Efficacy of a mouthwash containing 0.8% arginine, PVM/MA copolymer, pyrophosphates, and 0.05% sodium fluoride compared to a commercial mouthwash containing 2.4% potassium nitrate and 0.022% sodium fluoride and a control mouthwash containing 0.05% sodium fluoride on dentine hypersensitivity: A six-week randomized clinical study

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Abstract

Objective: Evaluate the efficacy of 0.8% arginine, potassium nitrate and sodium fluoride mouthwashes on dentine hypersensitivity reduction.

Methods: Six week randomized, double blinded, two cell, parallel single centre clinical study in the Dominican Republic; subjects were randomized into three treatment groups: mouthwash containing 0.8% arginine, PVM/MA copolymer, pyrophosphates, and 0.05% sodium fluoride in an alcohol-free base (arginine); mouthwash containing 2.4% potassium nitrate and 0.022% sodium fluoride (potassium nitrate); a control mouthwash containing 0.05% sodium fluoride (negative control). Tactile and air-blast dentine hypersensitivity assessments were conducted at baseline, thirty minutes post rinsing and two, four, and six weeks of twice-daily product use. For treatment group comparisons, ANCOVA and post hoc Tukey’s pair-wise comparisons (α = 0.05) were done.

Results: Seventy-five subjects were enrolled; 69 subjects completed the study. There were no differences after thirty minutes of a single use, among the three groups with respect to mean tactile and air blast hypersensitivity scores compared to potassium nitrate and negative control mouthwashes (p < 0.05). The arginine group presented a statistically significant improvement in the mean tactile scores compared to potassium nitrate and negative control groups after two, four, and six weeks (p < 0.001) of product use; the arginine group showed a statistically significant enhancement in air blast hypersensitivity mean scores compared to potassium nitrate and negative control groups after two (p = 0.001), four (p < 0.001), and six weeks (p < 0.001) of product use.
1. Introduction

Dentine hypersensitivity is defined as a short, sharp pain arising from exposed dentine in response to stimuli such as thermal, evaporative, tactile, osmotic or chemical, and which cannot be ascribed to any other form of dental defect or pathology. Usually, this sharp pain occurs when the surface of the root becomes exposed through gingival recession uncovering the dentine tubule orifices on its surface leading to a vital pulp. Previous studies have reported that dentine hypersensitivity prevalence is ranged 3–73%, in adults. Several risk factors have been described previously in the literature. For instance, the consumption of erosive dietary foods and drinks, gingival recession, abrasion, and removal of the tooth’s enamel, have been proposed as predisposing factors for dentine hypersensitivity. Other risk factors are age, chemical and/or physical forces such as instrumentation of root surfaces during scaling procedures, and aggressive tooth brushing. A transitory external stimuli such as a change in temperature, air movement or a physical stimulus may cause discomfort to the patient. The pathophysiological mechanism of dentine hypersensitivity was explained by Brännström’s hydrodynamic theory. This theory suggests that external stimuli cause movement of the dentine fluid in the tubules, resulting in a pressure change across dentine. This stimulates intra-dental nerve response signals that are ultimately interpreted by the brain as pain. Multiple agents and products partially or completely block the dentine tubules. The working mechanisms include: (1) creation of a natural smear layer to occlude the tubules, (2) creation of an artificial smear layer applying restorative resins or dentine bond agents over the open tubules forming a thin film coating, (3) creation of a layer of fine particles using a dentifrice with fine abrasive particles that creates a precipitate in situ using strontium and stannous fluoride, and (4) calcium phosphate-based mineral formation in situ such as arginine containing dental products to form a biological mineral within the opening of the dentine tubules. Treatments to relieve dentine hypersensitivity are based on two major approaches: the occlusion of exposed and open tubules to block the hydrodynamic mechanism of pain stimulation or the interruption of the neural responses to a stimulus.

Most desensitizing toothpastes contain potassium salts to interrupt the neural response of pain caused by dental hypersensitivity. In the United States, many of these desensitizing toothpastes typically contain 5% potassium nitrate (2% potassium ion). The clinical evidence suggests that desensitizing toothpastes based on potassium are effective. Nevertheless, others have reported that these toothpastes are no more effective than regular fluoride toothpastes. Gillam and coworkers have demonstrated that the 3% potassium nitrate and sodium fluoride mouthwash significantly reduces cervical dentine hypersensitivity compared to the sodium fluoride mouthwash after two and six weeks of use. Pereira et al. demonstrated that after two weeks, there were no statistically significant differences between the two groups using either method. At six weeks, however, the 3% potassium nitrate and 0.2% sodium fluoride mouthwash demonstrated a significant difference as compared to the 0.2% sodium fluoride mouthwash using the cold air technique.

Previous in vitro studies have demonstrated that dental products containing 8% arginine and calcium carbonate seal and plug dentine tubules. Other clinical studies have demonstrated that the toothpaste containing 8% arginine, calcium carbonate, and 1450 ppm fluoride provided statistically significant sensitivity relief after two, four, and eight weeks. In addition, Docimo and colleagues have shown statistically significant sensitivity relief for toothpastes with 8% arginine, calcium carbonate, and 1450 ppm fluoride compared to a negative control toothpaste containing 1405 ppm fluoride. Furthermore, several clinical studies have determined that when a toothpaste with 8% arginine, calcium carbonate, and 1450 ppm fluoride is applied directly to the affected tooth surface, an instant hypersensitivity effect can be measured relative to a 5% potassium nitrate and 1450 ppm sodium fluoride toothpaste and to a 1450 ppm sodium fluoridetoothpaste. Schiff et al. reported instant sensitivity relief from direct application of a dentifrice with 8% arginine, calcium carbonate, and 1450 ppm fluoride using a fingertip versus a cotton swab. Both methods demonstrated a statistically significant improvement in the mean tactile and mean air blast hypersensitivity scores. When these topical applications were followed by a one-week period of twice daily brushing with the dentifrice, the sensitivity relief was maintained.

Recently, a new mouthwash containing 0.8% arginine, PVM/MA copolymer, pyrophosphates and 0.05% sodium fluoride in an alcohol-free base was developed to address dentine hypersensitivity. The aim of this study was to determine if this new mouthwash, containing 0.8% arginine is more efficient as compared to a 2.4% potassium nitrate and 0.022% sodium fluoride mouthwash and to a 0.05% sodium fluoride mouthwash in reducing dentine hypersensitivity. Our hypothesis is that an alcohol-free mouthwash 0.8% arginine reduces dentine hypersensitivity compared to a 2.4% potassium nitrate and 0.022% sodium fluoride mouthwash and to a 0.05% sodium fluoride mouthwash.

2. Materials and methods

This randomized clinical double-blinded, single centre, two cell clinical study was conducted to assess three parallel treatment groups.

Conclusion: A mouthwash containing arginine provides a significant and superior reduction in dentine hypersensitivity compared to potassium nitrate and a negative control mouthwash after two weeks.
The sample of 75 subjects (25 per group) was determined based on a standard deviation (SD), for the response measure tactile sensitivity (or air blast) of 3.34 (or 0.31), a significance level of \( \alpha = 0.05 \), a 10% attrition rate and an 80% power level. The study was powered to detect a minimal statistically significant difference between the study means of 20%. Prospective study subjects reported to a private clinical facility in Santo Domingo, Dominican Republic, having refrained from all oral hygiene procedures, from chewing gum for eight hours, and from eating and drinking for four hours prior to their examination.

Inclusion and exclusion criteria:

1. Subjects ranged in age from 18 to 70 (inclusive), and were in generally good health.
2. Subjects had at least two hypersensitive teeth, anterior to the molars, that demonstrated cervical erosion/abrasion or gingival recession; and presented a tactile sensitivity stimuli score of 10–50 g of force (Yeaple Probe), and an air blast stimuli score of 2 or 3 (Schiff Cold Air Sensitivity Scale) at the baseline examination.
3. Subjects were available to participate for the duration of the six-week study and willing to sign an informed consent form.
4. Subjects were excluded from the study if they had gross oral pathology, chronic disease, advanced periodontal disease, had undergone treatment for periodontal disease (within the last 12 months), or had hypersensitive teeth with mobility greater than one. Subjects with teeth that had extensive/defective restorations (including prosthetic crowns), suspected pulpitus, caries, cracked enamel or that were used as abutments for removable partial dentures.
5. Subjects that were taking anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics within one month prior to the start of the study or, who started taking these drugs during the course of the study were excluded from participation.
6. Pregnant or lactating women, individuals who were participating in any other clinical study or who had participated in a desensitizing dentifrice study, or who had used a desensitizing dentifrice within the last three months, were not allowed to participate in the study.
7. Subjects with a history of allergy to the test products, or allergies to oral care/personal care consumer products or their ingredients, or subjects with existing medical conditions that precluded them from eating and drinking for periods up to four hours, were also excluded from the study.

The first seventy-five (75) prospective subjects who met the inclusion/exclusion criteria and signed an informed consent form received a baseline tactile hypersensitivity and an air blast hypersensitivity evaluation, along with an oral soft and hard tissue assessment. Qualifying subjects were then sequentially randomized using a list of random numbers, and assigned to one of three study treatments: (1) mouthwash (“potassium nitrate”) containing 2.4% potassium nitrate and 0.022% sodium fluoride, and (3) a mouthwash (“negative control”) containing 0.05% sodium fluoride. Mouthwashes were over-wrapped to maintain the blinding of the study participants, examiners and all study personnel. Site personnel not involved in the clinical evaluations distributed all test products in sealed opaque bags in an area separate from the examination room. The three products were letter coded.

After baseline evaluation and product assignment, subjects were instructed to brush and rinse with their assigned product as per the instructions provided. Subjects were instructed to brush their teeth and to swish 20 ml of their assigned rinse between their teeth for 30 s, and then to spit it out. They were then instructed to refrain from eating or drinking for 30 min. After 30 min, subjects were evaluated for dentine hypersensitivity following the same procedures employed at baseline. After this evaluation, subjects took their assigned product for unsupervised home use for a total of six weeks. At-home instructions consisted of brushing the teeth for one minute, twice daily, using only the toothpaste containing 1450 ppm fluoride and the soft toothbrush provided. After brushing, participants rinsed with water then rinsed for thirty seconds with 20 ml of their assigned mouthwash. Subjects were advised to refrain from any other oral hygiene procedures throughout the duration of the study. In addition, subjects were also instructed to refrain from chewing gum for eight hours and from eating and drinking for four hours prior to their follow-up hypersensitivity evaluations. There were no other restrictions regarding diet or smoking habits during the course of the study.

Subsequent evaluations were conducted after two, four and six weeks of product use. All examinations were performed by the same trained and standardized dental examiner, using the same procedures as employed at baseline. Oral soft and hard tissue assessments, as well as, tactile and air blast hypersensitivity were conducted. Subjects were interviewed with respect to the presence of adverse events and the use of concomitant medications.

3. Clinical scoring procedures

3.1. Tactile hypersensitivity assessment

Tactile hypersensitivity was assessed by use of the Model 200A Electronic Force Sensing Probe developed by Yeaple Research of Pittsford, NY. A #19 explorer tip, at a pre-set force measured in grams, was employed to measure dental hypersensitivity.

Teeth were evaluated for tactile hypersensitivity in the following manner:

1. The subject was instructed to respond at the point where he or she first experienced discomfort.
2. The explorer tip of the probe was applied to the buccal surface of each hypersensitive tooth at the CEJ.
3. The explorer tip was stroked perpendicular to the tooth beginning at a pre-set force of 10 g (0.01 kg) and increased by 10 g (0.01 kg) increments until the subject experienced discomfort, or until 50 g (0.05 kg) of force was applied.
(4) Subject scores were calculated by averaging the values measured on the two baseline-designated study teeth.

3.2. Air blast hypersensitivity assessment

Teeth were evaluated for air blast hypersensitivity in the following manner:

(1) The sensitive tooth was isolated from the adjacent teeth (mesial and distal) by the placement of the examiner’s fingers over the adjacent teeth.

(2) Air was delivered from a standard dental unit air syringe at 60 psi (4.22 kgf/cm²) ± 5 psi (0.35 kgf/cm²) and 70 °F (21) ± 3 °F (−16). The air was directed at the exposed buccal surface of the hypersensitive tooth for one second from a distance of approximately 1 cm.

(3) The Schiff Cold Air Sensitivity Scale was used to assess subject response to this stimulus.

This scale was scored as follows:

0 – Subject did not respond to air stimulus.
1 – Subject responded to air stimulus but did not request discontinuation of stimulus.
2 – Subject responded to air stimulus and requested discontinuation or moved from stimulus.
3 – Subject responded to air stimulus, considered stimulus to be painful and requested discontinuation of the stimulus.

3.3. Oral soft and hard tissue assessment

The dental examiner visually examined the oral cavity and peri-oral area using a dental light and dental mirror. This examination included an evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsillar and pharyngeal areas.

3.4. Adverse events

Adverse events were obtained from an interview with the subjects and a dental examination by the investigator.

4. Statistical methods

Statistical analyses were performed separately for the tactile and air blast hypersensitivity assessments. Comparisons of the treatment groups with respect to gender were performed using a chi-square analysis, and for age an analysis of variance (ANOVA). Comparisons of the treatment groups with respect to baseline-adjusted tactile and air blast hypersensitivity mean scores at the follow-up examinations were performed using an analysis of covariance (ANCOVA). A post hoc Tukey’s multiple comparison test was performed on all pair-wise means, when the ANCOVA showed a statistical significant difference among the treatment groups. All statistical tests of hypotheses were two sided, and employed a level of significance of \( \alpha = 0.05 \).

5. Results

During the second week of September, 2009 seventy-five (75) subjects were enrolled and were randomly assigned to three study groups of 25 participants. Sixty-nine (69) subjects complied with the protocol, and completed the six-week clinical study on the final visit during the third week of October, 2009 (Fig. 1). A summary of the gender and age of those subjects who completed the study is presented in Table 1. The treatment groups did not differ significantly with respect to either gender \( (p > 0.05) \) or age \( (p > 0.05) \). There were three adverse events reported to be unrelated to product use. Additionally, there were three subjects who did not complete the study due to non-protocol compliance.

Table 2 depicts the mean tactile hypersensitivity scores for each of the treatment groups during the study period. The mean tactile hypersensitivity scores at baseline among the treatment groups were similar \( (p > 0.05) \). However, the arginine group exhibited a statistically significant improvement in baseline-adjusted mean tactile hypersensitivity scores relative to the potassium nitrate group and the negative control group of 86.3% \( (p < 0.001) \) and 125.3% \( (p < 0.001) \), respectively after two weeks of product use. Furthermore, the arginine group showed statistically significant improvement in baseline-adjusted mean tactile hypersensitivity scores as compared to the potassium nitrate group and negative control group of 100.7% \( (p < 0.001) \) and 172.9% \( (p < 0.001) \), respectively after four weeks of use. After six weeks of use, the arginine group presented a statistically significant improvement in baseline-adjusted mean tactile hypersensitivity scores compared to the potassium nitrate group and negative control group of 86.2% \( (p < 0.001) \) and 232.6% \( (p < 0.001) \), respectively. There were no statistically significant differences between the potassium nitrate group and negative control group in baseline-adjusted mean tactile hypersensitivity score after thirty minutes \( (p = 0.72) \); and two \( (p = 0.632) \) and four \( (p = 0.280) \) weeks of product use. However, the potassium nitrate group exhibited a statistically significant reduction in baseline-adjusted mean relative to the negative control group of 78.7% \( (p = 0.005) \) after 6 weeks.

Table 3 represents a summary of the mean air blast hypersensitivity scores for each of the treatment groups during study period. The mean air blast hypersensitivity scores at baseline among the treatment groups were similar \( (p > 0.05) \). After 30 min of the initial rinsing, there

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Age (years) Mean (range)</th>
<th>Gender Male N (%)</th>
<th>Gender Female N (%)</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arginine</td>
<td>32 (21–47)</td>
<td>12 (50.0)</td>
<td>12 (50.0)</td>
<td>24</td>
</tr>
<tr>
<td>Potassium nitrate</td>
<td>33 (21–59)</td>
<td>19 (79.1)</td>
<td>5 (20.9)</td>
<td>24</td>
</tr>
<tr>
<td>Negative control</td>
<td>33 (21–48)</td>
<td>11 (52.4)</td>
<td>10 (47.6)</td>
<td>21</td>
</tr>
</tbody>
</table>

* No statistically significant difference was indicated between the three treatment groups with respect to either gender or age \( (p > 0.05) \).
Efficacy of a Mouthwash containing 0.8% Arginine, PVM/MA Copolymer, Pyrophosphates, and 0.05% Sodium Fluoride Compared to a Commercial Mouthwash containing 2.4% Potassium Nitrate and 0.022% Sodium Fluoride and a control Mouthwash containing 0.05% Sodium Fluoride on Dentin Hypersensitivity: A Six-Week Clinical Study

Assessed for eligibility (n=85)
- Excluded (n=10)
  - Not meeting inclusion criteria (n=10)
  - Declined to participate (n=0)
  - Other reasons (n=0)

Randomized (n=75)

Arginine
- Allocated to intervention (n=25)
  - Received allocated intervention (n=25)
  - Did not receive allocated intervention (n=0)

Potassium Nitrate
- Allocated to intervention (n=25)
  - Received allocated intervention (n=25)
  - Did not receive allocated intervention (n=0)

Sodium Fluoride
- Allocated to intervention (n=25)
  - Received allocated intervention (n=25)
  - Did not receive allocated intervention (n=0)

Follow-Up
- Lost to follow-up (n=1)
  - Discontinued intervention (n=0)

- Lost to follow-up (n=1)
  - Discontinued intervention (n=0)

- Lost to follow-up (n=2)
  - Discontinued intervention (n=2)

Analysis
- Analysed (n=21)
  - Excluded from analysis (n=4)

Fig. 1 – Patient flowchart.
Table 2 – Summary of the tactile hypersensitivity scores for subjects who completed the six-week study.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline(^a) (mean ± SD)</th>
<th>30 min (mean ± SD)</th>
<th>% difference 30 min(^b)</th>
<th>2 weeks (mean ± SD)</th>
<th>% difference 2 weeks</th>
<th>4 weeks (mean ± SD)</th>
<th>% difference 4 weeks</th>
<th>6 weeks (mean ± SD)</th>
<th>% difference 6 weeks</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arginine</td>
<td>10.83 ± 2.41</td>
<td>11.13 ± 1.43</td>
<td>-2.2 (p = 0.826)</td>
<td>25.32 ± 8.58</td>
<td>86.3 (p &lt; 0.001)</td>
<td>125.3 (p &lt; 0.001)</td>
<td>34.36 ± 9.80</td>
<td>100.7 (p &lt; 0.001)</td>
<td>172.9 (p &lt; 0.001)</td>
<td>39.58 ± 10.18</td>
</tr>
<tr>
<td>Potassium nitrate</td>
<td>10.42 ± 1.41</td>
<td>11.38 ± 1.43</td>
<td>1.7 (p = 0.898)</td>
<td>13.59 ± 8.60</td>
<td>17.12 ± 9.83 (p = 0.632)</td>
<td>30.8 (p = 0.280)</td>
<td>21.26 ± 10.21</td>
<td>21.26 ± 10.21</td>
<td>21.26 ± 10.21</td>
<td>21.26 ± 10.21</td>
</tr>
<tr>
<td>Negative control</td>
<td>10.95 ± 3.01</td>
<td>10.94 ± 1.43</td>
<td>4.0 (p = 0.574)</td>
<td>11.24 ± 8.59</td>
<td>12.59 ± 9.81 (p = 0.826)</td>
<td>25.32 ± 9.80</td>
<td>12.59 ± 9.81</td>
<td>12.59 ± 9.81</td>
<td>12.59 ± 9.81</td>
<td>12.59 ± 9.81</td>
</tr>
</tbody>
</table>

\(^a\) Treatments are not statistically significantly different from each other at baseline (p > 0.05).

\(^b\) Arginine vs. potassium nitrate and negative control mouthwash groups.

Table 3 – Summary of the air blast hypersensitivity scores for subjects who completed the six-week study.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline(^a) (mean ± SD)</th>
<th>30 min (mean ± SD)</th>
<th>% difference 30 min(^b)</th>
<th>2 weeks (mean ± SD)</th>
<th>% difference 2 weeks</th>
<th>4 weeks (mean ± SD)</th>
<th>% difference 4 weeks</th>
<th>6 weeks (mean ± SD)</th>
<th>% difference 6 weeks</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arginine</td>
<td>2.31 ± 0.38</td>
<td>1.90 ± 0.52</td>
<td>15.9 (p = 0.053)</td>
<td>0.98 ± 0.55</td>
<td>37.6 (p = 0.001)</td>
<td>51.2 (p &lt; 0.001)</td>
<td>0.44 ± 0.60</td>
<td>65.9 (p &lt; 0.001)</td>
<td>76.6 (p &lt; 0.001)</td>
<td>0.35 ± 0.53</td>
</tr>
<tr>
<td>Potassium nitrate</td>
<td>2.31 ± 0.55</td>
<td>2.26 ± 0.52</td>
<td>10.8 (p = 0.316)</td>
<td>1.57 ± 0.55</td>
<td>1.29 ± 0.60 (p = 0.025)</td>
<td>31.4 (p = 0.280)</td>
<td>1.10 ± 0.53</td>
<td>1.10 ± 0.53</td>
<td>1.10 ± 0.53</td>
<td>1.10 ± 0.53</td>
</tr>
<tr>
<td>Negative control</td>
<td>2.50 ± 0.47</td>
<td>2.13 ± 0.52</td>
<td>-6.1 (p = 0.0702)</td>
<td>2.01 ± 0.55</td>
<td>1.88 ± 0.60 (p = 0.0702)</td>
<td>1.88 ± 0.60</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

\(^a\) Treatments are not statistically significantly different from each other at baseline.

\(^b\) Arginine vs. potassium nitrate and negative control mouthwash groups.
were no statistically significant differences among baseline-adjusted mean air blast scores, arginine vs. potassium \((p = 0.053)\) and negative control \((p = 0.316)\). Nevertheless, the arginine group exhibited a statistically significant reduction in baseline-adjusted air blast mean hypersensitivity scores as compared to the potassium nitrate group and the negative control group of 37.6\% \((p < 0.001)\) and 51.2\% \((p < 0.001)\), respectively after two weeks of product use. In addition, the potassium nitrate group exhibited a statistically significant reduction in baseline-adjusted air blast hypersensitivity mean scores relative to the negative control group of 21.9\% \((p = 0.025)\), after two weeks. After four weeks, the arginine group exhibited a statistically significant reduction in baseline-adjusted air blast hypersensitivity mean scores, as compared to the potassium nitrate group and the negative control group of 65.9\% \((p < 0.001)\) and 76.6\% \((p < 0.001)\), respectively. Also, the potassium nitrate group exhibited a statistically significant reduction in baseline-adjusted mean air blast hypersensitivity mean scores when compared to the negative control group of 31.4\% \((p = 0.005)\) after four weeks. After six weeks of product use, the arginine group exhibited a statistically significant reduction in baseline-adjusted air blast hypersensitivity mean scores as compared to the potassium nitrate group and the negative control group of 68.2\% \((p < 0.001)\) and 80.4\% \((p < 0.001)\), respectively. Furthermore, the potassium nitrate group exhibited a statistically significant reduction in baseline-adjusted mean air blast hypersensitivity relative to the negative control group of 38.5\% \((p < 0.001)\), after six weeks.

6. Discussion

The aim of this randomized clinical trial was to evaluate the efficacy on dentine hypersensitivity reduction of a mouthwash containing 0.8\% arginine and 0.05\% sodium fluoride compared to a mouthwash containing 2.4\% potassium nitrate and 0.022\% sodium fluoride and a negative control mouthwash containing 0.05\% sodium fluoride through a six-week period.

Our hypothesis was that an alcohol-free mouthwash using arginine is more effective in reducing dentine hypersensitivity compared to a 2.4\% potassium nitrate and 0.022\% sodium fluoride and to 0.05\% sodium fluoride mouthwashes. Indeed, the participants assigned to the arginine mouthwash group showed statistically significant improvements in tactile and air blast dentine hypersensitivity relative to the potassium nitrate mouthwash group and to the negative control mouthwash group after two, four and six weeks of product use. However, the treatment groups did not show efficacy on dentine hypersensitivity reduction thirty minutes after the initial rinsing.

In this study, the participants in the arginine mouthwash group presented a faster and a greater magnitude of reduction in dentine hypersensitivity using tactile and air blast measurements compared to potassium nitrate and negative control groups. We also observed a reduction in dentine hypersensitivity using potassium nitrate mouthwash compared to negative control group, more evident in air blast measurement.

To our knowledge this is the first clinical trial reporting on the efficacy of a mouthwash containing arginine, PVM/MA copolymer, pyrophosphates, and sodium fluoride compared to potassium nitrate and negative control mouthwashes. However, our results are consistent with findings in several clinical studies that toothpaste containing 8\% arginine, calcium carbonate, and 1450 ppm fluoride provides a statistically significant relief in dentine hypersensitivity after two, four, and eight weeks of product use.

Instant hypersensitivity relief has been reported using an 8\% arginine, calcium carbonate and fluoride toothpaste compared to a 5\% potassium nitrate and 1450 ppm sodium fluoride toothpaste, and to 1450 ppm sodium fluoride toothpaste in other studies; however, it was not observed in the present study. This lack of hypersensitivity reduction might be explained by a lower concentration of arginine in the mouthwash compared to the toothpaste or by differences in application method. Gillam and coworkers have observed statistically significant differences between a 3\% potassium nitrate and sodium fluoride mouthwash and a sodium fluoride mouthwash after two and six weeks of treatment using air blast hypersensitivity mean scores. Pereira et al. have observed a statistically significant improvement in dentine hypersensitivity for a 3\% potassium nitrate and 0.2\% sodium fluoride mouthwash compared to a 0.2\% sodium fluoride mouthwash only at six weeks using the cold air technique. These results were consistent with those obtained in our study.

The mechanisms of action of an arginine containing mouthwash provide a calcium phosphate-based mineral formation within the opening of the dentine tubules. Our results support the hypothesis that this mechanism is more effective in the reduction of dentine hypersensitivity than the creation of a layer of fine particles using a dentifrice with fine abrasive particles that creates a precipitate in situ using potassium salts.

7. Conclusion

Our results support the hypothesis that an alcohol-free mouthwash using 0.8\% arginine mouthwash provides a significant and superior reduction in dentine hypersensitivity after two, four and six weeks of product use compared to mouthwash containing 2.4\% potassium nitrate and 0.022\% sodium fluoride and to a control mouthwash containing 0.05\% sodium fluoride.

Conflict of Interest Statement

Bernal Stewart, Sarita Mello, Lia Arvanitidou, Fotinos Panagkos and William De Vizio are employees of the Colgate-Palmolive Company.

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REFERENCES