

## **Blocking tubules technologies for dentin hypersensitivity in periodontal patients – pilot study**

**Eficácia das tecnologias de bloqueio dos tubos dentinários para tratamento da hipersensibilidade dentinária em pacientes periodontais – estudo piloto**

**Eficacia de las tecnologías de bloqueo de los túbulos para la hipersensibilidad dentinaria en pacientes periodontales - estudio piloto**

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### **Abstract**

Periodontal patients often report dentin hypersensitivity (DH) caused by root surface exposure or periodontal treatment. Tubular blocking technologies in toothpastes are effective for pain relief, but no specific chemical/physical agent has been reported for periodontal patients. This double-blind randomized clinical trial compared the effects of three technologies in reducing DH in periodontal patients. Eighteen (18) participants were randomly assigned into three groups: SEN (NOVAMIN technology); REG (REFIX technology); REGK (REFIX technology + potassium citrate). Periodontal patients presenting with DH were evaluated at 6 moments: T1 and T2 - immediately before and after scaling and root planing procedures (SRP); T3 - after polishing sensitive areas with their assigned dentifrice and T4, T5, T6 - after 2, 4 and 8 weeks of SRP respectively. Sensitivity was assessed by air blast (Schiff scale) and patients' perceptions using the visual analogue scale (VAS). Data were analyzed by two-way repeated measures ANOVA complemented by the Tukey test with significance set at 5% ( $p < 0.05$ ). Preliminary outcomes revealed SEN, REG and REGP reduced DH in periodontal patients ( $n=18$ ). All patients initially presented moderate to severe pain (64.3) and after treatment they reported mild pain (21.3). Similarly, the dentist evaluation showed significant reduction in DH with the use of the three technologies (2.26 to 0.56). No statistically significant differences were found between the three study groups for patients ( $p=0.751$ ) and dentist evaluations ( $p=0.632$ ). According to these preliminary outcomes, all three technologies equally reduced DH in periodontal patients. Clinical trials #NCT04422184

**Keywords:** Dentin hypersensitivity; Periodontal disease; Desensitizing agents.

## Resumo

Os pacientes periodontais frequentemente relatam hipersensibilidade dentinária (HD) causada pela exposição da superfície radicular ou tratamento periodontal. As tecnologias de bloqueio tubular em pastas de dentes são eficazes para o alívio da dor, mas nenhum agente químico/físico específico foi relatado para pacientes periodontais. Este ensaio clínico duplo-cego randomizado comparou os efeitos de três tecnologias na redução da DH em pacientes periodontais. Dezoito (18) participantes foram designados aleatoriamente em três grupos: SEN (tecnologia NOVAMIN); REG (tecnologia REFIX); REGK (tecnologia REFIX + citrato de potássio). Os pacientes periodontais que apresentavam DH foram avaliados em 6 momentos: T1 e T2 - imediatamente antes e depois dos procedimentos de escalonamento e aplainamento radicular (RAR); T3 - após o polimento das áreas sensíveis com seu dentífrico designado e T4, T5, T6 - após 2, 4 e 8 semanas de RAR, respectivamente. A sensibilidade foi avaliada pelo jato de ar (escala Schiff) e a percepção dos pacientes usando a escala visual analógica (VAS). Os dados foram analisados por medidas repetidas ANOVA de duas vias complementadas pelo teste de Tukey com significância definida em 5% ( $p < 0,05$ ). Os resultados preliminares revelaram SEN, REG e REGP reduzindo o DH em pacientes periodontais ( $n=18$ ). Todos os pacientes inicialmente apresentaram dor moderada a severa (64,3) e após o tratamento relataram dor leve (21,3). Da mesma forma, a avaliação dentária mostrou redução significativa da DH com o uso das três tecnologias (2,26 a 0,56). De acordo com estes resultados preliminares, todas as três tecnologias reduziram igualmente o DH em pacientes periodontais.

**Palavras-chave:** Hipersensibilidade dentinária; Doença periodontal; Agente dessensibilizante.

## Resumen

Los pacientes periodontales a menudo informan de hipersensibilidad a la dentina (HD) causada por la exposición de la superficie radicular o el tratamiento periodontal. Las tecnologías de bloqueo de tubos en los dentífricos son eficaces para el alivio del dolor, pero no se han descrito agentes químicos/físicos específicos para los pacientes periodontales. Este ensayo clínico aleatorio doble ciego comparó los efectos de tres tecnologías en la reducción de la EH en pacientes periodontales. Dieciocho participantes fueron asignados al azar en tres grupos: SEN (tecnología NOVAMIN); REG (tecnología REFIX); REGK (tecnología REFIX + citrato de potasio). Los pacientes periodontales que presentaban DH fueron evaluados en 6 momentos: T1 y T2 - inmediatamente antes y después de los procedimientos de raspado y alisado radicular (RAR); T3 - después de pulir las zonas sensibles con su dentífrico designado y T4, T5, T6 - después de 2, 4 y 8 semanas de RAR, respectivamente. La sensibilidad fue evaluada por el examinador encargado mediante el chorro de aire (escala de Schiff) y por la percepción del paciente mediante la escala visual analógica (EVA). Los datos se analizaron mediante un ANOVA de medidas repetidas de dos vías complementado por la prueba de Tukey con una significación del 5% ( $p < 0,05$ ). Todos los pacientes presentaban inicialmente un dolor de moderado a severo (64,3) y después del tratamiento refirieron un dolor leve (21,3). Asimismo, la evaluación del examinador mostró una reducción significativa de la EH con el uso de las tres tecnologías (de 2,26 a 0,56). Según estos resultados preliminares, las tres tecnologías redujeron por igual la EH en los pacientes periodontales.

**Palabras clave:** Hipersensibilidad dentinária; Enfermedad periodontal; Agentes dessensibilizantes.

## 1. Introduction

Dentin Hypersensitivity (DH) presents itself as short-duration acute pain caused by different tactile, chemical, thermal and osmotic stimuli, excluding other forms of dental pathologies (Patil, Naik & Suma, 2015; West, Seong & Davies, 2015; Amaechi et al., 2018; Van Loveren, 2013; Hu et al., 2018; Vilhena et al., 2020; Martins et al., 2020). The prevalence of DH varies from 3 to 57% in the general adult population (Splieth & Tachou, 2013; Cunha-Cruz et al., 2013; Miglani, Aggarwal & Ahuja, 2010) and in periodontal patients this value increases to 98% (Rosing et al., 2009).

Various dental procedures, including periodontal therapy could result in the occurrence of DH. Scaling and root planing with partial or total removal of cementum and/or root exposure as a consequence of periodontal disease progression could be linked to DH (Van Loveren, 2013).

Currently, two methods for DH treatment are described in the literature: interruption of the response to pain stimulus which decreases nerves excitability or through obliteration of the exposed dentinal tubules (Van Loveren, 2013; Hu et al., 2018; Vilhena et al., 2020; Martins et al., 2020).

DH treatment presenting less invasive and more conservative forms should be considered in the decision making process for product recommendations (Canadian Advisory Board on Dentin Hypersensitivity, 2003). With that in mind, dentifrices are viable options since they introduce components that act as desensitizers in an effective, inexpensive and easily accessible way (West, Seong & Davies, 2015; Van Loveren, 2013; Hu et al., 2018; Vilhena et al., 2020).

Among DH treatment compounds that are incorporated in dentifrices, potassium salts have been shown to be very effective (West, Seong & Davies, 2015; Martins et al., 2020). They have a depolarizing action on nerve fibers, reducing their excitability to the stimuli. Other important desensitizing compounds that act on the obliteration of dentinal tubules are: oxalates, Arginine, Hydroxyapatite, Bioglass and Silicon-based technologies (Patil, Naik & Suma, 2015; West, Seong & Davies, 2015; Amaechi et al., 2018; Van Loveren, 2013; Hu et al., 2018; Vilhena et al., 2020, Martins et al., 2020; Canadian Advisory Board on Dentin Hypersensitivity, 2003; Boneta et al., 2013; Hu et al., 2013, Amaechi & Van Loveren, 2013; Burwell, Litkowski & Greenspan, 2009). NOVAMIN® technology is extensively studied and indicated for HD, due to its obliterating property of dentinal tubules. The components in the mentioned technology are calcium and sodium phosphosilicate, which promote continuous remineralization (Lippert, 2013; Addy & Dowell, 1983).

Thus, this preliminary study compared the effect of three different technologies, NOVAMIN, REFIX and REFIX technology plus potassium citrate, in order to reduce DH in periodontal patients.

## 2. Methodology

This double-blind randomized clinical trial was approved by the Ethics Committee in Human Research (Protocol #3.325.186) and was conducted at the Periodontics Clinics of the Bauru School of Dentistry - University of São Paulo (FOB/USP). The study was registered on Clinicaltrials.gov (protocol #NCT04422184). The inclusion criteria were: patients diagnosed with periodontitis, ranging from 18 to 70 years old, healthy, without any allergy to the dentifrices components; patients who needed scaling and root planing procedures and who had at least 2 teeth with DH (incisors, canines or premolars). The exclusion criteria were: patients who were pregnant, in orthodontic treatment, who had oral tumors, caries, fractured teeth, suspected endodontic involvement or excessive mobility; patients who used medication that could mask the painful sensation or who had used desensitizing agents in the last 3 months.

After initial evaluation, patients received detailed information about possible causes of tooth root sensitivity. All selected patients received the dentifrices in packages with soft brush and dental floss. Experimental groups were divided in:

- SEN (Sensodyne Repair and Protect powered by NOVAMIN)-positive control group
- REG (Dentalclean Daily Regenerator powered by REFIX)
- REGK (Dentalclean Daily Regenerator powered by REFIX + potassium citrate).

Patients received verbal instructions for brushing, which should be performed twice a day (morning and evening) during one minute. All brushings were performed exclusively with the dentifrices determined for each experimental group. DH parameters were evaluated by one trained and calibrated examiner using a scale described by Schiff et al (1994). The sensitivity to air blast (triple syringe) was evaluated during one second at a distance of one centimeter from the tooth surface that presented the sensitivity. Adjacent teeth were prevented from receiving the air blast by placing the examiner's fingers on them. Air blast sensitivity evaluation presented with scores ranging from: 0 = Tooth/Subject does not show sensitivity in response to air stimulation; 1 = Tooth/Subject responds to air stimulus, but does not request discontinuation of stimulus; 2 = Tooth/Subject responds to air stimulus, and requests discontinuation or moves from stimulus; 3 = Tooth/Subject responds to stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus. Patient's perception of DH was also evaluated with a visual analogue scale (VAS), ranging from 0 being without any painful sensation to 100 being the most painful scenario. For the correct filling out of this scale by the patients, the examiner first instructed all in the same way. Immediately after the air blast, the examiner gave the scale for the patient to mark their sensitivity. Both professional and patient's parameters were evaluated at: T1 - immediately before scaling and root planing (SRP); T2 - immediately after SRP; T3 - after polishing sensitive areas with rubber cups and the dentifrice determined for each specific group of patients and T4, T5, T6 - after 2, 4 and 8 weeks of SRP

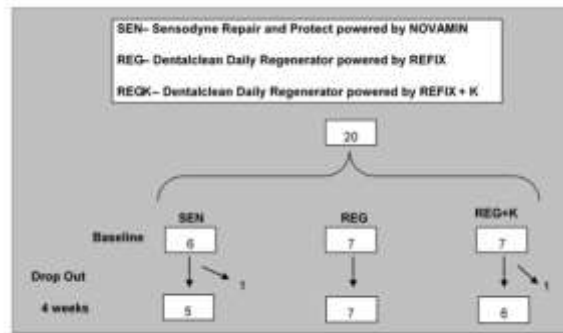
respectively. Patients were instructed to perform standard brushing exclusively with the dentifrice assigned to their group. These methodologies were based on the work of Docimo et al., (2009) and Hughes et al., (2010).

Mean values obtained from the evaluated teeth of each patient (professional and patient analysis) were calculated for the different periods (T1 to T6). The primary clinical outcome was the operator's assessment of sensitivity (Schiff scale). The secondary clinical outcome was patient-reported sensitivity. Data were analyzed by two-way repeated measures ANOVA complemented by Tukey test with the significance level set at 5% ( $p < 0.05$ ).

### 3. Results and Discussion

Preliminary outcomes demonstrated no statistical differences between groups for reduction in DH in the 18 periodontal patients (Figure 1), considering both evaluations done by the professional ( $p=0.632$ ) and the patient ( $p=0.751$ ).

**Figure 1** - Flowchart with preliminary sample size and drop-outs.



Source: Authors.

The professional evaluation showed a significant reduction in DH with the use of all three technologies (2.26 to 0.56) after T4 ( $p < 0.05$ ) (Figure 2). All patients initially presented moderate to severe pain (64.3) and after treatments reported mild pain (21.3).

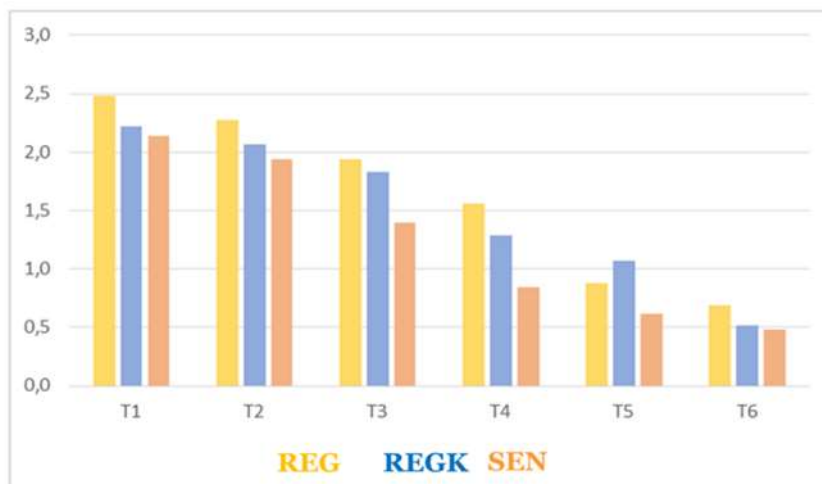
**Figure 2** - Professional evaluation in SEN, REG and REGK groups. REG group presented a DH mean of 2.5 at T1 and 0.7 at T6. REGK presented a DH mean of 2.2 at T1 and 0.5 at T6. SEN presented a DH mean of 2.1 at T1 and 0.5 at T6.



Source: Authors.

According to the VAS data, SEN and REG presented significant reductions in sensitivity on T4, T5 and T6 compared to T1 ( $p < 0.05$ ). REGK presented a statistically significant reduction ( $p < 0.05$ ) on T6 compared to T1 (Figure 3).

**Figure 3** – Patient perception for SEN, REG and REGK groups. REG presented a DH mean of 70 at T1 and 26 at T6. REGK presented a DH mean of 64 at T1 and 21 at T6. SEN presented a DH mean of 59 at T1 and 17 at T6.



Source: Authors.

Periodontal procedures are frequently associated with DH due to exposure of dentinal tubules after SRP or the presence of gingival recession associated with periodontal disease progression (Van Loveren, 2013; Vilhena et al., 2020). According to preliminary results of this study, all three dentifrices tested reduced the DH during periodontal treatment and maintenance. These outcomes are in accordance with the literature, which describes the significant decrease in DH when treated with specific dentifrices in daily brushing (Patil, Naik & Suma, 2015; West, Seong & Davies, 2015; Amaechi et al., 2018; Van Loveren, 2013; Hu et al., 2018; Vilhena et al., 2020; Boneta et al., 2013; Hu et al., 2013). One of the tested dentifrices contains the extensively documented NOVAMIN technology and was considered the positive control group. The active ingredient of this technology is calcium sodium phosphosilicate ('bioglass'), capable of promoting the obliteration of dentinal tubules. NOVAMIN could be considered a gold standard technology, since the mechanism of action is based on the release of Na, Ca and P ions in the oral environment. These elements when incorporated into the dentin structure, have been shown to promote the formation of a layer of hydroxyapatite similar to enamel (West, Seong & Davies, 2015; Amaechi et al., 2018; Hu et al., 2018; Martins et al., 2020; Amaechi & Van Loveren, 2013; Burwell, Litkowski & Greenspan, 2009; Lippert, 2013; Shen et al., 2018; Hench & Jones, 2015; Philip, 2019).

Through research progression, the development of new technologies showing satisfactory results can improve the quality of life for these patients with DH6. The new technology used in this study was REFIX, an innovation in dental regeneration. REFIX Dental Technology is an Acidified Bioactive Complex designed by an association of organic compounds and ingredients containing Silicon, Fluoride and Phosphates. During brushing, this innovative formula binds into the tooth, catching scattered particles in the oral environment, mainly calcium and this complex forms a protective hybrid layer containing Silicon-enriched Hydroxyapatite. This layer, a protective shield similar to the original enamel is able to re-mineralize the surface and subsurface of the dental enamel and protect against acid attacks. When the dentin is exposed, this shield forms over and within the dentin tubules in order to relieve the pain caused by tooth sensitivity (Vilhena et al., 2020; Tomaz et al., 2023). One of the experimental groups in this study, included REFIX technology with the incorporation of potassium salt (REGK), however the reduction of DH was similar to the other two groups. Effective results for this new product have been shown in other previous studies (Hu et al., 2018; Canadian Advisory Board on Dentin Hypersensitivity, 2003). In this study however, the K salt presented no improvement in the performance of REFIX technology. This is probably related to the prompt tubule obliteration action

provided by REFIX technology (Vilhena et al., 2020). Thus, the purpose of K salt in depolarizing nerve fibers did not improve the main action of dentinal tubules obliteration. However, these preliminary results could not define the possible benefit of incorporating K salt.

#### 4. Conclusion

One limitation of this pilot study is the sample size, but it is important to observe that the three tested technologies presented the ability to decrease DH in periodontal patients. Another limitation was the lack of a negative control for comparative evaluation but for ethical reasons, this group (placebo) was not included. Despite that, our methodology used NOVAMIN technology as a positive control for this comparison.

According to these preliminary outcomes, the three different technologies reduced DH equally in periodontal patients. Further investigation with a larger sample size is necessary to confirm these outcomes.

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