Section A-Research paper

DESENSITIZING EFFICACY OF POLYMERIC NANO CALCIUM FLUORIDE VARNISH VERSUS CASEIN PHOSPHOPEPTIDE AMORPHOUS CALCIUM PHOSPHATE FLUORIDE VARNISH: RANDOMIZED CLINICAL TRIAL

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Aim: This study was to evaluate the desensitizing efficacy of polymeric nano calcium fluoride containing varnish compared with Casein phosphopeptide amorphous calcium phosphate containing fluoride varnish in reducing Dentin hypersensitivity.

Methodology: in a randomized control trial, (100 lesions) in patients with chief complaint of generalized dentin hypersensitivity of the outpatient clinic in the restorative department, Faculty of dentistry, Cairo University; were enrolled then randomly allocated into one of the two groups according to the desensitizing agent was used either polymeric nano calcium fluoride varnish (OliNano SEAL®) or Casein phosphopeptide amorphous calcium phosphate fluoride varnish (MI varnish®). Sensitivity was confirmed by tactile and air test, each participant should have sensitive lesions with a visual analogue scale (score two or more). The manufacturer's instructions were followed during the varnish application. Degree of dentin hypersensitivity was assessed by VAS scale in response to Air test, while Schiff score was used in response to air water test. Records were collected at baseline T0, immediately after varnish application T1, 3 months T2 and 6 months later T3. Patients were instructed to follow the post – treatment protocol. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results: In the VAS scale, the intergroup comparison of the time intervals of each the intervention and control group results showed a statistically significant difference between the time intervals. However, the intragroup comparison between intervention and control group results showed a statistically significant difference between T0, T1, T2 and T3, which was in favor to the intervention group. In Schiff score, the intergroup comparison of the time intervals of each the intervention and control group results showed a statistically significant difference between the time intervals. However, the intragroup comparison between intervention and control group results showed no statistically significant difference between T0, T1, T2 and T3.

Conclusion: Both materials either polymeric nano-calcium fluoride varnish or Casein Phosphopeptide Amorphous Calcium Phosphate Fluoride varnish showed an improvement in dentin hypersensitivity treatment throughout the six months follow up. Using Polymeric nano calcium fluoride varnish as a desensitizing agent has the potential to be an

effective approach for dentin hypersensitivity treatment. The desensitization efficacy of the desensitizing agents is time dependent.The reliability of the schiff score revealed the importance of the accuracy of diagnostic tests for dentin hypersensitivity evaluation .

Keywords: Dentin hypersensitivity, Dentin sensitivity, nano calcium fluoride, nano fluorapatite, amine fluoride, Olaflur, Silicon Polymer, MI varnish, Dentin Desensitizing Agents, Casein Phosphopeptide Amorphous Calcium Phosphate fluoride varnish.

INTRODUCTION:

Dentin hypersensitivity (DH) is a clinical enigma for the dentists globally and one of the most common complaints in the dental clinics, it affects the patient's quality of life with a prevalence ranged from 8% to 98% .It is characterized by "short, sharp and acute pain in response to thermal, tactile, or other non-harmful stimuli" and cannot be related to any other form of dental defects or diseases, **Osmari et al., 2018.** The symptoms of dentin hypersensitivity extend from minor discomfort to severe pain that may lead to loss of normal oral hygiene maintenance due to the impact of dentin hypersensitivity pain on the daily brushing routine.

The most accepted theory which explained dentin hypersensitivity is the hydrodynamic theory by Brännström, the disturbance of the fluids flow through the dentinal tubules leads to the activation of the nerve endings through the pulp, **Liu et al., 2020.** Various agents have been introduced to eliminate or reduce this condition like tubule-occluding agents, tubule sealants (resins and adhesives) and laser**.** The desensitizing agents that occlude the patent dentinal tubules are the most commonly used for reducing dentin hypersensitivity symptoms. However, their effectiveness depends on their resistance to the various challenges in the oral environment**, Silva and Alves, 2019**. After many reviews and investigations, there is not a widespread agreement of which is the best material or procedure to treat dentin hypersensitivity as a "gold standard" .The most desensitizing agents have shown limited effectiveness which last up few weeks from the treatment application because they are not capable to deliver the drug continuity for long periods and require recall visits for the patients**, Irum et al., 2019.** The differ degrees of efficacy of these agents make the best treatment option a challenge**.** The newly introduced novel fluoride compounds showed higher desensitizing abilities with promising results when compared to conventional fluoride, the nano-sized particles in these novel varnishes enhanced their efficacy as they can easily penetrate and occlude the dentinal tubules. Therefore, additional studies were required to deepen the knowledge about these novel nano-based products**,Yanko, 2020.** Increasing the demand to find a desensitizing agent that should be biocompatible, easy to apply, painless, not changing the teeth color, fast onset and maintain a long-term effect gives a highlight to the patented formula of the polymeric nano calcium fluoride which was newly introduced into the practice for reducing dentin hypersensitivity. The null hypothesis of this study was that in an adult patient, the two products polymeric nano calcium fluoride containing varnish and Casein phosphopeptide amorphous calcium phosphate containing fluoride varnish will show the same clinical effectiveness in controlling dentin hypersensitivity.

Materials and method

The polymeric nano calcium fluoride (OliNano SEAL):

The novel "varnish-like" shield which is based on a true nano-technology that provides an optimum adhesion to enamel and dentin, it could be used as an effective desensitizing agent by forming a protective layer on the dentin which leads to tubular occlusion which can last up to 12 months as the manufacture claimed. Polymeric nano calcium fluoride varnish consists of four main components, silicone polymer, NANO-fluorapatite ,nano-calcium fluoride and amine fluoride (Olaflur), **Gillam, 2014.**

Casein phosphopeptide amorphous calcium phosphate fluoride varnish (MI varnish):

The (CPP-ACP) nano complex is a patented formula of RECALDENT™ with the combination of 2% sodium fluoride. It has both preventive and bacteriostatic effect. Evidence-based literatures suggested that CPP-ACPF could be used as a desensitizing agent due to its remineralization potential by minerals precipitation which occlude the open dentinal tubules and reduce the permeability of dentin, **Madrid et al., 2019 .**

Methods:

1.Study design

This two-armed, parallel-design, triple-blinded, single centered and randomized clinical trial was conducted at the outpatient clinic of conservative department, Faculty of Dentistry, Cairo University, Egypt. With the approval of the Ethics Committee in the Faculty of Dentistry, Cairo University, number (6/12/20). The study was filed as a clinical trial (NCT04614727) on Clinical Trials.gov (www.clinicaltrials.gov). The researcher was responsible for all activities associated with the research including recruitment of participants, explaining the aim of the study and the procedure , performing the procedures to the participants before they signed the informed consent. The trial protocol was designed following **Chebel et al.2018** and approved from Evidence Based Dentistry Committee, Faculty of Dentistry Cairo University.

2.Study setting and participants

The study was carried out on 20 patients (100 lesions) aged between 20 to 50 years who were complained of generalized dentin hypersensitivity and looked for dental care at the outpatient clinic of the Conservative Department, Faculty of Dentistry, Cairo University. Patients were screened and carefully examined until the target population was achieved after they were subjected to full intra/ extra oral examinations, medical and dietary habits histories to fulfill the eligibility criteria of the study. Once the patients were potentially eligible for this study they were identified and contacted by the research investigator who explained the study and ascertained the patient's interest. If interested, more detailed evaluations and preparations were made. The study was carried over a period of six months started from January 2021 until june2021.The Assessment of VAS score and Schiff score were done at the time intervals; T0: at baseline, T1: immediately after varnish application, T2: after 3 months and T3: after 6 months . Patients were instructed to follow the post treatment protocol.

3.a. Inclusion Criteria of participants: Jena & Shashirekha, 2015 .

- Patients with good oral hygiene and free medical history
- The age range of 20-50 years,.
- Both genders.
- Good periodontal health (probing depth not more than 4) **,**
- Patient with three to five lesions with score of VAS was two or more with tactile and air stimulation.
- Co-operative patients who were interested to participate in the study and willing to sign the informed consent.

3.b.Exclusion criteria of participants:

- Patient with bad oral hygiene and smokers .

- Patients with constant use of analgesic, antihistaminic, anticonvulsive, sedative, tranquilizing, or anti-inflammatory medications 72 hours before treatment and pain assessment.
- Patients using desensitizing toothpaste.
- Medically compromised (They cannot tolerate the procedures).
- Pregnant females (They complain from nausea and repeated vomiting attacks).
- Presence of any large or defective restorations, cracked enamel or caries on the hypersensitive tooth.
- Dental pathology causing pain similar to dentin hypersensitivity.
- Participants that were involved into any other research in last 6 months

Pre-operative examination procedure

One week before the study was started; eligible participants were prepared for the study with the scaling and polishing session (without polishing paste to eliminate cofounder). The hypersensitive lesions were confirmed by receiving tactile and air blast stimulus to confirm dentin hypersensitivity, with VAS score 2 or more identified as eligible for the study**,** .All demographic data, extra oral examination, intraoral examination (soft and hard tissue examination), any abnormalities and any history of para-functional habits were documented in the diagnostic dental charts for detailed assessment. A standard dental brush and toothpaste were given for daily brushing (two minutes twice per day) , **Abbas et al., 2021, and Gillam, 2022**.

Clinical procedures:

On the first day of the study, the informed consent was read carefully and signed by each participant before starting the procedure .The participants were informed that they should not take any other type of dentin hypersensitivity treatment during the follow-up periods. Both desensitizing agents were applied according to manufacturer instructions. The measurements of both VAS scores and Schiff scores were collected at T0, T1, T2 and T3**.** Case report form was specially designed for this study to be used in recording the outcome for each participant.Way of assessment regarding the stimuli used and scoring system for dentin hypersensitivity was conducted according to **Chebel et al., 2018**.

Evaluation procedure

The primary outcome Visual Analogue Scale (VAS)

The VAS is a scale that allows the patient to self-assess the pain felt by means of a slider, a ruler on the front which was drawn as a line which the patient moves the pointer from the "no pain" end to the "maximum pain" end. On the back of the slide, the investigator read the pain felt by the patient using a graduation in millimeters (from 0 to 100 mm). This scale will finally be interpreted as follows: Pain absent: 0, Low pain: 1 – 3, Moderate pain: 4 – 6 Intense pain: 7 – 9, Extremely intense pain: 10. The previously confirmed hypersensitive lesions were tested by air blast stimuli to assess the response of pain. A short blast of air with standard pressure (40 psi ±5) from conventional dental unit air syringe was applied approximately (5mm±1) measured by endo ruler perpendicular to the cervical third of the lesion surface, with temperature of (21±5°C) and duration for 3±1 seconds to avoid dentin desiccation. The adjacent teeth were isolated by cotton rolls**.** The VAS scale confirmed by several investigators as a reliable and valid measuring tool for dentin hypersensitivity pain assessment**.** In air blast stimulus, the rapid outward fluid movement of dentinal fluid stimulates the receptors in the pulp and elicits immediate pain sensation more than other stimulations. Air test is considered as the most validated test for diagnosis and assessment of dentin hypersensitivity management , **Gillam, 2022** .Other studies

found that the evaporative test was a more reproducible method than the tactile test for assessing dentin hypersensitivity, **Bansal & Mahajan, 2017,Abbas et al., 2021**.

The secondary outcome Schiff air score test :

The Schiff air scores were recorded according to the Schiff air index; the scores were oriented by the investigator not the participant. Scores were from 0 to 3 which represent 0- Tooth/subject did not respond to the air stimulus.1- Tooth/subject responded to the air stimulus but did not request discontinuation of the stimulus. 2- Tooth/subject responded to the air stimulus and requested discontinuation or moved from the stimulus. 3- Tooth/subject responded to the air stimulus, considered the stimulus to be painful, and requested discontinuation of the stimulus. An air water was applied using triple air water syringe coupled to the dental unit, with standard pressure (40 ips ±5) at temperature of (21±5°C), for (3±1 sec) and a distance of 5 ±1 mm which was measured by endo ruler perpendicular to the cervical area of the lesion surface of the affected tooth. To eliminate the risk of bias whether in VAS or Schiff, when two adjacent teeth were tested, the sensitive tooth was isolated from adjacent teeth with cotton rolls. There was a minimum of 2 min was allowed between the two stimuli to minimize interactions between stimuli **.**Many literatures suggested that the Schiff scale was developed precisely for dentin hypersensitivity assessment due to its high sensitivity and specificity for dentin hypersensitivity evaluation, it had the maximum correct results with fewest false negatives and false positives in relation to the actual diagnosis for dentin hypersensitivity,**Oliveira & Rocha, 2020**. It was recommended that two hydrodynamic stimuli to be used in the clinical trial, both physiologic and controllable**.** Even if dentin exposure is visually detectable or not, air blast with water elicit the transient pain which was able to confirm the diagnosis, **Samuel et al, 2015.**

Application procedure

Polymeric nano calcium fluoride varnish (group A):

The cheek retractor was placed; the surface of the experimental lesion was polished carefully by a polishing brush with low-speed hand piece, and without polishing paste followed by adequate rinsing. Drying was applied for 5 seconds only to avoid tooth desiccation. The gingival tissues were protected by cotton rolls while isolation from saliva was done by the cotton rolls and suction tip. The bottle was shaked vigorously then the varnish liquid was dropped into its application plastic tray, the disposable brush was soaked once into the plastic tray then one coat of varnish was applied on the lesion surface and let to be dried for 1 minute. Dryness could be accelerated by gentle streaming of air for 10 seconds. The patients were informed to not eat or brush in the next two hours as the manufactures instructions

Casein phosphopeptide amorphous calcium phosphate fluoride varnish (group B):

The cheek retractor was placed, the lesion surface was polished carefully without polishing paste followed by adequate rinsing and drying for 5 seconds. Gingival tissues were protected by cotton rolls. Isolation from saliva was done by cotton rolls and suction tip. The foil cover of the unit dose container was removed. The disposable brush was used to mix the varnish then soaked once in the unit dose container, the varnish was applied in a single uniform layer on the lesion surface then left undisturbed. Any Excess was removed by using cotton pellets. Patients were instructed to avoid hard, hot, sticky food, also tooth brushing, flossing and products containing alcohol (oral rinses, beverages) for the next 4 hours The routine use of fluoride tablets by patients should be interrupted for several days after treatment.

Postoperative evaluation for the dentin hyper- sensitivity

Lesions were reexamined by the same stimuli as done preoperatively and the data were collected in the participants case report form. The process was repeated at the follow up periods, which. The assessment times were chosen according to **Chebel et al. 2018**. The importance of the commitment to the appointments was assured to participants. The participants of the study were adhered until the end of the follow-up period except one participant in each group at T2.

The examiner asked the participants if they had any adverse effects, none of them notified any adverse effects or harms (e.g., allergies, gingival inflammation or enamel-staining) during the visits.

Statistical analysis:

Data were analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 25 (SPSS Inc., Chicago, IL). Continuous data were described using mean and standard deviation. Comparison between continuous data was performed using t-test and ANOVA was used to test interaction of variables. Categorical data was described as absolute risk for each intervention independently and relative risk when comparing both interventions. Comparisons between categorical variables were performed using the chi square test. A p-value less than or equal 27 to 0.05 was considered statistically significant and all tests were two tailed. Statistical power of the study was set at 80 % with 95 % confidence level.

RESULTS

VAS score:

The Effect of time:

For Intervention group:

There was a statistically significant difference between (T0), (T1), (T2) and (T3) groups where (p<0.001)**.** A statistically significant difference was found between (T0) and each of (T1), (T2) and (T3) groups where (p<0.001)**.** Also, a statistically significant difference was found between (T2) and each of (T1) and (T3) groups where (p=0.005) and (p=0.009) respectively**.** No statistically significant difference was found between (T1) and (T3) groups where (p=0.358).

For Control group:

There was a statistically significant difference between (T0), (T1), (T2) and (T3) groups where (p<0.001)**.** A statistically significant difference was found between (T0) and each of (T1), (T2) and (T3) groups where (p<0.001)**.** Also, a statistically significant difference was found between (T2) and each of (T1) and (T3) groups where (p=0.004) and (p=0.004) respectively**.** No statistically significant difference was found between (T1) and (T3) groups where (p=0.732).

The Effect of the desensitizing material:

For baseline measurement: There was a statistically significant difference between (Intervention) and (Control) groups where (p<0.001)**.Immediate after application of desensitizing agent:** there was a statistically significant difference between (Intervention) and (Control) groups where (p=0.038)**.Three months follow-up:** there was a statistically significant difference between (Intervention) and (Control) groups where (p<0.001)**.Six months follow-up:** there was a statistically significant difference between (Intervention) and (Control) groups where (p=0.013)**.**

Table (1): The mean, standard deviation (SD) values of VAS score of different groups.

Variables	VAS score								p-value
	Intervention group				Control groups				
	Mean	SD	Min	Max	Mean	SD	Min	Max	
T0	5.46 [a]	1.52	2.67	8.00	6.06 [e]	1.74	3.50	9.00	**<0.001***
T1	2.84 [b]	0.91	1.00	4.33	3.72 [f]	1.43	2.00	8.00	**0.038***
T2	2.14 [c]	0.70	1.00	3.33	2.86 [d]	0.72	1.50	4.00	**<0.001***
T3	2.57 [b]	0.69	1.50	3.67	3.59 [f]	1.33	1.33	6.00	**0.013***
p-value	**<0.001***				**<0.001***				

***; significant (p<0.05) ns; non-significant (p>0.05)**

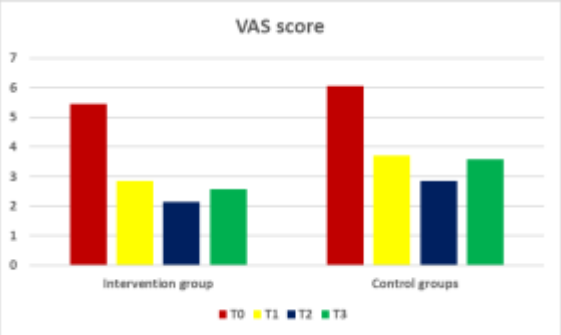

Figure (2): Bar chart representing the effect of desensitizing material in VAS score for different groups

The effect of time:

For intervention group:

There was a statistically significant difference between (T0), (T1), (T2) and (T3) groups where (p<0.001). A statistically significant difference was found between (T0) and each of (T1), (T2) and (T3) groups where (p<0.001), (p<0.001) and (p=0.002). Also, a statistically significant difference was found between (T3) and each of (T1) and (T2) groups where (p=0.013) and (p=0.001) respectively. No statistically significant difference was found between (T1) and (T2) groups where (p=0.458).

For control group:

There was a statistically significant difference between (T0), (T1), (T2) and (T3) groups where (p<0.001). A statistically significant difference was found between (T0) and each of (T1), (T2) and (T3) groups where (p<0.001), (p<0.001) and (p=0.009). Also, a statistically significant difference was found between (T3) and each of (T1) and (T2) groups where (p<0.001) and (p=0.001) respectively. No statistically significant difference was found between (T1) and (T2) groups where (p=0.250).

Effect of the desensitizing material:

For baseline measurement: there was no statistically significant difference between (Intervention) and (Control) groups where (p=0.911)**.Immediate after application of desensitizing agent:** there was no statistically significant difference between (Intervention) and(Control) groups where (p=0.841)**.Three months follow-up:** there was no statistically significant difference between (Intervention) and(Control) groups where (p=0.124)**.Six months follow-up:** there was no statistically significant difference between (Intervention) and (Control) groups where (p=0.115)**.**

Table (2): The mean, standard deviation (SD) values of Schiff Air score of different groups.

Variables	Schiff Air score								p-value
	Intervention group				Control groups				
	Mean	SD	Min	Max	Mean	SD	Min	Max	
T0	2.08 [a]	0.68	1.00	3.00	2.04 [e]	0.69	1.00	3.00	**0.911ns**
T1	0.89 [c]	0.38	0.33	2.00	0.97 [f]	0.55	0.00	2.00	**0.841ns**
T2	0.87 [c]	0.49	0.00	1.50	1.18 [f]	0.56	0.00	2.00	**0.124ns**
T3	1.40 [b]	0.41	1.00	2.00	1.76 [g]	0.67	1.00	3.00	**0.115ns**
p-value	**<0.001***				**<0.001***				

***; significant (p<0.05) ns; non-significant (p>0.05)**

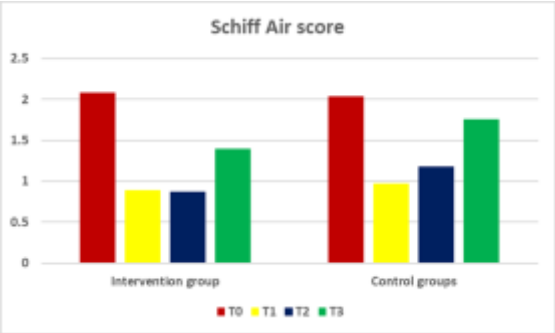

Figure (5): Bar chart representing the effect of desensitizing material in Schiff Air score for different groups

DISCUSSION

Dentin hypersensitivity is a clinical enigma for the dentists globally. Many authors discussed the way pain transit through dentin but the most accepted theory is the hydrodynamic theory by Brännström. The theory states that the environmental, mechanical, thermal, and chemical changes cause movement of the fluid flow through the dentinal tubules leading to the activation of the nerve periphery through the pulp, **Liu et al., 2020**. Several clinical conditions play a role in the development of dentin hypersensitivity such as loss of enamel due to attrition, abrasion, abfraction, erosion, enamel malformation, bruxism, acidic diet habits, gastric reflux, bulimia and bleaching. In addition to dentin exposure which could be due to: gingival recession, obsessive tooth brushing or periodontal procedure, **Chebel et al., 2018.**

Treatment modalities of dentin hypersensitivity were categorized according to the mode of action to: nerve desensitization, occlusion of the dentinal tubules physically or chemically, laser, dentin adhesives sealers and protein precipitation. The nerve desensitization agents depends on potassium salts which decrease the excitability of the A nerve fibers present in dentin leading to reduction of pain from dentin hypersensitivity, **Pereira et al., 2018**. The physical occlusion takes place by deposition of a layer of fine particles such as calcium and phosphate to act as a physical artificial barrier on the exposed dentinal tubules without any type of adhesion as in dentin bonding agents or adhesive resin. While the chemical occlusion depends on the chemical adhesion within the dentinal tubules as in fluoride varnish, glutaraldehyde-based agents, sodium fluoride iontophoresis and mineralization- promoting cements. The chemical occlusion type consider more durable in desensitizing efficacy than the physical occlusion type, **Ali et al., 2021.** Furthermore the advanced approaches aimed for dentin hypersensitivity management such as the bioactive glass , biomimetic systems and nano based agents which aimed to restore the integrity of both enamel and dentin since both of them do not have the inherent ability to regenerate themselves, **Rattan et al., 2021 .**

Conventional fluoride varnish is considered the most commonly used agent for dentin hypersensitivity, however it have a short life span in the oral environment since it is removed easily and rapidly **.** Most desensitizing agents have shown limited effectiveness and different degrees of efficacy that made the choice of the best treatment option a great challenge for the dentist This highlighted the need to develop a new treatment or product to relief the pain and maintain a long-term effect**, Osmari et al., 2018.**

The polymeric nano calcium fluoride (OliNano SEAL) is a novel "varnish-like" shield which is based on a true nano-technology that provides an optimum adhesion to enamel and dentin, it could be used as an effective desensitizing agent which can last up to 12 months, while other available products were effective for maximum 2-3 months as the manufacture claimed, but there were not any clinical trials that investigated or supported this claim. It consists of four components: silicone polymer which provides optimum adhesion to enamel and dentin**.** NANO-fluorapatite which penetrating into the dentinal tubules and occluding them ultimately**.** As for the nano-calcium fluoride which increases

the deposition and retention of fluoride therefore decreases dentin permeability**.** The fourth component amine fluoride (Olaflur) which formed a protective layer on the dentin which leads to tubular occlusion, **Gillam, 2014.**

The control material (CPP-ACP) nano complex is considered as a patented formula RECALDENT™ by Reynolds at Melbourne University, Australia, with the combination of 2% sodium fluoride. It has both preventive and bacteriostatic effect. Evidence-based literatures suggested that CPP-ACPF could be used as a desensitizing agent due to its remineralization potential by minerals precipitation which occlude the open dentinal tubules and reduce the permeability of dentin. The promising ions release was detected when compared with other conventional fluoride varnishes**.** However, further studies are needed to approve its clinical advantage over other desensitizing strategies, **Madrid et al., 2019 .**

Pain arising from dentin hypersensitivity is a hugely subjective symptom and to achieve adequate management careful diagnosis and periodic assessment of patient must be done. Assessment of the severity of the pain arising from dentin hypersensitivity or evaluating the efficacy of it could be done by using the categorical scale, visual analog scale (VAS) and Schiff scale **Oliveira & Rocha, 2020**. Hugely there was a lack of clinical studies about the polymeric nano calcium fluoride varnish. Since there was not any previous clinical trial on this newly introduced agent. Some studies evaluated the efficacy of the active components separately, while other studies evaluated the efficacy of one of these ingredients on enamel remineralization rather than dentin remineralization. Each component had a role which acted directly or indirectly to decrease the permeability of the dentinal tubules through the six months.

Results of this current clinical trial demonstrated that in the VAS scale the intergroup comparison of the time intervals of each of the intervention and control group, results showed a statistically significant difference between the time intervals. In the VAS score, regarding the intergroup comparison of the intervention, the results revealed that the onset of the efficacy of the material started at T1 (immediate after application) then the effect was continued until T2 (3 months). However, a decline of the effect was noticed at T3 (6 months). This may be due to the varnishes being subjected to many mechanical and chemical challenges which may cause fluctuation in the amount of ions released in the oral environment as conducted in**, Gullo et al., 2021.**

Also, in the intergroup comparison of the control group showed that the highest efficacy of the material was noticed at T2 (3 months) then the material efficacy decreased at T3 (6 months). This may be due to the result of the precipitated minerals of CPP-ACPF varnish which were not able to withstand the continued effect of acidic fluctuation in the oral environment, this was agreed with a study made by **Chebel et al., 2018.** The varnish showed fast release of the ions that may be due to the high water solubility and inferior longevity of the CPP-ACP complexes as suggested in **Cochrane et al., 2014** .

However, the intragroup comparison between the polymeric nano calcium fluoride varnish and casein phosphopeptide amorphous calcium phosphate fluoride varnish, results showed a statistically significant difference between them revealing the superior effect of the intervention more than the control group. This may be explained by the higher efficacy of the polymeric nano-calcium fluoride varnish may be due to the quadruple components that depends on the biomimetic and nano-technology as different maneuvers for minerals precipitation ,the efficacy of the component as conducted in **Sun and chow,2008, Xu et al., 2010, Taha et al., 2015**, **Xu et al., 2017 ,Toledano-Osorio et al., 2018** , **Feroz & Khan,2020, Herman et al., 2021**.On the other hand, the results were against the results of studies made by **Chhatwani et al., 2021** and **Erbe et al.,2021** which revealed that the protector CaF2 Nano one step seal had the lowest outcomes through other varnishes.

In the Schiff score regarding the intergroup comparison of the time intervals of each the intervention and control group, results showed a statistically significant difference between the time intervals. In the intervention group, the highest efficacy of the material was noticed at T2 (3 months), then the efficacy was decreased at T3 (6 months). The reason behind this may be due to the various challenges on the oral environment which effect the desensitizing ability during time. This reason was supported with **Gullo et al., 2021** and **Osmari et al., 2018.** On the other hand, the

intergroup comparison of the control group showed that the highest efficacy of the material was noticed at T1 (immediate after application) followed by a slight recurrence at T2 (3 months) with continuous decrease in the efficacy at T3 (6 months). The recurrence of the hypersensitivity may be due to the fluoride interaction with the ACP component then precipitated out as calcium fluoride which interrupted the varnish efficacy , this reason was agreed by a study made by **Madhavan et al., 2012**. In addition to a literature by **Madrid et al., 2019** that supposed that the blocking action of the CPP-ACPF varnish in the dentin tubules is partial and similar to other desensitizing approaches such as the arginine or strontium acetate by time.

However, the intragroup comparison between intervention and control results in Schiff score, showed no statistically significant difference between them, the equivalence between the intervention and the control may be due to three reasons: first, the higher sensitivity and specificity in the Schiff score which were superior than the VAS score .Second, may be due to the duplication of the stimulus with the double effect in the Schiff which may trigger higher pain sensation, **Oliveira & Rocha, 2020**. Thirdly, it could be suggested that the differences in formulations between these two products are minimal, perhaps limited only to their active ingredients or fluoride formulations.

Both materials showed a decrease in dentin hypersensitivity since they depend on the mechanism of occlusion of the dentinal tubules by formation of precipitates basically, as it was considered as the most common mechanism used for reducing dentin hypersensitivity, **Osmari et al., 2018.** The null hypothesis of this study was that in an adult patient, the two products polymeric nano calcium fluoride varnish and casein phosphopeptide amorphous calcium phosphate fluoride varnish will show the same clinical effectiveness in controlling dentin hypersensitivity. After conducting the results, both materials showed an improvement in the treatment of dentin hypersensitivity. However, the polymeric nano calcium fluoride varnish showed a higher desensitizing potential than the control group in the VAS scale while in the Schiff scale there was no statistical significance difference Indicating that the null hypothesis is partially accepted.

CONCLUSION

Under the limitations of this trial, the following conclusions could be listed:

1. Both materials, polymeric nano calcium fluoride varnish or Casein Phosphopeptide Amorphous Calcium Phosphate Fluoride varnish deep improved the treatment of dentin hypersensitivity.

2. Using polymeric nano calcium fluoride varnish as a desensitizing agent is an effective approach for dentine hypersensitivity treatment.

3. The desensitization efficacy of the desensitizing agents is time dependent.

RECOMMENDATIONS :

- Further studies are needed to support the manufacture claims, investigate different varnishes with different fluoride deliverance pattern, due to the lack of evidence data.
- The reliability of the Schiff score revealed the importance of the accuracy of diagnostic tests used for dentin hypersensitivity evaluation.

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