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Efficacy of fluoride varnish containing xylitol coated calcium phosphate or potassium nitrate gel versus conventional fluoride varnish in management of hypersensitivity of exposed root surfaces in adult patients: A randomized clinical trial

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***Abstract*---**Objective: This clinical trial was conducted to compare the efficacy of fluoride varnish containing xylitol coated calcium and phosphate or potassium nitrate gel versus conventional fluoride varnish in the management of hypersensitivity of non-carious exposed root surfaces in adult patients. Material and Methods: 35 patients having 105 hypersensitive teeth were randomly allocated to be treated either using Embrace varnish (PULPDENT Corporation, Watertown, MA, USA) or UltraEz gel (Ultradent Products Inc. South Jordan, UT, USA) or Fluoride varnish FluoroDose (Centrix Inc., Milford, Connecticut, USA), all agents were used according to the manufacturers' instructions. Hypersensitivity scores were assessed using the visual analogue scale (VAS), after applying different stimuli.

The assessment was done at baseline, after 4 hours of application, after two days, then after 4, 8 and 12 months. Results: UltraEZ gel showed the best immediate relief with a significant difference from other treatment methods, fluoride varnish showed the best relief at both short and long term follow up periods. Embrace varnish showed the least success in reducing hypersensitivity. Conclusions: Fluoride varnish showed the best reduction in hypersensitivity values while UltraEZ showed the best immediate relief and Embrace varnish showed the least efficacy

***Keywords*---**Hypersensitivity, Embrace varnish ™, Ultra EZ™ gel, Potassium nitrate, Fluoride varnish, FluoroDose™, Exposed roots.

Introduction

The exposed root surfaces are considered a well-recognized consequence of periodontal problems because of gingival recession. Various factors may cause the gingival recession, as trauma from tooth brushing, teeth malposition, thin mucosa covering the root and due to muscle pull. Some iatrogenic factors may increase gingival recession such as periodontal therapy or orthodontic tooth movement. [1, 2]

Dentinal hypersensitivity may be presented by the patients differently ranging from a minor inconvenience to disturbing pain affecting their life quality, also the treatment modalities are considered a challenge to dental practitioners with low success rates in relieving the pain which is characterized by being localized or generalized ranging from a single tooth to many teeth surfaces and pain usually disappears after the removal of the stimulus. [3]

Management of dentin hypersensitivity could be accomplished through two main strategies either dentinal tubule occlusion or reducing nerve excitability [4]. Previous studies demonstrated the benefits of using potassium nitrate as a desensitizing agent. Potassium nitrate was approved by American Dental Association (ADA) in 1986. The mechanism of action mainly depends on the active ingredient of potassium cations, which is concentrated in the dentinal tubules, leading to depolarization of the nerve terminals allowing a period of reduced sensitivity [4]

Different desensitizers and fluoride-containing materials showed potential capabilities to cause a partial or total blockage of dentinal tubules causing the reduction in hypersensitivity The tubule occlusion concept is considered a rational conclusion according to the hydrodynamic theory. [5]

The main mechanism of fluoride in reducing hypersensitivity is its ability to block and decrease dentinal fluid movement by the deposition of calcium fluoride and forming fluorapatite crystals. [5] Nowadays, several desensitizing materials act by that mechanism of action. Their effectiveness is greatly affected by their ability to withstand the mechanical and chemical challenges found in the oral environment. Calcium phosphate compounds are very promising modalities of treatment

because of their remineralization capacities and their high biocompatibility. Currently, there are various calcium phosphate-containing materials available on the market, but only a few data are evaluating their efficacy to treat hypersensitivity. [6]

EMBRACE™ Varnish is a resin-based varnish, as the manufacturer claims it can reduce dentin hypersensitivity by providing sustained release of fluoride as well as calcium and phosphate ions. The calcium and phosphate salts are bioavailable and nano-coated with xylitol, upon exposure to saliva the xylitol coat is dissolved causing the release of the calcium and phosphate ions, which can react constantly with fluoride ions forming protective fluorapatite deposits on the exposed tooth surface, thus decreasing hypersensitivity.[7]

The null hypothesis stated that there was no difference in the management of hypersensitivity between fluoride varnish containing xylitol coated calcium and phosphate or potassium nitrate gel and conventional fluoride varnish.

Materials and Methods

Materials' specifications, composition, and manufacturers are represented in Table 1.

Table (1): Materials' specifications, composition, manufacturers:

Material	Specifications	Composition	Manufacturer
Embrace Varnish	**5% Naf with CXP™ Xylitol-coated Calcium and Phosphate**	**Hydrogenated rosin < 35%, ethanol< 20%, sodium fluoride 5%, amorphous fumed silica< 3%, xylitol-coated Calcium and Phosphate**	**PULPDENT Corporation Watertown, MA, USA www.pulpdent.com/embrace-varnish**

UltraEZ gel	**Potassium nitrate and fluoride gel**	**Glycerine<80%, potassium Nitrate≤3%, sodium hydroxide≤2.5%, sodium fluoride 0.25%**	**Ultradent Products Inc. South Jordan, UT, USA www.ultradent.com/products/categories/whitening/desensitizing-gel/ultraez**
FluoroDose	**Resin-based varnish in ethanol carrier with 5% Sodium Fluoride and Xylitol**	**Rosin 50-70% ethanol 10-30%, sodium fluoride 1-10%**	**Centrix Inc., Milford, Connecticut, USA www.centrixdental.com/fluorodose.html**

Study Design

The trial design is a randomized, three parallel arms clinical trial held in the outpatient clinic of the Conservative Dentistry Department – Faculty of Dentistry, Cairo University. This clinical trial was conducted to evaluate the efficacy of fluoride varnish containing xylitol coated calcium and phosphate or potassium nitrate gel compared to sodium fluoride varnish in the treatment of hypersensitivity of non-carious exposed root surfaces in adult patients over a 12-month period.

Study setting and population

Patients were recruited for this clinical trial from the clinic of the Conservative Dentistry Department at the Faculty of Dentistry, Cairo University, from which eligible patients were recruited to fulfil the eligibility criteria one week before intervention.

Inclusion and exclusion criteria

The inclusion criteria for patients were males or females of age ranging from 20-50 years old and having exposed non-carious root surface with hypersensitivity

VAS >5. Patients with physical disabilities, pregnant or lactating women and patients who did any periodontal surgeries within the previous 6 months or who were allergic to any ingredients used in the study were excluded. Also, teeth with hypersensitivity VAS <5, carious or mobile (Grade 2 or Grade 3) were excluded from the current study.

Sample size calculation

The sample size was calculated using Power and Sample (PS) Software, version 3.1.2 for windows (Vanderbilt University, Nashville, Tennessee, USA) using an independent t-test. The sample size was calculated to be 35 per group to be able to reject the null hypothesis with a probability (power) of 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

35 patients having 105 teeth with dentin hypersensitivity were included in the present study. The participants' flow in the current trial is shown in the CONSORT flow diagram (**Figure 1)**.

Randomization, blinding, and allocation concealment

An independent researcher randomized the participants to either Embrace varnish group or Potassium nitrate gel or fluoride varnish group with 1:1 allocation ratio by a computer-generated randomization list (www.random.org) and made sequentially numbered opaque sealed envelopes indicating each of the intervention groups according to the random list number, after that each participant chose and sign a sequentially numbered opaque sealed envelope and allocated to the assigned group accordingly.

This study was a double-blinded study, the participants, as well as the assessors, were blinded. Outcome assessors and analysts were blinded to the intervention group assigned to the patients also the participants were blinded from knowing the material used. The operator was not blinded to apply both interventions following the manufacturer's instructions.

Trial Registration

This clinical trial was registered on www.clinicaltrials.gov with a unique identification number (NCT04472182). The protocol of the current study was reviewed and approved by Research Ethics Committee at the Faculty of Dentistry, Cairo University with reference number (19-7-47). The study type was a randomized clinical trial with parallel groups, a superiority framework and a 1:1 allocation ratio following CONSORT 2010 guidelines for reporting of clinical trials.

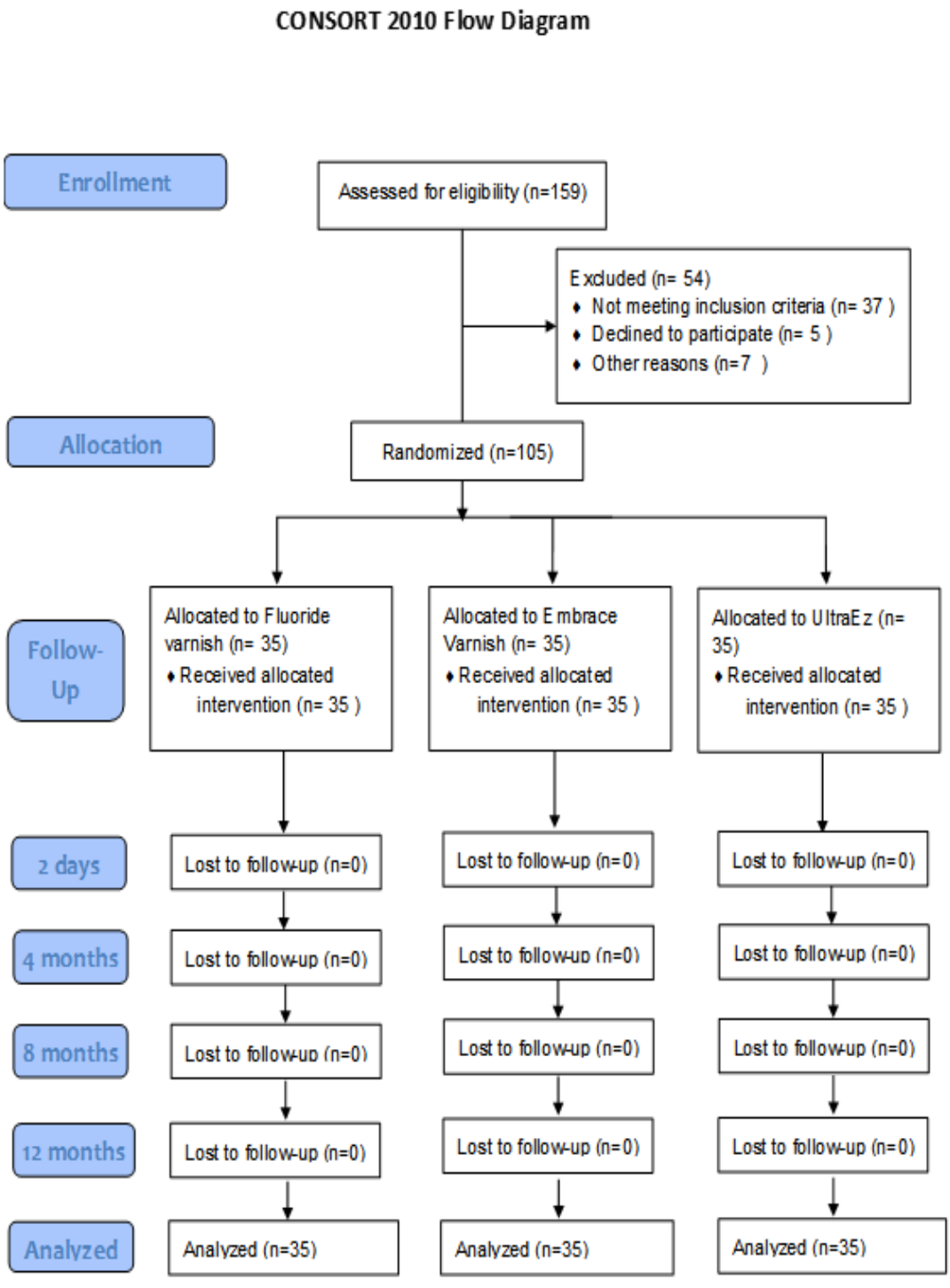

Figure (1): Consort Flow Diagram

Clinical procedures:

Assessors' training and calibration:

Two assessors with at least 10 years of experience in the field of Conservative Dentistry and Cariology (M.A.E and A.H.I) were trained and calibrated to use VAS for hypersensitivity assessment method on patients 2 weeks prior to the beginning of the study. Some patients were recruited and assessed multiple times by both assessors independently till reaching a satisfactory calibration. The calibration process was very important to ensure that they record clinical observations in a similar way.[8]

Pre-operative examination procedure:

A controlled air stimulus was applied to the offending tooth using triple way syringe with adjusted pressure of 50 psi directed perpendicular at a distance 3 mm from the exposed root surface. The distance was fixed using a tongue depressor taped to the air-water tip at the required distance and its end gently touching the root surface.

The patient should point out the degree of sensitivity on the VAS scale. A plastic card with figures of facial expressions denoting the degree of pain. Color coding and numbers were used to ease the process of figuring out the degree of pain. (**Figure 2)** These cards were useful in standardizing the assessment method for the patient throughout the study and taking records without any verbal or emotional guidance from the assessors.

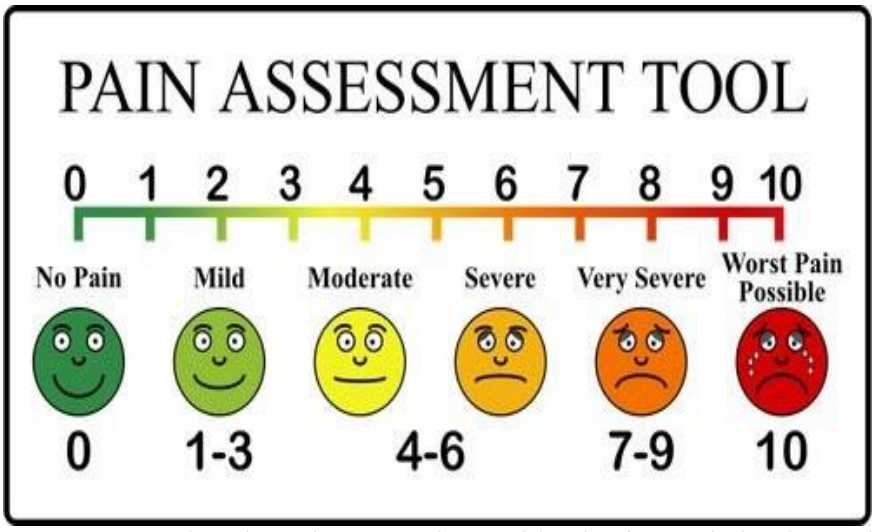

Figure (2): Visual Analogue Scale used in the form of plastic card

Application of desensitizing agents:

Embrace™ Varnish (5% sodium fluoride with CXP™)

According to the manufacturer's instructions, the tooth and root surface were cleaned using prophylaxis paste using a low-speed handpiece and rubber cup, then dried off with a gauze pad; after that, the varnish was dispensed from the tube on a pad, and a brush was used to apply a very thin layer of varnish on the desired root surfaces. The patients were instructed to refrain from eating hard foods or drinking hot liquids or alcohol for 3-4 hours after treatment and instructed not to brush their teeth for at least four hours.

UltraEZ™ gel (3% potassium nitrate, 0.11% by-weight fluoride)

The tooth and root surface were cleaned using prophylaxis paste, then dried off with a gauze pad, then the gel prefilled tray was placed in the patient's mouth, covering the root surface, and added gel was applied to the uncovered root surface using the gel syringe and left for 40 min according to the manufacturer's instructions.

FluoroDose® (5% sodium fluoride varnish):

Following the manufacturer's instructions, the tooth and root surface were cleaned using prophylaxis paste, then dried off with a gauze pad then a thin film of the varnish was applied onto the treatment area using a brush. Patients were advised to remain on a soft food diet and only drink cold fluids for two hours after treatment and not to brush for a minimum of 4 hours.

Dentin hypersensitivity assessment methods:

Dentin hypersensitivity was elicited using evaporative, thermal and tactile stimuli. The evaporative stimulus was applied on the offending tooth using a triple way syringe with adjusted pressure of 50 psi directed perpendicular at a distance of 3 mm from the exposed root surface. The duration of the air blast ranged from 1-5 seconds according to the patient's response. As soon as the patient reported pain, the stimulus was stopped, and pain intensity was recorded; if no response was recorded after 5 seconds, a total absence of pain was concluded. Thermal stimulation response was assessed using Refrigerant spray (Endo Frost, Roeko, Coltène/Whaledent, Germany). A sponge with a diameter of about 2-3 mm was applied using a carrier and placed in contact with the tooth surface for a maximum of 5 seconds. The sponge was removed as soon as the patient-reported sensitivity and then recorded on the VAS card; if no response was recorded after 3 seconds, total relief was concluded.

For tactile stimulus**,** the tip of sharp explorer No.3 (Hu-Friedy, Chicago, IL) was used to gently scratch the entire exposed root surface in an apico-coronal direction with short strokes. The height of the stroke varied as to the height area of sensitivity. The force applied with the stroke was standardized as a single operator examined all participants. Patients were immediately asked to report the grade of pain response on the Visual Analogue Scale (VAS card) [9]. After each test, the patient should point out the pain score on the plastic card used with VAS presented; this score was recorded in the patient's chart of follow-ups. There was a minimum of 5 min delay between the end of each assessment of hypersensitivity and the beginning of the following evaluation to allow the tooth to recover.[10]

Data collection:

Baseline data and scores were collected through medical and dental history sheets.After interventions, follow-up scores were recorded by the outcome assessors and all scores were inserted electronically in a Microsoft Excel sheet file and then coded and stored online.

Data analysis

Data were analysed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Data was explored for normality using Kolmogorov Smirnov test and Shapiro Wilk test. Continuous data showed normal distribution and were described using mean and standard deviation. Intergroup comparison between continuous data was performed using one-way ANOVA, while intragroup comparison was performed using repeated-measures ANOVA. Two-way ANOVA was used to test the interaction of variables followed by Tukey post-hoc test. A P value less than or equal to 0.05 was considered statistically significant and all tests were two-tailed.

Results

Demographic data

This study was conducted on 105 teeth with dentin hypersensitivity in 35 participants that were randomly allocated to the interventions and the control arms (n=35). After 12 months all participants completed the follow-up with 100% retention rate. 21 females (40%) and 14 males (60%) participated in the current clinical trial, there was no statistically significant difference between all groups regarding gender (P = 0.6258), the gender distribution among groups is shown in Table 2. There was 75 anterior teeth (71.5%) and 30 premolars (28.5%) in the current trial, there was no statistically significant difference between all groups regarding tooth type (P = 0.5954), the teeth distribution among groups is shown in Table 3. Mean age of the participants in the current trial was 38.9±7.3 years; mean age within Embrace group was 39±7.3 years, mean age within Ultra EZ group was 38.4±7.7 years, while within the Fluoride group mean age was 41.2±6.6 years, there was no statistically significant difference between all groups regarding age (P = 0.741).

Table (2): Gender distribution among groups:

Gender	Embrace	Ultra EZ	Fluoride	Total
Males	4 (64%)	5 (36%)	6 (43%)	14 (40%)
Females	8 (36%)	7 (64%)	5 (57%)	21(60%)
Total	12 (34.25%)	12 (34.25%)	11 (31.5%)	35

Table (3): Teeth distribution among groups:

Tooth	**Embrace**	**Ultra EZ**	**Fluoride**	**Total**
Anterior	28 (80%)	26 (74.3%)	21 (60%)	75 (71.5%)
Premolar	7 (20%)	9 (25.7%)	14 (40%)	30(28.5%)
Total	35 (33.33%)	35 (33.33%)	35 (33.33%)	105

2. Effect of material and follow-up on VAS of dentin hypersensitivity:

Intergroup comparison between all materials has shown no statistically significant difference at baseline (P = 0.307), while after 4 hours, 2 days, 4-, 8- and 12-months intergroup comparison revealed a statistically significant difference (P<0.001). Intragroup comparison within Embrace, Fluoride and Ultra EZ have shown statistically significant difference between different follow-up periods (P < 0.001). **(Table 4)**

Table (4): Mean and standard deviation of VAS for dentin hypersensitivity of all materials at each follow-up:

Intervention / Follow-up	Embrace		Ultra EZ		Fluoride		P value
	Mean	SD	Mean	SD	Mean	SD	
Baseline	$7.8^{A,a}$	1.6	$7.3^{A,a}$	1.58	$7.3^{A,a}$	1.4	0.307 NS
4 hours	$7.1^{AB,a}$	1.66	$3^{D,c}$	1.4	$4.2^{BC,b}$	1.5	<0.001*
2 days	$5.3^{C,a}$	1.7	$1.9^{D.c}$	1.1	$3.5^{C,b}$	1.2	<0.001*
4 months	$5.3^{C,a}$	1.4	$4.2^{C,b}$	1.3	$3.6^{C,b}$	1.3	<0.001*
8 months	$6^{BC,a}$	1.4	$5.4^{B.a}$	1.3	$4.3^{BC,b}$	1.3	<0.001*
12 months	$6.3^{BC,a}$	1.6	$6.1^{B,a}$	1.5	$4.7^{B,b}$	1.3	<0.001*
P value	<0.001*		<0.001*		<0.001*		

*Means that do not share a letter (upper-case letters vertically and lower-case letters horizontally) are significantly different, * corresponds to statistically significant difference, NS corresponds to no significance*

Discussion

Dentinal hypersensitivity is characterized by a sharp and acute pain radiating from exposed dentin surfaces of teeth after receiving a thermal, tactile, evaporative, osmotic, or chemical stimulus without the presence of any tooth defect or pathology. It is considered a common problem of adult patients in a dental practice, with a prevalence ranging from 11% to 33% and age range between 20–50 years where female patients show greater affection by this problem. Although various studies assessed different treatment protocols for hypersensitivity, it is considered as the most inconsistently treated pain in dental practice and with the least success rates recorded accordingly. **[11-13]**

Dentinal hypersensitivity develops when the dentin becomes denuded, and the dentinal tubules are exposed, causing the tooth to be susceptible to stimuli; this

is contributed mainly to the loss of enamel and/or gingival recession, tooth wear lesions, periodontal diseases, and after periodontal treatments such as subgingival root planning. Dental hypersensitivity due to exposed root surfaces occurs due to the removal of the cementum or smear layers that cover the exposed root. Moreover, erosive chemicals can be an essential factor in opening the dentinal tubules of the exposed dentin. [14,15]

Various theories were proposed to describe the mechanism of dentinal hypersensitivity following dentin exposure; among these theories, the most accepted was the hydrodynamic theory, according to this theory, when the exposed dentin is subjected to external stimuli movement of fluids in the dentinal tubules occurs, and this consequently stimulates the pulp tissue nerve endings causing pain sensation. [13]

Treatment protocols for dentin hypersensitivity are based mainly on two strategies: reducing and modifying the neuronal response and transmission by depolarization or occluding the dentinal tubules and preventing the movement of the dentinal fluids. Many different materials were used to relieve hypersensitivity by blocking the neural transmission as silver nitrate, potassium nitrate, formaldehyde, and strontium chloride. Potassium nitrate is considered the most accepted formulation containing potassium ions which can efficiently influence neural transmission by interrupting the pain stimuli. Potassium deposits cause an increase in the extracellular potassium ion concentration, which can pass through the dentinal tubules and depolarize the nerve synapses causing blocking of transmission. [16,17]

Throughout many years various products were introduced aiming to reduce the fluid flow in the dentinal tubules by blocking the exposed ends and consequent pain relief. Among these used products are protein precipitants such as formaldehyde, strontium chloride, tubule-occluding agents such as potassium oxalate and sodium fluoride (NaF) and sealants such as resins and adhesives, and lasers. [18]

Fluoride varnishes were introduced to enhance the efficacy of NaF and provide a more sustained release to the tooth surface; fluoride vanishes showed a great potential for occluding dentinal tubules. Varnishes consist of resin-based vehicles for fluoride and are highly adhesive to the tooth structure when the organic solvent evaporates, it leaves a thin layer of the material covering the exposed tooth surfaces, and fluoride forms a deposition of calcium fluoride on the tooth surface as well as the formation of fluorapatite, these deposits can successfully occlude the dentinal tubules providing sustained pain relief, The main drawback of fluoride varnishes is the washing out by saliva, brushing and acidic food consumption hindering its effect and tubules occlusion capabilities. [19,20]

Saliva can provide a natural mechanism of occluding dentinal tubules by supplementing calcium and phosphorus ions, which can progressively occlude the exposed dentinal tubules by deposition of a superficial layer formed of glycoprotein, calcium, and phosphates. This process is considered very slow to be able to relieve hypersensitivity, so additional amounts of calcium and phosphates ions are required to be available in the oral cavity to speed up this process.

Fluoride varnish containing xylitol coated calcium phosphate particles reduces hypersensitivity by a sustained release of fluoride ions to form fluorapatite crystals in conjunction with the required calcium and phosphate ions forming a barrier against pain-causing stimuli. Xylitol component can decrease biofilm by inhibiting bacterial aggregation and reducing plaque adherence with increased pH, thus significantly affecting dentinal sensitivity. [21]

It is recommended to assess hypersensitivity using at least two hydrodynamic stimuli. [22]. This study evaluated sensitivity using evaporative, thermal, and tactile stimuli. These tests were selected as they resemble the normal everyday stimuli, which can cause sensitivity sensation on the exposed root surface, a minimum of 5 min delay is required between the end of each assessment method to minimize interactions between them. Tactile stimulation was applied first, followed by evaporative stimulus and at last cold application, because the least painful stimulus is recommended to be used first to prevent interpretation error. [23]

Hypersensitivity scores were recorded using the VAS scale in which the patient marks the pain intensity on a 10- cm line card where 0 = no pain and 10 = extreme pain. Also, figures of facial expressions were added on the card below the 10- cm line to be easily understood by patients with a low level of education and allow better patient cooperation. The main challenge in this evaluation method was the subjectivity involved, as the reported degree of pain depends on many patients' related factors as pain threshold, physiological and emotional status. [24]

Assessment intervals for hypersensitivity scores were at baseline, after 4 hours, two days, 4, 8 and 12 months. After 4 hours, the assessment was considered an immediate post-operative evaluation, according to the manufacturer's instructions, after using any fluoride-containing varnishes, patients were instructed to refrain from eating hard food or drinking hot fluids and not to brush their teeth for 4 hours, in order to maintain the effectiveness of the varnish. Two days follow-up was used to properly assess the plaque adherence values. The 4-, 8- and 12-month follow-up periods were done to evaluate the long-term pain relief effect. The current study aimed to motivate the patient throughout the 12 months evaluation period, expecting that their compliance may decrease. Moreover, it allowed the patients themselves to comply with proper care of their teeth and refrain from any notorious habits that may have caused the hypersensitivity problem. [10]

Randomized clinical trials (RCTs) are the final step in restorative and preventive dentistry to determine whether a new or modified dental material or restorative technique is suitable for its specific indication of intraoral use, such as restoring function, improving/maintaining aesthetics, and not causing any harm to adjacent biological tissues, as well as to determine whether the proposed material/technique can be applied by the majority of dental healthcare professionals who will perform a similar procedure. [25]

The current study was conducted on 105 teeth with dentin hypersensitivity in 35 patients, they were randomly allocated to the interventions and the control arms. Evaluation of all outcomes was done immediately after 4 hours, after a short

follow-up period (2 days and 4 months), and after an extended follow-up period at 8 and 12 months. After 12 months all participants were evaluated with a 100% retention rate.

Hypersensitivity assessment was done using the VAS, the best immediate relief was for potassium nitrate gel application, with a significant difference in VAS scores in comparison to the baseline values and with a significant difference when compared to other treatment methods. This quick effect may be attributed to the mechanism of action of the material, where it acts as an anaesthetic or analgesic agent on the pulpal nerve fibres by depolarization of synapses and preventing re-polarization and this was demonstrated by various previous studies. [25,26] In addition, the viscous gel form and the long application period allowed the gel to form a blockage layer on the root surface. [28,29] The depolarization effect was sustained for a short period until four months owing to the high concentration of potassium nitrate ions in the bio-adhesive gel allowing more ions penetration through the dentinal tubules, causing a cumulative effect along time. [4] After more extended periods for 8 and 12 months follow-up, the sensitivity values increased significantly than short-term values. This could be explained by the normal decreasing concentration of potassium ions inside the dentinal tubules and the salivary washing out effect. [28]

Similarly, fluoride varnish showed immediate significantly lower sensitivity values on VAS scale compared to baseline, with a gradual decrease after short term and that effect was sustained for both the short and long term periods. This result may be explained by the tubule occlusion potential of sodium fluoride, through the formation of calcium fluoride deposits as well as fluorapatite crystals blocking the dentinal tubules preventing the dentinal fluid movement upon exposure to different types of stimuli. These results are in agreement with various previous studies. [4, 30, 31] The immediate effects were caused by the coating effect and adherence of the resinous content of the varnish while maintenance of these results may be contributed to the sustained release of fluoride from the varnish for a long period. The slight relapse at 12 months was in agreement with the results obtained by Camilotti et al. [19] ,where they explained this by the dissolution of the fluoride varnish layer by oral fluids, eating and brushing.

Embrace varnish, on the contrary, showed lower efficacy at immediate application with no significant difference than baseline values; this can be justified by the low resinous content of the material compared to conventional fluoride varnishes, which showed lower viscosity and less adherence upon application. Moreover, the presence of xylitol-coated calcium phosphate particles required enough time to dissolve by saliva, gradually releasing calcium and phosphate ions in the oral cavity, this was in accordance with previous studies [28, 32] . The process of calcium and phosphates deposition, supersaturation and the formation of calcium phosphate crystals as well as remineralization by forming hydroxyapatite is a time-consuming process; this observation explained the lower sensitivity values after 2 days and 4 months intervals while for longer follow-up periods the effect decreased gradually [15] This was justified by the gradual dissolution of the calcium phosphate deposits and the inability to survive the acidic challenge in the oral environment. The overall efficacy of calcium phosphate-containing desensitizers was doubted by previous studies. [34,35]

Upon comparing the efficacy of different agents for the short term follow-up period after 4 months, the best relief was achieved by fluoride varnish, followed by potassium nitrate with insignificant difference between them; these results were in agreement with a previous trial where similar results were obtained after 3 and 4 months [29].On the contrary, the current results were not in agreement with Pandit et al [4] where fluoride varnish showed significantly better results than potassium nitrate after 3 months. Regarding the long-term efficacy, fluoride varnish showed the least hypersensitivity values on the VAS scale, with a significant difference when compared to potassium nitrate, and this result was explained by the difference in the mode of action where the potassium nitrate acts by nerve depolarization which is a transient and reversible effect, while fluoride varnish works by tubule occlusion and blockage layer deposition. [18,27]

Regarding Embrace varnish, it showed the least short and long-term efficacy, this was in disagreement with the previous studies [28, 36] . The current results could be attributed to that Embrace varnish has the best initial fluoride release after a few hours but with the least substantivity and highest depletion rate, thus explaining its significantly lower efficacy than other used agents after long-term evaluation. [37]

After 12 months, fluoride varnish containing xylitol-coated calcium and phosphate (Embrace varnish) was less effective than conventional fluoride varnish in the management of dentin hypersensitivity, therefore the proposed null hypothesis was rejected. The current study evaluated the effect of a single application of different desensitizing agents to reduce hypersensitivity after a one-year period, additional applications could have been more beneficial and could have affected the results differently after one year.

Study limitations:

- The assessment of hypersensitivity using VAS is subjective an objective assessment method would be more beneficial.
- A parallel in vitro study could have strengthened the study by assessing the occlusion of the dentinal tubules after interventions.[38]

Study Strength points:

- Assessment of three different hypersensitivity management materials
- Long-term follow-up period (up to 12 months).
- Testing a new material to treat hypersensitivity (EMBRACE™ Varnish) which was not previously assessed in previous studies.
- Large sample size included.

Conclusions and Recommendations

Under the limitations and conditions of this study, the following conclusions were obtained:

Ultra-EZ gel application is efficient in immediate relief from hypersensitivity with good efficacy for up to 4 months period. Fluoride varnish showed higher efficiency for reducing hypersensitivity for both short- and long-term periods. The unique component CXP (xylitol coated calcium phosphate) found in Embrace varnish couldn't add any benefit in reducing hypersensitivity. Moreover, the varnish failed to provide a better reduction in hypersensitivity than conventional fluoride varnish.

According to the present conclusions and what was accomplished by the current study, it is recommended to re-apply the anti-hypersensitivity agent after 4 months to achieve better and longer-term effects. Ultra-EZ gel is recommended to be the material of choice for immediate relief of dentin hypersensitivity.

Ethics

Approval

All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

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