

Comparative Evaluation of Efficacy of Diode Laser and Clinpro XT Varnish for Treatment of Dentin Hypersensitivity: A Randomized Clinical Trial

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ABSTRACT **Context:** Dentin hypersensitivity (DH) is a very common dilemma and often results in temporary relief by the conventional treatment method. An *in vivo* comparative study of various methods and materials helps in evaluation of a superior method to provide a long-lasting relief. **Aim:** The aim of this study was to evaluate the efficacy of diode laser (DL) and Clinpro XT Varnish for managing DH. **Materials and Methods:** This study was a randomized, single-blinded, clinical trial, designed, adhering to the CONSORT (Consolidated Standards of Reporting Trials) Guidelines using DL and fluoride-based varnish for managing DH. A total of 40 teeth were selected from eight patients and randomly divided into two groups. All patients received tactile and air syringe stimulus to assess for DH and a visual analog scale (VAS) was used to obtain readings at baseline, 15 min, 1 week, and 3 weeks, posttreatment. Student's *t* test was used, paired *t* test was for the intragroups, and unpaired *t* test was for intergroups. **Results:** This study showed that the effect of DL and Clinpro XT Varnish results in a significant decrease of DH. However, success decreased gradually over time. **Conclusion:** Clinpro XT Varnish presented superior immediate effect and DL effect tends to become better with time. Hence, both had good results in the end.

KEYWORDS: Dentin hypersensitivity, diode laser, randomized clinical trial, varnish, visual analog pain scale (VAS)

INTRODUCTION

Dentin hypersensitivity (DH), is a common clinical response to thermal, chemical, tactile, or osmotic stimuli, often the result of attrition, abrasion, erosion, gingival recession, periodontal treatment, and bleaching of teeth.^[1] Hydrodynamic theory explains movement of dentinal fluid inside the dentinal tubules as the mechanism of DH.^[2,3]

Facio-cervical regions and root surfaces are the most common sites where DH is located clinically. Incidence of DH was found more in women; in general population, it was 5%–18%, highest in periodontal patients accounting to 72%–98%, and most common in the age group 20–50 years.^[4-6] Salivary minerals and

dentinal fluids form intratubular crystals that reduce the incidence of DH.^[7] Various treatment modalities exist such as desensitization of nerve endings, occlusion of dentinal tubules, and iontophoresis. Several desensitizing agents such as potassium nitrate, calcium silicate, stannous fluoride, strontium chloride varnishes, restorations using composites, and more advanced treatments namely, lasers, and invasive treatments like periodontal soft-tissue grafting are used. Homeopathic

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agents such as plantago major and propolis are also used in the form of toothpastes or gels.^[8] Management of DH in-office is most commonly based on tubular occlusion using varnishes such as Gluma Desensitizer (Heraeus Kulzer, Hanau, Germany), and Duraphat (Colgate, New York). However, newer generation varnishes such as Clinpro XT Varnish (3M ESPE, Australia) and MI Varnish (GC America, Illinois) promise a better mode of action and enhanced efficacy.^[9] On the contrary, lasers are also used for management of DH.^[10]

Our literature search discovered that scarce studies were found comparing these newer generation varnishes with lasers to treat DH. Thus, the aim of this study was to evaluate the efficacy of Clinpro XT varnish and diode laser (DL) in reducing DH.

MATERIALS AND METHODS

This study was a randomized, single-blinded, clinical trial, designed, adhering to the CONSORT (Consolidated Standards of Reporting Trials) Guidelines^[11] and was conducted in the Department of Conservative Dentistry and Endodontics, RKDF Dental College and Research Centre, Bhopal, Madhya Pradesh, India. This study was also molded by the study rationale and design described according to a similar study conducted by Aghanashini *et al.*^[10]

SAMPLE SIZE, ETHICAL APPROVAL, AND SAMPLE RECRUITMENT PROCEDURE

For the study, a sample size of 40 teeth in total and 20 teeth in each group was calculated. Ethical clearance was obtained (RKDF/DC/IAC/2020/01) prior to this study from the Institutional Ethics Committee. The methodology was explained in a simple language that the patient can understand and written consent was obtained from every patient.

Patients coming to the Department of Conservative Dentistry and Endodontics in RKDF Dental College and Research Centre were assessed and those who fulfilled the inclusion criteria were selected by the operator under the guidance of the Departmental Post Graduate Staff.

The inclusion criteria of the study included an age limit between 20 and 50 years and was irrespective of the gender, visual analog scale (VAS) ≥ 2 , absence of local pathologies (e.g., caries and fractures), lack of any contraindicating factors like allergies to desensitizing agents, etc., and good systemic health of the selected patients with clinically elicitable DH. The exclusion criteria of the study included carious lesions, abrasion, attrition, and defective restorations associated with the teeth diagnosed as DH and is not specific to any type or

location of teeth. Other exclusion criteria of the study also included teeth having unhealthy neighboring teeth, history of using of desensitizing agents for the previous 3 or 4 months, or any history of dental treatment in the teeth diagnosed as DH and in process of considering inclusion in the study in the past 6 months irrespective of type or location of teeth, current usage consumption of NSAIDS, habits of smoking and conditions like pregnancy.

All patients received oral prophylaxis, diagnosed for pulpal pathology after performing vitality tests, and evaluated for DH using tactile stimuli technique with the straight probe with mild surface probing, cervically and mesiodistally. An Airway syringe stimulus technique was also used for evaluating DH using three-airway syringe directing to the tooth area for 3 s at a distance of 1 cm from buccal surface.

RANDOMIZATION AND GROUPING PROCEDURE, CLINICAL PROCEDURE, AND BLINDING

Patients with teeth fulfilling the inclusion criteria were further allotted for randomization. Randomization was done by the same operator using two opaque white envelopes containing, a sheet of paper mentioning allocation of the groups. After shuffling the envelopes, patients were asked to select any one of them. The patient is then allocated to the respective group as per the type of group mentioned in the sheet selected. A total of 40 teeth and 20 in each of the two groups are obtained.

Forty teeth were selected from eight patients, randomly divided into two groups and treatment was performed [Figures 1 and 2]. No specific arch or teeth were considered for standardization. However, patients having DH in a minimum average of three teeth in any arch were considered. If a patient has DH in six or more teeth in different arch, split-mouth technique was performed. Therefore, of total eight patients, four each were finally allotted to Group 1 and Group 2. A total of 40 teeth and 20 teeth in each of the two groups were obtained.

Patients in Group 1 ($n = 20$): Gingival dam was placed to isolate the teeth. Teeth in this group received irradiation with DL (iLase, Biolase) beam of 940 nm wavelength (0.5 W), directing perpendicularly on surface of the tooth as close as possible without any tooth contact. Each area was irradiated for 30 s.

Patients in Group 2 ($n = 20$): Cotton rolls were used to isolate the tooth surface to prevent contamination with saliva. Teeth in this group received a thin film of the Clinpro XT Varnish (3M ESPE), painting the tooth surface using applicator tip as per the directions



Figure 1: Group 1 where diode laser (iLase, Biolase) was used and was directed perpendicularly to the exposed tooth surface where area was irradiated for 30 s: (A) preoperative, (B) tactile stimulus, (C) air stimulus, (D) gingival barrier, (E) initiation, and (F) laser therapy

provided. 2–3 coats of varnish were applied and light cured for 20s. The coating was then wiped with a moist applicator.

Laser used in the study is a class IV DL, launched by BIOLASE, Irvine, California in the year 2010 under the trademark iLase and has 940nm wavelength, maximum of 5 W peak output power and continuous-wave output power, automatic factory set pulse interval of 0.2–1 ms, pulse duration of 0.1–1 ms. It is a Class 1 nominal ocular hazard distance of 2.61 m.

Varnish used in the study is a new resin-modified glass ionomer cement varnish by 3M ESPE, Pymble, New South Wales, Australia launched as Clinpro XT Varnish durable fluoride releasing coating in January 15, 2009. It contains the following:

2-hydroxyethyl methacrylate, (1-methylethylidene) bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate, 2Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica, copolymer of acrylic and itaconic acids, 2-hydroxyethylmethacrylate, calcium glycerophosphate, and water.

POSTTREATMENT INSTRUCTIONS

1. Patients were restricted from consuming any carbonated drinks or food for 1 h, posttreatment.
2. Patients in both groups were advised to use toothbrushes with soft bristles for brushing teeth twice a day.
3. They were directed to refrain from any other desensitizing dentifrice or mouth rinse during the



Figure 2: Group 2 where a thin film of the varnish (Clinpro Xt Varnish, 3M ESPE) was used and was painted on the surface with a disposable applicator tip as per the manufacturer’s instructions: (A) preoperative, (B) tactile stimulus, (C) air stimulus, (D) dispense and mix, (E) application, and (F) light cure

trial but were allowed to continue their normal oral hygiene practice.

STATISTICAL ANALYSIS

The analysis parameter recording for the severity of DH was done using VAS of 0–10, where 0 represented “no pain” and 10 represented “greatest pain” to obtain the readings at baseline, 15min posttreatment. The patients in both groups were again recalled after 1 week and 3 weeks, posttreatment, and VAS is measured again using both stimuli. These data were then transferred to Microsoft Word Document in a table format and sent for Statistical Analysis. All operations were done by the same operator. The Statistical Analysis was blinded for this study.

RESULTS

Statistical analysis was done and Student’s *t* test was used. Paired *t* test for the intragroups and unpaired *t* test for intergroups. Results of the study are summarized in Tables 1 and 2.

INTRAGROUP COMPARISON

In Group 1, airway syringe and tactile stimulus show that there was a significant decrease in mean VAS from baseline to 15min, 1 week, and 3 weeks posttreatment ($P < 0.05$). In Group 2, airway syringe stimulus shows a significant decrease in mean VAS from baseline to 15min, 1 week, and 3 weeks posttreatment ($P < 0.05$); however, tactile stimulus showed zero VAS at all time intervals.

Table 1: Mean difference in VAS for airway syringe stimulus b/w diode laser and Clinpro XT varnish group treated teeth at different time intervals

Time interval	Group	N	Mean	Standard deviation	Mean difference	T Value	P Value
Baseline (A)	DIODE LASER	20	6.57	1.859	1.526	2.830	.007*
	CLINPRO XT	20	5.05	1.676			
	VARNISH						
15 min after treatment (A)	DIODE LASER	20	1.48	1.601	.567	1.172	.248
	CLINPRO XT	20	.91	1.571			
	VARNISH						
1 week after treatment (A)	DIODE LASER	20	1.24	1.300	.420	1.076	.288
	CLINPRO XT	20	.82	1.259			
	VARNISH						
3 weeks after treatment (A)	DIODE LASER	20	.33	.483	.333	3.239	.002*
	CLINPRO XT	20	.00	.000			
	VARNISH						

*P < 0.05 (significant)

Table 2: Mean difference in VAS for tactile stimulus b/w diode laser and Clinpro XT varnish group treated teeth at different time intervals

Time interval	Group	N	Mean	Standard deviation	Mean difference	T Value	P Value
Baseline (T)	DIODE LASER	20	1.24	1.868	1.238	3.110	.003*
	CLINPRO XT	20	.00	.000			
	VARNISH						
15 min after treatment (T)	DIODE LASER	20	.05	.218	.048	1.024	.312
	CLINPRO XT	20	.00	.000			
	VARNISH						
1 week after treatment (T)	DIODE LASER	20	.05	.218	.048	1.024	.312
	CLINPRO XT	20	.00	.000			
	VARNISH						
3 weeks after treatment (T)	DIODE LASER	20	.00	.000 ^a	0.0	0.0	NA**
	CLINPRO XT	20	.00	.000 ^a			
	VARNISH						

**It cannot be computed because the standard deviations of both groups are 0

*P < 0.05 (significant)

INTERGROUP COMPARISON

In intergroups comparison where airway syringe stimulus was used. At baseline, higher mean VAS was found in DL as compared to Clinpro XT Varnish group and this was statistically significant (P < 0.05). However, after 15 min and 1 week, posttreatment, again higher mean VAS was found in DL as compared to Clinpro XT Varnish group but this was not statistically significant (P > 0.05). But after 3 weeks posttreatment in both the groups, higher mean VAS was found in DL as compared to Clinpro XT Varnish group and this was statistically significant (P < 0.05).

In intergroup comparison where tactile stimulus was used, at baseline, higher mean VAS was found in DL as compared to Clinpro XT Varnish group and this was statistically significant (P < 0.05). However, after 15 min and 1 week, posttreatment, again higher mean

VAS was found in DL as compared to Clinpro XT Varnish group but this was not statistically significant (P > 0.05). But, after 3 weeks, posttreatment in both the groups, VAS reduced to zero, so no statistical difference could be calculated.

DISCUSSION

DH is a very common clinical presentation, an enigma being frequently encountered yet, less understood.^[9,12-14]

Even though treatment of DH is done by blocking the dentinal tubules which then prevents the dentinal fluid shifts, still no gold standard for the treatment is available.^[15] But using dental fluoride products as toothpastes, etc., is the most preferred method for the management of DH.^[16] However, in a study conducted by Sharma *et al.*^[9] new generation varnishes, like Clinpro XT Varnish (3M ESPE), showed huge potential for superior efficacy in DH management.

Lasers have been introduced in 1985 as a treatment modality for DH.^[10] According to studies done by Asnaashari and Moeini^[17] and Aranha *et al.*^[18] DLs with low output power 830–980 nm wavelength therapy are effective in decreasing DH by promoting biomodulatory effects, minimizing pain, and reducing inflammation. This is the reason why this study selected a low output power DL.

An airway syringe was used to introduce a short air blast from a dental three-way syringe unit at a distance of 1–3 mm from the exposed buccal or cervical tooth surface at 45–65 psi and a temperature between 14°C and 26°C. In order to standardize the clinical trial, studies recommend to use at least two stimuli. Therefore, tactile stimulus was also used to measure the intensity of DH by using VAS.^[9,10,19-23] To rule out pathologies, radiovisiography (RVG) was used and electric pulp vitality tests were performed.

In this study, Clinpro XT Varnish showed better efficacy and also produced immediate relief from DH. It is a resin-modified glass ionomer material that releases fluoride, calcium and phosphate. This makes it unique in comparison to other in-office desensitizers in the first 24 h. It has an excellent fluoride releasing durability as it releases more fluoride than a conventional fluoride varnish (FV).^[24] A study conducted by Virupaxi *et al.*^[25] has also reported findings that, Clinpro XT Varnish released consistently and substantially more fluoride than Fluoritop SR and Fluor Protector varnishes during 6-month analysis. This may be a supporting evidence to what the manufacturers have reported in their data that it promotes constant fluoride recharge every time the patient brushes with fluoride toothpaste. Therefore, patients not only get the protection of a physical barrier but also they get long-term fluoride delivery.^[24] Further study conducted by Rusin *et al.*^[15] also found that the application of Clinpro XT Varnish promotes the obliteration of dentinal tubules and no significant increase in dentin permeability could be detected, post three consecutive acid attack challenges even after a single application.

A higher mean VAS was found in DL as compared to Clinpro XT Varnish group, may be because low-power lasers (DLs) reduce the DH probably by decreasing the dentin fluid flow, whereas high-power lasers (Nd:YAG and Er:YAG) seal the open tubules.^[25] The effect of radiation temporarily alters the endings of sensory axons and blocks both C and A beta fibers.^[26,27]

A study conducted by Aghanashini *et al.*^[10] found that both DL and FV groups showed no significant difference up to 15 days. However, another study conducted by Suri *et al.*^[28] found FV showing better

efficacy than lasers up to 24-h interval. However, in both these studies, as time progressed DL's showed more efficiency than FV in reducing DH.

This study was a 3-week follow-up study, so further studies with a long-term observation and a better design are required to determine after how much time interval Clinpro XT Varnish has to be re-applied. Other limitations of the study may also include certain factors; split-mouth technique in which the side that received DL could have some influence on the other side that received Clinpro XT Varnish because of the laser light reflection that could reach its side. The same from the Clinpro XT Varnish, fluoride released could be reaching the teeth on the DL side. However, split-mouth technique minimizes potential inter-subject variability and also requires lesser number of patients when compared to parallel-study design.^[29] The operator conducting the treatment and doing the HD tests is also a deviation point. However, being the same operator from the beginning of the diagnosis throughout the study provides a uniformity in the study thus minimizing the potential variability that may be caused otherwise due to multiple operators involved.

CONCLUSION

Within limitations of this study, it can be concluded that through time, the effectiveness of 940 nm DL with 0.5 W output power presented no statistical difference from the Clinpro XT group for both types of stimuli. Clinpro XT presented superior immediate effect and DL effect tends to become better with time. Hence, both had good results in the end.

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Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest.

AUTHORS CONTRIBUTIONS

B. Bhavsar, M. Vaz, and K. Neilalung contributed to conception, design, data acquisition, analysis

and interpretation, drafted and critically revised the manuscript. T. Das contributed to conception, design and interpretation, drafted and critically revised the manuscript. S. Majumdar and J. Talukdar contributed to conception and interpretation, drafted and critically revised the manuscript. Conception and design, acquisition of data, data analysis, interpretation of data, drafting the article, article revision and final approval was done by all the authors of this research work. All authors gave final approval and agree to be accountable for all aspects of the work.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

Ethical clearance was obtained (RKDF/DC/IAC/2020/01) prior for this study from the Institutional Ethics Committee, RKDF Dental College and Research Centre, Bhopal (462026), Madhya Pradesh, India.

PATIENT DECLARATION OF CONSENT

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request at e-mail drmichelleendodontist@gmail.com.

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