tactile hypersensitivity and air blast hypersensitivity mean scores

Parameter	N	Test paste[1] Mean±SD	Control paste[2] Mean±SD	Sig[3].
Air-blast scores	65	2.37±0.22	2.41±0.41	0.590
Tactile scores	65	2.36±0.24	2.26±0.38	0.074

[1]Desensitizing paste containing 8% arginine and calcium carbonate.
[2]Nupro pumice prophylaxis paste.
[3]No statistically significant difference was indicated between the two treatments.

Table 3: Summary of the immediate after topical application mean air blast hypersensitivity scores

			Within-treatment analysis		Between-treatment comparison	
Treatment	N	Immediate after topical application summary (Mean ± S.D.)	Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	65	1.45±0.34	38.9	P<0.05	22.9	*P*<0.05
Control paste[2]	65	2.00±0.43	16.0	P<0.05		

[1]Desensitizing paste containing 8% arginine and calcium carbonate.
[2]Nupro pumice prophylaxis paste.
[3]Percent change exhibited immediately after topical application relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the final examination.
[4]Significance of paired t-test comparing the baseline and the immediate after topical application examinations.
[5]Difference between the immediate after topical application means expressed as a percentage of the immediate after topical application mean for the Control paste.
[6]Significance of paired t-test comparing the baseline and the immediate after topical application examinations.

Test group and the Control groups exhibited statistically significant improvements in mean tactile hypersensitivity scores immediately after topical product application (25.6%).

Post-scaling (final) examination data

Air blast hypersensitivity: Table 5 presents a summary of the mean tactile hypersensitivity scores measured after dental scaling procedure. The mean post-scaling tactile hypersensitivity scores were 1.50 for the Test group, 1.95 for the Control group. The percent changes from baseline were 37.4% for the Test group, 17.8% for the Control group, all of which were statistically significant. Relative to the Test group and the Control groups exhibited statistically significant improvements in mean tactile hypersensitivity scores immediately after topical product application (19.6%).

Tactile hypersensitivity: Table 6 presents a summary of the mean tactile hypersensitivity scores measured after dental scaling procedure. The mean post-scaling tactile hypersensitivity scores were 1.35 for the Test group, 1.88 for the Control group. The percent changes from baseline were 42.4% for the Test group, 16.4% for the Control group, all of which were statistically significant. Relative to the Test group and the Control groups exhibited statistically significant improvements in mean tactile hypersensitivity scores immediately after topical product application (26.0%).

Table 4: Summary of the immediate after topical application mean tactile hypersensitivity scores

			Within-treatment analysis		Between-treatment comparison	
Treatment	n	Post-scaling summary (Mean ± S.D.)	Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	65	1.42±0.39	40.2	*P*<0.05	25.6	*P*<0.05
Control paste[2]	65	1.93±0,48	14.6	*P*<0.05		

[1]Desensitizing paste containing 8% arginine and calcium carbonate.
[2]Nupro pumice prophylaxis paste.
[3]Percent change exhibited immediately after topical application relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the final examination.
[4]Significance of paired t-test comparing the baseline and the immediate after topical application examinations.
[5]Difference between the immediate after topical application means expressed as a percentage of the immediate after topical application mean for the Control paste.
[6]Significance of paired t-test comparing the baseline and the immediate after topical application examinations.

Table 5: Summary of the post-scaling tactile hypersensitivity mean scores

			Within-treatment analysis		Between-treatment comparison	
Treatment	N	Post- scaling summary (Mean ± S.D.)	Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]		1.35±0.44	42.4	*P*<0.05	26.0	*P*<0.05
Control paste[2]		1.88±0.41	16.4	*P*<0.05		

[1]Desensitizing paste containing 8% arginine and calcium carbonate.
[2]Nupro pumice prophylaxis paste.
[3]Percent change exhibited post-scaling relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the final examination.
[4]Significance of paired t-test comparing the baseline and the final examinations.
[5]Difference between the post-scaling means expressed as a percentage of the post-scaling mean for the Control paste.
[6]Significance of paired t-test comparing the baseline and the final examinations.

Table 6: Summary of the post-scaling air blast hypersensitivity mean scores

			Within-treatment analysis		Between-treatment comparison	
Treatment	N	Immediate after topical application summary (Mean ± S.D.)	Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]		1.50±0,48	37.4	*P*<0.05	19.6	*P*<0.05
Control paste[2]		1.95±0,46	17.8	*P*<0.05		

[1]Desensitizing paste containing 8% arginine and calcium carbonate.
[2]Nupro pumice prophylaxis paste.
[3]Percent change exhibited post-scaling mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the final examination.
[4]Significance of paired t-test comparing the baseline and the final examinations.
[5]Difference between the post-scaling means expressed as a percentage of the post-scaling mean for the Control paste.
[6]Significance of paired t-test comparing the baseline and the final examinations.

Discussion

Dentin hypersensitivity is a relatively common problem arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical [1]. This condition may impact on the quality of life of the individual during eating, drinking, brushing and sometimes even breathing, thus limiting dietary choices, effective oral hygiene and esthetics can also be negatively affected [14].

Dentine hypersensitivity can even be provoked by some dental procedures, therefore a regular dental visit can make unpleasant and painful for the patient, especially dental scaling procedures. Dental scaling procedures cause stimuli such as vibration of scaler, the spray of water jet. The discomfort due specifically to dentine hypersensitivity may add stress to an already stressful experience for the patient. These experiences remembered by patients may influence their anticipation of discomfort during the next visit. Negative perceptions may make a patient hesitant about seeking further diagnostics and/or care [15]. Therefore, the prevention is very important, especially patients with dentin exposure prior to a dental prophylaxis procedure. So we carried out this study to evaluate the efficacy of an in-office desensitizing product on acute dentin hypersensitivity before a dental procedure. From these results, sensitivity patients could be reduced discomfort during dental scaling procedures in particular and periodontal therapy in general.

This clinical trials study have reported statistically significant dentine hypersensitivity relief instantly following 8% arginine and calcium carbonate desensitizing paste product application and after the completion of the dental scaling procedure. Through this result, this in-office desensitizing paste can help patient reduce

dentin hypersensitivity immediately after applied and this efficiency can maintain throughout the process of dental scaling in advance of dental procedures. This product has the potential to be of great assistance to clinicians in dealing with acute dentin hypersensitivity, especially when carrying out procedures which can irritate dentin hypersensitivity in office.

In this study, we did not use Yeaple Probe for detection of tactile hypersensitivity. However, we evaluated tactile hypersensitivity by use of a sharp dental explorer and air blast hypersensitivity using the air was delivered from a standard dental unit air syringe at 60 psi and 70°F. These methods are considered as being simple, effective, uncostly and can apply in any private clinic setting.

A breakthrough technology based upon arginine and calcium carbonate provides clinically proven benefits with respect to rapid and lasting relief of dentin hypersensitivity. It is unique in that two of its key components, arginine and calcium, are found naturally in saliva, and that the arginine and calcium carbonate work together to accelerate the natural mechanisms of occlusion to deposit a dentin-like mineral, containing calcium and phosphate, within the dentin tubules and in a protective layer on the dentin surface [16].

The results of this double-blind clinical study support the conclusions that (1) the test paste, a desensitizing paste containing 8% arginine and calcium carbonate, provides a statistically significant reduction in dentin hypersensitivity immediately following product application and after the completion of the dental scaling procedure when applied as a single treatment before a dental prophylaxis; and (2) the test paste, a desensitizing paste containing 8% arginine and calcium carbonate, provides a level of dentin hypersensitivity reduction that is statistically significantly better than that of the control paste, Nupro pumice prophylaxis paste, when applied as a single pre-procedural treatment to a dental prophylaxis.

Availability of data and materials

The dataset supporting the conclusions of this article is included within the article.

Authors' Contributions

Dr. Thu TA Nguyen collected clinical data, analyzed data and wrote the initial draft of the paper. Dr. Thuy AV Pham, who is acting as the corresponding author, designed the study, collected clinical data, analyzed data, and wrote the manuscript. All authors have critically discussed the results, revised the manuscript, and approved the final version.

Ethics approval and consent to participate

This study protocol was approved by the ethics committee of University of Medicine and Pharmacy at Ho chi Minh Vietnam (Number: 685/QD-DHYD-RHM). Informed consent was obtained from all individual participants included in the study.

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