Review

Safety of Oscillating-Rotating Powered Brushes Compared to Manual Toothbrushes: A Systematic Review

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Background: Oscillating-rotating power toothbrushes have been proven clinically efficacious. To our knowledge, a comprehensive review of all clinical and laboratory investigations solely comparing the safety of these toothbrushes to the standard of care (i.e., manual toothbrushes) has not been published. The aim of this systematic review is to examine the literature concerning the relative soft and/or hard tissue safety outcomes with the use of oscillating-rotating toothbrushes compared to manual toothbrushes.

Methods: With the use of electronic databases of the National Library of Medicine (PubMed-MEDLINE), the Cochrane Central Register of Controlled Trials (Cochrane-CENTRAL), and the Excerpta Medical Database (EMBASE), a search of in vivo and in vitro trials through May 2010 was conducted to identify appropriate studies that evaluated the effects of an oscillating-rotating power toothbrush compared to a manual toothbrush with respect to soft and/or hard tissue safety. Eligible trials incorporated a safety evaluation as a primary or secondary outcome parameter (i.e., gingival recession, observed/reported adverse events, and hard tissue effects) or used a surrogate parameter (i.e., stained gingival abrasion and brushing force) to assess safety. Data extraction for the primary- and surrogate-measure safety studies, which included mean values and SDs when available, and a meta-analysis of the gingival recession data were performed.

Results: Independent screening of the titles and abstracts of 697 PubMed-MEDLINE, 436 Cochrane-CENTRAL, and 664 EMBASE papers resulted in 35 publications that met the eligibility criteria. The mean change in gingival recession was not significantly different among toothbrush groups in the two selected trials with safety as a primary outcome (weighted mean difference: 0.03). A meta-analysis of the five trials that evaluated safety with a surrogate parameter was not possible; however, there were no significant between-group differences at the study end in any trial. A descriptive analysis of the 24 selected studies assessing safety as a secondary outcome revealed few brushing-related adverse events. The heterogeneity in objectives and methodology of the four in vitro trials that met the eligibility criteria precluded generalization of the results.

Conclusion: A large body of published research in the preceding 2 decades has consistently shown oscillating-rotating toothbrushes to be safe compared to manual toothbrushes, demonstrating that these power toothbrushes do not pose a clinically relevant concern to hard or soft tissues. *J Periodontol 2011;82:5-24.*

KEY WORDS

Dental hygiene; evidence-based dentistry; gingival recession; meta-analysis; oral hygiene; toothbrushing.

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Power toothbrushes, once primarily termed electric, were commercially launched in the 1960s, and are in wide use today. Power-brush users appear to appreciate the benefits afforded by the current technologically advanced generation of models that incorporate innovative oscillating-rotating and/or sonic-based technology.[1-3] Further, clinical studies showed that these toothbrushes can promote greater brushing motivation compared to manual toothbrushes, including more optimal brushing duration and frequency.[4-7]

Although the effectiveness of power toothbrushes was initially a question,[8,9] research over several decades has established that, in general, power toothbrushes produce appreciable whole-mouth and approximal plaque removal, although they do not replace interdental cleaning devices.[10,11] One category of power toothbrush has been shown to be statistically significantly more efficacious relative to a standard manual toothbrush. In a 2005 Cochrane review,[12] an independent meta-analysis of 42 clinical trials that evaluated multiple classes of power toothbrushes characterized by modes of action (sonic, counter-rotational, rotary/circular, oscillating-rotating, ionic, and ultrasonic) concluded that power toothbrushes with an oscillating-rotating mode of action provided superior plaque removal for short-term observation periods and gingivitis reduction for short- and long-term observation periods.

It is plausible that the higher cleaning effectiveness of oscillating-rotating toothbrushes compared to manual toothbrushes might potentially be associated with more adverse events from greater applied force, deeper bristle penetration, or more pronounced use. Although laboratory and clinical trials[13-15] demonstrated that toothbrushing with any toothbrush, manual or power, could lead to transient gingival abrasions, extensive reporting in the literature[12] on the clinical efficacy and safety of power toothbrushes (oscillating-rotating and others) compared to manual toothbrushes has not generated a well-recognized concern that they produce a greater relative risk for gingival injury or hard tissue damage.

A casual review of the literature suggests there is little supportable controlled clinical and/or survey-based evidence that power toothbrushing generates safety concerns beyond the minimal and generally transient risks of manual toothbrushing.[3,7,12,16-20] The Cochrane review[12] noted that, compared to manual toothbrushes, power toothbrushes, including oscillating-rotating toothbrushes, were not more injurious. However, safety endpoints were not the primary focus of the meta-analysis.[12] To our knowledge, a comprehensive systematic review centering specifically on comparisons of soft and/or hard tissue safety outcomes with the use of these two toothbrush classes has not been published. There is considerable variation in the priority level given to safety assessment and methodologies used across laboratory and human trials in this large body of research, making an individual search, review, and collective analysis cumbersome. Therefore, the aim of the present investigation is to converge and systematically review and assess all relevant literature concerning the safety of oscillating-rotating toothbrushes compared to the most frequently used type of toothbrush (i.e., the manual toothbrush).

MATERIALS AND METHODS

Focused Questions
In children and adults in good general health, with respect to hard and/or soft tissue safety, what are the effects of an oscillating-rotating power toothbrush when compared to a manual toothbrush? Additionally, when measured in vitro, what are the effects on hard tissue safety of an oscillating-rotating power toothbrush compared to a manual toothbrush?

Search Strategy
To search for published articles that reported on the focused questions for inclusion in the review, the electronic databases of the National Library of Medicine (PubMed-MEDLINE), the Cochrane Central Register of Controlled Trials (Cochrane-CENTRAL), and the Excerpta Medical Database (EMBASE) by Elsevier were accessed, which encompassed all available potentially relevant reports through the end of May 2010. Search terms are shown in Figure 1. The search design sought to identify any published study that evaluated the effects on hard and/or soft tissue safety of an oscillating-rotating power toothbrush compared to a manual toothbrush. Searching was not restricted to articles written in English. Letters, case reports, and narrative reviews were not included. The asterisk (*) was used as a truncation symbol.

Study Selection
From the delineated search method, all retrieved article titles and abstracts were independently screened by two reviewers (FAV; P.A. Walters, Procter & Gamble, Cincinnati, OH) for potential eligibility. If no information relevant to the eligibility criteria was available in the abstract, or if the title was relevant but the abstract was not available, the article was selected for a full reading of the text. For those articles deemed relevant, the full-text articles were evaluated by the two reviewers. All reference lists of selected studies were hand searched for additional articles that might satisfy the eligibility criteria of this review. Any discrepancies or disagreements of the two reviewers were resolved after an additional

A

The following terms were incorporated in PubMed-MEDLINE and Cochrane-CENTRAL database searches:

(<(Toothbrushing [Mesh] OR Toothbrush (textwords))

AND

(Rotating OR Rotation OR rotational OR Rotat* OR Oscillating OR Oscillation OR Oscillat* OR Pulsating

OR Pulsation OR Pulsat* OR Triumph OR power OR electric (textwords))>

OR

<power* toothbrush* OR Braun/Oral-B OR Braun Oral-B OR Braun/Oral-B Plaque Control OR

Braun/Oral-B Plak Control OR Braun Oral-B 3D excel OR Braun Plaque remover OR Braun Plak remover

OR Braun Electric toothbrush OR Braun Plaque Control OR Braun Plak Control OR Braun D5 OR Braun D7

OR Braun D9 OR Braun 3D OR Oral-B plaque remover OR Oral-B plak remover OR Oral-B electric

toothbrush OR Oral-B Plaque Control OR Oral-B Plak Control OR Oral-B Triumph OR Electric toothbrush

OR Philips Jordan plaque remover OR Philips Jordan plak remover OR Philips Jordan 2-action OR Philips

Jordan sensiflex OR Philips HP510 OR Philips HP735 (textwords)>}

B

The following terms were incorporated in the EMBASE database search:

(<('toothbrush'/exp OR 'toothbrushing'/exp)

AND

(rotating OR 'rotation'/exp OR rotational OR rotat* OR oscillating OR 'oscillation'/exp OR oscillat* OR

pulsating OR pulsation OR pulsat* OR triumph OR power OR electric)>

OR

< power* AND toothbrush* OR (braun AND 'oral b') OR (braun AND 'oral b' AND plaque AND

'control'/exp) OR (braun AND 'oral b' AND plak AND 'control'/exp) OR (braun AND 'oral b' AND 3d AND

excel) OR (braun AND plaque AND remover) OR (braun AND plak AND remover) OR (braun AND electric

AND 'toothbrush'/exp) OR (braun AND plaque AND 'control'/exp) OR (braun AND plak AND

'control'/exp) OR (braun AND d5) OR (braun AND d7) OR (braun AND d9) OR (braun AND 3d) OR ('oral b'

AND plaque AND remover) OR ('oral b' AND plak AND remover) OR ('oral b' AND electric AND

'toothbrush'/exp) OR ('oral b' AND plaque AND 'control'/exp) OR ('oral b' AND plak AND 'control'/exp)

OR ('oral b' AND triumph) OR (electric AND 'toothbrush'/exp) OR (philips AND 'jordan'/exp AND plaque

AND remover) OR (philips AND 'jordan'/exp AND plak AND remover) OR (philips AND 'jordan'/exp AND

'2 action') OR (philips AND 'jordan'/exp AND sensiflex) OR (philips AND hp510 OR philips AND hp735)>}

Figure 1.
Search terms for the PubMed-MEDLINE and Cochrane-CENTRAL searches (A) and the EMBASE search (B).

discussion, and if unresolved, the judgment of a third reviewer (CED) was determinative. Articles were selected for inclusion in the systematic review if they met the following eligibility criteria: 1) If conducted in humans, the research was a randomized clinical trial (RCT) or a controlled clinical trial; 2) Human subjects were free of systemic disorders (in good general health); 3) The intervention included a rechargeable, oscillating-rotating power toothbrush; 4) The control was a manual toothbrush; 5) A safety assessment (hard and/or soft tissue) was included as a primary or secondary outcome measure; and 6) Safety was assessed by the surrogate outcome parameters of gingival abrasion or toothbrushing force.

For in vitro studies, the following criteria were used: 1) The intervention included an oscillating-rotating power toothbrush; 2) The control was a manual toothbrush; 3) A safety assessment (hard and/or soft tissue) was included as a primary or secondary outcome measure; 4) Safety was assessed by the surrogate outcome parameters of gingival abrasion or toothbrushing force; and 5) Orthodontic brackets and restorative materials were excluded.

Assessment of Heterogeneity

Heterogeneity was evaluated separately for studies with safety as a primary outcome, studies with safety as a secondary outcome, studies in which surrogate parameters were used to assess safety, and in vitro studies with safety as a primary outcome. Any or all of the following variables were used to determine heterogeneity as applicable: study design and length of evaluation, subject characteristics, toothbrush type, brushing instructions/frequency, outcome parameters, and substrates and brushing methodologies (in vitro).

Quality Assessment

Two reviewers (DES; SLC) scored the methodologic quality of included in vivo studies with primary safety-outcome and surrogate safety-outcome measurements, and this was referred to as the authors' estimated risk of bias. Any disagreement between the two reviewers was resolved after additional discussion. If a disagreement persisted, the judgment of a third reviewer (FAV) was decisive. An assessment of the methodologic study quality was performed as proposed by the RCT checklist of the Dutch Cochrane Center[21] and was completed with quality criteria and recommended approaches that were obtained from the statement (2010) of the Consolidated Standards of Reporting Trials,[22] the statement of the Standards for Reporting of Diagnostic Accuracy,[23] Moher et al.,[24-26] Needleman et al.,[27] the Jadad scale,[28] and the Delphi list.[29] This combination resulted in the quality criteria used in this review. Criteria were designed to address each domain of internal validity, external validity, and statistical methodology.

Each aspect of the score list was given a plus (+) for an informative description of the item at issue for a study design meeting the quality standard, a minus (−) for an informative description and a study design not meeting the quality standard, and a question mark (?) for missing or insufficient information. When random allocation, defined inclusion and exclusion criteria, masking of the examiner, balanced experimental groups, identical treatment among groups except for intervention, and report of follow-up criteria were present, the study was classified as having a low risk of bias. Studies that were missing one of these five criteria were considered to have a moderate potential bias risk.[30] Studies missing two or more of these criteria were considered to have a high potential risk of bias.[30] In addition, the levels of evidence[31] according to the Center for Evidence-Based Medicine (CEBM) (CEBM 2009) were assessed. In this system, the level of evidence was scored as follows: a score of 1 b was given to individual RCTs, and a score of 2 b was given to individual cohort studies, including low-quality RCTs.

Data Extraction

To ensure accuracy, two independent reviewers (SLC; Marta Somoygi-Mann, independent statistician) extracted the data. Any discrepancies were decided by a third reviewer (FAV). Means and, if possible, SDs of clinical safety data from selected articles wherein safety was the primary clinical outcome or safety was assessed via a surrogate parameter are presented within this systematic review (Tables 1 through 4). Where needed, baseline or end-of-treatment means and/or mean differences after treatment were calculated and are designated accordingly. Data on surrogate safety parameters (Table 4) were extracted from the original articles where significance was presented within and between groups.

Data Analyses

A meta-analysis was performed, and weighted mean differences (WMDs) were calculated by means of a computer statistical analysis program‖ (using a random-effect model) using the data from the articles that assessed safety as a primary outcome (Figure 2). Only baseline data and end-of-trial assessments were available. Consequently, it was not possible to perform a meta-analysis of the differences because the SD of the differences was not provided and could not be calculated. Therefore, data for baselines and final visits are presented separately. An analysis was performed for both time points.

The studies that presented data on secondary safety clinical outcomes (Table 5) were highly heterogeneous in terms of outcome measurements and

‖ Review Manager (RevMan) (computer program), Version 4.2 for Windows, 2003, The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark.

Table 1.

Study Characteristics of In Vivo Studies Presenting Safety as a Primary Outcome

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Outcome Parameters	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
1. Dentino et al., 2002[32] Braun/Oral-B	RCT, parallel, single-masked, and baseline prophylaxis 6 months	Generally healthy adults with mild to moderate gingivitis (MGI ≥1.2 and/or ≥20% sites with BOP); ≥20 teeth. No previous power toothbrush usage. Mean age: 32 years; age range: 18 to 61 years Males: 53; females: 104	Gingivitis, plaque, stain, calculus, BOP, molar GCF, PD, and recession	Braun/Oral-B Ultra Plaque Remover (D9); N = ? (76) ADA reference toothbrush ; N = ? (81) 2 minutes (twice a day); home use	There were no significant changes among groups in recession or attachment loss at sites predisposed to recession. The power toothbrush can be used safely without formal oral-hygiene instruction.
2. Dörfer et al., 2009[19] Procter & Gamble	RCT, parallel, and single-masked 6 months	General healthy adults with ≥2 teeth with facial recession ≥2 mm; ≥18 scorable teeth. Mean age: 33 years; age range: ? Males: 51; females: 55	Gingival recession	Oral-B Professional Care 7000 (D17); N = 55 (53) ADA reference toothbrush; N = 54 (53) 2 minutes (twice a day); home use	There was no difference in the amount of gingival recession in the power or manual group. In both groups, preexisting gingival recession was significantly reduced. No adverse effects on oral hard and soft tissues were observed in either group.

MGI = modified gingival index;[74] BOP = bleeding on probing; GCF = gingival crevicular fluid; PD = probing depth; ADA = American Dental Association; ? = not specified/unknown.

presentations of results. This rendered it impossible to carry out a quantitative analysis of the data and subsequent meta-analysis of all selected studies; thus, a descriptive manner of data on secondary clinical outcomes was used in this review. Similarly, the marked variability in substrates and methodologies within the four in vitro trials selected for review (Table 6) precluded analysis of combined results and necessitated a descriptive presentation of the results.

RESULTS

Search and Study-Selection Results

As depicted in Figure 3, 1,797 citations resulted from the PubMed-MEDLINE, Cochrane-CENTRAL, and EMBASE searches. Duplicate article listings in the searches were deleted, with 899 unique titles and abstracts available for screening. The subsequent screening yielded 149 full-text articles for reading, and 114 of these articles were eliminated after review because they did not ultimately include an oscillating-rotating/manual toothbrush comparison (76 studies), make reference to a safety assessment (30 studies), identify the toothbrushes (three studies); were narrative reviews (three studies), or, if in vitro, evaluated orthodontic brackets or restorative materials (two studies). No additional articles were identified for full-text reading from a hand search of the references. Ulti-

mately 35 articles (31 in vivo articles[15,19,32-60] and four in vitro articles[61-64]) were determined to meet all eligibility criteria and were designated for data extraction and analysis. Publications by McCracken et al.[47] and Heasman et al.[58] presented the results of the same clinical trial but separately reported on either the gingival-abrasion or brushing-force outcomes, respectively; thus, this single trial is listed in the in vivo secondary results tables (Table 5) and the surrogate safety-parameter tables (Tables 2 and 4). Two other[57,60] articles reported on more than one investigation within the individual publication, but only the data for study 1 of Danser et al.[57] and part II of Van der Weijden et al.[60] that met the aforementioned study-selection criteria are presented in the tables.

Of the 35 trials[15,19,32-64] selected for this systematic review, 19 trials reported a commercial sponsor (Tables 1 through 6). Braun/Oral-B provided full or partial funding for 10 trials, Procter & Gamble supported five studies, and Philips Oral Healthcare fully or partially sponsored four studies.

In Vivo Studies: Assessment of Heterogeneity

Safety as a primary outcome. Table 1 shows the study characteristics for the two clinical trials in which the primary outcome parameter was soft tissue safety and considerable homogeneity was observed.

Table 2.

Study Characteristics of In Vivo Studies Presenting Safety Using a Surrogate Parameter

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Primary Outcomes (surrogate safety outcome)	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
27. Danser et al., 1998[57] (study 1) ?	RCT, crossover, single-masked, split-mouth, and baseline prophylaxis 3 weeks (acclimation) and 1 day	Generally healthy students with ≥6 teeth in each quadrant. No periodontal disease. Mean age: ?; age range: ? Males: ?; females: ?	Plaque (gingival abrasion scores)	Braun Oral-B Ultra Plaque Remover (D9), EB9 brush head Butler 411 manual toothbrush Total N = 50 (47) 2 minutes (60 seconds per contralateral quadrants); single use under supervision	The incidence of gingival abrasion was comparable between the manual and power toothbrushes.
28. Mantokoudis et al., 2001[15] Partially supported by the Clinical Research Foundation for the Promotion of Oral Health	RCT, crossover, and single-masked Three 2-week test periods	Generally healthy students. No excessive supragingival calculus. Mean age: 25 years;* age range: 23 to 41 years* Males: 16;* females: 10*	BOP and plaque (gingival abrasion scores)	Braun Oral-B Plak Control Ultra Braun Oral-B 3D Paro medium manual toothbrush Total N = 26 (24) 2 minutes (twice a day); home use	In a group of dental students trained in a manual toothbrushing technique, there was no evidence of greater gingival abrasion with either the Braun Oral-B Plak Control Ultra or 3D toothbrushes compared to a manual toothbrush.
29. Rosema et al., 2008[59] Procter & Gamble	RCT, parallel, single-masked, and baseline prophylaxis 9 months	Generally healthy adults with ≥5 evaluable teeth per quadrant. No periodontal disease. Mean age: 22 years; age range: ? Males: 22; females: 92	Gingivitis (BOMP) and plaque staining (GMSI) (gingival abrasion scores)	Oral-B Triumph Professional Care 9000 (D25) with Floss Action (EB25) brush head refill; N = ? (37) ADA reference toothbrush without and with floss; N = ? (77) 2 minutes (twice a day); home use	No adverse effects were reported, and there were no statistically significant differences in gingival abrasion scores among groups. Data showed that all regimens were safe.
30. Heasman et al., 1999[58] ?	RCT, parallel, single-masked, and baseline prophylaxis 6 weeks	Adults subjects with ≥20 permanent teeth. No periodontal disease. Mean age: ?; age range: 18 to 25 years Males: 30; females: 44	Plaque and gingivitis (brushing force)	Philips/Jordan 2-Action plaque Remover (HP 735); N = 25 (25) Braun/Oral B D7; N = 25 (25) Oral-B 35 Advantage manual toothbrush; N = 25 (24) ≥90 seconds (twice a day); supervised toothbrushings to record pressures; home use	Toothbrushing forces were significantly higher in subjects using manual toothbrushes compared to subjects using powered toothbrushes.

Table 2. (continued)

Study Characteristics of In Vivo Studies Presenting Safety Using a Surrogate Parameter

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Primary Outcomes (surrogate safety outcome)	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
31. Van der Weijden et al., 1996[60] (part II) ?	RCT, single-masked, and split-mouth 3 weeks (acclimation) and 1 day	Generally healthy students with ≥24 teeth deemed "good brushers" (screening plaque score <25%). No periodontal disease. Mean age: ?; age range: ? Males: ?; females: ?	Plaque (brushing force)	Braun (power toothbrush) ? manual toothbrush Total N = 20 (?) 2 minutes (30 seconds per quadrant); single-use under supervision	With a manual toothbrush, considerably more force was used than with the electric toothbrushes.

? = not specified/unknown; BOP = bleeding on probing; BOMP = bleeding on marginal probing; GCF = gingival crevicular fluid; GMSI = Gründemann modification of the staining index;[75] ADA = American Dental Association.
* Data reported for enrolled cohort, not completing cohort.

Studies 1 (Dentino et al.[32]) and 2 (Dörfer et al.[19]) used a randomized, controlled, examiner-masked design of 6-month duration, and study 1 included a baseline prophylaxis. Study 1 also reported on 3-month evaluations; however the authors of this review only used the baseline and final data in these two articles for purposes of comparison. Study 1 selected adults with mild to moderate gingivitis, whereas Study 2 focused on preexisting gingival recession by enrolling only subjects with a ≥2 teeth with facial recession of ≥2 mm. Study 2 further excluded dental students and professionals to reduce bias.

An evaluation of safety was performed by assessing gingival recession (in millimeters) relative to the cemento-enamel junction before and after intervention in both investigations. Study 1 power-toothbrush users had toothbrushes with built-in timers, whereas manual-toothbrush users were not given timers to more closely approximate typical home-use practices.

Safety as a secondary outcome. The 24 studies that compared an oscillating-rotating power toothbrush and comparator manual toothbrush and reported on safety as a secondary outcome (Table 5) revealed a high level of heterogeneity in study design and duration. All of these studies were examiner-masked RCTs, and roughly one-half of the studies included a baseline prophylaxis. The total length ranged from 4 days (Study 11) to 3 years (Study 7). There was considerable diversity across the enrolled subject populations, which encompassed adults with and without elevated plaque, gingivitis, and/or bleeding levels, children with and without orthodontia, and periodontal patients. A predetermined plaque level was required for entrance in nine studies, whereas eight trials se-

lected subjects with some degree of gingivitis. Thirteen other studies specifically disallowed individuals with periodontal disease and/or gingival recession (Tables 5).

Power toothbrushes from one manufacturer¶ were included in five studies, and 21 trials used power toothbrushes produced by another manufacturer.# There was little consistency in the comparator manual toothbrushes, with eight different marketed brands, a standard manual reference toothbrush,** and an unidentified toothbrush represented. In the majority of studies, the bulk of the toothbrushing of subjects was via at-home, unsupervised use. Study 6 included one treatment group in which a "power flosser" was combined with power toothbrushing. In three other studies (Studies 7, 14, and 18), subjects in both toothbrush groups were directed to additionally use interdental cleaning aids.

Although none of the 24 studies evaluated safety as a primary outcome, most studies provided information on how safety was assessed. A thorough examination of the hard and soft tissues like that described by the American Dental Association[33] was performed in Studies 3, 8, 10, 12, 14, 20, 21, and 26. Studies 4 through 6, 13, 15, 16, 18, 19, 23, and 25 included some form of clinical examination of the hard and/or soft tissues. The means of examinations were not specified in Studies 9, 17, 22, and 24. Five trials (Studies 7, 9, 11, 16, and 19) used subject self-reports as a singular or adjunct means of assessment.

¶ Philips Oral Healthcare, Snoqualmie, WA.
# Braun/Oral-B, Kronberg, Germany and Cincinnati, OH.
** American Dental Association, Chicago, IL.

Table 3.

Results of In Vivo Studies Presenting Safety as a Primary Outcome

Study Number and Reference	Index/Parameter	Test Groups/ Brand	Baseline (mean [SD])	End (mean [SD])	Difference (SD)	Significant Difference From Baseline to End	Significant Difference Among Groups
1. Dentino et al., 2002[32]	Gingival recession (mm) relative to the cemento-enamel junction	Braun/Oral-B Ultra Plaque Remover	−0.17 (0.40)	−0.14 (0.37)	+0.03*	?	No
		ADA reference toothbrush	−0.15 (0.45)	−0.15 (0.36)	0*	?	
2. Dörfer et al., 2009[19]	Gingival recession (mm)	Oral-B Professional Care 7000	2.4 (0.4)	2.0 (0.6)	−0.4 (0.4)	P <0.001	No
		ADA reference toothbrush	2.3 (0.3)	1.9 (0.5)	−0.4 (0.3)	P <0.001	

ADA = American Dental Association.
* Calculated by the authors of this review.

Surrogate parameter to assess safety. A summary of the five studies that reported on the use of a surrogate parameter to evaluate safety is shown in Table 2, with three studies (Studies 27 through 29) assessing stained gingival abrasions, and two studies (Studies 30 and 31) evaluating toothbrushing force. Study lengths varied from ≈3 weeks (Study 27) to 9 months (Study 29). Only pre- and postbrushing data were used in this review. All five trials, except for Study 28, excluded adults with periodontal disease. When age was identified, subject mean ages were similar.

Study 30 included an oscillating-rotating power toothbrush with an embedded controlled-pressure system wherein the user was aware of "excessive" force via an audible click (set at 260 g). The manual comparator toothbrush differed across the trials. Manual toothbrush users in Study 30 were instructed in the modified Bass technique, whereas power-brush users followed instructions of the manufacturers.

Three trials assessed potential gingival abrasions associated with toothbrushing interventions by disclosing the gingiva and then assessing any abrasion via either the method adapted by Breitenmoser et al.[65] (Studies 27 and 29) or Van der Weijden et al.[66] and Versteeg et al.[67] (Study 28). Study 27 used on-site supervised, single-use toothbrushing (2 minutes total), whereas alternatively subjects brushed unsupervised at home in studies 28 and 29 for 2 minutes twice daily. About one-half of the manual toothbrush users in Study 29 were concurrently assigned to use dental floss. Studies 30 and 31, in evaluating brushing force, required subjects to brush supervised for ≥90 seconds[58] or 2 minutes.[60] Both investigations used the same strain-gauge monitoring technique to quantify brushing force.

In Vitro Studies
The four selected in vitro studies, which all assessed hard tissue safety, were disparate in objectives and methodologies (Table 6). Human dentin substrate wear with manual and power toothbrushing was measured in Study 32 using three-dimensional laser triangulation, in Study 33 using relative dentin abrasion, and in Study 34 using profilometry. Study 35 uniquely evaluated toothbrushing wear on bovine enamel loss after an erosive challenge using contact profilometry. The oscillating-rotating power toothbrush in each trial had a shared manufacturer,[††] whereas the manual comparator toothbrush varied by investigation. The four selected trials diverged in the brushing-simulation methodologies used, as shown in Table 6.

In Vivo Primary and Surrogate Measure Safety Studies: Study Quality
For studies wherein safety outcome data are presented in this systematic review (two studies assessed safety as a primary outcome parameter, and five trials assessed safety as a surrogate safety parameter), detailed study-quality assessments are presented in Table 7. Based on a summary of these criteria, the estimated potential risk of bias was low in all six trials, and all trials received a CEBM score of 1B, allowing a grade A recommendation to emerge form this review.

STUDY OUTCOME RESULTS
In Vivo Studies
As shown in Table 3 for the two studies that assessed safety as a primary outcome, there were no significant gingival-recession differences in the sites assessed between the power- and manual-toothbrush groups

†† Proctor & Gamble, Cincinnati, OH.

Table 4.

Results of In Vivo Studies Presenting Safety Using a Surrogate Primary Outcome

Study Number and Reference	Index/Parameter	Test Groups/Brand	Baseline (mean [SD])	End (mean [SD])	Difference (SD)	Significant Difference From Baseline to End	Significant Difference Among Groups
27. Danser et al., 1998[57]	Gingival abrasions (n sites with small [≤5 mm] or large [>5 mm])	Braun Oral-B Ultra Plaque Remover (D9) with EB9 brush head Butler 411 manual toothbrush	Prebrushing 3.9 (2.4) (small) 1.7 (0.5) (large) 3.3 (3.1) (small) 1.7 (1.0) (large)	Postbrushing 4.5 (2.7) (small] 1.9 (0.8) (large) 3.8 (3.0) (small) 2.2 (1.8) (large)	+0.6* +0.2* +0.5* +0.5* +0.5*	? No ? No	No
28. Manto-koudis et al., 2001[15]	Gingival abrasions (n sites with small [≤5 mm] or large [>5 mm])	Braun Oral-B Plak Control Ultra Braun Oral-B 3D Paro medium manual toothbrush	Prebrushing Overall mean: 8.7 (2.8)	Postbrushing 12.5 (4.6) (small) 10.8 (5.5) (small) 12.2 (5.0) (small)	+3.8* +2.1* +3.5*	No No No	No
29. Rosema et al., 2008[59]	Gingival abrasions (n)	Oral-B Triumph Professional Care 9000 (D25) with Oral-B Floss Action (EB25) brush-head refill ADA reference toothbrush ADA reference toothbrush and dental floss	5.1 (3.7) 4.3 (3.3) 4.8 (4.0)	6.7 (6.1) 7.8. (6.9) 6.0 (4.0)	1.6* 3.5* 1.25*	? ? ?	No
30. Heasman et al., 1999[58]	Brushing force (g/force)	Philips/Jordan 2-Action plaque remover (HP 735) Braun/Oral B D7 Oral-B 35 Advantage manual toothbrush	NR NR NR	194 (86) 141 (57) 297 (113)	NR NR NR	NR NR NR	P <0.0001 (both power toothbrushes versus manual)
31. Van der Weijden et al., 1996[60]	Brushing force by surface (g/mm²)	Braun ? manual toothbrush	NR NR	146 (54) 267 (73)	NR NR	NR NR	P <0.00005

? = not specified/unknown; NR = not relevant because brushing force could only be assessed after a brushing exercise; ADA = American Dental Association.
* Calculated by the authors of this review.

at 6 months. Results of a meta-analysis of the collective data of Studies 1 and 2 are illustrated in Figure 2, showing no significant differences in baseline scores (WMD: 0.04; 95% confidence interval [CI]: −0.08 to 0.16; N = 134; P = 0.51). At study ends, there were again no significant between-group differences (WMD: 0.03; 95% CI: −0.07 to 0.13; N = 134; P = 0.55).

The outcomes for studies where a surrogate safety measure was used are summarized in Table 4. When gingival abrasions were assessed pre- and postbrushing intervention, there were no significant differences in mean abrasions at study ends between the manual- and power-toothbrush groups. We calculated the within-group differences for the baseline and end of treatment of studies and consistently showed post-treatment increases in the mean number of abrasions: overall, these changes ranged from 0.2 to 4.3 in the power-brush groups and from 0.5 to 5.6 in
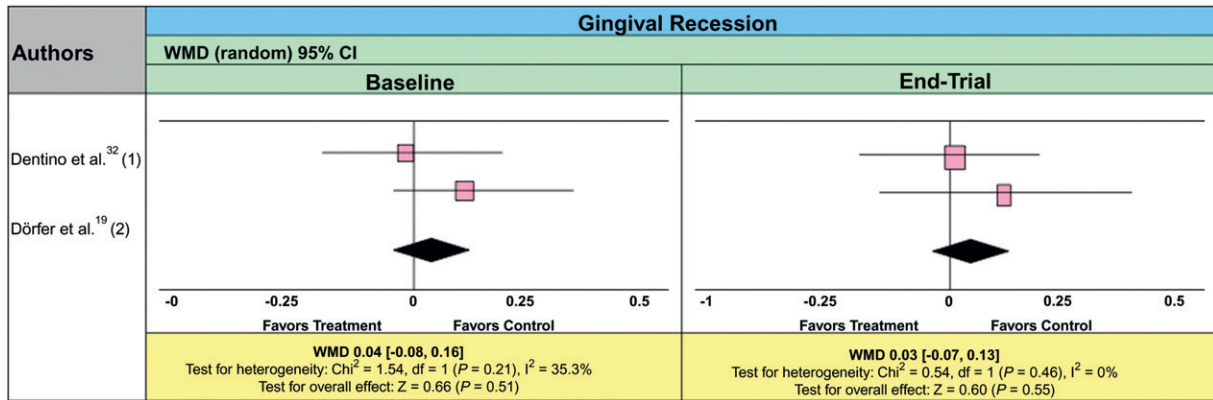
Figure 2.
Gingival recession data for the two studies (study 1 = Dentino et al.,[32] study 2 = Dörfer et al.[19]) where safety was a primary outcome parameter. The Forrest-plot shows baseline values and values for gingival recession in millimeters. The size of each box signifies the weight (i.e., importance) of the trial. WMDs (95% CIs) (♦) between toothbrush test groups are shown.

the manual-brush groups. However, when reported by the study authors, there were no statistically significant postintervention changes in the manual- or power-toothbrush groups. The two investigations of toothbrushing force presented in Table 4 show analogous outcomes. In trials 30 and 31, the average brushing force with the use of a manual toothbrush was significantly ($P \leq 0.0001$) greater than with use of the oscillating-rotating power toothbrushes.

For studies in which safety was a secondary outcome, safety conclusions of the authors of the publications (or observations elsewhere in the reports if there was not a conclusion section) are shown in Table 5. Because safety was not an exclusive interest, these statements were predominately of a qualitative nature or reflected anecdotal findings. Some authors gave multiple descriptions of safety. In total, nine articles concluded that there were no adverse events during the trial or none that were attributable to the interventions, and one study also stated that no subjects withdrew because of product-related adverse events. Five articles[4,10,12,19,25] concluded the toothbrushes used were "safe." Eleven publications[3,5,8,13,15-17,20-23] indicated there were no reports of gingival or soft tissue abrasion or trauma or mucosal desquamation, and one study[26] stated that soft tissue abrasion was negligible and not clinically significant. An absence of hard tissue abrasion in any subject was specified in five articles.[6,7,9,11,24] In three other articles,[14,18,25] gingival abrasions were reported post-treatment but were predominately attributed to interdental aids (Study 14) or were comparably distributed between the power- and manual-toothbrush groups (Studies 18 and 25).

In Vitro Studies
Table 6 summarizes the safety conclusions (or observations, as available) of the authors of the four se-

lected in vitro investigations. The three trials that evaluated human dentin found comparable or lesser wear with the use of power toothbrushes compared to manual toothbrush use. The authors of Study 35 concluded that a loss of tooth structure in erosive acid-softened enamel might be relatively greater with the use of power toothbrushes versus comparator manual toothbrushes.

DISCUSSION
Brushing of the teeth by any means is a known risk factor for soft or hard tissue damage.[68,69] In vitro simulations of long-term toothbrushing predicted theoretical tooth surface loss, albeit minimal, with the use of any toothbrush: of the 2-mm thick enamel, perhaps 10 to 15 μm will be removed via the dentifrice/toothbrush combination over a lifetime with normal use.[70] Whether such wear is precipitated in greater measure by the additive effect of the abrasivity of the adjuvant dentifrice rather than the toothbrush bristles alone has been debated.[17,70,71] However, tooth wear is multifactorial. Toothbrushing alone, in the absence of abusive use (e.g., horizontal scrubbing, too-frequent use, and excessive abrasive dentifrice) is unlikely to generate clinically significant tooth-surface loss.[17,72] Gingival abrasions associated with toothbrushing were also observed in clinical trials of manual and power toothbrushes. As with tooth wear, such abrasions may be, at times, more a result of individual inappropriate brushing techniques rather than of the toothbrush itself.[17,68]

A doubt remains regarding the use of RCTs to find adverse effects. RCTs are usually designed and powered to find common and intended outcomes, whereas adverse effects tend to be less frequent and unintended. Trials upon which this review is based might be useful to detect systematic adverse effects

Table 5.

Study Characteristics of In Vivo Studies Presenting Safety as a Secondary Outcome

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Primary Outcomes	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
3. Aass and Gjermo, 2000[33] Philips Oral Healthcare	RCT, crossover, single-masked, and baseline prophylaxis Three 3-week test periods	Adults with ≥24 natural teeth and ≥20% of surfaces visibly plaque covered. Mean age: ?; age range: 18 to 60 years* Males: 13; females: 37	Gingivitis and plaque	Philips Jordan 2-action Plaque Remover HP510 Jordan V-Shape medium manual toothbrush; total N = 50 (50) 2 minutes (twice a day); home use	No adverse effects on the soft tissue could be attributed to any of the toothbrushes.
4. Ainamo et al., 1997[34] ?	RCT, parallel, single-masked, half-mouth assessment, and baseline prophylaxis 12 months	Adults with no dental training and bleeding at ≥30% of all sites. Mean age: 38 years; age range: 20 to 63 years Males: 64; females: 47	Gingivitis, plaque, and BOP	Braun Oral-B Plak Control; N = 56 (55) Jordan manual toothbrush; N = 56 (56) 2 minutes (twice a day); home use	The Braun Oral-B Plak Control was safe. No gingival abrasion was observed at any occasion throughout the study in either group.
5. Barnes et al., 1993[35] Braun/Oral-B	RCT, parallel, single-masked, and baseline prophylaxis 12 weeks	Adults with ≥20 natural teeth and MGI ≥1.5 and TMQHPI plaque ≥2.0. No periodontal disease. Mean age: ?; age range: 18 to 65 years Males: ?; females: ?	Gingivitis	Braun Oral-B Plaque Remover (D5); N = 35 (34) Reach manual toothbrush; N = 35 (35) ? minutes (? times a day); home use	The power-toothbrush group demonstrated significant reductions in whole-mouth and interproximal gingival inflammation without increasing soft tissue trauma compared to the manual-toothbrush group.
6. Biesbrock et al., 2007[36] Procter & Gamble	RCT, parallel, single-masked, and baseline prophylaxis 8 weeks	Generally healthy adults with ≥16 natural teeth and ≥15 L&S GI bleeding sites. Mean age: ? age range: 18 to 69 Males: 54; females: 120	Gingivitis and plaque	Oral-B Professional Care Series with and without power flosser; N = ? (57) Colgate Wave manual toothbrush; N = ? (59) Oral-B CrossAction manual toothbrush; N = ? (58) 2 minutes (twice a day); supervised toothbrushing and home use	No subject discontinued treatment because of product-related adverse events.
7. Bogren et al., 2008[37] National Institute of Dental and Craniofacial Research	RCT, parallel, single-masked, and multicenter 3 years	Adult periodontal maintenance patients in recall programs for supportive periodontal therapy ≥1 year at 3 centers. Mean age: 59 years* age range: 34 to 82 years* Males: 53;* females: 75*	BOP, PD, and RAL	Oral-B [oscillating-rotating toothbrush]; N = 65 (64) Conventionally designed, multitufted, soft manual toothbrush; N = 63 (60) ? minutes (twice a day); home use	None of the patients who completed the study reported adverse events related to participation in the study.
8. Clerehugh et al., 1997[38] Braun/Oral-B	RCT, parallel, and single-masked 8 weeks	Generally healthy orthodontic patients with full upper and lower fixed appliances; modified PI ≥1.25 and gingival bleeding at ≥30% of sites. No periodontal disease. Mean age: ?; age range: 10 to 18 years* Males: 37;* females: 47*	Plaque, gingivitis, and interdental bleeding	Braun Oral-B Plaque Remover (D5) with OD5 brush head; N = 41 (37) Reach Compact Head medium manual toothbrush; N = 43 (42) 2 minutes (twice a day); home use	There was no evidence of adverse events or of safety hazards to the soft or hard tissues or the fixed orthodontic appliances because of participation in the study or use of study products.
9. Costa et al., 2007[39] ?	RCT, crossover, and single-masked Three 30-day test periods	Generally healthy orthodontic patients with ≥20 teeth and fixed appliances for ≥1 year. No periodontal disease. Mean age: 15 years; age range: 12 to 18 years Males: 11; females: 10	Gingivitis, plaque, PD, and *Streptococcus mutans* level	Braun Oral-B 3D Plaque Remover Oral-B Model 30 manual toothbrush; Total N = 21 (21) 2 minutes (three times a day); home use	All patients completed with no adverse effects reported by subjects or noted by examiners.

Table 5. (continued)

Study Characteristics of In Vivo Studies Presenting Safety as a Secondary Outcome

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Primary Outcomes	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
10. Cronin et al., 1998[40] Braun/Oral-B	RCT, parallel, and single-masked 3 months	Generally healthy adults with ≥18 natural teeth and TMQHPI ≤2.0. No periodontal disease. Mean age: ?; age range: 18 to 65 years* Males: ?; females: ?	Gingivitis, plaque, and BOP	Braun Oral-B 3D Plaque Remover; N = 57 (55) ADA reference toothbrush; N = 57 (50) 2 minutes (twice a day); home use	The 3D was safe to use. For all subjects, there was no evidence of any hard tissue abrasion. Soft tissue abrasion was negligible in both groups and considered not clinically significant.
11. Farrell et al., 2008[41] Procter & Gamble	RCT, crossover, and single-masked Four roughly 24-hour test periods	Generally healthy adults with ≥20 teeth and previous reproducible breath malodor. Mean age: 42 years; age range: 27 to 60 years Males: 10; females: 15	Breath malodor	Oral-B Vitality Precision Clean with Oral-B Precision Clean brush head ADA reference toothbrush Total # N = 28 (25) 2 minutes (twice a day); home use	All regimens were well-tolerated, and there were no reports of adverse events in the clinical study.
12. Garcia-Godoy et al., 2001[42] Braun/Oral-B	RCT, parallel, and single-masked 30 days	Generally healthy children willing to abstain from all other oral-hygiene measures for the study duration. Mean age: ?; age range: 6 to 11 years Males: 39;[†] females: 27[†]	Plaque	Braun Oral-B Kids' Power Toothbrush (D10); N = 35 (34) ADA reference toothbrush for children N = 35 (32) 1 minute (twice a day); supervised single-use; home use	Results indicate that this new power toothbrush for children is safe. There was no gum or tooth abrasion reported, and no adverse events were reported by the manual or power group.
13. Grossman et al., 1996[43] Braun/Oral-B	RCT, crossover, single-masked, and baseline prophylaxis Three 5-day test periods with brushing on day 5	Generally healthy adults with ≥16 natural uncrowned teeth. Mean age: ?; age range: 18 to 65 years Males: ?; females: ?	Extrinsic stain	Braun Oral-B (D7) Plaque Remover) Braun Oral-B Ultra Plaque Remover (D9) Crest Complete manual toothbrush Total N = 24 (23) 2 minutes (once a day); supervised single-use brushing	No untoward or unexpected side-effects of adverse events were reported during the study, and there was no evidence of soft or hard tissue abrasion.
14. Gugerli et al., 2007[44] Braun/Oral-B	RCT, parallel, single-masked, and baseline supragingival prophylaxis 28 days	Generally healthy adults with ≥12 scorable teeth. No periodontal disease. Mean age: 49 years; age range: 23 to 81 years Males: 32; females: 38	Gingivitis, BOP, PD, and plaque	Oral-B Professional Care Series 8000 (D18/EB17); N = 35 (35) ADA reference toothbrush; N = 35 (35) ? minutes (twice a day); home use	Repeated examinations of the soft tissues of subjects using powered toothbrushes revealed signs of abrasion that may have been caused by brushing in only one case, at one spot, and only at one time point. Three subjects in the power-toothbrush group and three subjects in the manual-toothbrush group showed additional signs of soft tissue abrasion. In these instances, interdental cleaning methods were the obvious cause.
15. Heasman et al., 1998[45] ?	RCT, crossover, single-masked, and presequence prophylaxis Three 4-week test periods	Generally healthy orthodontic patients with ≥12 brackets or bands per dental arch. No previous use of a power or manual orthodontic toothbrush; no periodontal disease. Mean age: 14 years age range: 10 to 16 years Males: 21; females: 39	Gingivitis, BOP, and plaque	Braun Oral-B Plaque Remover (D7) with dedicated orthodontic brush head OD5-1; Oral-B P35 orthodontic manual toothbrush total N = 20 (20) Power: ≥3 minutes (twice a day); manual: ≥2 minutes (twice a day); unsupervised home use	There was no evidence of gingival trauma in any subject at any time during the study.

Table 5. (continued)

Study Characteristics of In Vivo Studies Presenting Safety as a Secondary Outcome

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Primary Outcomes	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
16. Hickman et al., 2002[46] Braun/Oral-B	RCT, parallel, and single-masked 8 weeks	Generally healthy orthodontic patients with gingival bleeding on ≥20% of sites. No periodontal disease. Mean age: 15 years;* age range: ? Males: 26; females: 34	Gingivitis, plaque, and interdental bleeding	Braun Oral-B Plaque Remover 3D (D5); N = 33 (31) Reach Compact Head Medium manual toothbrush; N = 30 (29) 2 minutes (twice a day); home use	There were no reports or observations of damage to the oral tissues from either toothbrush over the duration of the trial.
17. McCracken et al., 2001[47] ?	RCT, parallel, single-masked, and baseline prophylaxis 6 weeks	Adult subjects with ≥20 permanent teeth. No previous use of a power toothbrush or current possession of one in the family unit; no periodontal disease. Mean age: ?; age range: 18-25 years* Males: 30; females: 44	Plaque	Philips/Jordan 2-Action Plaque Remover (HP735); N = 25 (25) Braun/Oral-B (D7); N = 25 (25) Oral-B 35 Advantage manual toothbrush; N = 25 (24) ≥90 seconds (twice a day); supervised brushing to record pressures; home use	Only three small gingival abrasion lesions were detected in three different subjects, and these lesions were all noted at baseline.
18. McCracken et al., 2004[48] Philips Oral Healthcare	RCT, parallel, and single-masked 16 months	Adult periodontal patients with ≥20 teeth, TMQHPI ≥2.0; ≥10 sites with PD ≥5 mm. No prior power toothbrush use. Mean age: 49 years; age range: 32 to 68 years Males: 18; females: 14	Plaque	Philips Sensiflex 2000; N = 20 (16) Oral-B Advantage; N = 20 (16) 2 minutes (twice a day); home use	Twenty-one soft tissue lesions (ulcers and abrasions) were recorded for five subjects in group 1 (power-toothbrush group) and eight subjects in group 2 (manual-toothbrush group). All lesions were <3 mm in diameter; and patients were told to return if they had not resolved in a week. None of the subjects returned.
19. Moran et al., 1995[49] Braun/Oral-B	RCT, crossover, single-masked, and presequence prophylaxis Three 21-day test periods	Generally healthy adults with ≥24 teeth and a high standard of oral and gingival health. Mean age: ?; age range: 19 to 51 years Males: 12; females: 12	Extrinsic stain	Braun Oral-B Plaque Remover Crest Complete manual toothbrush Total N = 24 (24) 2 minutes (twice a day); home use	All toothbrushes were found to be safe. No untoward side effects were reported for any of the subjects that could be attributed to toothbrush use.
20. Pizzo et al., 2010[50] No sponsor	RCT, crossover, single-masked, and prestudy prophylaxis for subjects with obvious gingivitis. Crossover and then a 30-day period of power-toothbrush use only. ? total duration	Generally healthy adults; ≥20 natural teeth with two scorable surfaces. Prebrushing whole-mouth plaque score ≥2. No recession ≥2 mm and/or other signs of periodontitis. Mean age: 37 years; age range: 18 to 59 years Males: 38; females: 28	Plaque	Oral-B Professional Care 8500 Oral-B CrossAction Vitalizer manual toothbrush Oral-B Indicator manual toothbrush Total N = 66 (?) 60 seconds (timed); single-use, supervised toothbrushing without use of a mirror	No postbrushing changes in oral tissues were reported or observed with any toothbrush after single use.
21. Roscher et al., 2004[51] ?	RCT, crossover, single-masked, and baseline prophylaxis Two 14-day test periods	Adult patients of a university periodontal clinic with ≥18 remaining teeth and ≥15% of buccal or lingual surfaces with visible plaque. Mean age: 49 years; age range: 26 to 64 years Males: 15; females: 21	Plaque	Philips Jordan Sensiflex Butler 411 manual toothbrush Total N = 36 (36) 2 minutes (twice a day); home use	No adverse effects of either toothbrushing regimen were recorded.

Table 5. (continued)

Study Characteristics of In Vivo Studies Presenting Safety as a Secondary Outcome

Study Number, Reference, and Sponsor	Design and Evaluation Period	Subject Population, Age, and Gender (n)	Primary Outcomes	Test Groups/Brand, N at Baseline (end), and Brushing Regimen	Authors' Observations/ Conclusions
22. Steenackers et al., 2001[52] Philips Oral Healthcare	RCT, parallel, single-masked, and baseline prophylaxis 9 weeks	Adult periodontal maintenance patients with ≥20 teeth except third molars, and pockets ≤5 mm around the recorded teeth. Mean age: 35 years; age range: 22 to 66 years Males: 18; females: 31	Gingivitis, plaque, and BOP	Philips Jordan 2-Action HP735 Plaque Remover; N = 22 (22) Lactona M3 manual toothbrush; N = 27 (27) ? minutes (twice a day); home use	No mucosal desquamation was found in any of the patients.
23. Stoltze and Bay, 1994[53] ?	RCT, parallel, and single-masked 6 weeks	Generally healthy students with ≥20 natural teeth and L&S GI and S&L PI >1. Mean age: ?; age range: 18 to 30 years Males: ?; females: ?	Gingivitis and plaque	Braun Plak Control (D5); N = 20 (20) Tandex 40 manual toothbrush; N = 20 (18) 2 minutes (twice a day); home use	No gingival abrasion was observed at any occasion.
24. Terezhalmy et al., 2008[54] Procter & Gamble	R RCT, parallel, single-masked, and baseline dental prophylaxis for manual group 2 weeks	Generally healthy adults. No recession and/or periodontal disease. Mean age: 49 years; age range: 32 to 70 years Males: 11; females: 19	Extrinsic stain	Oral-B Vitality Pro White; N = ? (15) ADA reference toothbrush; N = ? (15) 2 minutes (twice a day); home use	No adverse events were seen in either treatment group.
25. Van der Weijden et al., 1994[55] ?	RCT, parallel, single-masked, and prophylaxis at 1 month 8 months	Generally healthy students with ≥24 teeth and moderate gingivitis (≥35% test sites with BOP and MGI ≥1). No periodontal disease or previous experience with a power toothbrush. Mean age: 22 years; age range: ? Males: 37; females: 40	Gingivitis, plaque, and BOP	Braun Plak Control; N = 44 (42) Butler GUM 311 manual toothbrush; N = 43 (35) Butler GUM 311 manual toothbrush; N = 43 (35) ≥2 minutes (? times a day); home use	This investigation demonstrated that the Braun Plak Control was a safe home-care device. No serious adverse reactions were observed affecting either the hard or soft tissues. Occasionally, gingival abrasion was observed, but this was equally divided between both groups.
26. Warren et al., 2001[56] Braun/Oral-B	RCT, parallel, and single-masked 3 months	Generally healthy adults; L&S GI ≥1.0 and TMQHPI ≥1.8; ≥18 scorable teeth. No periodontal disease. Mean age: ? age range: 18 to 65 years Males: ?; females: ?	Gingivitis and plaque	Braun Oral-B Plak Control (D17); N = ? (52) ADA reference toothbrush ; N = ? (49) 2 minutes (twice a day); home use	The Braun D17 and manual toothbrushes were safe as used in the context of this study, with no evidence of clinically relevant hard or soft tissue abrasion.

? = not specified/unknown; BOP = bleeding on probing; MGI = modified gingival index; TMQHPI = Turesky modification of the Quigley-Hein plaque index; ADA = American Dental Association; L&S GI = Löe and Silness gingival index; PD = probing depth; RAL = relative attachment level; PI = plaque index; S&L PI = Silness & Löe plaque index; GI = gingival index.
* Calculated by the authors of this review.
† Data reported for enrolled cohort, not for the completing cohort.

such as the potential for greater gingival recession but might be less advantageous for other events. In contrast, in the 31 human clinical trials that met the eligibility criteria for this review (Tables 1 through 5) and encompassed ≈2,000 children and adult subjects in various clinical settings between 1993 and 2010, 25 publications concluded that the use in their studies of the oscillating-rotating power toothbrushes and manual-toothbrush comparators yielded unremarkable safety outcomes[19,32-43,45-47,49-54,56,58,60] and categorized the findings in one or more ways: tooth-

brushes were safe, there were no brushing-related adverse events and/or subject withdrawals, there was no hard tissue abrasion, and there was no gingival/soft tissue abrasion or trauma. When potentially brushing-associated gingival abrasion was reported, authors described it as negligible/not clinically significant or of comparable incidence in the power- and manual-toothbrush test groups and not significantly different when statistically tested. Two investigations (Studies 30 and 31) that assessed the relative force of power and manual toothbrushes under similar conditions

Table 6.

In Vitro Studies With Safety as Primary Outcome

Study Number, Reference, and Sponsor	Design and Primary Outcome	Substrate and Any Modification Additional Media	Test Groups/Brand (n specimens)	Brushing Methodology	Authors' Observations/Conclusions
32. Knezevicet al., 2010[61] Partially supported by Ministry of Science, Education, and Sport, Zagreb, Croatia	Parallel Dentin-surface loss measured by three-dimensional laser triangulation	Sound, polished human dentin Slurry: 11.2 g glycerin, and 11.2 g deionized water; 44.2 g Tragant solution; 33.4 g calcium-hydrogen-phosphate	Oral-B 3D Excel D17, with Flexisoft EB17-4 (24) ADA reference manual toothbrush (12)	Power toothbrush: total of 12,500 strokes, 90 g vertical load (12 samples), and 150 g (12 samples) Manual toothbrush: total of 12,500 strokes and 250 g vertical load	Powered toothbrushes produced less dentin wear than manual toothbrushes.
33. Schemehorn and Zwart, 1996[62] ?	Crossover (same specimens used for both groups) RDA with radiotracer technique	Irradiated sound human dentin Slurry: 25 g of 1,100 ppm sodium fluoride (silica) toothpaste in 40 ml water	Braun Oral-B Ultra Plaque Remover (D9) (8) ADA reference manual toothbrush (8)	Power toothbrush: total of 374 strokes, 8.5 minutes, and 150 g brushing force Manual toothbrush: total of 1,500 strokes, 8.5 minutes, and 150 g brushing force	The mean RDA of the power toothbrush was found to be low (16) and was markedly less than that of the manual toothbrush (100).
34. Sorensen and Nguyen, 2002[63] Partially sponsored by Philips Oral Healthcare	Parallel Dentin-surface loss measured by profilometry	Dentin sections modeled to simulate the teeth curved prominences Slurry: 0.5 parts sodium fluoride dentifrice, 0.8 parts water; and 1.0 part artificial saliva	Braun Oral-B 3D Excel (24) Oral-B 35 manual toothbrush (12)	Manual toothbrush: 12,500 strokes and 250 g brushing force Power brush: 52 minutes and 150 g brushing force	There was no significant difference in dentin loss between the manual toothbrush and the power toothbrush at 150 g load. The power toothbrush at a 90-g load produced significantly less dentin loss than the manual toothbrush.*
35. Wiegand et al., 2006[64] ?	Parallel Erosion-abrasion pH-cycling model; enamel-surface loss measured by contact profilometry	Eroded; polished bovine enamel; slurry: artificial saliva and fluoridated toothpaste (Elmex, RDA 77) in a 3:1 ratio to make 20 ml	Oral-B 3D Excel (normal power level) (30) Oral-B 3D Excel (lower power level) (30) Aronal manual toothbrush (30)	5- to 10-minute brushing periods within a pH cycling model Power toothbrushes: activated mode, supplemented by linear back and forth movement (20 strokes per minute) Manual toothbrush: 100 or 80 or 20 strokes per minute. Brushing load of 2.5 N for all groups	Under a similar brushing technique and force, enamel loss after an acidic attack may be increased by using certain power toothbrushes compared to the tested manual toothbrush.

? = not specified/unknown; RDA = relative dentin abrasion; ADA = American Dental Association.
* Conclusion was not extracted textually from the article but derived by the review authors from the results presented.
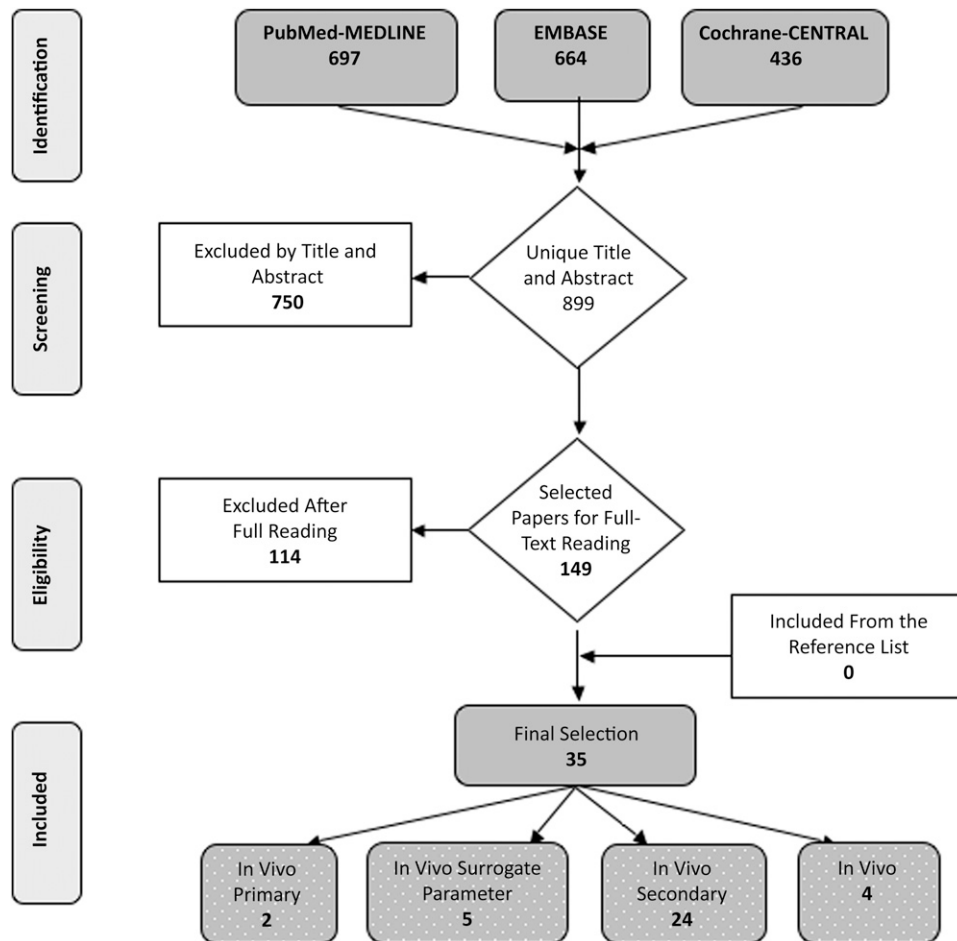
Figure 3.
Search and selection results.

both found power-toothbrush use was associated with a lower mean force. If excessive brushing force can contribute to tooth-surface loss, as some researchers have speculated,[13,14] power toothbrushes may prove more protective relative to manual toothbrushes,[68] particularly given that some leading brands now have built in pressure-sensor features.

Dentino et al.[32] (Study 1) and Dörfer et al.[19] (Study 2) selected gingival recession as the primary safety outcome measure in their respective long-term investigations. These trials used a precalibrated examiner whose measurements were verified by impression-based casts in Study 1 and by intraexaminer-reliability assessments in Study 2. The use of the same methodology allowed for pooling of the data from both trials for analysis (Fig. 2), and it can readily be seen from this and the individual study results (Table 3) that there were no significant differences in gingival recession between subjects who used an oscillating-rotating toothbrush compared to manual-toothbrush users.

Only four in vitro studies (Studies 32 through 35) met the selection criteria for this review, and they were limited to the analysis of surface loss from dentin or enamel, with none of them evaluating soft tissue. Three studies (Studies 32 through 34) tested sound dentin and found that oscillating-rotating power toothbrushes did not produce more wear than manual toothbrushes under simulated clinical conditions. The fourth study (Study 35) evaluated the use of the toothbrushes on eroded enamel and suggested that enamel loss after acidic attack may be increased by certain power toothbrushes when used at the same brushing force. However, it was difficult to extrapolate the potential clinical implications from this study because brushing forces have been shown to be significantly higher when manual toothbrushes are used, as discussed previously.[59,61] In addition, another in vitro study of eroded dentin,[73] which was not included in this review because of the lack of a manual-toothbrush comparison, found no increase in wear with an oscillating-rotating power toothbrush. A significant number of the subject participants in the 31 in vivo studies included in this systematic review likely had regular exposure to erosive events (e.g., orange juice) during the

Table 7.

Methodologic Aspects of Quality Assessment

Quality Aspects	In Vivo Safety as the Primary Outcome		In Vivo Safety Using a Surrogate Parameter (force and abrasion)				
	1. Dentino et al.[32]	2. Dorfer et al.[19]	27. Danser et al.[57]	28. Manto-koudis et al.[15]	29. Rosema et al.[59]	30. Heasman et al.[58]	31. Van der Weijden et al.[60]
Internal validity							
Random allocation	+	+	+	+	+	+	+
Allocation concealment	?	?	?	?	?	?	?
Masked to the subject	NA	NA	NA	NA	NA	NA	NA
Masked to the examiner	+	+	+	+	+	+	+
Masking during statistical analysis	?	?	?	?	?	?	?
Reported loss to follow-up	+	+	+	+	+	+	−
Dropouts (n [%])	15 (9.5*)	3 (2.7*)	3 (6.4*)	2 (9.2*)	8 (6.6*)	1 (1.4*)	?
Treatment identical, except for intervention	+	+	+	+	+	+	+
External validity							
Representative population group	+	+	+	+	+	+	+
Eligibility criteria defined	+	+	+	+	+	+	+
Statistical validity							
Sample-size calculation and power	+	−	?	?	?	+	?
Point estimates	+	+	+	+	+	+	+
Measures of variability presented for the primary outcome	+	+	+	+	+	+	+
Per-protocol analysis	+	+	+	+	+	+	+
Intention-to-treat analysis	−	−	−	−	−	?	?
Estimated potential risk of bias	Low	Low	Low	Low	Low	Low	Low
Levels of evidence (center for Evidence-Based Medicine, 2009[31])	1b	1b	1b	1b	1b	1b	1b

+ = informative description; met quality standard; ? = not specified/unclear; NA = not applicable; − = informative description; did not meet quality standard.
* Calculated by the authors of this review.

trial periods, but no noticeable hard tissue wear was reported. Certainly, clinical measurement of hard tissue damage is challenging, potentially lengthy, and unlikely to be detected with current methodologies unless it is pronounced. There is no existing standard methodology with sufficient sensitivity for long-term clinical assessment. Until such a clinical method is developed and validated, in vitro studies have an important role in identifying potential safety concerns that would be difficult to discover clinically. The development of standard protocols to evaluate the abrasion potential of power toothbrushes would be beneficial for consistent comparisons across different laboratories.

Despite the large number (i.e., 31) of qualifying clinical trial reports deemed eligible for inclusion in this review, only two studies, Dentino et al.[32] (Study 1) and Dörfer et al.[19] (Study 2), focused on safety as a primary outcome and accordingly included quantifiable, standardized measurements to compare baseline with postintervention results. In contrast, the 24 trials

(listed in Table 5) wherein safety outcomes were of secondary interest provided, at minimum, a summary statement regarding toothbrush safety but did not incorporate quantitative safety indices for gingival recession or surrogate-safety effects. Their descriptions of oral hard and/or soft tissue clinical evaluations, where provided, varied in explicitness, with eight studies[33,38,40,42,44,50,51,56] citing the ADA (or comparable) method, and 10 studies[34-36,43,45,46,48,49,53,55] referencing an unspecified oral and/or hard tissue examination method. Five articles[37,39,41,46,49] described subject self-reports, and four studies[39,47,52,54] did not detail the means of safety assessment. To increase the rigor of the findings and ability to compare results among comparable investigations, we recommend that, in future studies in which the safety of power toothbrushes is evaluated, a quantifiable parameter (i.e., gingival recession or an appropriate surrogate parameter) should be scored and reported, including measures of variability.

Because of the dissimilar and unmaskable inherent designs of power and manual toothbrushes (e.g., size, noise, and brush-head movement), it is impossible to mask the subject user from the knowledge of toothbrush assignment in trials with these comparisons, and thus, the lack of such masking in the seven trials assessed for study quality was not included as a primary factor in the estimate of bias (Table 7). Although Heasman and McCracken[16] noted that this lack of double masking in efficacy trials would inevitably introduce some degree of bias to the results, potentially as a result of a "novelty effect" for new power-toothbrush users, for safety outcomes, any such effect or the documented increased compliance and brushing duration and/or frequency associated with power toothbrushes[4-7] might, in fact, lead to an overrepresentation of power-toothbrush adverse effects relative to manual-toothbrush use. In other words, more frequent power-toothbrush exposure compared to manual toothbrushing could theoretically lead to a greater relative incidence of untoward hard and/or soft tissue effects. Such findings were not seen in this systematic review, suggesting that the lack of double masking was probably not a significant influence on safety outcomes.

CONCLUSIONS

The safety of power toothbrushes has frequently been evaluated in tandem with efficacy investigations and less frequently as a primary or surrogate safety outcome. This systematic review of a large body of published research in the preceding 2 decades consistently showed oscillating-rotating toothbrushes to be safe compared to manual toothbrushes, and collectively indicated that they do not pose a clinically relevant concern to either hard or soft tissues.

It is recommended that future clinical investigations should include a toothbrush safety assessment with quantifiable primary or surrogate outcome parameters and measures of variability.

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