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Hypersensitivity Assessment of Non-Carious Cervical Lesions After Treatment with Different Desensitizing Protocols: A Randomized Clinical Trial

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ABSTRACT

Trial design This is a three-arm, parallel-group, randomized, controlled, superiority, double-blinded experiment with a 1:1:1 allocation ratio. Using the Visual Analogue Scale (VAS scale), this study compared the clinical efficacy of fluoride varnish and light-cured resin-based desensitizer and bioactive glass powder in treating dentin hypersensitivity (DH) in adults with cervical non-carious lesions over a six-month follow-up period. **Methods 75** individuals with non-carious cervical lesions (NCCL) who met the predefined inclusion and exclusion criteria were randomly assigned to one of three parallel groups (n=25) based on the treatment they received. Group 1 received fluoride varnish for their NCCL, Group 2 received "Sylc® dry powder" with the help of a "AquaCareTM Twin" air abrasion unit, and Group 3 received light-cured desensitizer agent SHIELD FORCE PLUS (Tokuyama). All participants had a pre-operative hypersensitivity test, and only those patients whose VAS score indicated a level of discomfort equal to or more than five were accepted into the study. Using an air blast with a standardized length and pressure, hypersensitivity was evaluated both immediately following treatment and three months later. The VAS's ordinal data were represented by median and range values. The Friedman test of repeated measures and the Mann Whitney U test were used for intragroup and intergroup comparisons, respectively. The significance criterion was set at $P \leq 0.05$ for each test. **Results** The application of fluoride varnish caused the considerably highest VAS, followed by the application of sylc powder air polishing and light-cured desensitizer. The overall effect of the three interventions revealed a statistically significant difference in the VAS score ($p<0.001$). Even while there was a notable statistically significant difference between the three interventions' baseline VAS scores within the two follow-up intervals, there was no statistically significant difference in the baseline records within each follow-up interval.

Conclusions and Clinical relevance. A quick and long-lasting solution for NCCL hypersensitivity is a light-cured desensitizing agent. Conversely, fluoride varnish remains an effective treatment for dentin hypersensitivity, but it is unreliable when used only once.

Keywords: *varnish, light-cured desensitizer, sensitivity, dentin sensitivity, dentin hypersensitivity, visual analog scale, VAS, sylc powder, sylc air polishing, bioactive glass, and randomized controlled study.*

INTRODUCTION

A common long-term condition that can be difficult to diagnose and treat is dentin hypersensitivity (DH). (1) (2) There are several steps that must be followed in order for dentin hypersensitivity (DH) to manifest; the first of them is lesion location, which exposes the dentin surface. (3) The mechanism of dentin hypersensitivity (DH) has been described by several ideas. (4)(5) The pulpo-dentinal junction's nerve terminals may then experience discomfort as a result. (6) Nevertheless, electron imaging revealed that the odontoblastic processes only reach between one-third and half of the dentinal tubule's length from the pulpal end. (7)(8)

Gysi initially proposed the hydrodynamic hypothesis in the nineteenth century without any supporting research, and it is currently the most frequently recognized theory. (9) This theory is still the most widely recognized and well-liked explanation to this day, having been validated by numerous research conducted over the past 20 years (10)(11). According to the hydrodynamic theory, there are two main approaches to treating dentin hypersensitivity (DH): either physically blocking the patent dentinal tubules, which can be accomplished in a number of ways, or preventing the sensory response of the nerve ends. (12) Many remineralizing agents were introduced with the intention of reducing sensitivity, as one of the therapeutic options involves blocking the dentinal tubules and preventing fluid migration. (13) Long-term success is ensured by materials that can chemically and physically attach to dentin, reducing the likelihood of dentinal tubules reopening. (14).

Bioactive glass, which was primarily developed to replace and repair human hard tissues, is another intriguing therapeutic option. (15) In an effort to prolong its desensitizing effect, researchers began to refine the substance and enhance its capacity to release minerals. (16) Sylc, a prophylactic powder based on air flow, is the most recent version of bioactive glass. Novamin was still the active component. In this state, it can create a mineral layer that is extremely robust, acid-resistant, and biologically stable. When this layer reacts with saliva, it can continuously release calcium and phosphate ions, providing dentinal tubules with protection and sealing for an extended period of time. (17). Dentin sealers are an additional therapy option. Dentinal tubules can be penetrated by the light-cured single component TOKUYAMA® SHIELD FORCE PLUS, which can then polymerize in situ to physically plug the tubules and provide instant relief from dentin hypersensitivity. (18)(19)(20).This study investigated various approaches to treating dentin hypersensitivity that may be effective in controlling pain and boosting patient acceptability and motivation to follow recommended treatment guidelines. Over the course of three months of research utilizing the Visual Analog Scale (VAS), the null hypothesis is that there is no difference in the hypersensitivity treatment of non-cancerous cervical lesions by fluoride varnish, air polishing, bioactive glass, and light-cured dentin sealer.

Materials and Methods

Materials:

The following materials were used in this study:

Fluoride varnish: BiFluorid 10 (Voco, Germany).

Bioactive Glass powder: Sylc® original Stain Removal (SR) (DENFOTEX Research Ltd., UK).

Light cured resin-based desensitizer: Shield force plus® (Tokuyama, Japan).

Devices:

The following devices were used in this study:

AquaCare™ Twin: Air abrasion and polishing unit.

Elipar™ Deep Cure- L: LED curing light unit.

Methods:

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement was adhered to in the conduct of this randomized controlled clinical trial.The Research Ethical Committee (REC) of Suez Canal University's Faculty of Dentistry gave its approval to this study.

Patients and teeth selection

This study comprised 75 patients who were between the ages of 18 and 40. Every patient signed a consent form, agreed to participate, and was made aware of the purpose of the study. The following inclusion and exclusion criteria were applied when enrolling patients and examining teeth:

Inclusion criteria of participants:

Cooperative patients complaining of spontaneous hypersensitivity of both genders with age range 18 to 30 years having good oral hygiene.

Exclusion criteria of participants:

Patients with Systemic disease, Pregnant females, Patients who are allergic to any ingredients used in the study and Patients who did any periodontal surgeries within the previous 6 months.

Inclusion criteria of teeth:

Non carious cervical lesions with DH, VAS >5.

Exclusion criteria of teeth:

Carious or Chipped teeth and teeth with mobility Grade 2 or 3.

Participant timeline:

Clinical procedures were carried out at two visits.

First visit:

Application of desensitizer agent, hypersensitivity baseline assessment (immediate records).

Second visit:

At which the three months hypersensitivity assessment was done.

Sample size calculation:

This study aimed to evaluate the effectiveness of light-cured desensitizing agent, fluoride varnish, and Sylc air polishing bioactive glass technology in treating hypersensitivity of non-cancerous cervical lesions. Ritter et al. (2006) projected that the difference in VAS scores would be 7±5. We had to look at 17 subjects per group with an 80% power and a 5% significance threshold. This figure was increased to 20 in each group to allow for non-parametric errors and to 25 in each group to account for possible losses during follow-up. The sample size was determined using the PS: Power and Sample Size Calculation Software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA).

Recruitment:

Following an explanation of the advantages and disadvantages of applying the intervention and control, patients who met the eligibility requirements based on participant timeline and tooth inclusion and exclusion criteria were gathered from the clinic of the operative dentistry department at Suez Canal University's Faculty of Dentistry.

Diagnosis:

After identifying the patients who would be eligible for this study, the researcher got in touch with them to describe the study and gauge their interest, and they signed a written consent form. The clinical examination, which was tentatively conducted led to the diagnosis of hypersensitivity. Following diagnosis confirmation, the patient was added to the trial.

Sample grouping:

After meeting the inclusion criteria, 75 patients were added to the trial. A tooth of complaint that met the inclusion criteria was chosen for each patient, for a total of 75 teeth included. Based on the treatment used, teeth were divided into three groups. Patients in group 1 were randomized at random to the fluoride varnish group, those in group 2 to the air abrasion with bioactive glass group, and those in group 3 to the light-cured desensitizer group. Sensitivity tests were performed on each patient using a visual analog scale both immediately following application and three months later.

Sequence generation:

Using the Random Sequence Generator, simple randomization was carried out by creating numbers starting at 1:75.

Implementation:

The allocation sequence was carried out by a dentist who was not the primary researcher, and the tooth was assigned to either light-cured desensitizer, bioactive glass, or fluoride varnish.

Allocation concealment mechanism:

This was accomplished by giving each patient instructions to select an envelope at random from a box that had several opaque, sealed envelopes. According to the allocation sequence created, each envelope contains a numbered piece of paper that matches one of the available treatment possibilities.

Blinding:

Since the primary operator was in charge of implementing the intervention and control, it was not practicable to blind the operator. However, the assistant colleague who was blinded to the treatment regimen was the one who performed the hypersensitivity test. Additionally, a statistician evaluated the therapy outcomes in a blind manner.

Baseline preoperative data collection:

The operator filled out medical, dental, and examination records for each patient. Patients were only enrolled using their serial numbers, which are the initial letter of their first and last names and their birthdate. A controlled air stimulus was applied perpendicular to the exposed surface using a triple airway syringe set at 40–65 psi and 1 cm away. A pre-measured plastic micro-brush (1 cm) was affixed to the nozzle tip using duct tape in order to guarantee uniform distance and angulation. The VAS scale, a graduated plastic card with facial expressions (0–10), was used to help the patient communicate the level of discomfort. Patients were only included in the trial if their reported level of pain was at least five.

Fluoride varnish group

In order to guarantee uniformity in the quantity of fluoride varnish applied, the manufacturer recommended the use of Bifluorid 10 (VOCO). Using a polishing brush and no paste, the designated tooth was completely cleaned, and its surface was allowed to air dry. Bifluorid 10 (by VOCO) in single dose form was utilized. The microbrush was used to apply a thin layer to the tooth's surface. Using a dental syringe, the varnish was allowed to air dry for 10–20 seconds.

Bioactive glass (Sylc) group

Dentin hypersensitivity was treated and polished using commercially available Sylc® dry powder (calcium sodium phosphosilicate), which is based on NovaMin. The sensitive areas were treated with Sylc® dry powder (calcium sodium phosphosilicate) using a "AquaCareTM Twin" air abrasion equipment (Velopex International, UK). The air stream was set between 40 and 46 psi per the manufacturer's recommendations. With 60–80 degrees on the buccal surfaces, the hand piece was held at a consistent distance (3–4 mm) from the tooth surface. The powder was applied in a circular motion for 5–10 seconds per tooth.

Shield Force group

To treat hypersensitive dentin, SHIELD FORCE PLUS (Tokuyama), a single-component, single-application, light-cured protective sealant, was applied. Following a 5-second air drying period and using a microbrush (Microbrush International, USA), the Shield force plus was applied to every dentinal surface in accordance with the manufacturer's recommendations. The sealant was applied in a single coat and rubbed for 20 seconds. Five seconds of gentle air thinning were then performed. Following additional five seconds of strong air application per the manufacturer's directions, the material was light cured for ten seconds using an LED curing lamp.

Hypersensitivity assessment:

The Visual Analog Scale (VAS) was used to assess sensitivity both before and after surgery. With a descriptor at the far left end signifying no pain and at the far right signifying the worst agony possible, it is a horizontal line with a grade of 1 to 10. Color-coded facial expression illustrations were placed beneath the Visual Analog Scale's 10-centimeter line.

Base line assessment:

The baseline record was assessed twice before to treatment. The original technique used a sterile metal triple-way syringe. The stimulus was stopped as soon as the patient complained of pain, and the level of pain was noted. The second approach involved the use of Sharp Explorer. The participants used the following VAS scale to score their level of pain: they marked at the far-left end of the line if they had no pain at all, and at the far-right end if they had the worst pain possible.

Immediate assessment:

The sensitivity was evaluated using the same methodology as described in the baseline evaluation after three minutes of desensitizer application.

Three months assessment:

Three months later, using the same procedure as described in the baseline assessment, the patient was brought back for a sensitivity evaluation.

Statistical analysis:

The median and range values were used to represent ordinal data from the visual analogue scale (VAS). The Mann Whitney U test was used for intergroup comparisons, and the Friedman test of repeated measures and Wilcoxon signed ranks test with p-value modification using Bonferroni correction were used for intragroup comparisons. For every test, the significance level was set at $P \leq 0.05$. IBM® (IBM Corporation, NY, USA) SPSS (SPSS, Inc., an IBM Company) ® Statistics Version 25 for Windows was used to conduct the statistical analysis.

Results

Regarding the evaporative test, there was a statistically significant difference in VAS between intervention groups ($p<0.001$). **Fluoride varnish application** produced the significantly highest VAS, followed by **Sylc powder air polishing,** then **light-cured desensitizer application.** While for the tactile test, The difference in VAS between the intervention groups was statistically significant ($p<0.001$). The VAS from applying fluoride varnish was statistically comparable to that from applying Sylc powder air polishing. The use of light-cured desensitizer, however, demonstrated the noticeably lowest VAS.

Discussion

Many of the standards for treating dentin hypersensitivity (DH) that Grossman set down in 1935 are still applicable today. By blocking the dentinal tubules, fluoride varnish reduces dentin hypersensitivity through one of its main modes of action. Calcium fluoride (CaF) and sodium fluoride (NaF) are both present in the dental varnish Bifluorid 10. In the high calcium environment of dentinal fluid and saliva, the NaF dissociates, producing fluoride ions (F-). In order to clog the tubules and lessen dentin hypersensitivity, these F-ions diffuse into the dentinal tubules and precipitate as CaF by forming a semi-permanent barrier. (21) Bioactive glass is a successful treatment for dentin hypersensitivity. (22) Because of this, it is perfect for blocking dentinal tubules and lessening tooth sensitivity. Dentin hypersensitivity is increasingly being treated using air-polishing devices. These powders have two purposes: they desensitise and polish teeth. (23) Sylc powder is one of these newly created powders.Hydroxycarbonate apatite (HCA), a mineral that closely resembles the mineral present in teeth naturally, is formed when saliva and sylc mix. Sylc bioactive glass has been shown to significantly reduce dentin permeability when air-polished and used as a prophylactic toothpaste with a dental rubber cup. (24). Light-cured desensitizing agents are another well-known method of treating dentin hypersensitivity. Shield Force Plus is a light-cured desensitizer made of just one ingredient. The exposed dentin is covered with it, and it is light-cured for 20 seconds. After that, the resin creates a barrier of defense over the dentin, preventing sensitivity and obstructing fluid movement via the dentinal tubules. This layer serves to stop fluid passage through the dentinal tubules and shields the dentin from additional abrasion and degradation (25).

As advised by clinical trial standards, dentin hypersensitivity was evaluated in this investigation using the Visual Analog Scale (VAS). (26) The tactile stimulus caused less frequent and less intense discomfort than the evaporative stimulus. Each assessment period yielded nearly identical responses to the evaporative stimuli. Tactile stimulation caused the least degree of pain because it had less of an effect on the flow of peri-odontoblastic fluid. Evaporative stimuli increase pain because they directly encourage fluid flow, which affects odontoblast cells and the neural plexus. The findings of (Fiocchi, Moretti et al. 2007, da Rosa, Lund et al. 2013, Madruga, Silva et al. 2017) are in line with this. (27)(28)(29)

The findings of this clinical study didn't support the null hypothesis that there would be no difference between the different protocols employed to treat dentin hypersensitivity. Within each follow-up period: both interventions were almost identical at the baseline and three minutes. The VAS of the intervention groups differed statistically significantly after 3 months. The application of fluoride varnish yielded the highest results, followed by air polishing with Sylc powder and light-cured desensitizer. Regarding baseline records, there was no statistically significant difference between intervention groups for various therapies and follow-up intervals for evaporative. Sylc powder air polishing had the greatest VAS after three minutes, followed by the application of fluoride varnish and light-cured desensitizer. The difference between the intervention groups was statistically significant after three months. The application of fluoride varnish had the considerably greatest VAS, whereas the applications of light-cured desensitizer and Sylc powder air polishing produced statistically comparable VAS. Since the high-pressure air stream may make the application more forceful and irregular, obstructing some dentinal tubules while opening others, Sylc's effects may be tied to how it is administered. Dentinal tubules are largely obliterated by the slow chemical reaction of the bioactive glass, leaving the dentin hypersensitivity treatment incomplete. However, at three months, the median Sylc powder readings were nil, suggesting that dentin hypersensitivity was successfully and sustainably treated. This is most likely due to the Novamin base found in Sylc powder. Together with Ca2+ and PO43- ions from Novamin, salivary mineral ions can create a calcium phosphate (Ca-P) layer inside tubules or on dentin surfaces. The result is physical tubule blockage**.** Bioactive glasses have been associated with the development of a hydroxycarbonate apatite layer on their surfaces in addition to their mechanical blockage of dentinal tubules. Bioactive glass powder, which mechanically and chemically kills most dentinal tubules, may be responsible for this result. (30)

The production of calcium fluoride (CaF2) crystals on the dentinal tubule openings as a result of the reaction between fluoride (F-) and calcium ions (Ca2+) in dentinal fluid can be used to explain the slow action of fluoride varnish. One application of fluoride varnish would not be sufficient to decrease the diameter of dentinal tubules because CaF2 has a crystal size of just 0.05 micrometers. Consequently, multiple applications are needed to achieve a discernible occlusive effect. Furthermore, the incapacity of the CaF2 and fluoroapatite compounds to maintain dentinal tubule occlusion may also be the reason of the progressive loss of efficacy. This could be the consequence of tooth brushing abrasion or acidic challenges from erosive beverages throughout the follow-up periods. In conclusion, the gradual action and short duration of fluoride varnish's efficacy are likely caused by a number of factors, including the small size of CaF2 crystals, the potential for occlusive layer abrasion or erosion, and the need for multiple applications to achieve a significant occlusive effect.

Calcium fluoride is deposited on the surface of teeth as a result of the gradual process of fluorapatite production. During the first two weeks of treatment, fluoride is released because fluoride varnish operates consistently. As demonstrated by the study's early results, this may reduce hypersensitivity. This mineral has the ability to fully seal dental tubules, obliterate dentinal tubules, and encourage the deposition of reparative dentin. However, the short-term effects of fluoride varnish could be due to the removal of the CaF2 barrier due to salivary dissolution.

According to earlier research (Collaert and Fischer 1991, Gaffar 1998, Ritter, de Dias et al. 2006, Cummins 2009, Abdelwahed, Temirek et al. 2019, Favaro Zeola, Soares et al. 2019, Sivaramakrishnan and Sridharan 2019), topical fluoride applications are very helpful in treating dentin hypersensitivity, but they are not a permanent solution. These results are in line with those of those studies. (31)(32)(33)(34)(35)(36)(37). Jalaluddin & Almalki's (2019) findings do not align with ours. (38). However, considering that they used a laser in conjunction with sodium fluoride, this makes sense. The laser may have improved the effects of sodium fluoride by enhancing its bio-modulatory actions and reducing inflammation and discomfort. Lasers can potentially block dentinal tubules by melting the dentin at the tubule apertures. During subsequent follow-up periods, VAS values significantly decreased in relation to the application of light-cured desensitizer. The VAS values at three minutes and three months were statistically equivalent, however the baseline records had the noticeably highest VAS values. The apparent decrease in dentin hypersensitivity brought on by shield force is due to the presence of resinous desensitizing chemicals. Dentinal tubule obstruction is the outcome of this reaction. Additionally, it was determined that the application of Shield Force occluded the tubules, creating a smoother, softer surface that was more consistent with the topography of the tubules at the time of application. This was demonstrated by Shield Force-treated scanning electron microscopy experimentsThese results align with those reported by Nomura et al. (2013) (39). This is attributed to the sealing ability of Shield Force. Our results concur with those of Gazhva et al. (2017), Bharath et al. (2016), and Gazhva et al. (2018).(40) (41) (42) This is explained by the way Shield Force works. Tokuyama Shield Force Plus is thought to work through a double-block effect. In the afflicted area, the adhesive monomer (3D-SR monomer) in Shield Force Plus reacts with the calcium in the tooth material. The reaction product builds up in the dentinal tubules as well as on the coated surface.

Our results do not support those of Ashari et al. (2021). (43) This can be explained by the fact that Ashari et al. used a laser in conjunction with sodium fluoride varnish. The laser may have occluded the tubules and intensified the effects of sodium fluoride varnish because it melted the dentin at the tubule openings. Low-level lasers improve dentin hypersensitivity (DH) by influencing nerve terminals and promoting cell division and proliferation.

The quantity and technique of applying minerals have an impact on the depth of dentinal tubule occlusion as well. A deeper occlusion depth is expected with long-term applications of nano-scaled bioactive glass, such as those pastes used with trays at home. (44)(45)(46). Numerous of these minerals were available at the exposed surface thanks to the use of an air polishing delivery system. Furthermore, it's possible that the air pressure contributed to the deep penetration of these nanoscale particles into the dentinal tubules that offers better efficacy and durability. Moreover, the application of bioactive glasses (BGs) may raise the local pH, which could also supply the necessary alkaline environment for this process. The calcium phosphate layer eventually crystallizes into hydroxycarbonate apatite (HCA), which is structurally and chemically similar to biological apatite as a result of the ongoing reactions and Ca-P complex deposition. (47)(48)(49)

Conclusions and Recommendations

Conclusions:

The present study's limitations allow for the derivation of the following conclusions.
1. A very effective and long-lasting treatment for dentin hypersensitivity is bioactive glass.
2. A light-cured desensitizing agent is a quick and long-lasting way to treat hypersensitivity, offering both immediate comfort and long-lasting protection.
3. Although fluoride varnish is still thought to be an effective treatment for dentin hypersensitivity, it is not dependable when used only once.

Recommendations:

1. Dental school curricula must include patient education on preventing known causes of hypersensitivity.
2. To evaluate various short- and long-term therapy strategies for dentin hypersensitivity, more research is neede.

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