

## Short-term Clinical Evaluation of Four Desensitizing Agents

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### Abstract

**Aim:** To evaluate the effectiveness of four topical desensitizing agents in providing short-term relief of dentin hypersensitivity.

**Methods and Materials:** One hundred sixteen hypersensitive teeth with a positive response to intraoral testing for dentin hypersensitivity were included in this study. The four desensitizing agents tested were Duraphat™, 2% fluoride iontophoresis, copal varnish (CV), and Gluma™ Comfort Bond Plus Desensitizer. Following a specific regimen randomly determined desensitizing agents were applied in an alternating order when patients presented in a clinical setting with a complaint of hypersensitive teeth. A visual analogue scale was used to determine the degrees of hypersensitivity at three points in time. The first being just before the treatment to establish a baseline, then at 24 hours post-treatment, and the last at seven days post-treatment. Differences in the mean pain scores (MPS) between the baseline and post-treatment evaluation periods were used to determine the reduction in dentin hypersensitivity.

**Results:** At baseline the MPS for teeth treated with CV was 5.34 (SD: 2.39), Duraphat™ was 4.66 (SD: 1.82), Gluma™ was 6.03 (SD: 2.37), and iontophoresis was 5.76 (SD: 1.37). At 24 hours post-treatment the MPS for CV was 2.1 (SD: 0.95), Duraphat™ was 1.38 (SD: 1.86), Gluma™ was 0.79 (SD: 1.45), and iontophoresis was 1.62 (SD: 1.97). The reduction in dentin hypersensitivity at 24 hours (difference between baseline MPS and 24

hour MPS) was 5.28 for Gluma™, 4.14 for iontophoresis, 3.28 for Duraphat™, and 3.24 for CV which were all statistically significant ( $p < 0.05$ ). At seven days, the MPS for CV was 1.55 (SD: 1.44), Duraphat™ was 1.0 (SD;1.89), Gluma™ was 0.10 (SD;0.44), and iontophoresis was 0.3 (SD;0.98). Reduction of hypersensitivity between 24 hours and one week was 1.32 for iontophoresis, 0.69 for Gluma™, 0.55 for CV, and 0.38 for Duraphat™. Only the reductions for iontophoresis and Gluma™ were statistically significant at seven days ( $p < 0.05$ ).

**Conclusions:** All agents caused a statistically significant reduction in dentin hypersensitivity within 24 hours of treatment. Gluma™ performed best at 24 hours while iontophoresis appeared to have an edge at seven days. Long-term studies are needed to determine why this difference exists. Dentin hypersensitivity presents as an emergency condition requiring an effective means of providing immediate relief in the clinician's treatment armamentarium.

**Keywords:** Hypersensitive teeth, desensitizing agents, iontophoresis, Gluma™, copal varnish, CV, Duraphat™

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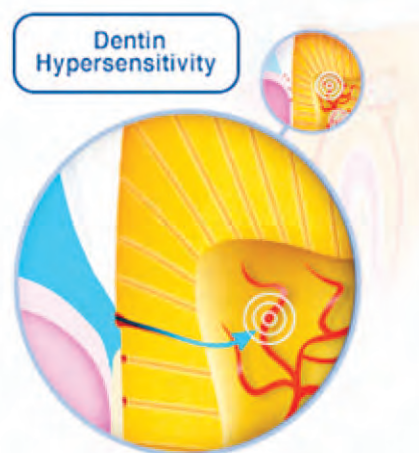
## Introduction

Dentin hypersensitivity is characterized by short, sharp pain arising from exposed dentin in response to stimuli such as thermal, evaporative, tactile, osmotic, or chemical and which cannot be ascribed to any other form of dental defect or pathology.<sup>1</sup> Hotz<sup>2</sup> and coworkers have indicated 80% of the population will suffer from the symptoms of dentin exposure at some time during their lifetime. In the forthcoming years prevalence of dentin hypersensitivity is expected to increase as people live longer and retain more teeth.<sup>3</sup>

Dentin exposure may result from enamel loss by attrition, abrasion, erosion, or abfraction as well as root surface exposure resulting from gingival recession or periodontal treatment. Most hard tissue loss probably occurs from a combination of these factors.

The sensitivity of vital teeth is best explained by the 'hydrodynamic theory' proposed by Brannstrom<sup>4</sup> who theorized the movement of fluid within dentinal tubules stimulates pulpal nerve receptors and, thereby, causes pain. This remains the most widely accepted theory of pain of dentin hypersensitivity.<sup>5,6</sup> The severe pain of dentin hypersensitivity has prompted researchers to seek treatment alternatives to provide relief for affected patients.

Treatment can be invasive or non-invasive in nature. Conventional conservative therapy is based on using topically applied desensitizing



agents either professionally or prescribed to the patients for home use.<sup>7</sup> Potassium-containing toothpastes are the most widely used at-home treatments<sup>8</sup> and are the most inexpensive and efficacious first line of treatment for most patients.<sup>5</sup> Most in-office treatments employ some form of "barrier" created by a topical solution, gel, or an adhesive restorative material.<sup>8</sup>

West,<sup>6</sup> in a recent review, hinted conclusive evidence of successful treatment regimens of dentin hypersensitivity remains elusive despite a multitude of products available for treatment. The efficacy of most of them was described as varied, not well established, and unpredictable.<sup>8,9</sup> Therefore, clinicians are left to determine the most satisfactory and effective treatment approach for relief of dentin hypersensitivity for patients in their practices.

Four topical desensitizers were employed in the study. Copal varnish (CV), a product with low fluoride concentration, has been suggested to help in desensitizing hypersensitive dentin when applied topically.<sup>10</sup> Simple application of CV has been said to seal dentinal tubules under crowns to avoid sensitivity.<sup>11</sup> Arends et al.<sup>12</sup> noted CV is used mainly in caries prevention, but in their study of the penetration of varnishes into demineralized root dentin they found the penetration of varnish into dentin is valuable with respect to caries prevention and for the reduction of the discomfort of dentin hypersensitivity. The varnish presumably seals the tubules partially or completely.

Gluma™, also a non-fluoride product, is one of the systems marketed solely for treatment of dentin hypersensitivity. It is a dentin bonding system containing gluteraldehyde (GA), a biological fixative. Gluma™ acts as a desensitizer through the reaction of GA with part of the serum albumin in dentinal fluid which induces a precipitation of serum albumin. This reaction of GA with serum albumin is said to induce polymerization of HEMA. The function of Gluma™ as a desensitizer to block dentinal tubules occurs via these two reactions.<sup>13</sup> Dondi dall'Orologio et al.<sup>14</sup> also concluded the gluteraldehyde in Gluma™ played an active and effective role as a desensitizing agent. Kakaboura et al.<sup>15</sup> found Gluma™ reduced hypersensitivity in dentin for up to nine months. Cochran<sup>16</sup> found Gluma™ performed better than oxalate systems in terms of longevity of their effectiveness.

Duraphat™ is a varnish with a high fluoride content and is said to improve discomfort from dentin hypersensitivity.<sup>17</sup> Fluoride varnish is said to form a protective layer of calcium fluoride that prevents fluid flow in open dentinal tubules, thereby, reducing dentin sensitivity.<sup>18</sup> Fluoride is thought to increase the stability of the dentin surface by reducing the solubility of dentin, thereby, shifting the equilibrium at the surface level in favor of non-sensitivity.<sup>3</sup> In a study the efficacy of AllSolution™ fluoride varnish in reducing hypersensitivity was said not to be significantly different from Duraphat™.<sup>19</sup> Merika et al.<sup>20</sup> studied the efficacy of Duraphat™ and suggested it can be considered an effective therapy for dentin sensitivity. Duraphat™ is

also said to be effective in treating cervical hypersensitivity, but the use of a low level laser is preferred for teeth with high sensitivity scores.<sup>21</sup>

Iontophoresis is the use of an electric current to drive relative concentrations of ionic drugs into hard or soft tissue. Using this approach, fluoride ions are driven deeper into the tubules, thereby, causing greater fluoride uptake than is possible with a topical application.<sup>22,23</sup> It is also suggested reparative dentin could be induced by iontophoresis.<sup>24</sup> The fluoride ions react with calcium in the hydroxylapatite to form fluoroapatite. The CaF<sub>2</sub> precipitates leaving the tubules blocked with the insoluble compound.<sup>22</sup> fluoride iontophoresis with HEMA-G (an aqueous solution of hydroxy-ethyl-methacrylate and glutaraldehyde), both agents were found to be equally effective immediately after application, however, the 2% NaF was comparatively better than HEMA-G in providing long-term relief.<sup>26</sup>

Few studies have evaluated the effectiveness of these desensitizing agents *in vivo*. The purpose of this study was to assess the efficacy of four desensitizing agents in providing short-term relief from dentin hypersensitivity.

### Methods and Materials

One hundred sixteen teeth from 25 patients with a positive response to intraoral testing for dentin hypersensitivity in the Conservative Dental Clinic of the Obafemi Awolowo University Teaching Hospitals Complex in Ile-Ife, Nigeria were recruited for the study. The patients consisted of 15 males and ten females whose ages ranged between 17 and 55 years. The selection of patients and teeth were based on the following criteria:<sup>1,27</sup>

1. Selected teeth were those having any type of cervical lesion with dentin hypersensitivity taking into consideration abrasion, abfraction, erosion, and gingival recession as the primary etiological factors.
2. The absence of severe systemic and/or psychological diseases, i.e., bulimia and uncontrolled diabetes mellitus.
3. Patients who had not received professional treatment with desensitizing agents in the previous six months.
4. Freely given informed consent by the patients

Table 1. Desensitizing agents used.

	CV	Duraphat™	Gluma™	Iontophoresis
<b>Manufacturers</b>	Henry Schein	Colgate-Palmolive UK	Heraeus Kulzer, Germany	Packell Electronics, NY, USA
<b>Lot/Batch numbers</b>	Ref. 100-0045	PL0049/0042	010042	
<b>Contents</b>	Gum copal, Fluoride (from sodium fluoride) 0.055%, Alcohol, Dichloromethane	Sodium fluoride 2.26%, Ethanol 96%, Whitewax, Shellac, Colophony, Mastic, Saccharin, Raspberry essence.	Methacrylate, 4-META, Ethanol, Gluteraldehyde, photoinitiators	Desensitron II equipment, 2% sodium fluoride.
<b>Procedures Used</b>	(a) Clean the tooth. (b) Rinse and air dry.* (c) Apply using a miniature cotton swab or brush..	(a) Clean the tooth. Excess plaque may be removed (b) Rinse and air dry.* (c) Apply Duraphat using a miniature cotton swab or brush. Dentist may decide how much Duraphat™ to apply.	(a) Clean the tooth with an oil-free polishing paste. (b) Rinse with water and air dry.* (c) Conditioning with Gluma™ Etch 20 Gel (20% phosphoric acid). <b>NOTE</b> Dry surface re-moistened by damp pellet (d) Dispense Gluma™ with disposable brush. Two additional coats may be applied. (e) Light cure for 15 seconds.	(a) Excess plaque and calculus removed. (b) Tooth cleaned and air dry.* (c) Setting-up the desensitron equipment. The current control set to 0.5mA Saturation of the cotton tip with several drops of 2% sodium fluoride. (d) The saturated cotton tip applied to the area of sensitivity for one minute.

\* The surface was dried by gentle air stream from the air-water jet of the dental chair.

as recommended by the World Medical Association<sup>28</sup> and by the Ethical Committee of the Obafemi Awolowo University Teaching Hospitals Complex in Ile-Ife, Nigeria.

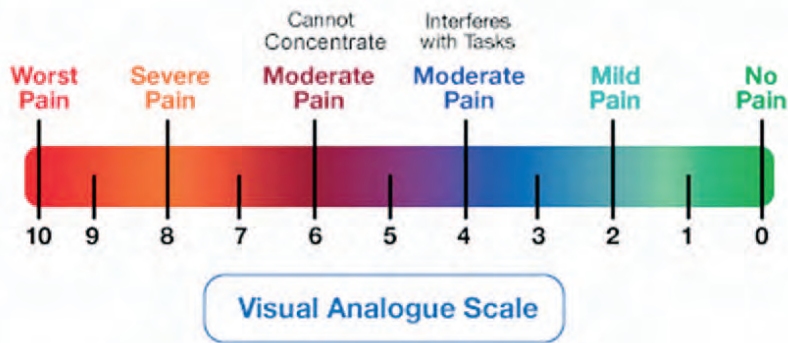
Patients who were excluded were those with:

- Teeth having extensive caries
- Cracks or fractures
- Grossly worn down teeth
- Extensive and unsatisfactory restorations
- Recent restorations
- Tooth mobility

- Recent treatment in a dental clinic in the last six months prior to the onset of the study

The desensitizing agents studied, CV; Duraphat™; Gluma™ Comfort Bond Plus Desensitizer; and 2% fluoride iontophoresis, are shown in Table 1.

Following the diagnosis of dentin hypersensitivity in the first examination session, initial (baseline) hypersensitivity patterns were recorded. Each tooth received a tactile stimulus (probing). The use of tactile stimulus was performed simply by



scratching the suspected site of the lesion with a dental probe until the patient reported pain similar to the level of discomfort motivating him to seek treatment.

The patients were given a VAS proforma (Visual Analogue Scale) on which they were asked to place a pencil mark at a point on a linear scale marked from 0 to 10<sup>29</sup> to describe the pain experienced. After each stimulus of the suspected site, the degree of hypersensitivity was determined from 0 to 10 as the baseline VAS score for each individual painful tooth. A total of 116 teeth were tested.

As patients come to the clinic and hypersensitive teeth were encountered, the desensitizing agents were applied in an alternating order following a specific regimen randomly determined. For patients with more than one hypersensitive tooth, the hypersensitive teeth were then individualized immediately after recording the initial hypersensitivity scores and numbered according to FDI annotation. The agents were then applied following an ascending order of the teeth within the arch and among the four hemiarches. Each agent was applied to every fourth consecutive hypersensitive tooth in a patient or among consecutive patients. A few patients with severe pain were given local anesthesia before treatment, especially when they were designated to receive Gluma™ requiring acid etching.

The investigator wore examination gloves for each of the patients, and the procedures for application of the different agents followed the manufacturers' instructions (Table 1).

Two coats of CV and Duraphat™ were applied and repeated after five minutes. This was to ensure adequate desensitization because of the thin film produced from these materials.

Two layers of Gluma™ and two applications of iontophoresis were applied also to ensure adequate desensitization. For Gluma™, the air-inhibited surface was removed by gentle wiping with a damp pellet.

All the patients were instructed not to brush or chew food for three hours following treatment. Patients were to maintain the same eating habits and to maintain good oral hygiene during the course of the investigation. All patients were recalled at 24 hours and seven days after the completion of treatment for assessment of responses of the sensitive teeth.

The data collected during the treatment revealed the patients' subjective answers according to the VAS and were analyzed using SPSS for Windows® version 9.0 (SPSS Inc., Chicago, IL, USA). Analysis included frequency, calculation of mean pain scores (MPS), and standard deviation. The difference between mean values was tested intra-groups in order to assess the performance of each agent. In all cases a p-value of less than 0.05 was established as the significance level.

### Results

Application of the experimental agents resulted in a significant reduction of dentin hypersensitivity within 24 hours and was sustained throughout the evaluation period.

Within 24 hours of treatment 69% of the teeth receiving Gluma™ became painless (VAS score of zero) followed by Duraphat™ and iontophoresis with 48.3% while CV had 3.4%. More than 60% of the teeth evaluated at seven days for Duraphat™, Gluma™, and iontophoresis treatment were painless while about 5% of the painless teeth were seen in the CV group (Table 2). The Gluma™ group had the highest number of painless teeth at 24 hours and seven days of

**Table 2. Presence of painful teeth (hypersensitivity) at 24 hours and seven days post-treatment.**

		CV	Duraphat™	Gluma™	Iontophoresis
Painful teeth at <b>baseline</b>		29	29	29	29
<b>24 Hours</b>	Painless* teeth	0	14	20	14
	Painful teeth	29	15	9	15
<b>1 week</b>	Painless* teeth	5	12	20	18
	Painful teeth	17	7	1	2

Painless\* = Zero VAS score

**Table 3. Mean pain (VAS) scores and standard deviations at baseline, 24 hours, and seven days for the desensitizing agents.**

	CV	Duraphat™	Gluma™	Iontophoresis
<b>Baseline</b>	5.34 (2.39)	4.66 (1.82)	6.03 (2.37)	5.76 (1.27)
<b>24 Hours</b>	2.1 <sup>3.24</sup> (0.95)	1.38 <sup>3.28</sup> (1.86)	0.79 <sup>5.24</sup> (1.45)	1.62 <sup>4.14</sup> (1.97)
<b>Seven days</b>	1.55 <sup>0.55</sup> (1.44)	1.0 <sup>0.38</sup> (1.89)	0.1 <sup>0.69</sup> (0.44)	0.3 <sup>1.32</sup> (0.98)

The superscripts at 24 hours row represent differences between baseline and 24 hours scores while the superscripts at seven days row represent differences between 24 hours and seven days.

treatment while the CV group had the least number of painless teeth.

A statistically significant reduction of pain of hypersensitivity by an individual agent was observed at 24 hours, however; only Iontophoresis and Gluma™ caused a statistically significant reduction between 24 hours and the seven-day evaluation period. Comparing the differences, Gluma™ caused the greatest degree of pain reduction at 24 hours while Iontophoresis slightly had an edge between 24 hours and seven days (Table 3).

### Discussion

Many treatment modalities and agents have been used in the treatment of dentin hypersensitivity, but the efficacy of most of them has been varied and not well established. The aim of this study

was to evaluate the effectiveness of four topical desensitizing agents in providing short-term relief of pain of dentin hypersensitivity. While the methodology did not include a carefully placebo controlled clinical trial, the results indicated significant reduction in pain scores at 24 hours and one-week post-treatment evaluations.

Only 25 patients were recruited to participate in this study which imposes limitations on the results. However, this did not affect the objective of the study. At the conclusion of the study, four groups having an equal number of hypersensitive teeth were obtained by a systematic random sampling and each group treated by any of the four desensitizing agents.

The highly subjective nature of pain of dentin hypersensitivity makes it difficult to evaluate



objectively.<sup>27</sup> In the present study the VAS was used in the pre- and post-treatment assessment measurement of hypersensitivity. It has been considered to be the most commonly used method of quantitative scoring of pain.<sup>30</sup> It is quick, simple to complete,<sup>31</sup> and is considered to be a good method of assessing post operative pain.<sup>32</sup> The major drawback of a VAS is the placement of the pencil mark in one particular position on the scale by two different patients does not mean each patient experienced the same degree of pain. This drawback did apply to the present study, but the authors agreed the effect would be minimized because of the randomization patients.

The tactile method employed in stimulation of the pain (scratching the suspected site with a dental explorer) is a procedure which is difficult to control. This is due to the difficulty of standardizing the tactile pressure of the dental explorer. However, this problem was minimized because only one of the authors performed the test.

It was difficult to obtain patient consent to undertake this aspect of the experimental protocol which was intended to stimulate pain. This was especially the case with patients having more than one sensitive tooth. The study design included measurement and recording of the baseline pain scores followed by the application of the desensitizing agents during the same visit. Patients then returned 24 hours later for assessment of the responses of the treated hypersensitive teeth. This was to ensure the effect of the pain stimulation and/or treatment minimally influenced the patient responses during post-treatment assessment.

Anecdotal reports from other workers in the hospital revealed the tendency of patients to decline the recall visit after getting a profound pain relief. This problem was anticipated so the evaluation period was limited to one week. Lending credence to this explanation was the return of only about 70% of the patients for the recall visit at one week post-treatment. The lack of incentives for the patients may have also played a role in this level of participation in the recall.

The results showed all experimental agents caused a significant reduction of dentin hypersensitivity, at least for a period of one week. This finding was supported by the results of previous studies,<sup>11,12,15,16,19,20,25,26</sup> which have reported the effectiveness of CV, Duraphat™, Gluma™, and iontophoresis in reducing dentin hypersensitivity.

Gluma™ performed best at 24 hours having the highest difference between the baseline and 24 hour MPS. This agent may act both by the coagulation of dentin tubular protein by the glutaraldehyde component and secondly by the polymerization of the adhesive resin component.<sup>13</sup> The 2% sodium fluoride iontophoresis appeared to perform best between the 24 hours and seven days. It also has a dual effect by first causing a greater uptake of fluoride ion to form fluoroapatite<sup>33</sup> and by the production of reparative dentin.<sup>24</sup> This finding is similar to Singal et al.<sup>26</sup> who reported both agents were found to be equally effective immediately after application, but iontophoresis was comparatively better in providing long-term relief. Duraphat™ and CV act more superficially to seal the dentinal tubules which explained their weaker performance in comparison with Gluma™ and iontophoresis.

Ideally, the evaluation period should have been more than one week but the authors anticipated the problem of patient compliance. Long-term evaluation of effectiveness of these agents needs to be carried out to know the longevity of their performances and at what time interval hypersensitivity would reoccur.

Although clinical studies<sup>34,35</sup> have reported a decrease in dentin hypersensitivity with the use of placebo, there is a need to conduct a placebo-controlled study for a standard clinical protocol with these agents. Further research should also

investigate the real benefits of these materials in terms of cost, ease of manipulation, and patient satisfaction before recommending their routine application in dentistry.

### Conclusions

Within the limitations of the study, it can be concluded short-term evaluation of dentin hypersensitivity treated with CV, Duraphat™, Gluma™ Comfort Bond Plus Desensitizer, and

2% sodium fluoride iontophoresis showed a statistically significant reduction of pain sensation when stimulated by probing. Gluma™ performed best within 24 hours of treatment.

A greater difference in the degree of reduction of hypersensitivity at seven days achieved by iontophoresis suggests the need for a long-term study in order to better understand the performance of these desensitizing agents.

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