

Casein phosphopeptide-amorphous calcium phosphate varnish versus dentin desensitizer in the treatment of non-carious dentin hypersensitivity

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ABSTRACT

Background: Dentin hypersensitivity (DH) is one of the most common conditions clinicians encounter in clinical practice. New techniques are continuously being set forth to treat this condition. In recent times, casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) has garnered attention owing to its ability to improve remineralization and prevent enamel demineralization. Consequently, it has been indicated as an advanced treatment for DH. **Purpose:** This clinical trial aims to assess the efficacy of a CPP-ACP varnish in the management of non-carious cervical hypersensitivity and compare it with that of a dentin desensitizer. **Methods:** Patients between the ages of 20 and 65 years who reported to our institute with complaints of DH were selected for this study. Forty teeth were chosen for this study and randomly assigned to two groups. The test group was treated with a CPP-ACP varnish (MI Varnish®, GC Corporation, Japan), while the control group was treated with a dentin desensitizer (Gluma®, Heraeus-Kulzer, Germany). Dentin hypersensitivity assessments were conducted during pre-treatment, immediately following treatment, and 2 and 4 weeks after treatment. Statistical analysis was performed after data collection. **Results:** An intragroup comparison showed both the CPP-ACP varnish and the dentin desensitizer achieved a maximum decrease in sensitivity in the time interval from baseline to post-op, and these desensitizing effects were sustained through the second and fourth week following treatment. An intergroup comparison revealed no statistically significant difference in sensitivity between the two groups at different time intervals. **Conclusion:** It could be concluded that CPP-ACP varnish and dentin desensitizer possess similar efficacy in the treatment of DH.

Keywords: casein phosphopeptide-amorphous calcium phosphate varnish; dentin desensitizer; dentin sensitivity; MI Varnish; non-carious lesions

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INTRODUCTION

Dentin hypersensitivity (DH) is one of the most common conditions clinicians encounter in clinical practice. It is a short-lived, exaggerated, intense pain that presents with variable intensity and is triggered by tactile, thermal, osmotic, or chemical stimuli.^{1, 2} Numerous factors are responsible for dentin hypersensitivity, including premature occlusal contact, improper tooth-brushing techniques, gingival recession, and large quantities of acids (both exogenous and endogenous) in the diet.³ Several therapeutic

approaches are available for the management of DH, and numerous methods are available for the diagnosis and treatment of DH that may be challenging to justify.⁴

The dentin desensitizer (Gluma®, Heraeus-Kulzer, Germany), not only exhibits immediate post-operative effects—its benefits are also sustained over a longer period. Thus, it is the preferred material in the treatment of shallow, non-carious lesions.⁵ Posner first described amorphous calcium phosphate (ACP) and more recently, casein phosphopeptide (CPP)-ACP has garnered attention due to its ability to improve remineralization and prevent

enamel demineralization.⁶ Consequently, it has been indicated as an advanced treatment for DH.⁶ Studies have also shown that available topical forms of CPP-ACP in the form of mouthwashes and chewing gum are effective in remineralizing enamel, dentin, and cementum.⁷ Although many *in vitro* studies have been conducted to determine the efficacy of CPP-ACP in the treatment of DH, only a few *in vivo* studies have been conducted to the same end.

The goal of the current study is to evaluate the clinical efficacy of a dentin desensitizer against a CPP-ACP varnish in relieving DH immediately and four weeks following topical application. The hypothesis is that the effects of a CPP-ACP varnish would be statistically different from those of a desensitizer. Hence, the objective of this clinical trial is to evaluate and assess the efficacies of CPP-ACP varnish and dentin desensitizer individually and comparatively in the treatment of non-cariou cervical hypersensitivity.

MATERIALS AND METHODS

Patients reporting to the department of conservative dentistry at the A. J. Institute of Dental Sciences in Mangalore, India with complaints of dentin sensitivity were selected for this study. Ethical clearance was obtained from the institute's ethical board (Approval no.: IEC/UGCONS21/92/V1). Participants were between 20 and 65 years of age, and the duration of the study was 3 months.

Patients presenting with non-cariou cervical lesions (abfractions, abrasions, and erosions with or without mild recession of <2 mm) of shallow depth (1–2 mm; Miller Class I) in permanent teeth; having good oral hygiene; with a history of sensitivity; and willing to participate in the clinical trial were included in this study. Patients with carious lesions on symptomatic or neighboring teeth; abutment teeth for removable/fixed prostheses; severe periodontal disease (Miller Class II–IV); parafunctional habits; and psychological disorders, as well as those prescribed desensitizing pastes in the last 6 months and pregnant females, were excluded from the study.

A prospective interventional controlled trial was conducted in patients with non-cariou cervical hypersensitivity wherein a test group ($n = 20$) received CPP-ACP varnish and a control group ($n = 20$) was treated with a dentin desensitizer. The sample size was estimated using G*Power v. 3.1.9.6 software. An effective sample size of 12 in each group would have a power >0.95 with an α -level of 0.05 (i.e., a 5% chance of incorrectly rejecting the null hypothesis; effect size = 1.20; no. of groups = 2). Considering an attrition of 15%, the minimum sample size was estimated to be at least 14 for each group. However, we were able to recruit and treat 20 teeth, hence the sample size was 20 teeth per group ($n=20$). Convenience sampling was used to select subjects for the study.

Clinical examination was conducted by a single examiner (Operator 1) at the staff clinic in the stated department of the study institute. Objectives, treatment

plan, and requirement of follow up visits was explained to eligible patients, and written consent was obtained from all participants. A cold-water test was conducted to establish a baseline, and the scores from the test were recorded before any treatment was rendered. The patients were then sent to Operator 2 for intervention at the undergraduate clinic of the department. Participants were randomized to either the CPP-ACP varnish group or the dentin desensitizer group at a 1:1 ratio. Group A (the test group) was administered a CPP-ACP varnish (MI Varnish®, GC Corporation, Japan), and Group B (the control group) was given a dentin desensitizer (Gluma®, Heraeus-Kulzer, Germany). Throughout the duration of the trial, the patients were evaluated by a single examiner (Operator 1) to remove any inter-examiner bias. Cotton rolls were used to isolate teeth, and the cold-water test was conducted to assess hypersensitivity.

To perform the cold-water test, a disposable, precooled syringe was filled with 1 cc of freshly melted ice-cold water, and 0.2 mL of this water was then gradually ejected from the syringe onto the surface of the specified tooth after it had been isolated. Patient responses were documented according to the following scoring criteria: 0 = no significant discomfort or awareness of a stimulus; 1 = discomfort, but no severe pain; 2 = severe pain upon application of the stimulus; and 3 = severe pain during and after application of the stimulus.

After the cold-water tests were completed, teeth with ratings ≥ 1 were selected for the study. Treatment via the topical application of a CPP-ACP varnish or a dentin desensitizer was carried out by Operator 2 at the undergraduate clinic. The teeth that required treatment were cleansed with a rubber cup and pumice flour, then dried and isolated using cotton rolls. Forty teeth were chosen for this study and randomly assigned to either the test or the control group. The 20 teeth in the test group were treated with a CPP-ACP varnish (MI Varnish®, GC Corporation, Japan), while the 20 teeth in the control group were treated with a dentin desensitizer (Gluma®, Heraeus-Kulzer, Germany).

Participants were asked to avoid fluid consumption and eating for 2 h post-procedure, to avoid abrasive food for the next 24 h, and to use only soft-bristled toothbrushes. Inter- and intragroup comparisons of non-cariou cervical hypersensitivity were performed between the two groups. Sensitivity assessments were conducted immediately post-treatment and at 2 and 4 weeks after treatment. Blinding of the participants and of Operator 1 was maintained until all clinical data were collected (i.e., until the end of the clinical trial).

Descriptive statistics were used for statistical analysis. Friedman test was employed for showing decrease in sensitivity over different time intervals and a Wilcoxon test was used for intragroup comparison. A Mann–Whitney test was employed to compare the effect on sensitivity of the CPP-ACP varnish with that of the dentin desensitizer at different time intervals. Statistical significance was set at $p < 0.05$.

RESULTS

At baseline, 15–20% of teeth had severe pain (a score of 2) during the application of the cold-water stimulus, while 80–85% had a sensitivity score of 1. No patients reported severe pain (a score of 3) during or even after the application of the stimulus. There was an immediate decrease in sensitivity in the post-operative period, with 85% of the CPP-ACP group and 80% of the dentin

desensitizer group reporting sensitivity scores of 0. About 15% teeth of the test group and 20% of those in the control group experienced only mild discomfort with no severe pain (a sensitivity score of 1). In the second and fourth weeks after treatment, 75% of teeth in both groups had a sensitivity score of 0, and 25% had a sensitivity of score 1. No patients had scores of 2 or 3 immediately post-treatment, nor at the 2- and 4-week re-evaluations, as seen in Table 1.

Table 1. Distribution of teeth/samples based on sensitivity scores at different time intervals in the test and control groups

Time interval	Sensitivity score	CPP-ACP varnish: n (%)	dentin desensitizer: n (%)
Baseline	0	0	0
	1	85%	80%
	2	15%	20%
	3	0	0
Post-op	0	85%	80%
	1	15%	20%
	2	0	0
	3	0	0
2 nd week	0	75%	75%
	1	25%	25%
	2	0	0
	3	0	0
4 th week	0	75%	75%
	1	25%	25%
	2	0	0
	3	0	0

CPP-ACP = casein phosphopeptide-amorphous calcium phosphate

Table 2. Effect on sensitivity of casein phosphopeptide-amorphous calcium phosphate varnish and dentin desensitizer at different time intervals, assessed using the Friedman test ($p < 0.001$)

Time interval	CPP-ACP varnish		dentin desensitizer	
	mean rank	chi-squared value	mean rank	chi-squared value
Baseline	3.90	52.800	3.90	51.195
Post-op	1.90		1.95	
2 nd week	2.10		2.08	
4 th week	2.10		2.08	

CPP-ACP = casein phosphopeptide-amorphous calcium phosphate

Table 3. Comparison of the effect on sensitivity of casein phosphopeptide-amorphous calcium phosphate varnish at different time intervals, assessed using a Wilcoxon signed-rank test

Time interval	Group	n	Mean rank	Sum of ranks	Z-value	p-value
Baseline to post-op	Negative ranks	20	10.50	210.00	-4.472	<0.001
	Positive ranks	0	.00	.00		
	Ties	0				
Baseline to 2 nd week	Negative ranks	18	9.50	171.00	-4.243	<0.001
	Positive ranks	0	.00	.00		
	Ties	2				
Baseline to 4 th week	Negative ranks	18	9.50	171.00	-4.243	<0.001
	Positive ranks	0	.00	.00		
	Ties	2				
Post-op to 2 nd week	Negative ranks	0	.00	.00	-1.414	0.157
	Positive ranks	2	1.50	3.00		
	Ties	18				
Post-op to 4 th week	Negative ranks	0	.00	.00	-1.414	0.157
	Positive ranks	2	1.50	3.00		
	Ties	18				
2 nd week to 4 th week	Negative ranks	0	.00	.00	0.000	1.000
	Positive ranks	0	.00	.00		
	Ties	20				

Table 2 shows that, in the CPP-ACP varnish group and the dentin desensitizer group, a maximum decrease in sensitivity was seen from baseline to post-op. A statistically significant reduction in sensitivity was seen in the CPP-ACP varnish group (Table 3) and in the dentin desensitizer group (Table 4) when comparing baseline to different time intervals ($p < 0.001$). There was no statistically significant difference ($p > 0.05$) in sensitivity values in the intragroup comparison during the post-op period with subsequent follow-up visits.

Table 5 shows a comparison of the effect on sensitivity of the CPP-ACP varnish with that of the dentin desensitizer at different time intervals using the Mann–Whitney test. There was no statistically significant difference in sensitivity between the two groups at different time intervals ($p > 0.05$)

DISCUSSION

In our study, the cold-water test was used as a stimulus, and patients’ responses were recorded. This test is a commonly employed and efficient method to assess sensitivity, since

it is more sensitive than other tests that are normally used to determine DH. Additionally, there is a stronger association between this test and the hypersensitivity symptoms observed in everyday life. Assessment was conducted immediately post-treatment and the second and fourth week after treatment. Patients’ reactions to stimuli were evaluated using a 4-point rating system. It has been shown by several researchers that visual analogue rating is more precise in differentiating between therapies and variations in pain intensity. The issue with visual analogue rating, however, is that patients are unable to provide an accurate score and may find it quite confusing, given the extensive array of scoring available from zero to ten. However, the previous quantization technique seems to be more clinically straightforward and precise, since patients can easily understand the grade range of 0 to 3, and was therefore used in our study.⁸

Abuzinadah et al.⁹ assessed Gluma®, Tetric N-Bond self-etch adhesive, and a fluoride varnish for their therapeutic effectiveness in treating hypersensitivity after a single topical application in a total of 70 teeth. The Schiff cold scale was utilized to measure cold and air blast stimuli, whereas a visual analogue score (VAS) was employed to

Table 4. Comparison of the effect on sensitivity of dentin desensitizer at different time intervals, assessed using a Wilcoxon signed-rank test

Time interval	Group	n	Mean rank	Sum of ranks	Z-value	p-value
Baseline to post-op	Negative ranks	20	10.50	210.00	-4.472	<0.001
	Positive ranks	0	.00	.00		
	Ties	0				
Baseline to 2 nd week	Negative ranks	18	9.50	171.00	-4.146	<0.001
	Positive ranks	0	.00	.00		
	Ties	2				
Baseline to 4 th week	Negative ranks	18	9.50	171.00	-4.146	<0.001
	Positive ranks	0	.00	.00		
	Ties	2				
Post-op to 2 nd week	Negative ranks	1	2.00	2.00	-0.577	0.564
	Positive ranks	2	2.00	4.00		
	Ties	17				
Post-op to 4 th week	Negative ranks	1	2.00	2.00	-0.577	0.564
	Positive ranks	2	2.00	4.00		
	Ties	17				
2 nd week to 4 th week	Negative ranks	0	.00	.00	0.000	1.000
	Positive ranks	0	.00	.00		
	Ties	20				

Table 5. Comparison of the effect on sensitivity of casein phosphopeptide-amorphous calcium phosphate varnish and dentin desensitizer at different time intervals, compared using the Mann–Whitney test

Time intervals	Group	Mean rank	Sum of ranks	Z-value	p-value
Baseline	CPP-ACP	20.00	400.00	-0.411	0.681
	Gluma®	21.00	420.00		
Post-op	CPP-ACP	20.00	400.00	-0.411	0.681
	Gluma®	21.00	420.00		
2 nd week	CPP-ACP	20.50	410.00	0.000	1.000
	Gluma®	20.50	410.00		
4 th week	CPP-ACP	20.50	410.00	0.000	1.000
	Gluma®	20.50	410.00		

CPP-ACP = casein phosphopeptide-amorphous calcium phosphate; Gluma® = the dentin desensitizer used in the control group

evaluate tactile stimuli. Sensitivity was assessed directly after treatment and again after 2 weeks and 1 month. It was found that Gluma® outperformed other materials, with statistically significant results in reducing sensitivity both immediately and one month after treatment.⁹ Thus, the dentin desensitizer, Gluma®, was used in the control group in our study.

The aqueous solution of Gluma® is comprised of 35% hydroxyethyl methacrylate and 5% glutaraldehyde. According to certain theories, dentinal tubules are blocked as a result of the chemical response of plasma proteins from the dentinal fluid, since glutaraldehyde is an organic fixative. Dentin bonding agents such as hydroxyethyl methacrylate are hydrophilic monomer compounds that may penetrate wet, acid-etched dental hard tissue.¹⁰ To the best of our knowledge, there is a paucity of literature on the use of MI Varnish® for DH in vivo. Hence, MI Varnish®, a CPP-ACP varnish, was used on the test group in our study.

Casein phosphopeptide-amorphous calcium phosphate is a substance that promotes enamel remineralization. It contains ACP, a precursor to dental hydroxyapatite. By binding ACP to CPP, CPP-ACP stabilizes Ca²⁺ and PO⁴³⁻ ions in the solution, forming nanoclusters that have a remineralizing effect.¹¹ Milk also contains casein and can help remineralize early enamel defects.¹² Although milk is easily available and cheaper, patients could be non-compliant. Casein phosphopeptide-amorphous calcium phosphate is also known for its substantivity (i.e., its ability to achieve prolonged adherence to the tooth surface), which increases its duration of action compared to other commercially available materials.

Saraf et al.¹³ conducted a study to assess the efficacy of CPP-ACP in alleviating dentinal hypersensitivity after non-surgical periodontal therapy. Twenty participants with hypersensitivity were included in this trial. The authors concluded that CPP-ACP has immediate action on hypersensitivity.¹³ In a study conducted by Bapna et al.,¹⁴ MI Varnish® was compared with a sodium fluoride-based varnish in 40 subjects. Sensitivity was re-assessed after 14 days using a VAS scale. The authors concluded that MI Varnish® and sodium fluoride-based varnish have similar effectiveness in decreasing sensitivity.¹⁴

In a study conducted by Sharma et al. on 25 teeth comparing Clinpro XT with MI Varnish®, MI Varnish® showed better results than Clinpro XT when evaluated with a VAS cold-water test. The main drawback of this study is that it had a short recall period of only 1 week. In our study, consistent results were seen even after the second and fourth week after treatment for both groups. In patients with severe sensitivity at baseline, there was a reduction in sensitivity after treatment, but it was not eliminated. No statistically significant difference in sensitivity was observed between the two groups at different time intervals ($p > 0.05$).

The presence of calcium and phosphate ions in CPP-ACP varnish facilitates the remineralization of enamel,¹¹ thereby improving the density of hydroxyapatite. Thus,

CPP-ACP treats the cause of hypersensitivity (namely, enamel loss and exposure of dentinal tubules), whereas the dentin desensitizer, Gluma®, promotes tubule occlusion within dentin. Gluma® desensitizer achieves its effects via the precipitation of plasma proteins, which reduces dentinal permeability and occludes peripheral dentinal tubules. This inhibits the flow of fluid through the tubules—the cause of sensitivity⁹—thus providing only a symptomatic relief from the pain. It can therefore be inferred that CPP-ACP varnish is as efficacious as standard desensitizers (such as Gluma®) in reducing sensitivity.

More recently, laser therapy for DH has gained prominence. In a randomized clinical trial by Bou Chebel et al.¹⁶ involving 12 patients with 54 teeth, CPP varnish was compared with an Nd:YAG laser that uses air stimulation. Scoring was completed using a VAS, a tactile score, and a thermal test. It was noted that there was no difference in the effect on sensitivity between the Nd:YAG laser and the MI Varnish® at various time intervals up to 6 months.¹⁶

A study by Guanipa Ortiz et al.¹⁷ involving 21 participants found that CPP-ACP and CPP-ACP + laser were equally effective in treating sensitivity when evaluated by tactile stimulus, but that CPP-ACP + laser showed better results than CPP-ACP alone when evaluated with a DH questionnaire and evaporative stimulus test. In an in vitro study by Murugesan et al.¹⁸ using a scanning electron microscope, MI Varnish® showed a better obliteration of tubules than Clinpro or Propolis; however, in the acidic abrasive challenge, Propolis performed better. A meta-analysis by Zhou et al.¹⁹ involving 13 studies assessing 1,053 teeth states that there was low-quality evidence to conclude supremacy of lasers over topical agents and hence advised topical agents as the first choice for DH and laser treatment when topical agents are ineffective. However, this meta-analysis excluded studies that did not use an air-blast test or VAS scoring.¹⁹

A meta-analysis (Cochrane database) involving 23 studies assessing hypersensitivity in 930 participants and involving 2,296 teeth was published by Mahdian et al.²⁰ The studies included used the air-blast test and tactile stimulus and scoring was completed using a VAS scale. The analysis showed that there is limited, uncertain evidence that laser treatment may improve pain when compared with a placebo. The long-term benefits of laser treatment are questionable. Further studies may be required to test its efficacy, and its cost-effectiveness needs to be ascertained.²⁰ By virtue of its dual role and efficacy in treating both remineralization and DH, CPP-ACP varnish is a cost-effective material for clinicians.

Considering the limitations of this study, it would be reasonable to conclude that the dentin desensitizer, Gluma®, and CPP-ACP varnish are equally effective in treating DH. To ascertain the long-term effectiveness of CPP-ACP varnish, additional randomized controlled clinical trials with larger study populations, greater sample sizes, and long-term follow-up intervals are required. With age, there are structural and chemical changes to dentinal

tubules that may have interfered with our results. A longer recall time and a narrower age range as inclusion criteria may be needed to assess the prolonged effects of CPP-ACP varnish and Gluma® on DH.

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