

Clinical study of NovaMin-containing dentifrice ability to produce consumer noticeable whitening and brightening effects.

NovaMin Research Report

Research Institution:
HillTop Research
Cincinnati, OH

Abstract: The purpose of this study was to determine if a 7.5% NovaMin-containing dentifrice could produce whitening that users could see for themselves and, additionally, if the users were more likely to report that effect as “whitening” or “brightening”.

The study was completed by 98 healthy volunteers who were recruited to have moderate discoloration (Vita shade A-3 or greater on the maxillary central incisors). Participants were supplied with dentifrice containing 7.5% NovaMin® (Oravive IMT™). Volunteers were required to maintain diaries complete questionnaires throughout the study to capture perceived changes in whiteness and brightness.

Nearly 9 out of 10 participants perceived their teeth as whiter, most typically within the first 7 days of use. The participants did not generally distinguish between “whiter” and “brighter” in this study. There is not enough information to determine if this represents an inability of the participants to judge the qualitative difference in these two terms or if the product just produced similar results on both measures.

Tooth whitening products enjoy substantial popularity with consumers who strive to enjoy the social benefits of a white, bright smile. Current product focus on either intrinsic color change through peroxide bleaching that penetrates into the dentin to alter the normally yellow or grey color of dentin with transmits through the enamel changing the perceived color of the tooth. These products, when overused, can produce a dull ‘chalky’ white that becomes an aesthetic negative to some consumers. Furthermore, while use of these products are generally well-tolerated they do carry toxicity risk and can cause dentinal hypersensitivity in many users and continued use has been shown to damage enamel and irritate surrounding soft tissues^{1,2,3}.

Alternatively, stain removing toothpastes can remove extrinsic stain, but can cause considerable abrasive damage to the tooth surface, especially dentin and restorative materials.^{4,5}

All of these products share a common perception problem that, while scientifically demonstrated in controlled settings to remove stain and whiten teeth, many consumers are skeptical of claims because their personal experience does not match an expectation of whiter teeth⁶.

Notably, many consumers become more concerned with tooth color as they age, wishing they could get back the white teeth of their youth.

NovaMin, as an active ingredient in dentifrice has been shown to deliver significant therapeutic benefits in the areas of sensitivity relief; remineralization of enamel and dentin and gingival health benefits as well.^{7,8,9,10}

Previous work has shown that NovaMin containing products can deposit new hydroxycarbonateapatite (HCA) on the tooth surface⁹. This new HCA is nearly indistinguishable from normal enamel mineral and, when formed on the surface, is

unstained and very white (as is characteristic of HCA with minimal organic content). Further, this HCA has been seen microscopically to be in the form of small, disorganized crystallites¹¹. Further, NovaMin is an abrasive and can remove stain through normal abrasion, and has also been associated with chemical removal of tannins through its ionizing reaction with saliva¹¹.

It has been hypothesized that as people age, the HCA crystals of enamel become more polarized, resulting in a somewhat more translucent enamel. This translucent enamel allows the natural off-white color of the underlying dentin to shine through, resulting in progressively more yellow or grey teeth with age.^{12,13}

The purpose of this study was to determine if a NovaMin containing dentifrice could produce whitening that users could see for themselves and, additionally, if the users were more likely to report that effect as “whitening” or “brightening”. The reason

for this distinction is that the new HCA formed by NovaMin deposition would be less polarized, therefore less translucent and more reflective. This would be in addition to any stain removal done through abrasion or chemical means. The measure of both variables (brightening and whitening) would allow investigators to determine if consumers made a distinction, visually, between these two related phenomena.

Study design:

The study was completed by 98 healthy volunteers who were recruited to have moderate discoloration (Vita shade A-3 or greater on the maxillary central incisors). Participants were supplied with a tube of dentifrice containing 7.5% NovaMin in a non-aqueous base (Oravive IMT). Participants were instructed to brush twice daily for 2 minutes, using toothbrushes supplied by study personnel.

Volunteers were required to maintain diaries throughout the study to capture perceived changes in whiteness and brightness. They were also required to complete questionnaires at 2, 4, 8 and 12-week intervals. The questionnaires asked them if they had noticed any whitening of their teeth or brightening of their teeth since their previous questionnaire, and if so, at which day point. They also rated this effect on a scale of 1-10.

Results:

Ninety-eight (98) participants completed the study. A large majority, 87%, of participants reported some whitening or brightening, most typically within the first 2 weeks.

The extent of the whitening or brightening effect was typically modest,

with a mean “Brightness” of 2.5 on a scale of 1-10. A significant minority (32%), however, perceived substantially “Brighter” teeth (grade = 4 or higher), frequently after as little as just 7 days.

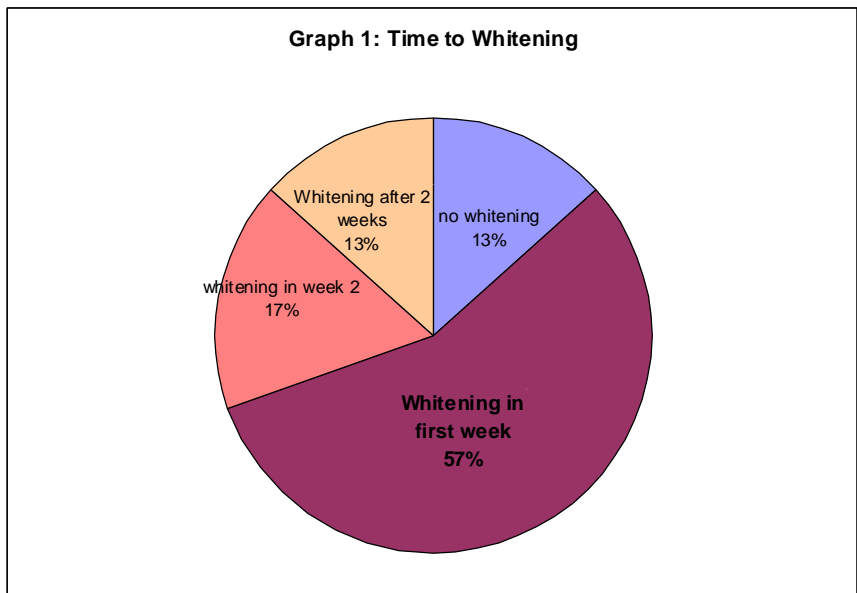
Most participants did not seem to distinguish, in this study, a difference between brightness or whiteness. The mean difference in “Brighter” and “Whiter” scores (1-10 scale) was only 0.8, less than a one grade difference. A small number of participants (about 5%) did identify substantial differences in these two distinctions, however, indicating that for some small subset of the population this might be a meaningful differentiator.

This study indicated that participants tended to see results quite rapidly, most frequently in less than 1 week. Graph 1 below illustrates this:

Conclusions:

This study indicates that users of a 7.5% NovaMin dentifrice can expect to see rapid whitening effects, although they may not be as substantial as seen with peroxide-based whiteners. However, when coupled with NovaMin’s known benefits in other oral health concerns (sensitivity reduction; remineralizing; gingival health benefits) such a product could become a very attractive alternative to more destructive whitening products.

From this study it was not conclusive if NovaMin dentifrices would produce a qualitatively different type of white (i.e brighter) or if most consumers can even distinguish this difference.



References:

- Collins LZ, Maggio B, Gallagher A, York M, Schaefer F, *Safety evaluation of a novel whitening gel, containing 6% hydrogen peroxide and a commercially available whitening gel containing 18% carbamide peroxide in an exaggerated use clinical study.* J Dent, 32 Suppl 1(): 47-50 2004
- Watt BE, Proudfoot AT, Vale JA. *Hydrogen peroxide poisoning.* Toxicol Rev, 23(1): 51-7 2004
- Leonard RH, Garland GE, Eagle JC, Caplan DJ. *Safety issues when using a 16% carbamide peroxide whitening solution.* J Esthet Restor Dent, 14(6): 358-67 2002
- Joiner A, et al. *The measurement of enamel and dentine abrasion by tooth whitening products using an in situ model.* Int Dent J, 55(3 Suppl 1): 194-6 2005
- Turssi CP, Faraoni JJ, Rodrigues Jr AL, Serra MC *An in situ investigation into the abrasion of eroded dental hard tissues by a whitening dentifrice.* Caries Res, 38(5): 473-7 2004
- McKlone. J Article on www.toothwhitening reviews.com, October 2006
- Greenspan, D. C., Clark, A. & LaTorre, G. P. (2004) *In-vitro antimicrobial properties of a bioactive glass (NovaMin) containing dentifrice.* Journal of Dental Research 83, 1586.
- Du MQ, Tai BJ, Jiang H, Zhong JP, Greenspan DC, Clark AE. *Efficacy of dentifrice containing bioactive glass (NovaMin®) on dentine hypersensitivity.* J Dent Res, Spec Issue A 2003; 82:1546
- Litkowski LJ, Hack GD, Sheaffer HB, Greenspan DC. *Occlusion of dentin tubules by 45S5 Bioglass®.* In, Bioceramics 10, Proceedings of the 10th International Symposium on Ceramics in Medicine, Paris, France, Oct. 1997. eds. Sedel L, Rey C
- Tai BJ, Bian Z, Jiang H, Greenspan DC, Zhong J, Clark AE, Du MQ. *Anti-gingivitis effect of a dentifrice containing bioactive glass (NovaMin) particulate.* J Clin Periodontol 2006; 33: 86–91. doi: 10.1111/j.1600-051X.2005.00876.x.
- Data on file, NovaMin Technology Inc.
- Lakovic KP, Wood RE *Tooth root colour as a measure of chronological age.* J Forensic Odontostomatol. 2000 Dec;18(2):37-45
- A. Watts, M. Addy *Tooth discoloration and staining: a review of the literature* British Dental J MARCH 24 2001, VOLUME 190, NO. 6, PAGES 309-316