Randomized Trial of Oscillating-Rotating versus Manual Brush after Hypersensitivity Treatment Response

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Abbreviations: DH, dentinal hypersensitivity; O-R, oscillating-rotating; VAS, visual analog scale

Knowledge Transfer Statement (75/75 words)

This practice-based research study may guide recommendations on toothbrush options for patients with dentinal hypersensitivity who undergo in-office oxalate treatment. The data suggest that patients who are currently using an electric brush need not be transitioned over to a manual toothbrush to preserve the benefits of in-office treatment. In addition, patients with dentinal hypersensitivity who currently use a manual brush may be encouraged to change to an oscillating-rotating electric brush after in-office treatment, when practical.

Abstract (283/300 words)

Introduction: Few studies are available to guide practitioners when advising patients about toothbrush use after professional, in-office oxalate treatment for dentinal hypersensitivity.

Objectives: This randomized, controlled, double-blind study conducted in adult patients with dentinal hypersensitivity (DH) compared the effects of using an oscillating-rotating (O-R) electric toothbrush versus a manual toothbrush for 30 days after an in-office oxalate/potassium salt solution treatment, with at-home use of stannous fluoride dentifrice.

Methods: Twenty-four adults with ≥1 tooth with DH, as assessed using the air blast challenge, were eligible. The visual analog scale (VAS) and the Schiff Index were the two primary outcome measures. After baseline measurements, all subjects received treatment with a 3% oxalate/ potassium salt solution (Super Seal® Desensitizer) on up to two teeth. Subjects were randomized 1:1 to a soft manual toothbrush (Oral-B® CrossAction Pro-Health) or an O-R electric toothbrush (Oral-B® Professional Care 4000 toothbrush). All subjects received 0.454% bioavailable stannous fluoride dentifrice (Crest®). Subjects used the toothbrush and dentifrice in place of their normal oral hygiene routine for 30 days. VAS and Schiff assessments were completed at baseline, after in-office oxalate/potassium salt solution treatment, and at day 30.

Results: Oxalate treatment immediately reduced DH by 28% (mean Schiff score) and 32% (mean VAS score). By day 30, O-R electric toothbrush users still exhibited a significantly lower mean Schiff score relative to baseline, while manual toothbrush users did not. Both groups exhibited significantly lower mean VAS scores at day 30 relative to baseline; however, the mean VAS score was significantly lower for O-R brush users than for manual brush users.

Conclusion: Use of an O-R electric toothbrush over 30 days improved DH responses to a professionally applied oxalate/potassium salt solution treatment.

Introduction

Dentinal hypersensitivity is characterized by the perception of short, sharp pain from exposed dentin in response to thermal, evaporative, tactile, osmotic, or chemical stimuli (CABDH 2003). It is a widespread clinical problem, affecting approximately 12% to 30% of the adult population in the United States (Favaro Zeola et al. 2019). While the complex pathophysiology of dentinal hypersensitivity is not fully elucidated, the most widely accepted model is based on hydrodynamic theory. The theory posits that, in healthy teeth, fluid flow in dentin tubules changes in response to desiccation, temperature, or osmotic balance fluctuations, resulting in nociceptor activation in the pulp/dentin border area (Gholampour and Jalali 2018; Oskui et al. 2014). Nociceptor activation is then perceived as painful (Lee et al. 2019; Sato et al. 2018). Changes to dentin microtubule structure may play a role in the etiology of dentinal hypersensitivity. Scanning electron micrograph studies have shown that hypersensitive teeth have about 8 times the number of tubules per unit area than non-sensitive teeth, and that tubule diameters are about twice as wide in hypersensitive teeth than in non-sensitive teeth (Absi et al. 1987; Rimondini et al. 1995).

Based on these data, a key strategy for the treatment of dentinal hypersensitivity is the use of agents to promote occlusion of the dentin tubules (West et al. 2013). For example, a variety of oxalate preparations promote the deposition of oxalate crystals in exposed dentinal tubules (Cuenin et al. 1991; Oberg et al. 2009), significantly reducing the dentinal fluid flow rate (Kim et al. 2013). Professionally applied oxalate preparations have been shown to be effective desensitizing agents with rapid-onset action that may last for several weeks to several months after application (Anderson et al. 2018; Osmari et al. 2018; Sharma et al. 2013). The durability of the desensitization produced by professional treatment with oxalate preparations can be explained by the relative resistance of oxalate crystal deposits in dentinal tubules to dissolution by salivation, brushing, dentifrices, and acids (Pillon et al. 2004; Sharma et al. 2013; Varoni et al. 2017).

The effects of at-home, real-world oral hygiene strategies upon the durability of the clinically relevant desensitization seen after professional and/or at-home sensitivity treatment are not well understood. In particular, the effects of toothbrush type upon the durability of desensitization treatments have not been thoroughly investigated. In general practice, many professionals recommend that patients select an electric toothbrush due to demonstrable oral health benefits over manual brushing (Grender et al. 2013; Van der Weijden and Slot 2015). For example, a Cochrane review and meta-analysis found that electric toothbrush use results in an 11% reduction in plaque in the short term and 21% reduction in the long term, as well as a 6% to 11% reduction in gingivitis, as compared with manual toothbrush use (Yaacob et al. 2014). A large, 11-year study in Germany found that electric toothbrush users had significantly lower mean probing depth, significantly fewer mean clinical attachment loss progressions, and almost 20% more teeth retained than did manual toothbrush users (Pitchika et al. 2019). Despite these findings, there is a misperception among some dental professionals that electric toothbrushes are more aggressive than manual toothbrushes and should be avoided by patients undergoing treatment for dentinal hypersensitivity. This perception exists despite a body of research showing that electric toothbrush use does not produce a greater amount of gingival recession than manual toothbrush use (Dorfer et al. 2016; Rosema et al. 2014; Van der Weijden et al. 2011). Some preliminary data also indicate that electric toothbrush use may actually reduce dentinal hypersensitivity, possibly by the need for less force to remove plaque than a manual brush as well as through the production of a tubule-occluding smear layer (Hefti and Stone 2000; Sehmi and Olley 2015). Still, few studies are available to guide dental professionals when advising patients about toothbrush use after professional oxalate treatment for dentinal hypersensitivity. To address this question, the current study compared the effects upon dentinal hypersensitivity of regular at-home use of an oscillating-rotating (O-R) electric toothbrush versus a manual toothbrush for 30 days after a professionally applied oxalate/potassium salt solution treatment in adult patients recruited from a real-world dental practice.

Materials and Methods

Study Objective and Ethical Compliance

The objective of this randomized, controlled, double-blind study conducted in adult patients with dentinal hypersensitivity was to compare the effects of regular at-home use of an O-R electric toothbrush versus a manual toothbrush for 30 days after a professionally applied oxalate/potassium salt solution treatment, with at-home use of a stannous fluoride dentifrice. Institutional review and approval were obtained from Schulman Associates IRB (NEED NUMBER). After institutional review, subjects were recruited in MONTH YEAR from a general dental practice (Fresno, California, USA). All subjects provided written, informed consent. The study was conducted in compliance with the International Conference on Harmonization's Good Clinical Practice Consolidated Guidelines and with the Declaration of Helsinki, and it was registered with clinicaltrials.gov prior to the start of the study (NCT02513212).

Subjects

Only generally healthy adults 18 years of age or older with at least one tooth with a positive dental hypersensitivity response were eligible for this study. Subjects were ineligble if they were pregnant or nursing, had severe periodontal disease, or were undergoing active treatment for periodontitis. Enrolled subjects were required to refrain from dental prophylaxis or any elective dentistry during the study period.

Assessment of Dentinal Hypersensitivity

Dentinal hypersensitivity was assessed using the air blast challenge, in which a one-second application of air from a standard dental unit syringe is delivered onto a single target tooth. The air blast challenge is perceived as painful for subjects with dentinal hypersensitivity (Meier et al. 2012). The visual analog scale (VAS) and the Schiff Index were the two primary outcome measures in this study and were given in response to the air blast challenge. For each tooth tested, the examiner recorded a score on the Schiff scale (Table 1) (Schiff et al. 2009). Following assignment of the Schiff score, the examiner asked the subject to look at a VAS on a tablet device and to click on the appropriate level of pain experienced, with 0 meaning "no pain at all", and 100 meaning "the worst tooth pain ever before experienced".

Interventions and Outcomes

This was a randomized, controlled, double-blind study comprised of two study visits: Screening/Baseline/Oxalate Treatment (Visit 1) and Day 30 Follow Up (Visit 2). During Visit 1, subjects gave written informed consent, and then were screened for study eligibility, personal health history, and demographic information. Each subject received a comprehensive clinical examination of the oral and perioral regions, including the hard and soft tissues. After the examination, the air blast challenge was conducted. For each subject, the examiner identified up to two target teeth in different quadrants that displayed dentinal sensitivity, defined as a Schiff score of ≥ 1. Subject-identified VAS scores were also recorded after each air blast challenge. These Schiff scores and VAS scores were identified as the baseline values. Upon completion of the air blast challenge, each subject received treatment with a marketed 3% oxalate/potassium salt solution (Super Seal® Desensitizer, Phoenix Dental, Inc., Fenton, Michigan) on up to two identified target teeth. The oxalate/potassium salt solution was professionally applied by the examiner according to the manufacturer's instructions for use. Immediately thereafter, the examiner performed the air blast challenge to the treated teeth, followed by subject self-assessment of pain using the VAS and examiner's assessment of clinical sensitivity using the Schiff Index.

Stratification was conducted using baseline Schiff score, baseline VAS score, age, and sex. Within strata, subjects were randomly assigned to one of two groups using block randomization via an encoded program supplied by the study sponsor. Subjects received a kit box corresponding to their randomly assigned group; all kit boxes had a unique number used for assignment. Kit box products were overlabeled for blinding and were provided by The Procter & Gamble Co., Cincinnati, OH, USA. The blinded kit boxes all contained 0.454% bioavailable stannous fluoride dentifrice (Crest® Sensi Prevent and Repair Paste) plus a manual or electric brush. Subjects randomized to the manual toothbrush group received a soft toothbrush (Oral-B® CrossAction Pro-Health) in their kit box. Subjects randomized to the O-R electric brush group received an Oral-B® Professional Care Healthy Clean + ProWhite Precision 4000 (D29/EB18) toothbrush in their kit box. Subjects were told to use the test products (toothbrush and toothpaste) in place of their normal oral hygiene routine.

Study Visit 2 occurred on Day 30, and included a comprehensive oral examination to evaluate the oral and perioral region, including hard and soft tissues. The air blast challenge was then performed to the teeth that had been treated at Visit 1. Subjects self-assessed the level of pain using the VAS, and the examiner assessed clinical sensitivity using the Schiff Index. Adverse events were assessed during the examination and via interview.

Statistical Analysis

Sample size calculations show that 12 subjects per group yields 85% power to detect a mean change from baseline for the dentinal hypersensitivity assessments using two-sided testing at 5% significance levels. This estimate assumes the effect size (mean treatment difference divided by the standard deviation) is approximately 0.64 or higher.

Standard summary statistics of the demographic data and safety data were performed by group and overall. Sensitivity scores were averaged amongst target teeth for each subject at baseline, after professional oxalate treatment, and at Visit 2 (Day 30). The treatment groups were compared, and the mean difference was estimated using a non-parametric analysis of covariance with baseline as a covariate. Changes versus baseline were tested using a non-parametric Wilcoxon Signed Rank Test. Additionally, a repeated measures model was used to analyze the differences between visits within each treatment group. Statistical comparisons were two-sided using a 5% significance level.

Results

Baseline Demographics

A total of XX subjects were assessed for study eligibility. Of these, XX were excluded for not meeting inclusion criteria and XX declined to participate. A total of 24 subjects (92% female) were enrolled and randomized 1:1 between groups. The mean (SD) age was 44.6 (12.4) years. There were no significant differences in age and sex between groups (Table 2). Of the 24 subjects, 23 completed the study; one subject in the manual toothbrush group withdrew from the study before the Day 30 evaluation for personal reasons unrelated to the study treatment. [is this right?]

Hypersensitivity Response to Professional Oxalate Treatment

The overall baseline mean (SD) Schiff score was 2.4 (0.7) and overall baseline mean (SD) VAS score was 57.9 (17.0). After professional, in-office treatment with the oxalate/ potassium salt solution (Table 3), the overall mean (SD) Schiff score decreased to 1.7 (0.99), a 28% reduction ($p<0.001$), and the overall mean (SD) VAS score decreased to 39.1 (25.7), a 32% reduction from baseline ($p<0.0001$).

Schiff Scores and VAS Scores at Day 30

In order to determine whether manual versus O-R electric toothbrush brushing over 30 days had differing effects on dentinal hypersensitivity after a professional oxalate/potassium salt solution treatment, Schiff scores and VAS scores were assessed at Visit 2/Day 30. At that timepoint, only the electric toothbrush group exhibited a significantly lower mean Schiff score relative to baseline (*p*=0.0078). The manual toothbrush group did not exhibit a significant (*p*=0.1250) difference in mean Schiff score relative to baseline (Table 4). The between-group analysis found that there was no significant difference (*p*=0.1075) in median Schiff score between the groups at Day 30 (Table 5). For the VAS scores, both groups exhibited significantly ($p \leq 0.03$) lower mean scores relative to baseline at Day 30 (Table 4). However, the between-group analysis revealed that the median VAS score was significantly lower (*p*=0.0059) in the electric toothbrush group than in the manual toothbrush group (Table 5).

Safety

The study regimens were well-tolerated, and no patients discontinued the study due to adverse events.

Discussion

In over 150 clinical studies, O-R electric toothbrushes have been compared to manual toothbrushes for plaque and gingivitis reduction, with several systematic reviews/meta-analysesconfirming their statistically significantly improved efficacy (Grender et al. 2020; Van der Weijden and Slot 2015; Yaacob et al. 2014). In addition, O-R electric toothbrushes have also been found to have statistically significantly improved efficacy compared to marketed sonic electric toothbrushes (Grender et al. 2020; Van der Weijden and Slot 2015). Guided by these data, practitioners often recommend electric toothbrushes to patients in general practice. However, there have been a paucity of data to guide practitioners in what type of brush to recommend to the subset of patients with dentinal hypersensitivity who undergo in-office desensitizing treatment.

In this randomized, controlled, double-blind, practice-based study conducted in adult patients with dentinal hypersensitivity, we have demonstrated that 30 days of use of an O-R electric toothbrush versus a manual toothbrush improved dentinal hypersensitivity responses to a professionally applied oxalate/potassium salt solution treatment plus at-home care with a stannous fluoride dentifrice. As is consistent with previous studies (Camilotti et al. 2012; Camps and Pashley 2003; Osmari et al. 2018; Pillon et al. 2004), the in-office oxalate/potassium salt solution treatment in this study reduced dentinal hypersensitivity immediately by 28% as assessed by mean Schiff index score and by 32% as assessed by mean VAS score. Interestingly, by Day 30 only the electric toothbrush group still exhibited a significantly lower mean Schiff score relative to baseline. While both groups exhibited significantly lower mean VAS scores relative to baseline, the between-group analysis at Day 30 revealed that the mean VAS score was significantly lower in the O-R electric toothbrush group than in the manual toothbrush group.

The results of this study may be surprising to some practitioners, given the possible perception that electric toothbrushes are more "aggressive" than manual toothbrushes. In fact, aggressive tooth brushing with any type of toothbrush has been implicated in the etiology of dentinal hypersensitivity by increasing the risk for gingival recession, which leaves dentinal tubules exposed. For that reason, it may be that tooth brushing force itself is an important consideration in the management of dentin hypersensitivity. One of the factors that weighs heavily into the amount of toothbrushing force exerted is the type of brush that is used. Studies that have measured the force used by people in the general population who have not received any training in tooth brushing technique reveal that manual brush users exert a force between 2 N and 4 N to each tooth (Boyd et al. 1997; Ganss et al. 2009). In contrast, untrained users of O-R electric toothbrushes exert a force of about 1.50 N to each tooth (van der Weijden et al. 1996). Moreover, advanced O-R models contain a pressure sensor that signals the user and reduces the brush speed if too much force is applied during brushing. These data are consistent with our finding that use of an O-R electric brush versus a manual brush improved dentinal hypersensitivity responses at Day 30 after tubule-occluding treatment with professionally applied oxalate/potassium salt solution plus at-home use of stannous fluoride dentifrice. While further studies may help elucidate the precise mechanism of action, the current study provides real-world, practical guidance for dental professionals that it is not necessary to transition patients with dentinal hypersensitivity over to a manual toothbrush if they are currently using an electric brush. Further, it is worth considering a recommendation that patients with dentinal hypersensitivity who are currently using a manual brush could be encouraged to change to an O-R electric brush.

While this study benefitted from the real-world setting of a general dentistry practice, it was limited by enrollment to comparing the use of a single type of O-R electric toothbrush with the use of a manual toothbrush. Further studies to address the effects of other manual and electric toothbrush designs upon dentinal hypersensitivity after professional oxalate treatment will be needed to determine if our results are applicable or limited to the manual and O-R electric toothbrushes evaluated in this study. Another limitation of the study design is that it is impossible to pinpoint the contributions of professional oxalate treatment versus the contributions of the at-home stannous fluoride treatment toward the improved Schiff index and VAS scores at Day 30. When present in dentifrice, stannous fluoride has been found to effectively occlude dentinal tubules by forming a smear layer across the tubule orifice (Earl and Langford 2013). Regular at-home use of stannous fluoride dentifrice has been associated with significant reductions in dentinal hypersensitivity when compared with regular use of control dentifrice (He et al. 2014; He et al. 2017; Hines et al. 2019). Still, because all of the patients in the study received the same in-office oxalate treatment and used the same, controlled stannous fluoride dentifrice at home, the results of the comparison between the O-R electric toothbrush and the manual toothbrush are still useful to guide treatment decisions in everyday practice.

Conclusion

In this practice-based research study conducted in adults with dentinal hypersensitivity, use of an O-R electric toothbrush versus a manual toothbrush over 30 days at home improved dentinal hypersensitivity responses to a professionally applied oxalate/potassium salt solution treatment plus at-home care with a stannous fluoride dentifrice. These data can help inform dental healthcare professionals as they advise patients with dentinal hypersensitivity on at-home oral hygiene regimen options. The data provide confirmation that patients with dentinal hypersensitivity who are currently using an O-R electric brush need not be transitioned over to a manual toothbrush in order to preserve the benefits of in-office desensitizing treatment. In addition, patients with dentinal hypersensitivity who are currently using a manual brush may be encouraged to change to an O-R electric brush after in-office desensitizing treatment, when practical.

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Declaration of Conflicting Interests

CJA has received honoraria from The Procter & Gamble Company and was contracted by The Procter & Gamble Company to perform the research. RG is an employee of The Procter & Gamble Company. GK and MF have nothing to disclose.

Table 1. The Schiff Index Sensitivity Scale

Score	Criteria
0	Subject does not respond to stimulus
1	Subject responds to stimulus, but does not request discontinuation of stimulus
2	Subject responds to stimulus, and requests discontinuation of stimulus or moves away from stimulus
3	Subject responds to stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus

Table 2. Baseline Demographics

Demographic/ Statistic or Category	Manual Brush	Electric Brush	Overall	P-value
Age (Years)				
Mean (SD)	42.6 (14.7)	46.7 (9.6)	44.6 (12.4)	0.4305[a]
Min. - Max.	21 - 67	23 - 60	21 - 67	
Sex				
Female	10 (83%)	12 (100%)	22 (92%)	0.1396[b]
Male	2 (17%)	0 (0%)	2 (8%)	

[a] Two-sided ANOVA *p*-value for the treatment comparison
[b] Two-sided chi-square *p*-value for the treatment comparison

Table 3. Schiff Air Index scores and Visual Analog Scale scores at baseline and immediately post professional treatment (PPT) with a 3% oxalate/potassium salt solution

Treatment	N	Mean (SD) Baseline Score	PPT Mean (SD) Change from Baseline	PPT Mean Percent Change from Baseline	P-value[a]
Overall Schiff Air Index score	24	2.4 (0.7)	-0.67 (0.8)	27.9%	<0.001
Overall Visual Analog Scale score	24	57.9 (17.0)	-18.8 (20.3)	32.5%	<0.0001

[a] Comparison versus baseline (2-sided non-parametric Wilcoxon Signed Rank Test)

Table 4. Mean change from baseline for Schiff Air Index scores and Visual Analog Scale scores at Visit 2/Day 30

Endpoint	Group	N	Mean (SD) Change from Baseline at Day 30	P-value (Day 30 vs. Baseline)[a]
Schiff Air Index Score	Manual toothbrush	11	-0.41 (0.7)	0.1250
Schiff Air Index Score	Electric toothbrush	12	-0.92 (0.7)	0.0078
Visual Analog Scale Score	Manual toothbrush	11	-11.0 (12.9)	0.0322
Visual Analog Scale Score	Electric toothbrush	12	-28.5 (21.1)	0.0005

[a] Comparison versus baseline (2-sided non-parametric Wilcoxon Signed Rank Test)

Table 5. Between-group comparison at Day 30 for Schiff Air Index scores and Visual Analog Scale scores

Treatment	N	Median value at Day 30	P-value[a]
Schiff Air Index Score			
Manual toothbrush	11	2.0	0.1075
Electric toothbrush	12	1.0	
Visual Analog Scale Score			
Manual toothbrush	11	53.0	0.0059
Electric toothbrush	12	23.5	

[a] Comparison between groups at Day 30 (2-sided Non-Parametric Analysis of Covariance Summary

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