

Efficacy of Gluma Desensitizer® on dentin hypersensitivity in periodontally treated patients

Eficácia do Gluma Desensitizer® sobre hipersensibilidade dentinária em pacientes periodontalmente tratados

Camila de Azevedo de Assis*

Raquel Pippi Antoniazzi*

Fabício Batistin Zanatta*

Cassiano Kuchenbecker Rösing**

ABSTRACT: The aim of this double-blind, controlled, split-mouth designed clinical trial was to assess the effect of a single application of Gluma Desensitizer® on alleviating dentin hypersensitivity. Twelve subjects entered the study and ten completed the protocol. Each subject had two teeth treated: one with Gluma Desensitizer® according to the manufacturer's instructions and one with water. The assessment of pain was performed with the VAS (Visual Analogue Scale), after tactile (probe), thermal (cold blast of water) and thermal/evaporative (cold blast of air) stimuli at baseline, immediately after treatment, after 1 week and after 4 weeks. The mean VAS values for the test and control teeth were compared by the paired *t* test ($\alpha = 0.05$). Repeated measurements ANOVA was used to compare the different experimental times. The results showed that for test teeth, at baseline, mean VAS values were 1.76 (± 2.82), 7.10 (± 2.10) and 4.75 (± 2.65), and, after 4 weeks, the mean values were 1.70 (± 2.31), 5.50 (± 3.30) and 4.61 (± 3.14), respectively for probe, water and air stimuli. For the control teeth, at baseline, the mean VAS values were 1.86 (± 2.92), 6.61 (± 2.31) and 4.08 (± 2.91) and, after 4 weeks, 2.66 (± 3.07), 6.32 (± 2.94) e 4.76 (± 3.26). There were no statistically significant differences between test and control teeth at any time. No intra-group differences were demonstrated either. It was concluded that Gluma Desensitizer® had no effect on hypersensitive teeth from periodontally treated patients for a period up to 4 weeks.

DESCRIPTORS: Dentin sensitivity; Dentin-bonding agents; Randomized controlled trials.

RESUMO: O objetivo deste estudo clínico duplo-cego, controlado, de boca-dividida foi avaliar o efeito de uma aplicação única do Gluma Desensitizer® no alívio da hipersensibilidade dentinária. Doze sujeitos participaram do estudo, sendo que destes dez completaram o estudo. Cada um dos participantes teve dois dentes tratados, um com o Gluma Desensitizer®, de acordo com as orientações do fabricante, e o outro com água. Para a avaliação da dor foi utilizada a EVA (Escala Visual Analógica), após os estímulos tátil (sonda), térmico (jato de água frio) e térmico/evaporativo (jato de ar frio) no início do experimento, imediatamente após o tratamento, uma e quatro semanas após. Os valores médios encontrados na EVA foram comparados pelo teste-*t* pareado ($\alpha = 0,05$). Para os diferentes tempos experimentais utilizou-se ANOVA para medidas repetidas. Os resultados mostram que, no início do tratamento, os valores médios foram de 1,76 ($\pm 2,82$), 7,10 ($\pm 2,10$) e 4,75 ($\pm 2,65$) para os dentes teste e, após quatro semanas, os valores médios foram de 1,70 ($\pm 2,31$), 5,50 ($\pm 3,30$) e 4,61 ($\pm 3,14$) respectivamente para os estímulos sonda, água e ar. Para os dentes controle, no início do tratamento, os valores médios segundo a EVA foram de 1,86 ($\pm 2,92$), 6,61 ($\pm 2,31$) e 4,08 ($\pm 2,91$) e, após 4 semanas, 2,66 ($\pm 3,07$), 6,32 ($\pm 2,94$) e 4,76 ($\pm 3,26$). Não ocorreram diferenças estatisticamente significativas entre os dentes teste e controle em nenhum dos tempos experimentais. Também não ocorreram diferenças intragrupo. Concluímos que o Gluma Desensitizer® não tem efeito sobre a hipersensibilidade dentinária de pacientes periodontalmente tratados num período de até quatro semanas.

DESCRIPTORIOS: Sensibilidade da dentina; Adesivos dentinários; Ensaios clínicos controlados aleatórios.

INTRODUCTION

Dentine hypersensitivity is characterized by short, sharp pain arising from exposed dentine in response to tactile, evaporative, chemical or thermal stimuli and which cannot be ascribed to any other dental defect or pathology^{1,16}. The pain most often occurs after exposure of the root dentine by

removal of cementum and overlying periodontal tissues⁴.

How the pain is transmitted from the dentin to the pulp is not fully understood. The most accepted explanation is the hydrodynamic theory in which external stimuli cause a rapid flow of fluid in the

* Graduate Students; **Professor of Periodontology – Graduate Program in Dentistry, Lutheran University of Brazil.

dentinal tubules, activating mechanoreceptors at the pulp-dentin interface, leading to pain. The flow of dentinal fluid is influenced by configuration of tubules, the tubular diameter, and the number of open tubules⁵.

The prevalence of root sensitivity in adults ranges from 3.8 to 74%, and after periodontal therapy the prevalence is around 54%¹⁷.

Over the years, many treatment methods for tooth hypersensitivity with varying outcomes have been reported². Professional treatments used to reduce tubule occlusion usually involve resins, varnishes, and dentine bonding agents or restorative materials.

The application of resin to reduce dentin hypersensitivity was initially proposed by Dayton *et al.*⁶ (1974) and later tested in several clinical studies where dentin bonding agents were tested.

The desensitizing component used in the adhesive is glutardialdehyde (GA), which is likewise the active ingredient in Gluma Desensitizer®. Glutardialdehyde reacts with serum albumin in the dentin fluid by coagulation, thus counteracting the hydrodynamic mechanism of dentin hypersensitivity³. However, controlled clinical studies providing evidence for the use of this material in tooth hypersensitivity are lacking.

The aim of this double-blind, controlled, split-mouth designed clinical trial was to assess the effect of a single application of Gluma Desensitizer® on alleviating dentin hypersensitivity.

MATERIAL AND METHODS

Subjects

Twelve subjects (10 female and 2 male) aged 29-63 were selected at the Department of Periodontology, Lutheran University of Brazil. To participate in the study the subjects should have two teeth that were hypersensitive to thermal/evaporative stimulation with a blast of air, after periodontal treatment.

After receiving oral and written information about the aims of the study, the subjects signed an informed consent form. The study protocol was approved by the Ethical Committee of the Lutheran University of Brazil.

Exclusion criteria

Individuals should not be under analgesic, anti-inflammatory or tricyclic antidepressant treatment regimes, should not be pregnant, should not be receiving orthodontic therapy nor have any eating disorders.

Teeth were excluded if they: were carious, extensively restored or fractured; were non-vital or had symptoms of pulp damage; had been subjected to periodontal treatment within the past three months or had congenital enamel/dentin defects.

Final study population

Two individuals used anti-hypersensitivity dentifrices during the study, not complying with the instructions, and were thus excluded. Hence the final study population consisted of 8 females and 2 males.

Pain assessment

Pain was assessed after mechanical, thermal and thermal/evaporative stimuli. A Williams's periodontal probe (Neumar Instrumentos Cirúrgicos Ltda., São Paulo - SP, Brazil) was scraped following a mesial to distal direction with approximately 15 g of pressure (Probe). A blast of water (Water) and a blast of air (Air) were applied 0.5 cm from the tooth surface as thermal and thermal/evaporative stimuli, respectively. All stimuli were applied on the cervical region of the experimental teeth and the adjacent ones were covered with cotton rolls. After the stimulus, the patient was asked to mark the intensity of pain on a Visual Analogue Scale (VAS), with 10 cm, which was marked on the left end with "no pain" and on the right end with "extreme pain". An interval of 5 minutes was given between stimulations.

The pain was assessed in test and control teeth at baseline, immediately after treatment, one week after treatment and four weeks after treatment.

Patients used the same standard dentifrice (without any anti-hypersensitivity component) and their conventional toothbrush.

Treatment procedures

After baseline pain assessment, the 2 selected hypersensitive teeth were randomly assigned by means of the flip of a coin to test or control. The test tooth was treated with Gluma Desensitizer® (Heraeus Kulzer South America Ltda., São Paulo, SP, Brazil) in accordance with the manufacturer's instructions. It was applied for 60 s, dried lightly and washed for 60 s. The control tooth received water with the same instructions. The examiner and the patients were blinded to the product applied.

TABLE 1 - Mean VAS values (s.d.) for test and control teeth over 4 weeks after Gluma Desensitizer®/Water application.

	Probe		Water		Air	
	Gluma®	Control	Gluma®	Control	Gluma®	Control
Baseline	1.76 (2.82)	1.86 (2.92)	7.10 (2.10)	6.61 (2.31)	4.75 (2.65)	4.08 (2.91)
IAT	2.36 (2.76)	1.60 (1.97)	6.00 (2.10)	5.75 (2.38)	3.89 (2.60)	3.07 (1.90)
1 week	2.24 (3.00)	2.01 (2.77)	7.30 (0.9)	6.85 (1.44)	6.85 (1.52)	5.59 (3.10)
4 weeks	1.70 (2.31)	2.66 (3.07)	5.50 (3.30)	6.32 (2.94)	4.61 (3.14)	4.76 (3.26)

No inter-group statistically significant differences were observed for either stimuli using the paired sample *t* test, $p > 0.05$; no significant differences over time were detected for either group with either stimuli. IAT: immediately after treatment.

Statistical procedures

Mean VAS scores were calculated after each stimulus for test and control teeth.

Inter-group comparisons were performed by the paired sample *t* test and over time differences were tested by repeated measurements ANOVA. Mean differences between 4 weeks and baseline were calculated for test and control teeth for each stimulus and statistically analyzed by the paired sample *t* test. An alpha level of 0.05 was used.

RESULTS

During the study period there were no reported adverse events like allergic reactions or pulp damage.

For all stimuli, no statistically significant differences were found between test and control teeth at baseline or after any study period (Table 1). Moreover, no significant improvement in mean VAS values was observed over time using the different stimulations both in test and control teeth.

With the mechanical stimulus (Probe), mean VAS values for test teeth were 1.76, 2.36, 2.24 and 1.70; for control teeth, mean VAS values were 1.86, 1.60, 2.01 and 2.66, respectively at baseline, immediately after treatment, 1 week after treatment and 4 weeks after treatment.

The other stimuli (Water and Air) produced higher mean baseline values, with the same pattern of no intra- or inter-group differences throughout the study. For example, with the Water stimulation, mean VAS values of 7.10 and 6.61 were obtained at baseline, and of 5.50 and 6.32 after 4 weeks, respectively for test and control teeth. Despite some drop in mean values, these did not reach statistical significance. With the blast of air, the same pattern was obtained.

Table 2 demonstrates the mean difference between 4 weeks after treatment and at baseline

TABLE 2 - Mean difference (4 weeks in relation to baseline) for Gluma Desensitizer and Control after different stimulations.

	Gluma Desensitizer®	Control
Probe	0.22 (3.61)	1.24 (2.28)
Water	-1.64 (3.53)	-0.34 (3.56)
Air	-0.20 (4.07)	0.18 (2.29)

No statistically significant differences were observed in test and control teeth using the paired sample *t* test, $p > 0.05$.

for test and control teeth. No statistically significant differences were demonstrated (paired sample *t* test, $p > 0.05$).

DISCUSSION

Dentine hypersensitivity is a very common painful problem which is difficult to solve, despite the fact that a large variety of treatments exist⁹. The occurrence of hypersensitivity is particularly important as an adverse event of periodontal therapy. It has been demonstrated that root exposure due to loss of attachment and shrinkage of periodontal tissues leads to exposure of the cemento-enamel junction and tooth hypersensitivity^{4,17}. Taking these facts into consideration, there is a need to develop treatment approaches which permit the relief of the symptoms of dentine hypersensitivity. Controlled studies have up to now failed in demonstrating a gold standard treatment approach for tooth hypersensitivity^{8,15}.

In general terms, there are two approaches to dentine hypersensitivity: the first is directed to obliterate dentin tubuli of exposed dentine, blocking up sensitivity of dental nerves. The other one is decreasing the sensitivity of dental nerves, reducing the pain stimuli transmission⁵.

The tolerance to the same pain can vary considerably among individuals and within them depending on the time and circumstances because

the perception of pain depends on individual factors such as psychological factors, educational level, personality, among others¹².

The present paper reports a randomized, double-blind controlled study with a split-mouth design. This is considered the gold standard study design for testing the hypotheses of no differences between treatment approaches. A power calculation based on the results of the present study, taking into consideration the split-mouth design and a clinically significant reduction of 50% of the VAS values with the blast of air, was performed and resulted in a value of 0.78, meaning that the sample size was adequate.

More than one stimulus to assess pain was used, according to the recommendation of Holland *et al.*¹⁰ (1997). This recommendation arises from the fact that different stimuli can elicit different pain sensations and could lead to more reliable conclusions. A periodontal probe was used as a mechanical stimulus and blasts of water and air were used as thermal and thermal/evaporative stimuli, respectively.

Pain associated with dentine hypersensitivity is difficult to quantify and reproduce¹¹. The Visual Analogue Scale (VAS) has been reported as reliable in the literature for pain assessment^{14,18}.

Immediately after treatment (both control and Gluma Desensitizer®), a light drop, albeit not significant, was observed with thermal and thermal/evaporative stimuli. However, this tendency was not maintained throughout the study. A strong placebo effect is commonly described in clinical dentine hypersensitivity trials, and we can suggest that this effect was not clear in the present study. Interestingly, with the mechanical stimulus, not even a light decrease in sensitivity was demonstrated. The absence of effect was the reason why 2 of the initially selected individuals started using an anti-hypersensitivity dentifrice, and they were excluded from the study.

Investigators have described patients obtaining relief without any treatment due either to the placebo effect or to self-healing of the problem as time passes. The relief consists of a mixture of physiological and psychological interactions, depending considerably on the doctor-patient relationship, with both parties needing to consider the treatment valuable and desiring to obtain relief of symptoms¹³.

Duran, Sengun (2004)⁸ compared the effectiveness of five desensitizer products, including the Gluma Desensitizer®, in a split mouth design. The VAS scores at post-treatment evaluation points were significantly decreased compared with baseline data ($p < 0.05$), but they did not use a placebo

control. Dondi dall'Orologio *et al.*⁷ (1999) found Gluma Desensitizer® to be successful as well, in a non-controlled trial. Evidence from studies without controls should be considered with high caution, since they are not capable to really assess the effect of the tested approach.

In contrast with other studies, it was shown in the present study that Gluma Desensitizer® did not alleviate discomfort from tactile, thermal (cold) and thermal/evaporative (cold) stimulation in tooth hypersensitivity within the 4-week period of the study. However, a different study design could account for the achieved results.

Despite the claim of Gluma Desensitizer® as being able to decrease tooth hypersensitivity by means of a direct obliteration of the exposed dentin tubules, the results of the present study could not demonstrate it. Another form of looking at the results, focusing on the differences between evaluations at the end of the study and at baseline, could not demonstrate a superior efficacy of the test product in relation to water application either.

The present study population – periodontally treated patients experiencing tooth hypersensitivity – should also be considered. These patients are undergoing major transformations in habits and in oral characteristics, probably experiencing enhancement in recession, which leads to a greater importance of their mouths, being more concerned with all situations. These facts should also be considered, since 4 weeks after treatment, they could still be overestimating the importance of what is happening, leading to less alleviating effects. Studies with longer periods of time could be interesting. However, without any difference in tooth hypersensitivity in the initial periods, it is most unlikely that additional treatment-related decreases would occur. They could happen as a function of the time elapsed in relation to a psychological and biological balance¹⁹. Studies with consecutive applications of the product should be considered.

The previous reports about a placebo effect in tooth hypersensitivity¹⁵ should be considered in the treatment approach, using good standards of communication between the dentist and the patient, maybe achieving higher alleviation.

CONCLUSION

In conclusion, the efficacy of Gluma Desensitizer® in reducing tooth hypersensitivity after periodontal treatment was not demonstrated over a period of 4 weeks.

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