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

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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

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 overzealous 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 dentinhas 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 dentinal 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 "dentin hypersensitivity" [Title/Abstract]) OR "dental sensitivity" [Title/Abstract]) OR "dentin sensitivity" [Title/Abstract]) OR "tooth hypersensitivity" [Title/Abstract]) OR "sensitivity"[Title/Abstract]) OR "Hypersensitivity"[Title/Abstract]) Filters: Randomized Controlled Trial; Publication date to 2018/07/31AND "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

| P: Participants | I: Intervention | C: Comparison | O: Outcome | S: Studies |
|-----------------|-----------------|---------------|------------|-----------|
| Patients with DH. | Application of Novamin molecule in any form, any concentration, and at any frequency. | Comparing with dentifrice containing other dentin tubule occluding molecule or treatments which occlude dentinal tubules (laser therapy, iontophoresis, dental varnishes, etc) | Primary outcome: Reduction of DH, evaluated for at least four weeks. Secondary outcome: Any uneventful events like allergic reactions associated. | 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 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 underwent 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...
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 | 100 %. and 7.5%, respectively | Thermal and Tactile | VAS* scale (0-10) | Before, baseline, one week, two weeks, and four weeks |
|      |                     |             |                          |                        |                        | G2: Tooth paste containing Novamin only and placebo powder. | 7.5%              |                        |                             |                                                |
|      |                     |             |                          |                        |                        | G3: Tooth paste containing Potassium nitrate and sodium fluoride | 5 % and 0.221% respectively. |                        |                             |                                                |
| 2.   | 2010                | Pradeep and Sharma[6] | India                   | 110                    | 20 – 60 years Mean age 40 years | G1: Novamin | 5% | Evaporative and thermal | VAS scale (0-10) | Baseline, 2 weeks, and 6 weeks |
|      |                     |             |                          |                        |                        | G2: Potassium nitrate | 5% |                        |                             |                                                |
|      |                     |             |                          |                        |                        | G3: Tooth paste without any desensitizing agents | Nil |                        |                             |                                                |

*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.                          |                   |                      |                              |                                               |
|      |                     |                                 |                          |                        |                        |                                                 |                   |                      |                              |                                               |
| 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                                      |                   |                      |                              |                                               |
| 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       |
|      |                     |                                 |                          |                        | Mean age 41.5 years    |                                                 |                   |                      |                              |                                               |
| 6    | 2014                | Rao et al[20]                   | India                    | 80                     | 18 – 70 years          | G1: Novamin                                      | 5%                | Evaporative           | VAS scale (0-10)                           | Before application, 1 min 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 Mean age 39 years | G1: Nano-Hydroxyapatite containing tooth paste     | Not mentioned       | Thermal, Evaporative, and tactile | VAS scale (0-10)              | Baseline, 4 weeks                          |
|      |                     |             |                           |                        |                        | G2: Novamin                                       | 5%                  |                        |                                |                                               |
| 9.   | 2015                | Jena and Shashirekha[16] | India                     | 45                     | 18 – 50 years Mean age 34 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 |
|      |                     |             |                           |                        |                        | G2: Tooth paste containing Arginine                | 8%                  |                        |                                |                                               |
|      |                     |             |                           |                        |                        | G3: Hydroxyapatite Nano particles                  | 15%                 |                        |                                |                                               |
| 10.  | 2016                | Majji and Murthy[21] | India                     | 160                    | 20–60 years Mean age 40 years | G1: Potassium nitrate                              | 5%                  | Tactile, Thermal and Evaporative | VAS scale (0-10)              | Baseline, 2 weeks, 1 month, 2 months after application |
|      |                     |             |                           |                        |                        | 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 Man 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

| Author name and year | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants and personnel (performance bias) | Blinding of outcome assessment (detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias | Quality of the study |
|----------------------|---------------------------------------------|------------------------------------------|----------------------------------------------------------|-----------------------------------------------|----------------------------------------|--------------------------------------|-----------|----------------------|
| Narongdej et al, 2010 [18] | Unclear risk | High risk | Unclear risk | Low 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 |
| Athulu 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 |
| Vazhakka 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 CSPS 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 CSPS at concentrations higher than 5%, various CSPS formulations are available in market with concentrations from 2.5 to 15%. Concentrations of professional-administered CSPS formulations are generally higher compared to home-use or self-administered ones [5].

Different positive controls were compared to CSPS. 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% CSPS 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 CSPS regarding immediate and long-term desensitizing effects. Development of adverse effects with the usage of 5% CSPS-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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