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Benefits of Sodium Hexametaphosphate-Containing Chewing Gum for Extrinsic Stain Inhibition

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Purpose. This study was designed to examine the ability of sodium hexametaphosphate delivered from a chewing gum to prevent extrinsic tooth stain formation.

Methods. This study was a negative-controlled, randomized, two-period crossover design, with a 10-day washout period between treatments. The two treatments were a chewing gum containing 5.6% sodium hexametaphosphate and a negative control chewing gum. Eleven subjects who met study criteria were enrolled, and 10 completed the study over a two-week period. Each treatment period lasted approximately 48 hours and was separated by a washout period. After a dental prophylaxis, a digital image of the anterior teeth was taken to assess baseline stain. The three-day stain induction phase consisted of the patient using a 10 ml 0.2% chlorhexidine rinse for 60 seconds, followed by chewing two pellets/sticks of their assigned gum for five minutes and rinsing with 10 ml of cold tea solution for 60 seconds. No oral hygiene was permitted other than use of the test products. During both treatment periods, each subject followed the same regimen eight times, once per hour, throughout the day.

Results. On Days 2 and 3, the adjusted mean L* measurement was statistically significantly greater for the sodium hexametaphosphate gum than for the control gum. Moreover, nine of the 10 subjects had whiter teeth while on the experimental gum treatment at both Day 2 and Day 3.

Conclusion. The results of this study support that sodium hexametaphosphate delivered from a chewing gum prevents dental stain formation and leads to a patient-desired whitening benefit.

Keywords: tooth stain, chewing gum, sodium hexametaphosphate

Introduction

Stains on the teeth are not etiologic factors for any disease. Discoloration or extrinsic staining of the teeth caused mostly by food products containing tannins, such as tea, coffee, tobacco, red wine and colas, is very common.[1] Research has shown that, despite regular oral care such as tooth brushing and flossing, many individuals develop extrinsic stains on the surfaces of their teeth from using products that contain tannins or a product such as PeridexM-BM-. mouthrinse, used to treat gingivitis.[2]

Most individuals are concerned with the staining of their teeth for aesthetic, not health, reasons and look for an easy method to remove such stain. During a routine dental appointment, professionals remove extrinsic stains by polishing teeth with

an abrasive paste applied to a rubber cup and attached to a motorized handpiece.[3] The aesthetic benefits of this procedure, however, last only a short time.

Chewing gum bases possess a number of therapeutic benefits, including increased saliva flow and the removal of food debris, plaque, and surface stains.[4] The concept of using chewing gum to deliver agents within the oral cavity is well established. For example, in the past five years, chewing gum has been used as a means to deliver whitening and tartar prevention agents. One study comparing three chewing gums containing various levels of baking soda reported significant reductions, 65% to 72%, in mean stain score at both a two-week and four-week read relative to baseline.[5] A second study reported a statistically significant ($p<0.001$) 51% reduction in mean stain scores, relative to baseline, over a four-week use of chewing gum containing baking soda.[6] Additionally, in one four-week study, subjects with natural stain chewed a baking soda-containing gum twice a day for 20 minutes and reduced the mean stain score from baseline by 29.7% (with $p=0.004$).[7] Importantly, the proof of efficacy in these two studies was based on change from baseline comparisons, as opposed to superiority testing versus a placebo gum. Thus, clinical effectiveness cannot be attributed to the presence of baking soda alone.

A new active ingredient, sodium hexametaphosphate, has been incorporated into dentifrices to deliver tartar and stain prevention and removal benefits.[8] One of the potential advantages of high molecular weight-condensed phosphate analogues, such as sodium hexametaphosphate, is a greater inhibitory activity in preventing crystallization or stain chromogen adsorption.[8,9] A six-week clinical study that examined the removal of extrinsic, natural tooth stain found that a dentifrice containing 7.0% sodium hexametaphosphate resulted in a statistically significant (29%) lower extrinsic stain score at six weeks, relative to a control fluoride dentifrice.[10] Similar results were observed in a second six-week clinical study that tested the removal of induced chlorhexidine/tea extrinsic tooth stain with a sodium hexametaphosphate-containing dentifrice.[11]

A chewing gum that contains sodium hexametaphosphate has been developed recently for the primary purpose of whitening teeth through extrinsic stain prevention and removal. Sodium hexametaphosphate can disrupt the in vivo salivary film at the tooth surface, creating a more hydrophilic tooth surface. This allows greater desorption and diffusion of surface chromogen into saliva, presumptively reducing overall extrinsic staining.[12] This current study was designed to examine the ability of sodium hexametaphosphate delivered from a chewing gum to prevent induced stain formation.

This study was a randomized, examiner-blind, two-period crossover, single-center study that compared the reduction in induced extrinsic stain formation, as measured by digital image analysis (DIA) of a chewing gum containing 5.6% sodium hexametaphosphate, compared to a commercially available "non-sodium hexametaphosphate" chewing gum, which served as a negative control.

Materials and Methods

This study was conducted in a suburb of London, United Kingdom. The study was a negative-controlled, examiner-blind, randomized, two-period crossover design (each subject used both treatment sequences), with a 10-day washout period between treatments. The two treatments were an experimental chewing gum containing 5.6% sodium hexametaphosphate and a negative control chewing gum containing no sodium hexametaphosphate (Wrigley's ExtraM-BM-.-peppermint flavor). Eleven volunteers who met the entrance criteria of being at least 18 years old and having a minimum of 16 natural teeth, including at least seven of the eight anterior incisor teeth, were enrolled. Subjects were excluded if they reported known hypersensitivity to chlorhexidine digluconate or polyphosphates. Additional exclusion criteria included the presence of anterior facial restorations, evidence of TMJ dysfunction, presence of oral ulcers, self-reported diabetes, or self-reported pregnancy. The treatment periods lasted three days and were separated by a minimum washout period of 10 days (Figure 1).

Figure 1: Study Design

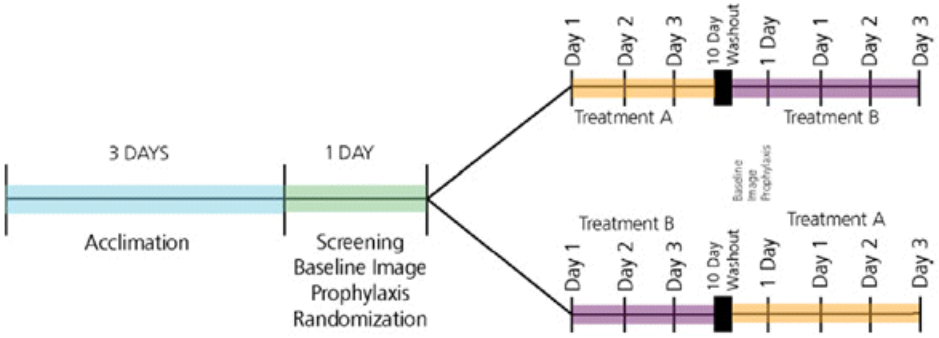

Figure 1. Study Design.

Three days prior to the screening visit, volunteers were given a manual toothbrush and a marketed sodium fluoride toothpaste and told to brush normally. At the screening/baseline visit for Period 1, subjects who met the entrance criteria signed an informed consent and provided demographic data. In addition, a baseline oral soft tissue examination was performed. Each subject received a thorough dental prophylaxis, which included scaling and polishing by a single dental hygienist in a single day. A digital image of the anterior teeth was taken to assess baseline stain for Period 1. Prior to dismissal, subjects were given instructions to cease all oral hygiene practices after 11:00 p.m. of the day that the baseline images were taken.

Subjects visited the study site the next day and started their supervised staining induction phase, which consisted of rinsing with 10 ml of 0.2% chlorhexidine for 60 seconds, followed by chewing two pellets/sticks of their assigned gum for five minutes and rinsing with 10 ml of cold tea solution for 60 seconds. Each subject followed the same regimen eight times, once per hour, throughout the day. The subjects repeated the regimen on Day 2 and Day 3. During the three-day stain induction phase, no oral hygiene was permitted other than use of the test products. Prior to the digital image being taken on Day 2 and Day 3, the subjects waited one minute after their final rinse with tea and then rinsed with 10 ml of water for 10 seconds.

After completing the first period, subjects entered a washout period and were again given a manual toothbrush and a marketed sodium fluoride toothpaste and told to brush normally for the next 10 days. Following the washout period, subjects returned for the baseline visit of Period 2 where they received a thorough dental prophylaxis and an oral soft tissue assessment. A baseline digital image of all anterior teeth was taken. Prior to dismissal, subjects were advised to cease all oral hygiene practices after 11:00 p.m. on the day their baseline images were taken. Again, during the three-day stain induction period, no oral hygiene was permitted other than the use of the test products. The second treatment period followed the same regimen outlined in Period 1, with the notable exception that subjects used the other chewing gum product.

The digital image analyses photographic system used in this study consisted of a high-resolution HC1000CCD digital camera manufactured by Fuji. Two 150-watt lights located on each side of the CCD camera provided lighting. The system was equipped with a Fujinon 7.5M-bM-^@M-^S30 motorized zoom lens and a linear polarizer to permit cross-polarized light. The unit was connected to a personal computer that recorded and analyzed the images. Prior to daily use, the system was calibrated to assure proper operation. Additionally, a color standard was centered and imaged every hour, prior to imaging subjects. For imaging the anterior teeth, each subject sat on a stool in front of a chin rest used to both reproducibly reposition the head and hold it still. The subject then used cheek retractors to retract lips and cheeks. The teeth were placed in an anterior incisal edge to incisal edge position and centered in the camera by the subject tilting their head per the DIA technician's instructions. Prior to exposure, subjects were instructed to position their tongues away from the linguals of the anterior teeth. The same technician was used throughout the study.

Tooth color change in L*, a*, and b* color space was assessed based on evaluation from the digital images. The difference in the color of digitally imaged teeth between two time periods can be measured by difference in lightness or white M-bM-^@M-^S black (delta L*), redness-greenness (delta a*), and yellowness-blueness (delta b*).[13] The change from baseline (post-treatment minus baseline) in L* was calculated and defined as delta L* because of the nature of

chlorhexidine-tea stain, which is primarily brown to black. Higher L* values indicate whiter teeth. The efficacy variables were analyzed for treatment group differences using analysis of covariance (ANCOVA) (with the baseline L* score as the covariate) for a crossover design. The four maxillary incisors, four mandibular incisors, and two mandibular canines formed the basis of the analyses. All tests were two-sided with a 5% significance level.

Results

Eleven subjects were randomized into one of two treatment sequences in this examiner-blind, two-period crossover study. Ten subjects completed both treatment periods. Six male and four female subjects ranged in age from 22 to 58, with a mean age of 30.4 years. One subject in the experimental (chewing gum first/negative control gum second) sequence dropped from the study due to an adverse event, reported and diagnosed by the examiner as acute parotid swelling and described as non-serious, mild in severity, and possibly related to the use of the product. The adverse event was followed to positive resolution. In this study, subjects chewed a negative control gum during one period and, in the other period, a gum containing 5.6% sodium hexametaphosphate. A summary of the baseline mean L* scores are reported in Table I.

Table I: Day 2 L* Results

Chewing Gum Treatment	N	Baseline (BL) Value (Mean ± SD)	Day 2 Delta L* (Adj. Mean[a] ± s.e.)
Placebo	10	78.28 ± 1.57	-5.51 ± 0.34
Sodium Hexametaphosphate	10	78.52 ± 1.30	-3.26 ± 0.33

The difference in adjusted means between the two treatments is statistically significant (p=0.002)
a-Adjusted means and standard errors from analysis of covariance with baseline L* as the covariate

Analysis of covariance, with baseline value as the covariate, determined that the stain intensity increased (L* has decreased) from baseline with both chewing gums. The accumulation of stain from baseline, however, was significantly lower for the sodium hexametaphosphate gum when compared to the negative control gum on both Days 2 and 3 (Table I, II). The change in mean L* from baseline was -5.51 for the placebo and -3.26 for the sodium hexametaphosphate gum on Day 2. A smaller change in mean L* indicates less stain. Day 3 delta L* results for the negative control gum and sodium hexametaphosphate gum were -7.27 and -4.67, respectively.

Table II: Day 3 L* Results

Chewing Gum Treatment	N	Day 3 Delta L* (Adj. Mean[a] ± s.e.)
Placebo	10	-7.27 ± 0.41
Sodium Hexametaphosphate	10	-4.67 ± 0.42

The difference in adjusted means between the two treatments is statistically significant (p=0.003)
a-Adjusted means and standard errors from analysis of covariance with baseline L* as the covariate

Figures 2 and 3 show that nine of the 10 subjects had whiter teeth while on the sodium hexametaphosphate gum treatment at both Days 2 and 3. The majority of subjects demonstrated less change in L* measurements (teeth have less darkening through stain deposition) from baseline with the sodium hexametaphosphate chewing gum compared to the negative control chewing gum on both the second and third day of rinsing/dosing. One subject exhibited virtually no difference in stain

prevention between the two chewing gum treatments. Figure 4 shows a visual comparison of digital images at Day 3 of induced staining following dosing with either the negative control gum or the 5.6% sodium hexametaphosphate gum.

Figure 2: Change in L* Scores from Baseline to Day 2 for Each Subject

(negative changes indicate darker teeth)

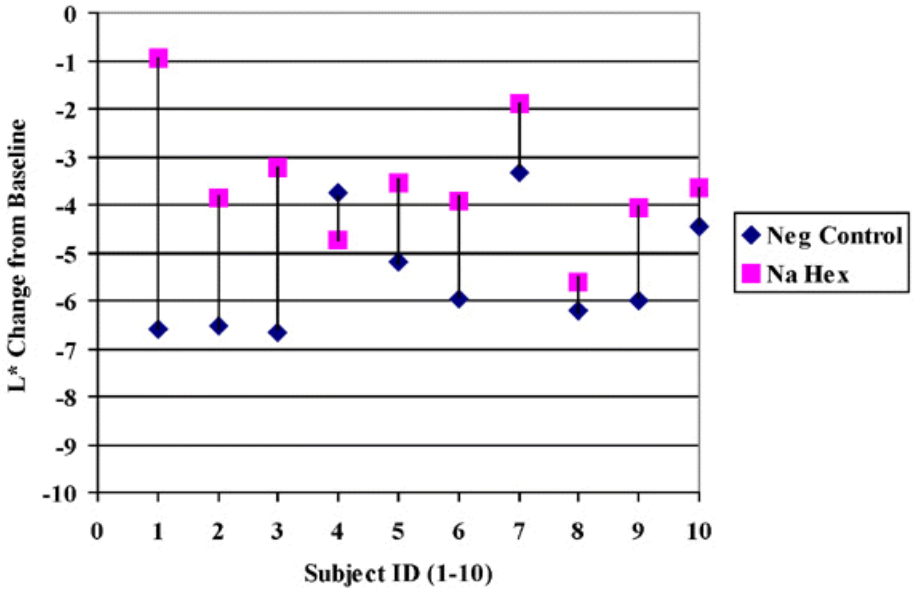

Figure 2. Change in L* Scores from Baseline to Day 2 for Each Subject.

Figure 3: Change in L* Scores from Baseline to Day 3 for Each Subject

(negative changes indicate darker teeth)

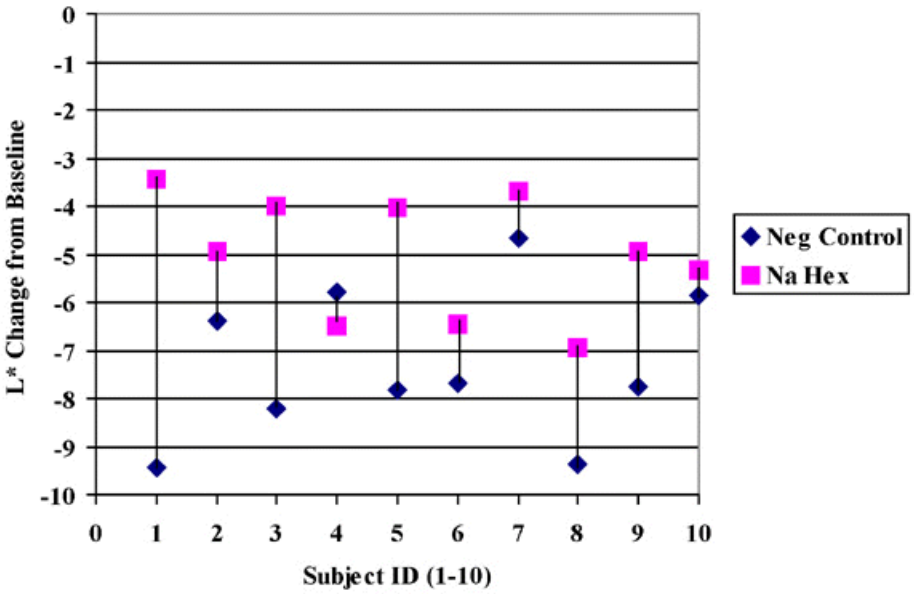

Figure 3. Change in L* Scores from Baseline to Day 3 for Each Subject.

Figure 4: Digital Images at Day 3 of Induced Staining

Figure 4. Digital Images at Day 3 of Induced Staining.

Discussion

The results of this study suggest that sodium hexametaphosphate delivered from a chewing gum may prevent dental stain formation, leading to a perceived whitening benefit. Sodium hexametaphosphate is a calcium-sequestering agent that has strong reactivity to enamel surfaces and produces significant anti-stain and anti-tartar effects in the teeth.[8] The agent has been shown to interact directly with salivary film (pellicle) composition, displacing nitrogen from the salivary film by sodium hexametaphosphate adsorption to the tooth surface in a chewing gum vehicle.[12] The adsorption of sodium hexametaphosphate interferes with the adsorption of stain chromogen onto tooth surfaces and pellicle proteins, resulting in stain prevention.[14]

In this study, relatively low levels (5.6%) of sodium hexametaphosphate in a chewing gum prevented deposition of extrinsic dental stain better than a chewing gum without sodium hexametaphosphate. Statistical significance was shown after two and three days of rinsing/dosing, with $p=0.002$ and $p=0.003$, respectively. Potential limitations of this study regarding generalization include the low number of participants, the chlorhexidine-induced stain mechanism, and the short-term

nature of the study. These results are consistent, however, with several studies that have previously shown that sodium hexametaphosphate in a dentifrice reduces extrinsic stain by 29% to 33%, when compared to a standard control dentifrice over a period of six weeks.[11,15] All of these studies utilized a well-developed clinical model of deliberate induction of dental stain induced by rinsing with chlorhexidine mouth rinse and tea repeatedly.[16-18] The models allow the ability to more tightly control formation of both intensity and duration of stain. Extrinsic stain formation resulting from chlorhexidine and tea use has been reported to be consistent with natural stain formation.[16] In both natural stain formation and chlorhexidine-mediated stain formation, the stain is caused by the precipitation of dietary chromogen.[19] These similarities suggest that results from induced stain models are reasonable predictors of the outcomes of natural stain.

Consumer interest in improving oral aesthetics is evidenced by increased sales in tooth whitening products in recent years. Introducing a chewing gum that is effective in preventing and reducing stain may be beneficial to both the consumers and oral health care professionals by providing an alternative whitening treatment with portability advantages. Others have suggested that the perceived whitening of teeth can have an effect on patients' level of dental health awareness, resulting in improvement of overall oral health.[20] Based on the results of this study and others evaluating sodium hexametaphosphate as a new active ingredient added to both dentifrice and chewing gum, the dental hygienist can offer other options to patients expressing concern about the stain or color of their teeth. Aesthetics is playing an increasingly large part during in-office discussions between the patient and dental professionals.[8] Some patients may not need tooth whitening products that are effective against intrinsic staining, but rather need an ongoing treatment to inhibit new extrinsic stain formation between office visits.

Conclusions

Analysis of the stain intensity data from this study suggests that the sodium hexametaphosphate-containing chewing gum can significantly reduce induced extrinsic dental stain formation, compared to a non-sodium hexametaphosphate chewing gum. This finding is directly linked to the presence of the sodium hexametaphosphate and its ability to modify the tooth surface to inhibit deposition of stain from tea and chlorhexidine rinses. In addition, both products were well tolerated by this population. A logical next step is a longer-term natural stain prevention study.

Acknowledgements

Notes

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