Comparison of Power Versus Manual Toothbrush in Reducing Gingivitis

Keerthi Kamreddy
Marquette University

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By
Dr. Keerthi Kamreddy

A Thesis submitted to the Faculty of the Graduate School,
Marquette University,
in Partial Fulfillment of the Requirements for
the Degree of Master of Science

Milwaukee, Wisconsin
May 2019

ABSTRACT

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Introduction:
The purpose of the present 4-week, parallel-arm, single-blinded, clinical study is to investigate the efficacy and safety of a new power toothbrush in comparison with a standard flat trim ADA approved manual brush. The primary objective of this study is to evaluate the efficacy of powered toothbrush on gingivitis reduction compared to a manual toothbrush. Secondary objectives of this study are to evaluate the effectiveness of plaque removal.

Materials & Methods:
The study was a single-blinded parallel arm randomized controlled interventional trial. Forty-six male and female subjects with gingivitis (32 female and 16 males) with a mean age of 26 years were enrolled but only 44 completed 4-week visit. The subjects were assigned to either of the two different groups (powered brush and manual brush). The test group was assigned to a new power toothbrush while the control group was assigned the ADA approved manual flat trim soft bristle toothbrush for the duration of the 4-week home use trial. Written instructions on brushing and professional brushing demonstration were provided at the outset of the study and repeated at 2- and 4-weeks. Before each visit, subjects had at least 7 hours, but no more than 12 hours of accumulated, non-brushed, undisturbed plaque/debris.

Results:
The site level reduction was statistically significant in both Manual (Group B) and Powered brush (Group A) for facial sites compared to interproximal sites in percentage BOP (bleeding on probing), MGI (modified gingival index), and PI (plaque index). In group B more reduction in BOP was seen at 2 weeks inter-proximally compared to facial sites whereas the reduction in both facial and interproximal aspects is similar in Group A. At 4 weeks BOP in both groups A and B was significantly reduced in facial sites compared to proximal sites. The patient level analysis showed a trend toward reductions in signs of gingivitis over this short time frame but did not show any statistically significant reductions in % BOP, MGI, or PI.

Conclusion:
Both groups demonstrated a reduction in signs of gingivitis (BOP and GI) in this non-flossing population after being repeatedly trained in toothbrush use over a 4-week period. Both tooth brushes were equally effective in reducing overnight plaque as a single use exercise after initial professional training. In the short term, subjects well-trained in the use of either an oscillating-rotating power brush or a manual toothbrush can demonstrate reductions in plaque and gingivitis, but the reductions were not statistically significant.

ACKNOWLEDGEMENTS

Dr. Keerthi Kamreddy B.D.S

First and foremost, I need to thank the person who brings out the best in me. Without my husband Srikanth's support, I would never have been afforded the opportunity to begin this journey, let alone finish it. Thank you for everything. I also want to thank my immediate family. My parents, in-laws and my sibling who has been there for me throughout this process, thank you.

Next, I need to thank my committee. Dr. Andrew Dentino for teaching me good research practices and taking me through this whole process has made me appreciative of the literature I have read throughout these years. Dr. Swati Rawal, thank you for always being there, to ask about kinds of writing, or just share a moment in the most stressful period. Dr. Paul Luepke your, generosity and encouragement is appreciated more than I have had a chance to let you know.

Finally, I would like to thank my co-residents and friends. My co-resident and I have always been able to bounce ideas and philosophies off each other and provide support and guidance, but also have gained lifelong friendships and mutual respect along the way.

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Introduction

Dental plaque is a bacterial biofilm consisting of complex communities of bacterial species (1). Plaque can be supragingival or subgingival and can be adherent or non-adherent to teeth or tissue. In addition, the microbial composition of plaque varies from person to person and site to site within the same mouth (2). Maintenance of effective plaque control is the cornerstone of any attempt to prevent and control periodontal disease. Natural self-cleansing mechanisms include tongue movements on the oral and vestibular aspects of the teeth as well as mastication of food. These natural mechanisms, however, are not sufficient to control plaque buildup. Therefore, to maintain oral health, regular personal plaque removal measures must be undertaken. The most widespread means of removing plaque is tooth brushing.

Most historian's trace the development of the first toothbrushes in China, which were ivory brush handles with bristles. The bristle brush was reinvented in the late 18th and early 19th centuries, but due to the high price of hog bristles, brushes did not become widely used until the end of the 19th century. ln, the late 1930s, nylon filaments began to replace natural bristles, and wood and plastic replaced bone handles. This made toothbrushes inexpensive enough and more affordable and so they dominated the oral care market in mechanical plaque control. During the past 30 years, oral hygiene has improved, and in industrialized countries, 80 to 90 % of population brush their teeth 1 or 2 times a day (3). Mechanical plaque removal with a manual toothbrush remains the primary method of maintaining oral hygiene for most of the population. When performed well for an adequate duration of time, manual brushing is highly effective. However, for most patients, neither of these criteria is fulfilled. One possible way to overcome the limitations associated with manual brushing was to develop a mechanical brushing device.

In 1961 the first electric toothbrush was launched which mimicked the back-and-forth motion commonly used with a manual toothbrush. When first introduced there were many reports of the effectiveness of such devices. However, an early authoritative report reviewed the research on both manual and electric toothbrushes and stated that they were equally effective in removing plaque (4). Because of the lack of superiority, powered toothbrushes fell out of favor, and during the late 1960s, they gradually disappeared from the market. However, powered brushes continued to be recommended for the handicapped and for persons with reduced manual dexterity.

At the World Workshop in 1966, the consensus from the research reports on tooth brushing stated that in non-dentally oriented persons, in persons not highly motivated to oral health care, or in those who have difficulty in mastering suitable hand brushing technique, the use of an electric brush may result in more frequent and better cleansing of the teeth.

Since then, tremendous advances have been made in the technology of electrically powered toothbrushes with the development of oscillating-rotating brushes which move at high frequency back and forth from a center point and does not rotate in full circles (5). Rotary action single tuft brush (Rotadent) with small bristles that reach one surface per tooth comes with three different brush heads in different shapes to improve access in areas hard to reach in the oral cavity. The next innovation was the Interplak electric toothbrush which has a rectangular brush head with 6 to 8 bristle tufts which individually counter-rotate. Further innovations resulted in the launch of an oscillating rotating toothbrush by Braun (Oral B). Oral B plaque remover D5 oscillates at a speed of 2800 oscillating rotations per minute. Further development of this brush resulted in Oral-B Ultra-Plaque Remover which has a frequency of 3600 oscillation rotations per minute. Philips introduced another oscillating rotating brush the HP 510 similar to Oral B, but which has, in addition, an active tip at the end of the brush head which makes a small sweeping motion. Another development in technology was the Sonicare electric toothbrush introduced in 1993 which has a rectangular brush head with bristles arranged in a saw-tooth design. Philips has different versions of the Sonicare brush. The mechanism of the Sonicare model is side-to-side movement at a high frequency of 262 Hz (6). In sonic toothbrushes, the vibration results in cavitation and acoustic streaming which generate fluid movement and may provide cleaning slightly away from the tip.

Numerous clinical studies have been done to compare the efficacy of manual to power toothbrushes and between differently powered toothbrushes. The purpose of the present 4-week, parallel-arm, single-blinded, clinical study is to investigate the efficacy and safety of a new power toothbrush in comparison with a standard flat trim ADA approved manual brush. The primary objective of this study is to evaluate the efficacy of power toothbrush on gingivitis reduction compared to a manual toothbrush in a well-trained population of non-flossers. This is a self-administered procedure to control gingivitis without the confounding effects of interdental cleaning or use of topical antiseptic rinses over a short time period.

The patients participating in the study receive repeated professional training and instructions to control brushing time and frequency. Secondary objectives of this study are to evaluate the effectiveness of plaque removal.

Literature Review

Host Factors and Gingivitis

Loe et al (7) investigated the onset of gingivitis by a withdrawal of all measures of oral hygiene in twelve healthy persons with clinically normal gingiva. Lack of oral hygiene resulted in the development of marginal gingivitis in all subjects. The time necessary to develop gingivitis varied from ten to twenty-one days. Reinstitution of oral hygiene resulted in healthy gingival conditions and re-establishment of the original bacterial flora. This landmark study showed that plaque formation and maturation was responsible for the development of gingivitis and that subjects varied in the speed with which they developed gingivitis. It also demonstrated that re-institution of oral hygiene would reverse gingivitis in all subjects in a short time period.

In gingivitis, there is elevated vascular permeability and vasodilatation. There is an increase in bleeding on probing (BOP). Greenstein et al (8) demonstrated that when there is BOP there are inflammatory cells in gingival tissue. Others have shown that the positive predictive value of BOP for periodontal disease progression was only 6% while the negative predictive value was 98%, which renders continuous absence of BOP a reliable predictor for the maintenance of periodontal health (9).

Effect of Manual Dexterity

Neelima et al (10) reported a crossover study on differently abled participants to compare plaque reduction in manual and power tooth brushing. After receiving the power toothbrush subjects followed the manufacturer's instructions and were allowed to use the brushes for 8 days. On the eighth-day plaque, status was assessed before and after brushing. Participants were requested to refrain from oral hygiene practices for 6 h on the scheduled day of assessment (8th day). There was no significant difference in plaque-removing efficacy between power and manual toothbrushes among differently abled subjects in a single

brushing although they found significant reduction post brushing compared to pre-brushing values for both these brush types.

Goyal et al (11) reported 6-month outcomes for mentally challenged individuals using manual toothbrushes reinforced with audio-visual instructions and observed that such training resulted in a comparable reduction in plaque and gingival index to the use of powered toothbrushes. The regular visits and the constant reinforcement that the inmates received through the caretakers may be a major reason for better compliance to improve oral hygiene.

Other diseases and conditions such as arthritis, pregnancy, orthodontic treatment, mentally challenged, differently abled persons suggest that different subjects may respond differently to difficult oral hygiene methods.

Orthodontic treatment

Adolescent orthodontic patients often show ineffective plaque control because of the difficulty of removing plaque while fixed appliances are in place (12).

A study was performed by Heasman et al (13) to compare the efficacy of three toothbrushes in a cohort of children undergoing fixed appliance orthodontic therapy. The brushes used were Dental Logic HP550 with regular brush head HP5924, Braun Oral B Plaque Remover (D7) with the dedicated orthodontic brush head, and a manual dedicated orthodontic toothbrush (P35). Each subject was randomly allocated to one of three groups with brushing sequences 1-2-3, 2-1-3, and 3-2-1. The first brush was given 2 weeks after baseline. The time interval for using each brush was 4 weeks at the end of which visible plaque and gingival bleeding indexes were recorded and further prophylaxis was given. All the patients were given instructions on the use of each power or manual brush and brushed twice daily for 2 minutes. This 4 week, cross-over study demonstrated that the Philips HP550, the dedicated electric Braun D7, and the manual (Oral B) orthodontic brushes were equally effective in removing plaque and reducing gingival inflammation as indicated by bleeding on probing in patients undergoing fixed orthodontic treatment.

Effect of Oral hygiene on Disease Remission or Progression

A study was performed by Lang et al (14) to determine the rate and pattern of plaque development in dental students with excellent oral hygiene and clinically healthy gingival conditions. The subjects were divided into different groups and were asked to perform hygiene at 12, 48, 72 or 96 hours over an observation period of 6 weeks. They found that subjects who performed hygiene after 72 and 96 hours of plaque accumulation developed clinical signs of gingivitis, while subjects performing plaque control every 12 or 48 hours did not show gingival inflammation despite a mean plaque index almost identical to that of subjects performing hygiene at 72 and 96 hours. This study demonstrated that effective and complete plaque control at intervals of 48 hours is compatible with the absence of clinical signs of gingival inflammation. However, gingivitis develops when the interval between complete plaque removals exceeds 48 hours. The results should be interpreted with caution because the study population is a highly-motivated group compared to the general population.

A study in teenage boys performed by Rosa et al (15) investigated the pattern of plaque accumulation and removal with daily tooth brushing during a 28-day period following prophylaxis. They found on average 60% of the plaque was left after brushing, promoting rapid regrowth. The results suggested that the average person is not effective at tooth brushing and probably has large amounts of plaque on their teeth constantly, even though they brush once every day.

Manual Brushes

There are numerous manual toothbrush designs, and claims of superiority for plaque removal by individual brands have been made in the past. However up to 1998 (European workshop on mechanical plaque control), no manual toothbrush design was better than any other, but more recently, cross action designs had better reduction plaque level (16).

Reardon et al (17) reported on two single-use studies comparing the Colgate precision, the Oral-B P35, and the Crest Complete toothbrushes. In their studies plaque was evaluated with the Turesky modification of the Quigley-Hein Plaque index. No significant differences were found between any of the toothbrushes.

In contrast, Grossman et al (18) found the Colgate Precision and three other toothbrushes were less effective than the Oral-B Advantage Plaque Remover in whole mouth plaque removal and in the reduction of gingivitis.

Double and triple-headed toothbrushes

Several studies have indicated that a double (triple) headed toothbrush may improve plaque control, especially lingually, in the molar areas, where the tongue may sometimes "guard" the gingival margins which are more difficult to see, and reach compared to buccal surfaces and anterior teeth (19).

Gibson et al (20) compared a double-headed brush with a conventional flat trim brush (Oral-B 32) in 44 subjects for 1 week. This novel design was significantly more effective in overall plaque removal and this effect was most evident on all lingual surfaces, especially in the lower arch and molar regions.

Yankell et al (21) tested a new triple head toothbrush design that claimed to enable simultaneous plaque removal on buccal, lingual and occlusal surfaces. The brush was compared with a standard flat-headed toothbrush (Oral-B P35) using the guidelines for testing chemotherapeutic agents, which require six months of assessment for long term reduction of plaque and gingivitis. At six-month examination during a one-minute unsupervised brushing, the test group removed significantly more plaque both buccal and lingual compared to the flat-headed toothbrush which removed a significant amount of buccal plaque only. By six months triple headed brush was significantly better than the flat-headed toothbrush on gingivitis reduction in the lingual areas.

Effect of bristle design

A single use study comparing the crisscross and flat-trim toothbrushes reported (16) highly significant plaque reductions from baseline with all five models (Crisscross and standard bristle designs) of manual toothbrushes. Significant plaque reduction was seen not only for the entire mouth (at least 84%) but also at interproximal areas (at least 95%). Of specific interest, and of direct importance for differentiating between brushes in terms of their plaque removal effectiveness, was the finding that cross action brushes were consistently and significantly better than standard at removing plaque according to the Rustogi Modified Navy Plaque Index. A number of design features may differentiate commercially available brushes, but the defining feature of the three brushes that showed superiority in this study is the bristle configuration, specifically, Criss-Cross bristles angled in opposing directions. These results can be seen to support that in conventional flat-trim toothbrushes, the major shortcoming is due to the blocking effect of tight bristle tufts, which prevent individual tufts from reaching interproximal areas. Modern toothbrushes have additional filament patterns designed to enhance plaque removal from areas which are hard to reach. Multilevel or angled toothbrush designs improve plaque removal compared to flat-trim brushes.

Effect of Oral Hygiene instructions and Learning curve associated with powered brush usage

Compliance with oral hygiene recommendations is generally poor (22). Meticulous, self-performed plaque removal measures can modify both the quantity and composition of subgingival plaque (23). Proper oral hygiene results in a non-specific reduction of plaque mass. This therapeutic approach is based on the rationale that any decrease in plaque mass benefits the inflamed tissues adjacent to bacterial deposits.

Glavind et al. (24) evaluated the effects of different types of oral hygiene instruction including a pamphlet, a self-instruction manual or instructions delivered by a hygienist given once. There was no significant difference between simple written and professional instruction over 24 weeks, as all three groups showed decreases in both plaque and gingivitis. The patients in this study were given instructions on interdental cleaning aids and disclosing tablets in their oral hygiene kit. This suggests that maintenance of a high level of oral hygiene in adult patients participating in a preventive program can be ascribed to psychological and feedback mechanisms rather than to professional prophylaxis and instructions.

Van der Weijden and coworkers (25) compared 3 brushes; a manual, a D3 horizontal action power brush, and the original oscillating-rotating round head D5 power brush in a three-part study. The initial aim was to discern the efficiency of plaque removal by a professional using each brush on the subjects who came in with 24 hours accumulated plaque. The clinician was limited to brushing 30 seconds per quadrant in a split-mouth design. These data showed that both powered brushes were more efficient in plaque removal by a professional and that the D5 oscillating-rotating powered brush was more effective at plaque reduction compared to the D3 horizontal scrubbing powered brush. The second part of the study provided written instructions but no other training to each subject for the brushes assigned. Subjects were allowed 3 weeks of home use to develop their skills in using each of their assigned brushes before coming in a second time with 24 hours accumulated plaque and having their pre-and post-brushing scores recorded again after they brushed their own teeth. Subjects were not timed and only told to brush as they had been brushing at home during the trial period. These data suggested that without more than written instructions, all three brushes performed the same, and there was less plaque removal than was seen in the first experiment. The final experiment involved assessment of single-use plaque removal by subjects after they had been

professionally trained on proper use of the assigned brush and given another three weeks to develop skill with each brush. Van der Weijden noted when subjects were properly trained there was a significant reduction in plaque scores between the brushes, and the D5 was more effective than either the manual or the D3. They concluded that professional instruction/training in the use of the new oscillating-rotating (O-R) power brush was an important factor in optimizing plaque reduction. In contrast, Dentino et al (26) showed that one could see a beneficial reduction in gingivitis over 6 months when comparing an O-R power brush (Braun Plak Control D5 head) to a flat trimmed manual brush even if patients were only provided written instructions, and not given professional training.

Renton et al (27) compared the efficacy of an electric toothbrush in an untrained individual with a 2-minute timer when instructions were given in video versus written instructions. Whole-mouth plaque reductions were 10% greater in the Video trained group and reached peak reduction (15%) at lingual surfaces. They concluded that during the early period of learning to use of an electric toothbrush, plaque removal can be improved by using an instructional video as compared to the written instructions provided in a leaflet.

Duration of brushing

Van der Weijden et al (28) compared an unspecified manual brush, a conventional horizontal motion power brush (Blendadent), an oscillating rotating power brush (Braun Plak Control with D5 head), and a multi-tuft rotational brush (Interplak) for plaque removal efficacy in a timer study varying from 7.5 s per quadrant to 90 s per quadrant of professional tooth brushing. A dental hygienist performed brushing for all the subjects in the study. From 15 s through 90 s, Interplak and oscillating rotating brushes were equally effective. Both were, significantly more effective than the Manual and Blendadent brushes.

Evaluation of the efficacy in relation to brushing time showed for all brushes that the greater part of the effect is reached after 30 s of brushing per quadrant. The brushing time appears to be an important variable in the evaluation of plaque removing effectiveness.

These data are consistent with a later study comparing the same power brush to a manual brush (26), where subjects were instructed to brush their teeth like they normally would, and they were covertly timed and then scored for remaining plaque levels using the Turesky Plaque index. The data showed an overall

negative correlation for PI and brushing time. The authors concluded that the R-O power brush safely provided clinical benefits in plaque and calculus reduction over a manual brush even in subjects with no formal oral hygiene instruction. The range of brushing times was large, from 28 to 270 seconds. However, 50 out of 76 powered brush users spent at least 2 minutes. In contrast, only 14 out of 81 patients using a manual brush spent 2 minutes or more for brushing.

Wear and replacement

The efficacy of plaque removal is also dependent on the wear or how long a toothbrush has been used. The extent of toothbrush wear, such as the amount and degree of tapering and matting, may be closely related to the efficacy of plaque removal by the brush.

Daly et al (29) examined the effect of progressive toothbrush wear on plaque control. At baseline, each of 20 subjects was given a new toothbrush which was used for the 9-week study period. At weeks 0, 3, and 6 all plaque was professionally removed, and the amount of plaque that accumulated in each of successive 3-week experimental periods was assessed at weeks 3, 6 and 9. Toothbrush wear was evaluated by measuring the increase in the brushing surface area of toothbrushes by computer analysis of tracings of the brushing surface outlines obtained from standardized photographs. Despite progressive toothbrush wear, the amount of plaque which accumulated in each successive 3-week period decreased significantly. Toothbrush wear varied significantly among the subjects, but no significant differences in plaque scores were found between subjects whose toothbrushes showed the highest and lowest wear.

In a study by Rosema (30) the results did not show a clinically relevant difference in plaque score reductions following a 2-minute brushing exercise among 3-month-old used and new manual toothbrushes. However, the wear rate of the brushes seemed to be the determining factor in a loss of efficacy, rather than the age of the toothbrush.

Hogan et al (31) compared the efficacy of plaque reduction when subjects brushed for 2 min with either a new brush, or a brush they had used for 3 months, and the plaque was then re-scored. R-O Powered toothbrushes with 3-month-old brush heads exhibiting various degrees of wear were as effective as new brush heads in plaque removal. The results indicated bristle age and wear on a powered toothbrush may not impede the effectiveness of plaque removal.

Power brushes

The main electric toothbrushes which are compared in the literature are the Braun Oral-B plaque remover (D5, D7, and D9), Interplak, Rotadent, and Sonicare. These electric toothbrushes have been studied in relation to their ability to remove plaque and improve the gingival condition in comparison with either manual brushes or with electric toothbrushes from different manufacturers (Walmsley 32).

Van der Weijden (25) tested the effectiveness of manual brush, Braun D5, D3 with a 2-minute timer. The results from this study indicated that electric toothbrushes were more effective than a manual brush when professional instructions were given. However, the significant difference between the manual brush and the D5 ranged only between 4 to 6%, but the efficacy of interproximal gain was 12 %. They considered the effect of this difference to be clinically significant.

In a systematic review by Sicilia (33), the analysis showed higher efficacy in the reduction of gingival bleeding or inflammation in the power toothbrush group as compared to the manual toothbrush users in 10 studies. This effect appears to be related to the capacity to reduce plaque and was more evident in counter-rotational and O-R power toothbrushes.

A Cochrane review by Yacob et al (34) evaluated 51 studies and observed did not do prophy at onset and resulted in the true reduction of MGI reported an 11% reduction in plaque for the Quigley & Hein index in short term and 21% reduction in the long term. With regard to gingivitis, there is moderate quality evidence that power toothbrushes which correspond to a 6% and 11% reduction in gingivitis respectively for the Sillness & Loe index. O-R power brushes showed statistically significant reductions in both plaque and gingivitis.

Rosema (35) compared the efficacy of power toothbrushes following an exercise. The overall effect of a power brushing exercise provides a plaque score reduction of 46%, with a range of 35-67% dependent on the index scale used to score plaque. The power supply (rechargeable or replaceable battery), mode of action, as well as brushing duration and type of instructions are all factors which contribute to the variation in the observed efficacy.

Heasman and co-workers (36) compared the efficacies of the Philips/Jordan HP 735 power toothbrush, the Braun/Oral B D7 power toothbrush and the Oral B Advantage B35 manual flat-trim toothbrush in a

cohort of 75 young adults over a 6-week period. The showed power toothbrushes are more efficacious in removing plaque than are manual brushes although a statistically significant difference was evident only at interproximal sites. The Philips/Jordan HP 735 and the Braun/Oral B D7 performed almost identically with respect to plaque removal although the HP 735 produced lower GI scores compared to the D7 after 6 weeks. Interpretation of the longitudinal changes in GI, however, must be undertaken with some caution because no data were recorded at screening and a possible Hawthorne effect may have influenced the study. Tooth brushing forces were significantly higher in manual brushes compared to those subjects using powered brushes, and the click threshold mechanism on the HP 735 reduced the variation in tooth brushing force which was seen when the brush was first used.

Van der Weijden (37) compared the ability of Braun, Sonicare and Philips Sensiflex 2000 to control plaque and reduce experimentally induced gingivitis in a split-mouth design. Subjects to become acquainted were given brushes with professional instructions 2 weeks before the development of experimental gingivitis. The reduction in bleeding on probing was more rapid and greater with the Braun compared to the other two brushes. There was no significant difference in plaque index at 4 weeks between all the three groups. The data from this study show that the design and action of the Braun Oral-B 3D Excel power toothbrush are more effective in resolving gingivitis than the Sonicare & the Philips Sensiflex 2000 power toothbrushes.

Lazarescu et al (38) reported an 18-week study with subjects using Philips/Jordan HP 735 powered brush or a manual brush (Oral-B). After each evaluation, both groups had supervised brushing for 3 min. Plaque index (PI) and gingival bleeding index (GBI) were assessed and demonstrated that the power brush was significantly more efficient in removing plaque and improving gingival health than the manual brush in the group of subjects unfamiliar with electric brushes. There was also a significant learning effect that was more pronounced with the electric toothbrush.

Safety of powered toothbrushes

Danser et al (39) add study period conducted a study to establish the incidence of gingival abrasion as a result of tooth brushing, using a manual toothbrush and the Braun Oral –B D9 electric toothbrush. This

investigation showed that both the electric toothbrush and the manual brush cause minor gingival abrasion as a result of the brushing.

Wilson et al (40) also evaluated gingival recession. They observed that neither the manual nor the electric group developed significant changes in the level of gingival recession over the one –year study period.

A systematic review by Van der Weijden et al (41) compared the safety of power toothbrushes. 24 studies assessed safety as a secondary outcome revealed few brushing-related adverse effects. In two selected trials mean difference was 0.03. This systematic review of a large body of published research in the preceding 2 decades consistently showed O-R power toothbrushes to be safe compared to manual toothbrushes, and collectively indicated that they do not pose a clinically relevant concern to either hard or soft tissues.

Dorfer et al (42) conducted a study to evaluate the progression of the recession in healthy subjects with pre-existing recession who brushed their teeth twice daily for 2 min with either manual or powered toothbrush. After three years, the mean gingival recession did not differ significantly between groups, but the pre-existing recession was significantly reduced after 3 years of brushing with a power compared to a manual toothbrush.

Effect of Interdental cleaning aids

When we consider the efficacy of interdental cleaning, we should compare the relative importance of tooth brushing versus interdental cleaning. Periodontitis and gingivitis lesions are predominantly inter-dental and it is the proximal or interdental sites which are most frequently coated with plaque (43). Thus, the interdental area is a major target area for any preventive regimen.

Methods of achieving interdental cleaning are numerous and include floss, tape, wood-sticks, toothpicks, interdental brushes, and a variety of electrical and mechanical device.

These devices should be considered with manual dexterity of the individual. When tooth brushing is accompanied by flossing, more plaque is removed from the proximal surfaces than by tooth brushing alone (44,45).

Graves et al (46), in a 2-week supervised clinical trial of patients with gingivitis, showed that interdental bleeding was reduced about 67% by flossing and brushing, compared to a 35% reduction achieved by tooth brushing alone. Similar reductions have been noted in subsequent trials employing similar protocols (47).

A study by Reitman et al (48) has shown increases in plaque-free surfaces between 30% and 80% when tooth brushing was supplemented using dental floss. These increases were in comparison to toothbrushes alone. This study demonstrates that combinations of interdental cleaning methods are clearly needed given the variety of tooth types within dentitions.

Rapley & Killoy (49), in a professional brushing study, compared the subgingival and interproximal plaque removal efficacy of a manual toothbrush to that of an oscillating counter-rotational electric toothbrush. The control group had 13.8% plaque-free interproximal surfaces, compared to 30.57 % for the manual group and 53.23% for the electric group. The interproximal plaque efficacy of electric brush was superior compared to other groups.

Cronin & Dembling (50) conducted a clinical study to compare the efficacy and safety of the new Braun Oral-B Interclean (ID2) with that of dental floss in healthy adults. With ID2, there were reductions in interproximal plaque scores of approximately 40% compared to 28% with dental floss. Bleeding on probing was reduced by 25% with the ID2 and by 34% with dental floss. Differences between treatment groups with respect to gingivitis and bleeding reductions were not statistically significant. It was concluded that the ID2 has equivalent efficacy to dental floss for the reduction of interproximal plaque and gingivitis.

Rosema et al (51) compared power brush, to manual brush alone and, manual brush with flossing over a 9-month period. All subjects were provided with professional oral hygiene instruction at 6 weeks and given prophylaxis. Gingival bleeding, plaque, staining, and gingival abrasion were assessed during the pre-experimental period and at baseline, 10 weeks, 6 and 9 months. The powered toothbrush maintained lower plaque levels for 9 months following the 3-week treatment phase better than the manual toothbrush with or without floss. There was no significant difference between BOP in powered brush and manual brush with flossing.

This background paved the way to test a new O-R power brush for better plaque removal and/ or reduction in gingivitis in subjects who are non-flossers, and who would be trained to maximize the benefits of tooth brushing with either an O-R power brush or a standard manual toothbrush.

Materials and Methods

Study procedure

The study was a single-blind, parallel arm, randomized, controlled interventional trial. Forty-six (46) male and female subjects (32 female and 16 males) with a mean age of 26 years were enrolled according to the admission criteria and accepted into this study. The subjects were assigned to either the powered brush or the manual brush based on levels of inflammation (%BOP, MGI-52), and plaque levels (53,54,55) using screening data. Brush assignment was randomized after screening, and only the PI and the Study coordinator had access to the randomization key.

The test group was assigned to a new power toothbrush while the control group was assigned the ADA approved manual flat trim soft bristle toothbrush. For the duration of the 4-week home use trial. Both groups agreed to refrain from the regular use of mouthwash and any interdental device, such as floss, floss picks, toothpicks, water flossing device, interdental brush or chewing gum during the length of the study. Written instructions on brushing and professional brushing demonstration were provided at the outset of the study and repeated at 2- and 4-weeks. Brushes or brush heads were replaced at 4 weeks. Before each visit, subjects had at least 7 hours, but no more than 12 hours of accumulated, non-brushed, undisturbed plaque/debris.

The study also has an extended component, up to 12 weeks, to determine the longer term effect and to see patient motivation when there is no oral hygiene instruction or supervised brushing between 4 to 12 weeks. The results for the 12 weeks, however will be analyzed as a different paper.

Description of Clinical Parameters used in the study

Oral cavity examination

Oral cavity examination for safety assessments included evaluation of the lips, tongue, hard and soft palate, gingiva, all mucobuccal fold areas, the inner surface of the cheeks and sublingual areas, tooth surfaces and restoration surfaces. All areas were assessed and reported as normal or abnormal with an explanation of any abnormality by one of the calibrated study examiners.

Lobene modification of the Loe and Silness Gingival Index

0= Absence of inflammation

1= Mild inflammation; a slight change in color, little change in the texture of any portion of but not the entire marginal or papillary gingival unit.

2 = Mild inflammation; criteria as above but involving the entire marginal or papillary gingival unit

3 = Moderate inflammation; glazing, redness, edema, and or hypertrophy of the marginal or papillary gingival unit

4 = Severe inflammation; marked redness, edema and or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration

Lobene modification of Turesky Plaque Index

0 = No plaque.

1 = Separate flecks of plaque at the cervical margin of the tooth.

2 = A thin continuous band of plaque (up to one mm) at the cervical margin of the tooth.

3 = A band of plaque wider than one mm but covering less than one-third of the crown of the tooth.

4 = Plaque covering at least one-third but less than two-thirds of the crown of the tooth.

5 = Plaque covering two-thirds or more of the crown of the tooth.

Probing Pocket Depth

Full-mouth Probing Pocket Depth (PPD) was measured at six locations of each tooth (mesial-buccal, buccal, distal-buccal, mesial-lingual, lingual, distal-lingual) using a periodontal probe and recorded to track probing depth changes over time.

Bleeding on Probing Index

The Bleeding on Probing index (BOP) was recorded from the gingival sulci of all teeth after periodontal probing at all six locations per tooth. The presence of any bleeding within 30 seconds of gentle probing was considered a positive response and given a score of 1. Sites which did not bleed on probing were be scored as 0.

Randomization blocks:

List 1: Low PI ($\leq$ 2.0) and Low GI ($\leq$ 1.33)

List 2: Low PI ($\leq$ 2.0) and Medium GI (> 1.33 to $\leq$ 2.67)

List 3: Low PI ($\leq$ 2.0) and High GI (> 2.67)

List 4: High PI (> 2.0) and Low GI ($\geq$ 1.33)

List 5: High PI (> 2.0) and Medium GI (> 1.33 to <= 2.67)

List 6: High PI (> 2.0) and High GI (> 2.67)

Examiner Calibration

All the examiners in the study were calibrated.

Table 1: Intra examiner reliability

Examiner	Time point	Sites	Kappa Statistics
1	Screening 2	64	0.5 for GI
2	Screening 1	464	0.4 for MGI, 0.34 for PI
3	Screening 1	464	0.5 for PI
2	Screening 2	64	0.47 for GI
1	Screening 3	72	0.49 for GI
2	Screening 3	72	0.5 for GI
3	Screening 3	72	0.42 for PI

Inter examiner reliability for examiner 1 and 2 for gingival index was 0.37 for 64 sites at second screening.

Inclusion Criteria

Age 18-65 yrs

Routine manual toothbrush user

A Subject, who agrees to use assigned toothbrush and refrain from interdental cleaning/ mouth rinsing.

Mild to moderate gingivitis as defined by Modified Gingival index above 1.2, and/or Bleeding on probing of at least 20% but not more than 50%.

Probing pocket depth of 4mm or lower

At least 20 natural teeth

Exclusion Criteria

Current electric toothbrush user

Professional prophylaxis within one month.

Use of antibiotic within one month

Signs of moderate to severe periodontitis

Participated in oral care study in the last 90 days

Pregnant or lactating women

History of cardiovascular disease, diabetes, cancer, AIDS or organ impairment

History of rheumatic fever, kidney or liver disease

Limited use of NSAIDs

Current smoker (last 3 months)

Table 2

Procedure	Performed by	Visit			
		Screening	Baseline	2-week	4-week
Plaque accumulation	Subject	7-12hrs	7-12 hrs	7-12hrs	7-12hrs
Patient information					
Informed consent form	Study coordinator/staff	X			
Patient demographics	Study coordinator/staff	X			
Medical/dental history	Study coordinator/staff	X			
Oral cavity exam	Examiners 1,2,3	X	X	X	X
Gingival Index (MGI)	Examiners 1 and 2	X	X	X	X
Probing Pocket Depth	Examiners 1 and 2	X	X	X	X
Bleeding Index	Examiners 1 and 2	X	X	X	X
Plaque Index	Examiners 2 and 3	X	twice	X	X
Examiner calibration	All examiners	X			
Product introduction and instruction	Un blinded staff/study coordinator		X	x	x
Brushing at clinic	Subject		X	x	x
Scheduling future visit	Study coordinator/staff	X	X	X	X

Figure 1
Study and visit procedures

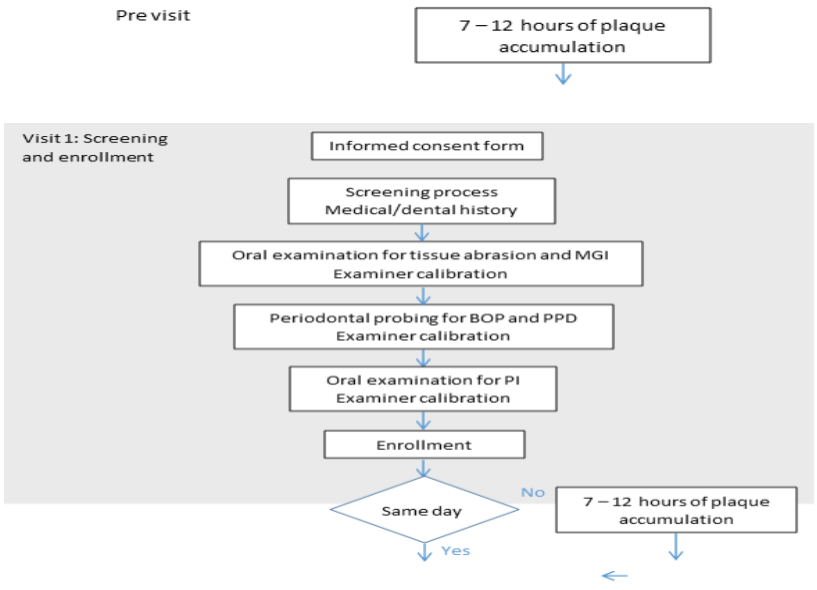


Figure 2

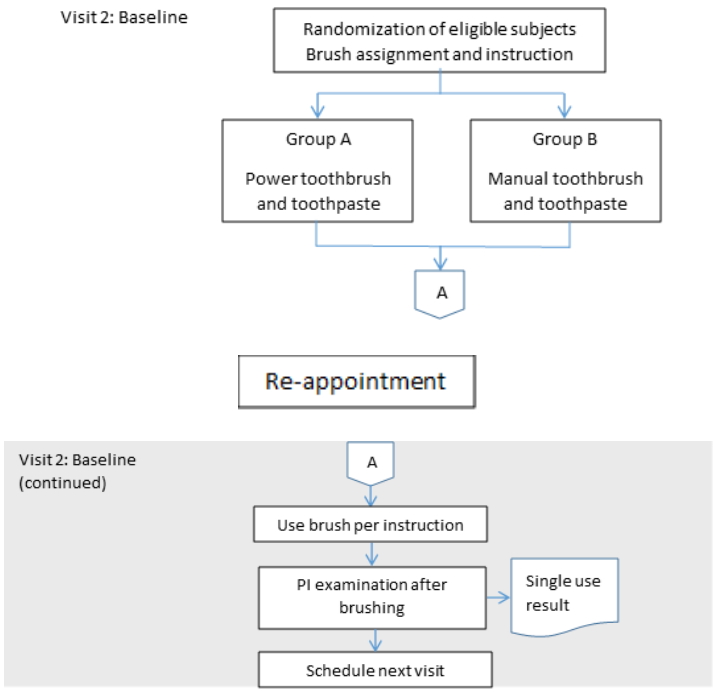


Figure 3

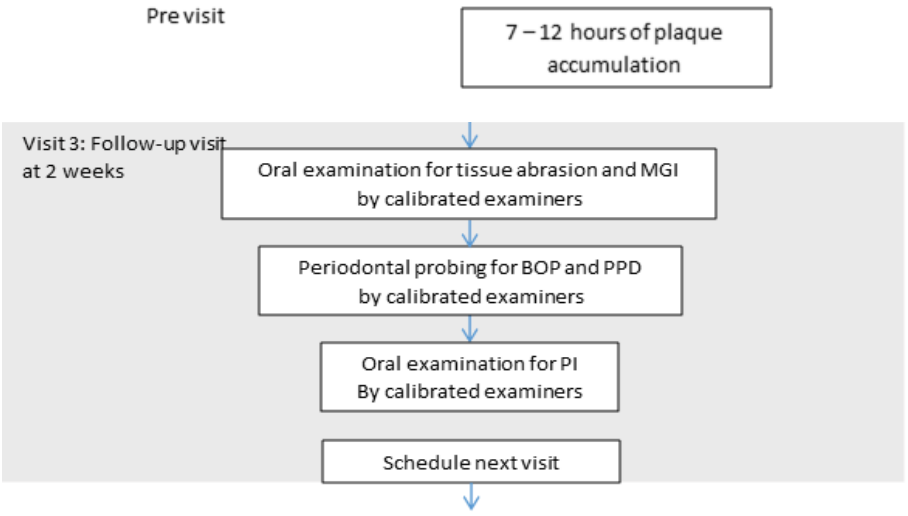


Figure 4

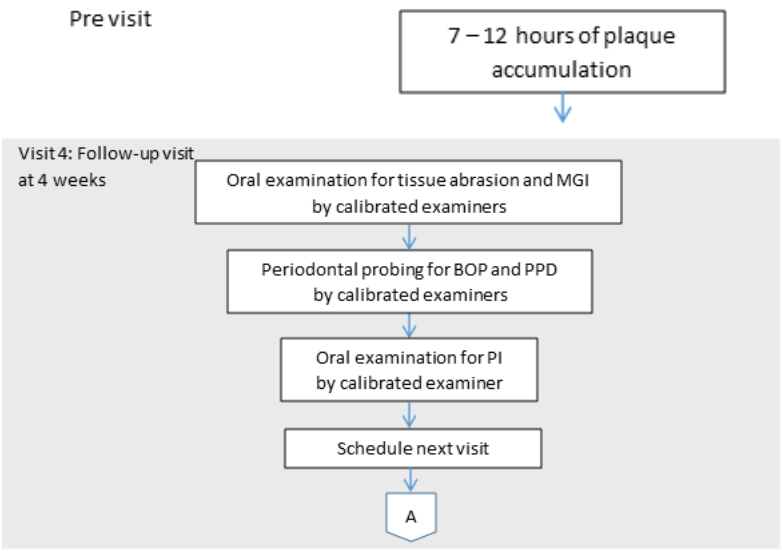


Table 3.

	Group A (Power brush users)	Group B (Manual brush users)
Number of subjects	24	22
Number of females	18	14
Number of males	6	8
Average age (years)	26.7	25.5

Results

Gingivitis measures over time were assessed using mean BOP and MGI scores. For patient-level analysis T-tests were conducted. The results are summarized as follows:

Bleeding on probing

Table 4. Mean BOP (+/- SD) Over Time

Time	Power Brush Mean BOP	(+/- SD)	Manual Brush Mean BOP	(+/- SD)
Baseline	22%	2%	27%	2%
2 week	17%	1%	21%	2%
4 week	16%	1%	19%	2%

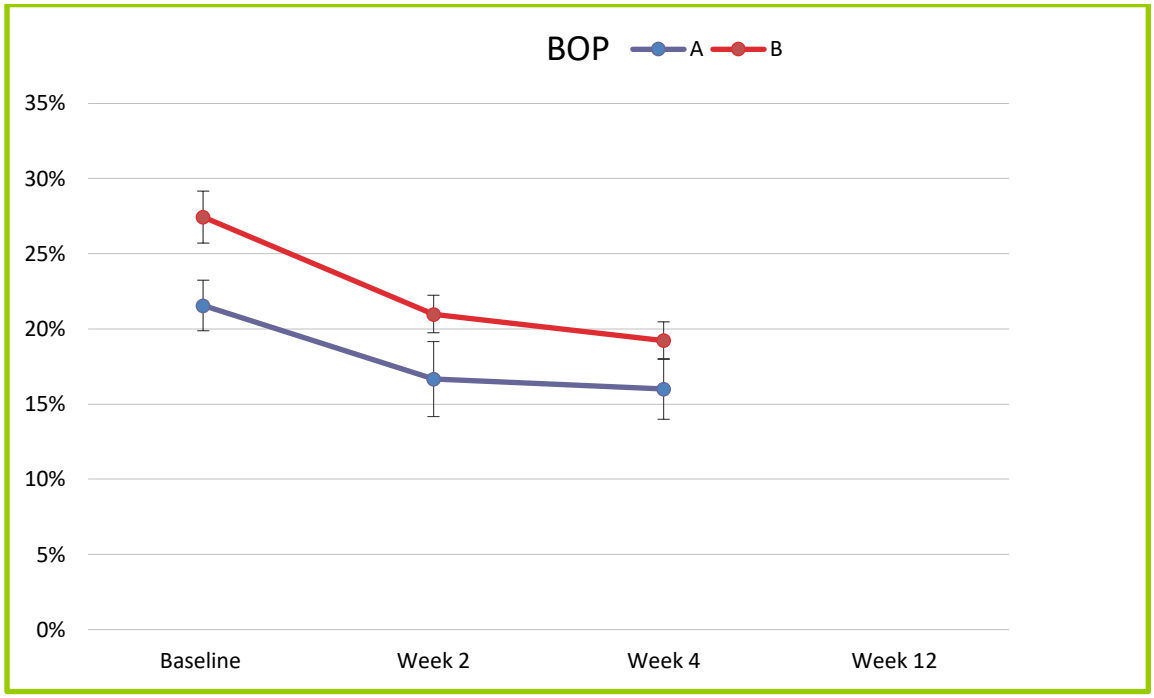
Table 5. Difference week 2 -Baseline

Brush type	N	Mean	Std Dev	Minimum	Maximum	P value
Power	26	-0.05	0.09	-0.29	0.11	0.6061
Manual	23	-0.06	0.12	-0.34	0.17	

Table 6. Difference week 4 -Baseline

Brush type	N	Mean	Std Dev	Minimum	Maximum	P value
A (Power)	24	-0.05	0.08	-0.23	0.14	0.2680
B (Manual)	22	-0.08	0.10	-0.29	0.10	

Figure 5: Bleeding on Probing Change over Time



BOP decreased from baseline 22% to 17% at 2 weeks and 16% at 4 weeks for Power users (Group A). For Manual users (Group B) BOP decreased from baseline 27% to 21% at 2 weeks and 19% at 4 weeks, so both groups had a reduction in BOP but there was no statistical significance for either group (Tables 5 and 6, Figure 5).

Similar observations were made for the Modified Gingival index (Table 7 and 8, Figure 6).

Modified Gingival Index

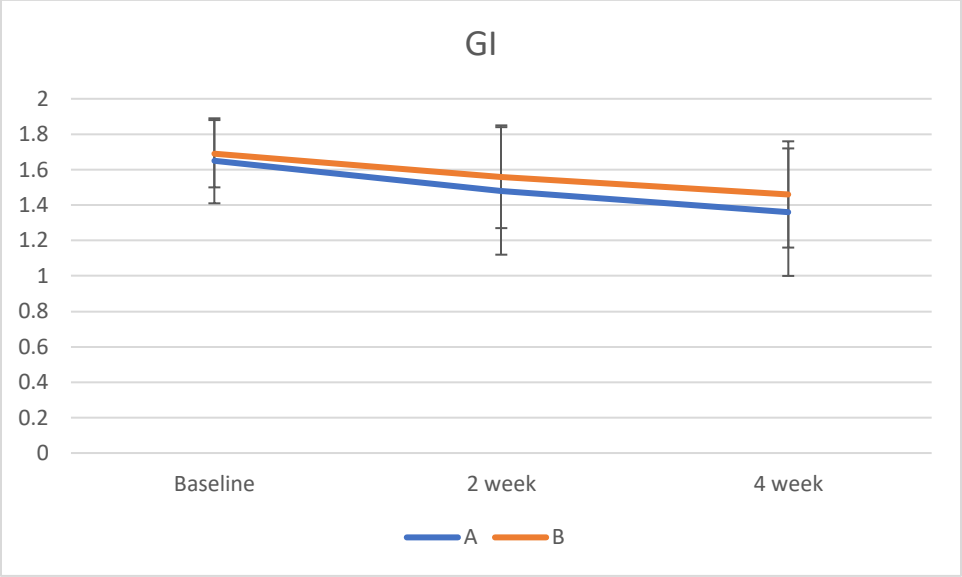
Table 7. Difference week 2 –Baseline

Brush type	N	Mean	Std Dev	Std Err	Minimum	Maximum	P value
A	27	-0.17	0.29	0.06	-0.84	0.51	0.6683
B	22	-0.13	0.30	0.06	-0.78	0.46	

Table 8. Difference week 4 -Baseline

Brush type	N	Mean	Std Dev	Std Err	Minimum	Maximum	P value
A	25	-0.27	0.33	0.07	-1.00	0.46	0.7211
B	21	-0.24	0.28	0.06	-0.62	0.46	

Figure 6: Modified Gingival Index



Gingival index for Power users (Group A) decreased from 1.65 at baseline to 1.48 at 2 weeks and 1.36 at 4 weeks and for Manual users (Group B) Gingival Index at baseline was 1.69 and 1.56 at 2 weeks, 1.46 at 4 weeks. There was no statistical significance for either group.

Plaque assessments overtime are shown in Tables 9 and 10, as well as Figure 7.

Plaque Index

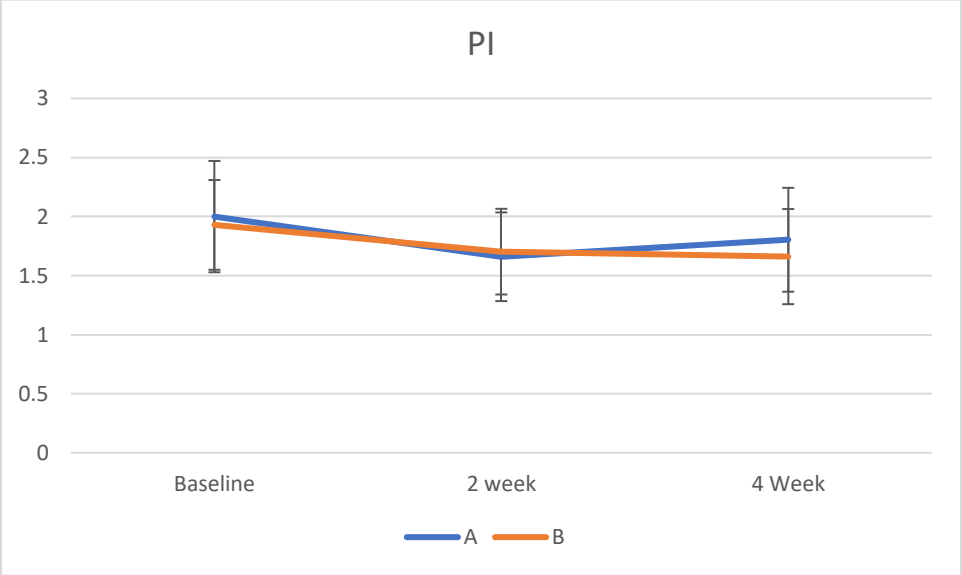
Table 9. Difference week 2 -Baseline

Brush type	N	Mean	Std Dev	Std Err	Minimum	Maximum	P Value
A	26	-0.3307	0.4595	0.0901	-2.0577	0.3214	0.4205
B	22	-0.2274	0.4131	0.0881	-0.8869	0.5417	

Table 10. Difference week 4- Baseline

Brush type	N	Mean	Std Dev	Std Err	Minimum	Maximum	P value
A	24	-0.1985	0.4701	0.096	-1.4231	0.6667	0.4031
B	20	-0.314	0.4286	0.0958	-1.0833	0.4103	

Figure 7: Plaque Index



Plaque index for Power users (Group A) at baseline was 2 and dropped to 1.6 at 2 weeks and was 1.8 at 4 weeks. Manual brush users (Group B) were 1.93 at baseline and dropped to 1.7 at 2 weeks and 1.6 at 4 weeks. There was no statistical significance in plaque reduction for either brush although there was a slight downward trend over all.

For site level assessment of BOP over time ANOVA was carried out. The results are summarized in Figures 8-10.

Bleeding on Probing

Both Brushes showed a downward trend from baseline to 4 weeks, but there was no statistical significance in any of the measures.

Figure 8: BOP at Facial sites

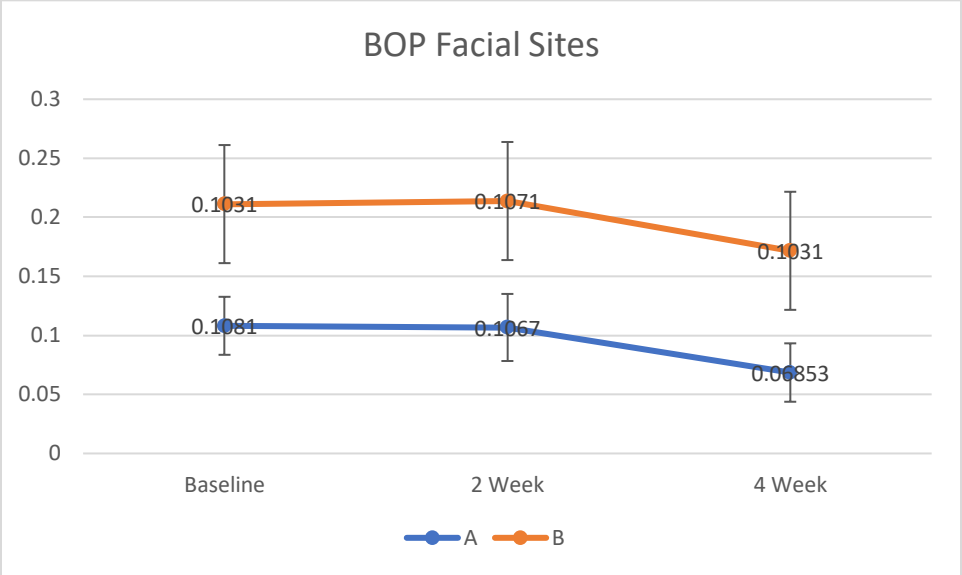


Figure 9: BOP at Lingual Sites

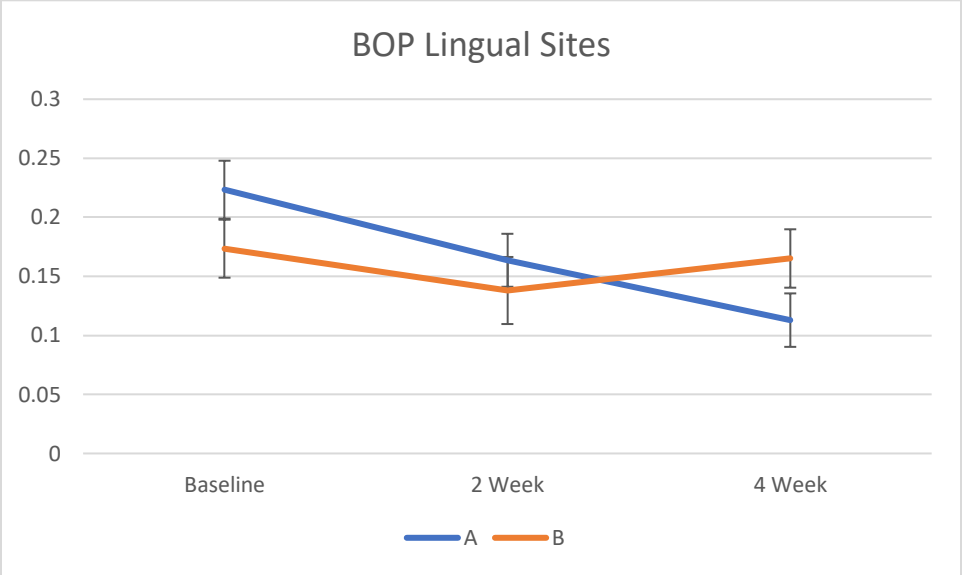
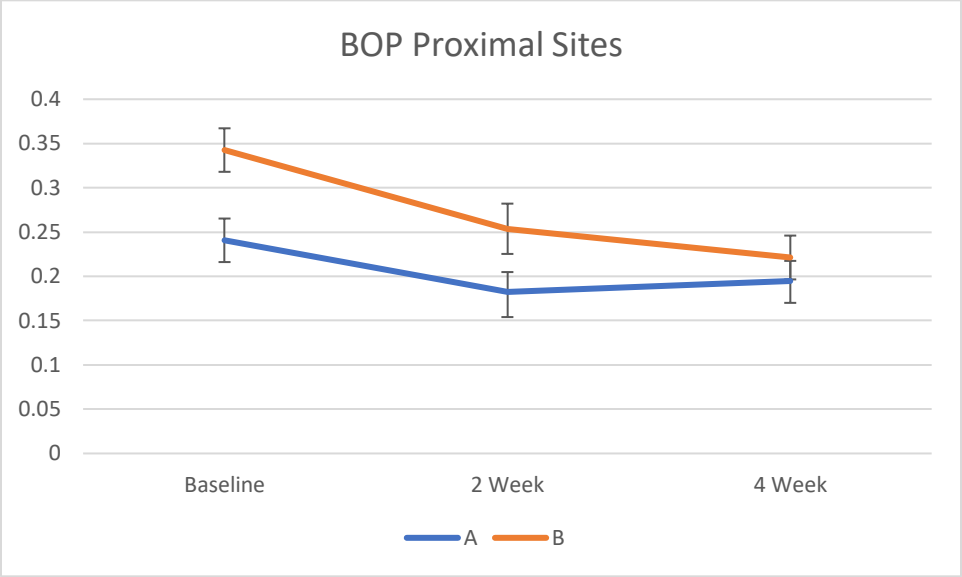


Figure 10: BOP at Proximal Sites



In both groups there was, however, a statistically significant reduction in BOP at facial sites compared to proximal sites over four weeks (data not shown).

Modified Gingival Index

Figure 11: MGI at Facial Sites

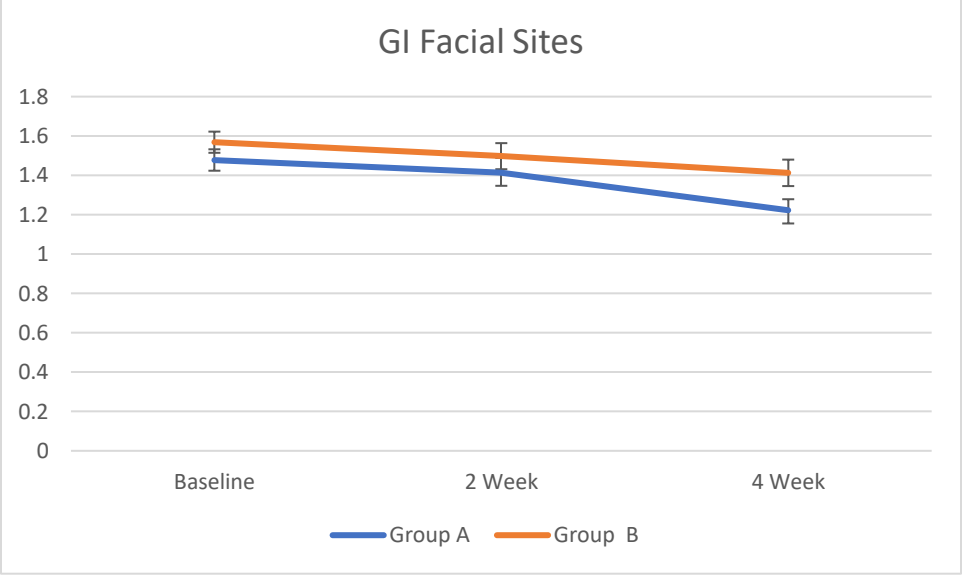


Figure 12: MGI at Lingual Sites

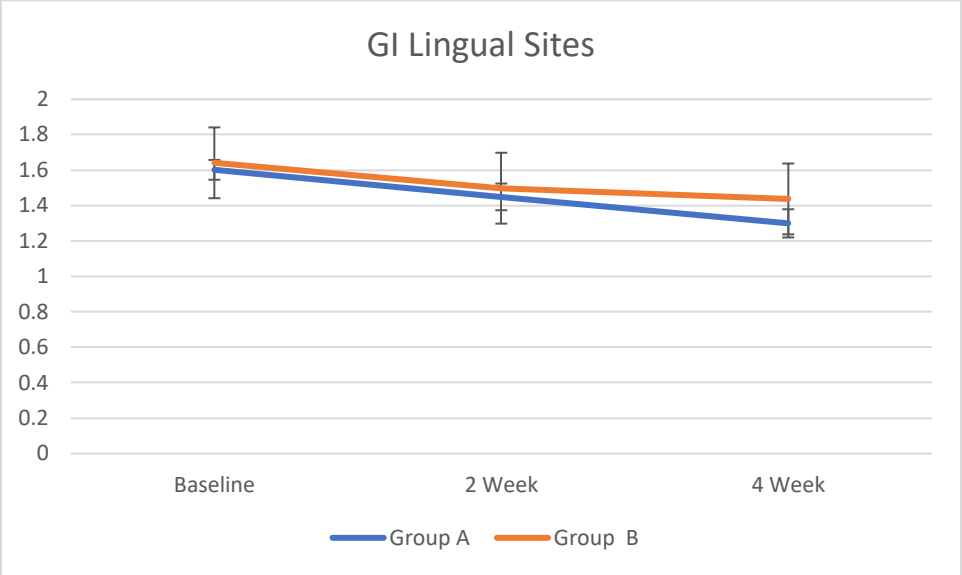
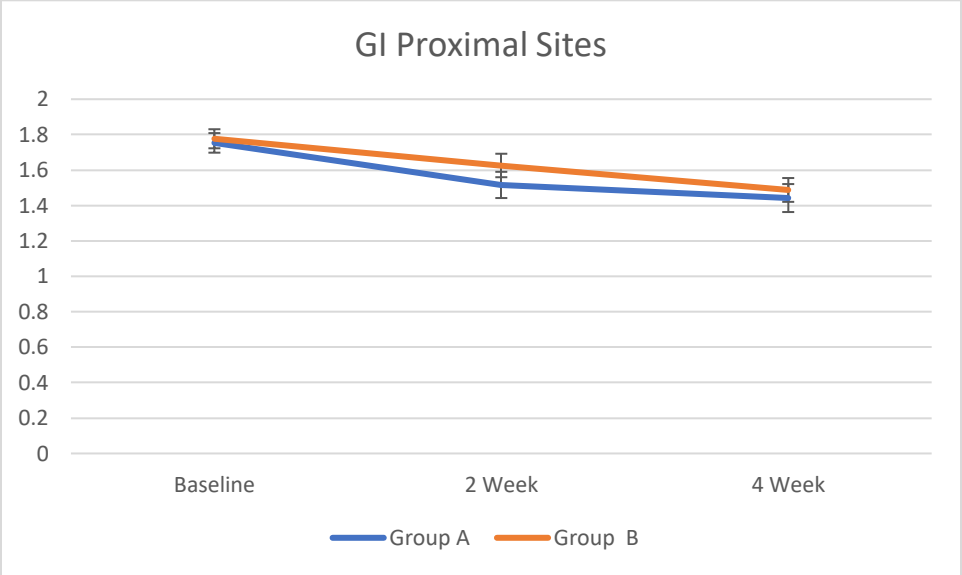


Figure 13: MGI at Proximal Sites



No statistically significant difference was seen for GI reduction for either brush over this short timeframe.

Plaque Index

Plaque levels also showed no statistically significant changes for either brush as seen in Figures 14-16. More reduction in Plaque index was seen for facial sites compared to proximal in both Group A and Group B. A significant reduction was seen in Facial sites compared to interproximal sites in both Group A and B.

Figure 14: MPI at Facial Sites

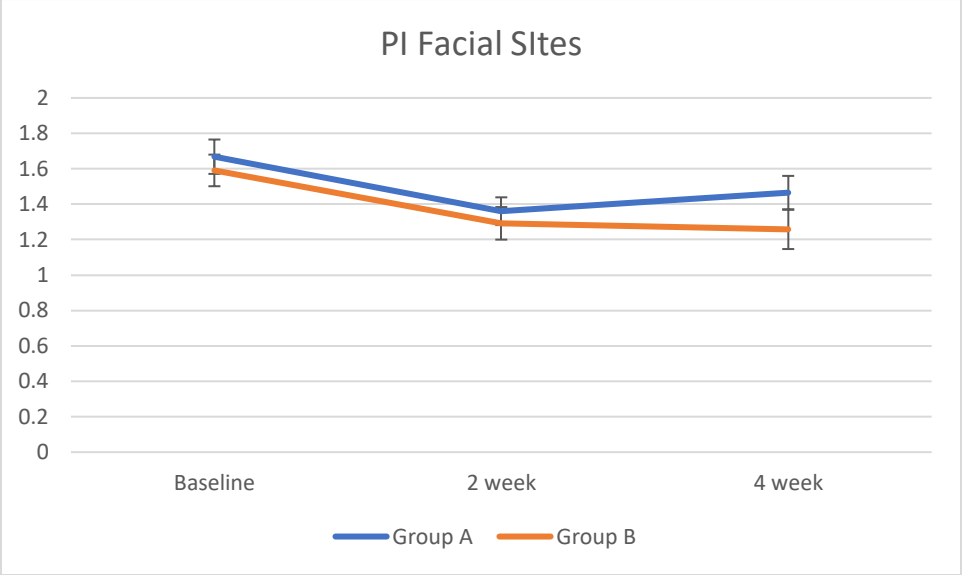


Figure 15: MPI at Lingual Sites

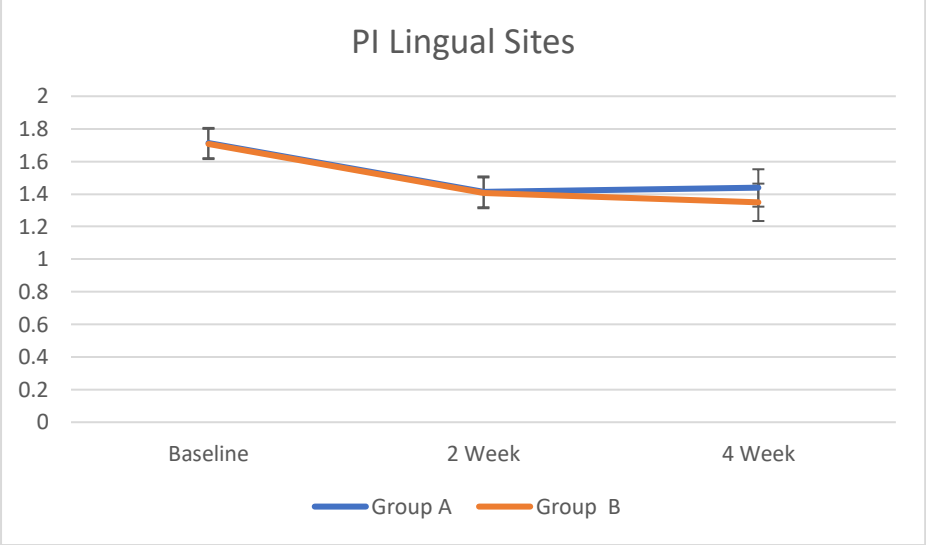
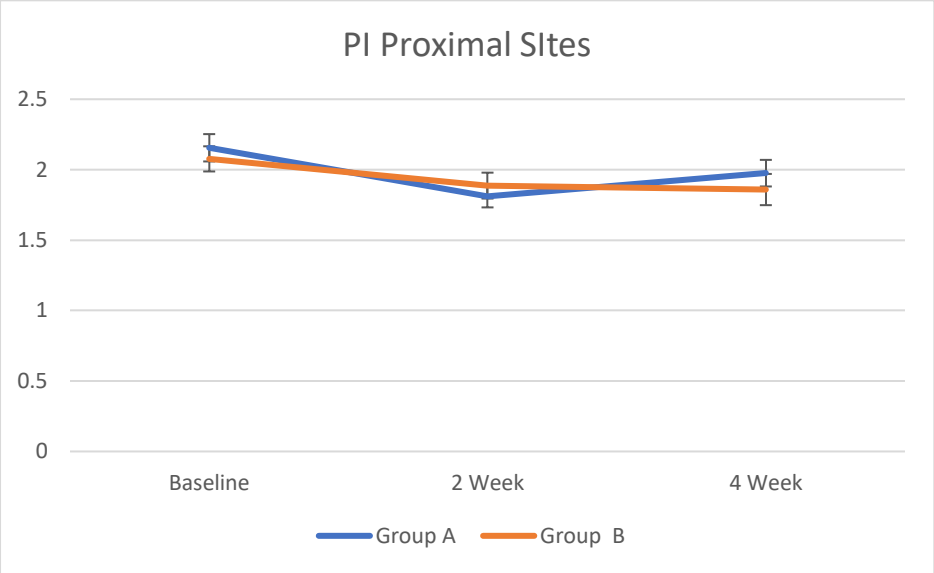


Figure 16: MPI at Proximal Sites



Patient-level analysis

BOP decreased from baseline 22% to 17% at 2weeks and up to 16% at 4 weeks for Power users (Group A), for Manual users, (Group B) bop decreased from baseline 27% to 21% at 2 weeks and 19% at 4 weeks, so both groups had a reduction in BOP but there was no statistical significance. Gingival index for Power Users, (Group A) decreased from 1.65 at baseline to 1.48 at 2 weeks and 1.36 at 4 weeks and for Manual Users (Group B) baseline is 1.69 and 1.56 at 2 weeks, 1.46 at 4 weeks. There was no statistical significance for either group. Plaque index for Power Users (Group A) at baseline was 2.0, and 1.6 at 2 weeks and 1.8 at 4 weeks, showing a slight increase from a 2-4 week, for Manual Users (Group B) 1.93 at baseline and 1.7 at 2 weeks and 1.6 at 4 weeks. There was again no statistical significance in plaque reduction for either group.

Site level analysis

The site level reduction is statistically significant in both groups for facial sites compared to interproximal sites in all clinical parameters BOP, GI, PI. In the Manual users (Group B) more reduction in BOP was seen at 2 weeks interproximally compared to facial sites whereas the reduction in both facial and interproximal aspects is similar in the Powered Users (Group A). Whereas at 4 weeks BOP in both groups

was significantly reduced in facial sites compared to proximal sites. A patient-level analysis showed a trend towards reduction in BOP, MGI, and PI from baseline to 4 weeks continuously in both Groups.

Discussion

Lazarescu and co-workers (38) evaluated habitual plaque levels and removal of 24 hours undisturbed plaque by supervised brushing for 3 minutes at baseline, 3 weeks, 6 weeks, 12 weeks and 18 weeks. They found a significant reduction in habitual plaque in the manual brushes starting from 3 weeks whereas, for the electric toothbrush users, a significant reduction was not found until 12 weeks. This suggests that subjects more easily trained on the manual brush compared to the electric brush.

Heasman et al (36) showed that difference in plaque index reduction achieved statistical significance at interproximal surfaces for powered brushes at 6 weeks. They found a significant reduction in plaque index at interproximal sites at 6 weeks and did not find a significant difference from baseline for the gingival index.

Jain et al (56) compared a manual to the oscillating-rotating power brush after providing instructions to dental students, and found there was a significant reduction in the gingival index at 2 weeks in power brush group which is in contrast to our current study. Together these observations may suggest that with the general population there is a learning curve associated with the oscillating-rotating power brushes.

In an 8 month study Van der Weijden (57) compared an oscillating rotating toothbrush to a manual toothbrush for reductions in plaque and gingivitis in a college population. The subjects in both groups were given timers and written instructions. After 4 weeks they received toothbrush specific professional instruction by a hygienist. By five months and eight months they showed significant reductions in Plaque and Gingival indices for both groups. These data suggest that when subjects are well trained it may be difficult to see clear differences in the efficacy of a well-used manual brush and a oscillating-rotating toothbrush. In our short term study this is the most striking observation we can make. It will be interesting to see if after and additional 8 weeks with no further intervention if both brushes continue to show similar measures of inflammation and plaque levels.

The Hawthorne effect also must be taken into consideration in a short term study such as presented in this clinical because both groups of subjects had very explicit instructions at every visit. This effect likely contributed to the reduction in gingivitis for both the groups at both two and four weeks.

Conclusion

Both groups demonstrated a reduction in signs of gingivitis (BOP and GI) in this non-flossing population after being repeatedly trained in toothbrush use over a 4-week period.

Both toothbrushes were equally effective in reducing overnight plaque as a single use exercise after initial professional training. Both brushes appeared to be safe in this short term trial.

The 12 week data will need to be evaluated to determine if a longer duration of use is helpful in discriminating the effects of either brush in reducing plaque and/ or gingivitis.

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