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Original Article

Dentistry Section

Efficacy of Biosilicate Glass-Ceramic and Gluma in the Treatment of Cervical Dentin Hypersensitivity: An Interim Results of Randomised Control Trial

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ABSTRACT

Introduction: Dentin Hypersensitivity (DH) is known to be a relatively common condition that affects a considerable portion of the population, and manifests itself in the form of acute pain, due to the exposure of dentin and open dentinal tubules, after the removal of enamel or root cement. It has a multifactorial aetiology.

Aim: To compare the efficacy in DH treatment using Biosilicate and Gluma Desensitiser.

Materials and Methods: This randomised clinical trial pilot study with a split-mouth design included seven participants. Two teeth presenting Gingival Recession (GR)-related DH were selected in each participant and allocated to treatment groups by simple randomisation. Gluma® desensitiser (GD) and Biosilicate® (BIO) were applied once a week for four weeks. The pain intensity under a volatile stimulus was measured using a Visual Analogue Scale (VAS) at baseline and after treatment, at 15 days and 6 months follow-up. Data analysis were performed by means of descriptive statistics, Paired t-test for inter-group comparison and Friedman test for intra-group comparison (p-value <0.05).

Results: The mean age of seven participants were 19.9 years, from which five were women (71.4%). The GD and BIO groups presented initial mean VAS values of 4.86±2.55 and 6.14±1.57, respectively. Fifteen days after treatment, both groups showed a significant improvement (GD group p-value=0.03 and BIO group p-value=0.02, Wilcoxon test) in pain intensity, with 71.4% teeth without sensitivity (VAS=0).

Conclusion: Both treatments resulted in a reduction in painful sensitivity under volatile stimuli 15 days after treatment. BIO group presented a better outcome regarding reduction in DH, without recurrence at the 6th month evaluation, when compared to GD group.

Keywords: Dentin desensitising agents, Dentin sensitivity, Pain intensity

INTRODUCTION

The DH is characterised by short, sharp pain, initiated after exposure of dentin to different stimuli- thermal, tactile, osmotic, or chemical and which cannot be explained by any dental defect or disease [1]. The pain remains as long as the stimulus is applied, being initially severe, but decreases after removal of the stimulus. Despite the heterogeneity in study methods and populations, the mean DH worldwide prevalence is 33.5%, with a higher incidence in young adults [2].

Cervical DH usually occurs as result of dentin exposure following GR or loss of enamel/cementum due to Non Carious Cervical Lesions (NCCL). DH, GR and NCCL are correlated and share some risk factors: age, gender, gastric disease and occlusal trauma. The depth and morphology of GR and NCCL contribute to high levels of dentin sensitivity. Pain induced in exposed dentine may be explained by the hydrodynamic theory, according to which the stimuli induce a rapid outward movement of fluid in the dentinal tubules sufficient to activate the sensory nerve fibres in the underlying pulp/dentin border zone [3].

Treatment strategies for DH aimed to address both aetiological factors and symptom relief. They may include instructions regarding brushing technique and the use of a less abrasive dentifrice, anxiety control, the use of a desensitiser and periodontal surgery [4]. The different desensitiser products available to treat DH aim to interrupt the pain neural answer by means of occlusion of the opened dentin tubules, thus blocking the hydrodynamic flow within them [5]. The ideal desensitiser treatment for DH should act quickly, be effective in the long-term be easy to apply, and should not be aggressive to the pulp, cause pain and or cause dental staining [6].

Gluma® desensitiser (Heraeus Kulzer, Hanau, Germany) is a well-accepted product by dentists. It was developed from Gluma Bond Original® and has glutaraldehyde as its active component, which promotes the precipitation of serum albumin present in the fluid of dentinal tubules and reacts by coagulation, counteracting the hydrodynamic mechanism of DH through tubule obliteration [7].

Biosilicate® (LaMaV, Federal University of São Carlos, São Paulo, Brazil) is a bioactive glass-ceramic developed by a multidisciplinary team for the treatment of DH [8]. It reacts with saliva leading to the formation and deposition of hydroxyapatite carbonate on the dentin surface, promoting the obliteration of open dentin tubules. Biosilicate® has two advantages, the particles can be safely added to various types of formulation used in the oral cavity and these particles may be produced in different granulations, allowing their insertion into dentine tubules with some ease [9]. According to an in-vitro study, 24 hours after the application of the product to specimens kept in artificial saliva, total obliteration of the dentinal tubules was observed, indicating that a mineralised layer had formed on the dentin surface [9]. The results of a clinical study using Biosilicate® for the treatment of DH proved that it was quite effective at reducing DH in patients with GR during a 6 month follow-up [10]. It has also been shown to be effective at reducing the sensitivity generated after tooth bleaching with hydrogen peroxide [11].

Although these two desensitisers are effective in reducing DH, they have different characteristics and mechanisms of action, and their comparative efficacy has not yet been tested. There is a hypothesis that the bioactive glass-ceramic may be more effective in reducing DH than Gluma® desensitiser.

Thus, the present study aimed to further compare the effectiveness of Biosilicate® in the treatment of DH by comparison with the well-known Gluma® desensitiser.

MATERIALS AND METHODS

This pilot study for a split-mouth randomised clinical trial was performed in the School of Dentistry, Universidade Federal de Goias, Goiânia, Goiás, Brazil, between September 2019 and April 2020, and was approved by the Ethics Committee of the Universidade Federal de Goiás, (protocol n.1.974.598). Patients were informed about the purpose and the design of the study, and they signed an informed consent form and related consent forms. This study was performed according to the Declaration of Helsinki and registered in the Registry of Brazilian Studies for Clinical Trials (RBR-67645p).

Inclusion criteria: The sample included dentistry students over 18-year-old, presenting at least two teeth with GR-related DH without history of DH treatment or root scaling in the past 6 months.

Exclusion criteria: Subjects being pregnant or lactating; having received periodontal treatment in the last six months; receiving orthodontic treatment; consuming an acid diet and chronic use of painkillers or anti-inflammatories; having prostheses that were using the sensitive teeth as pillars were excluded from the study.

Sample size calculation: The sample size for the RCT was estimated in 38, considering a power of 80% and a level of significance of 5% (two sided), for detecting a mean of the differences of 0.61 between pairs [10], assuming the standard deviation of the differences to be 1.3. Considering the risk of participants' drop out, this sample size estimation was increased in 10%, totalising 42 participants. For this pilot study, the sample size was estimated at 20% of the RCT sample.

Simple randomisation was performed to allocate sensitive teeth to two treatment groups:

- Gluma® Desensitiser (GD group)
- Biosilicate® (BIO group)

The DH intensity was assessed after exposure to a volatile stimulus using a VAS, which consisted of a numerical 100 mm scale, graded from 0-10. The extreme left (0) represented the absence of pain and the extreme right (100) represented excruciating pain. The participants indicated their answer by marking a position on the line, between these two extremes.

Study Procedure

All participants were instructed to use the modified Bass technique for teeth brushing during the study. A volatile stimulus was provided by means of local air application using a professional triple syringe, totally free of water and oil. An air jet was applied perpendicularly to the dentin surface, from a distance of 1 cm, for 3 seconds.

Treatment began after baseline pain assessment and was performed by the same researcher in all patients. It involved mechanical cleaning of the surface, using a flexible cotton stick, followed by relative isolation and desensitiser application. Each product was applied once a week, for 4 weeks [10].

Biosilicate®: This is made from Silicon Dioxide (SiO^2), Sodium Oxide (Na_2O), Calcium Oxide (CaO) and Phosphorus Pentaoxide (P_2O_5), and is produced by the Vitreous Materials Laboratory (LaMaV), in the Universidade Federal de São Carlos (Brazil). A mixture of 0.2 g of powder and 1 mL of water was placed in eppendorf tubes. This solution was lightly rubbed on the cervical region of the tooth with a microbrush, for 30 seconds, and left to rest for 2 minutes. Then, the excess was removed with water from a triple syringe.

Gluma®: This desensitiser was applied according to the manufacturer's recommendations: dentin cleaning, relative isolation, product application, 30 seconds resting, careful surface drying with an air jet and abundant washing.

The DH was measured before treatment, immediately after each session of treatment, and 15 days and 6 months later, verifying pain interruption and durability of pain remission. A different evaluator performed all DH assessment, blinded to the product applied.

STATISTICAL ANALYSIS

Descriptive statistics, paired t-test, Wilcoxon and Friedman tests were used for data analysis. Statistical significance was set at p-value <0.05. The Statistical Package for Social Sciences (SPSS Inc. Chicago, IL, USA) for windows software version 25.0 was used for all data analysis.

RESULTS

Twenty-four volunteers complaining of DH were screened, and seven fulfilled the inclusion criteria (mean age was 19.9 years, SD 0.9), from which five were women (71.4%). A researcher performed the two treatment protocols on seven teeth per group, in a split-mouth design. All the treated teeth were premolars or canines.

[Table/Fig-1] describes the volatile sensitivity measured by the VAS before and after treatment. Both treatments were effective at reducing pain intensity, and only three participants presented DH 15 days after treatment, including two teeth treated with Gluma® Desensitiser and two teeth treated with Biosilicate®. Both groups showed a significant improvement in pain intensity, with 10 teeth (71.4%) without sensitivity (VAS=0) at 15th day after treatment (GD group p-value=0.03 and BIO group p-value=0.02, Wilcoxon test). The teeth treated in BIO group presented better results. At six months after treatment, only one case treated in BIO group remained sensitive, at the same intensity, while three teeth treated in GD group presented DH, including two recurrences.

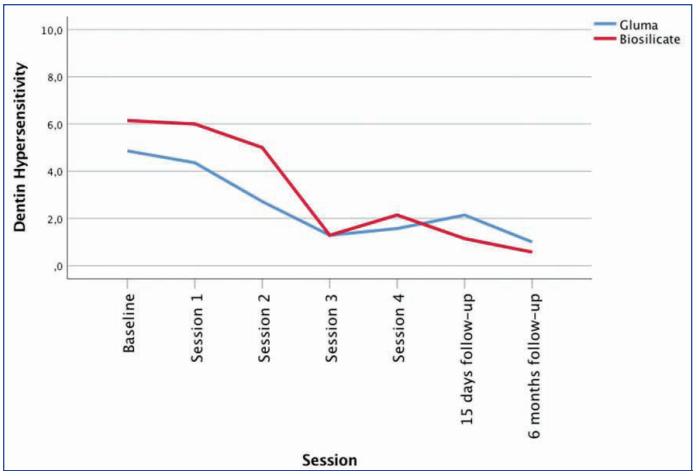
	GD Group				BIO Group			
VAS	Initial	Final	15 d	6 m	Initial	Final	15 d	6 m
Patient 1	5	0	0	0	6	1	0	0
Patient 2	2	0	0	1	3	0	0	0
Patient 3	7	3	8	0	7	7	4	0
Patient 4	8	8	7	4	6	0	0	0
Patient 5	2	0	0	2	8	7	4	4
Patient 6	7	0	0	0	7	0	0	0
Patient 7	3	0	0	0	6	0	0	0

[Table/Fig-1]: Dentin hypersensitivity intensity measured by Visual Analogic Scale (VAS) at baseline (initial), immediately after treatment (final) and at 15 days and 6 months follow-up.

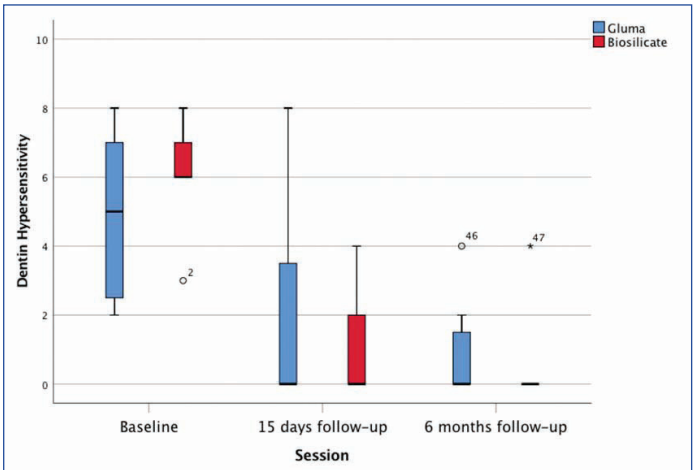
The mean sensitivity of groups in each session, measured by the VAS, is presented in [Table/Fig-2,3]. The two groups presented similar DH intensity at baseline (p=0.233), and a significant reduction of pain after treatment (GD group p-value=0.006 and BIO group p-value <0.001). There was no significant difference between DH at 15 days and 6 months follow-up, irrespective of treatment. Inter-group comparison revealed no significant difference at 15 days follow-up (p=0.415) or after 6 months (p=0.593). Data from the baseline and follow-up periods are represented by a boxplot in [Table/Fig-4].

Evaluation time	GD Group (Mean±SD)	BIO Group (Mean±SD)	p-value
Baseline	4.86±2.55	6.14±1.57	0.233[a]
1st session	4.36±3.25	6±1.29	0.145[a]
2nd session	2.71±3.4	5±2	0.176[b]
3rd session	1.29±1.89	1.29±1.98	1.0[b]
4th session	1.57±3.05	2.14±3.34	0.715[b]
15 days after treatment	2.14±3.67	1.14±1.95	0.414[b]
6 months after treatment	1±1.53	0.57±1.51	0.593[b]
p-value	0.006[c]	<0.001[c]	

[Table/Fig-2]: Intragroup and intergroup comparisons of dentin hypersensitivity measured by Visual Analogue Scale (VAS).
[a]paired t-test; [b]Wilcoxon test; [c]Friedman test



[Table/Fig-3]: Mean sensitivity of groups in each session measured by the Visual Analogue Scale (VAS).



[Table/Fig-4]: Visual Analogue Scale (VAS) data at baseline and during the follow-up periods are represented by boxplots.

During or immediately after Gluma® application, six patients reported a bitter taste or burning sensation.

DISCUSSION

This pilot study showed the effectiveness of both treatments at reducing DH, but BIO group presented superior results in both follow-up periods (15 days and 6 months). Furthermore, no patient reported a different or bad taste, or other side-effects, after Biosilicate® application, unlike with Gluma® desensitiser.

Several techniques and protocols for DH treatment are available and have been described in the literature and several studies have reported a significant reduction in pain after treating DH with several types of desensitising agents. However, there is no established treatment protocol for DH or a gold standard desensitising agent for use at home or in-office [12-16].

Biosilicate® is a biocompatible material that can induce osteogenesis and has been suggested for use as an adjuvant to treat teeth fissures and cracks, due to its generation in-situ hydroxyapatite [17]. In-vitro studies have attributed the effect of bioactive materials on DH reduction to the fast deposition of hydroxyapatite at the site of application, obliterating dentin tubules and contributing to enamel and dentin regeneration after bleaching treatments [18,19]. Biosilicate®, if used after bleaching treatment immediately, seemed to reduce or even demineralisation and prevent the exposure of dentin tubules [19].

Similar to our results, at least one study demonstrated the reduction of DH in the short-term by the clinical use of Biosilicate® mixed with distilled water, and this effect remained after 6 months follow-up [10].

A systematic review with meta-analysis verified that a commercial product, Nupro Sensodyne®, which is a compound of sodium and calcium phosphosilicate (likely a bioactive glass) with an active principle very similar to that of Biosilicate®, showed satisfactory results in terms of reducing DH [20]. Like Biosilicate®, when this product contacts oral fluids it reacts and deposits Hydroxycarbonate Apatite (HCA), which is a compound chemically similar to dental enamel [21]. Other studies found that prophylactic pastes (fluoridated or not) containing 15% Nupro® reduced DH for at least 28 days [22,23]. In another study, a single in-office application of the paste after scaling and root planning provided significant immediate hypersensitivity reduction for the whole six week [24].

A previous study compared the efficacy of Gluma® desensitiser with that of the biomimetic mineralisation system (BIMIN). Forty patients showed favourable DH reduction for 12 months, with no significant difference between the two products. However, dentin surface evaluation using a scanning electron microscopy revealed that a mineral layer concealed the dentinal tubules in the BIMIN group, while numerous dentinal tubules remained visible in the cervical defects that were treated with Gluma® [25]. Although Biosilicate® was not evaluated in that study, this bioactive glass-ceramic also promotes sealing of the dentinal tubules by the deposition of hydroxyapatite, as previously mentioned [9].

Two similar studies, one with six months follow-up [26] and the other with 18 months follow-up [27], assessed the application of Gluma® desensitiser by itself or associated with different protocols of low and high-power laser treatments, and reported favourable results in terms of DH-related pain reduction. Furthermore, in a recent study, the authors found that a group of patients treated with Gluma® desensitiser was the only set that presented no increase in pain over the course of time, meaning that it can be considered an effective and non invasive treatment option [27].

Another in-vitro study assessed the efficacy of five desensitisers in relation to dentin permeability, including Gluma® desensitiser and Nupro®, and the conclusion was that both were effective in the treatment of DH. The authors were unable to compare the effectiveness of one in relation to the other due to differences in protocols for use [28].

Limitation(s)

The results observed from this pilot study must be assessed carefully, considering the small sample size. The degrees of dentin exposure were not assessed, which may represent a limitation and will be reconsidered for performing the clinical trial. Another issue to be discussed in future studies is the method for assessing DH, which may include tactile, thermal, osmotic, and electric stimuli.

CONCLUSION(S)

The preliminary results presented in this study suggest that both biomaterials are effective in the treatment of DH, with a relevant reduction in pain sensitivity to volatile stimuli on the 15th day after the intervention. Considering the 6th month of follow-up, no recurrence was observed in the teeth treated with Biosilicate®, while two teeth treated with desensitiser Gluma® presented with recurrence. In addition, most participants reported a bitter taste or burning sensation during or immediately after the application of Gluma®, which was not observed with Biosilicate®.

REFERENCES

[1] Canadian Advisory Board on Dentin Hypersensitivity. Consensus-based recommendations for the diagnosis and management of dentin hypersensitivity. J Can Dent Assoc. 2003;69(4):221-26.
[2] Favaro Zeola L, Soares PV, Cunha-Cruz J. Prevalence of dentin hypersensitivity: Systematic review and meta-analysis. J Dent. 2019;81:01-06.
[3] Texeira DNR, Zeola LF, Machado AC, Gomes RR, Souza, PG, Mendes DC, et al. Relationship between noncarious cervical lesions, cervical dentin hypersensitivity, gingival recession, and associated risk factors: A cross sectional study. J Dent. 2018;76:93-97.
[4] Brännström M. The hydrodynamic theory of dentinal pain: Sensation in preparations, caries, and the dentinal crack syndrome. J Endod. 1986;12(10):453-57.

[5] Rösing CK, Fiorini T, Liberman DN, Cavagni J. Dentine hypersensitivity: Analysis of self-care products. Braz Oral Res. 2009;23(1 Suppl):56-63.
[6] Porto IC, Andrade AK, Montes MA. Diagnosis and treatment of dentinal hypersensitivity. J Oral Sci. 2009;51(3):323-32.
[7] Ishihata H, Kanehira M, Nagai T, Finger WJ, Shimauchi, H, Komatsu M. Effect of desensitising agentes on dentin permeability. Am J Dent. 2009;22(3):143-46.
[8] Zanotto ED, Ravagnani C, Peitl O, Panzeri H, Lara EH. FUNDAÇÃO UNIVERSIDADE FEDERAL DE SÃO CARLOS; UNIVERSIDADE DE SÃO PAULO. Process and compositions for preparing particulate, bioactive or resorbable biosilicates for use in the treatment of oral ailments. Int. C. C03C10/00, 20 Feb. 2004, WO2004/074199.
[9] Tirapelli C, Panzeri H, Soares RG, Peitl O, Zanotto ED. A novel bioactive glass-ceramic for treating dentin hypersensitivity. Braz Oral Res. 2010;24(4):381-87.
[10] Tirapelli C, Panzeri H, Lara EHG, Soares RG, Peitl O, Zanotto ED. The effect of a novel crystallised bioactive glass-ceramic powder on dentine hypersensitivity: A long-term clinical study. J Oral Rehabil. 2011;38(4):253-62.
[11] Pintado-Palomino K, Peitl Filho O, Zanotto ED, Tirapelli C. A clinical, randomised, controlled study on the use of desensitising agents during tooth bleaching. J Dent. 2015;43(9):1099-105.
[12] Moraschini V, da Costa LS, Dos Santos GO. Effectiveness for dentin hypersensitivity treatment of non-carious cervical lesions: A meta-analysis. Clin Oral Investig. 2018;22(2):617-31.
[13] Cunha-Cruz J, Zeola LF. Limited evidence suggests that many types of desensitising toothpaste may reduce dentin hypersensitivity, but not the ones with strontium or amorphous calcium phosphate. J Evid Based Dent Pract. 2019;19(4):101337.
[14] Hu ML, Zheng G, Zhang YD, Yan X, Li XC, Lin H. Effect of desensitising toothpastes on dentine hypersensitivity: A systematic review and meta-analysis. J Dent. 2018;75:12-21.
[15] de Oliveira RP, Alencar CM, Silva FA, Magno MB, Maia LC, Silva CM. Effect of desensitising agents on dentin hypersensitivity after non-surgical periodontal therapy: A systematic review and meta-analysis. J Dent. 2020;103:103498.
[16] Zhou K, Liu Q, Yu X, Zeng X. Laser therapy versus topical desensitising agents in the management of dentine hypersensitivity: A meta-analysis. Oral Dis. 2021;27(3):422-30.
[17] Lee BS, Kang SH, Wang YL, Lin FH, Lin CP. In vitro study of dentinal tubule occlusion with sol-gel DP-bioglass for treatment of dentin hypersensitivity. Dent Mater J. 2007;26(1):52-61.
[18] Wang Z, Jiang T, Sauro S, Pashley DH, Toledano M, Osorio R, et al. The dentine remineralisation activity of a desensitising bioactive glass-containing toothpaste: an in vitro study. Aust Dent J. 2011;56(4):372-81.
[19] Pinheiro HB, Lopes B, Klautau EB, Cardoso J, Silva BR, Cardoso PEC. Influence of bioactive materials used on the dentin surface whitened with carbamide peroxide 16%. Mat Res. 2010;13(2):273-78.
[20] Zhu M, Li J, Chen B, Mei L, Yao L, Tian J, et al. The effect of calcium sodium phosphosilicate on dentin hypersensitivity: A systematic review and meta-analysis. PloS One. 2015;10(11):e0140176.
[21] Andersson ÖH, Kangasniemi I. Calcium phosphate formation at the surface of bioactive glass in vitro. J Biomed Mater Res. 1991;25(8):1019-30.
[22] Neuhaus KW, Milleman JL, Milleman KR, Mongiello KA, Simonton TC, Clark CE, et al. Effectiveness of a calcium sodium phosphosilicate containing prophylaxis paste in reducing dentine hypersensitivity immediately and 4 weeks after a single application: A double-blind randomised controlled trial. J Clin Periodontol. 2013;40(4):349-57.
[23] Milleman JL, Milleman KR, Clark CE, Mongiello KA, Simonton TC, Proskin HM. NUPRO sensodyne prophylaxis paste with novamin for the treatment of dentin hypersensitivity: A 4-week clinical study. Am J Dent. 2012;25(5):262-68.
[24] Pepelassi E, Rahiotis C, Peponi E, Kakaboura A, Vrotsos I. Effectiveness of an in-office arginine-calcium carbonate paste on dentine hypersensitivity in periodontitis patients: A double-blind, randomised controlled trial. J Clin Periodontol. 2015;42(1):37-45.
[25] Guentsch A, Seidler K, Nietzsche S, Hefti AF, Preshaw PM, Watts DC. Biomimetic mineralisation: Long-term observations in patients with dentin sensitivity. Dent Mater. 2012;28(4):457-64.
[26] Lopes AO, Eduardo Cde P, Aranha AC. Clinical evaluation of low-power laser and a desensitising agent on dentin hypersensitivity. Lasers Med Sci. 2015;30(2):823-29.
[27] Lopes AO, de Paula Eduardo C, Aranha ACC. Evaluation of different treatment protocols for dentin hypersensitivity: An 18-month randomised clinical trial. Lasers Med Sci. 2017;32(5):1023-30.
[28] Yilmaz NA, Ertas E, Orucoğlu H. Evaluation of five different desensitisers: A comparative dentin permeability and SEM investigation in vitro. Open Dent J. 2017;11:15-33.

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