Original Article

Comparative clinical evaluation of two different formulated in-office newer desensitizing agents (Clinpro XT and Tokuyama Shield Force Plus) in reducing dentin hypersensitivity – A randomized clinical trial

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Abstract

Aim: The aim of this study was to assess the effectiveness of two various in-office newer desensitizing agents in reducing dentinal hypersensitivity in patients with mild-to-moderate sensitivity for a 1-month follow-up.

Materials and Methods: Forty subjects with cervical dentin hypersensitivity (otherwise healthy patients) were included. A split-mouth, randomized clinical trial was conducted. A Visual Analog Scale (VAS) was used to record the initial sensitivity levels at the baseline visit. Each individual has been exposed to thermal (ethyl chloride spray) and evaporative (air blast) stimuli to elicit sensitivity. A single application of two different in-office desensitizing agents, Clinpro XT Varnish (3M ESPE, Minnesota, USA) and Shield Force Plus (Tokuyama Dental, Tokyo, Japan), was done. The sensitivity scores were recorded after the application of the desensitizing agent immediately, after 1 week, and after 1 month using both air and cold stimuli in the same manner as initially.

Results: Mean VAS scores represent teeth that were more sensitive to cold stimuli compared to air blasts in both groups. For both stimuli at all-time intervals except baseline, there is a significant difference between CXT and SFP, with low mean VAS scores for CXT. *Post hoc* analysis revealed that in the CXT group, there is a significant difference in mean VAS score between pre-and postintervention at all-time intervals except between immediate and 1-week time intervals ($P < 0.001$) but only at immediate and 1-week time intervals in SFP.

Conclusion: Clinpro XT Varnish is more efficient compared to Shield Force Plus at all-time points irrespective of the stimuli after a 1-month follow-up.

Keywords: Clinpro XT Varnish; desensitizing agents; ethyl chloride spray stimuli; evaporative stimuli; Tokuyama Shield Force Plus

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INTRODUCTION

Dentin hypersensitivity becomes a consistent annoyance inducing psychological and emotional distractions in the

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patient's life. According to clinical studies, the prevalence of dentinal hypersensitivity (DH) varied according to the population analyzed, the study location, and the study design. It ranged from 2.8% to 74%.[1-4]

The etiology for hypersensitivity is exposed dentinal tubules to the external environment. Factors resulting in exposure to dentin are wearing of enamel, denudation of root surface, loss of cementum, and overlying periodontal tissues. This exposed dentin is most sensitive at the dentinoenamel junction, more sensitive close to the pulp, and increased sensitivity when the pulp is inflamed. Clinically manifest as short, sharp pain with rapid onset. This can affect younger, middle, and elderly age groups, but most commonly in the fourth and fifth decade of life.[5,6]

According to Brännström *et al*.'s hydrodynamic hypothesis,[7,8] the inciting stimuli enhance centrifugal fluid flow within the dentinal tubules, resulting in a pressure shift throughout the dentin. Based on this, two phases that are the exposing of dentin and the opening of the dentinal tubular system must occur simultaneously to cause dentin hypersensitivity. Therefore, the optimum treatment for DH should be able to either decrease fluid flow in dentinal tubules or inhibit pulpal nerve response or both.[9]

In general, conventional therapy for dentin hypersensitivity is based on using topical applied desensitizing agents, which can be applied either professionally or by the patient themselves at home. In-office topical application of desensitizing agents in the treatment of hypersensitivity used earlier were Gluma17 (glutaraldehyde and hydroxyethyl methacrylate), Cervatec17 (thymol and chlorhexidine), Duraphat, etc. These agents were worked by tubular occlusion.[10-13] Nowadays, newer agents having remineralization properties and superior bond strength come into existence. Clinpro XT (resin-modified glass ionomer-based) and Tokuyama Shield Force Plus (resin-based) are such desensitizing agents.

Several studies are comparing in-office topical application of desensitizing agents in the literature; however, there is relatively little information on these newer desensitizing agents used to treat DH.[14] Therefore, this study intends to assess the effectiveness of two in-office newer desensitizing treatments with various formulations, namely Clinpro XT (resin-modified glass ionomer-based) and Tokuyama Shield Force plus (resin-based), in lowering DH.

MATERIALS AND METHODS

This study is a split-mouth randomized double-blind clinical trial approved by Institutional Ethical Committee. The trial has been registered on the website of the Clinical Trial Registry of India (CTRI/2016/04/006882).

The procedure was performed in compliance with the recommendations for clinical trials on DH, as Holland and others have reported.[5] Forty subjects with a history of dentin hypersensitivity in the age group of 18–50 years with excellent systemic health conditions were recruited. Subjects with at least two or more lesions in different quadrants of the mouth and a preoperative visual analog scale (VAS) of ≥2 were preferred.

This study excluded subjects who have used desensitizing toothpaste in the last 3 months; were receiving periodontal therapy; with cervical defects >2 mm horizontally; were allergic to ingredients used in the study; were chronic users of anti-inflammatory and analgesic drugs; who were pregnant or nursing; with uncontrolled systemic diseases where oral hygiene is compromised; who had fractured or cracked teeth.

Using the G*Power 3.1.2 program (Heinrich Heine University Dusseldorf, Germany), the sample size was computed and set at 40 for each group. Two teeth (premolars) per patient in two different quadrants, which were categorized as mild-to-moderate sensitivity, were included. A dental professional unknown of what type of desensitizing agent was applied and calculated both initial and final sensitivity ratings. Before starting the study, all patients were explained about the study design, received informed consent, and were unaware of the agents which can be used for a particular tooth.

At the baseline assessment, the initial levels of sensitivity were noted. Evaporative (air blast) and thermal (cold test using ethyl chloride spray) stimulations were applied to each subject to trigger sensitivity. Cotton rolls and a suction tool were used for isolation. The exposed buccal cervical region of the tooth was then blasted air for 1 s at 40–60 psi from a 1 to 3 mm distance by keeping perpendicular to the tooth surface. Ten minutes following the evaporative evaluation, cold stimuli were tested on the middle of the exposed buccal cervical region of the chosen tooth using a cotton applicator soaked in ethyl chloride (Icy spray; DETAX GmbH and Co. KG, Germany). On a Visual Analog Scale of 0–10 (0 – no pain and 10 – worst conceivable pain), the reactions to both stimuli were scored.

The individuals were then randomly assigned to one of the treatment groups using the sequentially numbered, opaque, sealed envelopes method, which was suggested by Doig and Simpson,[15] after recording their baseline scores. Group 1 teeth were treated with Clinpro XT Varnish (3M ESPE, Minnesota, USA), and Group 2 teeth with Shield Force Plus (Tokuyama Dental, Tokyo, Japan). The application of agents was done by a single operator. Before applying, all tooth surfaces are cleaned thoroughly and rinsed with water. Excess pooled water was removed.

Procedure for Clinpro XT Varnish application

Clinpro XT Varnish was dispensed onto a mixing pad,

mixed for 15 s, and applied as a thin layer on the buccal side of the cervical area of the tooth and light cured for 20 s (manufacturer recommendations) is shown in Figure 1.

Procedure for Shield Force Plus application

Shield Force Plus varnish was dispensed into a sterile well and applied using an applicator tip, as a thin single coat on the buccal side of the cervical area of the tooth. Light cured for 15 s (manufacturer recommendations) is shown in Figure 2.

Following application, instant VAS scores were recorded. The individuals were then summoned back for additional

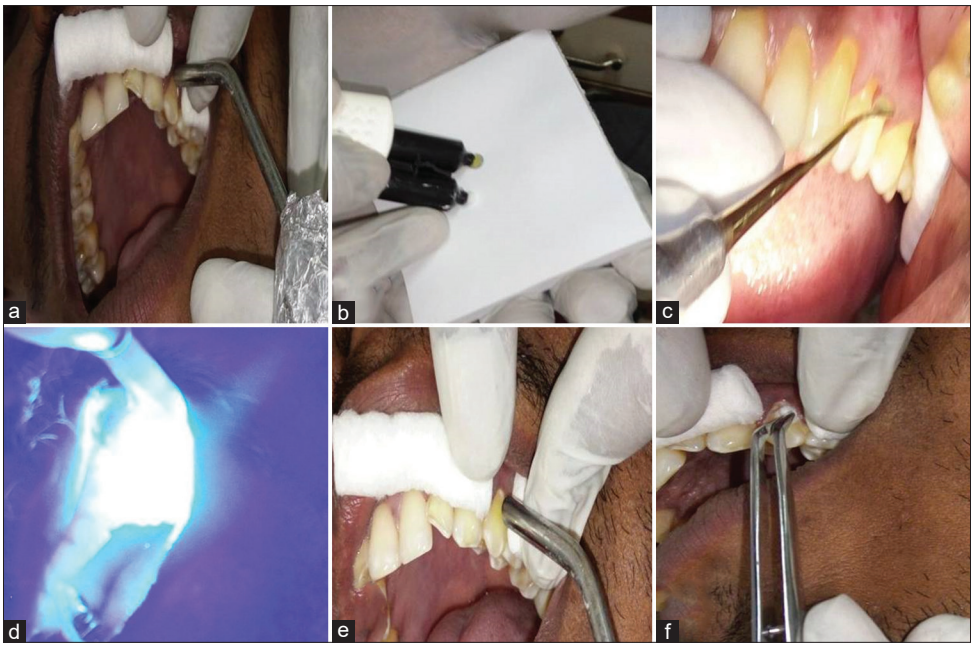

Figure 1: Procedure of Clinpro XT Varnish application. (a) Preoperative evaluation of sensitivity, (b) Dispensing Clinpro XT Varnish onto the mixing pad, (c) Application of Clinpro XT Varnish on tooth surface, (d) Light curing of Clinpro XT Varnish, (e) Postoperative evaluation of sensitivity with air blast, (f) Postoperative evaluation of sensitivity using a cotton applicator saturated with ethyl chloride

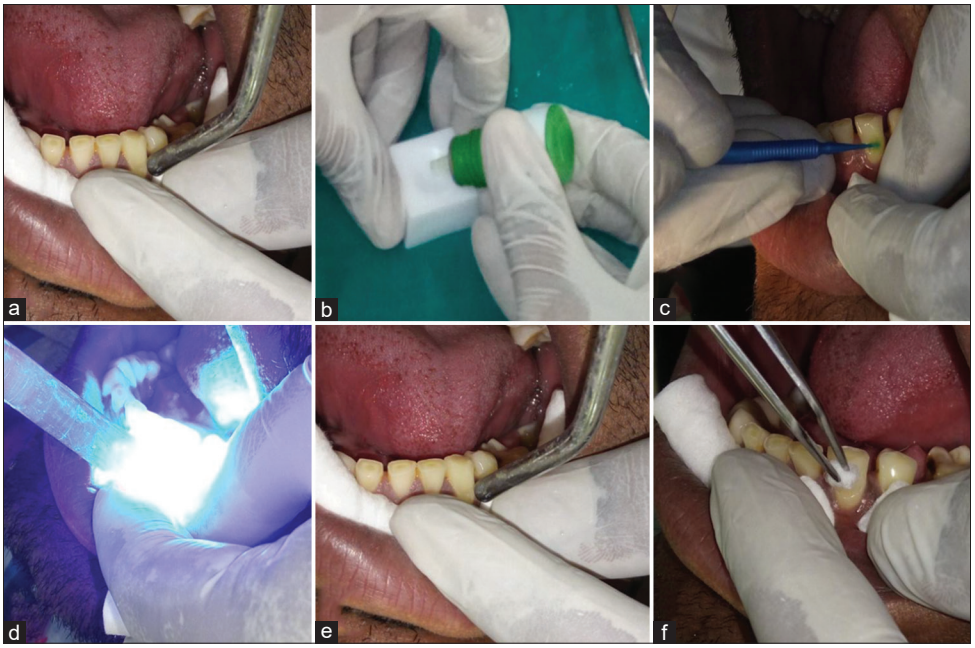

Figure 2: Procedure for Shield Force Plus application. (a) Preoperative evaluation of sensitivity, (b) Dispensing Tokuyama Shield Force Plus varnish onto mixing pad, (c) Application of Tokuyama Shield Force Plus varnish on tooth surface, (d) Light curing of Tokuyama Shield Force Plus varnish, (e) Postoperative evaluation of sensitivity with air blast, (f) Postoperative evaluation of sensitivity using a cotton applicator saturated with ethyl chloride

testing 1 week and 1 month after the agents were applied. The same method and order of stimuli were used to capture the responses in accordance with VAS.

Statistical analysis

The analysis was carried out by utilizing Statistical Package For Social Sciences 22.0 (IBM, Chicago, IL, USA). Two groups' VAS scores were compared using an independent *t*-test (if the $P < 0.05$, the difference is statistically significant). ANOVA with repeated measures and Bonferroni *post hoc* tests were used to compare VAS scores within the group at various time intervals (Statistical significance if the $P < 0.05$).

RESULTS

Table 1 shows that there was a statistically significant difference in VAS scores at different time intervals in both the groups using air blast and cold stimuli ($P < 0.05$). Table 2 represents Bonferroni's *post hoc* analysis showing that in the CXT group, there was a significant difference in VAS score between all pair-wise comparisons except for immediate versus 1 week after treatment both with air blast and cold stimuli ($P > 0.05$). However, in the SFP group, all pair-wise comparisons were statistically significant except for baseline versus 1-month and immediate versus 1-week intervals using both stimuli.

DISCUSSION

DH is mostly treated by either physically or chemically occluding the dentinal tubules or by desensitizing the nerves by depolarizing the cellular membrane of the nerve terminals. These induce a period of decreased sensitivity.[16]

The manufacturers of various products frequently present the dentist with a variety of options, each claiming to be efficient in providing both short-term and long-term pain relief. A perfect cure, or so-called gold standard, for DH, is still elusive.[17,18]

An ideal product for DH should meet a number of requirements to be both successful and acceptable to the patient and practitioner, according to Grossman[19] and Gillam.[20] The best desensitizing agent should be tooth-safe, easy to use, fast-acting, long-lasting in effectiveness, and pulpal-friendly.

A light-cured resin-modified glass ionomer-based varnish with silane-treated glass as its primary component is available in the market as Clinpro XT Varnish (3M ESPE, Minnesota, USA). It is supplied as a liquid/paste system. It also has fluorides, calcium, and phosphate, all of which assist the process of remineralization by avoiding demineralization and acid erosion. This in turn results in decreased DH.[21]

Table 1: Comparison of mean Visual Analog Scale scores within the experimental groups at different time intervals using repeated measures of ANOVA

Group	Stimuli	Interval	Mean	SD	*P*
CXT	Airblast	Baseline	39.42	8.92	<0.001*
		Immediate	3.35	5.97	
		1 week	4.30	6.22	
		1 month	15.82	5.22	
	Coldstimuli	Baseline	69.27	10.83	<0.001*
		Immediate	13.30	10.54	
		1 week	13.30	11.04	
		1 month	37.95	12.27	
SFP	Airblast	Baseline	40.25	10.36	<0.001*
		Immediate	22.05	9.37	
		1 week	25.90	9.42	
		1 month	40.50	10.23	
	Coldstimuli	Baseline	71.90	11.06	<0.001*
		Immediate	38.60	10.95	
		1 week	39.90	11.08	
		1 month	73.77	11.11	

*Statistically significant difference. SD: Standard deviation, SFP: Shield Force Plus, CXT: Clinpro XT

Table 2: *Post hoc* analysis of the mean difference in Visual Analog Scale scores at different time intervals after using both the stimuli in Clinpro XT and Shield Force Plus groups

Group	Stimuli	Pair 1	Pair 2	Mean difference	*P*
CXT	Airblast	Baseline	Immediate	36.07	<0.001*
			1 week	35.12	<0.001*
			1 month	23.60	<0.001*
		Immediate	1 week	−0.950	0.922
			1 month	−12.47	<0.001*
		1 week	1 month	−11.52	<0.001*
	Coldstimuli	Baseline	Immediate	55.97	<0.001*
			1 week	55.97	<0.001*
			1 month	31.32	<0.001*
		Immediate	1 week	0.000	1.00
			1 month	−24.65	<0.001*
		1 week	1 month	−24.65	<0.001*
SFP	Airblast	Baseline	Immediate	18.20	<0.001*
			1 week	14.35	<0.001*
			1 month	−0.25	0.99
		Immediate	1 week	−3.85	0.303
			1 month	−18.45	<0.001*
		1 week	1 month	−14.60	<0.001*
	Coldstimuli	Baseline	Immediate	33.30	<0.001*
			1 week	32.00	<0.001*
			1 month	−1.87	0.873
		Immediate	1 week	−1.30	0.953
			1 month	−35.17	<0.001*
		1 week	1 month	−33.87	<0.001*

*Statistically significant difference. SFP: Shield Force Plus, CXT: Clinpro XT

For the treatment of hypersensitive dentin, Shield Force Plus (Tokuyama Dental, Tokyo, Japan) was introduced in Japan as a protective sealant. It is distinguished by a three-dimensional cross-linking reaction, multi-point interactions with apatite calcium, and an SR monomer component that penetrates the tooth substrate. For greater bonding strength to the tooth substance, it creates a thin, even, hard covering on the tooth surface. Therefore, it was thought that using SR technology would help create a great sealant for the tooth surface.[22]

During this study, it was observed that teeth are more sensitive to cold spray stimuli than air blasts both at baseline (before treatment) and at different time intervals which were similar to results obtained by Pamir *et al*.[23] This indicates faster conduction of impulses due to cold stimulus than air stimulus by the activation of A-delta fibers in the dental pulp.

Irrespective of stimuli, Clinpro XT is more effective compared to Shield Force Plus in reducing DH at all-time intervals (immediately, 1 week, and 1 month).

Both Clinpro XT varnish and Shield Force Plus were effective in reducing dentin hypersensitivity immediately and for up to 1 week, which was evidenced by a decrease in VAS scores compared to baseline VAS scores. The VAS scores at 1 week were similar to that of immediate scores signifying the efficiency and integrity of varnish coating up to 1 week.

Both CXT and SFP groups showed an increase in VAS scores at a 1-month interval both for air and cold stimuli.

The Bonferroni *post hoc* test for the CXT group revealed a significant reduction in mean VAS score at the 1-month interval when compared to baseline. In contrast, the SFP group did not show significance at these intervals.

The difference in sensitivity reduction between these two groups can be explained by the nature of their viscosity, CXT having thicker film, and another probability may be due to the chemical adhesion of resin-modified glass ionomer-based varnish.

Clinpro XT Varnish was more efficient compared to Shield Force Plus at all-time intervals (immediately, 1 week, and 1 month after treatment) irrespective of the stimuli used. It may be attributed to its remineralizing nature besides forming a protective layer, which also prevents demineralization and acid erosion.

In the Shield Force Plus group, initially, phosphoric acid decalcifies the tooth for more penetration of resin tags that may be attributed to more VAS scores compared to Clinpro XT in immediate evaluation. Its desensitizing effect was maintained for up to 1 week. However, after 1 month, its effect decreased significantly with more VAS scores nearer to the baseline score, which may be due to its removal of the protective barrier by tooth brushing and lack of self-remineralizing capability.

In the present study, Clinpro XT Varnish maintained its significant reduction in dentin hypersensitivity at all-time points even after 1 month irrespective of stimuli, which was similar to the results obtained by Ding *et al*.[24] where they compared the efficacy of Clinpro XT Varnish with Gluma desensitizer and placebo.

In a systematic review, He *et al*.[25] noted that while varnish can have an instant desensitizing effect, these materials have limited adherence and are rapidly removed by saliva or brushing abrasion.

Thus, within the confines of this study, it can be stated that resin-modified glass ionomer-based varnish (Clinpro XT Varnish) has produced a reduction in DH and seems to be more effective than the SFP group.

At a month follow-up period, both the materials Clinpro XT Varnish and Shield Force Plus are not able to maintain the same efficacy, which was shown immediately after therapy, and repeated application of these materials is needed to keep the effectiveness.

Therefore, it is clear that restorative materials still have a place in the treatment of DH, especially in situations where varnishes and desensitizing agents have proven ineffective or only provide temporary relief. However, further research is required in this area.

CONCLUSION

We can draw the conclusion that both varnishes successfully decreased dentin hypersensitivity within the constraints of the study. Clinpro XT Varnish is more efficient compared to Shield Force Plus at all-time points irrespective of the stimuli over a 1-month follow-up. At 1-month follow-up, both the materials were not able to maintain the therapeutic effect, which was shown immediately after treatment. Therefore, the repeated application of these materials is needed to maintain their maximum efficacy.

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Conflicts of interest
There are no conflicts of interest.

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