Published in final edited form as:

Int J Dent Hyg. 2018 May ; 16(2): e79–e87. doi:10.1111/idh.12317.

A randomized clinical trial on the efficacy of a new oxalate-containing sensitivity relief strip following professional vs self-application

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Abstract

Objectives: The purpose of this study was to determine the efficacy of 3.14% dipotassium oxalate monohydrate-containing strip on the relief of dentinal hypersensitivity (DH). A second objective was to determine whether there was a difference in DH levels when the strip was self-applied vs applied by a dental professional.

Methods: Sixty subjects were randomized into self-applied, professionally applied or placebo-strip groups. Dentinal hypersensitivity was evaluated by a blinded examiner, using the Schiff Air Scale (SAS). A verbal rating scale (VRS) was also used to measure the subjects' perception of pain. Measures were taken at baseline, 30 minutes, 4 and 8 weeks post-treatment.

Results: There was a significant reduction in DH in all three groups ($P \leq .05$) at 30 minutes and 8 weeks post-treatment. At the 4-week follow-up, only the self- and professionally applied (active ingredient) groups had a significant reduction in DH compared to baseline. When comparing the reduction in DH levels between groups, the only significant difference occurred between the professionally applied treatment group and the placebo group at the 4-week follow-up. There were no significant differences in DH reduction levels achieved between the self- and professionally applied groups ($P > .05$).

Conclusions: This study confirmed the short-term (4 weeks) effectiveness of a single application of 3.14% dipotassium oxalate monohydrate-containing strip. Self- and professional application were not shown to be different.

Keywords

dentinal hypersensitivity; oxalate; tooth sensitivity

1 | INTRODUCTION

Dental hypersensitivity (DH) is a common complaint in the general population.^{1,2} It is defined as a short, sharp pain that arises from exposed dentin in response to thermal, evaporative, tactile, osmotic and/or chemical stimuli.^{1–13} The hydrodynamic theory is a widely accepted explanation of the mechanism of action of DH.^{3,12–16} It hypothesizes that when dentinal tubules are absent of a smear layer and subjected to stimuli, the fluid within the tubules activates receptors that trigger a pain response. Dentinal tubules can become exposed as a result of enamel loss from attrition, abrasion, erosion or abfraction. Dentin exposure may also result from gingival recession and loss of cementum from root surfaces. It is most frequently seen in canines and premolars and is also more prevalent in patients with periodontitis, especially following active periodontal therapy (scaling and root planing).^{17,18} Treatment options include both eliminating possible causes of dental hypersensitivity, such as a diet high in acidic foods or use of excessive pressure when brushing, and the use of desensitizing products for pain relief. Desensitizing products are either self-applied or professionally applied. Self-applied products include toothpastes, gels and rinses. Professionally applied agents include varnishes, precipitants, primers, and polymerizing agents. The mechanism of action differs depending on the product or treatment provided. Invasive treatments include gingival surgery to reposition the gingival tissue to cover exposed dentin, application of resins and using laser therapy. The mechanism of action for lasers is unknown at this time. Non-invasive treatments include topical agents such as potassium nitrate that use a mechanism that blocks the synapse between nerve cells. Other topical agents such as stannous fluoride and oxalates are designed to reduce fluid flow into or out of the dentin tubules by occluding the tubules.¹⁸ The extent of research conducted on these directly applied topical products varies widely. The literature reviewed revealed an abundance of methods for both treating and assessing DH, but did not identify one treatment as consistently superior over another.¹⁹

Recently, an over-the-counter product (Sensi-Stop™ sensitivity relief strips, Procter & Gamble, Cincinnati, OH, USA) has been marketed for home use and claims to provide immediate relief from DH, following a single application, which lasts up to 1 month. The thin flexible strips contain 3.14% dipotassium oxalate monohydrate gel on one side. Minimal research has been conducted on or published about the effectiveness of oxalates or about these self-applied sensitivity relief strips. The purpose of the following research was to determine the efficacy of 3.14% dipotassium oxalate monohydrate-containing strip on the relief of dental hypersensitivity (DH). A second objective was to determine whether there was a difference in DH levels when the strip was self-applied vs. applied by a dental professional. The findings from this clinical study may assist dental professionals and patients in making evidence-based choices regarding the use of these strips for treating DH.

2 | STUDY POPULATION AND METHODOLOGY

2.1 | Study design

The duration of this single-site, randomized, double-blind, placebo-controlled, parallel group clinical trial was 8 weeks. The study procedures were discussed thoroughly with each study volunteer, and we received their written consent prior to enrolling them in the study. All

study procedures followed good clinical practice (GCP) guidelines. The study examiner, operator and statistician report no conflict of interest. Full approval from the Human Subjects Protection Program (Institutional Review Board) at the University of Minnesota was obtained for the study protocol and the informed consent form.

The study participants were recruited from the metropolitan area of Minneapolis/St. Paul, Minnesota. One hundred and ninety-five queries about the study were received, either verbally, by email or by phone. A total of 108 participants were screened via telephone. Of those, 91 qualified for the in-person screening procedures; and of those, 60 participants were eligible for and agreed to participate in the trial.

The inclusion criteria included generally healthy males and females, aged 18 years and older, having at least one tooth with DH, willingness to proceed with the described study procedures and the provision of informed consent. The main inclusion criterion was the presence of at least one tooth with at least 1 mm of recession and with a rating of at least 1 on both the Schiff Air Scale (SAS) and verbal rating scale (VRS). Exclusion criteria included any pain-producing dental pathology that could confound the study findings, for example dental caries, pulpitis, fractured teeth, fractured restorations, chipped teeth, cracked teeth, gingival inflammation, post-restorative sensitivity, marginal leakage, severe periodontal disease, as characterized by purulent exudate, generalized mobility and/or severe recession.

One investigator trained in use of the SAS, served as the study examiner and performed all outcome measures throughout the trial. This examiner also performed the preliminary oral exams to check for any disqualifying pathology and to select potential qualifying study teeth. The SAS was performed on teeth with recession, and the participant's response to cold air stimulus (one-second of air, from a dental air/water syringe directed perpendicular to the exposed dentin) was recorded by the examiner. The participant was then asked to rate their level of sensitivity utilizing the VRS. Once the site qualified, it was isolated and a cold air stimulus was performed again to record the official baseline data. Recession and probing depths for the qualifying tooth were also measured. Once baseline data were obtained, the second investigator, who served as the study operator, randomized the participant to their respective study group.

2.2 | Test materials

The volunteers were treated one time with one of the following test strips:

1. Self-applied group: 3.14% dipotassium oxalate monohydrate-containing strip
2. Professionally applied group: 3.14% dipotassium oxalate monohydrate-containing strip
3. Professionally applied placebo: blank strip

Participants randomized to either the professionally applied DO-strip or placebo-strip group were seen by the study operator who then placed the appropriate strip on the study site.

2.3 | Outcome measures

Two outcome measures used were Schiff Air Scale (SAS) and Verbal Rating Scale (VRS). The dental examiner used the SAS (Table 1) to rate the participant's response to a 1 second air stimulus from the air/water syringe perpendicular to the site. The participant's used the VRS (Figure 1) to rate their perception of pain to the air stimulus.

Participants randomized to the self-applied DO group were shown the designated study tooth-surface, given a packaged DO strip, a copy of the manufacturer's instructions, and escorted to the clinic bathroom so that they could self-apply the DO strip as the manufacturer intended. For subjects in all three groups, the study protocol was as follows: the participant would be asked to brush their teeth with a toothbrush and toothpaste provided by the investigators. At 5 minutes post-brushing, the randomized treatment strip was placed and left in place for 10 minutes. No food or drink was allowed for the ensuing 30 minutes after which post-treatment measurements were taken by the study examiner who was blinded to group assignments. Each participant was instructed to avoid discussing the strip application with the study examiner to avoid un-blinding the examiner. Participants were scheduled for their 4- and 8-week follow-up appointments, received a \$20 gift card and parking voucher, were given a manual toothbrush and tube of Crest® cavity protection toothpaste that contained sodium fluoride, and instructed to only use the provided toothbrush and toothpaste for the remainder of the study. Study participants were also asked to only use the toothbrush and toothpaste given and to not use any mouthwashes that contained desensitizing ingredients until they had completed their 8-week visit. Study participants were also asked to stay away from any whitening products. The Schiff Air Scale was repeated and scored by the designated examiner and participants rated their DH level using the VRS at the 4- and 8-week post-treatment visits.

2.4 | Statistics

Block randomization was used to allocate participants to study groups using a schedule created by a biostatistician not involved in the conduct of the trial. Descriptive statistics were used to summarize and compare demographics and dentinal sensitivity levels at each test interval (ie, baseline, 30 minutes, 4 and 8 weeks). Changes in sensitivity levels were calculated within and between the groups. An analysis of covariance model was used to compare mean reduction in sensitivity scores (SAS and VRS) between groups at each post-treatment time point. A linear mixed effect model with group, time and baseline score as fixed effects and a random subject effect was used to compare the sensitivity outcomes between groups across time. The effect of location was also examined using this model. This method allowed modelling of the repeated measures data. To make within-group comparisons, t tests comparing the mean change to 0 were utilized. *P*-values for pairwise group comparisons were adjusted for multiple comparisons using the Tukey method. *P*-values less than .05 were considered statistically significant. SAS V9.3 (SAS Institute Inc., Cary, NC, USA) was used for analysis. The sample size of 20 participants per group was based on having 90% power to detect a one standard deviation difference between the DO-strip groups and the placebo group means (eg, assuming means of -1.2, -1.2, -0.6 and a standard deviation of 0.6) using analysis of variance with a 0.05 level of significance. SAS PROC POWER was used for the sample size/power calculation.

3 | RESULTS

3.1 | Demographics

Sixty participants were enrolled in the study; two participants were unable to complete the study; one participant withdrew because the qualifying tooth fractured (unrelated reasons), and another withdrew due to schedule conflicts. Baseline demographic characteristics are shown in Table 2. There were 44 females and 16 males in this study. Their mean age was 43.8 years. All groups were balanced demographically. Table 2 also presents the baseline mean sensitivity score based on the SAS and the VRS. The baseline mean sensitivity score based on the VRS was lowest for the professionally applied group and was significantly different than the self-applied group ($P = .0024$). Similar results were seen for SAS ($P = .0035$).

Table 3 shows a significant reduction in DH within each treatment group, for both outcome measures, at 30 minutes and 8 weeks post-treatment. There was also a significant reduction in DH for both the self- and professionally applied treatment groups at 4 weeks.

Table 4 shows that there was a significant reduction in DH within the treatment groups combined for both outcome measures at all time-points. There was also a significant reduction in DH for the placebo group for both outcome measures, at the 30-minute and 8-week follow-up, but not at 4 weeks.

Table 5 shows the mean reduction in sensitivity between groups.

At each time point, the self-applied and professionally applied DO-strip groups had larger mean reduction in SAS and VRS than the professionally applied placebo strip (Figures 2 and 3); however, a statistically significant difference in sensitivity level was only seen at 4 weeks post-treatment (Table 5). In pairwise comparisons at 4 weeks post-treatment, the professionally applied DO-strip group had a greater reduction in sensitivity than the placebo group (SAS $P = .0445$; VRS $P = .0179$). When considering all 3 time points, a group by time interaction was not significant for SAS or VRS ($P = .2463$ and $P = .2018$, respectively). The groups also did not differ for SAS and VRS ($P = .0969$ and $P = .0922$, respectively).

3.2 | Efficacy

To assess the overall efficacy of the DO strip, Table 6, Figures 4 and 5 show between-group comparisons of the combined self-applied group and the professionally applied DO-strip group versus the placebo group. Similar results were seen in the three group comparisons in that there were statistically significant differences in the sensitivity reduction for both the SAS and VRS measures in the combined active ingredient DO-strip groups when compared to the placebo-strip group. Again, considering all three time points, the group by time interactions were not significant for SAS or VRS ($P = .3193$ and $P = .1879$, respectively). However, the combined active ingredient strip group was significantly different when compared to the placebo group for SAS and VRS ($P = .0306$ and $P = .0318$, respectively).

3.3 | Self-applied vs professionally applied

To assess the effect of self-application, the self-applied group was compared to the professionally applied DO-strip group. In pairwise comparisons, no statistically significant differences were found at 30 minutes post- ($P = .3728$, $P = .6063$), 4 weeks post- ($P = .8059$, $P = .4934$) or 8 weeks post-treatment ($P = .9429$, $P = .7196$) for SAS and VRS measures, respectively (Table 5).

3.4 | Location

The reduction in sensitivity was compared between anterior teeth ($n = 10$) and posterior teeth ($n = 30$) in the professionally applied DO-strip and self-applied groups. The groups by location interactions were not significant for SAS or VRS ($P = .3614$ and $P = .4681$, respectively). There were no significant differences in sensitivity between the professionally applied and self-applied groups based on the location of the tooth (Table 7).

3.5 | Tolerability

The DO strip was well tolerated by all participants except one who exhibited a mild adverse or allergic reaction to either the strip material or the ingredients on the strip manifested by several small hives located in the neck region. The participant was offered medical treatment (Benadryl®) but declined, and the symptoms subsided without incident.

4 | DISCUSSION

Dentinal hypersensitivity is a problem globally with 4%–74% of the population reported to be affected.²⁰ Women are more likely to experience DH than men, and the highest prevalence occurs between 30 and 40 years of age.¹⁷ In the current study, 44 of 60 subjects were women and the average age was 43. This study set out to answer two research questions: (i) are the oxalate-containing strips effective? and (ii) is there a difference in DH when the oxalate-containing strip is self-applied vs professionally applied?

4.1 | Efficacy-within-group comparisons

The results of the present clinical investigation confirmed that the oxalate strips with the active ingredient work. There was a significant reduction in DH at each time point from baseline in both the self- and professionally applied groups and when the self- and professionally applied groups were combined. This is significant because the manufacturer claims that the oxalate strip is effective up to 30 days post-treatment after a single use. The current study confirmed this claim not only in within-group comparisons but in between-group comparisons. The placebo group also had a significant reduction at 30 minutes and 8 weeks post-treatment, but not at 4 weeks post-treatment. This is indicative of the influence of a possible placebo effect.

4.2 | Efficacy-between-group comparisons

The results of between-group comparisons confirmed that the oxalate strips with the active ingredient were effective at 4 weeks when compared to the placebo strips. Unlike the within-group comparisons, there was no significant difference at other measurement intervals with

between-group comparisons. However, the current study confirmed a significant reduction in DH levels in the combined oxalate-strip group at 4 weeks post-treatment compared to the placebo group. In pairwise comparisons, the professionally applied group had a significant reduction in DH compared to the placebo group at 4 weeks post-treatment. One might come to the conclusion that having the professional apply the oxalate strip may be beneficial in the reduction of DH.

4.3 | Self-applied vs professionally applied

When the self-applied group and the professionally applied group were compared, there was no significant difference between the reductions of DH levels in the two groups. The results did not demonstrate a significant difference in reduction levels by application method (self-applied vs professionally applied). It should be noted that two participants in the self-applied group placed the strip in a vertical orientation so that it wrapped over the occlusal surface of the tooth; however, they did manage to cover the site with DH. One participant put the strip on backward, so the active ingredient was facing their cheek. These participants were included in the analyses as randomized.

4.4 | Location

Due to possible anatomical involvement, location of tooth was considered. The results did not demonstrate a significant difference by location of the tooth (anterior vs posterior). This study had limited amount of teeth (40-in oxalate groups). There were more posterior teeth (30) than anterior teeth (10) which made it difficult to draw conclusions.

Overall, the current study confirmed that the DH levels in study subjects who received the DO-containing oxalate strips were significantly reduced 4 weeks post-treatment. The SAS mean reduction for the professionally applied DO-strip group was 5 times greater than the mean reduction for the placebo group 4 weeks post-treatment. The SAS mean reduction for the self-applied group was 3.9 times greater than the mean reduction for the placebo group 4 weeks post-treatment. When the DO-strip treatment groups were combined, the SAS mean reduction was 4.3 times greater than the mean reduction for the placebo group 4 weeks post-treatment. The VRS mean reduction for the professionally applied group was 11.1 times greater than the mean reduction for the placebo group 4 weeks post-treatment. The VRS mean reduction for the self-applied group was 6.7 times greater than the mean reduction of the placebo group 4 weeks post-treatment. The VRS mean reduction when the treatment groups were combined was 8 times greater than the mean reduction of the placebo group 4 weeks post-treatment.

Within all three groups, there was some reduction in DH compared to baseline. The reduction was significant at all-time points for the treatment (active ingredient) groups. For the placebo group, the reduction was significant only at 30 minutes and 8 weeks post-treatment. There are several plausible explanations for why the participants in the placebo group reported a reduction in DH at these two time points. First, the Hawthorne effect may have occurred indicating the patient's false belief of the intervention working. Second, at the 30-minute follow-up it is possible that while the blank plastic strip was compressed against the surface of the qualifying tooth, during the 10-minute application period, saliva may have

been forced into the exposed dentinal tubules, temporarily occluding and insulating the tubules from the air-blast during the follow-up study measures. Finally, the toothpaste distributed to participants for use during the study contained sodium fluoride. Over 8 weeks of use, the fluoride may have had a therapeutic effect on the DH levels in the control group subjects.^{1,18,19,21–23} These plausible explanations would also explain why the placebo subjects' DH levels were not significantly reduced at the 4-week follow-up time point.

4.5 | Comparison to other research

The present study demonstrated, for both SAS and VRS outcome measures, the professionally applied group saw a continued increase in mean reduction at each time point, whereas the self-applied group and the placebo group did not. When the two treatment groups were combined, there was a continued increase in mean reduction for both SAS and VRS at all-time points. In the present study, a significant reduction was seen in the combined treatment groups utilizing 3.14% dipotassium oxalate monohydrate strip 4 weeks post-treatment. This is consistent with the study by Hansson²⁴, whom found a 61.2% reduction in sensitivity 4 weeks post-treatment.

The results of the present study conflict and agree with the findings of Cooley, et al (1989). Cooley, et al²⁵ performed a study utilizing distilled water and 30% potassium oxalate followed by 3% monopotassium oxalate. Cooley found a decrease in sensitivity immediately after treatment, 1 week and 1 month; the present study also found a significant decrease in sensitivity at 30 minutes, 4 and 8 weeks post-treatment in within-group comparisons. Cooley did not find a significant difference between groups immediately, at 1 week or at 1 month, and the present study did find a significant decrease at 4 weeks post-treatment in between-group comparisons but not at 30 minutes or 8 weeks post-treatment. Both studies concur that there is a reduction in DH immediately following treatment and 4 weeks post-treatment.

The results of the present study also conflict with the findings of Muzzin, et al 1989. In the study by Muzzin, et al,² 30% dipotassium oxalate (DO) and 3% monohydrogen-monopotassium oxalate (MO) were compared on their effects on dentinal hypersensitivity. This study showed that 3% MO resulted in a significant reduction in DH, but 30% DO alone did not. Muzzin also found that 30% DO followed by 3% MO had a significant decrease in DH 1 week and 2 weeks after treatment but not immediately or 4 weeks post-treatment. The current study showed a significant reduction in DH 4 weeks post-treatment for within-group and between-group comparisons which conflicts with Muzzin's findings that DO alone does not have a significant reduction in DH.

Differences in methodology may account for such differences. Cooley followed the 30% potassium oxalate up with a 3% monopotassium oxalate. Cooley and Muzzin also used distilled water to test the thermal sensitivity, whereas the current study used air.

The current study confirms that the two treatment groups had a significant reduction of DH from baseline at all-time points, and between-group comparisons revealed a significant reduction in DH 4 weeks post-treatment.

4.6 | Limitations

There are limitations in this study. First, we cannot ensure that all subjects were compliant with the homecare instructions that they agreed to, both verbally and in writing, when they signed their informed consent that outlined the study procedures. At each follow-up visit, the study subjects were also queried as to whether they complied with the homecare instructions to use only the dentifrice and toothbrush provided by the study staff. While subjects confirmed their compliance, we cannot guarantee this.

Second, although each study subject was randomly assigned to their study group, it turned out that the professionally applied group presented with less sensitivity compared to the self-applied and placebo group at baseline. This was due to chance and between-group analyses were adjusted for baseline sensitivity; however, stratified randomization could have limited this imbalance.

Third, while the sample size/power calculation was based on a per patient analysis, the investigators could have increased the sample size by selecting multiple teeth in each of the 60 study subjects rather than limiting it to one tooth per study subject. This may have increased power but that is dependent on the level of correlation between teeth within a subject. We decided to recruit 60 individuals and to treat the most sensitive tooth per subject to maximize the number of individual opinions included in the analyses rather than recruit a smaller number of subjects with multiple teeth per subject.

Fourth, while the examiner attempted to conduct the SAS test in a standardized way throughout the study, we cannot ensure that the air stimulus was administered from a standard distance, nor can we ensure that the air pressure administered was standardized for each study subject. While some investigators report the use of a Yeaple probe to confirm DH, a study by Lopes, et al,²⁶ concluded that using air to stimulate DH is better for evaluation purposes because all of their participants had some degree of pain with air but only 60 to 80 per cent reported pain with probe stimulation so we opted to only use air as a stimulus.

Fifth, the placebo strip used in this study consisted of the blank plastic strip that is used to manufacture the commercial oxalate strips. Ideally, the placebo strip would contain the same ingredients as the actual strip, minus the active ingredient (dipotassium oxalate), so that it would be indistinguishable from the test strip. For this reason, only the study operator placed the placebo strips so that the subjects could not see or touch the blank strips.

Finally, the toothpaste given to the participants contained sodium fluoride, which may have impacted the results. The abrasivity of the toothpaste may have also had an effect on the outcomes.

5 | CONCLUSION

The present study demonstrated that the oxalate strip was effective at reducing DH when compared to a placebo. A significant reduction in DH was noted within-group comparisons at all-time points for both treatment groups. Reduction in DH was not detected immediately

but 4 weeks post-treatment in between-group comparisons. The current study did not indicate a difference in application; therefore, it cannot be stated that it would be beneficial for a professional to apply the oxalate strip over a patient. With that said it should be noted that the between-group comparisons revealed the professionally applied group was significant at 4 weeks compared to placebo while the self-applied group was not. More studies are needed with larger sample size, and more control of environmental factors. As repeated exposures have shown to be more effective, study protocols evaluating the use of the oxalate strip repeatedly would be beneficial.

6 | CLINICAL RELEVANCE

6.1 | Scientific rationale for study

The results of this study advance the knowledge of the use of oxalates in the relief from dentinal hypersensitivity (DH).

6.2 | Principal findings

The present study demonstrated that the oxalate strip may be effective at reducing DH when compared to a placebo. The most significant difference in DH reduction occurred between the subjects who had the oxalate strips placed by a professional and the subjects in the placebo group at 4 weeks post-treatment.

6.3 | Practical implications

This oxalate strip warrants consideration by dental hygienist as another option in treating DH.

ACKNOWLEDGEMENTS

We would like to thank Procter & Gamble, Cincinnati, OH, for providing the Sensi-Stop™ sensitivity relief strips.

Funding information

Supported by scholarships from the University of Minnesota. The study protocol and informed consent form were approved by the University of Minnesota Human Research Protection Program (Institutional Review Board)

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FIGURE 1.
Verbal rating scale

FIGURE 2.

Raw mean schiff air scale score of all 3 groups over 8-week time line

FIGURE 3.

Raw mean verbal rating scale score of all 3 Groups over 8-week time line

FIGURE 4.
Mean schiff air scale score of treatment groups combined vs placebo over 8-week period

FIGURE 5.
Mean verbal rating scale score of treatment groups combined vs placebo over 8-week period

TABLE 1**Schiff air scale**

0	Tooth/Patient did not respond to the air stimulus
1	Tooth/Patient responded to the air stimulus but did not request discontinuation of the stimulus
2	Tooth/Patient responded to the air stimulus and request discontinuation or moved from the stimulus
3	Tooth/Patient responded to the air stimulus, considered the stimulus painful, and requested discontinuation of the stimulus

TABLE 2

Demographics

	Total N = 60	Self-applied n = 20	Professionally Applied n = 20	Placebo n = 20	P-value ^a
Age, mean (SD)	43.8 (14.6)	47.3 (12.0)	43.8 (16.1)	40.3 (15.4)	.3397
Female, n (%)	44 (73.3)	16 (80)	13 (65)	15 (75)	.6672
Race ^b , n (%)					
White	48 (80)	17 (85)	17 (85)	14 (70)	.5516
African/American	9 (15)	3 (15)	2 (10)	4 (20)	.8998
Asian	1 (1.7)	0	0	1 (5)	1.0000
Hispanic/Latino	2 (3.3)	1 (5)	1 (5)	0	1.0000
Native American	1 (1.7)	0	0	1 (5)	1.0000
Education, n (%)					
High school or less	2 (3.3)	0	1 (5)	1 (5)	1.0000
Some college	25 (41.7)	8 (40)	8 (40)	9 (45)	
College graduate	22 (36.7)	8 (40)	7 (35)	7 (35)	
Profession/Postgrad	11 (18.3)	4 (20)	4 (20)	3 (15)	
Baseline SAS, mean (SD)	1.9 (0.9)	2.3 (0.8)	1.4 (0.8)	2.0 (0.9)	.0048 *
Baseline VRS, mean (SD)	5.5 (2.1)	6.5 (1.8)	4.3 (1.9)	5.8 (2.1)	.0030 *

^aFrom Fisher's exact test for categorical variables and ANOVA for continuous variables.^bMay select more than one.* $P < .05$.

TABLE 3

Within-group comparisons of reduction in DH levels compared to baseline

	Self-applied	Professionally applied	Placebo
SAS			
30 min post	<.0001	0.0067	0.0220
4 week post	0.0019	<.0001	0.3659
8 week post	<.0001	<.0001	0.0025
VRS			
30 min post	<.0001	0.0037	0.0381
4 week post	0.0122	<.0001	0.6727
8 week post	0.0024	<.0001	0.0102

P-values from *t* tests of change versus 0.

TABLE 4

Within-group comparisons of reduction in DH levels compared to baseline treatment groups combined

	Professionally applied and self-applied combined	Placebo
SAS		
30 min post	<.0001	0.0243
4 week post	<.0001	0.3579
8 week post	<.0001	0.0022
VRS		
30 min post	<.0001	0.0406
4 week post	<.0001	0.6480
8 week post	<.0001	0.0091

P-values from *t* tests of change versus 0.

TABLE 5

Mean reduction in sensitivity between groups

	Self-applied	Professionally applied	Placebo	<i>P</i> -value ^a
SAS				
30 min post	-1.12 (0.23)	-0.66 (0.23)	-0.52 (0.22)	.1623
4 week post	-0.86 (0.26)	-1.11 (0.26)	-0.22 (0.24)	.0411*
8 week post	-1.12 (0.26)	-1.24 (0.26)	-0.78 (0.25)	.4092
VRS				
30 min post	-1.85 (0.41)	-1.27 (0.42)	-0.83 (0.39)	.2022
4 week post	-1.34 (0.52)	-2.22 (0.51)	-0.20 (0.48)	.0216*
8 week post	-1.66 (0.52)	-2.26 (0.52)	-1.33 (0.50)	.4435

^aMean (SE) and *P*-values are from ANCOVA models.* *P* < .05.

TABLE 6

Mean reduction in sensitivity (combined active ingredient groups vs placebo)

	Professionally applied & self-applied combined	Placebo	<i>P</i> -value ^a
SAS			
30 min post	−0.89 (0.16)	−0.52 (0.22)	.1733
4 week post	−0.99 (0.17)	−0.23 (0.24)	.0139 *
8 week post	−1.18 (0.17)	−0.78 (0.24)	.1928
VRS			
30 min post	−1.56 (0.28)	−0.82 (0.39)	.1287
4 week post	−1.78 (0.35)	−0.22 (0.48)	.0111 *
8 week post	−1.96 (0.35)	−1.34 (0.50)	.3084

^aMean (SE) and *P*-values are from ANCOVA models.*
P < .05

TABLE 7

Mean reduction in sensitivity by location

	Self-applied	Professionally applied	<i>P</i>-value^a
SAS			
Anterior	−0.69 (0.51)	−1.24 (0.36)	.3881
Posterior	−1.02 (0.24)	−0.93 (0.25)	.8108
VRS			
Anterior	−0.82 (0.97)	−2.02 (0.65)	.3159
Posterior	−1.66 (0.45)	−1.88 (0.50)	.7531

^aMeans (SE) and *P*-values are from linear mixed effect models.