Comparative Study on the Efficacy of OliNano Seal and Curodont D’Senz in the Treatment of Dentin Hypersensitivity (Clinical Trial and In Vitro Study)

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Purpose: The present study was carried out to assess and compare the efficacy of OliNano Seal (OS) and Curodont D’Senz (CS) in the treatment of dentin hypersensitivity (DH) and the reduction of dentin permeability. Materials and Methods: The current study was a single-blinded, clinical trial and in vitro study using OS and CS in the treatment of DH. A total of 72 hypersensitive teeth were selected from 18 patients and randomly divided into two groups. Prior to the desensitizing agent’s application (the baseline), as well as immediately, 2 weeks, 4 weeks, and 3 months afterward, the evaluated materials were applied. Patients were instructed to use the visual analogue scale (VAS) to score their perception of tactile, air, and cold stimuli (VAS). In total, 90 samples were used for the evaluation, and they were randomly divided into two main groups: group A₁, which had the smear layer fully removed, and group A₂, which had the smear layer partially removed. According to the desensitizing agent used, each group was divided into three subgroups: OS, CS, and the control group that was left untreated. The results of the dentin permeability test were analyzed using the analysis of variance test, whereas the pain scores were analyzed using the Mann–Whitney test. Results: The study showed that there was a high statistically significant difference between pain scores prior to and after the application of both tested desensitizing agents. Permeability results revealed a high statistically significant difference between the study groups, with the lowest statistically significant mean depth of dye penetration found with OS-treated samples. Conclusion: OS and CS were both effective in the treatment of DH and the reduction of dentin permeability, with OS being more effective within 1 week and sustained up to 3 months.

Keywords: Curodont D’Senz, dentin hypersensitivity, dentin permeability, OliNano Seal
acknowledged mechanism of occurrence. It states that dentinal tubule fluid is vibrated following the stimulus, which in turn activates pulpal sensory nerves.[6]

There are numerous types of desensitizing treatments that are available on the markets. Only those that obliterate dentinal tubule orifices revealed a statistically significant difference from placebo groups in alleviating DH.[7,8] However, long-lasting retention of these agents is a challenge.[9]

A novel, varnish-like silicon polymer (OliNano Seal [OS]) was introduced to the markets by Olident (Christo Botewa, Kraków, Poland). It has a potent remineralizing and desensitizing action, thanks to its unique triple action composition (nano-fluorapatite, nano-calcium fluoride, and amine fluoride olaflur). Besides, the biomaterial of silicon polymer has been proven to adhere well to both enamel and dentin without prior conditioning.[10] Nano-fluorapatite penetrates into the dentinal tubules obliterating them and reducing their permeability.[11] Moreover, nano-calcium fluoride and amine fluoride olaflur are fluoride reservoirs that cause sustainable fluoride release and dentinal tubule occlusion.[12,13]

Self-assembling peptide matrix (P14) supplied commercially as Curodont D’Senz (CS) gel (Credentis AG, Windisch, Switzerland) is based on the nanofiber technology that enhances biomimetic repair and the remineralization of dental tissues. Self-assembling peptide matrix hydrogel revealed more reduction of the opened dentinal tubules in comparison to other selected desensitizing toothpaste.[14]

A previous randomized trial has evaluated the desensitizing effect of CS gel in comparison to 5% arginine and calcium carbonate containing toothpaste, and it has been found that CS demonstrated faster desensitization (after 1 week of application) that lasts to the end of the investigation and follow-up period (90 days) than arginine (8%) and calcium carbonate (CaCO3) dentifrice.[15]

Therefore, the aim of the present study is to evaluate and compare the efficacy of OS and CS in the treatment of DH. The authors assumed the null hypothesis that there will be no statistically significant difference between the tested interventions.

**Materials and Methods**

The current study was a single-blinded, clinical trial and in vitro study. It was conducted in the Operative Dentistry Department, College of Dental Medicine, Al-Azhar University-Girls’ Branch, Cairo, Egypt. The study rationale and design presented in accordance with a related study carried out by Schlee et al.[15] The study was registered by clinicalTrials.gov (ClinicalTrials.gov Identifier: NCT05122312).

**Sample size, ethical approval, and sample recruitment**

A total sample size of 72 teeth, with 36 teeth in each group, was determined for the clinical investigation. All procedures carried out as a part of this study involving human participants complied with the 1964 Helsinki declaration and its related policies or equivalent ethical standards, as approved by the Research Ethics Committee at the College of Dental Medicine, Al-Azhar University-Girls’ Branch, Cairo, Egypt (approval Id # REC-PD-21-06). The patients were given clear explanations of all the procedures in a language they could understand, and informed consent was assigned prior to the study.

The patients were recruited from the outpatient dental clinic of the Operative Dentistry Department at the College of Dental Medicine, Al-Azhar University-Girls’ Branch. The procedure, possible discomfort, and benefits were explained to the patients.

Inclusion criteria included the following: (a) patients who continuously complain of DH, with an age range from 20 to 49 years, (b) patients having at least two hypersensitive teeth, (c) teeth provided a pain score of one or more to air, tactile, and cold stimuli, (d) teeth with DH on the facial aspect only, and (e) patients who desire to participate in the clinical study. On the other hand, the exclusion criteria included the following: (a) patients who received desensitizing treatment in the last 3 months either professionally or self-administered, (b) patients recorded a score of four on the ICDAS “International Caries Detection and Assessment System,” (c) teeth diagnosed with irreversible pulpal inflammation, (d) teeth restored with partial or complete coverage, (e) the existence of cervical restoration that interferes with the application of stimuli for pain score recording, (f) patients with any medical or dental condition that could have an effect on the results of the study, (g) patients who presented a history of drug addictions, (h) patients who administer potent analgesic and/or anti-inflammatory drugs, and (h) lactating or pregnant women.[16]

**Randomization and grouping procedure, clinical procedure, and blinding**

Patients who met the criteria for inclusion were thereafter assigned for randomization that was done per patient using tossing a coin to assign the patient to be either treated with OS or CS. A participant dentist other than the main researcher performed the allocation sequence. Blinding the main researcher here was not possible as he was responsible for applying the
intervention. However, the assessor who investigated the results was blind.[16]

Seventy-two teeth were selected from 18 patients (each patient has four hypersensitive teeth), randomly divided into two groups. No particular arch or set of teeth was taken into account when standardizing.

Patients were randomly assigned into two groups (each group having nine patients) according to the material applied (A), into group A₁ (n = 36): caries-free cervical lesions with DH were treated with OS, a varnish-like protector based on silicone polymer that contains nano-fluorapatite, nano-calcium fluoride, and amine fluoride olaflur, and group A₂ (n = 36): caries-free cervical lesions with DH were treated with Curodont D’Senz, P₁₄ calcium phosphate, and fluoride-containing agent.[15] Patients were randomly assigned into two groups (each group having nine patients) according to the material applied (A), into group A₁ (n = 36): caries-free cervical lesions with DH were treated with OS, a varnish-like protector based on silicone polymer that contains nano-fluorapatite, nano-calcium fluoride, and amine fluoride olaflur, and group A₂ (n = 36): caries-free cervical lesions with DH were treated with Curodont D’Senz, P₁₄ calcium phosphate, and fluoride-containing agent.[15] As directed by the manufacturer, the agents were topically administered to the exposed dentin. Patients were instructed to use the visual analogue scale (VAS) to score their sensation of tactile, air, and cold stimuli. The response was evaluated at baseline, 1 day, 1 week, 2 weeks, and 3 months, respectively. Following the application procedure, patients were restricted from consuming citrus or carbonated beverages. They were advised to use soft toothbrushes. In addition, they were restricted from using any desensitizing toothpastes or mouth rinses throughout the study period.[16]

**Dentin permeability (dye penetration test) assessment**

For this part of the study, a sample size of 90 sample teeth in total and 30 in each group was calculated. Forty-five intact human premolars extracted for orthodontic reasons were used, following the approval and signature of informed consent collection from patients attending the orthodontic clinic at the Faculty of Dental Medicine for Girls in Al-Azhar University according to the previously mentioned Research Ethical Committee approval. Teeth were inspected to be free from decay, defect, or restorations. They were cleaned to remove any plaque, calculus, or any attached tissue and then stored in the artificial saliva in tightly closed containers at room temperature.[17]

Forty-five teeth were used for the dye penetration test. In a mesiodistal orientation, each tooth was divided longitudinally, into two parts (buccal and lingual). Two-millimeter depth and 0.8 mm width had been prepared in cavities on the cervical region 1 mm coronal to the gingival line. Samples were randomly divided into two main groups: group A₁, completely removed the smear layer; samples were treated with 37% phosphoric acid gel for 30 s, followed by 30 s of washing with deionized water, and 30 s of air drying. This procedure was repeated an additional two times, and group A₂, partially removed smear layer; samples were treated with the same acid gel for 15 s followed by rinsing and air drying. Three subgroups were established for each group based on the tested desensitizing agent used: subgroup B₁, OS; subgroup B₂, CS; and subgroup B₃, the control (left untreated).[18,19] Treatments were topically applied to the cavities of the samples according to their division. The assessment of dentin permeability was done using a dye penetration test to evaluate the occluding capacity of each treatment modality.[20]

**Statistical analysis**

Data from the clinical study were not normally distributed. As a consequence, after verifying the assumptions, data were analyzed by using Mann–Whitney test. Data of the in vitro study (dentin permeability assessment) were normally distributed. Data were analyzed using analysis of variance (ANOVA). Statistical analysis was done using IBM SPSS Version 26 (1 New Orchard Road, Armonk, New York 10504–1722, United States).

**Results**

The results of the clinical study revealed that there was a high statistically significant difference between pain scores before and after treatment for both tested groups, using tactile, air, and cold stimulus on the VAS. CS needed four applications for complete relief, whereas the OS group needed only one application for complete relief [Table 1].

Dentin permeability results showed that there were highly statistically significant differences between the study groups in the dye penetration test [Table 2 and Figure 1A–F].

**Discussion**

In this study, results showed a significant decrease in DH after 1 week in the OS group and after 4 weeks in the CS group. Moreover, the permeability results showed that there was a significant decrease in the dye penetration depth in the OS group than in the CS group and the control group, respectively.

The efficacy of OS products in the treatment of DH and the reduction of dentin permeability has not been studied before. However, the desensitizing effect of each constituent has been reported in various previous studies. The significant decrease in DH, shown by the OS group, might have been attributed to its triple action composition. It contains the three-potent desensitizing constituents in a nanoparticle form, a form that magnifies the effects of the three of them on the reduction of hypersensitivity as well as the suppression of root caries.[20] First, nano-
Microcrystalline fluorapatite was investigated to release calcium, phosphorus, and fluoride ions and to provide more occlusion of dentinal tubules.\textsuperscript{[21]}

Second, nano-calcium fluoride (nano CaF\textsubscript{2}) has been shown that it can be used as an effective desensitizing agent as it increases the labile fluoride (F) concentration in saliva and thus enhances the dentinal tubule occlusion and the reduction of dentin permeability.\textsuperscript{[22]} The third constituent of OS is amine fluoride olaflur, which proved a substantial reduction of DH as reported by Petersson \textit{et al.}\textsuperscript{[23]}

Furthermore, the clinical results revealed that the OS-treated group provided the lowest mean verbal rating scores immediately after treatment, after 1, 2, and 4 weeks at probing air and cold stimuli, and VAS. Hence, OS provided a quicker and longer lasting effect. Its tubular sealing action, which blocks the passage of dentinal fluid in the tubules and consequently prevents any alteration in the positioning of the odontoblastic process and nerve terminals, may be the cause of the rapid relief. The persistent stability of the deposits created in this way may be the cause of the OS’s long-lasting effects. As with all in-office treatments, the persistence of tubule obliteration is an important parameter. The deposits formed by OS were little influenced by rotation in artificial saliva. This would be due to the strong affinity of deposits for dentine and possibly could be the cause of lasting relief from DH.

However, this study is not intended to address the retention and stability of the OS deposits in a challenging oral environment, a point that needs further investigation.

The results of the clinical study revealed that there was a statistically significant decrease in pain scores before and after treatment for the CS group, using tactile air and cold stimulus on a VAS. For the treatment of DH, CS is a dental biomaterial that combines the P\textsubscript{11-4}-based Curolox Technology together with minerals (calcium phosphate and fluoride) content. It was shown that as a consequence to the concomitant increase of mineral gain and the prevention of mineral loss, peptide therapy greatly increased the net mineral gain. Besides, the self-assembling peptide P\textsubscript{11-4} was found to induce hydroxyapatite nucleation \textit{de novo}.\textsuperscript{[24]} P\textsubscript{11-4} is a self-assembling peptide with a systematic design. This category of peptides goes through a hierarchically planned process of assembly. It is capable to form a 3D meshwork of fibrils when subjected to certain environmental factors.\textsuperscript{[25]} It was also claimed that the three-dimensional form of meshwork is being constructed directly after the gel’s peptides diffusion inside the subsurface micropores, promoting tooth tissue crystal formation within 90 days.\textsuperscript{[17]} This might explain the significant decrease in DH of the CS group after 4 weeks as it takes some time for the hydroxyapatite crystallization to form. However, patients treated with CS needed four applications for a complete relief. This specific finding was in accordance with Hamouda \textit{et al.}
who concluded that CS was effective to manage DH based on the biomimetic mineralization concept. This mineralization mode might take a longer time to provide a higher and long-lasting desensitizing effect. Future studies should investigate the desensitizing effect of CS for longer follow-up periods.

CONCLUSION
OS and CS were effective in reducing dentin permeability, occluding dentinal tubules, and alleviating the hypersensitivity symptoms, with OS being the most effective within 1 week and sustained up to 3 months. The authors suggest the testing of the efficacy of these desensitizing agents over much more prolonged follow-up period.

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CONFLICTS OF INTEREST
There are no conflicts of interest.

AUTHORS’ CONTRIBUTION
Not applicable.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT
All procedures performed in this study involving human participants were in accordance with the ethical standards
of Research Ethics Committee at the Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt; approval Id # REC-PP-21-06, approval date was June 1, 2021, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the clinicalTrial.gov (ClinicalTrials.gov Identifier: NCT051223212). The article adheres to the CONSORT reporting guidelines of original articles (Clinical Trial Studies).

**PATIENT declaration of consent**

All patients signed informed consent that was in accordance with the ethical standards of Research Ethics Committee at the Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt; approval Id # REC-PP-21-06, approval date was June 1, 2021, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the clinicalTrial.gov. ClinicalTrials.gov Identifier: NCT051223212.

**DATA availability statement**

The data set used in the current study is available on request from Dr. Asmaa A. Mosleh (asmaamosleh.26@azhar.edu.eg).

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