

## Original Research Article

# Efficacy of calcium sodium phosphosilicate containing dentifrice in reducing dentin hypersensitivity compared to other dentifrices with dentin tubule occluding molecules: A systematic review

Sunil Kumar Vaddamanu<sup>1</sup>, Saad M AlQahtani<sup>2</sup>, Ravi Kadur Sundarraj<sup>3\*</sup>, Raghavendra Reddy Nagate<sup>4</sup>, Vijay Apparaju<sup>5</sup>

<sup>1</sup>Department of Dental Technology, <sup>2</sup>Department of Periodontics and Community Dental Sciences, College of Dentistry, <sup>3</sup>Department of Pediatric Dentistry and Orthodontic Sciences, College of Dentistry, <sup>4</sup>Department of Periodontics and Community Dental Sciences, College of Dentistry, King Khalid University, Abha, Kingdom of Saudi Arabia, <sup>5</sup>Department of Periodontics, Dr Vijay's Multispeciality Dental Care, Bangalore, India

\*For correspondence: **Email:** [sundarraj@kku.edu.sa](mailto:sundarraj@kku.edu.sa)

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### Abstract

**Purpose:** To assess the effectiveness of calcium sodium phosphosilicate in reducing dentin hypersensitivity compared to other dentin tubule occluding molecules.

**Methods:** A structured research question was formulated, and an electronic search of available literature was carried out via PubMed, Google Scholar, and Scopus. A hand search as well as a gray literature search were also carried out. The search produced a total of 67 articles. Of these, only eight articles were eligible to be included in our review. Risk of bias and study quality were checked using Cochrane tool. The review was registered in The International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD42018096200.

**Results:** The results show a reduction in dentin hypersensitivity with calcium sodium phosphosilicate compared to many other molecules. However, nanohydroxyapatite showed a better desensitizing effect compared to Novamin.

**Conclusion:** According to the available evidence, 5 % calcium sodium phosphosilicate containing toothpaste is more effective reducing dentin hypersensitivity compared to many other dentinal tubule occluding molecules.

**Keywords:** Dentin hypersensitivity, novamin, calcium sodium phosphosilicate, potassium nitrate

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### INTRODUCTION

Dentin hypersensitivity (DH) is usually defined as acute sharp lingering pain associated with exposure of dentinal tubules to thermal,

evaporative, tactile, or chemical stimuli which can't be attributed to any other dental pathology or anomaly [1].

Several etiologies are associated with DH.

Gingival recession is the most frequent etiology of DH, followed by attrition and erosions. Dentinal tubule exposure due to dental caries and attrition usually occurs in children and young adults. Meanwhile, gingival recession due to periodontal disease and following periodontal treatment is more frequent in older patients. In addition, excessive occlusal force, premature occlusion, erosion, or abrasion due to over zealous tooth brushing may cause enamel loss and subsequently DH [2]. Dentin hypersensitivity affects 3 to 98 % of general population and, on average, 15 % of adult population [3]. Although DH affects various age groups, its peak prevalence occurs at 30 – 40 years age group. In addition, females are more affected by DH than males [3]. Dentin hypersensitivity is one of the main problems for which patients seek dental treatment [2].

Several theories were proposed to explain DH including direct innervation theory, odontoblast repair theory, and hydrodynamic/fluid moment theory. Of these, hydrodynamic theory is the most widely accepted [1,2]. According to hydrodynamic theory, any fluid moment in dentinal tubules may stimulate nerve fibers. Hence, targeting dentinal tubule occlusion or blocking nerve conduction may reduce DH [4]. Dentifrices with dentinal tubule occluding molecules or potassium or sodium salts (that decrease nerve transmission), laser therapy, and iontophoresis are some of the proposed DH treatment methods [5]. Potassium salts act as nerve-numbing agents by increasing potassium ion concentration in extracellular dentinal fluids [6]. Nevertheless, according to few clinical studies, this effect of potassium salts (potassium nitrate) is transient [7].

Several clinical studies showed calcium sodium phosphosilicate (CSPS) to have superior desensitizing effect compared to potassium nitrate [4,6,8–10]. Calcium sodium phosphosilicate is a bioactive glass material that reacts with saliva to form hydroxyapatite-like crystals on dentinal surface. This newly-formed mineralized layer dentin has the same mineral content as bone, enamel, and dentin. Furthermore, it acts as a barrier against oral fluids preventing further DH [11].

Several systematic reviews were conducted on Novamin (a dentifrice containing calcium sodium phosphosilicate). One study reviewed clinical trials comparing CSPS with placebo [12]. Another review included studies comparing CSPS to other desensitizing dentifrices [13]. However, none of previous systematic reviews did review studies comparing CSPS to other dentinal tubule

occluding molecules. Therefore, in this study we review studies comparing CSPS to other dentinal tubule occluding molecules.

## METHODS

### Protocol and registration

This study was conducted according to PRISMA guidelines (Preferred Reporting Items for Systematic review and Meta-Analysis) [14]. Study protocol was registered in PROSPERO (International prospective registration of systematic reviews) under registration no. CRD42018096200.

### Research question

We systematically reviewed randomized clinical trials (RCTs) to investigate our research question. Our formulated research question was "What is the immediate and long-term efficacy reducing dentin hypersensitivity of dentifrice containing calcium sodium phosphosilicate (Novamin) compared to dentifrices containing other dentin tubule occluding molecules in patients with dentin hypersensitivity?".

### Search strategy

PubMed (MEDLINE), Scopus, and Google scholar were searched for studies published till July 2018 without any language restrictions. Search was conducted in PubMed (MEDLINE) with Mesh terms and keywords. Search details were "Search ("NOVAMIN"[Title/Abstract]) OR "Calcium sodium phosphosilicate"[Title/Abstract]) OR "Bioactive glass"[Title/Abstract]) AND ("sensitive tooth"[Title/Abstract]) OR "dental hypersensitivity" [Title/Abstract]) OR "dentinal hypersensitivity" [Title/Abstract]) OR "dentinal sensitivity" [Title/Abstract]) OR "dentin sensitivity" [Title/Abstract]) OR "dental sensitivity" [Title/Abstract]) OR "tooth hypersensitivity" [Title/Abstract]) OR "sensitivity"[Title/Abstract]) OR "Hypersensitivity"[Title/Abstract]) Filters: Randomized Controlled Trial; Publication date to 2018/07/31 AND "humans" [MeSH Terms]". Filter options were utilized to further limit search results. Searching was conducted by two separate blinded researchers (VA and VSK). In addition, we searched OpenGray, ClinicalTrials.gov, WHO clinical trials registration platform, and Google Scholar for gray literature. A separate hand search was also conducted reviewing references of electronic search results. Inter-raters reliability was assessed by Cohen's kappa coefficient.

## Inclusion and exclusion criteria

Criteria for study inclusion in review are mentioned in Table 1.

**Table 1:** Inclusion criteria

<b>P: Participants</b>	Patients with DH.
<b>I: Intervention</b>	Application of Novamin molecule in any form, any concentration, and at any frequency.
<b>C: Comparison</b>	Comparing with dentifrice containing other dentin tubule occluding molecule or treatments which occlude dentinal tubules (laser therapy, iontophoresis, dental varnishes, etc)
<b>O: Outcome</b>	<i>Primary outcome:</i> Reduction of DH, evaluated for at least four weeks. <i>Secondary outcome:</i> Any uneventful events like allergic reactions associated.
<b>S: Studies</b>	Randomized clinical trials (RCTs)

- Observational studies, animal studies, In-vitro studies, letters to editors, and reviews all were excluded from review. In addition, we excluded studies with patients having any systemic disease, who are already undergoing any treatments or undergone any procedures for DH, who are using analgesics, with tooth fractures, or with post-restoration DH. Studies with improper methodologies such as, Improper or no measuring tool for DH, inappropriate or unpublished results, or no patient follow-up were also excluded. Finally, studies where low-power laser therapy was used were excluded as well, as low-power laser therapy would affect nerve transmission rather than dentin tubule occlusion.

Search results were first screened by titles and abstracts by two blinded reviewers (NRR and VSK). Any disagreements were resolved by discussion, if required, with a third researcher to reach a consensus. Authors of the reviewed publications were contacted by a fourth researcher when ever needed. Duplicate search results were eliminated. Remaining studies were subjected to full-text evaluation.

### Data extraction

Data extraction was done by two independent researchers. Any disagreements were resolved

by discussion with a third researcher to reach a consensus. For each study, data were extracted regarding year of publication, author names, study location, number of participants, age range and mean age of participants, study groups, interventions used, type of stimulus used, follow up intervals and maximum follow-up period, and primary and secondary outcomes of interest.

### Assessment of study quality and bias

Risk of bias was evaluated by two separate reviewers according to instructions of Cochran handbook of systematic reviews of intervention.. Studies were assessed for randomization, allocation of participants, blinding of participants and outcome, incomplete outcome data, and selective reporting. Overall good and fair quality studies were included for review, while poor quality studies were excluded from review. Any disagreement between the two reviewers was clarified by a discussion between both of them or with a third author to reach a consensus. Reviewers checked acknowledgments in studies and author's disclosure forms for conflicts of interests based on Friedman and Richter criteria. For missing data and unpublished information, another researcher contacted corresponding authors when needed.  $I^2$  analysis was used to assess study heterogeneity. Due to significant variations in studies protocols and follow-up periods, a meta-analysis wasn't carried out.

## RESULTS

### Study selection

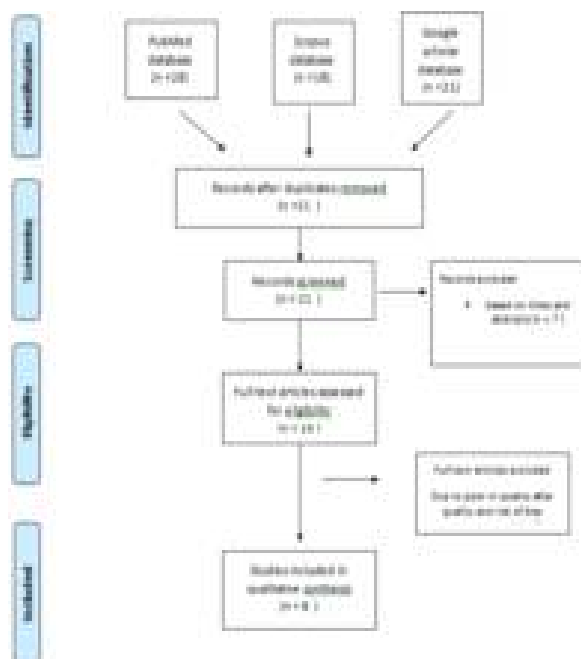
Our initial search produced a total of 67 results. Twenty-one duplicate records and seven unrelated articles (screened out by reviewing titles and abstracts) were excluded. Finally, 14 articles undergone full-text evaluation. After eliminating seven ineligible and poor quality articles, eight articles [4,6,8-10,15-17] were included in this review. Figure 1 shows a flowchart of study selection for review.

### Characteristics of included studies

A detailed description of the eight included studies is mentioned in Table 2. Quality assessment summary and quality of individual studies are stated in Table 3.

### Study outcomes

In all included studies, Novamin was used at a concentration of 5% [4,6,8-10,15,16]. Five [4,6,8-10] out of eight studies showed Novamin



**Figure 1:** Flowchart showing study design according to PRISMA 2009 guidelines

to be superior to comparison molecule, while, three studies [15–17] showed comparison molecules (arginine, nanohydroxyapatite, and fluoro calcium phosphosilicate) to be superior to Novamin. Out of eight included studies, five studies compared Novamin with 5% potassium nitrate [4,6,8–10]. These five studies all showed Novamin to be superior to potassium nitrate regarding reduction in DH. One study with a maximum follow-up period of 12 weeks showed a mean visual analog scale (VAS) score of 8.06 to 3.37 with Novamin, which was significantly different from potassium nitrate (baseline VAS = 7.20 and at 12 weeks = 5.00) [10]. Meanwhile, one out of eight included studies compared Novamin to 8% arginine [16]. Surprisingly, this study showed arginine to be superior to Novamin regarding mean reduction in DH. Novamin was compared to 3.85 % amine fluoride in two of the included studies [4,10].

In both studies, Novamin showed superior effects compared to amine fluoride after six weeks, and even after twelve weeks in one of the two studies [10]. Two studies compared Novamin with nano hydroxyapatite particles. In both studies, nanohydroxyapatite showed superior results compared to Novamin at follow-up after four weeks [15,16]. One study compared Novamin to 5 % fluoro calcium phosphosilicate and showed fluoro calcium phosphosilicate to be superior to Novamin even after eight-week follow-up. Notably, none of the included studies reported any adverse effects associated with the use of Novamin.

## Risk of bias and quality assessment

After assessing the risk of bias in different aspects using Cochrane collaboration tool, final quality of studies were evaluated. Seven studies were excluded because of poor quality and high risk associated with their inclusion in review.

## DISCUSSION

The current systematic review was conducted to assess evidence regarding effect of Novamin on dentin hypersensitivity (DH) compared to other dentinal tubule occluding molecules. We also aimed to assess immediate and long-term adverse effects of Novamin. In this systematic review, we aimed to only consider randomized controlled clinical trials for inclusion. Studies in which Novamin was compared with placebo were excluded. Only RCTs of at least one dentinal tubule occluding molecule in addition to Novamin were included.

Due to the similarity to bone mineral, calcium sodium phosphosilicate was proposed in the late nineteenth century as a regenerating materia [24]. Later, this molecule was introduced to the field of oral care for repairing damaged dentinal surfaces. Novamin is nothing but a calcium sodium phosphosilicate molecule which can occlude dentinal tubules by forming a mineralized layer on the exposed dentinal tubules. The newly-formed layer of Novamin is proposed to be resistant to pH fluctuations of saliva, and therefore resistant to dislodgment off dentinal surface [24]. A recent systematic review of studies comparing Novamin with placebo concluded that Novamin is effective in reducing DH compared to a negative control [12]. In addition, Novamin was compared to various dentinal tubule occluding molecules.

West *et al* reviewed effectiveness of several professional and self-administered desensitizing agents, and concluded that Novamin and strontium chloride were more effective compared to other molecules [5]. Another summary review [1] suggested superiority of Novamin over comparison, but surprisingly showed strontium chloride to have no advantage over placebo which is contradicting results of a previous systematic review [5].

**Table 2:** Characteristics of RCTs included in review

S.NO	Year of publication	Author name	Place of study conducted	Number of participants	Age range and mean age	Groups and Active ingredients used in dentifrices	Concentration used	Type of stimulus used	Scale used to measure DH	Follow up intervals and maximum follow-up period
1.	2010	Narongdej et al[18]	Thailand	60	26–70 years Mean age 44.8 years	G1: Novamin powder+ Novamin containing tooth paste G2: Tooth paste containing Novamin only and placebo powder. G3: Tooth paste containing Potassium nitrate and sodium fluoride.	100 %. and 7.5%, respectively 7.5% 5 % and 0.221% respectively.	Thermal and Tactile	VAS* scale (0-10)	Before , baseline, one week, two weeks, and four weeks
2.	2010	Pradeep and Sharma[6]	India	110	20 – 60 years Mean age 40 years	G1: Novamin G2: Potassium nitrate G3: Tooth paste without any desensitizing agents	5% 5% Nil	Evaporative and thermal	VAS scale (0-10)	Baseline, 2 weeks, and 6 weeks

\*VAS = Visual Analog Scale

**Table 2:** Characteristics of RCTs included in review (continued)

S.NO	Year of publication	Author name	Place of study conducted	Number of participants	Age range and mean age	Groups and Active ingredients used in dentifrices	Concentration used	Type of stimulus used	Scale used to measure DH	Follow up intervals and maximum follow-up period
3	2012	Ananthakrishna et al[19]	India	40	20 – 50 years	G1: Novamin	7.5%	Evaporative and Thermal	VAS scale (0-10)	Base line, 2 weeks, 4 weeks and 6 weeks
					Mean age 35 years	G2: Strontium Chloride.	10%			
4	2012	Pradeep et al[4]	India	149	20 – 60 years	G1: Potassium Nitrate.	5%	Evaporative and Thermal	VAS scale (0-10)	Baseline, 2 weeks, and 6 weeks
					Mean age 40 years	G2: Novamin	5%			
						G3: Amine fluoride	3.85%			
						G4: Placebo	Nil			
5	2013	Acharya et al[8]	India	20	18 – 65 years	G1: Novamin	5%	Thermal and Evaporative	VAS scale (0-10)	Base line, 2 weeks, 4 weeks and 8 weeks
6	2014	Rao et al[20]	India	80	18 – 70 years	G1: Novamin	5%	Evaporative	VAS scale (0-10)	Before application, 1min immediately after application, and after 15 days.
					Mean age 44 years	G2: Arginine	8%			

\*VAS = Visual Analog Scale

**Table 2:** Characteristics of RCTs included in review (continued)

S.NO	Year of publication	Author name	Place of study conducted	Number of participants	Age range and mean age	Groups and Active ingredients used in dentifrices	Concentration used	Type of stimulus used	Scale used to measure DH	Follow up intervals and maximum follow-up period
7	2014	Satyapal et al[9]	India	60	Not mentioned	G1: Novamin	5%	Thermal and Evaporative	VAS scale (0-10)	Baseline, 3 weeks, and 6 weeks
						G2: Potassium nitrate	5%			
8	2015	Gopinath et al.[15]	India	36	18 – 60 years	G1: Nano-Hydroxyapatite containing tooth paste	Not mentioned	Thermal, Evaporative, and tactile	VAS scale (0-10)	Baseline, 4 weeks
					Mean age 39 years	G2: Novamin				
9.	2015	Jena and Shashirekha[16]	India	45	18 – 50 years	G1: Tooth paste containing Novamin	5%	Evaporative, and tactile	VAS scale (0-10) Schiff cold air sensitivity score	Before, Immediately, 1 week, and 4 weeks after application
					Mean age 34 years	G2: Tooth paste containing Arginine	8%			
					G3: Hydroxyapatite Nano particles	15%				
10.	2016	Majji and Murthy[21]	India	160	20– 60 years	G1: Potassium nitrate	5%	Tactile, Thermal and Evaporative	VAS scale (0-10)	Baseline, 2 weeks, 1month, 2 months after application
					Mean age 40 years	G2: Novamin	5%			
					G3: Strontium Chloride	10%				
					G4: Herbal formulations	Not mentioned				

**Table 2:** Characteristics of RCTs included in review (continued)

S.NO	Year of publication	Author name	Place of study conducted	Number of participants	Age range and mean age	Groups and Active ingredients used in dentifrices	Concentration used	Type of stimulus used	Scale used to measure DH	Follow up intervals and maximum follow-up period
11	2017	Athuluru et al[10]	India	68	18 – 75 years  Mean age 46.5 years	G1: Potassium nitrate  G2: Novamin  G3: Amine fluoride  G4: Placebo	5%  5%  3.85%  Nil	Evaporative	VAS scale (0-10)	Baseline, 6 weeks, and 12 weeks
12	2017	Bansal and Mahajan[22]	India	45	20 – 50 years  Mean age 35 years	G1: Novamin  G2: Arginine  G3: Herbal tooth paste	5%  8%  Nil	Evaporative and Tactile	VAS scale (0-10)	Before, immediately after application, 2 weeks and 4 weeks after treatment
13	2017	Vazhakkat and Shobha[23]	India	30	18– 65 years  Mean age 41.5 years	G1: Arginine  G2: Novamin	8%  Not mentioned	Evaporative and Thermal	VAS scale (0-10) and Schiff cold air sensitivity testing scale (0-3)	Before, Baseline, 1 week, 2 weeks, and 4 weeks after treatment
14.	2018	Ashwini[17]	India	60	Any age above 18 years	G1: Fluoro calcium phosphosilicate.  G2: Novamin	5%  5%	Thermal	VAS scale (0-10)	Before, Baseline, 1, 2, 4, and 8 weeks after treatment

\*VAS = Visual Analog Scale



**Table 3:** Summary of risk of bias assessment

<b>Author name and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete outcome data (attrition bias)</b>	<b>Selective reporting (reporting bias)</b>	<b>Other bias</b>	<b>Quality of the study</b>
Narongdej et al, 2010 [18]	Unclear risk	High risk	Unclear risk	Unclear risk	Low risk	Low risk	Unclear risk	Poor Quality
Pradeep & Sharma, 2010 [6]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Good quality
Ananthakrishna et al, 2012 [19]	Unclear risk	High risk	High risk	Unclear risk	Low risk	Low risk	Low risk	Poor quality
Pradeep et al, 2012 [4]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Good quality
Acharya et al, 2013 [8]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Good quality
Rao et al, 2014 [20]	Unclear risk	High risk	High risk	High risk	Low risk	Low risk	Unclear risk	Poor quality
Satyapal et al, 2014 [9]	Unclear risk	Unclear risk	Low risk	Low risk	Low risk	Low risk	Low risk	Fair quality
Gopinath et al, 2015 [15]	Unclear risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Fair quality
Jena & Shashirekha, 2015 [16]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Good quality
Majji and Murthy, 2016 [21]	Unclear risk	High risk	Low risk	Unclear risk	Low risk	Low risk	Low risk	Poor quality
Athuluru et al, 2017 [10]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Good quality
Bansal & Mahajan, 2017 [22]	Unclear risk	High risk	High risk	High risk	Low risk	Low risk	Unclear risk	Poor quality
Vazhakkat and Shobha, 2017 [23]	Unclear risk	High risk	High risk	High risk	Low risk	Low risk	Unclear risk	Poor quality
Ashwini et al, 2018 [17]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Good quality

Another systematic review by Bae *et al* [13] also supported the efficacy of Novamin along with other dentinal tubule occluding molecules, and highlighted the non-superiority of strontium chloride over placebo. These results are also similar to Levenson's review results [1].

Recent clinical trials comparing Novamin with nanohydroxyapatite particles [15,16], highlighted the superiority of nanohydroxyapatite particles over Novamin. Cold and tactile tests at four-week follow-up showed a superior reduction in mean VAS scores with nanohydroxyapatite particles, but evaporative stimulus showed Novamin to be superior in reducing baseline mean VAS score in a study by Gopinath *et al* [15]. Dentin tubule occlusion capacity of Novamin was also tested in *in-vitro* studies using scanning electron microscopy [25]. However, this microscopy study revealed lower tubular occlusion capacity and resistance after acid challenge of Novamin when compared to arginine-calcium carbonate and propolis extract. Another *in-vitro* study confirmed formation of hydroxyapatite like crystals when CSPA is mixed with saliva on dentin slabs [26].

Dentin hypersensitivity usually occurs due to exposure of dentinal surface to the oral environment due to loss of gingiva, decay, or after periodontal surgery. Dentin hypersensitivity following periodontal surgery might be due to the inadvertent removal of cementum during root planing procedure and apical shift of marginal gingiva after the procedure [2]. Dentin hypersensitivity occurring due to decay or gingival recession differs from DH occurring after periodontal surgery. Dentin hypersensitivity occurring after periodontal surgery usually peaks immediately after surgery and improves spontaneously after a few days. Hence, treatment of DH occurring after periodontal surgical procedure could be postponed intentionally [2].

Although many clinical trials didn't use CSPA at concentrations higher than 5%, various CSPA formulations are available in market with concentrations from 2.5 to 15 %. Concentrations of professional-administered CSPA formulations are generally higher compared to home-use or self-administered ones [5].

Different positive controls were compared to CSPA. Potassium nitrate, arginine, amine fluoride, nanohydroxyapatite are the most commonly tested positive control molecules [4,6,10,15,16]. Another commonly used positive control molecule is fluoride salts [17]. Usage of fluoride-containing positive control is still controversial since a high concentration of

fluorides would occlude dentinal tubules, while lower concentration reduces nerve conduction process [4]. Potassium nitrate was used as a positive control to assess efficacy of Novamin in many studies [4,6,10,15]. Potassium nitrate containing dentifrices also show dual mechanism of action as potassium salts would occlude dentinal tubules, while increased potassium ions would increase threshold of nerve conduction and finally block nerve conduction [18]. Although, United States FDA approved using potassium nitrate as a desensitizing agent and many clinical trials also support that, long-term desensitizing effects aren't evident.

### Study limitations

This systematic review is mainly limited by the nature of included studies. Some of the included studies were sponsored by medical industries, therefore, raising potential conflicts of interests. While other trials had small sample size, short follow-up periods, or only one stimulus type used to check DH. In addition, all included fair-quality studies didn't provide information regarding randomization and allocation concealment which would potentially increase risk of bias.

### CONCLUSION

According to results of this systematic review, 5 % CSPA containing tooth paste is expected to be more effective compared to many other dentinal tubule occluding molecules. However, evidence shows nanohydroxyapatite to be superior to CSPA regarding immediate and long-term desensitizing effects. Development of adverse effects with the usage of 5 % CSPA-containing dentifrices wasn't reported in any of the included studies.

### DECLARATIONS

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#### Conflict of Interest

No conflict of interest associated with this work.

#### Contribution of Authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them.

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