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Evaluation of the Effectiveness on Dentin Hypersensitivity of Sodium Fluoride and a New Desensitizing Agent, Used Alone or in Combination with a Diode Laser: A Clinical Study

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Abstract: (1) Background: Dentine Hypersensitivity (DH) is a frequent clinical problem that causes long-term painful discomfort to patients and is a diagnostic and therapeutic challenge for dentists. The aim of this research was to verify the efficacy of a Sodium Fluoride (NaF) gel and the VivaSens® varnish used alone or in combination with a Creation Soft Diode Laser (DL) to treat DH pain. (2) Methods: The study included 121 Non-Carious Cervical Lesions (NCCLs) in 48 patients who complained of DH pain of variable intensity, between 4 and 7 points in VAS, after application of a cold stimulus. Four study groups of 12 patients each were created and subjected to four different types of treatment. Group 1 comprised 27 NCCLs with a total VAS score of 142, who received a topical treatment of NaF. Group 2 comprised 34 NCCLs with a total VAS score of 179, who were treated with NaF in association with DL. Group 3 comprised 31 NCCLs with a total VAS score 172, who received the VivaSens varnish. Group 4 comprised 29 NCCLS with a total VAS score of 155, who were treated with VivaSens in association with DL, using a power of 0.2 Watt in continuous emission and a fiber of 400 µm diameter. (3) Results: The results for each NCCL were evaluated by the cold stimulus response and recorded according to the VAS at the end of each treatment (t1) as well as after one week (t2), 1 month (t3), and 6 months (t4). All treatments resulted in pain relief at all study times, but the best results were obtained for Group 4 at t1, with a total VAS score of 26, and for Group 2 at t2, t3, and t4, with total VAS scores of 41, 51, and 65, respectively. (4) Conclusions: The treatment with VivaSens allowed pain relief immediately after its application, but the greatest long-term benefits (t2, t3, and t4) were obtained with the topical application of NaF associated with a DL.

Keywords: non-carious cervical lesion; dentine hypersensitivity; diode laser; tooth pain

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1. Introduction

Dentin hypersensitivity (DH) is a rather frequent clinical problem with a high prevalence rate. It manifests with pain of different intensity that could cause a non-negligible discomfort to patients, while for dentists it always represents a challenge for its difficult clinical diagnosis and, mainly, for the treatment plan options. Short and intense pain occurs in correspondence with the exposed dentine as a response to thermal, chemical, tactile, or osmotic stimuli and cannot be attributed to any other tooth defect or pathology [1]. DH is frequently associated with non-carious cervical lesions (NCCLs) which are often localized on the buccal surface of all teeth but with greater evidence on the premolars and canines [2,3]. The cervical area on the vestibular surface and the root of the tooth are the most common sites of dentine hypersensitivity. The frequency of DH occurrence is from 3 to 57%, and in patients suffering from periodontal disease, it is more common, being

72–98% [4]. Several theories have been proposed to explain the mechanisms of DH. The most widely accepted theory was proposed by Brannstrom and Astrom in 1972 and is known by the name of "hydrodynamic theory". According to this theory, pain is caused by moving fluid within the dentine tubules [5,6]. The ability to close the dentine tubules, reducing the movement of fluid in them, allows blocking the painful sensation in the pulp and is considered the ideal treatment of DH [7]. In the wake of the hydrodynamic theory, several methods have been used to occlude open dentine tubules, such as the application of sodium fluorides (NaF) in a gel, thus causing tubule obstruction by calcium fluoride precipitation in the tubules, the use of other desensitizing molecules causing a mechanical blockage of the dentinal tubules through the precipitation of proteins in the dentinal fluid, as well as the use of a casein phosphopeptide varnish and of silver nitrate [8–10]. Other desensitizing agents that act with different mechanisms to control DH pain have been studied, such as a potassium nitrate-based gel that reduces pain by acting on nerve conduction [11,12]. Furthermore, to improve and ensure a longer duration of the pain relief from DH, treatments with desensitizer agents that act with different mechanisms, such as the desensitizing VivaSens®, were proposed [13–15].

The study of Hall et al. confirmed the effectiveness of a mouthwash containing 3% potassium nitrate in causing a rapid relief of pain from DH, but the mouthwash did not provide statistically significant improvements on DH compared with use of fluoride toothpaste alone [16].

Pathan et al. evaluated the effectiveness of three desensitizing agents, i.e., Admira Protect, VivaSens, and Neo Active Apatite, in dentinal tubule occlusion and the duration of their action and found that Admira Protect was the most effective [17]. In recent decades, the behavior and the effectiveness of some desensitizing agents ,alone or in combination with lasers, on the relief of pain caused by DH have been studied. In the literature there are many studies conducted with different types of lasers, using different wavelengths and application times, revealing the effectiveness of this treatment, immediately after its application as well as after several months from the first treatment. Specifically, no comparison has been made between new desensitizing products based on a double-action system and the diode laser [18–21].

The aim of this research was to verify and compare the effectiveness of two topical agents on pain associated with DH, sodium fluoride (NaF) and VivaSens®, used alone or in association with a diode laser.

2. Materials and Methods

The vestibular surfaces of the teeth of 58 subjects (34 females and 24 males aged 22 to 68 years), afferent to the Conservative Dentistry Unit (Dental Materials Section) of the Dental Clinic of the University of Campania "Luigi Vanvitelli," from October 2019 to March 2022, complaining of DH, were examined by an experienced clinical operator using a probe tip and an ×4 magnifying lens. The tip of the probe was held perpendicularly to the tooth surface and inserted up to the bottom of the gingival sulcus crossing the cement-enamel junction (CEJ). Any irregularity in the cervical enamel and at the CEJ of the teeth was considered a NCCL. All subjects signed an Informed Consent after verbal and written information on the study was provided.

This study was conducted in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013. The research was approved by the Ethics Committee of AORN of Ospedali dei Colli with N. 1374/2019.

The first operator, after identifying 151 NCCLs responsible for DH, used exclusion criteria to filter those not suitable for this study.

Tooth with NNCLs with these characteristics were excluded from the study: (1) association with periodontal pockets or gingival recession; (2) presence of carious lesions or restoration; (3) evidence of cracks; (4) primary teeth, and (5) presence of subgingival NCCLs.

The second clinic researcher further selected NCCLs to be enrolled in this study based on the pain intensity elicited by each NCCL after a stimulus using the Evaporative Air Test (EAT). For this type of inclusion criteria, each patient evaluated the pain intensity associated with every NCCL at baseline (t0) using a visual analog scale (VAS) and recorded the perceived pain level using a numeric scale from 0 to 10, where 0 indicated the absence of pain, and 10 indicated the maximum pain ever felt. Only 102 patients who reported a pain intensity between 4–7, were considered suitable for this study. Using these restrictions, only 121 NCCLs belonging to 48 patients (26 females and 22 males from 22 to 65 years) were enrolled in this study. Evaporative Air Test (EAT): the degree of tooth sensitivity was determined using an air stimulus defined as a 3 s cold air blast (temperature range of 19–20 °C) at a distance of 2–3 mm from the test site. The tooth under examination was isolated using cotton rolls and by shielding the neighboring teeth with the gloved fingers of the operator. All patients were asked to report their degree of pain for each NCCL after the EAT using the VAS scale at each point of the timeline previously described.

The third examiner, who was not a clinician, divided the 48 patients into 4 study groups, each of 12 patients, using a random distribution software, and each group was assigned a different treatment protocol for DH that was administered by the fourth operator (an experienced clinician) after isolating each tooth with NCCL from the saliva using cotton rolls and after air-drying gently for 3 s [18].

Study group 1: 27 NCCLs (total VAS of 142, mean 5.29 and DS 1.09) were subjected to a protocol based on the topical application of fluoride (0.33% acidified sodium fluoride gel, MEDICAL, Treviso, Italy) for 12 s on the surface of each cervical lesion.

Study group 2: 34 NCCLs (total VAS 179, mean 5.26 and DS 1.11) were subjected to a therapeutic protocol based on the topical application of fluoride for 60" on the surface of each cervical lesion and then of irradiation by a diode laser (DL) (Creation, Soft Touch; 810 nm, 5 W) for the following 60". The parameters of the DL were: power of 0.2 Watt in continuous emission and fiber of 400 µm diameter. The tip of the fiber was kept immersed in the topical gel, avoiding touching the surface of the tooth for 60 s and performing rapid movements at the apical-coronal and mesiodistal surfaces to treat the whole surface of the dental lesion. With this protocol, the application of 0.2 W for 60 s led to an irradiance of 12 Joules for each tooth.

Study group 3: 31 NCCLs (total VAS 172, mean VAS 5.55 and DS 1.12) underwent a therapeutic treatment based on a desensitizer agent—VivaSens®, a lacquer based on ethanol, water, and hydroxypropyl cellulose, containing potassium fluoride, polyethylene glycol dimethacrylate—and other methacrylates (Ivoclar, Vivadent), applied in solution on the cervical lesion and, after 20 s, dried with a jet of air.

Study group 4: 29 NCCLs (total VAS 155, mean 5.34 and DS 1.11) received the same treatment as group 3, after which, the lesions were subjected to irradiation by DL using the same conditions and parameters employed for group 2 for 60 s, while keeping the fiber at a distance about of 0.2–0.5 cm from the dental lesion.

The second operator again evaluated the effectiveness of the different therapeutic protocols by recording the intensity of pain for each NCCL following the EAT stimulus and the VAS immediately at the end of the treatment and after 1 week, 1 month, and 6 months. Before starting any treatment procedure, all subjects received oral professional hygiene and instructions for maintaining it. In addition, each patient was examined to identify the causative factors of DH from NCCLs and given instructions to eliminate them.

3. Results

All patients completed the study. The NCCLs selected for analysis included those that did not meet the exclusion criteria, reported in Section 2. The results obtained from the Total Score of the VAS and the mean of the VAS values obtained after the EAT for the single study groups, at each time point of the therapeutic protocol, i.e., baseline (t0), at treatment completion (t1), at 7 days (t2), at 1 month (t3), and at 6 months (t4), are shown in Table 1.

Table 1. Total and mean values of discomfort scores (VAS) at baseline (t0), immediately after the treatment test (t1) and, after 1 week (t2), 1 month (t3) and 6 months (t4) for each study group. The values with greater pain control are highlighted in bold. Statistical correlation between VAS value at baseline vs. all VAS values at different times using the Wilcoxon signed-rank test.

Time	SG 1 (n28)		SG 2 (n34)		SG 3 (n32)		SG 4 (n30)	
	Total	Mean	Total	Mean	Total	Mean	Total	Mean
t0	142	5.29	179	5.26	172	5.55	155	5.34
t1	38	1.41	43	1.26	30	0.97	**26**	**0.90**
t2	46	1.70	**41**	**1.20**	39	1.26	50	1.72
t3	59	2.19	**51**	**1.5**	62	2	72	2.48
t4	86	3.19	**65**	**1.91**	99	3.19	101	3.63
p value	$p < 0.0001$		$p < 0.0001$		$p < 0.0001$		$p < 0.0001$	

The statistical analysis to compare the VAS scores at baseline (t0) vs. those at t1, t2, t3, and t5 of each study group was performed by means of the Wilcoxon signed-rank test (Table 1), while to compare the VAS scores between each group study we used an unpaired *t*-test and the GraphPad Prism V 6.0 software (GraphPad by Dotmatics, San Diego CA, USA) (Table 2). Values of $p < 0.05$ were accepted as statistically significant.

Table 2. Statistical correlation of VAS scores between each group immediately at end of treatment (t1), at 7 days (t2), at 1 month (t3), and at 6 (t4) months from the treatment. P: Wilcoxon signed-rank test.

Study Groups	t1	t2	t3	t4
SG 1 vs. SG 2	0.43	0.99	0.00 **	0.00 **
SG 1 vs. SG 3	0.01 *	0.75	0.00 **	0.96
SG 1 vs. SG 4	0.00 **	0.91	0.28	0.03 *
SG 2 vs. SG 4	0.04 *	0.00 **	0.00 **	0.00 **
SG 3 vs. SG 4	0.63	0.00 **	0.99	0.02 *

* $p < 0.05$; ** $p < 0.01$.

A significant reduction of the VAS value was estimated for all study groups at t1, t2, t3, and t4 compared with the same score assessed at t0 ($p < 0.0001$ for each tested pair of every study group). The best results of the VAS score at t1 were obtained for SG 4, while at t2, t3, and t4 better pain control was achieved in SG 2.

The analysis of the data showed that there was a rapid reduction of DH pain associated with NCCLs topically treated with the VivaSens agent in association with DL irradiation at t1 (Group 4), while at t2, t3, and t4, the painful symptomatology appeared to be in greater control for SG 2 when the NCCLs were topically treated with the Fluorine gel followed by irradiation with the DL.

The statistical comparison of the VAS scores at t1, t2, t3, and t4 between each pair of study groups revealed statistically significant differences between the Groups at the different times of the evaluation (Table 2).

4. Discussion

DH is a very annoying clinical problem. DH patients feel an intense pain when teeth come in contact with hot, cold, acidic, or sweet liquids and foods.

The clinician has to identify and correct the responsible factors and establish a therapeutic plan with a desensitizing effect that leads to the cessation of pain as fast as possible and for the longest time. Nowadays, there is no verified protocol that can eliminate the pain from DH, even when combining various protocols. The treatment of DH is based on the concept of reducing the fluid movement inside the dentin tubules by narrowing or occluding the tubules' openings. In fact, according to the hydrodynamic theory, the effectiveness of dentin-desensitizing agents is directly related to their capacity of sealing the dentin canaliculi, maintaining a constant intracanalicular pressure [22,23].

The present study was realized using a single-blind and randomized design evaluating the effectiveness of NaF in a gel and of a desensitizer agent, VivaSens, used either alone or in association with a DL for the treatment of DH caused by NCCLs, on the basis of the VAS score recorded by each patient after EAT stimulus immediately at end of treatment (t1), after 1 week (t2) and after 1 (t3) and 6 (t4) months from the treatment. The results demonstrated that all procedures used provided clinical improvement, with the reduction of pain. The analysis of the total VAS scores for each group after EAT showed a higher relief of pain immediately at the end of the treatment when the solution of VivaSens—that created a film like a varnish on the teeth surface with NCCLs—was used in association with laser irradiation (Group 4, with a total VAS score 26 and mean of 0.90), compared to the results obtained when VivaSens was used alone (Group 3, with a total VAS score 30 and mean of 0.97) or when NaF was applied alone (Group 1, with a total VAS score 38 and mean of 1.41) or in association with DL (Group 2, with a total VAS score 43 and mean of 1.26). On the other hand, the best results in pain reduction after EAT stimulation recorded using the VAS score, both after 1 week and after 1 and 6 months, were found for patients in Group 2, with total VAS scores of 41, 51, and 65 and means of 1.20, 1.5, and 1.91, respectively. This indicates that VivaSens is quickly effective when used alone and even more performing when associated with diode laser irradiation compared to NaF, used alone or associated with DL. Several studies have shown the efficacy of VivaSens as an in-office desensitizing agent. Our findings are consistent with the findings of Asrani H.M. et al. who evaluated the ability of the desensitizing agents VivaSens and DL on dentinal tubule occlusion and their effectiveness over time using scanning electron microscopy on extracted teeth. The search concluded there was no statistically significant difference between the VivaSens and the Laser groups. This indicates that both agents are equally effective in the obliteration of dentinal tubules [24]. Our study shows that NaF associated with DL represents the treatment of choice in the short and long term (t2, t3, and t4, with total VAS scores of 41, 51, and 65, respectively). These data are in agreement with a previous study performed by Femiano F. et al. that showed that the use of NaF associated with DL diode laser had a very high capability to provide relief of DH-related pain, both immediately and after 1 and 6 months from the treatment, compared to NaF and DL used alone and to the Gluma Desensitizer [18].

The effectiveness of NaF is related to mechanical occlusion linked to the precipitation of insoluble calcium fluoride (CaF) crystals within the tubules, without adhesion. The lower short- and long-term efficacy of NaF in comparison with NaF plus DL may be attributed to a fairly rapid loss of the occluding layer of CaF due to dissolution in saliva [25].

VivaSens is a desensitizer agent in an alcohol-based liquid solution, containing polyacrylic acid modified with methacrylate and potassium fluoride without glutaraldehyde, which creates a film-like varnish on the tooth surface and relieves pain through various mechanisms.

VivaSens seals the dentinal tubules by inducing the precipitation of proteins and calcium in the dentinal fluid (mechanical work), while the presence of potassium fluoride provides additional protection with a rapid pain reduction resulting from the depolarization of nerve fibers (neural mechanism). This explains the rapidity of action of this agent on pain relief, which improves with the association with a DL (total VAS score and mean in SG3 of 30 and 0.97 and in SG4 of 26 and 0.90, respectively) immediately at the end of the treatment.

The association of DL with VivaSens does not enhance the effect for a long time probably because, over time, the effectiveness of potassium fluoride is reduced, leaving only the precipitation of proteins in the dentinal fluid to guarantee a mechanical blockage of the open dentinal tubules. These results are in agreement with previous in vivo studies evaluating the efficacy of VivaSens on DH pain and detecting a rapid pain relief, though with no statistical difference in comparison with other tested desensitizing agents [26,27]. The data in our study showed a higher long-term effectiveness of NaF in association with DL used at a low power (0.5 Watt) on the reduction of pain caused by DH, in comparison

with NaF used alone, probably because at the power chosen, DL had bio-stimulating effects on dentin, promoting the formation of new dentin, which could justify the longer duration of the protective effect on pain. In addition, the higher effectiveness of the use of NaF when associated with the DL compared to VivaSens may be related to the action of the diode laser that could allow a deeper penetration of NaF into the dentin tubules, facilitating the precipitation of CaF, which, in combination with laser-induced occlusion derived from the superficial melting of proteins into the dentin fluid, maintains the occlusion of tubules longer, lessening the discomfort from DH [28]. Certainly, one of the main limitations of our study is the lack of randomization in the distribution of the subjects in the different groups, which were even slightly inhomogeneous at the start of the study. This can be a cause of bias, although the sample size greatly reduced the impact on the results. Another limitation of our research protocol is the absence of a sham laser irradiation control to monitor the effects of the laser. This may have influenced the results, but in our opinion, it is an uncontrollable parameter in clinical practice and therefore does not affect the relevance of the study in relation to its clinical implications.

5. Conclusions

Our results showed that the VivaSens agent used in association with DL was very effective in providing relief to DH-related pain immediately at the end of the treatment (SG4, with a total VAS score of 26 and a mean of 0.90). In contrast, the control of DH pain after EAT stimulation after 1 week and after 1 and 6 months was more effective when NCCLs were treated with a DL-associated NaF gel. In light of these considerations, from the data of this study, we can affirm that the use of VivaSens in association with DL effectively reduced pain caused by DH, achieving higher effects immediately after its application, while the maximum pain relief were obtained after 1 week and 1 and 6 months with the use of NaF combined with the DL. Surely, further studies are needed to evaluate the long-term stability of the improvement in the cervical dentin hypersensitivity.

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Informed Consent Statement: All subjects gave their consent for the publication of data for scientific purposes.

Data Availability Statement: All raw data are available for consultation and for a collaboration request at the following email address: felice.femiano@unicampania.it.

Conflicts of Interest: The authors declare no conflict of interest.

Abbreviations

DH	Dentine Hypersensitivity
DL	Diode Laser
NCCLs	Non-Carious Cervical Lesions
CEJ	Cement-Enamel Junction
SG	Study Group
NaF	Sodium Fluoride

CaF	Calcium Fluoride
VAS	Visual Analogic Scale
EAT	Evaporative Air Test

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