

Impact of a Novel Power Toothbrush with SmartGuide Technology on Brushing Pressure and Thoroughness

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Aim: Toothbrushing effectiveness can be improved with at-home reinforcement of proper technique. This study evaluated the ability of a power brush with a wireless remote display (Oral-B® Triumph® with SmartGuide™) to improve brushing force and thoroughness.

Methods and Materials: At baseline, 61 pre-screened subjects were videotaped while brushing. The wireless display was also videotaped. Subjects were then randomized to the power brush alone or the power brush with the wireless display. After 30 days of home use, subjects returned and brushed for two minutes using a two-way mirror. Brushing behavior and the wireless display were videotaped.

Results: Fifty-eight subjects were included in the pressure sensor analysis. The reduction in pressure sensor activation time at day 30 versus baseline was 88.5% for the power brush with wireless display and 53.4% for the power brush alone. The difference between groups was statistically significant in favor of the power brush with display ($p=0.034$). Forty-six subjects were included in the brushing thoroughness assessment. Subjects using the power brush with the wireless display showed statistically significantly more thorough brushing across the dentition and lingual/buccal surfaces relative to baseline. The power brush alone did not show a significant difference relative to baseline.

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Conclusion: Subjects using the power brush with the wireless display brushed with less force than subjects using the power brush alone after 30 days of home use.

Clinical Significance: The power brush with the wireless display can be incorporated in patients' home care routine to improve brushing technique, including brushing pressure and thoroughness.

Keywords: Toothbrushes, toothbrushing, computer-assisted instruction, dental plaque, periodontics, patient education, oral hygiene, motivation

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Introduction

Bacterial plaque has been definitively established as the etiologic agent in the development of gingivitis.¹ Inadequate plaque control results in the development of a more pathogenic microflora which, in turn, induces gingivitis, a host inflammatory response. Gingivitis can be the precursor to periodontitis, which is a destructive disease of the supporting periodontium.^{2,3} Mechanistically, effective plaque control is a necessity for the maintenance of oral health. The use of toothbrushes remains the most widely employed form of oral hygiene for plaque control, with 80-90% of populations in industrialized countries brushing their teeth at least one to two times per day.^{4,5} However, the effectiveness of toothbrushing is a function of how frequently and effectively patients use the toothbrush in their daily oral care routine. Important variables for efficacy include brushing time, force, and frequency, as well as the efficiency of brushing every surface of each tooth.

There is a large discrepancy between the time patients believe they brush their teeth and the time they actually spend brushing.^{6,7} In a study conducted in Switzerland among army soldiers and residents of Zurich mean toothbrushing time for the soldiers was 83.5 seconds and the mean time for the residents was 72.8 seconds. Subjects estimated their brushing time to be between 134.1 and 148.1 seconds.⁶ Another study used data loggers in Philips® Jordan Sensiflex 2000 (Philips, Snoqualmie, WA, USA) toothbrushes to study subject compliance and toothbrush use over a two month period.⁷ The subjects were instructed to brush for two minutes each morning and evening

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and to keep a brushing diary. After analyzing the diaries and data loggers, 48% of the brushing events were found to be non-compliant, either 30 seconds above or below the recommended brushing time of two minutes. Beals and colleagues corroborated findings of actual brushing time being insufficient.⁸ Based on results from two independent studies, they concluded an adult brushes on average 46 seconds, less than half the recommended two minutes.

Clinical studies have found brushing habits can increase gingival abrasion, and an individual's oral sensory perception alone is not enough to prevent gingival abrasion while brushing.^{9,10} One study found when subjects brushed their own teeth, they caused more gingival abrasion than when brushing was performed by a professional.⁹ In this study, subjects brushing each quadrant

of the mouth for 30 seconds caused more abrasion on the buccal than the lingual surface, 6.28 and 0.60 sites, respectively. There was no significant difference for the professional brushing on buccal or lingual surfaces, 1.88 and 1.30 sites, respectively. Another longitudinal study focused on individuals with high standards of oral hygiene and found they exhibited frequent loss of attachment on the facial surfaces of teeth that could be attributed to toothbrush trauma.¹⁰ This study, involving four cohorts of subjects aged 18-29, 30-41, 42-53, and 54-65, found the pattern of attachment loss and gingival recession in the 18-41 year old age groups was not consistent with known periodontal disease development and was attributed to toothbrush trauma. Power brushes with pressure sensors usually alert the user when a two to three Newton (N) threshold has been exceeded by making a noise or by pausing pulsations. Another study found in addition to causing gingival abrasion, excess brushing force can also decrease plaque removal.¹¹ When the Oral-B D17 was used at 1.5 N and 3.5 N of pressure, there was no significant difference in incidence of gingival abrasion but less plaque was removed with 3.5 N.

In clinical trials feedback devices used with oral care products have helped improve plaque removal as well as patient attitude and motivation toward their oral hygiene. One study found when subjects were given a erythrosine tablet, which disclosed the amount of plaque on their teeth



immediately before brushing, their brushing time increased by more than 20% compared to brushing without using the tablet.¹² The same study gave a questionnaire to a group of test subjects given saliva test strips, which change color within the pH range of 6.5-10, to test the effectiveness of their brushing. This study found the subjects were more motivated in their oral hygiene practices than a group of control subjects not given saliva test strips. A different study found reinstruction in brushing behavior helped lower plaque scores.¹³ Behavioral studies suggest having visual and audio feedback devices will help improve at home oral care. In a ten year longitudinal study conducted with 400 Swedish young adults, the subjects learned about dental health through programs on caries, gingivitis, and knowledge and behavior during the first three years.¹⁴ At the end of three years, the test subjects exhibited more knowledge and better oral care behavior than a control group with approximal cleaning behavior increasing from 50% of individuals at baseline to 90% of individuals. After a ten year follow up, it was found the test group still had the same oral health knowledge but their approximal cleaning behavior fell from 90% to 70% of individuals. This supports the preception behavior will decrease when reinforcement is withdrawn.^{15,16} Arguments have been made that timers on toothbrushes and sounds to discourage harmful brushing behavior will help improve proper oral hygiene practices and will modify behavior.¹⁵

Recently, a new rotation-oscillation power toothbrush with a wireless remote display (Oral-B® Triumph® with SmartGuide™, Procter & Gamble, Cincinnati, OH, USA), has been marketed. The power toothbrush has been clinically proven to be superior in plaque removal and gingivitis reduction relative to other powered and manual toothbrushes.¹⁷ The wireless display and toothbrush communicate via an electronic chip in the handle of the toothbrush.



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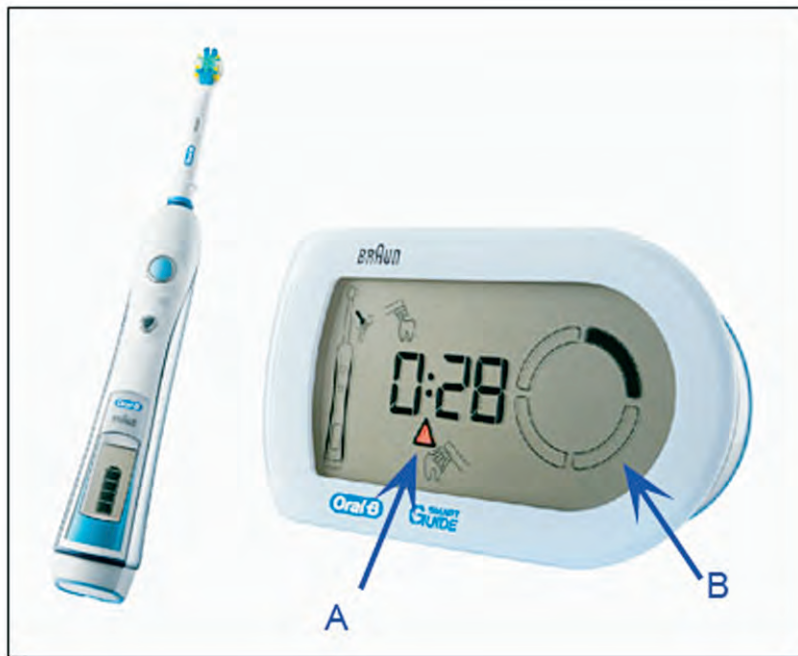


Figure 1. Power brush with the wireless remote display.
A. Pressure sensor activated. **B.** Quadrant timer.

The display can be placed up to 10-15 feet away from the patient so they can easily view the two-minute timer, brushing mode, quadrant timer, and pressure signal which lights up when force above 3 N is applied (Figure 1).

Previous research has reported brushing at forces greater than 3 N results in less effective plaque removal.¹¹ A study has been completed on this power brush with the wireless display proving the wireless display feature helps patients brush for the recommended two minutes.¹⁷ This 30-day, at home randomized, open label, parallel group clinical trial split subjects into two groups, one using the power brush with the wireless display and the other using a manual toothbrush. Subjects in the power brush with wireless display group brushed for an average of 137.4 seconds while the manual brush group brushed for an average of 98.9 seconds. The power brush with wireless display subjects were also more compliant with brushing twice daily; they brushed for two minutes twice daily for 67.8% of days while subjects with the manual brush brushed for two minutes twice daily for 13.3% of days. It was concluded the power brush with wireless display made subjects 5.1 times more compliant to brush twice daily for two minutes than subjects with a manual brush.

This 30-day study tested the effectiveness of the power toothbrush with wireless display in changing brushing behavior. The primary objective was to determine if subjects who exert high pressure while brushing continue to exert high pressure after brushing for 30 days with the power brush with the wireless display. The secondary objective was to determine if the wireless display feature helps to change brushing behavior such as brushing each quadrant of the mouth and brushing the lingual and buccal surfaces for an equal amount of time. The control toothbrush in this study was the power toothbrush (Oral-B Triumph) without the wireless display. This toothbrush contains a display screen in the handle which records brushing time, brushing mode, battery charge, and brush head replacement tools as well as an auditory quadrant timer and pressure sensor.

Methods and Materials

This study, which was conducted in Miami, OH, USA in March and April of 2007, employed a two-treatment, open label, randomized, parallel group, 30-day design. Healthy subjects between the ages of 18 and 70 with at least 20 teeth, who self-reported regular visits to their dentist, were recruited. Exclusion criteria included: severe periodontal disease; five or more carious lesions



requiring restorative treatment; active orthodontic therapy or removable prosthesis; or any disease or condition at baseline that could interfere with examination procedures or the subject completing the study.

Since there was no prior knowledge of the endpoints of interest (brushing time and brushing thoroughness) for this toothbrush, sample size calculations were not carried out. A sample size of approximately 150 subjects enrolled to qualify 80 subjects was based on logistical considerations. At the screening visit, 149 subjects completed an informed consent form and were reviewed for study inclusion/exclusion criteria. Subjects meeting the criteria were given an Oral-B Triumph study toothbrush and toothpaste and instructed to brush for two minutes in front of a two-way mirror according to manufacturer's instructions. On the opposite side of the mirror, a wireless display was digitally videotaped in order to record the length of time the pressure sensor display was activated during two minutes of brushing. A card identifying the subject number and initials was placed near the wireless display so this information was present on all recordings. In addition, a second video camera recorded each subject brushing his or her teeth, and this recording was used to assess time spent in each quadrant and on buccal and lingual surfaces.

After an initial training on how to read the pressure sensor and timer of the wireless display, a study site staff person reviewed the video recordings to record the cumulative time

the sensor went off for each subject. Subjects with screening times of at least four seconds were scheduled for a baseline visit. Based on screening data, subjects were balanced according to their gender and number of seconds that the pressure sensor on the wireless display was activated and were randomly assigned in approximately equal numbers to one of two treatment groups (power brush alone or power brush with the wireless display). Subjects residing in the same household were assigned to the same treatment group. A statistician who was not a member of the project team carried out the balancing and assignment procedure.

Sixty-nine of the 149 (46.3%) subjects at the screening exerted high pressure against their teeth for at least four seconds and were scheduled for a baseline visit. Sixty-seven subjects returned for the baseline visit. Continuance criteria were assessed. Each subject was then instructed to brush for two minutes with his or her screening toothbrush (same brush used during screening) and enough marketed toothpaste to cover the head of the brush in front of a two-way mirror. On the other side of the mirror, a digital video camera was mounted to record each subject's brushing technique and a second digital video camera recorded the wireless display as at the screening visit. The subjects were randomized into one of two treatment groups (power brush alone or power brush with the wireless display) according to the results from the balance and assignment procedure described above. Six subjects were not randomized to treatment since their baseline pressure sensor time was zero seconds. Therefore, 61 subjects were asked to take their randomly-assigned toothbrush and toothpaste (Crest® Cavity Protection, Procter & Gamble, Cincinnati, OH, USA) home with them to use for 30 days. Subjects were given verbal and written versions of the manufacturer's instructions for use of their assigned toothbrush. Subjects were asked to complete a usage diary each day to indicate they brushed their teeth twice a day (AM and PM). Subjects were rescheduled for the next appointment.

Thirty days after the baseline visit, subjects returned to the clinic with their product and diary. Continuance criteria were assessed. One

subject did not return to this follow up visit, thus 60 subjects completed the study. Each subject was then instructed to brush according to manufacturer's instructions for two minutes with his or her assigned toothbrush (the power brush with wireless display group used same brush used at home for 30 days with the wireless display visible to them, and the power brush alone group used the same brush head used at home but the handle of the brush was the same one they used during screening and baseline) and enough marketed toothpaste to cover the head of the brush in front of a two-way mirror. Separate video cameras recorded each subject's brushing technique and the wireless display as at the baseline visit. Use of a two-way mirror in the video recording process helps assure videotaping has minimal influence on subject brushing response. The subjects returned all product, reported any oral adverse events, subject accountability was documented on the appropriate electronic case report forms, and subjects were exited from the study.

The amount of time the pressure sensor feature of the wireless display was activated was determined for each brushing episode. The site staff person who viewed the digital recordings was blinded to treatment assignment. The change in time (baseline minus 30 days) was calculated for each subject and was the primary variable of interest as stated in the study protocol. The primary hypothesis test was a within-treatment group comparison to see if the average change in time was greater than zero. This hypothesis was tested for each toothbrush group using a t-test. The two treatment groups were also compared for the change in time using a nonparametric analysis of covariance with baseline time as the covariate.¹⁸

The brushing behavior exhibited by each subject at baseline compared to brushing behavior at 30 days was also analyzed. Each subject's baseline and 30 day two minute brushing videos were viewed by an experienced dental hygienist who was blinded to treatment assignment. The dental hygienist determined and recorded the amount of time spent in each quadrant (upper left, upper right, lower left, and lower right) and amount of time spent brushing buccal versus lingual surfaces. The statistical variance among the four quadrant brushing times and the difference

in brushing time between buccal and lingual surfaces were calculated at baseline and at 30 days for each subject. The primary hypothesis tests for brushing behavior were within group comparisons to see if the change in variance between quadrants was equal to zero and the difference in brushing time between buccal and lingual surfaces was equal to zero. These comparisons were performed using Wilcoxon Signed-Rank Tests. The two treatment groups were also compared for the change in variance between quadrants and for the change in the difference in brushing times for buccal/lingual surfaces using a nonparametric analysis of covariance with the appropriate baseline value as the covariate.

Results

For the pressure study, the final digital recordings of the wireless display were unreadable for two subjects, therefore, 58 subjects (29 in each treatment group) were included in the statistical analysis. In the power brush with wireless display treatment group there were 21 females and 8 males ranging in age from 20 to 66 with a mean age of 45.5 years. In the power brush treatment group there were 22 females and 7 males ranging in age from 19 to 62 with a mean age of 42.6 years. Due to subjects being out of the viewing screen or unreadable videos, 46 subjects had complete sets of baseline and 30 day brushing behavior data: 25 in the power brush with wireless display group and 21 in the power brush alone group.

Brushing Pressure

In the primary brushing pressure analysis, at baseline, the subjects using the power brush with the wireless display averaged 25.0 seconds of brushing time with the pressure sensor activated (out of 120 seconds total brushing time). At the final visit after 30 days of in home use, the average time the pressure sensor was activated was 2.9 seconds, a decrease of 88.5% since the baseline visit (Table 1).

The difference in time the pressure sensor was activated from baseline to final visit, 22.1 seconds, was statistically significantly different from zero seconds ($p = 0.001$). At baseline, the subjects using the power toothbrush averaged 18.9 seconds of brushing time with the pressure

Table 1. Pressure sensor activation (seconds).

Treatment Group	N	Baseline Pressure Sensor Activation (Mean ± S.D.)	Day 30 Pressure Sensor Activation (Mean ± S.D.)	Percent Reduction	Reduction p-value
Power brush and wireless display	29	25.0 ± 28.3	2.9 ± 9.9	88.5%	0.001
Power brush alone	29	18.9 ± 18.6	8.8 ± 17.3	53.4%	0.032

Time reduction difference between treatments p-value = 0.034.

Table 2. Quadrant variance.

Treatment Group	N	Baseline Variance (Mean ± S.D.)	Day 30 Variance (Mean ± S.D.)	Reduction p-value
Power brush and wireless display	25	71.3 ± 51.3	34.9 ± 71.5	0.005
Power brush alone	21	108.4 ± 84.3	95.8 ± 136.9	0.448

Variance reduction difference between treatments p-value = 0.175.

sensor activated. At the final visit after 30 days of in home use, the average time the pressure sensor was activated was 8.8 seconds, a decrease of 53.4% since the baseline visit (Table 1). The difference in time the pressure sensor was activated from baseline to final visit, 10.1 seconds, was statistically significant from zero seconds ($p = 0.032$). The difference between groups was statistically significant and the decrease in pressure sensor activation time was greater in the power brush with wireless display subjects ($p = 0.034$). A total of 27 of 29 (93.1%) subjects using the power brush with wireless display showed a decrease in pressure sensor activation from baseline to day 30 while 21 of 29 (72.4%) of the power brush users showed a decrease. Furthermore, the proportion of subjects with a decrease in the time the pressure sensor was activated from baseline to final visit was higher for the power brush with wireless display group than for the power brush alone group ($p = 0.039$ from a One-tailed Fisher's Exact Test).

Brushing Thoroughness

In the secondary brushing behavior analysis the brushing thoroughness of the subjects was tested by measuring the time spent brushing in

each quadrant and the time spent brushing the buccal versus lingual surfaces. The variance in quadrant brushing times, as well as the difference in time spent brushing the buccal/lingual surfaces, was calculated with values closer to zero being viewed as more thorough and consistent brushing. For two minutes of brushing, a variance equal to zero would indicate brushing in each quadrant (upper left, upper right, lower left, lower right) for 30 seconds each and a difference of zero in time between buccal and lingual surfaces would indicate brushing each of these surfaces for 60 seconds.

The subjects using the power brush with wireless display had an average baseline variance among quadrant brushing times of 71.3. After 30 days, this average variance among quadrants decreased to 34.9 (Table 2).

The reduction in variance was statistically significant ($p = 0.005$). The group using the power brush alone had an average baseline variance of 108.4 and at 30 days this decreased to 95.8. This reduction in variance was not statistically significant ($p = 0.448$). The decrease in variance was not statistically significant between the two groups ($p = 0.175$).

Table 3. Difference in buccal/lingual brushing times (seconds).

Treatment Group	N	Baseline (Mean ± S.D.)	Day 30 (Mean ± S.D.)	Reduction p-value
Power brush and wireless display	25	25.2 ± 18.9	14.9 ± 13.1	0.022
Power brush alone	21	28.5 ± 22.5	22.7 ± 16.1	0.268

Time reduction difference between treatments p-value = 0.113.

Table 4. Percent of subjects showing improvement from baseline to 30 days.

Treatment Group	N	Quadrant	Buccal/Lingual	Either or Both
Power brush and wireless display	25	80%	76%	92%
Power brush alone	21	67%	57%	90%

For brushing buccal/lingual surfaces, subjects using the power brush with wireless display reduced the difference of time spent brushing buccal vs. lingual surfaces from an average of 25.5 seconds at baseline to 14.9 seconds at 30 days (Table 3).

This was a statistically significant reduction ($p = 0.022$). Subjects using the power brush alone did not significantly change the difference between buccal and lingual times from an average of 28.5 seconds at baseline to 22.7 seconds at 30 days ($p = 0.268$). The change in buccal vs. lingual brushing time was not statistically significant between the two groups ($p = 0.113$).

Each subject's data was studied independently to find the percent of subjects having improved brushing behavior (i.e., thoroughness) at 30 days from baseline. In the power brush with wireless display group 80% improved brushing the four quadrants (reduced their variance), 76% improved brushing buccal/lingual (reduced their difference in times), and 92% improved brushing by either or both of these measures. In the power brush alone group 67% improved quadrant brushing, 57% improved buccal/lingual, and 90% improved either or both (Table 4). No adverse events were reported during the study.

Discussion

Various factors play a role in the amount of plaque removed by toothbrushing, such as brushing time, pressure, technique, and bristle configuration. The action of the brush itself, or lack thereof, is another consideration. Power toothbrushes with an oscillating-rotating motion have been shown to remove significantly more plaque than manual toothbrushes.^{19,20} Clinical research has also demonstrated considerably less force is used with power brushes, including those with oscillating-rotating action, as compared with manual brushes.²¹ Manual brush users were found to have a mean brushing force more than 100 g greater than means for the power brush groups. Thus, oscillating-rotating brushes offer some inherent advantages in greater plaque removal and reduced brushing force relative to manual brushing.

This study evaluated the impact of the most recent innovation in oscillating-rotating power toothbrushes, a power brush with a wireless remote display, on brushing thoroughness and pressure compared to the power brush without the wireless display. Users in both groups significantly reduced brushing pressure after 30 days of use. Nine of 10 subjects in the power brush with wireless display group reduced pressure relative to baseline compared with more than 50% in the power brush group (Figure 2).

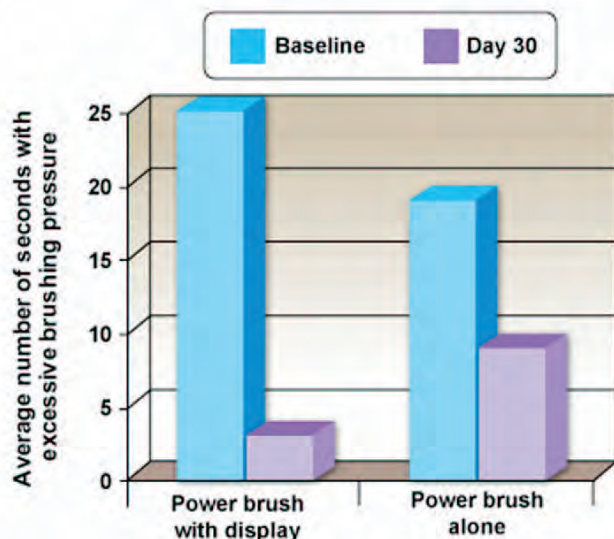


Figure 2. Excessive brushing pressure results.

Reducing brushing pressure is an important factor in improving at home oral care since many people brush with excess force and this practice can lead to gum recession. In the screening phase of this study it was found 69 out of 149 subjects (46.3%) activated the pressure sensor for at least four seconds out of a two minute brushing time, supporting brushing with too much pressure is prevalent in the general population. Use of a power brush alone for 30 days significantly reduced this practice, and a further benefit was seen when the wireless display was incorporated.

The power brush with wireless display also helped improve the thoroughness and consistency of brushing behavior while the power brush alone did not. The power brush with wireless display statistically significantly reduced the variance in brushing time among the four quadrants of the mouth (Figure 3).

This means each quadrant, upper left, upper right, lower left, and lower right, was brushed more evenly during the two minute period. The power brush alone showed a directional but not statistically significant improvement in quadrant brushing consistency. Furthermore, the results for the difference between buccal and lingual brushing times were statistically significantly different for the power brush with the wireless display compared to the power brush alone. For the power brush with wireless display users, the difference between time spent brushing the buccal versus lingual surfaces decreased

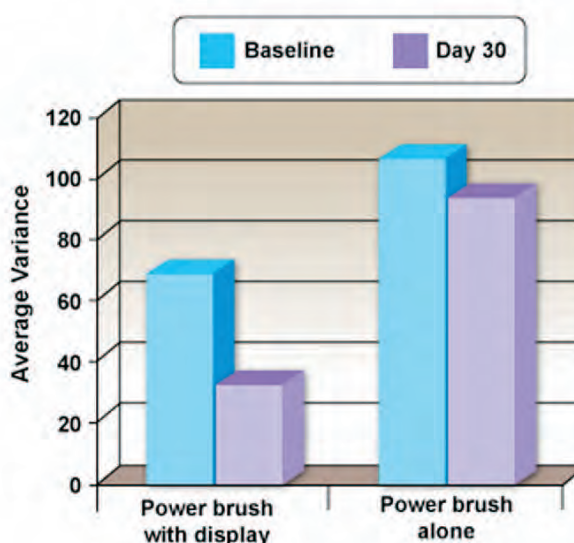


Figure 3. Variance among quadrant times.

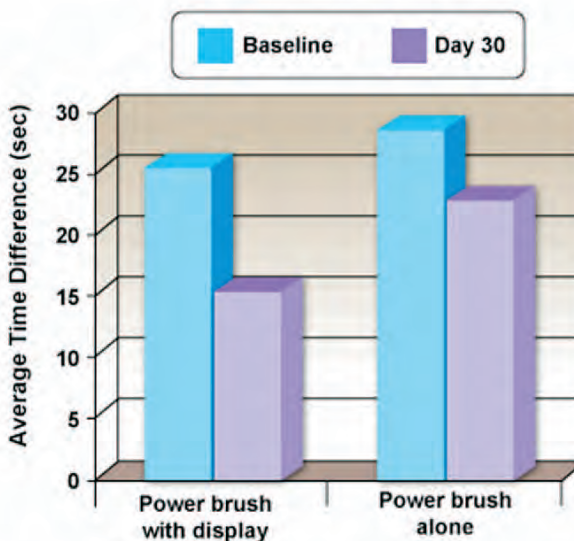


Figure 4. Time difference between buccal/lingual surfaces.

statistically significantly from baseline to 30 days showing the wireless display was effective in promoting even cleaning of both tooth surfaces. The results for the power brush group showed the power brush alone had no significant effect in promoting brushing both surfaces (Figure 4). Taken together, the brushing behavior results show patients who used the power brush with the wireless display at home for 30 days brushed their dentition more evenly and thoroughly versus the way they brushed at the baseline visit. Thorough and consistent brushing of all tooth surfaces should allow these subjects to clean their teeth more efficiently.

This observation that subjects increased their brushing thoroughness and spent more time brushing their lingual surfaces may have important consequences for maintaining good plaque control and oral health. The literature supports people spend more time brushing their buccal surfaces than their lingual surfaces. A number of studies have reported based on brushing strokes, buccal surfaces receive more brush strokes than occlusal surfaces, and occlusal surfaces receive more brush strokes than lingual surfaces.²²⁻²⁴ In one study involving 57 children, 13 years of age, the subjects brushed an average of 301 strokes per brushing, with 286 strokes on the buccal surfaces and only 15 strokes on the lingual surfaces.²⁵ The quadrant timer appears to have encouraged subjects to have a more even distribution of brushing time in each quadrant, which in turn led to increased brushing time in the linguals. Subjects may have been likely to brush all tooth surfaces in a quadrant, as opposed to focusing primarily on facial surfaces because they spent close to thirty seconds in each quadrant.

Two power toothbrushes with and without a remote wireless display were compared for

effectiveness of brushing and pressure control applied on teeth surfaces. Taken collectively, the 30-day study supports the power brush with the wireless display helped to reduce brushing force and improved brushing thoroughness in nine out of ten people. The brushing behavior changes observed in this study are important since the time spent brushing teeth and the pressure applied during brushing show great variability within individuals often resulting with less time spent and more pressure applied than needed, potentially leading to less plaque removal and/or gingival recession. However, the impact of brushing more thoroughly with less pressure on plaque removal was not measured in this study.

Conclusion

Subjects using the power brush with the wireless display brushed with less force than subjects using the power brush alone after 30 days of home use

Clinical Significance

The power brush with the wireless display can be incorporated into patients' home care routine to improve brushing technique, including brushing pressure and thoroughness.

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Bruce Nelson, MS

Mr. Nelson is currently a clinical consultant and at the time of this study was the Technical Director for Oral Care clinical work at Hill Top Research. Following his receipt of a BS in Zoology from Iowa State University and a MS in Zoology from Rutgers University, he spent his career in clinical trial research in areas including skin care, hair care, antiperspirant and deodorant, and oral care research. He has authored and engineered over 45 clinical study reports and dental supplements during his clinical career over 30 years.

Robert D. Bartizek, MS



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