

Multi-center, single blind clinical study to assess stain removal potential of NovaMin dentifrices.

NovaMin Research Report

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Abstract: This was a multi-site, evaluator blind, parallel, randomized 12-week study to evaluate the stain removal potential of a NovaMin containing dentifrice as compared to a placebo. There were 53 patients completing in the placebo group and 55 in the NovaMin group. Patients were evaluated on Lobene stain removal index and by self-assessment questionnaire.

Both groups showed significant stain removal and over 80% of participants in both groups reported that they noticed their teeth were whiter. There were not statistical differences between placebo and test groups, however.

Introduction:

Extrinsic tooth staining is an important cosmetic issue for many individuals. Increasing consumption of coffee and other tannin-containing beverages, along with tobacco use, red wine consumption and a variety of other causes makes this a growing concern. Whitening products (tray systems, whitening strips, etc.) are effective at intrinsic stain removal and can result in lasting improvements in intrinsic tooth color. While they can also be effective at removing extrinsic stains, the frequency (almost daily) of new stain formation; the harshness of peroxides to dental tissues; and product cost make them less desirable treatments for extrinsic stains.

Dentifrices with above average abrasivity can also be used to abrade away stains and can be effective in extrinsic stain removal. This can be damaging to the teeth over extended use, however. NovaMin containing dentifrices (i.e. Oravive, SootheRx, etc.) has been demonstrated in other studies to actually fortify tooth mineral as opposed to depleting tooth mineral through abrasion. In addition, NovaMin itself has been

demonstrated in vitro to chemically remove tannin stains from tooth pellicles.

This study was intended to evaluate the potential of a dentifrice containing NovaMin as a product for safe removal of extrinsic stain.

Materials and Methods:

This was a multi-site, evaluator blind, parallel, randomized 12-week study. There were 53 patients completing in the placebo group and 55 in the NovaMin group. Participants were recruited to have at least a Lobene stain index of 8 on their incisors (at least 7 of 8 natural incisors required for inclusion).

They were instructed to brush twice per day for 2 minutes per brushing using 1 inch of dentifrice on a standard toothbrush.

The patients were evaluated at 2,4,8 and 12-week intervals using the Lobene stain assessment. They were also asked to complete a questionnaire self-reporting their whitening observations.

The study evaluated a non-aqueous 7.5% NovaMin concentration dentifrice (Oravive

IMT™) compared to an aqueous placebo dentifrice.

Results:

Both the placebo and test dentifrices resulted in reductions of stain as measured versus baseline by the Lobene stain index. This is consistent with the questionnaires, where over 80% of participants in both groups reported that their teeth were whiter. The test dentifrice recorded 18.7% greater improvements in Lobene index than the placebo, but this difference was not statistically significant at the 95% confidence level.

Conclusion:

The 7.5% containing dentifrice appears to provide a stain removal benefit as measured by user perception and Lobene stain index, although a larger scale study should be conducted to better understand statistical significance of these results.