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A Clinical Evaluation of Extrinsic Stain Removal: A Rotation-Oscillation Power Toothbrush versus a Dental Prophylaxis

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Abstract

Aim: To assess extrinsic stain removal efficacy of a power toothbrush and a dental prophylaxis followed by the use of a standardized American Dental Association (ADA) reference manual toothbrush.

Methods and Materials: This was a randomized, positive-controlled, examiner-blind, parallel group, two-week study. A Lobene stain examination was performed at baseline. Subjects were randomized to one of two treatment groups: ***Group 1:*** Oral-B® Vitality™ Pro White power toothbrush or ***Group 2:*** Subjects receiving a dental prophylaxis then using a standardized ADA reference manual toothbrush. Subjects were instructed to brush their teeth with the assigned toothbrush and a fluoride dentifrice in front of a mirror twice per day for 2 minutes. Stain was reassessed following 2 weeks of brushing.

Results: A significant reduction ($p < 0.001$) in mean Lobene composite scores after 2 weeks was found for Group 1 (90.6%) and Group 2 (94.4%). Both groups also showed a significant reduction ($p < 0.001$) in extent and intensity scores. There was no significant group difference in reduction in mean Lobene composite scores ($p > 0.1$).

Conclusions: The Oral-B Vitality Pro White power toothbrush showed effective stain removal at a level similar to receiving an oral prophylaxis followed by the use of an ADA reference manual toothbrush.

Clinical Significance: In this small study the Oral-B Vitality Pro White power toothbrush achieved statistically significant stain removal between dental visits.

Keywords: Extrinsic stain, stain removal, dental prophylaxis, power toothbrush, clinical trial, Oral-B Vitality Pro White power toothbrush

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Introduction

Toothbrush and dentifrice manufacturers generally aim to include improved dental stain removal as a feature of new products to meet the demands of a society that values the cosmetic aspects of oral health. In instances of extrinsic or surface stains, which result from staining of the pellicle, this tooth discoloration can result from the consumption of beverages (e.g., tea, coffee, red wine), smoking, and the use of certain medications (e.g., chlorhexidene antibacterial mouthrinse). Intrinsic stains, or those below the tooth surface, can result from the use of tetracycline antibiotics, dental fluorosis, or the natural dental aging process (Figure 1).

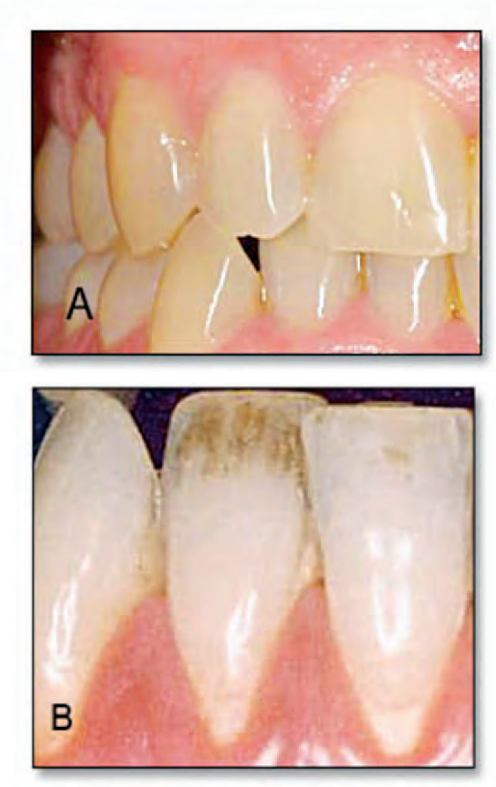

Figure 1. A. Intrinsic stain. **B.** Extrinsic stain.

Intrinsic stain can be removed by means of a peroxide-containing agent (bleaching gel/strip or a tray-based system) placed on the external surfaces of the teeth that bleaches through the enamel.[1-2] There appears to be a growing demand for this type of tooth whitening procedure that can be accomplished using a home bleaching kit or by a dental professional in a dental office.

Extrinsic stain removal is one of the functions of the scaling and polishing procedure done during a prophylaxis performed by dental professionals during an office visit to help maintain oral health and prevent periodontal disease. The dental prophylaxis, as defined by the American Dental Association (ADA)[3] and the American Dental Hygienists' Association (ADHA),[4] states stain removal is accompanied by removal of plaque, both supragingival and subgingival (i.e., below the gumline), and calculus.

New models of toothbrushes can be assessed for their extrinsic stain removing potential both in the laboratory and in clinical studies. In a laboratory investigation comparing the removal of stained pellicle from the surface of enamel specimens with two powered brushes (Sonicare® , Philips, Snoqualmie, WA, USA and Oral-B® Plaque Remover, P&G, Cincinnati, OH, USA) and a standardized manual brush, the power brush with the oscillating-rotating action (Oral-B) was found to be superior.[5] In a series of four independent 2-week clinical studies of healthy adults with longstanding visible extrinsic stain on the facial

surfaces of the 12 anterior teeth, a prototype-powered toothbrush group (Crest® SpinBrush® Pro Whitening, model formerly distributed by P&G, Cincinnati, OH, USA) was compared with a positive control powered toothbrush group (Sonicare® Personal 4100), and the prototype power toothbrush removed extrinsic stain at least as well as the positive control toothbrush across these four studies.[6]

Oral-B developed a specialized brush head (Oral-B Pro White), featuring an oval brush head with 16 outer tufts of filaments for regular cleaning and a thermoplastic elastomer polishing cup at the center of the head. In a 6-week clinical study that included naturally occurring extrinsic tooth stain removal, this brush head was compared with a standard brush head (EB17), both in combination with a recently developed powerbrush handle with an oscillating/rotating/pulsating action (Oral-B® ProfessionalCare® Series) and was also compared with a leading high frequency power brush (Philips Sonicare® Elite®).[7] Greater removal of extrinsic tooth stain was seen with the specialized Oral-B brush head for both tooth stain (Lobene stain index) and tooth shade (Vitapan Shade Guide) measurements. In addition to improved efficacy of plaque removal normally expected of new models of toothbrushes manufacturers are being challenged to offer an improved capacity for extrinsic stain removal to meet the growing esthetic demand by the public. In order to guide the public's choice of oral hygiene products clinical studies are required to evaluate the relative stain removal efficacy as new products are introduced (Figure 2). The present study used the Lobene stain index to measure the amount of stain removed at the end of a 2-week period in one group of subjects (Group 1) who used the novel Oral-B Vitality Pro White (Oral-B Vitality with Oral-B Pro White brush head) and a second group (Group 2) who received a routine dental prophylaxis followed by use of a standardized ADA reference manual brush (i.e., a positive control group).[8] An additional analysis compared stain removal in the two treatment groups.

Methods and Materials

Subjects and Study Design

This study was a single center, randomized, examiner-blind, parallel group design and

Figure 2. Patient brushing with a power brush.

Figure 3. Oral-B Vitality Pro White and Pro White Brush Head.

compared the Oral-B Vitality Pro White toothbrush plus Crest® Cavity Protection dentifrice with a thorough dental prophylaxis followed by use of an ADA reference manual toothbrush (positive control) over a 2-week period (Figures 3 and 4). This study utilized a dental prophylaxis as a positive control because a prophylaxis is widely accepted in the dental community as the gold standard for extrinsic stain removal.

Figure 4. Study design.

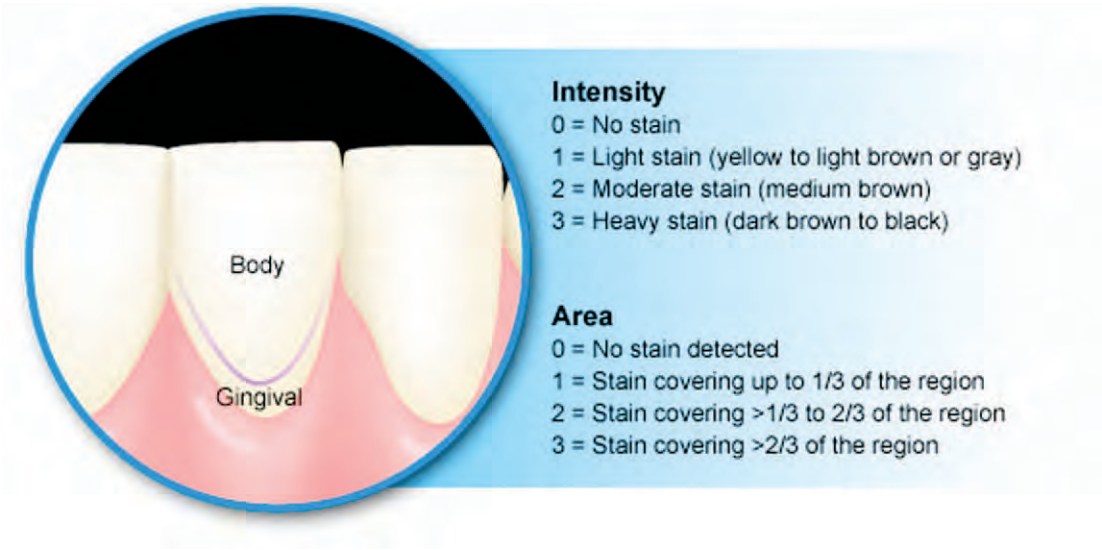

Figure 5. Lobene stain index

Before the start of the study, the protocol was approved by the University of Texas Health Science Center at San Antonio Institutional Review Board, and subjects gave informed consent before participating in any study procedures. Subjects from the general San Antonio, TX, USA population were screened for the study. For inclusion in the study, subjects were required to be in good general health, between 18 and 70 years of age, and to have had a dental prophylaxis in the last 24 months. The subjects were also required to have visible stain on four of the six maxillary anterior teeth and to have at least four of the eight central and lateral incisors with individual Lobene scores >1.0. In addition, subjects were required to be willing to refrain from using chlorhexidene and/or Listerine® (J&J, New Brunswick, NJ, USA) mouth rinse for the duration of the study.

Subjects were excluded from participating in the study for any of the following criteria: generalized recession of the gingiva or generalized malocclusion or overlapping of teeth, inability to comply with brushing instructions (e.g., dexterity or comprehension issues), obvious periodontal disease, or facial calculus on the anterior teeth.

Eligible subjects (i.e., those who gave signed informed consent and who qualified to participate in the study in terms of the inclusion and exclusion criteria) were given a modified Lobene stain examination on the eight central and lateral incisors (Figure 5) at their first study visit (baseline).[8]

The Lobene stain index measures the intensity and extent of extrinsic dental stain on the facial surface of the anterior teeth. The facial surface of each anterior tooth was divided into two regions. The first is the gingival region which was a crescent-shaped band of the labial surface about 2 mm wide adjacent to the free margin of the gingiva and extending to the crest of the interdental papillae of the adjacent teeth. The second is the body region which constitutes the remainder of the labial surface of the tooth. The gingival and body regions were scored separately. Intensity was scored from 0 (no stain) to 3 (heavy stain; dark brown to black) and extent was scored from 0 (no stain) to 3 (stain covering over two-thirds of the region). Scores were averaged for each subject for intensity (sum of all intensity scores/all sites graded) and extent (sum of all extent scores/all sites graded), and the composite stain score was calculated by multiplying the mean stain intensity by the mean stain extent. Intraoral photographs were taken of the 12 anterior teeth.

Eligible subjects had at least four of eight central and lateral incisors with Lobene stain scores of >1.0. They were stratified on gender and baseline Lobene composite scores (≤2 and >2) and were randomized to one of two treatment groups:

- **Group 1:** Oral-B Vitality Pro White toothbrush plus Crest Cavity Protection dentifrice (Vitality Pro White group)
- **Group 2:** A positive control consisting of a dental prophylaxis followed by use of an ADA reference manual toothbrush with Crest Cavity Protection dentifrice.

Following oral hygiene and toothbrush operation instructions, subjects were supplied with assigned products plus a timer and were required to brush in front of a mirror following their other normal oral hygiene practices (e.g., flossing was not to be altered but the use of chlorhexidene and/or a Listerine® mouth rinse was to be discontinued). Both groups were instructed to brush for 2 minutes twice a day, covering the entire toothbrush head with the study toothpaste each time. Subjects using the power brush (Group 1) received standard instructions for oscillating-rotating power toothbrushes (i.e., slowly guide the brush head from tooth to tooth, first on outside surfaces of teeth then on inside surfaces). Those in the manual group (Group 2) were instructed to brush in their normal manner.

After 2 weeks of brushing, subjects returned for their second study visit. At this visit, subjects had a second Lobene stain examination performed on the same central and lateral incisors that had a Lobene stain score >1.0 at baseline with the same examiner who performed the baseline examination. Intraoral photographs were again taken of the 12 anterior teeth.

Statistical Analysis

Of primary interest in this study was the change in average Lobene composite (intensity x extent) scores from baseline to week #2 for each group. Changes for each treatment group were assessed using paired t-tests. Of secondary interest were changes in average Lobene intensity and extent scores. In addition, score changes between treatment groups were compared using a one-way analysis of covariance (ANCOVA) using the baseline stain score as the covariate. These comparisons were two-sided and used a significance level of $\alpha=0.05$.

Results

A total of 32 subjects were enrolled in the study, and all completed the study except for two subjects who withdrew following the baseline visit because they were unable to meet the study appointments. The demographic data for the 30 subjects who completed the study are shown in Table 1. Twelve of the 15 subjects in Group 1 and all 15 subjects in Group 2 reported they used at least one of the following: coffee, tea, red wine, or tobacco. There was a statistically significant difference between the groups for age ($p=0.0145$).

The mean baseline and week 2 Lobene index scores for both groups as well as the changes from baseline are shown in Table 2.

The decreases from baseline were highly statistically significant ($p<0.001$) for each group and for all Lobene scores (composite, extent, and intensity). There was a statistically significant difference ($p=0.018$) in favor of Group 2 for the Lobene extent score.

The median percentage reductions in stain for the Lobene composite, extent, and intensity scores

Table 1. Baseline demographic characteristics.

	Treatment Groups	
	Vitality Pro White (Group 1)	Prophy/ADA Manual (Group 2)
Sex[1]		
Female	9	10
Male	6	5
Age (years)		
Mean	54.0	44.7
Min-Max	32 - 70	32 - 69

[1] Number of subjects included in analyses

Table 2. Baseline Lobene score and change in baseline Lobene score.

Treatment Group	Baseline (mean ± SD)	2-Week Score (mean ± SD)	Difference from Baseline (adjusted mean ± SE)	Change from Baseline P-value
Lobene Composite Score				
Group 1	2.60 ± 0.41	0.30 ± 0.28	2.21 ± 0.05	p <0.001
Group 2	2.35 ± 0.20	0.14 ± 0.12	2.29 ± 0.05	p <0.001
Lobene Extent Score				
Group 1	2.15 ± 0.12	0.25 ± 0.18	1.86 ± 0.04	p <0.001
Group 2	2.09 ± 0.14	0.14 ± 0.12	1.99 ± 0.04	p <0.001[1]
Lobene Intensity Score				
Group 1	1.20 ± 0.18	0.23 ± 0.18	0.95 ± 0.03	p <0.001
Group 2	1.11 ± 0.11	0.13 ± 0.11	0.99 ± 0.03	p <0.001

Group 1- Vitality Pro White, **Group 2-** Prophy / ADA reference manual brush.
SD- standard deviation
SE- standard error from ANCOVA
[1] Significant group difference in favor of Group 2: p=0.018

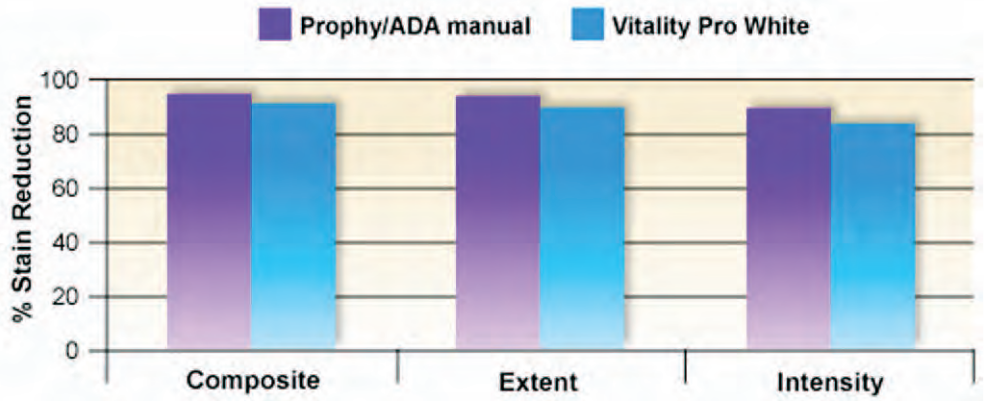

Figure 6. Median percent reduction in Lobene stain score.

were 90.6%, 88.9%, and 83.3%, respectively, for Group 1 and 94.4%, 94.1%, and 88.9%, respectively, for Group 2. These reductions are illustrated in Figure 6. No adverse events were seen in either treatment group.

Discussion

Superficial, extrinsic, tooth discoloration is an esthetic problem rather than a concern for oral health, but patient demand for whiter teeth requires an appropriate response from dental professionals who need to be informed about the relative merits of commercially available products before making recommendations. Proper toothbrushing with dentifrices containing abrasive components (e.g., aluminium oxide, silica) will help to remove stain mechanically, and dentifrices containing chemical agents such as sodium hexametaphosphate are clinically proven to have whitening benefits.[9] The advantages of power toothbrushes over manual brushes for plaque removal and reducing gingivitis are well documented, but less is known about the relative merits of different power brushes for extrinsic stain removal.[10-11] The increasing choice of commercially available models of power toothbrushes is a response not only to the need for continuing to improve plaque removal efficacy and to the promotion of gingival health but also by the need to optimize patient compliance and motivation, which play a crucial role in dental health outcomes.[12] The patient demand for whiter teeth may be an important motivational factor that brings with it benefits for improved oral hygiene in general.

The Vitality series has been developed by Oral-B as an affordable range of rechargeable

toothbrushes. It features the rotation-oscillation technology characteristic of Oral-B power toothbrushes associated with the advanced models offering additional features (e.g., Oral-B Professional Care 7000 series; Oral-B Triumph with SmartGuide).[12] This action, which has been the subject of numerous investigations and of systematic independent reviews, is clinically proven to offer advantages for removing plaque and for reducing gingivitis.[10-11] In common with top of the range models the Vitality series offers as a brush head the Pro White, which features a polishing cup for stain removal at its center; it was this combination (Oral-B Vitality Pro White) that was evaluated in the present study. The polishing cup, which holds toothpaste, works to gently remove stains similar to the action of a professional polish administered during a routine preventive dental visit.

Go to online journal article to view a video on power brushing.

The Lobene stain index has been used to differentiate between the stain removal efficacy of brushes, both in cases where stain is naturally occurring[7] and when stain is induced (using rinses of chlorhexidene and tea).[13] The present 2-week study used the Lobene stain index to assess the stain removal efficacy of the Oral-B Vitality Pro White power brush in one group of subjects (Group 1) and a routine dental prophylaxis followed by use of a standardized ADA reference manual brush (i.e., a positive control group) in a second group of subjects (Group 2). Both groups had visible stain on their anterior teeth at the start of the study and, after 2 weeks of brushing, statistically significant ($p<0.001$) amounts of stain had been removed in both groups (>90% median reduction using Lobene composite scores). There was no group difference in stain reduction ($p>0.l$ in Lobene composite score). Subjects were balanced with respect to baseline stain score which was the primary variable measured in the study as well as gender. Subjects were not balanced on age, and there was a statistically significant difference in age between the two groups. There is no reported relationship between age and extrinsic stain removal and the impact of age on extrinsic stain removal in this study is unknown.

Conclusions

- This 2-week study showed statistically significant ($p<0.001$) and effective naturally occurring stain removal (median reduction >90%), both in subjects who used Oral-B Vitality Pro White and in subjects who received a professional dental prophylaxis followed by use of an ADA manual toothbrush.
- Stain removal with Oral-B Vitality Pro White was not significantly different from stain removal by a professional dental prophylaxis followed by brushing with a standard manual toothbrush.
- Use of Oral-B Vitality Pro White, an entry level rechargeable toothbrush, following a professional dental prophylaxis can help to maintain the tooth color achieved by the prophylaxis.
- Toothbrushing is not intended to replace professional cleaning but with a proper technique the stain removal advantages associated with the Oral-B Vitality Pro White can complement the results achieved through professional cleaning.

Clinical Significance

In this small study Oral-B Vitality Pro White achieved statistically significant stain removal between dental visits.

References

1. Gerlach RW, Gibb RD, Sagel PA. A randomized clinical trial comparing a novel 5.3% hydrogen peroxide whitening strip to 10%, 15%, and 20% carbamide peroxide tray-based bleaching systems. Compend Contin Educ Dent. 2000; 21(Suppl 29):S22-S28.
2. Gerlach RW, Barker ML. Clinical response of three direct-to-consumer whitening products: Strips, paint-on-gel, and dentifrice. Compend Contin Educ Dent. 2003; 24:458-65.
3. American Dental Association. Glossary of dental terms. (http://www.ada.org/public/resources/glossary.asp)
4. American Dental Hygienists' Association. Position paper on the oral prophylaxis. (http://www.adha.org/profissues/prophylaxis.htm)
5. Schemehorn BR, Keil JC. The effect of an oscillating/rotating electric toothbrush and a sonic toothbrush on removal of stain from enamel surfaces. J Clin Dent. 1995; 6:194-7.
6. Terézhalmy G, Stookey GK, Mason S, Bartizek RD, Biesbrock AR. Tooth whitening through the removal of extrinsic stain with a power toothbrush: results of four randomized, examiner blind, positive controlled clinical studies. Am J Dent. 2004; 17:Spec No:18A-24A.
7. Goyal CR, Sharma NC, Qaqish JG, Cugini MA, Thompson MC, Warren PR. Efficacy of a novel brush head in the comparison of two power toothbrushes on removal of plaque and naturally occurring extrinsic stain. J Dent. 2005; 33 Suppl 1:37-43.
8. Lobene RR. Effect of dentifrices on tooth stains with controlled brushing. J Am Dent Assoc. 1968; 77:849-55.
9. Baig A, Tao H, Buisson J, Sagel L, Suszcynsky-Meister E, White DJ. Extrinsic whitening effects of sodium hexametaphosphate – a review including a dentifrice with stabilized stannous fluoride. Compend Contin Educ Dent. 2005; 26(Suppl 1):47-53.
10. Heanue M, Deacon SA, Deery C, Robinson PG, Walmsley AD, Worthington HV, Shaw WC. Manual versus powered toothbrushing for oral health (Cochrane Review). In: The Cochrane Library, Issue 2, 2003. Oxford: Update Software.
11. Robinson PG, Deacon SA, Deery C, Heanue M, Walmsley AD, Worthington HV, Glenny AM, Shaw WC. Manual versus powered toothbrushing for oral health. Cochrane Database Syst Rev. 2005; (1)18:CD002281.
12. Walters PA, Cugini M, Biesbrock AR, Warren PR. A novel oscillating-rotating power toothbrush with SmartguideTM: Designed for enhanced performance and compliance. J Contemp Dent Pract. 2007; 8(4):1-9.
13. Karpinia K, Magnusson I, Biesbrock AR, Walters PA, Bartizek RD. The effectiveness of two different battery-powered toothbrushes on whitening through removal of stain. J Clin Dent. 2002; 13(5):215-8.

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