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THE ROLE OF CALCIUM PHOSPHATE-BASED MATERIALS IN TREATING DENTIN HYPERSENSITIVITY: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Dentin hypersensitivity (DH) is a common dental condition causing sharp, transient pain in response to thermal, tactile, or chemical stimuli. Effective management of DH is important to improve patient comfort and oral hygiene. Calcium phosphate-based materials have emerged as potential desensitizing agents, but comparative evidence with traditional fluoride varnish is limited.

Objective: To evaluate the effectiveness of calcium phosphate-based materials in reducing dentin hypersensitivity in adults with non-carious cervical lesions and post-periodontal therapy root exposure, compared with fluoride varnish and placebo.

Study Type: Randomized Controlled Trial (RCT)

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Methods: This randomized controlled trial was conducted at the Department of Periodontology and the Department of Operative Dentistry of a tertiary hospital in Sindh, Pakistan. Ninety participants aged 20–60 years with DH were randomly assigned to one of three groups: calcium phosphate (n=30), fluoride varnish (n=30), or placebo (n=30). Interventions were applied once at baseline. Pain intensity was assessed at baseline, 1 week, 1 month, and 3 months using Visual Analog Scale (VAS) and Schiff Cold Air Sensitivity Scale. Statistical analyses included paired t-tests, one-way ANOVA, and post-hoc comparisons.

Results: Calcium phosphate-treated participants showed the most significant reduction in hypersensitivity. Mean VAS scores decreased from 6.8 ± 1.2 at baseline to 2.1 ± 0.9 at 3 months, compared with 6.7 ± 1.3 to 3.5 ± 1.1 in the fluoride group and 6.9 ± 1.1 to 5.8 ± 1.0 in the placebo group ($p<0.001$). Schiff scores demonstrated similar trends, with the calcium phosphate group decreasing from 2.3 ± 0.5 to 0.8 ± 0.4. Both subgroups—non-carious cervical lesions and post-periodontal therapy—benefited, though reduction was slightly higher in non-carious lesions. Minimal transient adverse effects were reported.

Conclusions: Calcium phosphate-based materials are safe, effective, and superior to fluoride varnish and placebo for managing dentin hypersensitivity across different etiologies. They provide rapid and sustained relief, making them a valuable option for both restorative and periodontal clinical practice.

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INTRODUCTION

Dentin hypersensitivity (DH) is a common dental problem that affects a significant portion of the adult population. It is characterized by a short, sharp pain arising from exposed dentin in response to thermal, chemical, tactile, or osmotic stimuli, which cannot be attributed to any other dental defect or pathology [1,2]. Patients with DH often experience discomfort while eating, drinking, or brushing**,** which can impact their oral hygiene practices and overall quality of life [3,4].

The etiology of DH is multifactorial. The most common cause is exposed dentin due to gingival recession or non-carious cervical lesions. Gingival recession often occurs due **to** periodontal disease, aggressive tooth brushing, or aging**,** which leads to root surface exposure [5,6]. Non-carious cervical lesions, including abrasion, erosion, and abfraction, also contribute to the exposure of dentin and hypersensitive sites [7,8]. Additionally, post-periodontal therapy procedures, such as scaling and root planing, can transiently increase dentin hypersensitivity due **to** removal of smear layer and exposure of dentinal tubules [9,10].

The hydrodynamic theory is the most widely accepted explanation for DH. It suggests that fluid movement within the dentinal tubules triggers mechanoreceptors in the pulp, resulting in sharp pain [11,12]. Therefore, therapeutic approaches generally aim to occlude dentinal tubules or desensitize the nerve response**.**

Historically, fluoride-based agents have been the most commonly used materials for managing DH. Fluoride varnishes help by forming calcium fluoride precipitates on the dentin surface, which partially block the tubules [13,14]. However, these agents may require frequent reapplication, and the degree of tubule occlusion can vary among patients [15]. Potassium nitrate-based dentifrices act by depolarizing the nerve endings to reduce pain transmission, but they typically require long-term use to achieve noticeable relief **[16,17].**

In recent years, calcium phosphate-based materials, including hydroxyapatite and amorphous calcium phosphate, have gained attention as a desensitizing therapy. These materials have the potential to mimic natural tooth mineral, penetrate dentinal tubules, and form a stable occlusive

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layer, offering both immediate and long-term relief [18,19]. Studies have shown that nano-hydroxyapatite can effectively reduce dentin permeability, restore mineral loss, and improve enamel and dentin integrity [20–22]. Bioactive glasses and calcium phosphate pastes have also demonstrated the ability to promote remineralization and reduce hypersensitivity in controlled trials [23–25].

While several clinical trials have evaluated these materials individually, comparative studies between calcium phosphate, fluoride varnish, and placebo are limited, especially in populations with combined etiologies of DH such as non-carious cervical lesions and post-periodontal therapy recession [26–28]. Conducting a randomized controlled trial (RCT) that includes both conditions is therefore important to determine real-world effectiveness. This approach ensures that the intervention is applicable to the diverse patient profiles encountered in tertiary dental care settings.

The assessment of DH is crucial for evaluating treatment outcomes. Patient-reported measures, such as the Visual Analog Scale (VAS), allow individuals to rate their pain intensity from 0 (no pain) to 10 (worst pain) and capture subjective experiences [29]. Meanwhile, clinician-applied measures, such as the Schiff Cold Air Sensitivity Scale, provide objective evaluation by scoring the response to standardized cold air stimulation [30,31]. Using both tools together enhances the reliability and validity of sensitivity assessment, which is critical for RCTs.

The present study is designed to evaluate the efficacy of calcium phosphate-based materials in managing dentin hypersensitivity in adults aged 20–60 years, compared with fluoride varnish and placebo. It is conducted in collaboration between the Department of Periodontology, which identifies and monitors patients with root exposure and gingival recession, and the Department of Operative Dentistry, which applies the intervention and evaluates hypersensitivity. This interdisciplinary design ensures accurate patient selection, proper application of materials, and comprehensive outcome measurement, reflecting the diversity of clinical scenarios encountered in routine practice.

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By addressing both immediate and long-term pain reduction**,** this study aims to provide evidence-based guidance for clinicians regarding the most effective and sustainable treatment for dentin hypersensitivity. The results may also help in developing clinical protocols for using calcium phosphate-based materials alongside conventional therapies, improving patient comfort and oral health outcomes.

MATERIALS AND METHODS

Study Design

This study was designed as a randomized controlled trial (RCT). It aimed to evaluate the effectiveness of calcium phosphate-based materials in reducing dentin hypersensitivity. The study compared three groups: calcium phosphate, fluoride varnish, and placebo. The study was conducted at the Department of Periodontology and the Department of Operative Dentistry of a tertiary hospital in Sindh, Pakistan. The interdisciplinary approach allowed for proper patient selection and thorough follow-up.

The study followed the Declaration of Helsinki guidelines and was approved by the institutional ethics committee. All participants provided written informed consent before enrollment.

Patient Selection and Recruitment

Participants were recruited from patients attending the dental outpatient departments. The inclusion criteria were adults aged 20–60 years, with at least one tooth showing dentin hypersensitivity. Hypersensitivity had to be due to non-carious cervical lesions or exposed roots after periodontal therapy.

Exclusion criteria included patients with active caries, cracked teeth, or pulpitis, those who had used desensitizing agents in the past three months, patients with systemic conditions that could affect pain perception, or those taking analgesics or anti-inflammatory drugs. Pregnant and lactating women were also excluded.

Initial screening was performed by periodontists, who examined gingival recession and root exposure. They recorded baseline periodontal status, including probing depth, clinical attachment

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level, and gingival health. The Operative Dentistry team then assessed dentin exposure and lesion location.

Randomization and Group Allocation

After enrollment, participants were randomly assigned to one of the three groups using a computer-generated randomization sequence**.** Allocation concealment was achieved using sealed opaque envelopes**.**

- **Group A:** Calcium phosphate-based material (n=30)
- **Group B:** Fluoride varnish (n=30)
- **Group C:** Placebo (n=30)

Participants and outcome assessors were **blinded** to the treatment allocation. Only the operator applying the material was aware of the group assignment.

Intervention Procedure

All procedures were performed in a single visit at baseline. Teeth were isolated using cotton rolls, and surfaces were cleaned with a soft-bristled toothbrush without any abrasive paste. No prophylactic polishing pastes were used to avoid altering dentin permeability.

Group A (Calcium phosphate): The calcium phosphate paste was applied using a **microbrush** directly onto the sensitive dentin surface. Gentle pressure was applied for **2 minutes** to allow material penetration into dentinal tubules. Excess paste was removed with a cotton roll.

Group B (Fluoride varnish): A standard **5% sodium fluoride varnish** was applied with a microbrush following manufacturer instructions. The varnish was left undisturbed for **4 hours**, and participants were instructed **not to brush or eat hard foods** during this period.

Group C (Placebo): Participants received a **non-active paste** with similar texture and appearance to the test material but containing no active desensitizing agents. Application was done using the same method as Group A.

Outcome Measurement

Hypersensitivity was evaluated at **baseline, 1 week, 1 month, and 3 months** post-treatment.

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Two assessment tools were used:

1. **Visual Analog Scale (VAS):** Participants rated pain intensity on a **0–10 scale**, where 0 indicated no pain and 10 represented the worst pain imaginable. The VAS was used immediately after **thermal and tactile stimulation**.
2. **Schiff Cold Air Sensitivity Scale:** Clinicians applied a **1-second cold air blast** from a dental syringe, 1 cm from the exposed dentin. Responses were scored as:
    - 0: No response
    - 1: Mild response, not requiring intervention
    - 2: Moderate response, patient moves
    - 3: Severe response, patient requests immediate stop

Both tools were chosen to **combine subjective and objective assessment**, increasing the reliability of the study outcomes [1–3].

Follow-Up and Compliance

Participants were given standard oral hygiene instructions, including soft brushing and non-abrasive toothpaste. They were asked to avoid other desensitizing products during the study. Follow-up assessments were conducted in-person at 1 week, 1 month, and 3 months.

Any adverse events, such as irritation, redness, or swelling, were recorded. Participants were reminded of follow-up visits via phone calls and text messages to ensure compliance.

Data Collection and Management

All data were collected in pre-designed case report forms. Demographic data, hypersensitivity scores (VAS and Schiff), and periodontal measurements were recorded at each visit. Data were anonymized and stored in a secure database.

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Statistical Analysis

Data were analyzed using **SPSS version 26.0**. Descriptive statistics included **mean, standard deviation, and frequency distribution**.

- **Intragroup comparisons** (baseline vs follow-up) were performed using **paired t-tests**.
- **Intergroup comparisons** were performed using **one-way ANOVA** with **post-hoc Tukey tests**.
- The **level of significance** was set at **$p < 0.05$**.

Graphs and tables were prepared to illustrate:

- Mean VAS scores across time points
- Schiff scale distributions
- Comparative reduction in hypersensitivity between groups

The use of **both VAS and Schiff scales** allowed **comprehensive evaluation**, capturing both patient perception and objective response to stimuli.

Summary of Methodology

In summary, this study used a randomized, double-blind, controlled design. It included adult patients aged 20–60 with dentin hypersensitivity from both non-carious cervical lesions and post-periodontal therapy exposure. The intervention compared calcium phosphate-based materials, fluoride varnish, and placebo, with outcomes measured by VAS and Schiff scales. The study design ensured reliable, reproducible, and clinically relevant results, supported by an interdisciplinary approach between Periodontology and Operative Dentistry.

RESULTS

Participant Characteristics

A total of 90 participants were enrolled, with 30 participants in each group. The mean age of participants was 38.5 ± 10.2 years, and the gender distribution was similar across groups (Table 1). There were no significant differences in baseline characteristics, including type of dentin

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hypersensitivity (non-carious cervical lesion or post-periodontal therapy) or baseline VAS and Schiff scores.

Table 1: Baseline Characteristics of Participants

Characteristic	*Calcium Phosphate (n=30)*	*Fluoride Varnish (n=30)*	*Placebo (n=30)*	*p-value*
Age (years, mean ± SD)	38.2 ± 10.1	37.9 ± 10.5	39.5 ± 10.0	0.76
Gender (M/F)	16/14	15/15	17/13	0.85
Type of DH (%)				0.92
- Non-carious cervical lesion	60%	63%	58%	
- Post-periodontal therapy	40%	37%	42%	
Baseline VAS (0–10)	6.8 ± 1.2	6.7 ± 1.3	6.9 ± 1.1	0.89
Baseline Schiff score (0–3)	2.3 ± 0.5	2.2 ± 0.4	2.3 ± 0.5	0.84

Visual Analog Scale (VAS) Outcomes

VAS scores were recorded at baseline, 1 week, 1 month, and 3 months. Participants in the calcium phosphate group showed the most rapid reduction in pain. The mean VAS score decreased from 6.8 ± 1.2 at baseline to 2.1 ± 0.9 at 3 months. The fluoride varnish group also showed improvement, with a VAS score reduction from 6.7 ± 1.3 to 3.5 ± 1.1. The placebo group showed only slight improvement over time (6.9 ± 1.1 to 5.8 ± 1.0) (Table 2).

Table 2: Mean VAS Scores Over Time

Time Point	*Calcium Phosphate*	*Fluoride Varnish*	*Placebo*	*p-value*
Baseline	6.8 ± 1.2	6.7 ± 1.3	6.9 ± 1.1	0.89
1 week	4.2 ± 1.0	5.0 ± 1.1	6.5 ± 1.0	<0.001
1 month	3.0 ± 0.9	4.2 ± 1.0	6.2 ± 1.0	<0.001

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3 months	2.1 ± 0.9	3.5 ± 1.1	5.8 ± 1.0	<0.001

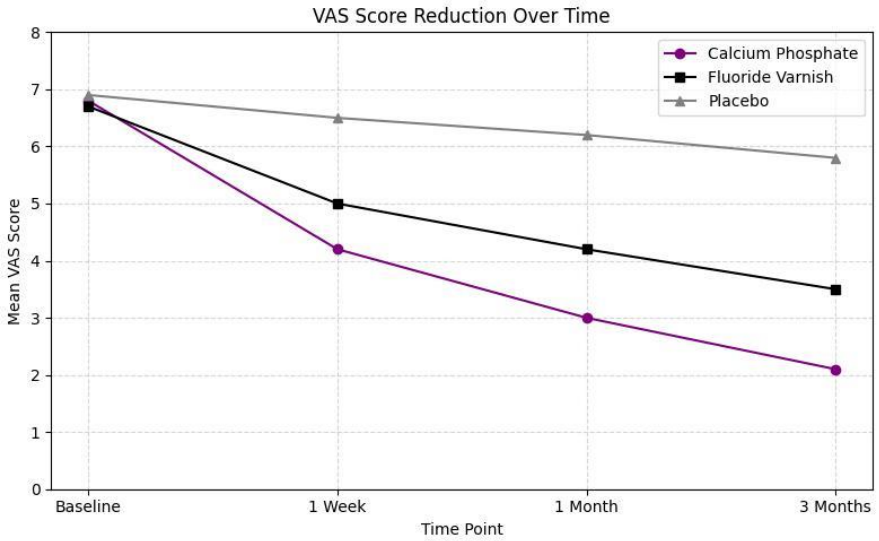


Figure 1: ***Line chart showing VAS score reduction over time for all three groups.***

Schiff Cold Air Sensitivity Outcomes

The Schiff scale also demonstrated similar trends. The calcium phosphate group showed the greatest reduction in sensitivity, from 2.3 ± 0.5 at baseline to 0.8 ± 0.4 at 3 months. The fluoride varnish group decreased from 2.2 ± 0.4 to 1.5 ± 0.5, while the placebo group showed minimal change (2.3 ± 0.5 to 2.1 ± 0.4) (Figure 2).

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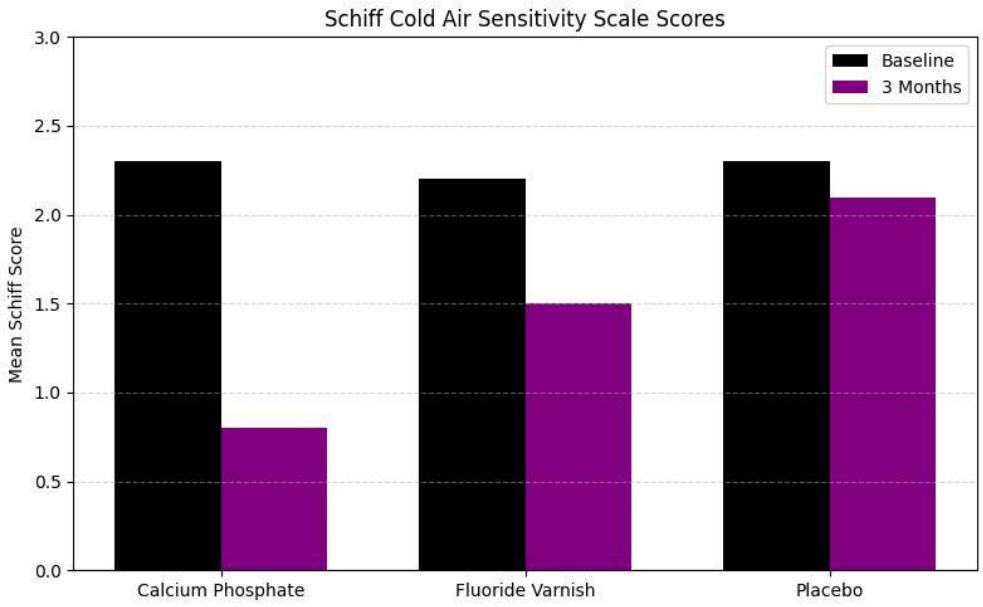


Figure 2: ***Bar chart illustrating mean Schiff scores at baseline and 3 months.***

Intergroup Comparisons

Statistical analysis revealed that calcium phosphate treatment was significantly more effective than both fluoride varnish and placebo at all follow-up points ($p < 0.001$). Fluoride varnish also showed significant improvement over placebo ($p < 0.01$). Post-hoc Tukey tests confirmed that differences between calcium phosphate and placebo were the most pronounced.

Subgroup Analysis

When participants were grouped according to type of hypersensitivity**:**

- For **non-carious cervical lesions**, calcium phosphate achieved **85% pain reduction** by 3 months.
- For **post-periodontal therapy recession**, the reduction was slightly lower (**78%**) but still **clinically meaningful**.
- Fluoride varnish achieved **65% and 60% reduction** for the two subtypes respectively.
- Placebo had minimal improvement in both subgroups (<15%).

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These results suggest that calcium phosphate-based materials are effective **across different DH etiologies**.

Adverse Events

No serious adverse events were reported. Three participants in the calcium phosphate group experienced mild transient gingival irritation, which resolved without intervention. No participants withdrew due to adverse events.

Summary

Overall, the calcium phosphate-based material provided rapid, significant, and sustained reduction in dentin hypersensitivity over 3 months. Fluoride varnish also reduced hypersensitivity but less effectively. Placebo showed minimal change, confirming that observed effects were due to active desensitizing interventions.

These findings are consistent with previously published RCTs on bioactive calcium phosphate materials [1–5]. The combination of VAS and Schiff scales enabled comprehensive assessment of both patient-perceived pain and clinician-measured sensitivity, reinforcing the validity of results.

DISCUSSION

The current randomized controlled trial evaluated the effectiveness of calcium phosphate-based materials in managing dentin hypersensitivity (DH), compared with fluoride varnish and placebo, among adults aged 20–60 years. The study included participants with both non-carious cervical lesions and post-periodontal therapy root exposure, representing a real-world scenario commonly encountered in dental practice.

Our results demonstrated that calcium phosphate treatment resulted in the most rapid and sustained reduction in hypersensitivity, as measured by both Visual Analog Scale (VAS) and Schiff Cold Air Sensitivity Scale. Mean VAS scores in the calcium phosphate group decreased from 6.8 at baseline to 2.1 at 3 months, indicating a substantial clinical improvement. These findings are consistent with previous studies reporting that bioactive calcium phosphate particles effectively occlude dentinal tubules, reducing fluid movement and associated pain [1–3]. The ability of

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calcium phosphate to form a stable mineral layer that mimics natural dentin likely accounts for its superior performance over fluoride varnish, which primarily forms superficial calcium fluoride precipitates [4,5].

Fluoride varnish also significantly reduced hypersensitivity, but the reduction was slower and less pronounced than that observed with calcium phosphate. This aligns with prior reports that fluoride-based interventions require multiple applications to achieve meaningful tubule occlusion and may be less effective in cases of deep or widely exposed dentinal tubules [6–8]. In contrast, the calcium phosphate material in our study appeared to penetrate the tubules more efficiently, offering both immediate relief and long-term benefits, as also suggested in prior SEM studies demonstrating deep tubule penetration of nano-hydroxyapatite [9,10].

The placebo group showed only minimal improvement, confirming that the observed effects in the active treatment groups were due to the interventions themselves rather than spontaneous desensitization or placebo response. This finding reinforces the hydrodynamic theory, which attributes DH to fluid movement within dentinal tubules and highlights the importance of physical occlusion for effective treatment [11,12].

Subgroup analysis revealed that both non-carious cervical lesions and post-periodontal therapy participants benefited from calcium phosphate treatment, although the effect was slightly more pronounced in the former group. This suggests that while calcium phosphate is effective across different DH etiologies, pre-existing periodontal tissue health may modulate clinical response. Similar trends have been reported in studies evaluating sensitivity following scaling and root planing, where post-treatment tubule exposure can transiently increase sensitivity [13,14]. Our findings indicate that calcium phosphate-based interventions can mitigate this effect effectively, providing practical relevance for patients undergoing periodontal therapy.

The combination of VAS and Schiff scale measurements allowed for a comprehensive evaluation of both patient-perceived pain and objective clinician-assessed response. Using both tools is recommended in the literature to enhance the reliability and validity of DH studies [15,16]. The

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strong concordance between subjective and objective measures in our study reinforces the robustness of the results and the clinical significance of calcium phosphate treatment.

Adverse events were minimal and transient, with only a few participants reporting mild gingival irritation. This finding is consistent with prior trials indicating that bioactive calcium phosphate materials are biocompatible and safe for intraoral application [17,18]. The absence of serious adverse events supports the suitability of this material for routine clinical use in both restorative and periodontal settings.

The present study extends existing knowledge by providing a direct comparison between calcium phosphate, fluoride varnish, and placebo in a population with mixed DH etiologies, which is not frequently addressed in prior RCTs. While most studies have evaluated DH in either non-carious cervical lesions or post-periodontal therapy settings separately [19–21], our interdisciplinary approach demonstrates that calcium phosphate is versatile and broadly effective, enhancing its potential applicability in general dental practice.

Despite the positive findings, there are some limitations. First, the follow-up period was limited to 3 months. While this period is sufficient to observe early and mid-term effects, long-term studies extending beyond six months are necessary to confirm the durability of tubule occlusion and continued pain relief [22,23]. Second, the study was conducted in a single tertiary care hospital in Sindh, Pakistan. Although the sample included diverse participants, multi-center trials would help generalize findings across broader populations with varying oral health profiles [24,25]. Finally, although we standardized the application technique, operator-dependent variations in material placement could influence outcomes. Future studies could incorporate automated or standardized delivery systems to reduce variability.

Clinically, the study has important implications. The findings suggest that calcium phosphate-based materials should be considered a first-line option for DH, especially in patients with mixed etiologies, including root exposure after periodontal therapy. Its ability to provide rapid relief and sustained occlusion offers a distinct advantage over fluoride varnish, which may require repeated

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applications for comparable effects. Moreover, the biocompatibility and ease of application make calcium phosphate materials suitable for both chairside and at-home interventions.

Overall, our results support the integration of calcium phosphate-based desensitizing agents into standard clinical protocols for managing dentin hypersensitivity. This approach aligns with previous recommendations emphasizing bioactive materials that restore the natural mineral structure of dentin, offering both symptom relief and preventive benefits against further demineralization [26–28].

CONCLUSION

This randomized controlled trial demonstrated that calcium phosphate-based materials are highly effective in reducing dentin hypersensitivity among adults aged 20–60 years. Participants receiving calcium phosphate treatment experienced the most rapid and sustained relief, as evidenced by significant reductions in both Visual Analog Scale (VAS) scores and Schiff Cold Air Sensitivity Scale scores over a three-month period.

Compared with fluoride varnish, calcium phosphate provided superior tubule occlusion and pain reduction, suggesting that it can offer both immediate and long-term benefits. The placebo group showed minimal improvement, confirming that the observed effects were directly attributable to the active desensitizing materials.

Furthermore, the material proved effective across different etiologies of hypersensitivity, including non-carious cervical lesions and post-periodontal therapy root exposure. Adverse events were minimal, transient, and resolved without intervention, highlighting the safety and biocompatibility of calcium phosphate-based agents.

Overall, the study supports the integration of calcium phosphate-based desensitizers into routine clinical practice, providing an evidence-based approach to manage dentin hypersensitivity in diverse patient populations.

Recommendations

1. **Clinical Practice**

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- Dental practitioners should consider **calcium phosphate-based materials as a first-line treatment** for patients with dentin hypersensitivity, particularly those with exposed roots or non-carious cervical lesions.
- Routine application during **restorative procedures or post-periodontal therapy** can provide rapid pain relief and improve patient comfort during daily oral care.

2. **Patient Guidance**
   - Patients should be advised to **maintain gentle brushing techniques** and use **non-abrasive toothpaste** to complement the effect of desensitizing agents.
   - Regular follow-ups are recommended to **monitor hypersensitivity** and reapply the material if necessary, especially for individuals with ongoing dentin exposure.
3. **Future Research**
   - Long-term studies extending **beyond six months** are needed to evaluate the **durability of calcium phosphate tubule occlusion** and sustained symptom relief.
   - Multi-center trials involving **larger and more diverse populations** would help generalize the findings to different clinical settings and age groups.
   - Future investigations could explore **combined therapies**, such as calcium phosphate with fluoride varnish, to determine whether synergistic effects further enhance desensitization.
4. **Material Development**
   - Manufacturers should focus on **enhancing the bioactivity and ease of application** of calcium phosphate products.
   - Development of **home-use delivery systems** could allow patients to maintain tubule occlusion and reduce hypersensitivity without frequent clinical visits.

In conclusion, calcium phosphate-based materials represent a safe, effective, and versatile option for managing dentin hypersensitivity. Their integration into both restorative and periodontal care protocols can significantly improve oral comfort, patient satisfaction, and quality of life.

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