Desensitizing treatments for dentin hypersensitivity: a randomized, split-mouth clinical trial

Veridiana Camilotti[a]
Juliana Zilly[a]
Priscilla do Monte Ribeiro Busato[a]
Carlos Augusto Nassar[b]
Patrícia Oehlmeyer Nassar[b]

[a] Department of Restorative Dentistry, School of Dentistry, Universidade Estadual do Oeste do Paraná - UNIOESTE, Cascavel, PR, Brazil.

[b] Department of Periodontics, School of Dentistry, Universidade Estadual do Oeste do Paraná - UNIOESTE, Cascavel, PR, Brazil.

Declaration of Interests: The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

Corresponding Author:
Veridiana Camilotti
E-mail: *vericamilotti@hotmail.com*

Received for publication on Feb 10, 2012
Accepted for publication on Apr 03, 2012

Abstract: The aim of this randomized, controlled, split-mouth, clinical study was to differentiate and clinically qualify the effectiveness of different desensitizing agents in the treatment of painful symptoms caused by cervical dentin hypersensitivity (CDH). Two hundred-and-fifty-two teeth of 42 patients were distributed into seven groups (n = 36): G1 – placebo; G2, G3, G4 and G6 – fluoride varnishes; G5 – sodium fluoride; G7 – potassium oxalate. Three applications were made one week apart. A three-score system (Alfa = 0, Bravo = 2, and Charlie = 3, respectively for no sensitivity, slight sensitivity and high sensitivity) was used to assess CDH after each application and after 30 days. The data were subjected to statistical analysis using the Kruskall-Wallis and Dun tests. After the second week, statistically significant differences were observed for all materials compared with the baseline. After 30 days, Group G7 had presented a significant gradual reduction along all the evaluated time intervals. It was concluded that all the desensitizing agents were capable of reducing dentin hypersensitivity, with the exception of the placebo and the sodium fluoride groups.

Descriptors: Dentin Sensitivity; Dentin; Fluorides; Gingival Recession.

Introduction

Cervical dentin hypersensitivity (CDH) is defined as an exaggerated response to the stimulation of vital dentin exposed to the oral environment, which causes extreme discomfort to the patient. It is characterized by short-term, acute pain of variable intensity, which occurs in response to thermal, volatile, tactile, osmotic or chemical stimuli that cannot be attributed to any other type of defect or dental pathology.[1] These stimuli are produced by the ingestion of hot or cold beverages, by contact with acidic foods, or by tooth brushing. Pain may be localized or generalized, affecting one or various tooth surfaces concomitantly, and generally ceases immediately after removing the pain stimulus.[2]

The etiology and mechanisms underlying the development of dentin hypersensitivity have not yet been well explained. Various theories have been propounded in an attempt to explain the mechanism involved in the generation of pain and transmission of the stimuli through dentin.[3] The transmission of stimuli from exposed dentin to the nerve endings located in the dental pulp may occur through the odontoblast process or by means of a hydrodynamic mechanism, the latter being considered the most plausible.[2]

The "Hydrodynamic Theory" proposed by Brännström[4] claims that when loss of enamel and/or cement occurs, the dentinal tubules are exposed to the

oral environment, and the presence of certain stimuli causes the displacement of fluids within the tubules, indirectly stimulating the pulp nerve endings and causing the sensation of pain.

There are various methods available for the treatment of dentin hypersensitivity, all with the aim of obliterating the dentinal canaliculi.[5] Dentinal tubule sealing can be secured with the use of restorations, dental adhesives or the formation of a smeared dentin surface.[6]

Fluoride varnishes were introduced on the market to increase the efficiency and permanence of fluoride when in contact with the tooth surface, in order to allow a slow and continuous release of fluoride.[7] Varnishes consist of natural resin-based vehicles for fluoride, and are highly adhesive to the tooth structure. They are easy to apply and are low-cost materials.[8] The fluoride is dissolved in an organic solvent, which evaporates when applied, leaving a thin layer of the material covering the exposed tooth surfaces. The mechanism of action is the deposition of calcium fluoride on the tooth surface, with the formation of fluorapatite.[9] In addition to fluoride, potassium oxalate may be used to treat dentin hypersensitivity. It reacts with the calcium of dentin to form insoluble, acid-resistant calcium oxalate.[10]

The aim of this study was thus to assess the effectiveness of four desensitizing agents in reducing dentin hypersensitivity in a randomized, double-blind, split-mouth clinical trial. The study hypothesis is that there are no differences between the desensitizing treatments.

Methodology

This research was conducted in the city of Cascavel, PR, Brazil, with patients from the Dental Clinic of the Universidade Estadual do Oeste do Paraná (UNIOESTE), after being approved by the institution's Ethics Committee on Research Involving Human Beings, protocol number 213/2010. The patients signed a Term of Free and Informed Consent and were informed of the characteristics and conditions of the research.

Selection of patients

Forty-two patients between the ages of 18 and 70 and presenting dentin sensitivity to thermal changes in the oral environment were selected from the files of the integrated clinic at UNIOESTE. Each patient had six teeth with dentin hypersensitivity, resulting in a total number of 252 teeth included in the study.

Initial dental sensitivity was assessed using modified U.S. Public Health Service criteria,[11] a three-score system composed by Alpha = 0 (no sensitivity), Bravo = 2 (slight sensitivity) and Charlie = 3 (high sensitivity). The scores were always recorded before and after the application of the test treatments. Each tooth received two stimuli: clinical probing (tactile stimulus) and air blast (thermal evaporative stimulus). The probe stimulus was applied under slight manual pressure in the mesiodistal direction on the cervical area of the tooth. The air blast was applied with an air syringe for 1 s at a distance of 1 cm from the tooth surface to avoid desiccating the dentin surface. The subjective experience of pain reported by the individual was then recorded, as shown in Table 1. The desensitizing agents and placebo were applied by one experienced operator (a PhD Assistant Professor from the Department of Restorative Dentistry of the institution where the study was conducted). The order in which the teeth were assessed within each subject was maintained at each visit. The examiner and the patients did not know which type of treatment corresponded to each tooth.

The following exclusion criteria were applied: presence of caries, restorations, and ongoing orthodontic or periodontal treatment at the CDH site; patients using medication or presenting systemic diseases; patients who had presented recurrent hypersensitivity in the last 30 days, who were pregnant or breastfeeding, or who had undergone exogenous dental bleaching within the previous 3 months. Those included were patients with teeth hypersensitive to air stimulus and good oral hygiene. The presence of gingival recession and/or non-carious cervical lesions was considered acceptable. The

Table 1 - Criteria for hypersensitivity assessment.

Category	Scores	Criteria
Dentin	A – 0	Absence of sensitivity to thermal and tactile stimuli
	B – 2	Slight sensitivity to thermal and tactile stimuli
	C – 3	High sensitivity to thermal and tactile stimuli

sample size was determined by a previous pilot study.

Treatments

After recording the baseline scores, the subjects were randomly and blindly assigned to one of the treatment groups or to the placebo (n = 36 teeth), according to the desensitizing agent used (Table 2). The randomization procedure was conducted before the clinical steps were performed, and was carried out by using sequentially-numbered, opaque, sealed envelopes prepared with unrestricted randomization.[12] The name of each treatment agent and "placebo" was written on a piece of paper that was then sealed inside each envelope before beginning the study. The dental operator who performed all treatments then opened an envelope for each case at the beginning of each treatment.

If the patient had two lesions side-by-side in the same quadrant (split-mouth), just one of the lesions would receive the treatment at that time. Thus, all patients would have at least one lesion treated per quadrant. Three applications of the material selected for the group were made for each group and in each patient, with a time interval of one week between applications.

The procedure for each weekly session consisted of rinsing with water, performing prophylaxis with prophylactic paste, isolating with cotton rolls, and conducting dentin drying with an air syringe. Application of the materials was made directly to the areas with dentin hypersensitivity following the manufacturer's instructions (Table 2).

Dentin sensitivity was assessed at each weekly session, according to the previously mentioned three-score system, before the material was applied, and using a triple syringe to apply an air/water spray to the teeth under treatment.

Clinical reassessment

Thirty days after the last application of each material, the patients were resubmitted to a sensitivity test performed with an air blast and with clinical probing on the exposed dentin surface of the teeth that had been treated with the desensitizing agents, and were once again clas-

Table 2 - Distribution of patients according to the treatments received.

Groups	Material	Manufacturer	Application Method	Composition
G1 (n = 36)	Placebo	–	Application with a disposable paintbrush, left to dry for 3 min	Distilled water with thickener
G2 (n = 36)	Duraphat	Colgate Oral Pharmaceuticals, Inc., New York, USA	Application with a disposable paintbrush, left to dry for 3 min	50 mg NaF (sodium fluoride) Colophony, ethyl alcohol, white beeswax
G3 (n = 36)	Fluorniz	S.S. White Artigos Dentários Ltda., Rio de Janeiro, Brazil		5.00 g% sodium fluoride, Colophony, toluene sulfonamide, vanillin, saccharine, absolute alcohol and ethyl alcohol
G4 (n = 36)	Duofluorid XII	FGM Dental Products, Joinville, Brazil		6% sodium fluoride, 6% calcium fluoride and solvents
G5 (n = 36)	Flutop	S.S. White Artigos Dentários Ltda., Rio de Janeiro, Brazil	Application for 4 min	2% sodium fluoride, hydroxyethyl cellulose, sodium hydroxide
G6 (n = 36)	Fluorphat	Inodon Laboratório Ind. de Prod. Odontológicos, Curitiba, Brazil	Application with a disposable paintbrush, left to dry for 3 min	5% sodium fluoride, natural varnish and zirconite powder
G7 (n = 36)	Oxa-gel	Art-Dent Ind. e Com. de Prod. Odontológicos Ltda., São Paulo, Brazil	Application with a disposable paintbrush, left to dry for 5 min	3% potassium oxalate monohydrate solution (pH 4), carboxymethylcellulose gel

Table 3 - Mean dentin sensitivity score values (SD) observed for the study groups.

Group	1st week	2nd week	3rd week	Reassessment (30 days)
1. Fluorniz	3 (0.000) A	1.83 (1.033) AB	1.33 (1.033) B	1.33 (1.328) B
2. Duraphat	3 (0.000) A	2 (1.095) AB	0.67 (1.033) B	0.33 (0.817) B
3. Duofluorid XII	3 (0.000) A	1.83 (1.472) AB	1.33 (1.033) B	1.33 (1.033) B
4. Placebo	3 (0.000) A	2.92 (0.554) A	2.84 (0.532) A	2.80 (0.147) A
5. Flutop	3 (0.000) A	2.46 (0.614) A	2.33 (0.585) A	2.06 (0.465) A
6. Fluorphat	3 (0.000) A	1.88 (0.560) AB	0.89 (0.587) B	0.81 (0.599) B
7. Oxa-gel	3 (0.000) A	2.06 (0.691) AB	1.14 (0.569) BC	1.04 (0.584) C

Means followed by different letters indicate significant differences among the experimental conditions in the different time intervals ($p < 0.05$) within the same group.

sified according to the pain sensation intensity reported by the patient.

After collecting the final hypersensitivity data, the scores were submitted to statistical analysis using the Kruskal-Wallis and Dunn tests. All analyses were performed with Sigma Plot 11.0 software for Windows (Europa Science Ltd., Cambridge, UK).

Results

Table 3 shows the mean scores observed for the materials after each time interval. As of the third week of application, the scores of all the materials used presented statistically significant differences compared to baseline scores, with the exception of the placebo and the sodium fluoride groups. Thirty days after the third application, it was observed that the potassium oxalate group had presented a significant gradual reduction in its response to thermal stimuli along the evaluated time intervals. The Placebo and Flutop groups showed no significant reduction in their sensitivity scores after all the evaluated time intervals.

Table 4 shows a comparison of the study groups at reassessment. Accordingly, it may be observed that Fluorphat (Inodon Laboratório Ind. de Prod. Odontológicos, Curitiba, Brazil) and Duraphat (Colgate Oral Pharmaceuticals, Inc., New York, USA) fluoridated varnishes presented the lowest sensitivity scores. No sensitivity reduction was observed in the Placebo Group at reassessment, since its scores were statistically similar to those observed at baseline.

Table 4 - Comparison among groups at reassessment (initial score = 3).

Group	Reassessment mean scores
1. Fluorniz	1.33 (1.328) BC
2. Duraphat	0.33 (0.817) C
3. Duoluorid XII	1.33 (1.033) BC
4. Placebo	2.80 (0.147) A
5. Flutop	2.06 (0.465) AB
6. Fluorphat	0.81 (0.599) C
7. Oxa-gel	1.04 (0.584) BC

*Means followed by different letters indicate significant differences among the experimental conditions ($p < 0.05$).

Discussion

Sensitivity assessments were performed on a weekly basis, before and after application of the test materials, and 30 days after the last application. During this period of time, a reduction was observed in the pain intensity reported by the individuals; however, few subjects reported the complete absence of pain. This could be attributed to the reaction that occurs between fluoride and the calcium ions in the dentinal fluid, which leads to the formation of calcium fluoride crystals that are deposited in the dentinal tubule openings.[13] Since the crystals formed are of a small size (0.05 µm), a single application of varnish would not be effective in occluding the dentinal tubules, and multiple applications would thus be required.[14] This theory is corroborated by the scores observed after the first week of application for Groups 2 (Fluorniz - S.S.White Artigos Dentários Ltda., Rio de Janeiro, Brazil), 3 (Duraphat), 4 (Duofluorid XII - FGM Dental Products, Joinville, Brazil) and 6 (Fluorphat). Different results were reported by Lan *et al.*,[15] who found that a fluoride varnish at a concentration of 2% was capable of diminishing the dentin hypersensitivity scores after the first application. Statistically significant

differences were found when the initial assessment (at first application) and the third assessment (at third application) were compared to the reassessment scores after 30 days for all the tested materials, except for the Placebo and Flutop (S.S.White Artigos Dentários Ltda., Rio de Janeiro, Brazil) groups. Hence, the study hypothesis that there are no differences between the desensitizing treatments was rejected. Different results were found by Hoang-Dao *et al.*,[16] who evaluated three fluoridated varnishes and observed that the action of Duraphat was more effective in diminishing hypersensitivity at reassessment, thirty days after the first application.

All the Groups in which the fluoridated varnishes were applied presented improvements in dentin hypersensitivity, with a reduction in pain, as expressed by the comparison between the initial and final means obtained during and after treatment. When Groups 1, 2, 3 and 6 were compared, there were no statistically significant differences. This made it possible to establish which of the fluoridated varnishes were clinically effective. These results are in agreement with those of other studies that have also reported a statistically similar action for different fluoridated varnishes used in the treatment of hypersensitivity after three weeks of application.[17,18] Nevertheless, it is important to point out that Fluorphat (Group 6) and Duraphat (Group 2) fluoridated varnishes presented statistically different results from those of the other varnishes tested, with scores close to zero at the time of reassessment (Table 4). They were thus considered as the most effective of the fluoridated varnishes for the treatment of dentin hypersensitivity.

The neutral fluoride gel Flutop (Group 5) showed no statistically significant reduction in dentin hypersensitivity for all the time intervals evaluated. *In vitro* studies on this material have shown that the layer of fluorides deposited on the dentin surface is easily displaced and ultimately removed by oral fluids. The action of oral fluids is enhanced during salivation and eating,[18] thus suggesting why sensitivity may possibly return, and also why these products—so widely used in dentifrices—do not eliminate sensitivity.

The potassium oxalate gel (Group 7), on the other hand, presented a statistically significant reduction in sensitivity between the first and third weeks of evaluation. This is in agreement with the study of Pilon *et al.*[19] and Assis *et al.*,[20] who found a significant reduction in dentin hypersensitivity after 21 days of potassium oxalate application. This rapid action may be explained by the presence of phytocomplexes formed after the dentin calcium reacts with the potassium oxalate. These complexes make the smear layer difficult to remove during meals.[21]

In the present study, the placebo was incapable of significantly decreasing the hypersensitivity scores after all time intervals, which is in agreement with data found in the literature.[12] Further studies with long-term analyses should be conducted to evaluate the real benefits of desensitizing agents.

Conclusion

Based on the results obtained in this study, it was possible to conclude that all the desensitizing agents were capable of reducing dentin hypersensitivity, with the exception of the agents in the Placebo and Fluotop groups. Oxa-gel (Art-Dent Ind. e Com. de Prod. Odontológicos Ltda., São Paulo, Brazil) showed a decrease in dentin hypersensitivity from the first to the second week, but no statistically significant difference was observed between the scores recorded at the third week and those recorded at reassessment. Considering the reassessment time of 30 days after the last application of the material, Duraphat and Fluorphat fluoridated varnishes presented the scores closest to zero, suggesting that these two varnishes may have the best effect in the treatment of dentin hypersensitivity.

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