

TREATING HYPERSENSITIVE DENTIN WITH THREE DIFFERENT POTASSIUM OXALATE-BASED GEL FORMULATIONS: A CLINICAL STUDY

TRATAMENTO DA HIPERSENSIBILIDADE DENTINÁRIA COM TRÊS DIFERENTES FORMULAÇÕES À BASE DE OXALATO DE POTÁSSIO: ESTUDO CLÍNICO

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Due to the high incidence of dentin hypersensitivity and diversity of treatments suggested, new products should be evaluated regarding their efficacy and applicability. The aim of this study was to assess the clinical responses of hypersensitive teeth after the application of three different potassium oxalate-based formulations. Ninety-four human canines and premolars that presented some degree of sensitivity (according to the Verbal Rating Scale) to probe and/or air stimulation were treated with either one of the three different potassium oxalate-based formulations: Oxa-Gel® (23 teeth), Experimental Solution 1 (27) and Experimental Solution 2 (27), or placebo (17) as control. The potassium oxalate-based formulations and placebo were passively applied for three minutes on wet dentin surface, the excess being removed afterwards. The degree of sensitivity was assessed before (baseline), after four applications (immediate results) as well as after 6 months and 1 year (mediate results). Data scores were submitted to Kruskal-Wallis statistical analysis and Friedman two-way ANOVA ($p < 0.05$). The application of all the substances, including placebo, regardless of the time period and stimuli used, resulted in an immediate statistically significant reduction in dentin hypersensitivity, which continued after 6 months and 1 year. The experimental solutions presented a statistically significant difference among themselves in reducing dentin hypersensitivity. Clinical variables may also have contributed to increase or reduce the effect of the desensitizing agents under study.

UNITERMS: Dentin; Dentin hypersensitivity, treatment; Potassium oxalate, clinical study.

INTRODUCTION

Most authors^{14,19} define dentin hypersensitivity as a temporary pain or an exaggerated response from the exposed dentin to chemical, tactile, thermal or osmotic stimuli in the buccal environment, which would not normally occur in a healthy tooth. Such

exposure may result from enamel loss by abfraction processes, erosion or abrasion and root surface stripping from gingival recession or periodontal treatment. Any tooth may be affected by hypersensitivity, but greater prevalence seems to occur with premolars and canines and almost invariably on the buccal surface¹⁴.

Many theories have been introduced to characterize dentin hypersensitivity. Nevertheless, the hydrodynamic theory proposed by BRÄNNSTRÖM¹ is the most widely accepted. According to its principles, the fluid movement inside the dentinal tubules leads to the sensorial activation of the nerve cells in the pulp, thus causing pain.

The severe pain due to the exposed dentin has prompted researchers to find alternatives for its relief. A great number of studies have presented various treatment approaches, which suggests that none of them has proved to be totally efficient^{13,19}. Dentin desensitization may sometimes occur spontaneously as a natural decrease of dentin permeability. In most cases, however, treatment is still necessary.

According to the hydrodynamic theory, agents that reduce the hydraulic conductance of the dentin are widely used to treat hypersensitivity. Therefore, the main purpose in treating such a clinical condition is to promote the sealing of the dentinal tubules. An effective sealing can be obtained by the topical application of oxalates that would penetrate inside the dentinal tubules in the form of insoluble crystal and reduce the fluid flow^{5,15}.

The mechanism of dentinal pain is still not quite understood and the signs and symptoms of hypersensitivity are subjective and non-specific. Conversely, a variety of products have been tested, but the results have proved to be mostly contradictory. Moreover, the so-called "placebo effect" has to be taken into consideration for its significant role often reported in clinical investigations^{2,6}.

Due to the large incidence of dentine hypersensitivity as well as the diversity of treatment approaches, the purpose of this study was to compare the desensitizing effects of two different potassium oxalate-based formulations (KOx) (Experimental Solution 1 and Experimental Solution 2) and a commercial desensitizing agent (Oxa-Gel[®]).

MATERIALS AND METHODS

Ninety-four canines and premolars from 19 patients (12 male and 7 female, ranging from 21 to 45 years old), who complained about sensitivity in the cervical region of teeth, were selected for the study. The patients should have at least two hypersensitive teeth in different hemiarcs. The selection of the patients and teeth was based on the

following criteria^{4,7,8}: 1) absence of severe systemic and/or psychological diseases; 2) oral condition that would allow for a correct diagnosis of dentin hypersensitivity; 3) non-use of any in-office desensitizing agent in the previous six month-period; 4) no periodontal surgery or scaling performed in the previous six months; and 5) the patient's personal agreement with the method used in the research, as recommended by the ethical principles of the World Medical Association²³ and by the Committee on Ethics of the University of Sao Paulo, Dental School at Bauru. Moreover, the teeth selected should not present caries, cracks or fractures, extensive or unsatisfactory restorations, recent restorations involving the buccal surface, prosthesis or orthodontic appliances, abnormal occlusal forces, periodontal pockets, mobility and severe occlusal trauma. The teeth selected presented gingival recession or any type of cervical lesion with sensitivity, regardless of the etiology. However, abfraction and erosion were taken into consideration as the main etiological factors.

The initial hypersensitivity patterns (baseline) were recorded in the first session. Each tooth received two stimuli: clinical probe (tactile stimulus) and air blast (thermal-evaporative). The use of the probe stimulus was performed in such a way to ensure that it would reach the lesion extensively under controlled pressure until the patient reported a pain similar to the one that had prompted him to take a treatment. The air blast was applied on the lesion with an air syringe for one second at 20°C to avoid desiccating the dentin surface.

After each stimulus, the degree of hypersensitivity was determined according to the Verbal Rating Scale – VRS⁹ from 0 to 3, in which: 0 = no discomfort, 1 = minimum discomfort, 2 = mild discomfort, and 3 = intense discomfort.

Immediately after recording the initial hypersensitivity scores, the teeth were randomly divided into four groups according to the desensitizing agents under study (Table 1). The four different desensitizing agents were applied to the same patient, in different hemiarcs, to permit data correlation regarding his/her sensitivity threshold.

The potassium oxalate-based agents and placebo were applied as follows: a) water rinse; dentin prophylaxis was not performed because the teeth did not present gross plaque accumulation or dental calculus; b) relative isolation with cotton rolls; c) dentin hydration with wet cotton pellets; d) dentin drying (using paper towel) in order to keep teeth moist²⁰; e) passive application of the experimental

TABLE 1- Groups, materials and compositions.

Group	Material	Gel	Composition	pH	Teeth
G1	Oxa-Gel® *	3 % KOx	+ Carboxymethyl cellulose	4	23
G2	Exp. Sol. 1	6 % KOx	+ Carboxymethyl cellulose	4	27
G3	Exp. Sol. 2	3 % KOx	+ Carbopol	2	27
G4	Placebo	H ₂ O	+ Carboxymethyl cellulose	7	17
* Art-Dent – Ind. Com. Produtos Odontologicos Ltda. Sao Paulo – Brazil				Total	94

xx Potassium oxalate - based formulation

gels using a brush, for 3 minutes; f) gel excess removal by using cotton pellets. The patients were instructed to maintain the same eating habits and mouth hygienization, including fluoride dentifrice, and to avoid using any other in-office-desensitizing agent in the course of the investigation.

This procedure was repeated at seven-day intervals for four weeks. The scores obtained immediately after the four applications were considered the immediate results of the treatment. Six months and one year after the fourth application of the solutions, the patients were recalled for re-assessment of the degree of dental sensitivity to air blast and probe stimuli. The data obtained in these sessions were identified as the mediate results of the treatment.

The data collected during the treatment reveal the patients' subjective answers according to the VRS. The hypersensitivity scores were submitted to Kruskal-Wallis and Dunn's tests for comparison among groups in the different periods. Friedman Two-Way ANOVA test was used to analyze the results obtained intra-groups in order to assess the materials performance in the various evaluation periods. In both tests a 5% significance level was adopted.

RESULTS

Table 2 presents the comparison of the variation of the results among the different assessment periods for all the groups, following Kruskal-Wallis test (H values). A statistical significant difference occurred in A6m-A4w (after six months and after the fourth application), and A1y-A6m (one year later and six months later) using air stimuli, and in A1y-A4w (after one year and after the fourth application) with

probe stimuli. Dunn's Test showed differences between Group 1 (Oxa-Gel®) and Group 2 (Experimental Solution 1) in A6m-A4w and A1y-A6m, and Group 1 (Oxa-Gel®) and Group 4 (Placebo) in A1y-A4w.

Table 3 shows the mean score distribution of the baseline, immediate (after four weeks - A4w) and mediate (after 6 months - A6m and after 1 year - A1y) results for the various materials and stimuli. It can be observed that, as for the two stimuli used, a significant reduction in dentin hypersensitivity occurred after the fourth application (immediate results) when compared with the results obtained before the first application (baseline) with all solutions. Nevertheless, the reduction was not statistically significant with the probe stimulus in Group 4 (Placebo). Such results prevailed after 6 months, when only Group 2 (Experimental Solution 1), probe stimulated, showed a reduction in hypersensitivity, though statistically not different from the baseline. When compared with the control period, Group 4 remained non-effective after probe stimulation. The comparison between the results obtained after six months and those found at the end of the treatment (after four applications) showed a tendency to hypersensitivity recurrence, but it was statistically significant only in Group 1 in which both stimuli were used.

On comparing the results obtained after one year with those of the baseline, a statistically significant decrease in the hypersensitivity levels can be observed in all groups (air stimulus) and in Group 3 (probe stimulus). On the other hand, it can be seen that, one year after the fourth application, hypersensitivity increased significantly in Groups 1 and 3 when probe was used. Air stimulation did not show a statistically significant decrease in hypersensitivity between a one-year period and the

TABLE 3- Mean scores of immediate (After 4 Weeks) and mediate (After 6 Months and After 1 Year) results for the different groups and stimuli (Friedman Test)

Groups / Materials	Stimuli	Mean Scores									
		(Standard Deviations)				Differences					
		Baseline n = 94	A4w n = 94	A6m n = 65	A1y n = 52	A4w x B1 n = 94	A6m x B1 n = 65	A6m x A4w n = 65	A1y x B1 n = 52	A1y x A4w n = 52	A1y x A6m n = 52
G1	Probe	1.43 (0.94)	0.52 (0.51)	0.83 (0.86)	1.46 (1.18)	-0.91*	-0.61*	0.27*	-0.06	0.93*	0.60*
Oxa-Gel®	Air	2.22 (0.67)	0.70 (0.70)	1.27 (0.82)	0.53 (0.64)	-1.52*	-0.88*	0.72*	-1.66*	0.00	-1.00*
G2	Probe	1.30 (0.95)	0.48 (0.57)	1.05 (0.94)	1.06 (0.79)	-0.82*	-0.40	0.60	-0.40	0.53	0.06
Exp. Sol. 1	Air	1.96 (0.75)	0.55 (0.75)	0.40 (0.59)	0.46 (0.74)	-1.41*	-1.50*	-0.25	-1.46*	-0.06	0.00
G3	Probe	1.74 (0.90)	0.59 (0.69)	0.75 (0.77)	1.38 (0.50)	-1.15*	-1.31*	0.00	-0.77*	0.69*	0.61*
Exp. Sol. 2	Air	2.11 (0.75)	0.59 (0.69)	0.68 (0.87)	0.61 (0.65)	-1.52*	-1.43*	-0.00	-1.53*	-0.15	0.00
G4	Probe	1.41 (0.93)	0.76 (0.83)	0.90 (1.0)	0.66 (0.86)	-0.65	-0.63	0.09	-0.88	-0.11	0.00
Placebo	Air	2.12 (0.69)	0.65 (0.70)	1.00 (1.0)	0.55 (1.13)	-1.47*	-1.18*	0.27	-1.44*	-0.11	0.00

* Statistically significant difference with $p < 0.05$

B1 = Baseline

A4w = immediate, after the 4th application

A6m = mediate, 6 months

A1y = mediate, 1 year

with the placebo results both at the immediate and mediate evaluations.

The clinical evaluation strategy adopted in this investigation aimed at establishing a comparison between different moments of dentine hypersensitivity treatment. Firstly, initial standards of pretreatment hypersensitivity were established. Thereafter, a comparison with the effects provided by the agents following the four applications (immediate results) was made. From this moment, other outcome of the results was considered relevant: the comparison of the immediate results with the results obtained after six months and one year later. The first situation establishes the effects of the treatment itself, and the second one determines the long-term effect following the fourth application. It must be highlighted that, after six months, 70% of the treated teeth were evaluated, and only 55% after one year, since some patients did not reply to the recalls.

After six months (A6m), the degrees of hypersensitivity were significantly lower than the baseline, except when the probe stimulus was used in Group 2 and Group 4. In these groups the dentine pain was not statistically different from the baseline. The maintenance of low pain sensation even after a six-month period may be attributed to the effect of potassium oxalate present in the different formulations used. The reaction between the potassium oxalate and the calcium present in the dentin and in dentinal fluid precipitates insoluble

calcium oxalate crystals in and into the dentinal tubules⁵. These calcium oxalate crystals are relatively big, measuring 1 to 2 mm in diameter⁵, coinciding with the mean diameter of the dentine tubules (0.9 to 2.5 mm)³. Calcium oxalate crystals are considered insoluble and acid resistant¹⁵, and may prevent the subsequent solubilization in the oral environment. Studies such as those by PASHLEY; GALLOWAY¹⁵ and PEREIRA; SEGALA; CARVALHO²⁰ have shown, in vitro, that the hydraulic conductance of dentin treated with potassium oxalate is maintained near the minimum even after the challenge with 6% citric acid. Conversely, scanning electron microscopy studies performed by KNIGHT et al.¹⁰ demonstrated that the calcium oxalate crystals precipitated on the dentine surface were easily removed by water spray. It is known, however, that dentin permeability is modified by crystal precipitation in the opening and inside the dentinal tubules and can only be seen along the tubules on fractured specimens.

The comparison between the results after the fourth application with those obtained after six months showed a significant increase in the hypersensitivity standards for Group 1 (with air and probe stimulus). These findings show that the results obtained after the fourth application lasted, in general, up to one year (only with probe stimulus), without any additional treatment. This long-lasting pain relief provided by the potassium oxalate formulations might be associated with the

spontaneous physiological decrease in dentin permeability, which may also be considered for the pain decrease in the placebo group.

The three active formulations used are basically 3% or 6% potassium oxalate solutions at pH 2.0 (Table 1). When carboxymethyl cellulose (CMC) is added to form the gel (Oxa-Gel® and Experimental Solution 1), the pH rises to 4.0. The main compositional difference between the experimental solutions is the gelling agent. Carbopol (CBP), the gelling resin used with Experimental Solution 2, is a high molecular weight acrylic acid-based polymer with pH ranging between 2.5 and 3.0. CBP keeps the solution pH at 2.52, which is expected to result in a gel with higher potential to ionize calcium from dentin and allow for precipitation of calcium oxalate crystals. Other *in vitro* studies have confirmed the significant reduction of dentin filtration with this formulation¹⁸. They also found that the interaction between Experimental Solution 2 and dentin is less influenced by variations on dentin substrate, such as pH and humidity. In the present clinical study, the data of Group 3 at the baseline (using both air and probe stimulation) showed a significant reduction in dentin hypersensitivity even one year after the treatment.

The immediate results (following the fourth application) also demonstrated a statistically significant decrease of dentine hypersensitivity when placebo was applied, although this reduction was not statistically significant when the probe stimulus was used. Such result may be attributed to the so termed "placebo effect". Other clinical studies^{2,6} have also reported a decrease in dentine hypersensitivity with the use of placebo, with success rates ranging from 20 to 45%. Since the placebo in the present work comprised inert ingredients such as water and carboxymethyl cellulose, with a neutral pH, the positive results may be related to other causes². According to TROWBRIDGE; SILVER²¹, the "placebo effect" results from physiological and psychological interactions. A positive dentist/patient relationship can reduce patient anxiety and improve his/her motivation to obtain relief^{2,21}. Furthermore, a positive and motivated emotional behavior may activate the central system pain inhibition, which controls the painful stimulus of the periphery by releasing endorphins. In studies on dentine hypersensitivity, the trust in the professional and the will to obtain relief undoubtedly contribute to the "placebo effect".

Another factor that might have occurred and

influenced the interpretation of the placebo results would be the "Hawthorne effect", described by WEST et al.²². According to these authors, this effect is a response to non-intervening procedures, such as the clinical exam. When participating in a clinical study, the patients take a more thorough care of their oral hygiene, because the dentist often sees them. The improvement in oral hygiene status, even though unconscious, may facilitate saliva access to dentine tubules and favor their obliteration through the deposition of calcium, phosphate and saliva proteins²¹.

Although the placebo formulation consists of inert substances, the hypothesis of a mechanical tubules occlusion by the particles of the carboxymethyl cellulose cannot be discarded. PASHLEY et al.¹⁶, in a study with desensitizing dentifrice, attributed the placebo effect to the abrasive particles present in the toothpaste, which are small enough to penetrate into the dentinal tubules and reduce the hydraulic conductance of the dentin. In the same manner, one can assume that the carboxymethyl cellulose particles may have been mechanically trapped in the opening or inside the dentine tubules.

CONCLUSIONS

The immediate and mediate assessment of dentin hypersensitivity treated with potassium oxalate gels showed a significant reduction of pain sensation when stimulated by air or probing. Clinical variables may also have contributed to increase or reduce the effect of the desensitizing agents under study.

The positive results achieved in the placebo group suggest the need for not only further clinical studies in order to better understand such intriguing event, but also for standard clinical protocols for the study of dentin hypersensitivity.

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RESUMO

Devido à alta incidência e à diversidade de tratamentos para a hipersensibilidade dentinária,

novos produtos devem ser testados quanto ao efeito e aplicabilidade. O objetivo deste estudo clínico foi avaliar a resposta de dentes hipersensíveis após a aplicação de três formulações à base de oxalato de potássio. Noventa e quatro caninos e pré-molares que apresentavam algum grau de sensibilidade aos estímulos sonda e jato de ar (de acordo com a Escala de Medida Verbal) foram tratados com as seguintes formulações: Oxa-Gel® (23 dentes), Solução Experimental 1 (27) e Solução Experimental 2 (27), tendo um placebo (17) como controle. Cada uma das formulações e o placebo foram aplicados passivamente por três minutos sobre a dentina ligeiramente úmida, sendo os excessos removidos. O grau de sensibilidade foi avaliado antes (baseline), após quatro aplicações (resultados imediatos) e também após 6 meses e 1 ano (resultados mediatos). Os escores foram submetidos à análise estatística pelos métodos Kruskal-Wallis e Friedman two-way ANOVA ($p < 0,05$). A aplicação de todas as formulações, incluindo o placebo, independente do tempo e do estímulo utilizado, resultou em diminuição estatisticamente significativa dos graus de hipersensibilidade dentinária, a qual permaneceu após 6 meses e 1 ano. O resultado positivo obtido com o uso do placebo sugere a necessidade da realização de novas pesquisas e de uma padronização dos protocolos para o estudo da hipersensibilidade dentinária.

UNITERMOS: Dentina; Hipersensibilidade dentinária, tratamento; Oxalato de potássio, estudo clínico.

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