Efficacy of a 3% potassium nitrate mouthrinse for the relief of dentinal hypersensitivity

An 8-week randomized controlled study

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ABSTRACT

Background. Mouthrinses containing potassium salts have been shown to be effective for the relief of dentinal hypersensitivity (DH) when used adjunctively to toothbrushing with a nonsensitivity toothpaste.

Methods. The authors conducted a randomized, 8-week, single-center, examiner-blinded, parallel-group clinical trial with 191 participants with DH. Participants were randomized to twice-daily use of either 3% potassium nitrate (KNO_3) mouthrinse plus fluoride toothpaste or the same fluoride toothpaste alone. The primary outcome was change from baseline in response to an evaporative (air) stimulus at 8 weeks, measured using the Schiff sensitivity scale. Secondary outcomes were response to an evaporative (air) stimulus with the Schiff sensitivity scale (4 weeks) and a visual rating scale (4 and 8 weeks) and response to a tactile stimulus (4 and 8 weeks).

Results. Both groups showed statistically significant improvements in evaporative (air) sensitivity from baseline after 4 and 8 weeks ($P < .0001$). At weeks 4 and 8, the authors observed significant improvements from baseline in tactile sensitivity only in the KNO_3 mouthrinse group ($P < .0001$). Between-treatment comparisons for all sensitivity measures at both time points showed statistically significantly greater DH reductions in the KNO_3 mouthrinse group compared with the toothpaste-alone group ($P = .0004$ for the visual rating scale at week 4; $P < .0001$ for all other measures and time points). Treatments were generally well tolerated.

Conclusions. Twice-daily use of a 3% KNO_3 mouthrinse, adjunctive to toothbrushing with fluoride toothpaste, provided significant improvements in DH compared with fluoride toothpaste alone.

Practical Implications. Addition of 3% KNO_3 mouthrinse to a typical oral hygiene regimen of toothbrushing with fluoride toothpaste provides an alternative strategy for the management of DH.

Key Words. Dentinal hypersensitivity; mouthrinse; potassium nitrate; desensitizing.

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Dentinal hypersensitivity (DH) is a common, painful oral condition that can potentially impact quality of life, including daily activities such as eating and drinking.[1,2] DH can develop when dentinal tubules are exposed after gingival recession or enamel loss owing to erosion or abrasion.[3,4] The hydrodynamic theory of DH attributes the transient, sharp pain of sensitivity in response to external thermal, evaporative, tactile, osmotic, or chemical stimuli to the movement of fluid within open dentinal tubules, which stimulates nerve terminals at the pulpal end of the tubule.[4-7]

The main approaches to DH management include blocking patent dentinal tubules with occluding agents to reduce fluid movement[8,9] and inhibiting neural transmission of the pain stimulus by means of reducing pulpal nerve activity through the use of agents such as potassium ions.[9,10] With regard to the latter, there is evidence from clinical studies that toothpastes containing potassium salts can reduce sensitivity and are effective in relieving the pain of DH when used as part of a typical daily oral hygiene regimen.[11-14] Mouthrinses provide an alternative means of delivering potassium ions to the dentin-pulpal junction. Although less well studied than toothpastes, the

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efficacy of mouthrinses containing potassium salts (2% potassium citrate, 2.4% or 3% potassium nitrate [KNO_3]) for the relief of DH has been investigated in randomized controlled studies.[15-19] Investigators reported improvements in sensitivity from baseline, with studies comparing KNO_3 mouthrinses with negative control or placebo mouthrinses also reporting significant improvements in DH versus their respective controls.[15,17,19]

In 2 8-week studies, we reported on the results of twice-daily use of a newly developed 3% KNO_3 mouthrinse, adjunctive to toothbrushing with a regular fluoride toothpaste, in participants with DH.[20,21] In study 1,[20] the use of 3% KNO_3 mouthrinse provided significantly greater improvements in DH for all clinical measures after 4 and 8 weeks of treatment compared with toothpaste alone. In study 2,[21] observed trends reflected the findings of the first study, and adjunctive use of 3% KNO_3 mouthrinse continued to provide significant amelioration of DH from baseline; improvements were not statistically significantly different between treatments. The efficacy of this novel potassium-containing mouthrinse for the relief of DH therefore warranted further investigation in a third study, conducted at a different study site, with a different clinical examiner, and in a different study population than either of the earlier studies.

As in the first 2 studies, the objective of this study (study 3) was to compare clinical efficacy of an experimental 3% KNO_3 mouthrinse, used as an adjunct to toothbrushing with a regular fluoride toothpaste, for the relief of DH, against toothbrushing with the fluoride toothpaste alone. We assessed efficacy after 4 and 8 weeks twice daily treatment by means of the participants' response to an evaporative (air) stimulus using the Schiff sensitivity scale[22] and a visual rating scale (VRS) and a tactile stimulus, with the tactile threshold recorded in grams.

METHODS

This was a single-center, 8-week, randomized, examiner-blinded, 2-treatment, parallel-group study in participants with at least 2 sensitive teeth. The study was conducted at Salus Research, Fort Wayne, IN. It was approved by an independent institutional review board before initiation (U.S. Institutional Review Board, Miami, Florida; institutional review board U.S.IRB2014SRI/12) and was conducted in accordance with the Declaration of Helsinki.[23]

At the screening visit, each participant provided written informed consent to participate in the study before we recorded their demographic characteristics, medical histories, and use of concomitant medications and conducted an oral soft-tissue (OST) examination. We assessed each participant's dentition sequentially for evidence of erosion, abrasion, and gingival recession; gingival health status using the gingival index (GI)[24]; tooth mobility using a modification of the Miller scale[25]; and sensitivity to an air-blast stimulus (with a "yes" response indicating sensitivity). To standardize oral hygiene practices, we supplied eligible participants with a regular fluoride toothpaste (1,000 parts per million fluoride as sodium monofluorophosphate; Colgate Cavity Protection, Colgate-Palmolive) and a toothbrush (Aquafresh Clean Control, GSK Consumer Healthcare) to use twice daily (morning and evening) for 4 to 6 weeks between the screening and baseline visits. First use of the toothpaste was conducted under supervision at the study site.

At the baseline visit, we reviewed the participants' use of concomitant medications and compliance with inclusion and exclusion criteria and assessed their continuing study eligibility. After an OST examination, we evaluated the sensitivity of the clinically eligible teeth identified at screening, first via response to a tactile stimulus, administered using a constant-pressure probe.[26] Teeth with a tactile threshold of 20 g or lower were then assessed for sensitivity to an evaporative (air) stimulus using the Schiff sensitivity scale[22] and a VRS. The investigator selected 2 nonadjacent "test teeth" to be evaluated for the remainder of the study from those that met the qualifying sensitivity criteria. A single dental examiner, blinded to treatment allocation and with a number of years' experience in assessing DH, performed all the clinical assessments of DH in all participants for the study duration.

Eligible participants were randomized to treatment with either the regular fluoride toothpaste plus an experimental mouthrinse (containing 3.0% KNO_3 and 90 parts per million sodium fluoride) or the regular fluoride toothpaste alone. We stratified randomization on the basis of the maximum baseline Schiff score (2 or 3) of the 2 selected test teeth according to a randomization schedule provided by the Biostatistics Department of GSK Consumer Healthcare. We assigned the randomization numbers in each stratum in ascending numerical order according to the sequence in which participants successfully met the inclusion and exclusion criteria at the baseline visit. We

ABBREVIATION KEY

AEs: Adverse events.
DH: Dentinal hypersensitivity.
GI: Gingival index.
KNO_3: Potassium nitrate.
OST: Oral soft tissue.
PP: Per protocol.
VRS: Visual rating scale.

randomly permuted treatment allocations within blocks of 4 to ensure balance in treatment allocation. The dental examiner, study statistician, data management staff, and any GSK Consumer Healthcare employee who could influence study outcomes were blinded to treatment group.

First use of allocated study treatment was conducted under study site supervision. Participants applied a full brush-head of toothpaste and brushed for 1 minute in their usual manner and then rinsed with 10 milliliters of water for 5 seconds. The mouthrinse group then rinsed with 10 mL mouthrinse for 1 minute and expectorated. Participants continued to use their assigned treatment as directed twice daily for 8 weeks, recording each use of study products in a diary. To maintain the blinded condition of the clinical examiner, we made every effort to ensure that all study staff (including the examiner) were not directly involved in the dispensing and on-site administration of the study product. The dispensing and supervised product use were performed in a separate room away from the clinical examination area, and participants were instructed not to discuss their treatment with the examiner or any other member of the study team not directly involved in the dispensing and administration of study product.

We reassessed tooth sensitivity in response to tactile and evaporative (air) stimuli after 4 weeks and 8 weeks (primary end point, Schiff sensitivity score at 8 weeks) of treatment. At each visit, we assessed compliance with study treatment via review of participant diaries and completed an OST examination before sensitivity assessments. Participants refrained from oral hygiene procedures and chewing gum for at least 8 hours, from eating and drinking for at least 4 hours, and from excessive alcohol consumption for 24 hours before an assessment visit. Water was permitted for taking medication within 4 hours of a visit but not within 1 hour. During the study, participants could not use any other oral health care products or any products or remedies for treating sensitive teeth. Use of dental floss was permitted only for the removal of impacted food. We asked participants not to have any nonemergency dental treatment (including prophylaxis) during the study.

Participants

Participants were aged 18 through 55 years and in good general health, with self-reported histories of DH for 6 months or longer but less than 10 years. All had 20 or more natural teeth and no known or suspected allergy or intolerance to the study materials and ingredients. At screening, eligible participants had a minimum of 4 accessible nonadjacent teeth (incisors, canines, or premolars) with signs of erosion, abrasion, and gingival recession; a GI score of 1 or less; clinical mobility score of 1 or less; and a positive response to a qualifying evaporative (air) assessment. At baseline, eligible participants had a minimum of 2 accessible nonadjacent teeth with signs of sensitivity as determined via a qualifying tactile stimulus threshold of 20 g or less and a Schiff sensitivity score 2 or higher.

General exclusion criteria included presence of any chronic debilitating disease, daily use of medication that could interfere with pain perception, any xerostomia-causing condition or medication, pregnancy, breast-feeding, participation in another clinical study or receipt of an investigational drug within 30 days of screening, participation in either of the previous studies in the series, and use of antibiotics within 2 weeks of baseline. General oral exclusions included dental prophylaxis within 4 weeks of screening, presence of dental implants or tongue or lip piercings, gross periodontal disease, treatment of periodontal disease within 12 months of screening, and desensitizing treatment or tooth bleaching within 8 weeks of screening. Specific dentition exclusions for test teeth included those with evidence of current or recent caries; treatment of caries within 12 months of screening; teeth with exposed dentin but with deep, defective, or facial restorations; teeth used as abutments for fixed or removable partial dentures; teeth with full crowns or veneers, orthodontic bands, or cracked enamel; sensitive teeth with contributing etiologies other than erosion, abrasion, or dentin exposed by gingival recession; and sensitive teeth that in the investigator's opinion were not expected to respond to treatment with an over-the-counter toothpaste.

Assessments

At screening, we assessed gingival health for teeth exhibiting facial cervical erosion, abrasion, and gingival recession using the GI.[24] We assessed tooth mobility for the teeth with a GI score of 1 or less using a modification to the Miller index.[25]

In accordance with consensus guidelines,[27] we used 2 independent stimulus-based clinical measures to assess DH. Firstly, we administered a tactile stimulus using a constant-pressure Yeaple probe,[26] which allowed application of a known force to the dentin surface. Testing began at a pressure of

10 g and was increased by 10 g with each successive challenge until either 2 consecutive "yes" responses (with "yes" indicating the stimulus caused pain or discomfort) were elicited from the participant at the same pressure setting (which was recorded as the tactile threshold in grams) or the maximum force was reached. The greater the tactile threshold was, the less sensitive the tooth was. At baseline, the maximum force was set at 20 g; at all subsequent visits it was 80 g. Secondly, we assessed evaporative (air) sensitivity by means of directing an air blast from a triple air dental syringe onto the exposed dentin surface, with the surface of the tooth under test isolated to prevent adjacent teeth or surrounding soft tissue from being exposed to the stimulus.[22] The examiner's assessment of the participant's response to the air stimulus was recorded on the 4-point Schiff sensitivity scale (0 = participant does not respond to air stimulus, 1 = participant responds to air stimulus but does not request discontinuation, 2 = participant responds to air stimulus and requests discontinuation or moves from stimulus, 3 = participant responds to stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus).[22] Participants rated the intensity of their response to the evaporative (air) stimulus using a 10-point VRS from 1 (no pain) to 10 (intense pain).

We based assessment of safety on OST examination findings at each study visit and on adverse events (AEs) reported by participants.

Data analysis

We planned to screen sufficient numbers of patients to randomize up to 200 participants and to ensure at least 180 participants (approximately 90 per group) completed the study. On the basis of a sample size of 90 participants per group, we calculated that the study would have at least 90% power to detect a between-treatment difference in change from baseline of 0.35 in mean Schiff sensitivity scores at a significance level of 0.05. We used a standard deviation of 0.046 for change in Schiff sensitivity score from baseline. We based the treatment difference and standard deviation used in the sample-size calculation on a review of data from the 2 companion studies.[20,21] We performed the sample-size calculation using a distribution for the mean treatment difference with a mean of on average 0.35 and standard deviation of 0.046. We calculated these parameters assuming that the 1% percentile and 99% percentile of the mean treatment difference distribution were 0.2 and 0.5, respectively.

We analyzed efficacy data for a modified intention-to-treat population, which comprised all randomized participants who received at least 1 dose of the study treatment and provided at least 1 post-baseline assessment of efficacy. We defined the per-protocol population as those in the modified intention-to-treat population who had at least 1 assessment of efficacy considered unaffected by protocol violations. We defined the safety population as all participants who were randomized and received at least 1 dose of study treatment.

We calculated the evaporative (air) and tactile threshold outcomes as the participant-level mean change from baseline for the 2 selected test teeth at weeks 4 and 8. The primary efficacy variable was change from baseline in Schiff sensitivity score after 8 weeks of treatment. We calculated the mean change from baseline after 4 and 8 weeks of treatment for each variable for each participant and analyzed the results using analysis of covariance. With treatment as a factor and baseline score as a covariate, for the tactile threshold and VRS analyses, we also included the baseline Schiff sensitivity score stratification value (2 or 3) as a factor. Baseline Schiff sensitivity score was already included as a covariate in the analysis of change in Schiff sensitivity score, hence the baseline Schiff stratification value was not required in the model.

We investigated the analysis of covariance model assumptions of normality and considered them satisfied for Schiff sensitivity score and VRS. For tactile threshold, we also performed a supportive nonparametric analysis because the normality assumption of residuals was not completely satisfied. We estimated the median treatment difference and 95% confidence intervals (CIs) using the Hodges-Lehmann estimation method. We calculated the *P* value for the treatment difference using the Wilcoxon rank-sum test.

RESULTS

We screened a total of 220 participants and randomized 191 to treatment (Figure 1). The first participant was enrolled on September 2, 2014; the last participant completed the study on December 5, 2014. The demographic characteristics of the treatment groups were similar (Table 1).

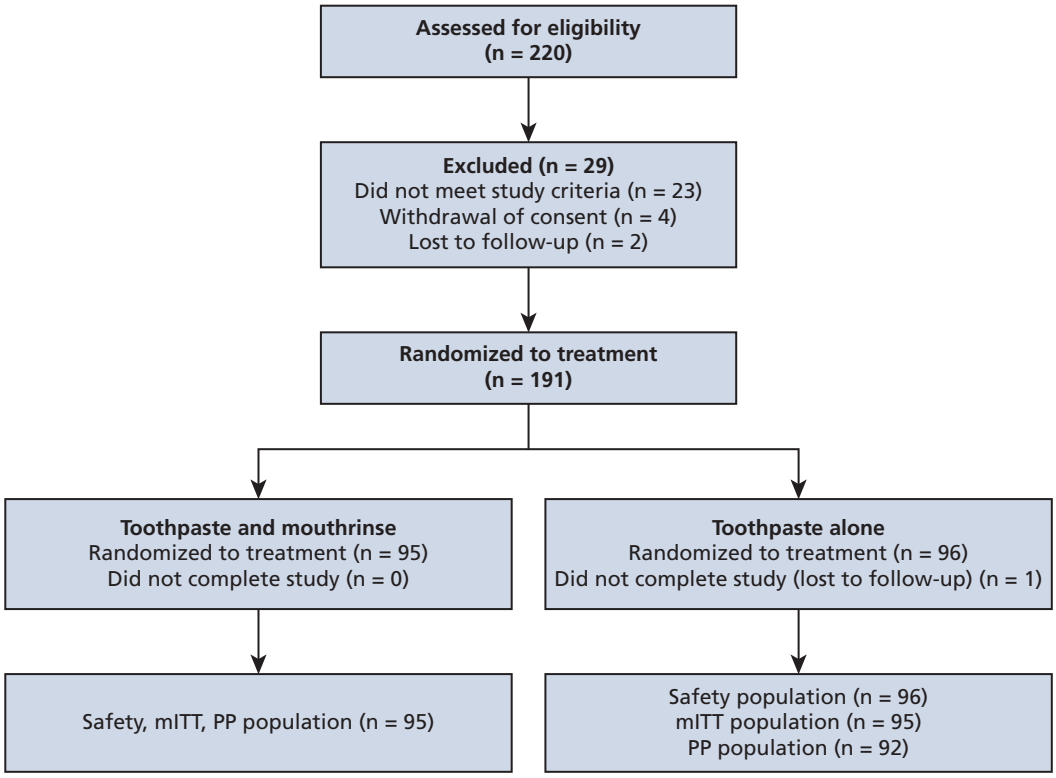

Figure 1. Participant disposition during the study. mITT: Modified intention to treat. PP: Per protocol.

Stratification according to baseline maximum Schiff sensitivity score ensured treatments were balanced by means of this variable in each stratum.

The raw data for the Schiff sensitivity score are shown in Figure 2. Before treatment, the mean baseline Schiff sensitivity scores were similar in the 2 treatment groups (toothpaste and 3% KNO_3 mouthrinse group, 2.53; toothpaste-alone group, 2.48). Change from baseline data are shown in Table 2. Both groups showed statistically significant reductions in sensitivity from baseline at 4 and 8 weeks, as measured by Schiff sensitivity score ($P < .0001$; Table 2). Decreases in Schiff sensitivity score were greater in the toothpaste and 3% KNO_3 mouthrinse group compared with the toothpaste-alone group at both time points: −0.92 (95% CI, −1.04 to −0.80) and −0.32 (−0.44 to −0.20), respectively, at week 4; −1.47 (−1.60 to −1.34) and −0.37 (−0.50 to −0.24), respectively, at week 8. We observed statistically significantly greater reductions in Schiff sensitivity score at 4 weeks (−0.61 [−0.78 to −0.44]) and 8 weeks, the primary end point (−1.10 [−1.28 to −0.92]), in the toothpaste and 3% KNO_3 mouthrinse group compared with the toothpaste-alone group ($P < .0001$) (Table 2).

The raw data for tactile threshold are shown in Figure 3. Mean baseline tactile threshold was similar in the 2 treatment groups (10.05 g for the toothpaste and 3% KNO_3 mouthrinse group; 10.11 g for the toothpaste-alone group). Change from baseline data is shown in Table 2. Only the toothpaste and 3% KNO_3 mouthrinse group showed statistically significant decreases in sensitivity from baseline at 4 and 8 weeks, as measured via tactile threshold ($P < .0001$) (Table 2). Increases in tactile threshold were much greater in the toothpaste and 3% KNO_3 mouthrinse group compared with the toothpaste-alone group at both time points: 14.09 (95% CI, 10.98 to 17.21) and 0.75 (−2.36 to 3.87), respectively, at week 4; 31.27 (26.87 to 35.68) and 3.78 (−0.62 to 8.18), respectively, at week 8. We observed statistically significantly greater increases in tactile threshold at 4 weeks (13.34 [8.93 to 17.75]) and 8 weeks (27.50 [21.26 to 33.73]) in the toothpaste and 3% KNO_3 mouthrinse group compared with the toothpaste-alone group ($P < .0001$) (Table 2). The supportive nonparametric analysis results were consistent with those from the analysis of covariance ($P < .0001$) (Table 2), with more nonzero changes from baseline in the toothpaste and 3% KNO_3 mouthrinse group than in the toothpaste-alone group (data not shown).

The raw data for the VRS score are shown in Figure 4. Mean baseline VRS scores were similar in the 2 treatment groups (toothpaste and 3% KNO_3 mouthrinse group, 6.79; toothpaste-alone group,

Table 1. Summary of baseline characteristics (safety population).

CHARACTERISTIC	TOOTHPASTE + 3% KNO_3* MOUTHRINSE (N = 95)	TOOTHPASTE ALONE (N = 96)
Sex, No. (%)		
Male	14 (14.7)	17 (17.7)
Female	81 (85.3)	79 (82.3)
Age, y		
Mean	41.7	39.7
Range	20-55	22-55
Race, No. (%)†		
White	80 (84.2)	83 (86.5)
Black and African American	12 (12.6)	10 (10.4)
American Indian and Alaska Native	1 (1.1)	1 (1.0)
Asian	1 (1.1)	1 (1.0)
Multiple	1 (1.1)	1 (1.0)
Maximum Schiff Sensitivity Score at Baseline, No.††		
2	33 (34.7)	33 (34.4)
3	62 (65.3)	63 (65.6)

* KNO_3: Potassium nitrate. † Percentages have been rounded to one decimal place so many not add up to 100. †† For the 2 selected test teeth.

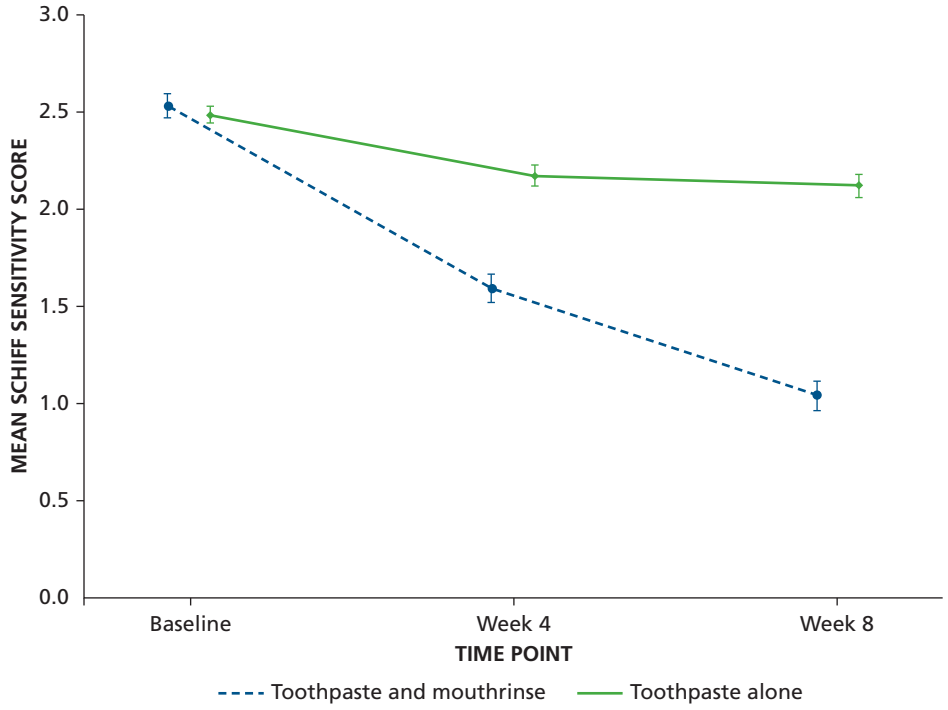

Figure 2. Schiff sensitivity score (raw mean, standard error) by treatment and visit (intention-to-treat population). Lower score is favorable; data have been offset for clarity.

6.73). Change from baseline data is shown in Table 2. Both groups showed statistically significant reductions in sensitivity from baseline at 4 and 8 weeks, as measured according to VRS ($P < .0001$; Table 2). Decreases were greater in the toothpaste and 3% KNO_3 mouthrinse group compared with the toothpaste-alone group at both time points: −1.63 (95% CI, −1.93 to −1.34) and −0.87 (−1.16 to −0.58), respectively, at week 4; −3.04 (−3.41 to −2.68) and −1.06 (−1.43 to −0.70), respectively, at week 8. We observed statistically significantly greater reductions in Schiff sensitivity

Table 2. Statistical analysis of change from baseline in Schiff sensitivity score, tactile threshold, and VRS* score (mITT† population).

TIME POINT	TOOTHPASTE and 3% KNO_3‡ MOUTHRINSE (N = 95)	TOOTHPASTE ALONE (N = 95)	TREATMENT COMPARISON§
Evaporative (Air) Sensitivity (Schiff Sensitivity Score)			
Baseline¶	2.53 (0.434)	2.48 (0.418)	NA#
Week 4**	−0.92 (−1.04 to −0.80), $P < .0001$	−0.32 (−0.44 to 0.20), $P < .0001$	−0.61 (−0.78 to −0.44), $P < .0001$
Week 8**	−1.47 (−1.60 to −1.34), $P < .0001$	−0.37 (−0.50 to −0.24), $P < .0001$	−1.10 (−1.28 to −0.92), $P < .0001$
Tactile Sensitivity (Tactile Threshold in Grams)			
Baseline¶	10.05 (0.513)	10.11 (0.722)	NA
Week 4††	14.09 (10.98 to 17.21), $P < .0001$	0.75 (−2.36 to 3.87), $P = .6351$	13.34 (8.93 to 17.75), $P < .0001$ 5.00 (0.00 to 5.00),‡‡ $P < .0001$§§
Week 8††	31.27 (26.87 to 35.68), $P < .0001$	3.78 (−0.62 to 8.18), $P = .0922$	27.50 (21.26 to 33.73), $P < .0001$ 25.00 (20.00 to 30.00),‡‡ $P < .0001$§§
Evaporative (Air) Sensitivity (VRS)			
Baseline¶	6.79 (1.658)	6.73 (1.666)	NA
Week 4††	−1.63 (−1.93 to −1.34), $P < .0001$	−0.87 (−1.16 to −0.58), $P < .0001$	−0.76 (−1.18 to −0.35), $P = .0004$
Week 8††	−3.04 (−3.41 to −2.68), $P < .0001$	−1.06 (−1.43 to −0.70), $P < .0001$	−1.98 (−2.50 to −1.46), $P < .0001$

* VRS: Visual rating scale. † mITT: Modified intention to treat. ‡ KNO_3: Potassium nitrate. § For Schiff sensitivity and VRS scores, negative difference favors toothpaste and 3% KNO_3 mouthrinse; for tactile threshold, positive difference favors toothpaste and 3% KNO_3 mouthrinse. ¶ Baseline values are raw means (standard deviation). # NA: Not applicable. ** Adjusted mean change (95% confidence interval) from baseline; data from analysis of covariance model with treatment as fixed factor and baseline Schiff sensitivity score as covariate. †† Adjusted mean change (95% confidence interval) from baseline; data from analysis of covariance model with treatment and baseline Schiff stratification value as factors and relevant baseline value as covariate. ‡‡ Supportive nonparametric analysis; estimated difference (95% confidence interval) from Hodges-Lehmann procedure. §§ Supportive nonparametric analysis; *P* value from Wilcoxon rank-sum test.

score at 4 weeks (−0.76 [−1.18 to −0.35]) and 8 weeks (−1.98 [−2.50 to −1.46]) in the toothpaste and 3% KNO_3 mouthrinse group compared with the toothpaste-alone group ($P < .0001$; Table 2).

Safety

A total of 23 treatment-emergent AEs were reported by 18 participants (9.4%). Of these, 14 were oral AEs: 6 in the toothpaste and 3% KNO_3 mouthrinse group and 8 in the toothpaste-alone group. Five AEs were treatment related: 2 in the toothpaste and 3% KNO_3 mouthrinse group (both sensitivity of teeth; 1 mild, 1 moderate) and 3 in the toothpaste-alone group (sensitivity of teeth, dry mouth, mouth ulceration; all mild). None of the AEs were serious or led to participant withdrawal.

DISCUSSION

After both 4 and 8 weeks of twice-daily use, rinsing with a 3% KNO_3 mouthrinse after toothbrushing with a regular fluoride toothpaste was associated with a significantly greater improvement in 3 clinical measures of DH compared with toothbrushing with the toothpaste alone. The mean changes from baseline in the Schiff sensitivity score, tactile threshold, and VRS score we observed in our study (study 3) were similar to those reported for 2 companion studies (studies 1 and 2), evaluating the same study treatments with the same clinical methodology.[20,21] The results of studies 1 and 3 show similar statistically significant improvements in DH for the 3% KNO_3 mouthrinse group compared with the toothpaste-only group.[20] In study 2, although the magnitude of mean change was greater for all measures in the KNO_3 mouthrinse group than in the toothpaste-only group, between-treatment differences were not statistically significant.[21] This was attributed to the placebo and Hawthorne effects known to impact the outcomes of DH studies.[11,16,28,29] The results of the our comparative analysis (study 3) confirm and extend the findings of the previous studies in this series.

The results of these 3 studies are consistent with the findings of other longitudinal studies demonstrating the efficacy of mouthrinses containing KNO_3 in the management of DH, that is, significant improvements in sensitivity to both tactile and evaporative (air) stimuli compared with control treatment.[15,17,19] Investigators in another study reported that rinsing with a fluoridated

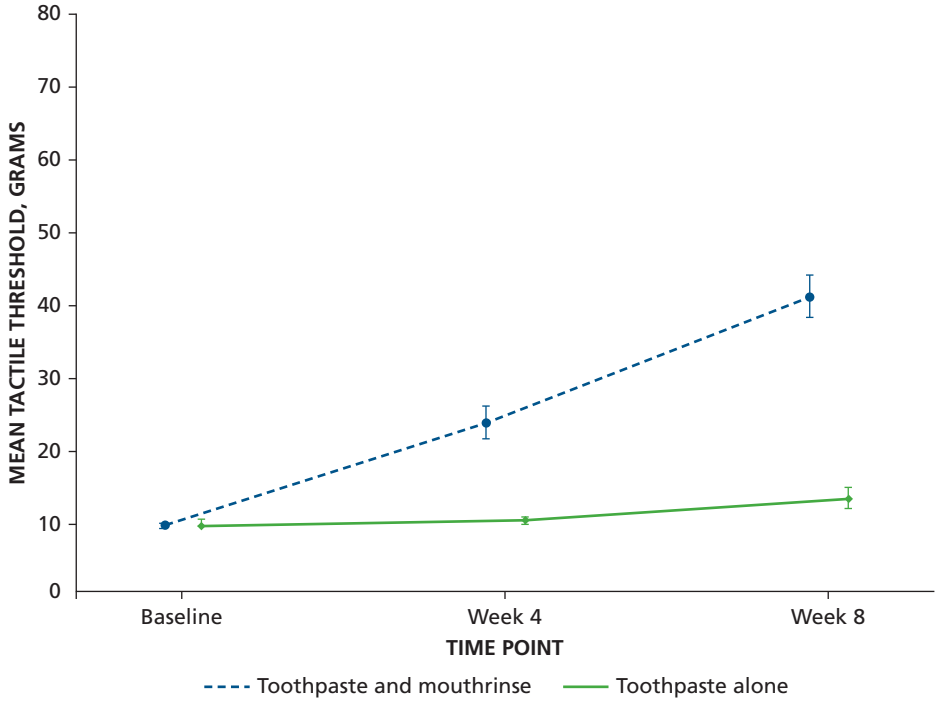

Figure 3. Tactile threshold (raw mean, standard error) by treatment and visit (intention-to-treat population). Higher value is favorable; data have been offset for clarity.

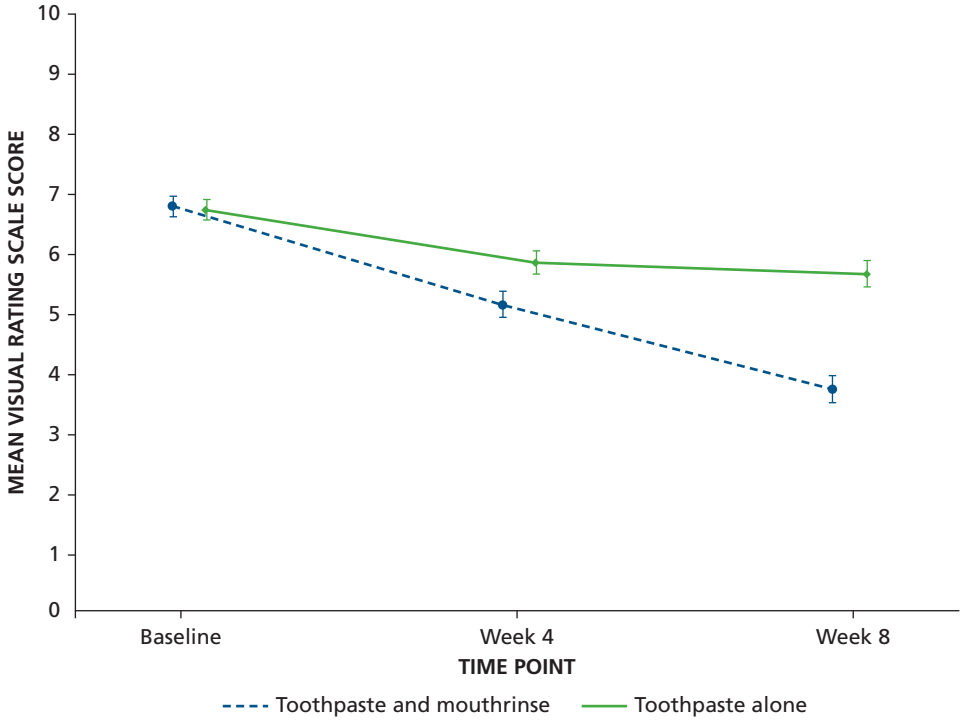

Figure 4. Visual rating scale score (raw mean, standard error) by treatment and visit (intention-to-treat population). Lower score is favorable; data have been offset for clarity.

mouthrinse containing 3% KNO_3 (adjunctive to toothbrushing with a nonfluoride toothpaste) was as effective as toothbrushing with a fluoridated toothpaste containing 5% KNO_3 in reducing sensitivity after 2 and 4 weeks of twice-daily treatment.[18]

Participants in our study and the 2 earlier companion studies[20,21] were not blinded to their allocated treatment, because the comparator group did not include a placebo or control mouthrinse.

Although this was a limitation of the study design, the aim in all 3 studies was to be representative of "real-world" behavior and evaluate the potential benefit of introducing a KNO_3 mouthrinse into a typical oral hygiene regimen (daily toothbrushing with fluoride toothpaste) for the relief of DH. Although our study was not specifically designed to explore safety, both treatments were generally well tolerated.

CONCLUSIONS

Our study confirms that twice-daily adjunctive use of a 3% KNO_3 mouthrinse after toothbrushing with a regular fluoride toothpaste provides significantly greater relief from DH after 4 and 8 weeks of twice-daily use than toothbrushing with the toothpaste alone. Use of an efficacious KNO_3 anti-sensitivity mouthrinse provides an alternative management strategy for people with DH who may prefer to retain their established tooth-brushing regimen with regular fluoride toothpaste. ■

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