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Penetration of Fluids into Periodontal Pockets Using a Powered Toothbrush/Irrigator Device

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Abstract

This study was a single-blind, randomized, controlled clinical trial. The researchers evaluated a powered brush/irrigating device (HydraBrush Oral Health System™; OHS) for its safety and ability to deliver a solution to the bottom of 5-6 mm pockets, compared to rinsing alone with a solution following brushing with a powered toothbrush (Sonicare Elite™ 7800; SE). An evaluation technique to measure the quantity and quality of solution able to enter the pocket was also introduced in this project.

Methods: Subjects were randomized in one of two-groups: brush plus simultaneous irrigation (OHS) versus brush plus rinsing (SE). Subjects used their devices at home for two weeks. At the measurement visit, subjects used the OHS to irrigate and brush simultaneously for 1 minute (30 seconds per each side of the mouth) with a 0.01% erythrosine disclosing solution in 10 oz of distilled water. Control subjects brushed for 2 minutes with a SE followed by a 1 minute rinse with an identical disclosing solution. A blinded evaluator collected six samples of approximately of 1 µL of sucular fluid from six 5-6 mm evaluation sites. This was accomplished by inserting a microcapillary tip with a 20 µL micropipette in the sulcus. Two-group repeated measures ANOVA was used to examine differences in two measures of the disclosing solution between OHS and SE subjects; the spectrometer reading of the disclosing solutions, and by visual inspection of the samples (positive/negative) to determine the presence or absence of solution in the samples. Subjects' diaries were collected. Bleeding and discomfort during the evaluation period was reported.

Introduction

Periodontal therapy patients with 5-6 mm pockets could possibly be maintained if they are able to clean to the base of the periodontal pockets. The use of chemotherapeutic liquids should offer promise in managing these conditions; however, their use has been limited due to the lack of a home care armamentarium to predictably deliver these agents to the depths of the periodontal pockets.[1] Studies have shown sulcus penetration of fluids by mouth rinsing alone is less than 2mm.[1-3]

Oral irrigators may have the potential to deliver liquids more efficiently than rinsing. Yet, studies conducted on oral irrigators concluded pockets great3.30 0 npene10 0 0 10 135.8067 360 Tm-0.01

teeth. Thus, it is possible there is a relationship between plaque and calculus removal and the successful irrigation of periodontal pockets. While powered toothbrushes have proven to be efficient in removing dental plaque[12-15], their use in conjunction with oral irrigation has not been tested as a method of improving sulcus penetration.

Various protocols have been established to evaluate the effectiveness of sulcular irrigation techniques. Published techniques include application of irrigation solutions containing disclosing dyes applied prior to tooth extraction, then measuring the stained tooth surfaces extra-orally.[2, 3, 6-8] Wunderlich[1] applied a fluorescent irrigating solution and then used photographs to measure the penetration of the solution into the pocket. While these techniques allow for accurate measure of sulcular penetration, none measure the volume and quality of the solution penetrating into the periodontal pocket.

The current study had three goals: 1) to compare a powered brush/irrigating device to rinsing with a solution following brushing with a powered toothbrush, 2) to evaluate the safety and adaptability of the patients to these devices and, 3) to introduce a new technique designed for efficient collection of samples from the base of the sulcus.

The first goal was to evaluate a powered brush/irrigating device (HydraBrush Oral Health System™ Oralbotics, Inc. Escondido, CA) for its ability to deliver a solution to the bottom of 5-6 mm pockets, compared to rinsing with a solution following brushing with a powered toothbrush (Sonicare Elite™ 7800 Philips Oral Healthcare, Inc. Snoqualmie, WA). The hypothesis in the present study was using an experimental device, the bristles of the unit may deflect the gingival tissue, allowing simultaneous improved irrigation of a solution into the periodontal pockets. The control protocol for this study was selected because the Sonicare Elite has been shown in laboratory studies to remove plaque up to 3 mm beyond its bristle tips[12,13] and up to 1 mm subgingivally in a clinical study.[14] Therefore, the investigators are of the opinion the effectiveness of this toothbrush at removing subgingival plaque may allow a deeper penetration of a rinsing solution.

Table 1. Inclusions and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
1. Ability to understand and provide informed consent. 2. General good health. 3. Male and female adults, ages 21 to 75, inclusive. 4. Availability to participate for the full duration of the study. 5. A minimum of twenty natural teeth. 6. Six periodontal pockets of not less than 5-6 mm depth with a minimum of 1 site * 6 mm of attachment loss on each side of the mouth. 7. Ability to comply with all study requirements.	1. Presence of any orthodontic appliances or severe malocclusion. 2. Soft or hard tissue tumors of the oral cavity. 3. Presence of extensive caries. 4. Acute periodontal disease characterized by the presence of pain, purulent exudate, or severe tooth mobility requiring immediate treatment intervention. 5. History of rheumatic fever, valvular heart disease, or any condition requiring premedication to prevent endocarditis. 6. Subjects with diabetes, hemophilia, or any other medical conditions requiring medical support and/or drug therapy that may interfere with the parameters being investigated. 7. Involvement in any concurrent study, the nature of which may affect the parameters being investigated in this study. 8. Use of any medications that significantly affect the flow of saliva or previous oral or maxillofacial radiation that might have affected salivation. 9. Heavy supra- and sub-gingival calculus.

Figure 1. Control powered toothbrush. Sonicare Elite 7800.

Figure 2. Experimental device: Hydrabrush Oral Health System

Figure 3. Oral Health System placed on one side of the mouth. Upper and lower quadrants are being brushed and irrigated simultaneously.

Secondly, the safety of the devices was evaluated by giving the subjects a diary in which to document any bleeding and discomfort, during the two weeks of this study. Finally, a new technique designed for efficient collection of samples from the base of the sulcus was introduced. The quantity and quality of penetration of the dye solution into periodontal pockets was evaluated by extracting the applied solution with the tip of a micropipette, and analyzing its color concentration.

Methods and Materials

After receiving Institutional Review Board approval, subjects were recruited from patients who came to the Department of Dental Hygiene and Periodontology for routine oral examinations. Potential subjects were invited to participate, and asked to sign an informed consent. Calibrated examiners conducted medical history, all oral tissue examinations, and probing depth measurements. Probing depth (measured from the gingival margin to the apical extent of the probable sulcus/pocket) was determined to the nearest millimeter using a manual Hu-Friedy PQOW periodontal probe with Williams' markings using normal probing force (20-30gms). Each evaluated tooth was assessed on six surfaces (mesiolingual, lingual, distolingual, distofacial, facial, and mesiofacial). Those who satisfied the inclusion/exclusion criteria were recruited into the study (Table 1).

Thirty subjects (17 females, 13 males, between the ages of 30 to 71, mean age 48.8) who met the above criteria were enrolled into the study. These subjects were assigned randomly to an experimental or control group.

At the first appointment, following randomization, the subjects were given their oral care device and received instructions on the brushing technique, according to the manufacturer's directions. The control group received a Sonicare Elite™ 7800 (SE) (Figure 1) and the experimental group received the HydraBrush Oral Health System™ (OHS). (Figure 2)

In the experimental group, subjects were advised to brush and irrigate their teeth simultaneously for 30 seconds on each side of the mouth, (each side has two quadrants) for a total of 1 minute using a timer (Figure 3).

In order to reduce potential soft tissue damage, two types of brush heads were used in this group, an extra soft and a soft. During the first or introductory week of the study, the subjects used a brush head with extra soft bristles for one minute; they changed to the soft brush head in the second week.

The control group was instructed to brush their teeth for a total of two minutes, as directed by the manufacturer, 30 seconds per quadrant, using the timer apparatus in the control toothbrush. The Sonicare Elite™ 7800 has a dual speed control (low and high). In order for the subjects to get used to the toothbrush, they brushed their teeth on low speed for the first week and on high speed during the second week.

Subjects were advised to use their assigned oral care devices twice daily, in the morning and before bedtime, in accordance with the manufacturers' directions. The subjects were requested to utilize only the dentifrice provided (Crest® Regular, Procter & Gamble, Cincinnati, OH).

In order to evaluate subjects' tolerance to their power toothbrushes, the subjects received a diary, and they were asked to record 'Yes' or 'No', if they experienced any bleeding, or discomfort while brushing with their powered devices. They were also asked to record the times and dates of brush usage in their diary (Table 2). They were asked to refrain from using any other oral hygiene products during the study, for example, dental floss, interdental stimulators, toothpicks, other toothpastes, other toothbrushes, anti-plaque mouthrinse, anti-plaque chewing gum, oral cosmetic preparations (tooth whitening products), or water irrigation devices (such as Water PIK™). There were no restrictions with regard to smoking or dietary habits. Subjects were informed the diaries had to be returned at the end of the examination.

Table 2. Sample of subjects' brushing diary for the first three days of the 14 day total.

Subject Initials:	First Day	Second Day	Third Day etc.
Directions for Use: *Record day and time when you brush your teeth	Date: Brushing time: AM: PM:	Date: Brushing time: AM: PM:	Date: Brushing time: AM: PM:
* Record if you have any bleeding when you brushed	Bleeding: Yes ____ No ____	Bleeding: Yes ____ No ____	Bleeding: Yes ____ No ____
* Record if you have any discomfort while brushing	Discomfort: Yes ____ No ____	Discomfort: Yes ____ No ____	Discomfort: Yes ____ No ____
Note: Do not use any oral rinses or different toothpaste than the recommended during the study.	Comments:	Comments:	Comments:

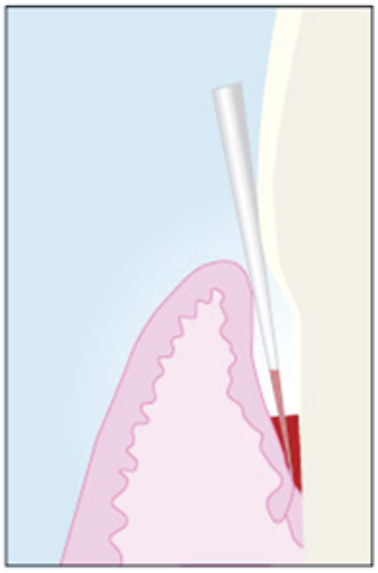

Figure 4. Micro capillary tip penetrating into the depth of the 5-6 mm pocket.

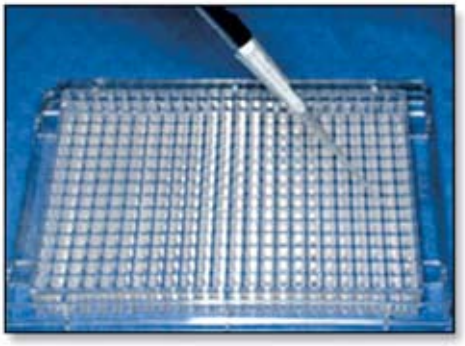

Figure 5. Sample placed in a 384 multi-well plate containing five microliters of water in each well.

After two weeks, all subjects returned to the clinical facility with their toothbrush. At that time, an examiner, blinded to case control status, performed clinical examination with mouth mirror and digital palpation. The lips, tongue, hard and soft palate, oro-pharynx, uvula, gingiva, mucobuccal folds, buccal mucosa, sublingual space, floor of the mouth, and teeth were assessed and reported by the examiner as normal or abnormal. Any reports of irritation, as well as any tissue changes observed during these examinations were recorded. Diaries were collected.

After the completion of the soft tissue examination, the examiner left the room while the subject brushed his/her teeth. This procedure was done so the examiner would have no knowledge of the patients' routine at the time the samples were taken.

Control subjects were asked to brush their teeth with the powered toothbrush for two minutes. After the subjects finished brushing, they were asked to rinse for one minute with .01% disclosing solution (20 drops). After the subjects finished rinsing, the examiner, who was blind to the study treatment, collected samples of approximately 1 microliter of sucular fluid from each of the evaluation sites. The examiner gently inserted a microcapillary tip in a 20 µL micropipette into the bottom of the periodontal pocket (Figure 4). In order to avoid collecting more superficial solution around gingival margin, a positive pressure was maintained on the tip until it reached the bottom of the pocket. Once the sample was collected, the tip of the micropipette was placed against a white paper filter as background and evaluated as negative or positive for dye. If the sample was positive (reddish colored solution in the apex of the micropipette), the sample was placed in a multiwell plate containing five microliters of water in each well (Figure 5).

Up to six samples were collected from each subject. The solutions in the plate were then placed into a plate reader for measuring of the concentration of disclosing solution retrieved from the base of the pocket, based upon color.

With subjects using the experimental device, .01% of disclosing solution (40 drops) and 10 ounces of distilled water were added to the irrigator receptacle. The subjects in this group were asked to brush their teeth and activate the water jets of the experimental device for one minute, 30 seconds per each side of the mouth. After they had finished brushing and irrigating, the samples from the base of the pockets of the designated sites were taken in the same manner as in the controls.

Laboratory Procedure

The optical densities of the samples were read at 530 nm using a spectrophotometer (FL600 Micro plate Fluorescence Reader KC 4. Bio-Tek Instruments, Inc. Vinooski, VA), capable of reading individual wells on a 384 well plate.

Statistical Analyses

For any sample visually evaluated as having no solution, the sample was not pipetted into the wells for spectrophotometer readings and, thus, no spectrophotometer data was determined for those negative samples (24% of the experimental samples, and 54% of the control samples).

Two-group repeated measures analysis of variance (ANOVA) was used to examine differences in two different measures of the disclosing solution between subjects using the Hydrabrush Oral Health System™ and subjects using the Sonicare™ toothbrush: the spectrometer reading of the disclosing solution, and an investigator's visual evaluation (positive/negative) as to whether the disclosing solution was present in the sample. Performing a repeated measures ANOVA is similar to performing a GEE model with repeated measures when the outcome is a dichotomous variable.[20-21] For each outcome measured, the subject was nested within the brush type and considered a random effect in the model. Brush type was included in the model and was considered a fixed effect. The F-test for brush type used the error term for subject nested within brush type as the denominator in the F-statistic. Statistical significance was assessed at an alpha level of 0.05 using SAS 8.2.

Examination of differences in periodontal disease, between the brush type groups, measured by initial pocket depth, was performed using repeated measures ANOVA. Bleeding and discomfort were evaluated at baseline and at follow-up during the two weeks of the evaluation. The assessment of complications reported by the patients was either positive (Yes) or negative (No) as to whether or not they experienced some type of adverse effect while brushing. A two-group repeated measures analysis of variance test was used to examine changes in bleeding, and discomfort across time between the two brush types. Statistical significance was assessed at an alpha level of 0.05. A Bonferroni correction to the alpha level was used to perform post hoc multiple comparisons.

Results

All patients completed and complied with the study protocol. Penetration of disclosing solution to the base of the 5-6 mm pockets was found 76% of time (65 out of 86 periodontal pockets) in the experimental group, and 46% of time (41 out of 89) in the control group. Thus, the experimental device had a significantly greater proportion of positive sites than the control (p=0.0001). The spectrophotometer was used to evaluate the intensity of the disclosing solution in the pocket. There was no statistical difference in intensity of the solution between the two groups among those for which the visual test was positive. (p=0.14) (Table. 3)

At the recall appointment, no severe adverse reactions were reported by any of the examiners for either of the devices.

Table 4 describes the differences in their initial probing depths. There were no statistically significant differences in initial probing depths between the two groups (p= 0.65). Table 4 also describes differences in the type of adverse reaction (bleeding, discomfort) across time and between the two brush types the subjects recorded in their diary while brushing.

Differences in bleeding and discomfort were observed between the two groups. In relation to bleeding, a significant interaction between time and brush type was observed. This indicated the effect of brush type across time on bleeding was different. The experimental group had significantly lower rates of bleeding at follow-up than at baseline (p=0.002, post-hoc analysis), while rates of bleeding in the control group remained similar (p=1.00, post-hoc analysis). Within the time period, the experimental group had significantly higher rates of bleeding at baseline (p<0.0001, post-hoc analysis). Rates of bleeding at follow-up were not different between the experimental and control groups (p=0.26, post-hoc analysis).

For discomfort, a significant interaction between brush type and time was not detected. Neither the experimental nor control groups had significantly lower rates of discomfort at follow-up than at baseline. Within the time period, the experimental group had significantly higher rates of discomfort than the control group at baseline (p=0.0087 post-hoc analysis) but not at follow-up (p=0.27, post-hoc analysis).

Table 3. Two-group repeated measures ANOVA results for mean spectrometer reading and visibility of the presence or absence of disclosing solution between brush types.

Outcome	Variable	Mean	SE	F-Value	P-Value
Spectrometer Reading	Subject (Brush Type)			3.74	0.0001
	Brush Type			2.35	0.1359
	HyrdraBrush	0.6599	0.0155		
	Sonicare	0.6229	0.0203		
Visibility of Solution	Subject (Brush Type)			0.77	0.7878
	Brush Type			21.31	0.1359
	HydraBrush	0.7556	0.0453		
	Sonicare	0.4622	0.0445		

Discussion

A pilot study was initiated to verify some clinical aspects of the evaluation of the toothbrushes used, and to see whether or not it would be feasible to visualize and read the samples of erythrosine extracted from the periodontal pockets in the spectrophotometer.

The amount of disclosing solution (10 ounces by 40 drops of 0.01% of erythrosine) was selected because the reservoir of the experimental device holds 10 ounces. It is also takes 1 minute to deliver all the water into the mouth. Control subjects used only half of that amount. Subjects were asked to rinse with 5 ounces of the same solution during one minute.

Initially, probing depth and plaque index were going to be tested on the evaluation day. Probing depth was excluded from the study because the probe may tear the sulcular epithelium and may contaminate the samples with blood. Plaque index was also deleted because the disclosing solution used to evaluate the plaque index may contaminate the pocket sample.

In this study, the researchers introduced a new intracrevicular method designed to collect representative samples from the base of the periodontal pocket. The advantage of the method used to collect subgingival samples in this study was using a positive pressure maintained on the tip until it is at the sample-collection depth, false positives, for example, superficial samples acquired while passing the sampling device through the solution around the gingival margin are avoided. Using a micropipette to extract the disclosing solution from the base of the pocket was a delicate technique. Problems with the micropipette collection technique and data

Table 4. Two-group repeated measures ANOVA results. This measured mean pocket depth, presence of bleeding, and discomfort reported by the subjects.

Outcome	Variable	Mean	SE	F-value	P-value
Pocket Depth	**Brush Type**			0.21	0.6525
	HydraBrush	5.2976	0.0662		
	Sonicare	5.2556	0.0644		
Bleeding	**Subject (Brush Type)**			1.81	0.0613
	Brush Type			9.21	0.0052
	HydraBrush	0.4	0.0777		
	Sonicare	0.0667	0.0777		
	Week			6	0.0208
	Baseline	0.3333	0.0577		
	Follow-up	0.1333	0.0577		
	Brush Type x Week			6	0.0208
	HydraBrush				
	Baseline	0.6	0.0816		
	Follow-up	0.2	0.0816		
	Sonicare				
	Baseline	0.0667	0.0816		
	Follow-up	0.0667	0.0816		
Discomfort	**Subject (Brush Type)**			2.68	0.0056
	Brush Type			2.91	0.0993
	HydraBrush	0.4	0.0968		
	Sonicare	0.1667	0.0968		
	Week			3.98	0.0559
	Baseline	0.3667	0.0591		
	Follow-up	0.2	0.0591		
	Brush Type x Week			1.43	0.2415
	HydraBrush				
	Baseline	0.5333	0.0836		
	Follow-up	0.2667	0.0836		
	Sonicare				
	Baseline	0.2	0.0836		
	Follow-up	0.1333	0.0836		

Mean indicates the mean pocket depth or the mean rate of outcome measure (under outcome in the table). For bleeding, discomfort, and any complication, this is the proportion of individuals indicating they had bleeding, discomfort, or any complication.

analysis included: contamination of the sample with blood or plaque and the absence of any visible sample in the micropipette. When there was contamination of blood or plaque in the sample, the sample was discharged, and a different site was selected and sampled. Other studies have reported similar difficulties using this technique, and have excluded the contaminated samples from their analyses.[17-19] In addition, another problem encountered was an absence of any visible sample in the micropipette, such samples were not evaluated in the spectrophotometer. This was a limitation in the technique used in the study, as it was impossible to obtain fluid samples from the base of some pockets. However, when fluid was able to be extracted using this technique, similar concentration of fluid was found regardless of the delivery method.

Since powered toothbrushes have proven to be efficient in removing dental plaque,[12-15] it was thought brushing before rinsing or brushing and irrigating simultaneously would allow better penetration of a solution into the periodontal pocket,[11] This assumption seems correct as each of the powered devices demonstrated improved pocket penetration when compared to previous studies. The control/rinsing protocol allowed penetration of the disclosing solution to the base of 46% of the pockets, while the experimental protocol did it to 76%.

Using only those samples for which spectrometric data was available, no statistically significant differences were found in the mean spectrometer readings between the experimental and control toothbrush systems ($p = 0.1359$) (Table 3). Therefore, it appears regardless of the brush used, similar intensities (concentrations) of solution were able to reach the depth of the pocket.

The increase in effectiveness of the experimental unit may be explained by its six-head brush design and the simultaneous brushing and flushing action. These features may physically remove plaque more effectively, allowing for better penetration of the irrigating solution.[15] These assumptions are in agreement with other supragingival irrigation studies.[1,6,11]

Pitcher et al[2] found the presence of subgingival calculus on the surface of the root and a tight sulcular epithelium have been reasons for lack of total penetration when using supra gingival irrigation. In addition, another study[11] suggested the use of brushing and interdental stimulation in conjunction with an oral irrigator was superior in reducing periodontal index as well as the amount of plaque and calculus accumulation than brushing and interdental stimulation alone. Therefore, the use of oral irrigation may be considered optimal when no calculus is present and plaque control has been achieved.

Researchers also have found irrigator tip design and placement of the tip affect the depth to which drugs can be delivered subgingivally.[6] When the tip of the irrigator is placed 3 mm below the gingival margin, fluid penetration occurs in 95% of the times regardless of pocket depth.8 However, subgingival irrigation may not be easy for most patients to use at home. The results in this study show it is possible to deliver an irrigant subgingivally with the experimental device at a similar level of pocket penetration as can achieved by an oral irrigator device.

During the two weeks of the study, the experimental group reported significantly higher rates of bleeding and discomfort than the control group at both baseline (Table 4) and at follow-up. However, at the end of the two weeks, no adverse events were reported other than those observed with regular brushing in either group. Both experimental and control groups showed significantly less self report bleeding and discomfort by the end of the second week, this results may reflect the reduction of inflammation and the adaptability of the subjects to use the powered devices.

The experimental unit's treatment regimen demands less time when compared to other oral care systems. The six-headed device may allow patients to clean more efficiently than any single-headed brush. The one minute therapy time is more compatible with the brushing behavior of the general population, and it may be an additional advantage of the experimental device.[16]

The researchers suggest the experimental device is safe to use and effective 76% of the time at delivering an irrigation solution to the base of 5-6 mm periodontal pockets. Because it

requires patients to use the system for only one minute, it may be recommended for convenient maintenance of a healthy periodontium and prevention of periodontal disease. The design of the experimental device opens the door for further studies to be done to access the effectiveness of this system for physically and mentally challenged patients as well as for children.

Conclusion

Based on the findings of this study, the following conclusions may be drawn:

1. The experimental device is more efficient in delivering a solution to the base of 5-6 mm pockets than a mouth rinse following the use of the control powered toothbrush.
2. Both powered devices have proven to be safe, well accepted devices.
3. The technique developed provides a useful method for studies of quantitative and qualitative solutions at the base of periodontal pockets.

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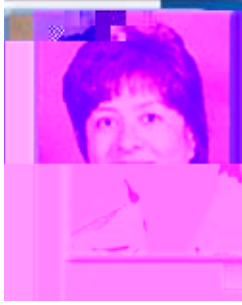

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