Chapter 1 HISTORY OF POWER BRUSH EVOLUTION

It is well accepted that regular oral hygiene is the key to oral health. Mechanical removal of plaque has been demonstrated to be the key to success. Twigs, fiber pencils, toothpicks, and the human finger have all been used in the past as a way to remove plaque. Although the precursor of the modern toothbrush was developed in the 1700s, it was not until the 1800s that the modern era of the toothbrush started. The 1900s brought about synthetic, nylon bristles replacing the natural swine bristles that were previously used. *[Beals, 2000, 5; Segrave, 2010, 5, 6]*

The first electric toothbrush was designed in Switzerland for Broxo in 1939. Initially these brushes were created for patients with limited motor skills. The first mass marketed brush was the Broxodent brush from Squibb and Son Pharmaceuticals in 1960 (See Figure 1).

Figure 1:

Squibb's Broxodent: Marketed in 1960, this was the first actively marketed power toothbrush.



In 1961, General Electric (GE) marketed a rechargeable cordless toothbrush with a back and forth motion, and a speed of 2000 strokes/minute. The brushhead featured a rectangular head shape and a flat trim, similar to that of a manual brush (See Figure 2). This brush reportedly removed 20% more food debris than manual brushing alone. In 1964, the ADA Council on Dental Therapeutics recognized the GE power toothbrush as an effective cleansing device mainly for people with limited physical or mental capacities. Two decades would pass before the power toothbrush arrived to stay. [Segrave, 2010, 135, 136, 140]

Figure 2:

GE cordless power toothbrush: This 1960s model had a rectangular head shape and a flat trim similar to a manual brushhead.

Between 1980s-1990s, a new generation of power toothbrushes were introduced to the marketplace. Manufacturer's introduced innovative brush designs and



modes of action that improved the effectiveness both in plaque removal and reduction of gingivitis. Before 1980 manual brushes were considered to be as effective as a powered toothbrush. Sometimes even more effective based on the evidence. Since 1980 though, the evidence has confirmed that power toothbrushes are now generally more effective than manual brushes.

The 1980's and early 1990's saw the introduction of a new series of power toothbrushes. Interplak introduced Rotadent which used circular motion in a single direction. The Sonicare power toothbrush which used "sonic" side-to-side technology was introduced in 1991, the Braun Oscillating-Rotating power toothbrush was also introduced. The power brushes available in most markets today are offered by Rotadent, Sonicare, Colgate and Oral-B. (See Table 1 in Appendix)

This technical manual will focus on the evolution of the design and feeature of teh Oral B ORP power toothbrush.

Figure 3:

Evolution of the Power Toothbrushes.



The Oscillating-Rotating (O/R) toothbrush introduced a completely different brushhead. The first powered

toothbrush to have the filaments on the brush circling first in one direction, then the other to provide rapid shearing forces on the surface of the tooth providing better plaque removal. The Braun D5 Plaque Remover (See Figure 4) emulated the motion of professional rotary instruments used in dental prophylaxis. The Oral-B-Braun power toothbrushes were the first proven to be more effective than manual toothbrushes with respect to both plaque removal and maintenance of gingival health. [Warren, 1996, S5]

Figure 4:

Braun D5 Plaque Remover: Professionally inspired design with oscillating-rotating movement.





In 1998, Gillette, who acquired Braun introduced the Oral-B 3D Plaque. This was considered a breakthrough in technology that it incorporated not just the movements from oscillation/rotation but also pulsations along the long axis of the bristle to more effectively disrupt and then sweep away the plaque (See Figure 5).

Figure 5:

A) Oscillating/Rotating/Pulsating Movement and B) The Braun Oral-B 3D Plaque Remover



More enhancements to the model resulted in the development (or introduction) in 2005 of the Oral-B Triumph[™] ProfessionalCare 9000 powered toothbrush. This toothbrush contained an onboard computing device in the handle and a microchip in each brushhead. This allowed for compliance alerts on when to replace the brushhead and an audible signal every 30 seconds letting the consumer know to move to another mouth quadrant. *[Segrave, 2010, 144]*

Table 1:

Powered toothbrushes: Contemporary powered toothbrushes are available with various modes of action and brushhead movements. [Davies, 2006, 160; Niederman, 2003, 1242]

Mode of Action	Brushhead Motion	Examples
Circular	Entire brushhead rotates in a full circle moving in one direction only	Rotadent
Multidirectional Sonic	Entire brushhead rotates in a full circle moving in one direction only	Colgate ProClinical
Side-to-side "Sonic"	Brushhead moves laterally in a side-to-side motion	Philips Sonicare/Colgate Oral-B Pulsonic
Oscillating- rotating- pulsating	Brushhead oscillates and rotates as well as pulsates along the axis of the brushhead	Oral-B Power Toothbrush

CHAPTER 2 SCIENCE BEHIND ORAL-B POWERBRUSH TECHNOLOGY

1) Oscillating-Rotating Technology

Oral-B power toothbrushes continue to be built on the fundamental understanding of how plaque is best disrupted from the tooth surface. The disruption and removal of plaque depends on the brushhead motion, supplied by the drive motor in the handle, and the brushhead design.

a Physics of direction change.

The motion of the Oral-B power toothbrush is designed to not only disrupt the plaque biofilm, but to lift and sweep it away (See Figure 7). High-speed photography and a robotic cleaning effectiveness demonstrated that the most effective interproximal space penetration occurs when toothbrush bristles change direction. Both the oscillation and rotating momentum by the motion of the bristles create high shear forces that help disrupt plague biofilm on the tooth surface. (See Figure 7). In addition, the brushing action provided by oscillatingrotating-pulsating bristles leads to deep interproximal penetration that lifts and sweeps plaque away on both the forward and backward movements. The efficacy of the O/R technology has been confirmed both in laboratory tests and in clinical trials relative to various manual brushes and other power brush technologies. [Beals, 2000, 8; Cugini, 2006, 323; Walters, 2007, 52]

Figure 6:

O/R movements: Plaque biofilm is lifted and swept away. A) Plaque biofilm is a sticky substance that adheres to the tooth's surface. B) O/R forces oscillate up to 8800 times/ minute to remove plaque biofilm.



Figure 7:

Bristles change direction: Oscillating-rotating movement causes high shearing forces that disrupt plaque biofilm.







b. Brushhead design:

A key part in the success of the Oral-B Power toothbrush is established partnership with dental professionals, dental advisory boards and universities. Their input in all stages of product development, research findings, professional knowledge and experience led to the design of a small round brushhead to fit on the O/R handle. Oral prophylaxis is considered the gold standard for plaque and stain removal. Therefore the brushead was designed to be similar to the professional dental instruments used for prophylaxis. (See Figure 8).

Figure 8:

Prophy angle with a round rotating rubber cup used during professional cleaning



The Oral-B circular brushhead rotates and oscillates. The cup-shaped brushhead has a diameter of approximately 13mm with the bristle tufts placed in strategic positions. This allows the brushhead to adapt to each tooth surface by cupping the tooth and reaching in between the teeth to aid in cleaning difficult-to-reach surfaces. Patients are instructed to brush each tooth individually, following the morphology of the tooth. In addition, the length of brush and the small, round brushhead allows access to other difficult-to-reach portions of the mouth such as the back teeth and the lingual anterior surfaces. (See Figure 9). *[Pizzo, 2010, 379, 380]*

Figure 9:

Oral-B brushhead: Small, round brushheads adapt to the various anatomical features of each tooth. Figure shows A) entire small, round brushhead; and B) cupping of each tooth.

A)



в)



Figure 10:

The Oral-B power toothbrush allows users to effortlessly reach the A) anterior lingual and B) posterior teeth.





c. Optimizing Oscillation Frequency and Oscillation Angle

New developments to the line of Oral-B power brushes include handles that are more ergonomic, specialty brushheads and compliance enhancing features. As part of these improvements, the frequency at which the brushhead oscillates has been optimized to 8800 oscillations per minute. In addition, the brushhead is angled 3-5 degrees from the handle to help users reach posterior regions and allow effortless progression from tooth to tooth. *[Pizzo, 2010, 380]*

2) Addition of Pulsating Technology

A third dimension of movement was introduced to the O/R toothbrush in 1998. The addition of pulsating action or up/down movement along the long axis of the bristles was developed in order to enhance plaque removal from hard-to-reach sites, such as interproximal surfaces and occlusal fissures (See Figure 11). In robot testing, the 3D movement oscillating/rotating/pulsating was shown to remove significantly more plaque substitute than its predecessor, the O/R brush. Clinical testing demonstrated that pulsations allow improved plaque removal efficacy compared to O/R alone from all sites of the whole mouth and interproximal surfaces by 50%. *[Ernst, 1998, Pizzo, 2010, 380; Walters, 2007, 50]*

Figure 11:

Pulsating movements



The pulsating movement was initially combined with the oscillating-rotating brushhead action in the Oral-B 3D and 3D Excel model toothbrushes. Unlike other power toothbrushes, the 3D brush pulsates in and out 40,000 times/minute while oscillating rotationally at 8,800 times/minute.

Improved tooth surface cleaning, as well as a reducing gingivitis, have been shown to be the greatest benefits of O/R/P power toothbrushes and have been demonstrated in both short and long term studies. [Niederman, 2003, 1241; Yankell, 2011, 55]

CHAPTER 3 HANDLE TECHNOLOGY AND CONNECTIVITY

1) Pressure Sensor

Oral-B introduced technology that could increase patient safety and compliance. There is an association between continued loss of structure and exposed dentin when abrasive toothpastes are combined with excessive force and pressure during tooth brushing. Studies have reported an increase in enamel abrasion in people who brush with greater frequency, with more pressure, and for longer periods of time in conjunction with the use of an abrasive dentifrice. The pressure sensor in the Oral-B toothbrush gives visual guidance on the right amount of pressure to use when brushing. If too much pressure is used, a red light on the brush handle will illuminate. This provides feedback to the user training them to apply the right amount of pressure. In a clinical trial, after just 30 days of at-home use, an 88% decrease in excessive brushing pressure time was activated by the subjects when compared to baseline.

When too much pressure is applied the brush head slows downs - the movements of the brush head the OR reduce the pulsations stop and they receive a visual alter. (See Figure 12). The pressure threshold (>2.4 Newtons or 250 grams) used in Oral-B power toothbrushes was established after numerous studies were conducted both in-vivo itali and in-vitro itali. [Janusz, 2008, 2, 3, 4, 9; van der Weijden et al]

Figure 12:

Pressure sensor: Technology in the handle senses when >2.4 Newtons of force is applied and handle is illuminated



2) Timer

Mechanical plaque removal through toothbrushing depends on a number of factors, including toothbrush design (eg, bristle shape and angle), brushing technique, and time spent brushing. To maximize the plaque removal efficacy, oral health professionals recommend people brush their teeth for at least 2 minutes, twice each day. A number of studies have demonstrated that the majority of people use inadequate brushing technique and brush their teeth significantly less than 2 minutes. Most individuals believe they brush their teeth for a longer time than they actually do. While people think they are brushing for more than 2 1/2 minutes, they are actually brushing **for less than a minute**. *[Beals, 2000, 5; Cugini, 2006, 323; Janusz, 2008, 2]*

Clinical studies have demonstrated that oral care products that provide visual and audio feedback improve patient compliance. The brush emits an audible and in some cases a visual signal every 30 seconds to remind the user to move the brush to a new quadrant, ensuring plaque removal throughout the oral cavity for a total of 2 minutes. Power toothbrushes with timers appear to help patients improve compliance and prolong brush time.. *[Janusz, 2008, 3; Walters, 2007, 52]*

3) Brushing Modes

Oral-B's most technologically advanced toothbrush also features up to 6 different modes to customize brushing. The button located on the handle directly below the power button is pressed to switch from mode to mode.

Daily Clean:

The daily clean mode is the standard mode for plaque removal and whole-mouth cleaning.

Deep Clean:

Deep clean mode, 3 minute cleaning (45 seconds per quadrant) has been shown to remove up to 99.7% of plaque from hard-to-reach areas.

Sensitive:

The sensitive mode offers gentle brushing and cleaning for the teeth and gums.

Massage:

The massage mode involves thorough yet gentle gum stimulation to maintain strong, healthy gums.

Polish:

The polish mode starts slow, becomes faster, and then repeats; it is clinically proven to help clean and whiten teeth.

Tongue Cleaning:

Dedicated mode for tongue cleaning post brushing

4) Connectivity-Smart Guide

Many models of the Oral-B premium power toothbrush are equipped with SmartGuide Technology. A microchip embedded in the power brush allows the handle to communicate with the user via the Oral-B SmartGuide shown in Figure 13. The brush handle and the smart guide provide signals and give clues to the user if they have brushed long enough and guides them to brush evenly across the mouth (See Figure 14). In addition the brush handle and SmartGuide informs the user when too much pressure is being applied. The timer displays total brushing time as well as a "smiley face" appearing on the display after 2 minutes of brushing. Both the 2 minute timer and 30 second quadrant reminder promote thorough brushing across the entire dentition. *[Janusz, 2008, 3; Walters, 2007, 52]*

Figure 13:

Oral-B Smart Guide



The wireless display can be positioned anywhere within 10–15 feet of the toothbrush handle, enabling the user to easily view the 2-minute timer, quadrant display, and brushing mode display while brushing. When the brush is not in use, the SmartGuide display works as a regular clock. *[Janusz, 2008, 4; Oral-B, 2012, 1; Walters, 2007, 53]*

Figure 14:

Oral-B SmartGuide quadrant display: Visual cues indicate when it is time to move to the next region of the oral cavity. Display includes the A) quadrant timer, and B) brushing reward.



The following studies demonstrate that patients increase their brushing times and thoroughness when using the Oral-B oscillation-rotating brush with SmartGuide.

Oral-B with SmartGuide vs Manual.

A key study compared brushing times for the Oral-B with SmartGuide vs a manual toothbrush.

- Randomized, open-label, parallel-group, 30day study of 40 healthy adult subjects
- Study objective: To evaluate the effect of the SmartGuide wireless display on brushing time
- Products: Oral-B with SmartGuide and Oral-B Advantage Plus[®] #40 manual toothbrush
- Results: Subjects using the Oral-B with SmartGuide had two brushing episodes at least 2 minutes long on 67.8% of days, while subjects using the manual toothbrush had two brushing episodes of at least 2 minutes

on only 13.3% of days which corresponds to a 5 fold increase in compliance (See Figure 15). *[Walters, 2007, 53]*

Additional data from this study also revealed 92% of patients who use the Oral-B power toothbrush improved their brushing thoroughness and 51% experienced more uniform brushing times across quadrants.

Figure 15:

Brushing for 2 minutes twice daily: Subjects showed increased compliance with the SmartSeries power brush compared with the manual brush.



Oral-B with SmartGuide vs Manual

As noted above, in addition to the brush handle the SmartGuide also includes a visual indicator that notifies the user when too much brushing force (>2.4 Newtons) is being applied. This image is shown in Figure 16. [Janusz, 2008, 4]

Figure 16:

Excessive brushing indicator: Red signal lights up when force above 2.4 Newtons is applied. A) handle light; and B) signal on wireless display.



The following study evaluated the contribution of the wireless display as well as audible handle signal to brushing thoroughness and force.

Janusz K et al. Impact of a novel power toothbrush with SmartGuide Technology on brushing pressure and thoroughness. *Journal of Contemporary Dental Practice.* 2008; 9(7):1-13.

 Results: Patients using the Oral-B power brush with SmartGuide showed statistically significantly larger reductions in pressure sensor activation times at day 30 vs baseline compared with patients using the Oral-B power brush with the deactivated pressure sensor. The Oral-B with SmartGuide group also showed statistically significantly more thorough brushing across the dentition and lingual/buccal surfaces relative to baseline.

The study concluded that people who used Oral-B's with SmartGuide improved their brushing force and thoroughness compared with those who brushed without pressure control (See Figure 17). *[Janusz, 2008, 1, 4]*

Figure 17:

Improved brushing habits: Pressure control and awareness of brushing force. Data from one patient over a brushing time of 2 minutes is shown, with less time spent above threshold (3 Newtons) when a toothbrush with pressure control (blue line) was used compared with a toothbrush without pressure control (red line).



5) Connectivity-Bluetooth

The latest advancement in Oral-B technology, is the world's first available Bluetooth connected power toothbrush. Data shows an increasing interest to use apps on smartphones and tablets to track health. Market research projects that half of 3.4 billion smartphone and tablet users worldwide will use mobile health apps by 2017.

Oral b has developed a free app for both ios and android devices to foster better brushing. The Oral-B power brush allows for two-way communication between the power toothbrush and the Oral-B app enabling real time feedback. This can lead to motivation and compliance rewards as well as a more personalized brushing routine.

The key features of the app include:

- delivers expert guidance with focused care, allowing a dental professional and the user to track their brushing routine and focus on problem areas
- programs personal brush settings by using their phone or tablet as a "remote control" to customize the brush to their needs, including preferred modes
- stores patient's data in brush for 20 different brushing sessions. Therefore, if you don't have your phone or tablet present the data will be transferred next time the app is activated.
- fosters better brushing by driving compliance with longer brushing, brushing all areas of the mouth, and using less pressure
- helps patients stay informed while they brush by offering news, weather and oral care tips



Professional's can use the app to help improve patient compliance by setting up personalized routines that identify areas that require extra care from patients, flossing reminders and rinsing reminders. They can also make product recommendations so the patient doesn't forget. With the patients agreement, the professional can use the data with them to assess compliance and

identify improvement areas.

The value of this technology is that patients can work hand-in-hand with dental professionals, essentially extending the professionals recommendations into the home routine and establishing healthy routines.

CHAPTER 4 BRUSHHEAD TECHNOLOGY

Earlier toothbrushheads were very large, using straight and stiff abrasive boar's hair bristles. Around 1950, Oral-B introduced the multi-tufted nylon filaments (bristles) that were flat-trim, vertical and end-rounded for safe brushing. To further develop the brushhead technology the engineers had to research how tufts and individual filaments behave during consumer use. In addition, they needed to understand how the filaments influenced plaque removal efficacy. (van der Weijden, Driesen, Warren)

Length, width and shape of the filaments come into play while developing both the manual and power brushheads used today. It was discovered that longer, thinner filament tufts are more effective interproximally. Shorter, thicker filament tufts are more effective on accessible tooth surfaces and angled bristles are superior in reaching approximal spaces. Other discoveries were that a filament is actually more actively cleaning during directional changes while brushing. If there is too much load (brushing pressure) applied to individual filaments they collapse and cannot enter the interproximal space effectively.

The brushhead options are designed to address different oral conditions and/or patient preferences. The individual brushhead designs include various types of filaments such as, coextruded bifilaments which reduce stiffness and increase interproximal penetration, micro pulse filaments to enhance plaque removal, while another has a polishing cup to facilitate stain removal. Some of the brushhead options also include rubber (non-latex) filaments that aid in plaque removal but also have the ability to stimulate the gingiva. Below are a few examples of filaments used in the power brushhead and the current portfolio of Oral-B brushheads: Crimped filaments designed to reduce axial stiffness



MicroPulse textured filaments

Rubber cup for polishing/whitening



The types of brushheads offered for the O/R power brush are described below by name and indication for use and design elements:

CrossAction Brush



The most recent innovation in brushhead technology incorporates Oral-B's CrossAction Technology. Patented CrossAction bristle design seen in the CrossAction manual toothbrush creates optimum shear force for outstanding plaque removal because the angled bristles are arranged with alternating lengths. The unique angled tuft design and trim covers 30% more surface area and includes increased tooth contour adaptation. Highest bristle density offers effective cleaning with even less brush force and a gentle feel. (Klukowska et al 2014)

Precision Clean



The precision clean brushhead incorporates an innovative arc brush topography with longer bristles and high bristle density. Novel bristle design provides excellent tuft surface density and penetration into deeper interproximal and marginal areas for a gentle cleaning experience. (Klukowska et al 2010)

FlossAction Brush



Designed for powerful tooth surface and interdental cleaning. This brushhead includes novel textured elements (MicroPulse Bristles) and multi-level flat trim lower density bristles and is the most researched brushhead in the collection.

MicroPulse Bristles are designed to create independent sweeping movements working in synergy with the pulsating movement of the brushhead. (Biesbrock et al 2008; Grender et al 2013)

Sensitive Brush



Brushhead for individuals with various hard and soft tissue sensitivity issues or who prefer a softer brushhead. The brushhead includes a high density field of crimped filaments that reduce axial filament stiffness, making it easier to cup the tooth surfaces which leads to a more gentle and effective way to disrupt and remove plaque. Recommended for use on sensitive gums after dental surgery.

Orthodontic Brush



The orthodontic brushhead was designed to be used by patients wearing orthodontic appliances containing brackets. The design includes special bristle configuration for removing plaque around orthodontic brackets where plaque tends to accumulate. The orthodontic is often used in conjunction with the Interproximal Power Tip shown below.

(Clerehugh et al 1997)

Interproximal Brush/Power Tip



This brushhead was designed to reach into difficult to clean areas such as, inter proximal areas, bridges, crowns, implants, orthodontic appliance and anatomical irregularities. The brush can be used in conjunction with the orthodontic brush. (Massad 2011)

Whitening Brush/Pro-White



Brushhead design to whiten teeth by removing surface stains. The polishing cup in the center of the brushhead is designed to deliver paste to the surface of the tooth. Effective surface stain removal aids in a whiter smile. (Klukowska et al 2008)

Children's Brush



This brushhead is recommended for use with children 8 years of age or older. The small round brushhead features filaments which allow greater paste retention, raised center row of filaments for improved cleaning of caries prone occlusal surfaces, soft for gentle cleaning and easy access to hard to reach areas for both parents and children.

Trizone/Deep Sweep



Oral-B sought to accommodate a segment of consumers who like the manual brushhead characteristics and have not adapted to the small round brushhead and tooth-specific focused cleaning approach. Therefore, an extensive research and development program was undertaken to develop a new brushhead to be used on the power brush handle. This novel brushhead, marketed as Oral-B TriZone or Oral-B Deep Sweep has unique features with a multidirectional movement derived from three distinct brush zones containing over 2000 bristles in contact with the tooth surface. Each zone collaboratively helps to provide improved plague removal. Zone 1 is the power tip for hard-to-reach back teeth; Zone 2 is a manual-like stationary bristles for thorough cleaning of the tooth surface; and Zone 3 is the wide sweeping-pulsating bristles for interdental cleaning. Laboratory and clinical effectiveness testing has shown that this new novel brushhead is very effective in disrupting plaque from the tooth surface.

This multi-direction power brush bead was designed for patients who use a scrub method of brushing or prefer a manual brush experience. The tip is positioned for hard to reach surfaces of posterior teeth. There are manual like stationary bristles as well as wide sweeping bristles to thoroughly clean both flat and inter proximal tooth surfaces. The TriZone brush action was inspired to mimic professionally recommended "modified bass" brushing technique. (Goyal et al 2011)

CHAPTER 5 GENTLENESS

A large body of research, in the last 2.5 decades, has demonstrated that Oral-B power toothbrushes are safe and do not pose a clinically relevant threat to hard or soft tissues. (van der Weijden, 2011) Over 103 in vivo itali clinical trials, which included a safety endpoint, involving more than 5500 subjects with study length ranging from 1 week to 35 months have been conducted.

One long-term study (35 months) compared the effects of brushing with an oscillating-rotating-pulsating power toothbrushes (n=55) to an ADA reference manual brush (n=54) in patients presenting with pre-existing gingival recession. Subjects were asked to brush their teeth for 2 minutes daily with their assigned brush and standard fluoride dentifrice. Assessments included clinical attachment loss and probing pocket depths at six sites per tooth by the same examiner over the course of 35 months. After 35 + 2 months, gingival recession in subjects with pre-existing recession was significantly reduced after three years of brushing with either the O/R brush or manual brush.



Gingival Recession at Sites with Pre-Existing Baseline Recession

A very complex dental abrasion safety assessment was also completed in this long-term study. To measure dental abrasion over time, each subject had a set of study models taken at 6, 12, 18 and 35 month time points. A 3-D Laserscan Profiler was used on each model to record the 3-dimensional profile of the cervical areas of the teeth for use in measuring depth of the abrasion present on the tooth surface. The data demonstrated that the Oral-B power brush had less abrasion at each time point but was not statistically significant from the manual toothbrush at any time point for depth of cervical dental abrasion. (Dorfer et al)



Abrasion

Another example of safety assessment is a 12 month study conducted to evaluate the effect of brushing with the TriZone power toothbrush or an ADA reference manual toothbrush on pre-existing mid-buccal gingival recession. All recession measurements were performed by one calibrated examiner for 107 subjects at baseline, 6 months and 12 months. Over the 12 months study period, the mean recession at sites with pre-gingival recession of > 2mm decreased significantly in both groups (p<0.05) and did not differ between manual and power groups at any time point.

2.0 1.74 1.72 Gingival Recession (mm) ADA Manual 10 Oral-B Brush 0. 0.0

Gingival Recession at Site with Pre-Existing Baseline Recession The trials described above exemplify the positive effect on gingival condition and hard tissue health over the long-term. The study summaries can be found at the end of the technical manual.

Since 1991 the Oral-B oscilating/rotating (OR) power toothbrush has consistently incorporated breakthrough technology to enhance the brushing experience. With each new technical advancement the toothbrush has become the most effective plague remover in the power toothbrush category currently.

The physics behind the direction change of the oscillating/rotating and pulsating movement of the O/R toothbrushhead ensures the most effective inter proximal space penetration and disruption of plaque on all tooth surfaces. Many toothbrushhead designs are available for both professionals and consumers to choose from to customize their brushing experience. In addition, features of the brush aid in controlling the pressure used while brushing, a timer to maximize plaque removal efficacy in all areas of the mouth and different brushing modes to further enhance compliance and customization.

The newest innovation added to the Oral-B power toothbrush is Bluetooth technology. The free app available to iOS and Android devices continue to help foster better brushing through real time feedback, motivation and compliance rewards allowing for a more personalized brushing routine. All of these innovations over the years are supported by over 100 clinical research studies. In the next section, we have highlighted some of the research studies that have been conducted to support claims of both superior efficacy and safety of the brush.

Baseline* 6 Months 12 Months

*Baseline values are means; Months 6 and 12 are adjusted means

**Difference between groups was statistically significant at Month 12 (P=0.005). N=107 subjects

CHAPTER 6 SCIENTIFIC EVIDENCE

The Oral-B power toothbrush has been studied extensively. To date there are over 120 clinical trials comparing the O/R/P power brush to either manual brushes, sonic technology or other power brush technology. Below is a table summarizing a few clinical studies that have been conducted over the last decade with the Oral-B power brush highlighting results for efficacy, safety and compliance versus both marketed manual toothbrushes and marketed sonic (side-to-side motion) power brushes. This is followed by the corresponding research summaries with references to the peer review publications included.

Oral-B Power Brush Head Type	Comparator	Duration	Measures	Statistically Significant Improvement in Plaque Removal vs Comparator?	Statistically Significant Improvement in Gum Health vs Comparator?
CrossAction	Sonicare DiamondClean	6 Weeks	Plaque/Gum Health	\checkmark	\checkmark
CrossAction	Colgate ProClinical A1500	6 Weeks	Plaque/Gum Health	\checkmark	\checkmark
CrossAction	ADA Manual Brush	4 Weeks	Plaque/Gum Health	✓	\checkmark
FlossAction	Sonicare DiamondClean	12 Weeks	Plaque/Gum Health	\checkmark	\checkmark
FlossAction	Sonicare FlexCare	12 Weeks	Plaque/Gum Health	\checkmark	\checkmark
FlossAction	Sonicare FlexCare Platinum	12 Weeks	Plaque/Gum Health	✓	✓
FlossAction	Colgate ProClinical A1500	12 Weeks	Plaque/Gum Health	✓	✓
FlossAction	Sonicare FlexCare	10 Weeks	Plaque/Gum Health	Х	~
Precision Clean	ADA Manual Brush	4 Weeks	Plaque/Gum Health	\checkmark	\checkmark
TriZone/Deep Sweep	Sonicare Essence	4 Weeks	Plaque/Gum Health	✓	\checkmark
TriZone/Deep Sweep	Sonicare Essence	8 Weeks	Plaque/Gum Health	~	✓
TriZone/Deep Sweep	ADA Manual Brush	4 Weeks	Plaque/Gum Health	✓	\checkmark

A 6-week Clinical Evaluation of the Plaque and Gingivitis Efficacy of an Oscillating-Rotating Power Toothbrush with a Novel Brush Head versus a Sonic Toothbrush

Reference: Klukowska M, Grender JM, Conde E, Goyal CR, Qaqish J, Schneider M. J Clin Dent 2014;25:6-12.

KEY CLINICAL RESULTS

• The oscillating-rotating brush with the novel brush head (O-R), Oral-B Triumph with SmartGuide with Oral-B CrossAction brush head, demonstrated statistically significantly greater reductions in all gingivitis and plaque measures compared to the sonic toothbrush, Sonicare DiamondClean.

The benefit for the O-R brush over the sonic brush was 32.6% for gingivitis (Figure 1), 35.4% for gingival bleeding, 32% for number of bleeding sites (Figure 2), 22% for whole mouth plaque, 24.2% for gingival margin plaque and 33.3% for interproximal plaque (Figure 3). $P \le 0.001$ for all measures, except gingival margin plaque where P = 0.018.

• Both brushes produced statistically significant reductions in gingivitis and plaque measures relative to Baseline (*P*<0.001 for all).



OBJECTIVE

To compare the efficacy of an oscillating-rotating power toothbrush with a novel brush head (Oral-B Triumph with SmartGuide with Oral-B CrossAction brush head) versus a sonic toothbrush (Sonicare DiamondClean) for plaque and gingivitis reduction over a 6-week period.

STUDY DESIGN

- This was a randomized, 2-treatment, parallel group study involving 65 subjects per group.
- To qualify for the study, subjects were required to have a Baseline plaque score greater than 0.5 and a gingivitis score greater than or equal to 1.75 and less than 2.3.
- Clinical evaluations were done at Baseline and Week 6. Gingivitis was assessed using the Modified Gingival Index and Gingival Bleeding Index. Plaque was assessed using the Rustogi Modified Navy Plaque Index. No oral hygiene was permitted 12 hours prior to each visit.
- Subjects were randomized to one of two brush treatments: Oral-B Triumph with SmartGuide with the Oral-B CrossAction brush head (D34/EB50) or the Sonicare DiamondClean brush with the standard brush head. Subjects used each brush according to the manufacturer's instructions twice a day for 6 weeks.
- Data was analyzed using Analysis of covariance with baseline as covariate.





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A10-Week Clinical Comparison of the Safety and Efficacy of Two Power Toothbrushes in the Reduction of Plaque and Gingivitis

Reference: Williams K, He T, Walters PA, Grender JM, Biesbrock A. Am J Dent 2009;22:345-349.

KEY CLINICAL RESULTS

• Oral-B[®] Triumph[®] had significantly lower gingivitis scores (p=0.038) and bleeding sites (p=0.028) compared to Sonicare[®] FlexCare after 10 weeks of use.

Additionally, Triumph delivered a statistically significant reduction in gingivitis scores (p=0.003) and bleeding sites (p<0.001) versus baseline after 10 weeks of use while FlexCare did not.

- There were no statistically significant differences between the two brushes at Week 4 or Week 10 for post-brushing or pre-brushing plaque scores.
- Both brushes were well tolerated.

Oral-B FlossAction/D25 vs. Sonicare FlexCare



Williams K et al. Am J Dent 2009; 22: 345-349





Williams K et al. Am J Dent 2009; 22: 345-349



OBJECTIVE

To evaluate and compare the efficacy and safety of two toothbrushes in reducing plaque and gingivitis over 10 weeks.

MATERIALS AND METHODS

- This was a single-center, examiner-blind, 10-week, 2-treatment, open label, parallel group, randomized study. 179 subjects with evidence of gingivitis were enrolled.
- Plaque measurements (pre-and post) were taken at Baseline, Week 4 and Week 10 using the Turesky Modification of the Quigley-Hein Plaque Index (TQHPI). Löe-Silness Gingivitis measurements were taken at Baseline and Week 10.
- At baseline, qualified subjects were stratified and randomly assigned to one of the two treatment (toothbrush) groups based on baseline plaque and gingivitis scores, gender and smoking:
 - Oral B-Triumph with oscillating-rotating technology (Procter & Gamble) or
 - Sonicare FlexCare with sonic technology (Philips)
- Subjects then received oral hygiene instructions and product usage instructions. They brushed according to the manufacturer's toothbrush instructions with their assigned toothbrush. Following brushing the examiner carried out a post-brushing plaque exam.
- Subjects were instructed to brush with their assigned toothbrush and dentifrice for 2 minutes twice daily at home according to the written and verbal usage instructions given to them during product distribution. Subjects were reminded to refrain from brushing their teeth for 12 hours and refrain from eating, chewing gum, drinking, smoking for four (4) hours prior to their next visit.
- Subjects returned for pre- and post-brushing plaque measures at 4 weeks and pre- and postbrushing plaque and gingivitis measures at 10 weeks.

STUDY POPULATION

- 179 subjects were enrolled and randomized to treatment. 172 subjects were evaluable for plaque at the second visit and 171 at the final visit.
- 165 subjects were evaluable for gingivitis.
- Treatment groups were balanced for age, gender, ethnicity, baseline pre-brushing plaque scores and baseline gingivitis scores.

A Randomized Clinical Trial Evaluating Gingivitis and Plaque Reduction of an Oscillating-Rotating Power Brush with Novel Angled Bristle Tufts versus a Marketed Sonic Brush with Self-Adjusting Technology

Reference: Klukowska M, Grender JM, Conde E, CCahuana-Vasquez RA, Goyal CR. Am J Dent 2014;27:179-184.

KEY CLINICAL RESULTS

- The oscillating-rotating brush with novel angled bristle tufts (Oral-B Triumph with SmartGuide with the Oral-B CrossAction brush head) demonstrated statistically significantly greater reductions (P<0.05) in all gingivitis measures as well as whole mouth and interproximal plaque measures compared to the sonic toothbrush (Colgate ProClinical A1500 with Triple Clean brush head).
- The benefit for the oscillating-rotating brush over the sonic brush was 21.3% for gingivitis, 35.7% for gingival bleeding, 34.7% for number of bleeding sites, 17.4% for whole mouth plaque, and 21.2% for interproximal plaque. See Figures 1–4.
- Both brushes produced statistically significant reductions in gingivitis and plaque measures relative to baseline after 6 weeks (P<0.001 for all).
- There were no adverse events reported or observed for either brush.



Figure 1. Reduction

Figure 2. Reduction in Number of Bleeding Sites





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OBJECTIVE

To compare the efficacy of an oscillating-rotating power toothbrush with a novel angled brush head with CrissCross bristles versus a marketed sonic toothbrush in the reduction of gingivitis and plaque over a 6-week period.

STUDY DESIGN

- This was a single center, randomized, open label, examiner blind, 2-treatment, parallel group study involving 65 subjects per group. See Figure 5.
- To qualify for the study, subjects were required to have a Baseline plaque score greater than 0.5 and an MGI score greater than or equal to 1.75 and less than 2.3.
- Subjects were randomized to one of two brush treatments: Oral-B Triumph with SmartGuide with the Oral-B CrossAction brush head (D34/EB50, Procter & Gamble, Cincinnati, OH) or the Colgate ProClinical A1500 sonic brush with the Triple Clean brush head (Colgate-Palmolive, New York, NY). Subjects used each brush according to the manufacturer's instructions twice a day for two minutes per brushing for 6 weeks.
- Clinical evaluations were done at Baseline and Week 6. Gingivitis was assessed using the Modified Gingival Index and Gingival Bleeding Index. Plaque was assessed using the Rustogi Modified Navy Plaque Index. No oral hygiene was permitted 12 hours prior to each visit.
- Data was analyzed using the Analysis of Covariance (ANCOVA) with baseline as the covariate.



Figure 5. Study Design

12-Week Clinical Comparison of Oral-B Triumph with Smart Guide versus Colgate ProClinical A1500 in Reducing Gingivitis and Dental Plaque

Reference: Klukowska M, Grender JM, Conde E, Goyal CR. J Clin Dent 2013;24:55-61.

KEY CLINICAL RESULTS

- Modified Gingival Index (MGI): The Oral-B[®] Triumph[®] with SmartGuide (oscillating-rotating, O-R) power toothbrush demonstrated a 31.3% greater reduction in MGI scores from Baseline at Week 4 and a 28.9% greater reduction at Week 12 relative to the Colgate ProClinical 1500 (sonic) toothbrush (P<0.001). See Figure 1.
- Number of bleeding sites: The O-R brush demonstrated a 47.5% greater reduction in number of bleeding sites from Baseline at Week 4 and a 29.9% greater reduction at Week 12 versus the sonic brush (P=0.002). See Figure 2.
- Dental Plaque: The O-R brush demonstrated a 37.5% greater whole mouth plaque reduction from Baseline at Week 4 and a 24.2% greater reduction at Week 12 versus the sonic brush (P<0.001). The O-R brush also showed advantages versus the sonic brush in reducing plaque along the gumline at Week 4 (36.4% difference, P=0.004) and interproximal plaque at Week 4 (38.9% difference, P<0.001) and Week 12 (26.4% difference, P<0.001).
- Safety: Both brushes were well-tolerated.



Figure 1. Change in MGI Score versus Baseline

Figure 2. Change in # of bleeding sites versus Baseline

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OBJECTIVE

To evaluate the efficacy of an advanced oscillating-rotating power toothbrush (Oral-B Triumph with SmartGuide, D34/EB25*) relative to a new sonic power toothbrush (Colgate ProClinical A1500) in the reduction of gingivitis and plaque over 12 weeks.

STUDY DESIGN

- This was a single-center, examiner-blind, open label, 2-treatment, parallel group, randomized study. Subjects brushed with their assigned toothbrush and a marketed anti-cavity sodium fluoride dentifrice (Crest Cavity Protection) following the manufacturer's instructions for 2 minutes twice daily at home for 12 weeks. See Figure 3.
- Gingivitis and plaque were evaluated at Baseline, Week 4 and Week 12 using the Modified Gingival Index (MGI), Gingival Bleeding Index (GBI, Number of Bleeding Sites), and Rustogi et al Modification of the Navy Plaque Index (RMNPI). Safety was also assessed at every visit.



Figure 3. Study Design

*Marketed as Oral-B Professional Care SmartSeries 5000 in the United States.

12-Week Clinical Evaluation of Oral-B[®] Triumph[®] versus Sonicare[®] DiamondClean[™] in Reducing Gingivitis and Plaque

Reference: Am J Dent, 2012; 25: 287-292. Klukowska M, Grender JM, Biesbrock AR, Mandl C, Goyal CR.

KEY CLINICAL RESULTS

- Modified Gingival Index (MGI): The Oral-B® Triumph® (oscillating-rotating, O-R) power toothbrush demonstrated a 31.9% greater reduction in MGI scores from Baseline at Week 6 and a 32.3% greater reduction at Week 12 relative to the Sonicare® DiamondClean™ (sonic) toothbrush (P<0.001). See Figure 1.
- Number of bleeding sites: The O-R brush demonstrated a 43.4% greater reduction in number of bleeding sites from Baseline at Week 6 and a 34.9% greater reduction at Week 12 versus the sonic brush (P<0.001). See Figure 2.
- **Plaque:** The O-R brush demonstrated a 15.8% greater whole mouth plaque reduction from Baseline at Week 6 and a 19.3% greater reduction at Week 12 versus the sonic brush (P<0.05). Similarly, for plaque along the gumline, the O-R brush showed a 24.1% greater reduction from Baseline at Week 6 and a 30.4% greater reduction at Week 12 (P<0.001 Week 12). The O-R brush also showed advantages in reducing interproximal plaque, with a 22.9% greater reduction from Baseline at Week 6 and a 24.4% greater reduction at Week 12 (P<0.05).
- Safety: Both brushes were well-tolerated.

Figure 1. Change in MGI Score

versus Baseline



Figure 2. Change in # of bleeding sites versus Baseline

-Continued on next page

OBJECTIVE

To evaluate the efficacy of an advanced oscillating-rotating power toothbrush (Oral-B Triumph with SmartGuide*) relative to a new sonic power toothbrush (Sonicare DiamondClean) in the reduction of gingivitis and plaque over 12 weeks.

STUDY DESIGN

- This was a single-center, open-label, examiner-blind, 2-treatment, parallel group, randomized study in which subjects brushed with their assigned toothbrush and a marketed dentifrice for 2 minutes twice daily at home for 12 weeks. See Figure 3.
- Gingivitis and plaque were evaluated at Baseline, Week 6 and Week 12 using the Modified Gingival Index (MGI), Number of Bleeding Sites, and Rustogi et al Modification of the Navy Plaque Index (RMNPI). Safety was also assessed at every visit.

Figure 3. Study Design



*Marketed as Oral-B Professional Care SmartSeries 5000 in the United States.



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A 12-Week Clinical Comparison of the Safety and Efficacy of Two Power Toothbrushes in the Reduction of Plaque and Gingivitis

Reference: CR Goyal, J Qaqish, T He, JM Grender, PA Walters, AR Biesbrock J Clin Dent. 2009;20(3):93-98.

KEY CLINICAL RESULTS

Plaque

- Oral-B® Triumph® had 30% and 33% lower post-brushing plaque scores at 6 and 12 weeks, respectively, compared to Sonicare FlexCare™ (p<0.001)
- Across the12-week usage period, Triumph had a 14.6% higher plaque reduction vs baseline than FlexCare (p<0.001)

Gingivitis

• Triumph had significantly lower gingivitis scores compared to FlexCare at Weeks 6 and 12 (p<0.001)

Bleeding

• Triumph had 29.4% lower bleeding scores compared to FlexCare after 12 weeks of use (p=0.010)



Less gingival bleeding vs Sonicare FlexCare

OBJECTIVE

To evaluate and compare the safety and efficacy of two toothbrushes in the reduction of gingivitis and plaque over a 12-week period.

STUDY DESIGN

- 175 subjects were randomized to treatment. 173 subjects were evaluable for Week 6 analyses and 171 for Week 12 analyses
- This was a single-center, examiner-blind, 12-week, 2-treatment, open label, parallel group, randomized study. 177 subjects with evidence of gingivitis were enrolled
- Plaque and gingivitis measurements were taken at three (3) timepoints: Baseline, Week 6 and Week 12. Plaque measurements were also taken pre- and post-brushing at each visit. Treatments were evaluated using the Rustogi Modification of the Navy Plaque Index (RMNPI), the Modified Gingival Index (MGI) and the Gingival Bleeding Index (GBI)
- At baseline, qualified subjects were stratified and randomly assigned to one of the two treatment groups based on baseline pre-brushing plaque and gingivitis scores, gender and smoking:
 - Oral-B Triumph with oscillating-rotating technology (Procter & Gamble) or
 - Sonicare FlexCare with sonic technology (Philips)
- Subjects then received oral hygiene instructions and product usage instructions. They brushed according to the manufacturer's toothbrush instructions with their assigned toothbrush. Following brushing the examiner carried out a post-brushing plaque exam
- Subjects were instructed to brush with their assigned toothbrush and dentifrice for two minutes twice daily at home according to the written and verbal usage instructions given to them during product distribution. Subjects were reminded to refrain from brushing their teeth for 12 hours and refrain from eating, chewing gum, drinking, smoking for four (4) hours prior to their next visit
- Subjects returned for gingivitis and pre- and post-brushing plaque measures at six (6) and twelve (12) weeks following the Baseline visit

Sonicare FlexCare is a trademark of Philips Oral Healthcare, Inc.

A 12-Week Clinical Comparison of an Oscillating-Rotating Power Toothbrush to a Novel Sonic Toothbrush in the Reduction of Gingivitis and Plaque

Reference: Klukowska M, Grender JM, Conde E, CCahuana-Vasquez RA, Goyal CR. J Clin Dent 2014;25:26-31.

KEY CLINICAL RESULTS

- The oscillating-rotating toothbrush, Oral-B Triumph with SmartGuide with FlossAction brush head (O-R), demonstrated statistically significantly greater reductions (P<0.04) in whole mouth plaque compared to the novel sonic toothbrush, Sonicare FlexCare Platinum, at Weeks 6 and 12.
- The O-R brush also demonstrated statistically significantly greater gingivitis reductions (P=0.007) over the long-term (12 weeks) compared to the sonic brush.
- Both brushes produced significant reductions in gingivitis and plaque measures relative to Baseline (P<0.001 for all).



OBJECTIVE

To evaluate the efficacy of a marketed oscillating-rotating power toothbrush to a newly marketed sonic brush in the reduction of gingivitis and dental plaque over a period of twelve weeks.

STUDY DESIGN

- This was a single-center, randomized, examiner-blind, 2-treatment, parallel group study involving 65 subjects per group over a 12 week period.
- To qualify for the study, subjects were required to have a Baseline plaque score greater than 0.5 and a gingivitis score greater than or equal to 1.75 and less than 2.3 and a minimum of 10 bleeding sites.
- Clinical evaluations were done at Baseline, Week 6 and Week 12. Gingivitis was assessed using the Modified Gingival Index and Gingival Bleeding Index. Plaque was assessed using the Rustogi Modified Navy Plaque Index. No oral hygiene was permitted 12 hours prior to each visit.
- Subjects were randomized to one of two brush treatments: Oral-B Triumph with SmartGuide with the FlossAction brush head (D34/EB25) or the Sonicare FlexCare Platinum brush with the Intercare standard brush head. Subjects used each brush twice a day, 2 minutes per brushing, according to the manufacturer's instructions for 12 weeks.
- Data was analyzed using Analysis of covariance with baseline as covariate.

A Clinical Evaluation of an Oral-B Power Toothbrush with TriZone/Deep Sweep Brush Head versus a Sonic Toothbrush in the Reduction of Plaque and Gingivitis over 4 Weeks

Reference: Goyal CR, Klukowska M, Grender JM, Cunningham P, Qaqish J. Am J Dent 2012;25 (Sp Is A):21A-26A.

KEY CLINICAL RESULTS

The Oral-B power toothbrush with TriZone/Deep Sweep brush head exhibited significantly greater reductions in gingivitis, gingival bleeding, whole mouth plaque, plaque along the gingival margin and interproximal plaque compared to Sonicare Essence 5500 after 4 weeks of brushing.

OBJECTIVE

- To evaluate the efficacy of an Oral B power toothbrush with TriZone/Deep Sweep brush head versus a marketed sonic toothbrush in the reduction of gingivitis and plaque after 4 weeks of use.
- This was a single-center, examiner-blind, 4-week, 2-treatment, open label, randomized, parallel group study.
- Oral Soft Tissue assessments, gingivitis (Modified Gingival Index), gingival bleeding (Gingival Bleeding Index), and plaque (Rustogi Modified Navy Plaque Index) measurements were taken at Baseline and Week 4.
- 130 qualifying subjects, showing evidence of gingivitis and plaque, were stratified and randomly assigned to one of the following treatment groups based on Baseline MGI scores, Baseline whole mouth plaque score, typical brush type (manual vs. power) and tobacco use: Oral-B Power Toothbrush with TriZone/Deep Sweep brush head (EB30/D16u, Procter & Gamble, Cincinnati, OH, USA) or Sonicare Essence 5500 with e-series standard brush head (Philips, Snoqualmie, WA, USA).
- Subjects were instructed to brush their teeth with their assigned toothbrush and a marketed sodium fluoride dentifrice (Crest Cavity Protection, Procter & Gamble, Cincinnati, OH, USA) for two minutes twice a day for 4 weeks following manufacturer's instructions.

RESULTS

- 130 subjects, with a mean age of 42.1 years, completed the study.
- Both brushes produced significant changes from baseline for all measurements (P<0.001). At Week 4, TriZone/Deep Sweep and Essence reduced gingivitis by 10.4% and 7.1%, gingival bleeding by 43.5% and 31.7%, whole mouth plaque by 24.1% and 18.9%, plaque along the gingival margin by 7.6% and 4.8%, and interproximal plaque by 40.5% and 30.6%, respectively. See Figures 1-5.
- The Oral-B TriZone/Deep Sweep demonstrated significantly greater reductions from baseline versus Sonicare Essence for all measurements: 48.3% for gingivitis; 51.5% for gingival bleeding; 26.3% for whole mouth plaque; 58.3% for plaque along the gingival margin; and 33.1% for interproximal plaque. See Table.











Figure 5. Interproximal Plaque

Sonicare Essence

0.665

0.958

0.96

Oral-B TriZone/

Deep Sweep

0.571

1.0

0.8

0.6

0.4

0.2

0.0



Table. Between Treatment Comparisons

	Adj Mean Reduction	Difference Between Brushes	P-value	Benefit for Oral-B TriZone / Deep Sweep	
Gingivitis					
TriZone/Deep Sweep	0.215	0.07	<0.001	48.3%	
Essence	0.145				
Gingival Bleeding					
TriZone/Deep Sweep	0.050	0.017	<0.001	51.5%	
Essence	0.033				
Whole Mouth Plaque					
TriZone/Deep Sweep	0.144	0.030	<0.001	26.3%	
Essence	0.114				
Gingival Margin Plaque					
TriZone/Deep Sweep	0.076	0.028	0.001	58.3%	
Essence	0.048				
Interproximal Plaque					
TriZone/Deep Sweep	0.389	0.097	<0.001	33.1%	
Essence	0.293				
*Benefit = difference between brushes Sonicare Essence adjusted mean change					

An 8-Week Clinical Comparison of an Oral-B Power Toothbrush with TriZone/Deep Sweep Brush Head versus a Sonic Toothbrush in Reduction of Plaque and Gingivitis

Reference: Klukowska M, Grender JM, Goyal CR, Qaqish J, Biesbrock AR. Am J Dent 2012;25 (Sp Is A):27A-32A.

KEY CLINICAL RESULTS

The Oral-B power toothbrush with TriZone/Deep Sweep brush head and SmartGuide demonstrated significantly greater reductions in gingivitis, gingival bleeding, whole mouth plaque and interproximal plaque compared to Sonicare FlexCare after 8 weeks of use.

OBJECTIVE

To evaluate the efficacy of an Oral-B power toothbrush with TriZone/Deep Sweep brush head and SmartGuide versus Sonicare FlexCare in the reduction of gingivitis and plaque over 8 weeks.

METHODS

- This was a single-center, examiner-blind, 8-week, 2-treatment, open label, randomized, parallel group study.
- Oral Soft Tissue assessments, gingivitis (Modified Gingival Index) and plaque (Rustogi Modified Navy Plaque Index) measurements were taken at Baseline and Week 8.
- 130 qualifying subjects, showing evidence of gingivitis and plaque, were stratified and randomly assigned to one of the following treatment groups based on Baseline MGI scores, Baseline whole mouth plaque score, typical toothbrush (manual vs. power) and tobacco use: Oral-B Power Toothbrush with TriZone/Deep Sweep brush head and SmartGuide (EB30/D34, Procter & Gamble, Cincinnati, OH, USA) or Sonicare FlexCare with ProResults brush head (Philips, Snoqualmie, WA, USA).
- Subjects were instructed to brush their teeth with their assigned toothbrush and a marketed dentifrice (Crest Cavity Protection, Procter & Gamble, Cincinnati, OH, USA) for two minutes twice a day for 8 weeks following manufacturer's instructions.

RESULTS

- 128 subjects, with a mean age of 43.3 years, completed the study.
- Both brushes produced significant changes from baseline for all measurements (P<0.001). At Week 8, TriZone/Deep Sweep and FlexCare reduced gingivitis by 14.5% and 11.1%, bleeding by 55.3% and 47.6%, whole mouth plaque by 12.3% and 8.7% and interproximal plaque by 24.6% and 14%, respectively. See Figures 1-4.
- TriZone/Deep Sweep demonstrated significantly greater reductions from baseline versus the FlexCare toothbrush for whole mouth bleeding (28.6%), interproximal plaque (76.9%), gingivitis (30%) and whole mouth plaque (44.2%). See Table.







Deep Sweep

Figure 2. Bleeding



Figure 3. Whole Mouth Plaque



Figure 5. Interproximal Plaque



Table. Between Treatment Comparisons

	Adj Mean Reduction	Difference Between Brushes	P-value	Benefit for Oral-B TriZone / Deep Sweep*
Gingivitis				
TriZone/Deep Sweep	0.299	0.069	<0.001	30.0%
FlexCare	0.230			
Bleeding				
TriZone/Deep Sweep	0.063	0.014	<0.001	28.6%
FlexCare	0.049			
Whole Mouth Plaque				
TriZone/Deep Sweep	0.074	0.023	0.003	44.2%
FlexCare	0.052			
Interproximal Plaque				
TriZone/Deep Sweep	0.237	0.103	<0.001	76.9%
FlexCare	0.134			
*Benefit =difference FlexCare a	e between brus djusted mean ch	hes nange		