A Supplement to
Compendium
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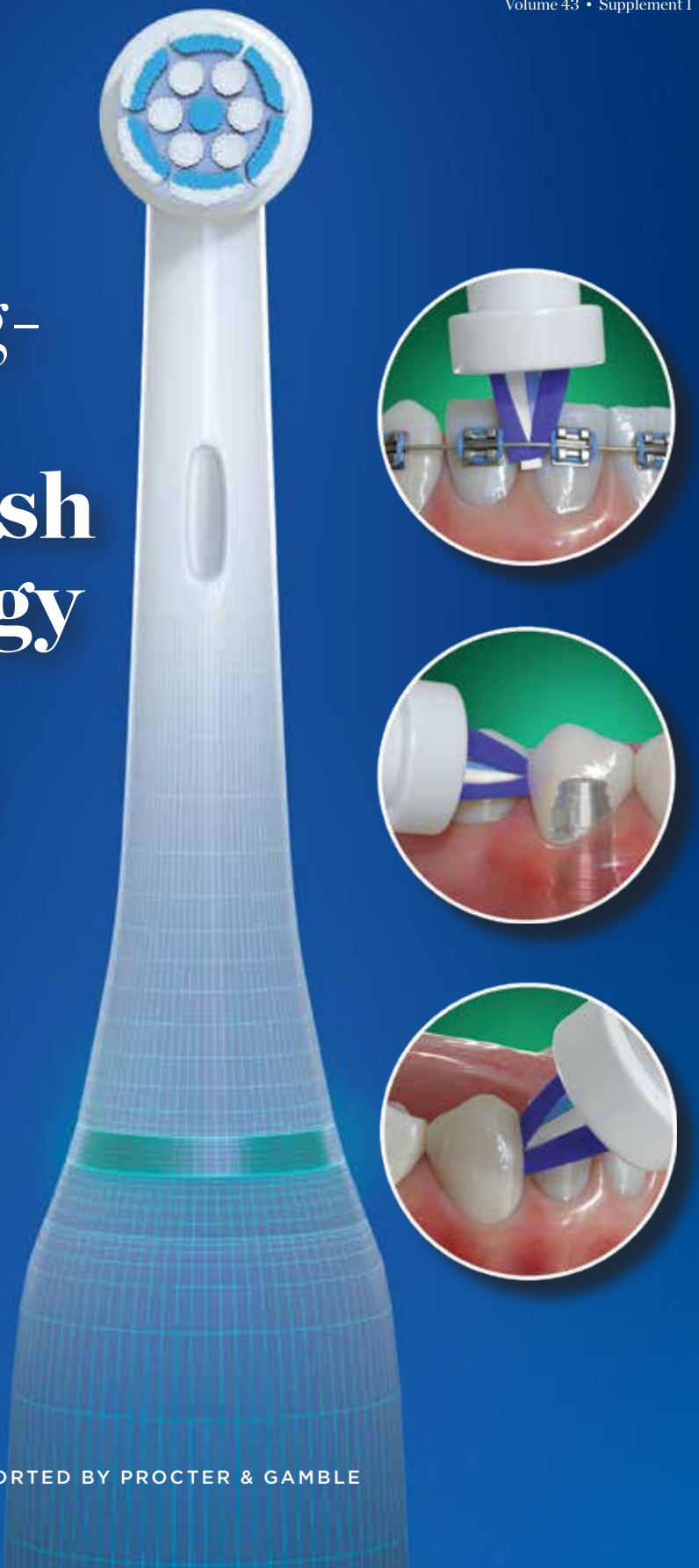
Oscillating-Rotating **Toothbrush Technology** to Meet Individual Patient Needs

Clinical and Practice-Based Research



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Oscillating-Rotating Toothbrush Technology

To Meet Individual Patient Needs

A Supplement to Compendium *of Continuing Education in Dentistry*

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Introduction

Oral Hygiene

Why Personalized Oral Hygiene Technology Matters

Susan Wingrove, BS, RDH

Dental professionals are in a unique position to help their patients personalize their brushing experience to better meet their specific oral health needs, whether for natural teeth (eg, misalignment), implants, or during orthodontic treatment. By exceeding patients' expectations and achieving improved oral health outcomes, clinicians can elevate their practice.

This supplement to *Compendium of Continuing Education in Dentistry* presents the latest evidence-based research that demonstrates how patients' oral hygiene regimens can be individualized by selecting oral hygiene aids that meet their specific clinical or motivational needs without compromising on efficacy. This also gives clinicians the tools to provide effective and impactful oral hygiene guidance to their patients.

Research shows that removal of 80% to 85% of oral biofilm twice daily as part of a patient's oral hygiene routine effectively controls the biofilm.[1] This is not only critical for patients' oral health, but it also has implications on their overall health. Bacterial biofilm, together with inflamed gingival epithelium, creates a corridor directly from the oral cavity to the systemic circulation, and evidence shows there is an association between oral health and certain diseases.[2] Oral hygiene technology has advanced to address the need to control oral biofilm in a personalized way; this includes innovations in electric toothbrush technology. According to the American College of Prosthodontists' Clinical Practice Guidelines for recall and maintenance of patients with tooth-borne and implant-borne restorations, patients should be using an electric toothbrush to effectively remove biofilm as one of the specific oral hygiene aids for at-home maintenance.[3]

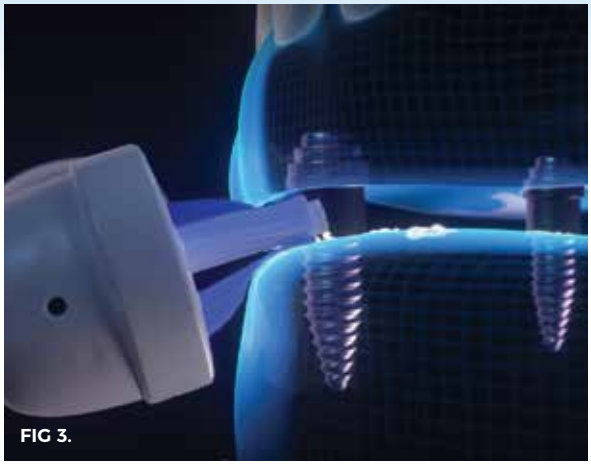
FIGS 1 AND 2.

Fig 1. Oral-B iO toothbrush with Ultimate Clean brush head. **Fig 2.** Oral-B Targeted Clean brush head.

Oral-B® iO™ Electric Toothbrush for Personalized Brushing

Among electric toothbrush technologies, the oscillating-rotating (O-R) technology by Oral-B stands out, with meta-analyses showing 50% greater reduction in bleeding sites compared to manual brushes and 28% greater reduction in bleeding sites versus sonic (side-to-side motion) brushes.[4] Oral-B's most recent advancement in oral hygiene technology is the Oral-B iO (Figure 1).[5] A next-generation O-R electric toothbrush with micro-vibrations, the Oral-B iO has a patented linear magnetic drive system to efficiently deliver energy to the tips of the bristles where they can most effectively disrupt and remove oral biofilm. Numerous randomized controlled trials demonstrate its superior plaque reduction and gingival health improvements, including two times greater bleeding site reduction versus a manual control toothbrush and 59% greater bleeding site reduction versus sonic brushes.[6-8]

The Oral-B iO is also equipped with artificial intelligence technology and an engaging patient-connected app via Bluetooth® that takes brushing guidance to another level. The brush provides real-time coaching to track brushing across all regions of the dentition to identify any tooth surfaces the brusher has missed. A recent analysis of 16.7 million brushing sessions showed that use of the app with live feedback resulted in a 94% average coverage, as well as longer brushing time and less overpressure compared to users who did not use live feedback.[9] It also has a smart pressure sensor with bimodal feedback; a green light shows that the patient is using the recommended pressure of 0.8 N to 2.5 N to successfully remove biofilm, and a red light indicates when the patient is brushing with too much pressure, >2.5 N.[5] The combination of O-R technology plus micro-vibrations creates a quiet, smooth patient brushing experience.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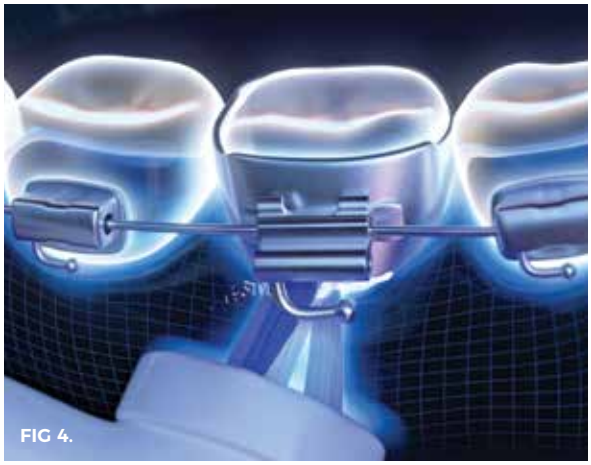
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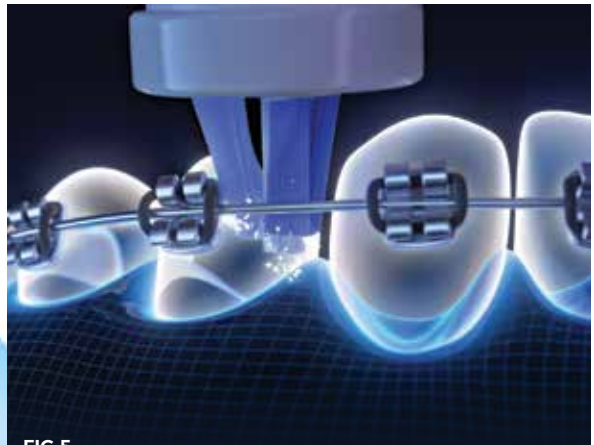
FIG 5.

Fig 3. Targeted Clean brush head can access the peri-implant crevice to remove biofilm around implant-borne restorations and beneath implant-supported fixed final prostheses. **Fig 4 and Fig 5.** Targeted Clean brush head pinpoints the bristles in and around orthodontic brackets (Fig 4), behind arch wires (Fig 5), and around molar bands to remove biofilm and food debris.

To personalize each patient's brushing experience, the Oral-B iO provides up to seven different brushing modes and specialized brush heads. The Daily Clean mode is designed for everyday brushing, and the Intense Clean mode provides enhanced cleaning results. The Sensitive and Super Sensitive modes allow for a perceptibly gentler experience for those users with sensitive mouths, patients in disease treatment, and patients who have just completed dental surgical procedures. The Tongue Cleaning mode completes a thorough brushing regimen.

The Oral-B iO specialized brush heads—Oral-B Ultimate Clean, Oral-B Gentle Care, and the novel Oral-B Targeted Clean™ (marketed as Specialised Clean in the European Union)—complete the specialized patient brushing experience. This supplement includes two case series reports utilizing the iO electric toothbrush with the Targeted Clean brush head for implant and orthodontic patients; the case series were conducted as part of a global practice-based assessment involving clinicians who specialize in periodontology and orthodontics.[10,11] An additional report of a randomized controlled trial evaluated gingival health benefits when the Oral-B iO was used with the Gentle Care brush head, utilizing the Sensitive mode.[12]

Targeted Clean Brush Head: For Areas Requiring Special Focus

The new Targeted Clean brush head has a unique center tuft with longer bristles on the inside, surrounded by shorter, higher-density bristles to effectively access and clean hard-to-reach areas (Figure 2). This design is particularly useful for patients with misaligned teeth, teeth impacted by periodontal issues (eg, black triangles, recession), or impacted molars. It is also an excellent choice for patients with implants, including single implant-borne restorations, implant-supported removable overdentures, and implant-supported fixed final prostheses, as well as for patients with fixed or removable orthodontics such as clear aligner treatments.

Benefits for Implant Patients

The Oral-B Targeted Clean brush head is a highly effective oral hygiene tool for implant patients. The design is particularly useful because the brush head can access the peri-implant crevice, where the implant connects with the abutment, to remove biofilm around the gingival tissue of implant-borne restorations (Figure 3). This brush head can also target biofilm in and around the stud attachments of removable overdentures and under implant-supported fixed final prostheses.

In Dr. Thomas Lambert's case series report (p. 5), peri-implant mucositis patients used the Oral-B iO O-R electric toothbrush with the Targeted Clean brush head as part of an oral hygiene regimen.[10] After 6 weeks, patients had reduced inflammation, less bleeding on probing, and reduced plaque

scores, demonstrating markedly reduced peri-implant mucositis. This practice-based research illustrates the importance of a collaborative approach between dentist and hygienist to develop a personalized motivational home care regimen that can dramatically improve patient compliance.

Benefits for Orthodontic Patients

For orthodontic patients, the Oral-B iO with the Targeted Clean brush head pinpoints the bristles in and around brackets, behind arch wires and hooks, and around molar bands to remove biofilm and food debris (Figure 4 and Figure 5). Clear orthodontic aligner patients can remove their aligners and use the Targeted Clean brush head to clean inside the aligner, along the gingival margins, and around composite attachments. Patients can utilize the iO brush with the Ultimate Clean or Gentle Care brush head to promote oral hygiene during orthodontic treatment. Good oral hygiene during orthodontic treatment helps patients avoid complications that can result in white-spot lesions, demineralization, and erythematous gingivae. These consequences of poor oral hygiene during orthodontic treatment can lead to longer treatment time and may require corrective treatments post-orthodontics, which can carry additional, unplanned costs to both the patient and the practice.

Dr. Dana van Elslande's case series (p. 12) shows that engaging and motivating young patients with fixed orthodontic appliances in their oral hygiene regimen is key to dramatically improving characteristic poor oral hygiene.[11] The cases show use of the Oral-B iO electric toothbrush with the Targeted Clean brush head increased brushing motivation, required less oversight by caregivers to ensure proper brushing, and reduced plaque in at-risk young orthodontic patients. These findings are particularly compelling, given that childhood gingivitis has been shown to reach a peak during puberty, which also coincides with the age when traditional orthodontic treatment begins.[13]

Gentle Care Brush Head

The Gentle Care brush head, designed with a distinctive dense arrangement of filaments and an overall concave structure, adapts to the curvature of each tooth for gentle contact and cushioning for consistent biofilm removal (Figure 6). This brush head effectively removes biofilm while providing a gentle brushing experience, which may be preferred by many patients, especially those with sensitive gum tissue or existing soft-tissue recession that may lead to experiencing hypersensitivity.

The randomized controlled trial reported by Grender et al (p. 17) evaluated the effects of using the Oral-B iO electric toothbrush with the Gentle Care brush head in Sensitive mode versus using a manual toothbrush for plaque and gingivitis reduction.[12] After 12 weeks, subjects in the Oral-B iO plus Gentle Care brush head group showed statistically significant gingival health improvements and plaque reductions compared to the manual control toothbrush. Furthermore, 92% of study participants using Oral-B iO plus Gentle Care transitioned from localized or generalized gingivitis ("not healthy") at baseline to periodontal health ("healthy") after 12 weeks compared to only 24% of subjects using the manual control toothbrush ($P < .001$).[12] These participants also had four times greater odds to transition from "not healthy" to "healthy" in as early as 1 week. Gingivitis scores and gingival bleeding sites were reduced by approximately three times more with use of the Oral-B iO plus Gentle Care versus the manual control toothbrush. The evidence-based research results show that, in combination, the specialized iO technology using the Sensitive mode, Gentle Care brush head, and Oral-B connected app can be used to dramatically improve the brushing experience for patients with sensitivity concerns.

FIG 6.

Fig 6. Oral-B Gentle Care brush head.

Summary

Dental professionals should invest the time to personalize their patients' home care regimen. Collectively, the data in this supplement supports the benefits of personalizing the Oral-B iO brushing experience with multiple brushing modes, specialized brush heads to effectively disrupt biofilm, and the Oral-B app to motivate patients for improved compliance. Readers are encouraged to review the reports on the performance of Oral-B iO technology demonstrated in this peer-reviewed supplement, and then tailor your recommendations for oral hygiene aids to your patients' clinical needs and personal motivations to help them achieve improved oral and overall health.

DISCLOSURE

The author is a member of the Oral-B Global Implant Advisory Board (Procter & Gamble).

ABOUT THE AUTHOR

Susan Wingrove, BS, RDH

International speaker, researcher, instrument designer, and author of *Peri-Implant Therapy for the Dental Hygienist*, 2nd edition, Wiley, 2022

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A Home Care Regimen With Oral-B iO Toothbrush and Targeted Clean Brush Head to Reduce Peri-Implant Mucositis

Thomas J. Lambert, DDS

Abstract: *Objective:* This practice-based case series evaluated the effects of the Oral-B® iO™ oscillating-rotating (O-R) electric toothbrush with the novel Targeted Clean™ brush head as part of a home care regimen on the health of the tissues surrounding implant-borne fixed restorations. *Methods:* Eight generally healthy, nonsmoking patients with peri-implant mucositis in at least one implant site and moderate-to-high plaque levels who had not had a professional cleaning in 3 months and were not currently using an O-R toothbrush were recruited from the author's practice. Fixed implant restorations on these eight patients were evaluated for plaque and gingival inflammation (erythema, swelling, and bleeding on probing [BOP]). In collaboration with the dental hygiene team, the patients were introduced to specific protocols for implant maintenance utilizing the Oral-B iO O-R brush and the Targeted Clean brush head. After 6 weeks the patients were re-evaluated. Clinical findings with photographs and probing as well as the impact of the intervention on each patient's motivation and compliance in maintaining oral hygiene at home were recorded. *Results:* After 6 weeks, implant sites with baseline peri-implant mucositis demonstrated no BOP or other signs of inflammation and reduced plaque scores. The patients' home care compliance and motivation to maintain effective oral hygiene around their implants saw a substantial improvement. *Conclusions:* The Oral-B iO O-R electric toothbrush with the novel Targeted Clean brush head, used as part of a home care regimen, markedly reduced peri-implant mucositis around fixed implant restorations among all eight patients in this case series. Key factors were the patient owning their disease pattern and the doctor/hygienist collaboration and use of education protocols to help improve the patients' home care compliance and motivation.

The use of dental implants as a sustainable restorative treatment has grown exponentially over the past two decades. The Dental Implants Global Market Report 2021 expected growth to $4.5 billion with a compound annual growth rate of 8.7% as more patients opt for this treatment modality to replace fractured and periodontally involved teeth with questionable prognoses.[1] Additionally, a growing number of completely edentulous patients are turning to full-arch fixed implant restorations as a solution for their esthetic and functional concerns, which in the United States alone has seen an increase in implant prevalence from 0.7% in 1999-2000 to 5.7% in 2015-2016.[2]

The success of an implant restoration is fundamentally dependent on effective planning, placement of the implant, and restoration, but the implant's long-term management then shifts to the hygienist and the ability of the patient to perform effective self-care at home. Historically, dental and dental hygiene education focused on the health of the periodontium, specifically the tissues surrounding the natural tooth. Little to no time was spent studying the health of the tissues surrounding the implant restoration itself. Today, with more fixed implant restorations in the mouths of patients than in the past, clinicians may often notice inflammation and bleeding from the tissues surrounding the implants. This peri-implant mucositis is frequently due to suboptimal plaque control around the implant and the surrounding tissues.[3] Left untreated, with ongoing poor plaque control, peri-implant mucositis can progress to peri-implantitis and potential loss of the implant.[4] Furthermore, the association between periodontal disease and systemic conditions, such as cardiovascular disease and diabetes, is well documented in the literature.[5] The good news is that with proper plaque control and patient motivation, peri-implant mucositis is reversible and the tissues can return to health.[6]

The World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions concluded the standard of care for managing peri-implant mucositis is mechanical biofilm control.[7] In addition, Clinical Practice Guidelines from the American College of Prosthodontists, which are based on findings from two comprehensive systematic reviews, recommend that patients with implant-borne restorations be educated about brushing twice daily and the use of oral hygiene aids, including water flossers, air flossers, interdental cleaners, and electric toothbrushes, as part of at-home maintenance.[8] Difficulties often occur when instructing patients to clean around narrow-neck implants with bulbous crowns. Additionally, fully edentulous patients with implant-supported fixed final prostheses are presented with unique challenges in removing plaque and biofilm from under and around the prosthesis and implants.

FIG 1.

Fig 1. Oral-B Targeted Clean brush head.

The type of toothbrush patients use along with their brushing behaviors are critical factors in their ability to achieve optimal plaque control. Electric toothbrushes have been consistently shown as superior to manual toothbrushes in removing plaque biofilm, reducing bleeding, and increasing retention of teeth as evidenced by systematic reviews, meta-analyses,[9,10] and multi-year observational research.[11] There are two main categories of electric toothbrushes. Oscillating-rotating technology, characterized by filaments continuously rotating in one direction and then another, was first introduced in the 1990s by Oral-B to maximize disruption and removal of plaque biofilm. Sonic toothbrushes are another common class of electric toothbrushes. They typically have a larger head size and vibrate side to side at a high rate of speed and emit a harmonic tone. Among electric toothbrushes, oscillation-rotation technology has demonstrated superior gingival health benefits compared to other electric toothbrush technologies, including sonic,[9] while findings on its efficacy among patients with implants and implant-supported fixed prostheses have shown significantly improved plaque control and gingival health.[12-16]

Oral-B iO and Targeted Clean Brush Head

In 2020, the author was invited to participate in a global practice-based program evaluating the new Oral-B iO toothbrush with Targeted Clean brush head with a select group of his implant patients. The Oral-B iO is a next-generation oscillating-rotating (O-R) electric toothbrush. It has the same clinically proven O-R motion as previous models, but the brush has been completely redesigned. Procter & Gamble researchers and engineers spent 7 years developing the Oral-B iO toothbrush, which is driven by a series of magnets, described as a "linear magnetic drive system" that directs energy to the bristle tips and also results in microvibrations that produce an enhanced brushing experience.[17]

The smart pressure sensor is a tremendous advancement for patients by providing optimal pressure feedback when flashing green, and flashing red when it senses excessive pressure; also, the user has a choice of colors that can be customized to indicate too little pressure. The organic light-emitting diode (OLED) smart display has up to seven brushing modes and provides personalized coaching and motivation. The Oral-B app provides real-time tracking to promote thorough brushing and proper pressure and increase patient motivation and compliance. The personalized feel of the brush is

designed for patients to take ownership of their own dental health and be motivated to achieve excellent outcomes.

Redesigned Oral-B brush heads include the Ultimate Clean brush head with an innovative tuft-in-tuft bristle pattern for enhanced reach and the Gentle Care brush head with the manufacturer's smallest-diameter filaments. The newest brush head is the Targeted Clean brush head (Figure 1), designed for effective plaque control around implants, braces, misaligned teeth, and other areas that require special focus.

Randomized controlled studies, ranging from single-use evaluations to 6-month trials, show the Oral-B iO technology provides significantly greater gingival health and plaque removal benefits compared to manual and sonic toothbrush controls.[18-21]

Case Series Overview and Practical Implications

This case series was designed to evaluate the impact of the Oral-B iO toothbrush, when used as part of a home care regimen, on dental implant health in a group of patients with fixed implant restorations over a 6-week period. The selection criteria included patients with peri-implant mucositis, good general health, and who were nonsmokers. Patients demonstrated pre-existing moderate to high plaque levels and had not had a professional cleaning in 3 months.

There were six females and two males; average age was 56.9 years (range: 35 to 66 years). This group of patients had inadequate compliance with oral hygiene, and they were currently not brushing with an O-R toothbrush. The group consisted of five patients with at least one single implant and crown restoration, one patient with a fixed implant four-unit implant-retained bridge, and two patients with maxillary and mandibular full-arch implant-supported fixed final prostheses. The average implant age was 2.8 years (all were 1 to 5 years in age). The occlusion in all patients was balanced with no lateral or protrusive inferences and light to minimal contact in centric occlusion. Six patients were currently using a sonic electric toothbrush and two were using manual toothbrushes.

The initial evaluation consisted of bleeding scores (yes-no), plaque levels (low-moderate-high), gingival inflammation assessments (yes-no), and intraoral photographs. An experienced dental hygienist in the author's practice was an integral part of this study. Her role was to assess the current techniques patients were using at home by asking them to describe their home care routine in detail. Additional questioning helped determine the motivational level of each patient (low-moderate-high) and educate the patient, using the so-called "co-discovery" strategy outlined in Figure 2.[22]

Each patient was provided their own Oral-B iO with an Ultimate Clean brush head, Gentle Care brush head, and Targeted Clean brush head. The dental hygienist reviewed the features of the Oral-B iO, including the pressure sensor, smart display, and app. With the patient holding a mirror, the iO brush with the Ultimate Clean brush head was demonstrated in the patient's mouth showing proper angulation and movement across the arch. The Targeted Clean brush head was placed on the Oral-B iO and demonstrated in the mouth with proper angulation around implants and areas that require special focus (Figure 3 and Figure 4). Patients who were currently using interproximal brushes and aids were asked to stop using them and replace them by cleaning those areas using the Targeted Clean brush head. Flossing technique was demonstrated for patients with intact dentitions.

Patients were instructed to first use the Oral-B iO brush for 2 minutes. This was to be followed with the Targeted Clean brush head used around each dental implant and other areas specifically recommended by the dental hygienist. Patients were dispensed a 0.07% cetylpyridinium chloride (CPC) rinse (Crest® Pro-Health Mouthrinse) and instructed to rinse their entire mouth twice daily for 60 seconds. A 0.454% bioavailable stannous fluoride dentifrice (Crest® Pro-Health Gum Detoxify) was dispensed, and the patients were instructed to brush their entire dentition three times daily while using the Oral-B iO, the Targeted Clean brush head, and the app.

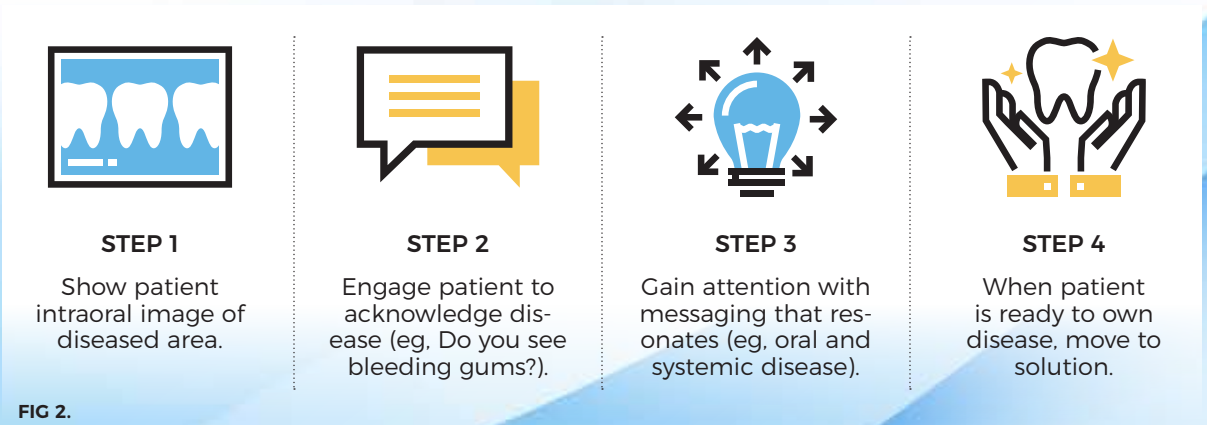

FIG 2.

Fig 2. Steps to co-discovery process.

Two patients presented with maxillary and mandibular full-arch fixed implant restorations. Both were using a water flosser, bridge threaders, and manual toothbrushes. As with the other patients, the dental hygienist instructed them on the use of the Oral-B iO with Ultimate Clean brush head for the prosthesis itself. The Targeted Clean brush head was also demonstrated to clean under the prosthesis and around the implants (Figure 5). The Targeted Clean brush head was positioned on the facial, lingual, and palatal aspects of the prosthesis as the patient observed the brush movement around each implant and under the prosthesis itself. The patients were dispensed the same CPC rinse and stannous fluoride dentifrice and directed to use them following the same instructions given the first group of patients.

Clinical and Behavioral Observations

2-Week Evaluation

All of the patients returned for a 2-week evaluation whereby their progress was assessed and adjustments were made to their home care routine. Bleeding and inflammation were reduced in each patient. Patients were asked what they liked and did not like about their brushing experience and which areas in their mouth they felt improvement was needed. The author and hygienist carefully observed the patients' use of their brush in their mouth. The proper positioning of the Targeted Clean brush head was reviewed to ensure proper plaque removal around implants and other critical areas as recommended by the dental hygienist.

The pressure sensor and the app helped reveal that several of the patients were brushing with insufficient pressure. One patient stated, "because of my recession I always felt like I was brushing too hard." The Gentle Care brush head and the Sensitive setting were then recommended for this patient. The option of two brush heads, the app, and the choice of power setting changed this patient's behavior and motivation in a positive direction.

6-Week Evaluation

At the 6-week evaluation, the six patients who had a mixture of natural teeth and dental implants demonstrated no bleeding and no inflammation around their implants. Plaque accumulation throughout their mouths was minimal. All patients displayed notably improved compliance and motivation and were pleased with the overall improvement in their dental health. Details of the patient evaluation are shown in Table 1.

Featured Patients

Patient No. 1 had presented with a full-arch smile makeover. Implant No. 10 in this patient had BOP and inflammation around the implant (Figure 6 and Figure 7). At the 6-week evaluation of the tissues of implant No. 10 there was no BOP and the patient had returned to health (Figure 8 and Figure 9). She was excited to learn that her new home care protocols with the Oral-B iO brush and Targeted Clean brush head had made a positive impact on the health of her mouth, stating that she "loved my Oral-B iO brush so much" that often times she brushed for 5 minutes and was "so happy" that her gums no longer bled and that her mouth was healthy and clean.

Patient No. 4 had presented with maxillary and mandibular fixed implant-supported prostheses. Upon removal of the prosthetics, inflammation, including BOP, was noted around

TABLE 1

Summary of Initial and 6-Week Assessments for All Patients

Patient	Brush Used Prior to Case Study	Home Care Compliance*		Gingival Inflammation†		Gingival Bleeding†		Plaque*	
		Baseline	6 weeks	Baseline	6 weeks	Baseline	6 weeks	Baseline	6 weeks
1	Sonic	Low	High	Yes	No	Yes	No	High	Low
2	Sonic	Low	High	Yes	No	Yes	No	High	Low
3	Sonic	Moderate	High	Yes	No	Yes	No	High	Low
4	Manual	Low	High	Yes	No	Yes	No	Moderate	Low
5	Sonic	Low	High	Yes	No	Yes	No	High	Low
6	Manual	Low	High	Yes	No	Yes	No	High	Low
7	Sonic	Low	High	Yes	No	Yes	No	Moderate	Low
8	Sonic	Low	High	Yes	No	Yes	No	Moderate	Low

Scales: *Low-Moderate-High, †Yes-No

the implant abutments. The prosthesis was cleaned (Figure 5), abutments debrided, and then torqued back into place. The patient returned following 6 weeks of using the Oral-B iO brush and the Targeted Clean brush head. The prosthetics were removed. Minimal debris was evident around the prosthesis and no BOP or other signs of gingival inflammation were present. The patient was highly motivated and stated, "This is the only powered brush I have found to actually reach under my teeth and clean the implants. My mouth feels fresh, clean, and healthy after using the Targeted Clean brush head."

Observations

A critical step in the success of these cases is related to the author's team's mission in dentistry to "educate and guide our patients toward the healthiest and most beautiful smile possible." The key word in this mission is "educate." Time management is typically a critical concern in dental offices, and all too often very little time is allocated for oral hygiene education. When educating the patients in this study, the team began by helping them understand why oral health is important, addressing the question, "Why should I change what I have always been doing?"

The "co-discovery" journey (Figure 2) starts with the dental hygienist handing the patient a mirror and probing an area around an implant or tooth with bleeding. An intraoral photograph is taken and shown in full screen on the monitor above the patient. We now engage the patient in the process by asking if they can see the bleeding. When they respond affirmatively, our response is always, "Healthy gums do not bleed." We then ask if they are aware that gum disease is associated with systemic disease, such as diabetes and heart disease.[5] This typically gets the patient's full attention.

At this point the patient is beginning to "own" their dental disease. They will often ask, "I don't like this; what can I do about it?" Once the patient understands their disease pattern and owns their problem, then and only then are they ready for a solution. The patient is now ready to learn and be open to adopting oral hygiene instruction, which should include personalized home care recommendations. Interactive electric toothbrushes, such as the one used in this study, provide a range of brushing modes and heads for specific patient needs, and they can be recommended with a dentifrice, mouthrinse, and/or interdental cleaner for an individualized oral hygiene routine. The Oral-B iO Test Drive program, in which the patient has the opportunity to experience the toothbrush in the operatory under the guidance of a dental professional, is an example of a hands-on method to facilitate oral hygiene adoption.[23] The co-discovery process is well worth the investment in time and can lead to better outcomes for patients, as demonstrated by this case series.

It is important to note that this was practice-based research involving case studies, not a single-variable clinical study; therefore, the author cannot determine the relative contribution of individual products or the co-discovery process to the outcomes. However, these findings are consistent with results from randomized controlled trials showing significant oral health benefits for regimens similar to the one evaluated here and for oral hygiene instructional methods.[24-26] Exploration of the relative benefit of each factor would require investigation in randomized controlled trials.


FIG 3.


FIG 4.


FIG 5.

Fig 3. Use of Targeted Clean brush head around implant. **Fig 4.** Use of Targeted Clean brush head around implant-supported fixed bridge. **Fig 5.** Use of Targeted Clean brush head under the prosthesis.

Conclusions

The Oral-B iO oscillating-rotating electric toothbrush with the new Targeted Clean brush head, used as part of an oral hygiene regimen, was shown to notably reduce peri-mucositis around implants, implant-borne restorations, or prostheses. A major factor was the patient owning their disease pattern through the co-discovery process and having customized home care instruction from the dental hygienist. The doctor/hygienist collaboration and education protocols dramatically improved patients' home care compliance and motivation.

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FIG 6.


FIG 7.


FIG 8.


FIG 9.

Fig 6 and Fig 7. Case No. 1. Baseline images show bleeding on probing on a full-arch smile makeover patient, implant in the No. 10 position. **Fig 8 and Fig 9.** Case No. 1. Six-week images show healthy gingiva.

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Use of an Oscillating-Rotating Electric Toothbrush and Novel Brush Head to Increase Brushing Motivation and Reduce Plaque Among Orthodontic Patients

Dana Van Elslande, DDS, MSc

Abstract: *Objective:* The aim of this case series was to evaluate the effect of the Oral-B® iO™ oscillating-rotating (O-R) electric toothbrush with micro-vibrations and the novel Oral-B Targeted Clean™ brush head on orthodontic patients' plaque accumulation and motivation to brush. *Methods:* Five patients, aged 9 to 22 years, with fixed orthodontia and poor oral hygiene were enrolled in the study and instructed on use of the O-R toothbrush with the novel brush head. At the beginning and end of the 9- to 14-week case study interval, patients completed a survey designed to assess estimated brushing time and patients' motivation to brush their teeth. At the same timepoints, each patient's plaque was disclosed with a plaque-disclosing gel, assessed by a dental professional, and photographed. Finally, each patient participated in an exit interview. *Results:* At the end of the case study participation, all patients' plaque accumulation was greatly reduced (range 15% to 45%) and most patients reported increased motivation to brush their teeth. While mean estimated brushing time remained relatively flat during the evaluation period (2:34 to 2:42 minutes), the substantial decrease in plaque levels seen with the Targeted Clean brush head shows it provided highly efficient plaque removal. Patients and their caregivers expressed satisfaction with the toothbrush and novel brush head. *Conclusions:* The Oral-B iO O-R electric toothbrush and Targeted Clean brush head were well received by orthodontic patients and their caregivers and produced clinically relevant plaque reductions in this at-risk population.

Orthodontic patients are uniquely susceptible to gingivitis, the earliest stage of periodontal disease.[1] The incidence of gingivitis increases throughout childhood and peaks sharply in adolescence because the hormonal changes of puberty enhance the body's inflammatory sensitivity to dental plaque.[2-4] Compounding this challenge to oral health, adolescence is the time during which orthodontic treatment typically starts,[5] and patients often have trouble cleaning around fixed orthodontic appliances.[6] This difficulty can lead to increased gingivitis as well as caries and decalcification.[7]

Moreover, the sequelae of poor oral hygiene can compromise the success of orthodontic treatment itself. Bonding of brackets or attachments is often weakened when surrounding tissues are inflamed, bleeding, or producing an increased flow of gingival crevicular fluid.[8] This weakening can necessitate repairs, sometimes in emergency situations, which

increases the overall time to treatment completion. These additional appointments are often irritating for patients, their caregivers, and the orthodontic care team, and reduce the profitability of each appointment. As the use of fixed orthodontic appliances remains prevalent,[9] especially among young patients,[10] maintaining healthy teeth and tissues with effective plaque control remains a critical component of successful orthodontic treatment.

The long-accepted key to controlling plaque, and thereby gingivitis,[11,12] is mechanical plaque removal by toothbrushing.[12-14] Multiple studies have shown that these goals are best accomplished with electric oscillating-rotating (O-R) toothbrushes rather than with manual toothbrushes[15,16] or other electric brushes.[16,17] In particular, electric toothbrushes with O-R movement have demonstrated robust performance in removing plaque in adolescent patients with fixed orthodontic appliances.[18,19]

In 2020, a novel O-R toothbrush (Oral-B iO) with several next-generation features was introduced to the market. The redesigned motor uses a linear magnetic drive that produces micro-vibrations, resulting in Oral-B's most advanced cleaning capabilities with a quieter brushing experience.[20] Artificial intelligence technology with real-time, 3D teeth tracking and a smart pressure sensor allows this brush to provide individualized coaching to the user. The Oral-B iO toothbrush has consistently demonstrated statistically significantly greater performance in plaque removal and the achievement of gingival health compared to manual and electric sonic toothbrush controls in assessments ranging from single use to 6 months.[20-23]

The latest brush head introduced for the Oral-B iO is Oral-B Targeted Clean. The brush head is designed with longer center-tuft bristles and high bristle density outer tufts to effectively access and clean areas that require special focus, such as around misaligned/crowded teeth, braces, and implants. As with all oral hygiene products, effectiveness depends on patient compliance, which can be problematic among orthodontic patients.[7,24]

Case Series

This practice-based study was designed to assess the effect of the Oral-B iO toothbrush and Targeted Clean brush head on patients' plaque accumulation and motivation to brush over a 9- to 14-week period in patients with fixed orthodontic appliances and a history of poor oral hygiene. The five enrolled patients ranged in age from 9 to 22 years, and all had active fixed orthodontic appliances. Additionally, all patients had poor oral hygiene, as measured with the Ortho Essentials Chairside Laminate Card (Procter & Gamble, dentalcare.ca)[25] and defined as a score of 1 at the last two to three orthodontic appointments. Poor oral hygiene was signified by erythematous gingivae with spontaneous bleeding with the presence of oral biofilm (plaque). White-spot lesions and demineralization were also common concomitant findings. All patients formally consented to participate in the study and to try the novel O-R electric toothbrush (Oral-B iO). Patient demographics are summarized in Table 1.

TABLE 1

Patient Demographics

Patient	Sex	Age: Years, Months
1	F	10, 1
2	M	12, 4
3	F	12, 5
4	F	22, 1
5	F	9, 7

F = female, M = male

Patients were instructed to use the O-R toothbrush with either the Oral-B Ultimate Clean or the Oral-B Gentle Care brush head (patient's choice), followed by use of the Oral-B Targeted Clean brush head. They continued using their normal toothpaste and/or rinse without any coaching on product.

At the beginning and end of case study participation, each patient's motivation and estimated daily brushing time were assessed using a six-question patient survey. The motivation scale ranged from 1 to 5, with 1 being the least motivated and 5 being the most motivated. In


FIG 1.


FIG 2.

Fig 1. Patient No. 3 baseline image showed a high level of mature plaque. **Fig 2.** Approximately 9 weeks later, plaque on patient No. 3 was substantially reduced.

addition, each patient's plaque was disclosed along the gingival margin and between brackets and wires with plaque-disclosing gel (GC Tri Plaque ID Gel™, GC America, gcamerica.com) and assessed by a dental professional. To accomplish this, orthodontic wires were removed, and the plaque-disclosing gel was applied to the tooth surfaces with a microbrush. After the patient rinsed their mouth lightly with water, photographic records were made of the disclosed plaque. This gel was designed to render freshly accumulated plaque pink or red; plaque that was at least 48 hours old, purple or blue; and mature plaque that produced strong acid, light blue.[26] At the conclusion of the study, subjects participated in an exit interview that included the motivation survey.

Results

Clinical observations. At the beginning of the case series, all patients exhibited purple and light blue disclosed plaque, indicative of mature, acid-producing biofilm. At the final visit, 9 to 14 weeks later, mature, strong acid–forming plaque was dramatically reduced. In addition, the total surface area covered with plaque was reduced in all patients, with an approximate mean reduction of 34% (range 15% to 45%). Figure 1 and Figure 2 illustrate visibly reduced plaque for patient No. 3 over 9 weeks. Plaque assessment results are summarized in Table 2.

Survey and interview results. Patients were eager to try the Oral-B iO O-R toothbrush and novel Targeted Clean brush head despite the challenges of fixed orthodontia. By

TABLE 2

Plaque Assessment Results at Baseline and at Final Visit (9 to 14 weeks)

Patient	Baseline		Final	
	Plaque Level; Disclosed Plaque Color	Plaque Coverage of Tooth Surface	Plaque Level; Disclosed Plaque Color	Plaque Coverage of Tooth Surface
1	High; light blue and purple	60%	Mild-moderate; some dark purple and light blue	30%
2	High; dark purple, light blue on gingival margin	50%	Low; minimal dark purple on gingival margin	<10%
3	High; dark purple with some light blue	50%	Low; very small amount of purple and red	<5%
4	Medium; dark purple on gingival margin, some light blue	20%	Low; minimal dark purple with some red on buccal surface	<5%
5	High; thick light purple and light blue	>90%	Low, substantially reduced; some purple on buccal surface	<50%
Approximate mean		**54%**		**<20%**

Plaque level scale: Low-Moderate-High

TABLE 3

Survey Results at Baseline and Final Visit (9 to 14 weeks)

Patient	Motivation Score		Brushings/Day		Time Spent on Each Brushing	
	Baseline	Final	Baseline	Final	Baseline	Final
1	3	4	2	2	1 min	2 min
2	3	3	1	2	3-4 min	2-3 min
3	4	3	2	2	4 min	3 min
4	2	5	3	2	1:20 min	2 min
5	3	5	2	1-2	2-4 min	4 min
Mean	**3**	**4**	**2**	**1.9**	**2:34 min**	**2:42 min**

Motivation scale: 1 = least motivated; 5 = most motivated

the end of the research, patients reported that they greatly enjoyed the O-R toothbrush and novel brush head. Survey data showed that most patients experienced an increased motivation to brush their teeth, with the mean motivation score increasing from 3 to 4. Parents and caregivers reported that their child was re-engaged in managing their own oral health and consequently required less coaxing to brush. Self-reported mean brushing time was relatively flat during the evaluation period (2:34 to 2:42 minutes), increasing by 8 seconds, but the substantial decrease in plaque levels demonstrates the highly efficient plaque removal provided by the brush and novel brush head. Results of the patient survey are summarized in Table 3.

Discussion

In this practice-based research involving five patient cases, use of the O-R electric toothbrush and novel brush head was associated with both objective and subjective improvements in at-home oral hygiene. This is a meaningful achievement in oral care for orthodontic patients, for whom plaque removal is uniquely difficult and important.

Among orthodontic appliances, fixed appliances make mechanical cleaning particularly difficult and thereby pose multiple health challenges. In comparison with removable appliances, fixed appliances are associated with significantly greater cariogenic oral bacteria[27] and worse periodontal health.[28-30] Furthermore, these outcomes can negatively affect orthodontic treatment when fluid from diseased tissue weakens orthodontic bonding.[8] This often results in extra appointments, longer treatment times, and reduced patient satisfaction. Effective biofilm control in orthodontic patients not only preserves overall oral health in this high-risk population, but also helps to optimize the orthodontic treatment process and outcome.

By the end of this case series, use of the O-R toothbrush with micro-vibrations, combined with a novel brush head designed for cleaning hard-to-reach areas, consistently reduced both overall plaque coverage and the proportion of mature plaque in patients with fixed orthodontic appliances after 9 to 14 weeks of brush use. Moreover, this brush aided orthodontic patients in overcoming the tendency to neglect proper oral hygiene,[7,24] as most patients in this study reported increased motivation to brush, and this attitude shift was confirmed by their caregivers.

Orthodontic patients have unique oral care needs. Ineffective brushes, as well as effective brushes that patients are not motivated to use, leave patients' oral health and orthodontic care at risk. By recommending this brush and novel brush head, providers can match orthodontic patients with a personalized tool to optimize their home oral care routine.

Conclusion

This case series evaluation, which was intended to complement the existing body of clinical evidence for O-R toothbrush technology, demonstrates that the O-R electric toothbrush and novel brush head improved patients' oral hygiene, showing highly efficient plaque removal, and had positive effects on motivation to brush. Offering superior cleaning, real-time user feedback, and a record of usage over time, this brush and brush head are an excellent choice for orthodontic patients.

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Randomized Controlled Trial

A 12-Week Randomized Controlled Trial Comparing a Novel Electric Toothbrush With an Extra Gentle Brush Head to a Manual Toothbrush for Plaque and Gingivitis Reduction

Julie Grender, PhD; C. Ram Goyal, DDS; Jimmy Qaqish, BSc; Hans Timm, PhD; and Ralf Adam, PhD

Abstract: *Objective:* This study compared the gingivitis and plaque reduction efficacy of a novel smart-connected oscillating-rotating (O-R) electric toothbrush with micro-vibrations, used in Sensitive mode with an extra gentle ("sensitive") brush head, to the efficacy of a soft manual toothbrush. *Methods:* This was a 12-week, examiner-blind, two-treatment, parallel-group clinical trial with 100 adult subjects (N = 100) having evidence of gingivitis and plaque at baseline. Subjects were randomly assigned to use either the O-R electric rechargeable toothbrush (Oral-B® iO™ with Oral-B Gentle Care brush head) or the soft manual toothbrush (Oral-B Indicator). Gingivitis was assessed with the modified gingival index (MGI) and the gingival bleeding index (GBI). Plaque was assessed with the Rustogi modification of the navy plaque index (RMNPI). Patients were classified as having a "healthy" (<10% bleeding sites) or "not healthy" (≥10% bleeding sites) gingival case status according to the criteria of the American Academy of Periodontology and the European Federation of Periodontology. Efficacy assessments and oral soft-tissue examinations were conducted before brushing at baseline, week 1, and week 12. The baseline assessment included both pre- and post-brushing plaque evaluations to evaluate single-use plaque removal efficacy. *Results:* All 100 subjects completed the trial. Subjects had a mean age of 49.1 years; 72% were females. The O-R brush group had a significantly higher percentage of subjects who transitioned from "not healthy" to "healthy" gingival case status than did the manual brush group (at week 12: 92% vs 24%; $P < .001$). At week 12, the O-R brush group also demonstrated a significantly greater ($P < .001$) mean number of bleeding sites reduced (23 vs 7), mean MGI reduction (0.45 vs 0.17), and mean GBI reduction (0.18 vs 0.06). Plaque reduction for the O-R brush group was also significantly greater ($P \leq .009$) than for the manual brush group for whole mouth, gingival margin, and interproximal region, from day 1 (single use) through 12 weeks. Both brushes were well tolerated. *Conclusion:* The novel O-R toothbrush with micro-vibrations used in Sensitive mode with an extra gentle brush head provided significantly greater gingivitis and plaque reduction than did a manual toothbrush over 12 weeks.

Gingivitis, the first stage of periodontal disease, is prevalent globally and affects more than 90% of American adults.[1] The condition stems from an inflammatory reaction to bacteria in dental plaque and results in gingival bleeding, redness, and swelling.[2] Gingivitis can negatively impact oral hygiene because mechanical plaque removal from inflamed gingiva may be painful. This was shown in a recent systematic review that found an association between gingivitis and pain along with difficulties in toothbrushing.[3] Patients might, therefore, avoid thorough hygiene in areas with gingivitis, worsening gingival inflammation and bleeding.

Fortunately, gingivitis can be reversed with appropriate treatment, including daily plaque control via toothbrushing.[4-7] There is abundant evidence demonstrating the benefits of electric toothbrushes over manual toothbrushes for plaque removal and gingivitis reduction,[8,9] with studies specifically showing efficacy advantages for oscillating-rotating (O-R) electric brush technology over manual and other electric toothbrush (eg, sonic) controls.[8-13] In a recent meta-analysis that analyzed gingival bleeding data using gingivitis case definitions from the World Workshop on the Classification of Periodontal and Peri-implant Diseases and Conditions,[14] significantly more subjects with "localized" (10% to 30% bleeding sites) or "generalized" (more than 30% bleeding sites) gingivitis who used an O-R electric toothbrush transitioned to "healthy," defined as less than 10% bleeding sites, compared to manual and sonic toothbrush controls.[11]

The demand for effective plaque removal that also delivers a brushing experience that is personalized to the user's sensory needs, such as in areas that are painful due to gingivitis, has led to the development of specialized toothbrushes and features. These include soft tapered bristles, modified brush head designs, and slower "sensitive" modes for electric toothbrushes. For optimal oral health, these options must be not only gentle but also effective in reducing plaque and gingivitis.

A novel smart-connected O-R electric toothbrush with micro-vibrations (Oral-B iO) was recently introduced with up to two Sensitive modes, depending on the model, and a Gentle Care brush head for gentle-feel cleaning. The brush, which employs clinically proven O-R technology,[8,11-13,15,16] has a linear magnetic drive system and has been demonstrated to be safe and more effective than manual or sonic toothbrush controls in studies ranging from single use to 6 months when used in Daily Clean mode with the Ultimate Clean brush head.[17-22] The present study was conducted to evaluate the performance of the novel O-R toothbrush in the removal of plaque and reduction of gingivitis among subjects with localized or generalized gingivitis when the brush was used in Sensitive mode with the Gentle Care brush head.

Methods and Materials

Ethical Aspects

The study was conducted in compliance with the Declaration of Helsinki and the Tri-Council Policy Statement (2nd Edition): Ethical Conduct for Research Involving Humans (2010) and conformed to the standards of Good Clinical Practices-Clinical Investigation of Medical Devices for Human Subjects (ISO) and those of the International Council for Harmonization. The study was registered in the ISRCTN Registry (ISRCTN77960012). Institutional review and approval of the protocol were obtained (Veritas IRB, Inc., Ref# 2020-2303-2707-3). Subjects were recruited by All Sum Research Center. All subjects provided written informed consent.

Study Population

All subjects were healthy adults who habitually used a manual toothbrush and who had at least 16 natural, scorable teeth. Qualifying subjects had a baseline whole-mouth modified gingival index (MGI)[23] score of at least 1.75 but not more than 2.5, a whole-mouth pre-brushing Rustogi modification of the navy plaque index (RMNPI)[24] score greater than 0.5, and at least 20 but not more than 90 bleeding sites (sites with a gingival bleeding index [GBI][25] score of 1 or 2). Exclusion criteria included a need for antibiotics before dental procedures; grossly carious teeth; severe periodontal disease; active treatment for periodontitis, cancer, or a seizure disorder; use of an antibiotic or chlorhexidine mouthrinse within the previous 2 weeks; oral or periodontal surgery within the previous 2 months; presence of orthodontic appliances, removable partial dentures, or peri/oral piercings; presence of a pacemaker or other implanted device; current or anticipated pregnancy; or nursing. All subjects agreed to avoid elective dentistry, use of non-study oral hygiene products, and participation in all other oral care studies.

Clinical Assessment

The same blinded examiner assessed gingivitis and plaque for each subject at each visit. Clinical information was recorded for all scorable teeth, excluding third molars, crowns, implants, bridges, or teeth with orthodontic appliances or restorations covering ≥50% of the tooth surface.

Gingivitis was evaluated according to the MGI and GBI.[23,25] MGI scores (six per tooth) ranging from 0 (normal) to 4 (severe inflammation) were assigned to the buccal and lingual marginal gingival regions and to the interdental papillae. GBI scores of 0 (absence of bleeding after 30 seconds), 1 (bleeding observed after 30 seconds), or 2 (immediate bleeding observed) were assigned to the buccal, mesial/distal, and lingual areas of the teeth after standardized probing with a 0.5 mm-tipped periodontal probe. Whole-mouth scores for each index were calculated by dividing the total score by the number of scorable sites examined. Patients were classified as having a "healthy" (<10% bleeding sites) or "not healthy" (generalized and localized gingivitis, ≥10% bleeding sites) gingival case status according to the criteria of the American Academy of Periodontology and the European Federation of Periodontology.[14]

Plaque was evaluated according to the RMNPI.[24] Plaque was scored on the buccal and lingual surfaces of each scorable tooth (nine sites per surface, for a total of 18 sites per tooth). Plaque was scored as absent (0) or present (1), and a mean plaque index (MPI) was calculated by dividing the total number of tooth areas with plaque by the number of tooth areas scored. Separate MPI scores were calculated to reflect the plaque status of the whole mouth, gingival margin, interproximal region, and lingual region.

Investigational Products

Subjects in the electric O-R brush group received kit boxes containing a rechargeable electric O-R toothbrush handle (Oral-B® iO, OP020), a charger, and a sensitive brush head (Oral-B® Gentle Care, OR017; Figure 1). Subjects in the O-R group had the option of using the Oral-B® iO app. Subjects in the control group received a kit box containing a manual toothbrush (Oral-B® Indicator 35 soft manual toothbrush, OM003). All kit boxes contained 1100 ppm sodium fluoride dentifrice (Crest Cavity Protection). All study products were manufactured by The Procter & Gamble Company (us.pg.com).

Study Design

This was a 12-week, single-center, examiner-blind, two-treatment, parallel-group, randomized, controlled clinical trial. Assessments were conducted at baseline (day 1), week 1, and week 12. Subjects were instructed to refrain from eating, drinking, chewing gum, or using lozenges, mints, or tobacco for 4 hours prior to each visit and to refrain from all oral hygiene procedures for 12 hours prior to each visit.

At the baseline visit, subjects provided medical history and demographic information. Inclusion/exclusion criteria were reviewed and documented. Subjects then received a pre-brushing oral examination and evaluations of MGI and GBI, all administered by an experienced examiner.[18,19,22] Next, the same examiner used Chrom-O-Red® erythrosine FD&C red 3 disclosing solution (Germiphene Corp., germiphene.com) to disclose plaque before performing an RMNPI assessment.

Qualifying subjects were stratified according to tobacco use (present or absent), number of bleeding sites (≤30 vs >30), and mean scores for whole-mouth pre-brushing MGI (≤2.1 vs >2.1) and RMNPI (≤0.62 vs >0.62). A balance and assignment procedure was used to randomly assign stratified subjects to one of two treatment groups. Following group assignment, subjects received their study products in a protected area to ensure that the examiner remained blind to treatment product.

Subjects were instructed to use their products at home twice per day (morning and evening) throughout the study. Subjects in the O-R brush group were directed to operate their brush in Sensitive mode and brush for 2 minutes at each use. Subjects in the manual brush group were directed to brush their teeth in their customary manner.

Subjects in the O-R toothbrush group were provided with assistance in downloading and connecting the Oral-B app if they desired to do so. All subjects were given supervised instructions for their assigned product use and asked to practice using the product in front of a mirror at the site. After this initial use, each subject received a second oral examination followed by plaque disclosure and RMNPI assessment from the same examiner.

At the week 1 visit (±2 days) and the week 12 visit (±3 days), subjects returned to the site and continuance criteria were assessed and recorded. The same examiner conducted a pre-brushing oral examination followed by MGI and GBI assessments, plaque disclosure, and RMNPI assessment, in that order.

Visual examination of the oral cavity/perioral area and dentition/restorations was conducted to assess oral soft

FIG 1.

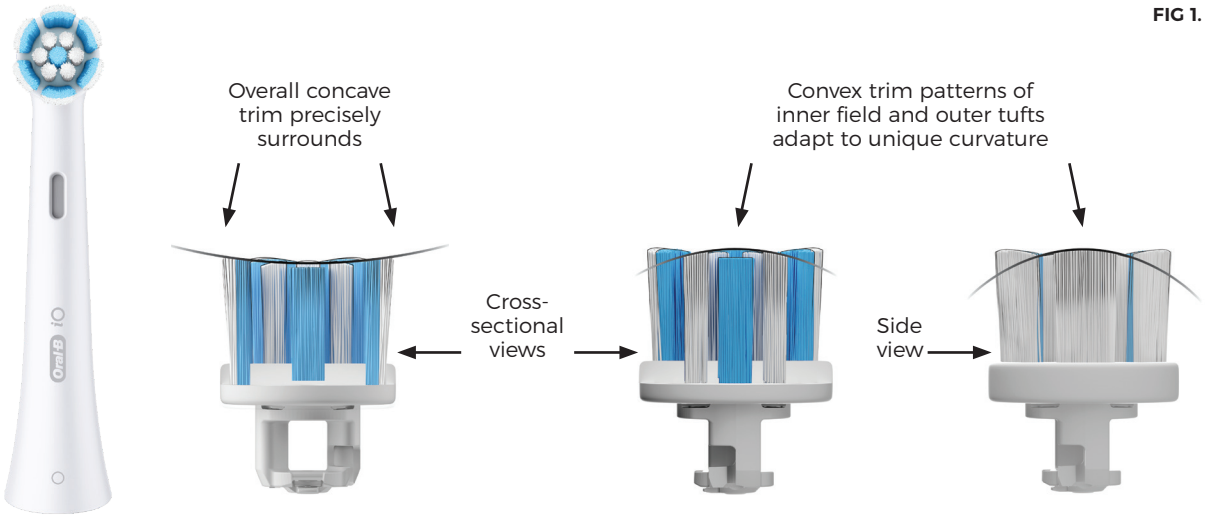


Fig 1. Oral-B iO Gentle Care brush head.

tissues and hard tissues, respectively. Any new abnormal finding that was noted after product distribution or that was previously noted and increased in severity during the treatment period was recorded as an "adverse event." All self-reported adverse events were recorded. Any whole-body adverse events potentially related to product use were collected.

Sample Size and Statistical Analysis

Using data from a similar study, power analyses were conducted with $\alpha = 0.05$, using a two-sided test and a sample size of 50 subjects per group. This sample size provided at least 90% power to detect a between-treatment difference of 3.5 in the number of bleeding sites and at least 90% power to detect a difference of 0.036 units in the whole-mouth mean RMNPI score.

The percentages of subjects classified as having "healthy" (<10% bleeding sites) and "not healthy" (≥10% bleeding sites) gingival case status were computed and compared between treatment groups using a chi-square test. The odds ratio of transitioning from "not healthy" to "healthy" was calculated at week 1 and week 12.

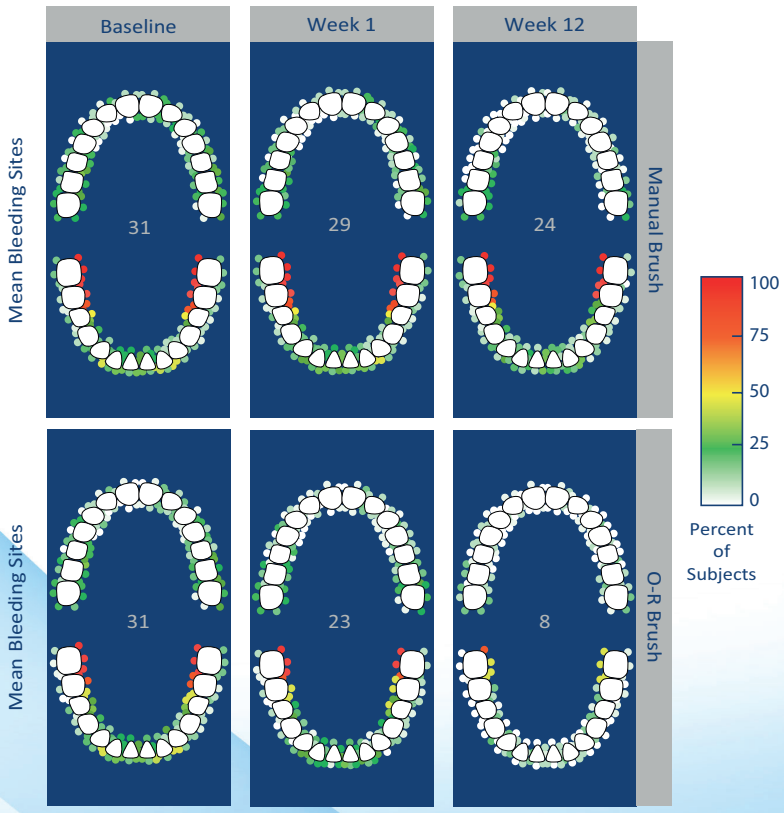
Statistical analyses for gingivitis efficacy were based on change from baseline of whole-mouth average MGI score, GBI score, and number of bleeding sites (baseline minus week 1 and baseline minus week 12). Treatment differences in whole-mouth average gingivitis reduction at week 1 and week 12 were performed using analyses of covariance (ANCOVA). Separate analyses were performed for each gingivitis endpoint, with the respective baseline gingivitis score as the covariate. Week 12 was the most important timepoint and MGI was the primary endpoint. Within-treatment differences from baseline gingivitis scores were tested versus zero using paired-difference *t* tests.

Whole-mouth, gingival margin, and interproximal plaque reductions after a single brushing at the baseline visit (pre-brushing minus post-brushing) were each analyzed for treatment differences using an ANCOVA model with the respective pre-brushing RMNPI score as the covariate.

Multiple-brushing plaque reduction efficacy analyses were based on the change from baseline of the pre-brushing whole-mouth average RMNPI score (baseline pre-brushing minus week 1 and baseline pre-brushing minus week 12). Treatment differences were analyzed using an ANCOVA model with baseline pre-brushing whole-mouth average RMNPI score as the covariate. An analysis of variance (ANOVA) was used to analyze the gingival margin and interproximal RMNPI endpoints since the baseline values for these endpoints were very similar across all subjects. Within-treatment differences from baseline RMNPI scores were tested versus zero using paired-difference *t* tests.

Gingivitis and plaque on the lingual surfaces of teeth were analyzed separately as described above. All treatment comparisons were considered two-sided with an $\alpha = 0.05$ significance level.

FIG 2.



O-R = oscillating-rotating
**Bleeding is color-coded based on the % of subjects (0%-100%) who have bleeding at that particular site.*

Fig 2. Percentage of subjects with bleeding by site.*

Results

Study Population

From among 100 subjects screened, all qualified and completed the study. The study population consisted of 72 females and 28 males, with a mean age (standard deviation, SD) of 49.1 (11.07) years (Table 1).

Transition to Gingival Health

At baseline all subjects presented in a state of localized or generalized gingivitis, classified as having a "not healthy" gingival case status per inclusion criteria (≥10% bleeding sites or >20 bleeding sites), with the number of bleeding sites ranging from 20 to 78. The percentage

of subjects who transitioned from "not healthy" to "healthy" gingival case status was significantly greater ($P < .001$) in the O-R brush group than in the manual brush group at week 1 (20% vs 6%) and week 12 (92% vs 24%) (Table 2). The odds ratio of transitioning from "not healthy" to "healthy" was 3.9 times greater (95% CI, 1.008-15.220) at week 1 and 36.4 times greater (95% CI, 10.855-122.173) at week 12 for the O-R brush group than for the manual brush group.

Gingivitis Reduction Efficacy

The baseline mean number of bleeding sites, MGI score, and GBI score did not differ significantly between groups,

TABLE 1

Baseline Demographics

Demographic/Clinical Measurement	Manual Brush (n = 50)	O-R Brush (n = 50)	Overall (n = 100)	*P* Value
Age (Years)				
Mean (SD)	48.6 (11.20)	49.6 (11.04)	49.1 (11.07)	0.660[a]
Range	19–69	18–71	18–71	
Sex[b]				
Female	38 (76.0%)	34 (68.0%)	72 (72.0%)	0.505[c]
Male	12 (24.0%)	16 (32.0%)	28 (28.0%)	
Race[b]				
Asian	3 (6.0%)	8 (16.0%)	11 (11.0%)	0.389[c]
Black or African American	15 (30.0%)	14 (28.0%)	29 (29.0%)	
Multiracial	1 (2.0%)	2 (4.0%)	3 (3.0%)	
White/Caucasian	31 (62.0%)	26 (52.0%)	57 (57.0%)	
Smoker[b]				
No	50 (100.0%)	49 (98.0%)	99 (99.0%)	1.000[c]
Yes	0 (0.0%)	1 (2.0%)	1 (2.0%)	

O-R = oscillating-rotating, SD = standard deviation
[a] two-sided ANOVA *P* value for the treatment comparison
[b] data are presented as number (percent) of subjects in each category
[c] two-sided Fisher's exact test *P* value for the treatment comparison

TABLE 2

Between-group Comparison of "Healthy" Vs. "Not Healthy" Gingivitis Case Status (All Subjects Had "Not Healthy" Gingivae at Baseline)

	Not Healthy n (%)	Healthy n (%)	*P* Value[a] (O-R Brush Vs. Manual Brush)
Week 1			
Manual Brush	47 (94%)	3 (6%)	$P < .001$
O-R Brush	40 (80%)	10 (20%)	
Week 12			
Manual Brush	38 (76%)	12 (24%)	$P < .001$
O-R Brush	4 (8%)	46 (92%)	

O-R = oscillating-rotating
[a] chi-square test for the treatment comparison

including whole mouth and lingual surfaces ($P \geq .670$). At week 1 and week 12, both groups exhibited significant reduction from baseline in all measures of gingivitis ($P < .001$ for all). The O-R brush produced significantly greater reductions in mean number of bleeding sites, whole-mouth MGI, and whole-mouth GBI at week 1 and week 12 than did the manual brush (week 12, by 3.2 times for number of bleeding sites, by 2.7 times for MGI, and by 2.9 times for GBI; $P < .001$ for all measures). Figure 2 displays the percentage of subjects with bleeding per site at baseline, week 1, and week 12. Measures of gingivitis were similarly reduced at the lingual subregions (week 12, by 4.3 times for lingual surface number of bleeding sites, by 2.4 times for lingual surface MGI, and by 3.9 times for lingual surface GBI; $P < .001$ for all measures) (Table 3).

Plaque Reduction Efficacy

Baseline whole-mouth, gingival margin, interproximal region, and lingual surface pre-brushing RMNPI scores did not differ significantly between groups ($P \geq .187$). After a single use, the O-R brush produced significantly greater adjusted mean reductions for whole-mouth, gingival margin, interproximal, lingual, lingual surface gingival margin, and lingual surface interproximal RMNPI scores ($P < .001$) than the manual brush.

Both groups demonstrated statistically significant reduction in all RMNPI scores for weeks 1 and 12 ($P \leq .040$), except for the manual brush group in the gingival margin subregion and lingual gingival margin subregion and for the O-R brush group in the lingual gingival margin subregion all at week 1 ($P \geq .322$). At week 1 and week 12, the O-R brush produced statistically significantly greater reductions in all adjusted mean RMNPI scores than did the manual brush ($P < .001$), with the exception of the lingual surface gingival margin subregion at week 1. Reductions at week 12 ranged from 2.6 to 6.9 times greater for the O-R brush over the manual brush (Table 4).

There were no adverse events reported or observed in the study.

Discussion

Previous studies have demonstrated advantages of the novel Oral-B iO in Daily Clean mode with the Ultimate Clean brush head in reducing gingivitis and plaque and promoting transitions to gingival health when compared to manual[18,20] and sonic[19,22] toothbrushes. This study demonstrates consistent performance when the Oral-B iO brush is used in Sensitive mode with an extra gentle brush head. After 1 and 12 weeks of use, the O-R toothbrush reduced gingivitis scores and gingival bleeding sites by approximately three times more than the manual brush, and the odds ratio of transitioning from a "not healthy" to "healthy" gingival case status was four times greater for O-R users as early as week 1. Plaque reduction was consistently greater for the O-R brush than the manual brush from first use through 12 weeks.

The O-R brush also provided significantly higher gingivitis and plaque reductions than the manual brush in the plaque-prone lingual regions.[26] At week 12, the difference in adjusted mean change from baseline number of bleeding sites was 3.2 times greater for the O-R brush group compared to the manual group for whole mouth, but 4.3 times greater for lingual surfaces. The disproportionate effectiveness in lingual areas demonstrated by the O-R brush with the Gentle Care brush head has also been shown in studies with the Oral-B Ultimate Clean brush head.[18,20,22] Both brush heads are round providing optimized cleaning efficiency to lingual areas that are difficult to access. Subjects who chose to use the app with the O-R brush may have also achieved more even brushing across the dentition from the active position detection coaching feature.

> **The demand for effective plaque removal that also delivers a brushing experience that is personalized to the user's sensory needs, such as in areas that are painful due to gingivitis, has led to the development of specialized toothbrushes and features.**

Designed to provide thorough, gentle-feel cleaning, this brush head features a complex profiled trim. The overall concave shape precisely surrounds the tooth surface, and the convex trim patterns of the inner field and outer tufts are designed to adapt to a tooth's unique curvature (Figure 1). Thin bristles are softer than thick bristles,[27] and the bristles of this O-R brush head are among the thinnest, softest, and most densely packed bristles in the Oral-B line. This brush head can be paired with the O-R brush's slower-speed, 2-minute Sensitive mode and smart pressure sensor[17] for customized plaque removal designed to feel gentle but without compromising cleaning efficacy.

As with all toothbrushing studies, there is a logistical limitation in that subjects are not blind to their treatment group. However, the examiner was blind to treatment and was experienced in plaque and gingivitis assessments. Furthermore, use of the app with the O-R toothbrush was not required or evaluated, so it was not possible to assess the impact of behavior change on clinical outcomes. Future research could assess the impact of subjects' brushing experience with the extra gentle brush head used in the Sensitive mode on brushing behavior (eg, brushing time, appropriate pressure) via tracking usage of the app, as user experience may have contributed to better brushing habits in this trial. Such research could also evaluate efficacy and self-reported

TABLE 3

Change From Baseline Results for Gingivitis Efficacy Endpoints, Analysis of Covariance Summary

	Adjusted Mean (SE) Change From Baseline	Treatment Ratio Relative to Manual Brush[c]	2-Sided *P* Value
Number of Bleeding Sites[a]			
Week 1			
Manual Brush	2.46 (0.273)	–	*P* < .001
O-R Brush	7.89 (0.273)	3.2	
Week 12			
Manual Brush	7.25 (0.345)	–	*P* < .001
O-R Brush	22.85 (0.345)	3.2	
Lingual Surface Number of Bleeding Sites[a]			
Week 1			
Manual Brush	1.02 (0.263)	–	*P* < .001
O-R Brush	4.04 (0.263)	4.0	
Week 12			
Manual Brush	2.96 (0.375)	–	*P* < .001
O-R Brush	12.65 (0.375)	4.3	
Modified Gingival Index (MGI) Score[b]			
Week 1			
Manual Brush	0.058 (0.0079)	–	*P* < .001
O-R Brush	0.134 (0.0079)	2.3	
Week 12			
Manual Brush	0.168 (0.0140)	–	*P* < .001
O-R Brush	0.451 (0.0140)	2.7	
Lingual Surface MGI Score[a]			
Week 1			
Manual Brush	0.065 (0.0130)	–	*P* < .001
O-R Brush	0.158 (0.0130)	2.4	
Week 12			
Manual Brush	0.179 (0.0179)	–	*P* < .001
O-R Brush	0.435 (0.0179)	2.4	
Gingival Bleeding Index (GBI) Score[a]			
Week 1			
Manual Brush	0.021 (0.0031)	–	*P* < .001
O-R Brush	0.068 (0.0031)	3.3	
Week 12			
Manual Brush	0.062 (0.0033)	–	*P* < .001
O-R Brush	0.177 (0.0033)	2.9	
Lingual Surface GBI Score[a]			
Week 1			
Manual Brush	0.015 (0.0048)	–	*P* < .001
O-R Brush	0.071 (0.0048)	4.7	
Week 12			
Manual Brush	0.050 (0.0055)	–	*P* < .001
O-R Brush	0.197 (0.0055)	3.9	

O-R = oscillating-rotating

[a] ANCOVA model included baseline, treatment, and baseline by treatment interaction effects

[b] ANCOVA model included baseline and treatment effects

[c] treatment ratio relative to manual brush = adjusted mean of O-R brush/adjusted mean of manual brush

TABLE 4

Change From Baseline Results for Plaque Efficacy Endpoints, Analysis of Covariance/Analysis of Variance Summary

	Adjusted Mean (SE) Change From Baseline[c]	Treatment Ratio Relative to Manual Brush[d]	2-Sided *P* Value
Whole-Mouth RMNPI[a]			
Single use (Day 1)			
Manual Brush	0.295 (0.0091)	–	*P* < .001
O-R Brush	0.522 (0.0091)	1.8	
Week 1			
Manual Brush	0.035 (0.0041)	–	*P* < .001
O-R Brush	0.080 (0.0041)	2.3	
Week 12			
Manual Brush	0.058 (0.0044)	–	*P* < .001
O-R Brush	0.150 (0.0044)	2.6	
Gingival Margin RMNPI[b]			
Single use (Day 1)			
Manual Brush	0.372 (0.0174)	–	*P* < .001
O-R Brush	0.775 (0.0174)	2.1	
Week 1			
Manual Brush	0.000 (0.0011)	–	*P* = .009
O-R Brush	0.005 (0.0011)	12.4	
Week 12			
Manual Brush	0.009 (0.0053)	–	*P* < .001
O-R Brush	0.061 (0.0053)	6.9	
Interproximal Region RMNPI[b]			
Single use (Day 1)			
Manual Brush	0.532 (0.0163)	–	*P* < .001
O-R Brush	0.881 (0.0163)	1.7	
Week 1			
Manual Brush	0.054 (0.0140)	–	*P* < .001
O-R Brush	0.153 (0.0140)	2.8	
Week 12			
Manual Brush	0.081 (0.0183)	–	*P* < .001
O-R Brush	0.322 (0.0183)	4.0	
Lingual Surface RMNPI[a]			
Single use (Day 1)			
Manual Brush	0.189 (0.0112)	–	*P* < .001
O-R Brush	0.477 (0.0111)	2.5	
Week 1			
Manual Brush	0.015 (0.0050)	–	*P* < .001
O-R Brush	0.066 (0.0050)	4.5	
Week 12			
Manual Brush	0.030 (0.0063)	–	*P* < .001
O-R Brush	0.123 (0.0063)	4.1	
Lingual Surface Gingival Margin RMNPI[b]			
Single use (Day 1)			
Manual Brush	0.209 (0.0220)	–	*P* < .001
O-R Brush	0.663 (0.220)	3.2	
Week 1			
Manual Brush	0.000 (0.0006)	–	*P* = .320
O-R Brush	0.001 (0.0006)	N/A	
Week 12			
Manual Brush	0.006 (0.0047)	–	*P* < .001
O-R Brush	0.038 (0.0047)	6.3	
Lingual Surface Interproximal Region RMNPI[b]			
Single use (Day 1)			
Manual Brush	0.421 (0.0234)	–	*P* < .001
O-R Brush	0.854 (0.0234)	2.0	
Week 1			
Manual Brush	0.032 (0.0154)	–	*P* < .001
O-R Brush	0.118 (0.0154)	3.7	
Week 12			
Manual Brush	0.053 (0.0188)	–	*P* < .001
O-R Brush	0.255 (0.0188)	4.8	

N/A = not applicable, O-R = oscillating-rotating, RMNPI = Rustogi modified navy plaque index

[a] ANCOVA model included baseline and treatment effects for single use (day 1); week 1 and week 12 visits additionally included baseline by treatment interaction effects

[b] ANOVA model included treatment effect

[c] change from baseline is (pre-brushing – post-brushing) for single use (day 1) and (baseline pre-brushing – final pre-brushing) for week 1 and week 12

[d] treatment ratio relative to manual brush = adjusted mean of O-R brush/adjusted mean of manual brush

brushing experience among a population with established gingival pain.

Conclusion and Clinical Implications

The findings of this study demonstrate that patients seeking a gentle brushing experience may use the novel O-R brush with an extra gentle brush head and Sensitive mode without compromising on plaque reduction efficacy or attainment of gingival health benefits.

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DISCLOSURE

Drs. Grender, Timm, and Adam are employees of The Procter & Gamble Company.

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