

Efficacy of manual toothbrush head size and shape on plaque and gingival indexes: a systematic review and meta-analysis

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ABSTRACT

Background: This systematic review evaluated whether manual toothbrush head design, including head size and shape, influences plaque removal, gingival inflammation, or gingival adverse events in systemically healthy adults. **Methods:** Five databases were searched through April 11, 2025, for randomized controlled trials comparing manual toothbrushes with varying head designs. Two reviewers independently screened studies, extracted data, and assessed risk of bias using the RoB 2 tool. Random-effects meta-analyses were conducted by follow-up period, and certainty was evaluated using GRADE. **Results:** Thirty-two trials were included. No statistically significant differences in plaque outcomes were found after single use (SMD = -0.01 ; 95% CI: -0.39 to 0.37), 7 days (SMD = 0.74 ; 95% CI: -1.63 to 3.11), 15 days (MD = 0.01 ; 95% CI: -0.07 to 0.09), or 28 days (SMD = -0.19 ; 95% CI: -0.61 to 0.23). Gingival-index scores showed a statistically significant but small difference at 15 days (MD = -0.07 ; 95% CI: -0.14 to -0.01), of which the clinical relevance remains uncertain. No clear difference was observed at approximately 4 weeks (SMD = -0.17 ; 95% CI: -0.35 to 0.00). No consistent short-term gingival safety signal was identified. Certainty ranged from “moderate” to “very low,” and several plaque analyses showed substantial heterogeneity. **Conclusion:** Current evidence does not demonstrate consistent clinically meaningful differences among manual toothbrush head designs. However, heterogeneity, concurrent differences in other toothbrush characteristics, and limited adverse-event reporting prevent conclusions regarding equivalence or long-term gingival safety.

Keywords: biofilm; dental hygiene; gingivitis; prevention; toothbrush; toothbrushing

CDHA Research Agenda category: oral health frameworks

INTRODUCTION

Periodontal health maintenance is a cornerstone of preventive dentistry, with daily oral hygiene practices being the core procedures protecting against plaque accumulation and gingival inflammation(1). Among available methods, toothbrushing with a manual toothbrush is the most widely practiced and universally recommended technique for biofilm disruption(2,3). Despite the universal adoption of manual toothbrushes, significant variability exists in their design, particularly in the size and shape of the brush head(4). These variations are not merely cosmetic or marketing choices; they may have a substantial impact on the efficiency of plaque removal, the risk of gingival lesions, and the subsequent development or prevention of gingivitis(5,6).

Gingivitis is one of the most prevalent oral conditions worldwide and represents the initial, reversible stage of periodontitis. Current estimates indicate that periodontal diseases—which include gingivitis and periodontitis—contribute to a substantial global health burden, with recent analyses suggesting that in 2021 more than 1.06 billion people were affected(1,7). While severe periodontitis receives much of the epidemiological attention due to its irreversible nature and links to tooth loss and systemic disease, the impact of gingivitis should not be underestimated(7,8). If left untreated, gingivitis may develop into periodontitis, representing a critical pathway in the natural progression of periodontal breakdown(9,10). Beyond its direct clinical implications, gingivitis carries indirect public health costs through reduced quality of life, increased dental care needs, and its high prevalence across populations(1). The primary etiological factor in gingivitis is the accumulation of supragingival biofilm, underscoring the importance of effective daily oral hygiene strategies(2,11).

Manual toothbrushes remain the most widely used oral hygiene tool globally, due to their accessibility, affordability, and familiarity(4). The literature demonstrates twice-daily manual toothbrushing as the foundation for plaque control(12). However, there is no specification for the optimal toothbrush head design for minimizing gingival inflammation and trauma. Manufacturers have introduced an array of toothbrush head shapes and sizes, ranging from compact to full-sized heads, with rectangular, tapered, or diamond-shaped contours. These are often promoted as enhancing access to interproximal or posterior areas, or as being gentler on gingival tissue. Despite these claims, evidence-based recommendations remain scarce, and clinicians often rely on personal preference, manufacturer marketing, or anecdotal experience when advising patients.

The design of a toothbrush head can influence oral health outcomes through both mechanical and biological mechanisms(13). Smaller or tapered heads may facilitate access to posterior molars, interproximal areas, and the gingival sulcus, potentially enhancing plaque removal in difficult-to-reach sites(14). Conversely, larger heads may cover greater surface area and reduce necessary brushing time; however, they may impede precise control and limit access to anatomical niches. In addition, head design may influence the risk of gingival lesions(13). Excessively large heads or those with sharp contours may increase the likelihood of mechanical abrasion or gingival recession, particularly if used with improper technique or excessive brushing force(15). Conversely, compact and contoured designs may minimize traumatic contact with the gingival margin, promoting safer brushing while maintaining plaque control(15,16). Thus, head size and shape are not merely ergonomic considerations but potentially significant determinants of both efficacy and safety in manual toothbrushing(13,15,16).

Most of the literature on this topic has concentrated on bristle arrangement, brushing technique, or comparisons of manual versus powered toothbrushes(17,18). The specific influence of toothbrush head size and shape on gingival lesions and inflammation has received comparatively little attention. Moreover, studies that have addressed head design often report plaque-related outcomes, without systematically evaluating gingival lesions or clinical signs of gingivitis.

No previous systematic reviews have synthesized the available evidence on this topic. While earlier reviews have explored broader aspects of toothbrush design, or compared manual and powered toothbrushes(19,20), none have specifically examined the role of head size and shape in relation to gingival lesions, plaque accumulation, and gingival inflammation. This represents a substantial gap in the literature, particularly given the widespread daily use of manual toothbrushes and the subsequent potential for small design differences to influence long-term oral health outcomes at the population level(21).

By evaluating randomized controlled trials (RCTs) that compare manual toothbrushes with different head sizes and shapes, this review aimed to determine their impact on gingival lesions, plaque accumulation, and gingival inflammation in systemically healthy adults.

MATERIALS AND METHODS

The focused question for this systematic review was: “Does the head size and shape of manual toothbrushes influence plaque index, gingival index, and gingival lesions in systemically healthy individuals?”

- **Population:** Systemically healthy individuals over 18 years old.
- **Intervention:** Manual toothbrushing with different brush head sizes and/or shapes in relation to comparator groups.
- **Comparator:** Manual toothbrushing with brushes with different characteristics of head size and/or shape, compared to those reported in intervention groups.
- **Outcomes:**
 - Plaque index (any index),
 - Gingival inflammation/gingivitis (any index),
 - Gingival lesion.

Registration of protocol

The strategy used to search for potential clinical research articles to be included in this review followed the recommendations of the National Health Service Centre for Reviews and Dissemination (CRD) and the meta-analysis studies in epidemiology (PRISMA; Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. In addition, this systematic review was registered in the International Prospective Register of Systematic Reviews (PROSPERO) with protocol number CRD420251011073.

Search strategy

A systematic search for potentially relevant studies was conducted up to April 11th, 2025. The explored databases were: EMBASE (<https://www.embase.com>), SCOPUS (<https://www.scopus.com>).

www.scopus.com), PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>), Web of Science (<https://access.clarivate.com/>), and the Cochrane Library (<https://www.cochranelibrary.com>). For PubMed, the following terms were considered, and were then adjusted for each database (Supplementary Table S1):

PubMed:

#1 “Toothbrushing”[MeSH] OR “Manual Toothbrush*”[tw] OR “Toothbrush*”[tw] OR “Tooth Brush*”[tw] OR “Brushing”[tw]

#2 bristle[tw] OR bristles[tw] OR end-rounding[tw] OR filament[tw] OR soft[tw] OR medium[tw] OR hard[tw] OR end-form[tw] OR tapered[tw] OR conical[tw] OR “toothbrush filament”[tw] OR “toothbrush design”[tw] OR “toothbrush bristle”[tw] OR manual[tw] OR “commercially available”[tw] OR “head size”[tw] OR shape[tw] OR small[tw] OR medium[tw] OR large[tw] OR round[tw] OR rectangular[tw]

#3 “Gingivitis”[MeSH] OR gingivitis[tw] OR “Gingival Inflammation”[tw] OR “Gum Inflammation”[tw] OR “gingival index”[tw] OR “bleeding on probing” OR “Periodontal Health”[tw] OR “Dental Plaque”[MeSH] OR “dental plaque”[tw] OR “Plaque Index”[tw] OR “Plaque Score”[tw] OR “Plaque”[tw] OR biofilm[tw] OR “oral hygiene index”[MeSH] OR “oral hygiene index”[tw] OR “antiplaque”[tw] OR “antigingivitis”[tw] OR “Gingival Recession”[MeSH] OR “gingival recession”[tw] OR “gingival atrophy”[tw] OR recession-type[tw] OR “root exposure”[tw]

#4 #1 AND #2 AND #3

The potential clinical studies were exported to Rayyan(22) (Qatar Computing Research Institute, Doha, Qatar). Duplicates were identified and removed by two reviewers (CM and RPP). Additionally, a gray literature search was performed on Google Scholar (Google Inc) on the first 300 studies. A further manual search was also performed on the reference lists of the included studies.

Eligibility criteria

For a study to be considered eligible, the reviewers verified the following criteria: RCT study design; published in a peer-reviewed journal; investigated the presence of plaque (using any validated index), gingival inflammation (any validated index), or gingival lesion for manual toothbrushes with different head sizes and/or shapes, compared to manual toothbrushes with standard rectangular heads. No language restriction was imposed. Clinical studies of underage patients and/or patients using orthodontic appliances and removable prosthetics were excluded.

Study selection and analysis

Screening of the studies was performed independently by two individual researchers (CM and HRO). In case of disagreements, a third researcher was involved (RPP) until consensus was achieved. After the preliminary search, two researchers (CM and HRO) independently screened identified publications, reviewing the titles and abstracts; a good concordance coefficient was achieved between the reviewers (Kappa Index = 0.83). Later, full analysis of the study texts was conducted, followed by the selection of studies and extraction of data. A good concordance coefficient was once again observed between the reviewers (Kappa index = 0.80). Discordance between the author reviews at this stage was discussed and agreed upon with the help of a third author (RPP).

Risk of bias

Two researchers (CM and RPP) assessed the risk of bias within the studies using the RoB 2 tool (Creative Commons Attribution, Bristol, UK) for intervention studies(23). The tool is divided into five different domains: (1) randomization process; (2) deviations from the intended interventions; (3) missing outcome data; (4) measurement of the outcome; and (5) selection of the reported results. Each domain was judged as having low risk of bias, some concerns, or high risk of bias based on responses to domain-specific signaling questions and the algorithm provided by the Cochrane Handbook. Disagreements were resolved by the expertise of a third researcher (FWMGM). Risk of bias assessment was performed independently for each outcome.

Data synthesis

The meta-analysis was performed whenever at least two studies demonstrated sufficient homogeneity to be pooled. When meta-analysis was not feasible, results were summarized qualitatively. Therefore, the pooled difference of means with 95% confidence intervals (95% CI) was reported for plaque and gingival indexes between patients using manual control or test toothbrushes. Differences between baseline and each follow-up visit were calculated for each study and each follow-up period.

For studies reporting comparable continuous outcomes, meta-analyses were performed using Review Manager (RevMan 5.4.1, The Cochrane Collaboration, Copenhagen, Denmark). Continuous variables were synthesized using mean differences (MD) when studies used the same plaque or gingival indexes, and standardized mean differences (SMD) when studies used different indices or scales; this allowed for standardization across heterogeneous measurement tools. A random-effects model was applied due to anticipated clinical and methodological heterogeneity among toothbrush designs, study protocols, and measurement indices.

Both parallel-group and crossover RCTs were eligible for inclusion. For crossover trials, effect estimates that accounted for the paired nature of the data were extracted directly from the original reports, or calculated from the reported within-participant comparisons when sufficient information was available. Washout periods between intervention phases were recorded when reported, and the potential for carryover effects was considered during data extraction and risk-of-bias assessment. Crossover trials with insufficient information to account for the paired design were not included in the quantitative synthesis, and were instead summarized narratively.

Because follow-up time can influence plaque and gingival outcomes, independent meta-analyses were conducted for each evaluation period (single use, 7 days, 15 days, and 28 days). When trials included more than two experimental arms, the sample size of the shared control group was divided proportionally to avoid unit-of-analysis errors, following Cochrane recommendations. Statistical heterogeneity was assessed using the I^2 statistic and the χ^2 test. To explore sources of heterogeneity, subgroup analyses were performed based on the type of index used for plaque measurement (e.g., RMNPI, Quigley & Hein [Q&H], O'Leary, or Silness & Loe).

“Leave-one-out” sensitivity analysis was conducted to evaluate the robustness of the meta-analytic estimates. In this procedure, the meta-analysis was repeated iteratively, removing one study at a time to examine the influence of each individual trial on the overall pooled effect. For

each iteration, a new summary effect size was calculated and compared with the original model to identify whether the exclusion of any single study produced meaningful changes in magnitude, direction, or statistical significance.

For meta-analyses including ten or more studies, a meta-regression was performed to explore potential sources of heterogeneity. The primary covariate examined was the type of plaque index used (*e.g.*, O’Leary, Turesky Modification of Q&H, Silness & Løe, or Suzuki Method). The goal was to determine whether differences in measurement scales contributed to variations in effect estimates between toothbrush head designs. Statistical significance was established as $p < 0.05$.

In addition, when at least ten studies were available, publication bias was assessed by visually inspecting funnel plot symmetry and conducting Egger’s regression test, which evaluates the association between study effect sizes and their standard errors. Statistical significance was established at $p < 0.05$.

GRADE assessment

The certainty of the evidence for each outcome (plaque index, gingival index, and gingival lesions) was assessed using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach. The GRADE assessment considered the following criteria:

- Risk of Bias: Downgraded when a substantial proportion of the evidence came from studies judged as having a high risk of bias or with some concerns, particularly when these studies contributed considerable weight to the pooled effect estimates.
- Inconsistency: Downgraded when there was substantial variation in study results that could not be explained by prespecified factors. Although I^2 values were considered (*e.g.*, $I^2 > 50\%$), downgrading was based primarily on the inability to account for heterogeneity after examining clinical diversity.
- Indirectness: Downgraded if the populations, interventions, comparison groups, or outcomes were not directly relevant to the review question.
- Imprecision: Downgraded if the confidence intervals were wide or the total sample size was insufficient.

- Publication Bias: Downgraded if there was evidence of publication bias based on funnel plot asymmetry and statistical tests (*e.g.*, Egger's test).

Each outcome was assigned a quality rating (high, moderate, low, or very low) based on the assessment of these criteria.

RESULTS

Study selection

The electronic search across all databases yielded a total of 7,331 records (PubMed: 1,545; Embase: 1,695; Scopus: 1,976; Web of Science: 1,249; Cochrane: 1,081). After removing duplicates, 2,976 unique records remained. Following title and abstract screening, 48 full-text articles were selected for eligibility assessment. After full-text review, 32 RCTs fulfilled the inclusion criteria and were incorporated into the qualitative synthesis. Sixteen studies were excluded for the following reasons: not randomized ($n = 6$), conducted on orthodontic patients ($n = 6$), or involving participants with dentures ($n = 4$). An additional gray literature search was performed on Google Scholar and study citations. This resulted in 14 studies, nine of which were duplicates, four were excluded for lack of randomization, and one was excluded as it was conducted on orthodontic patients.

Of the 32 included studies, 27 were eligible for quantitative synthesis (meta-analysis) of plaque index outcomes, and nine contributed to the meta-analysis of gingival index outcomes. Gingival lesions were reported in nine studies, all of which were included in the qualitative synthesis of adverse effects. These trials provided descriptive data on gingival abrasion, irritation, and soft-tissue reactions associated with different toothbrush head geometries. The PRISMA 2020 flowchart of study selection is presented in Figure 1.

Figure 1: PRISMA Flowchart of Study Inclusion. RCT: randomized clinical trials.

Study characteristics

The interventions compared manual toothbrushes differing in head size (e.g., compact vs. full size) and/or head shape (e.g., rectangular, tapered, or diamond-shaped). Control brushes were typically standard rectangular heads from recognized commercial brands.

Primary outcomes included plaque accumulation—measured using indices such as the Turesky Modification of Q&H(6,13,16,24–31), the Navy Plaque Index Modified by Rustogi(5,17,32–42), Silness and Løe(43–45), O’Leary(46), or the Suzuki method(47)—and gingival inflammation measured via the Silness and Løe Index(5,25,32,38,40) or Lobene Index(26). Follow-up periods ranged from single-use evaluations to 30-day interventions. Eight studies reported gingival lesions as adverse events(24,25,27,33–35,39) or specifically measured gingival abrasions(29). These data were extracted and documented where available. All included studies are summarized in Table 1 and Table 2.

Risk of bias

Plaque Index

Figure 2: Risk of Bias Assessment for Plaque Index

The risk of bias for the 32 RCTs evaluating plaque index was assessed using the Cochrane Risk of Bias 2 (RoB2) tool (Figure 2) (23). Most studies were judged to be at low risk of bias, with 27 of the 32 trials (84.4%) categorized as low risk across all domains. Four studies (12.5%) were rated as having some concerns, typically due to issues in the randomization process or deviations from intended interventions(16,17,40,45). Only one study (3.1%) was assessed as having a high risk of bias(48), primarily due to concerns across multiple domains, including missing outcome data and selection of reported results. Overall, the evidence base showed a predominance of studies with low risk of bias, supporting confidence in the reliability of the plaque index findings.

Gingival Index

The risk of bias for the seven studies evaluating gingival index outcomes is presented in Figure 3(5,25,26,32,38,40,49). Overall, the included studies demonstrated a low risk of bias, with six studies (85.7%) rated as having a low risk of bias(5,25,26,38,40,49) and one study (14.3%) showing some concerns(32). Importantly, none of the studies were judged to have a high risk of bias.

Gingival lesions

The risk of bias for the nine RCTs evaluating gingival lesions was assessed using the RoB2 tool (Figure 4)(24,25,27,29,33,34,39,49,50). All nine trials (100%) were judged to be at low risk of bias across all domains. Overall, the included studies were judged to have a low risk of bias for the reported gingival-lesion outcomes. However, this assessment relates to the internal validity of the available study results and should not be interpreted as indicating high certainty in the evidence. Gingival lesions were inconsistently defined and reported, events were uncommon, follow-up periods were short, and most trials were not specifically designed or powered to evaluate these specific lesions.

Qualitative synthesis

Plaque Index

Across the included RCTs, a wide variety of manual toothbrush head designs were evaluated, including different head sizes, shapes, and bristle configurations, compared with more conventional or ADA-type rectangular heads. Plaque was assessed with several validated indices, most frequently the RMNP and the Q&H index, but also the API, Silness–Löe, Suzuki, and O’Leary indices.

Overall, the direction and magnitude of plaque reduction were broadly similar between experimental and control toothbrushes. In many studies, plaque reduction values for test and control brushes were numerically close, suggesting comparable clinical performance(6,16,29,34). In these studies, toothbrushes with different sizes and heads showed very similar post-brushing plaque scores or reductions compared to traditional rectangular brushes, and reported differences

were small and not statistically meaningful. Likewise, several multi-arm studies showed that a range of head designs all produced plaque reductions in a similar order of magnitude, without a clearly superior design across outcomes(13,42,46).

Some trials did report numerical advantages for specific head designs, but these effects were inconsistent across the evidence base. For instance, Chałas et al. (2015)(51) and Grimaldi et al. (2022)(37) observed greater percent reductions in plaque for certain toothbrushes with a triangular shape compared with rectangular controls; Hari et al. (2021)(27) and Sowinski et al. (2018)(5) also showed larger plaque reductions for particular smaller and round brushes(5,27,37,51). In contrast, other studies showed slightly greater plaque reduction or lower final scores with traditional rectangular brushes. In several cases, the size of the difference was small, suggesting limited clinical relevance(39,45).

Gingival Index

Several studies showed minimal or absent clinically meaningful differences between experimental and control brushes in terms of gingival indices. For example, one study reported slightly lower gingival index scores for a triangular brush (0.11) compared with rectangular (0.18), but the magnitude of this difference was small(49). Similarly, another study found rectangular and triangular brushes to produce nearly comparable reductions (0.143 vs. 0.124) in gingival index scores(32). In a third study, although gingival index scores varied across triangular brush groups, differences between brushes were inconsistent(26).

Few studies reported numerical improvements favoring specific test brushes, but these were inconsistent across trials. One study found small differences between rectangular, round, and smaller brushes, but the gingival index reductions were again close in magnitude, suggesting limited clinical significance(5).

Similarly, another study reported slight reductions favoring triangular brushes (0.124 vs. 0.143) after 30 days, but the difference remained minor(38). In contrast, a single trial demonstrated clearer advantages, reporting statistically significant gingival improvements in favor of a triangular brush with X-aligned bristles(40).

Gingival lesions

A total of nine RCTs reported information on gingival lesions, either as adverse effects or through a structured assessment of gingival abrasion(24,25,29,33,34,36,39,49,50). Most trials documented no observable signs of oral irritation or gingival lesion following the use of the tested toothbrushes(24,33,34,36,49,50). These studies evaluated various head shapes—including standard rectangular, triangular, and small rectangular designs—and consistently indicated that none of the evaluated designs produced detectable soft-tissue injury under supervised or single-use conditions.

Two studies provided more detailed descriptions of soft-tissue findings(29,39). The first directly assessed gingival abrasions over a 15-day period, and found no statistically significant differences between standard rectangular and square head designs (mean number of abrasion sites: 8.43 vs. 8.91; $p = 0.707$), indicating similar safety profiles(29). The second study reported several cases of gingival sensitivity and redness, primarily in the group using a V-shaped tip brush (4 participants); meanwhile, the standard rectangular head group showed only one case of transient dentin hypersensitivity(39). Although one other study reported a higher frequency of soft-tissue reactions with a particular design, the events were described as minor and transient. Nevertheless, comparisons across studies were limited by inconsistent definitions, assessment methods, and reporting of gingival lesions. Most studies had short follow-ups and were not primarily designed to evaluate adverse soft-tissue outcomes; the absence of reported lesions should not be interpreted as evidence that clinically relevant differences in gingival safety do not exist.

Quantitative synthesis

Plaque Index

A total of 27 RCTs were included in the antiplaque meta-analyses. Different meta-analyses were conducted according to the time of evaluation (single use, 7, 15, and 28 days), and subgroup analysis was performed by plaque index type.

Single-Use Evaluation

Thirty-seven comparisons evaluated plaque removal after a single brushing session. The pooled analysis showed no statistically significant difference between toothbrushes with alternative head designs and standard rectangular-head toothbrushes (SMD = -0.01 ; 95% CI: -0.39 to 0.37 ; $p = 0.97$; $I^2 = 91\%$). Subgroup analyses according to plaque-index type did not identify a consistent advantage for either group. Detailed subgroup estimates are presented in Figure 5.

Seven-Day Evaluation

Two studies evaluated plaque outcomes after 7 days. The pooled analysis showed no statistically significant difference between groups, with substantial heterogeneity (SMD = 0.74 ; 95% CI: -1.63 to 3.11 ; $p = 0.54$; $I^2 = 98\%$). The individual studies reported effects in opposite directions, limiting the interpretability of the pooled estimate. Detailed study-level results are presented in Figure 6.

Fifteen-Day Evaluation

Eleven studies evaluated plaque outcomes after 15 days. The pooled analysis showed no statistically significant difference between toothbrushes with alternative head designs and standard rectangular-head toothbrushes (MD = 0.01 ; 95% CI: -0.07 to 0.09 ; $p = 0.77$; $I^2 = 46\%$). Detailed results are presented in Figure 7.

Twenty-Eight-Day Evaluation

At the 28-day follow-up, 11 comparisons involving 640 participants were included. The pooled analysis showed no statistically significant difference between toothbrushes with alternative head designs and standard rectangular-head toothbrushes (SMD = -0.19 ; 95% CI: -0.61 to 0.23 ; $p = 0.37$; $I^2 = 83\%$). Subgroup analyses according to plaque index produced similar findings and are presented in Figure 8.

Leave-one-out sensitivity analyses showed that the direction and magnitude of the pooled estimates were generally stable across plaque and gingival outcomes. The exclusion of several

individual studies reduced heterogeneity at specific follow-up periods, indicating that these trials contributed to between-study variability; however, their removal did not materially alter the overall conclusions. Detailed sensitivity analysis results are presented in Table 4.

Meta-regression analysis

Plaque Index—single use

Table 3: Meta regression for single-use plaque index. Legend: 95%CI: 95% confidence interval.

Table 4. Sensitivity analysis using the “leave-one-out” method.

Figure 9: Funnel plot for the single-use plaque index meta-analysis.

Meta-regression was conducted for the single-use plaque analysis to examine whether plaque-index type explained the observed heterogeneity between studies. No statistically significant association was identified, and the model explained none of the between-study variance ($R^2 = 0\%$). Detailed coefficients are presented in Table 3. Visual inspection of the funnel plot did not indicate substantial asymmetry, and Egger’s test did not suggest small-study effects ($p = 0.468$; Figure 9).

Gingival Index

Nine studies provided data on gingival inflammation included in the meta-analyses. Separate meta-analyses were performed according to time of evaluation (15 and 30 days), and subgroup analysis was performed by index type (Löe & Silness and Lobene).

Evaluation after Fifteen-Day Use

Figure 10: Forest plot for the comparison of toothbrushes of different shapes and sizes with standard rectangular brushes for gingival index reduction after 15-day evaluation.

Three studies evaluated gingival inflammation after 15 days of toothbrushing(25,40,49). Pooled analysis showed a statistically significant but small difference favoring toothbrushes with

alternative head sizes or shapes compared with standard rectangular heads (MD = -0.07; 95% CI: -0.14 to -0.01; $p = 0.03$; $I^2 = 0\%$). Although the results were statistically consistent across studies, the magnitude of the difference was small.

Twenty-Eight Evaluation

Figure 11: Forest plot comparing toothbrushes with alternative head sizes and shapes and standard rectangular-head toothbrushes for gingival index reduction at the 28-day follow-up.

At the 28-day follow-up, eight comparisons from six RCTs evaluated gingival inflammation. The pooled analysis showed a small borderline effect favoring alternative head designs; however, the confidence interval extended to the null value, and the clinical relevance remained uncertain (SMD = -0.17; 95% CI: -0.35 to 0.00; $p = 0.05$; $I^2 = 18\%$). Subgroup analyses (Figure 11) according to the gingival index type did not identify a statistically significant difference.

GRADE assessment

Table 5: GRADE assessment framework for all meta-analyses presented.

The certainty of the evidence for all outcomes was assessed using the GRADE framework (Table 3). Overall, certainty ranged from very low to moderate across follow-up periods. Most plaque-related outcomes (single use, 7 days, and 28 days) were rated very low certainty; this was mainly due to substantial and unexplained heterogeneity and serious imprecision, reflected by wide confidence intervals and small sample sizes. In contrast, the 15-day plaque index and both gingival index timepoints (15 and 30 days) reached moderate certainty, as risk of bias and inconsistency were generally not serious, and effect estimates clustered around the null with narrow variability. However, imprecision remained a limiting factor across all outcomes, given the modest number of participants and small effect sizes. Collectively, these GRADE judgments indicate that although the certainty of evidence varied, the direction of effects was consistently stable, with no clinically meaningful differences observed between toothbrush head geometries for any measured outcome.

Table 6: Narrative GRADE assessment framework for gingival lesion outcomes

The certainty of the evidence for gingival lesions was judged to be very low according to the GRADE approach, as presented in Table 4. Although nine RCTs with more than 500 participants assessed soft-tissue effects, most studies reported none or minimal, transient gingival lesions. The evidence was downgraded for serious inconsistency, as one study reported higher levels of gingival sensitivity with a specific head design, while others observed no adverse effects. In addition, the outcome was downgraded for very serious imprecision due to the extremely low number of events, heterogeneous reporting methods, and the absence of pooled estimates.

DISCUSSION

This systematic review and meta-analysis synthesized evidence from 32 RCTs to evaluate whether the size and shape of manual toothbrush heads influence plaque accumulation, gingival inflammation, or lead to gingival adverse effects in systemically healthy adults. Across all follow-up periods and analytic approaches, the findings consistently demonstrated a lack of clinically meaningful differences between alternative head geometries and standard rectangular designs for plaque removal. Gingival inflammation outcomes showed small, time-limited effects favoring some alternative designs at 15 days, but these effects were not sustained at 30 days. Collectively, the current evidence does not demonstrate a consistent short-term advantage of alternative toothbrush head designs over standard rectangular heads for plaque control or gingival health. However, as many toothbrushes differed in characteristics beyond head size or shape, the independent effects of these specific head features could not be definitively established.

Evidence concerning gingival lesions should be interpreted cautiously. Across nine RCTs, reported soft-tissue events were uncommon and generally described as mild or transient, and no consistent association with a particular toothbrush head design was identified. However, adverse-event definitions and assessment methods varied substantially, and several studies reported only the absence or presence of irritation, without using a standardized gingival-trauma index. In

addition, follow-up periods were short, and the main outcomes recorded in most trials were plaque indexes or gingival inflammation, rather than gingival injury. The small number of events and inconsistent reporting also limited the precision of the estimates and prevented quantitative synthesis. Therefore, the available evidence indicates only that no consistent short-term safety signal was detected; it does not establish equivalence between designs or confirm their long-term gingival safety. Longer trials using standardized and prospectively defined measures of gingival abrasion, gingival recession, hypersensitivity, and other soft-tissue outcomes are needed.

These findings are consistent with the broader periodontal literature, which indicates that toothbrushing technique, duration, adherence, and bristle characteristics may be more important determinants of plaque control and gingival response than toothbrush head design(14,17,19,20,29,52). Although individual trials occasionally reported numerical advantages for triangular, tapered, compact, or rectangular heads, these differences were small and inconsistent across studies(27,29,37,39,40). Therefore, the available evidence does not support recommending a particular manual toothbrush primarily based on head size or shape.

The pooled analysis identified a statistically significant reduction in gingival index scores associated with toothbrush design at 15 days; however, the absolute mean difference was small ($MD = -0.07$), and its clinical relevance is uncertain(38,49). Statistical significance indicates that the observed difference was unlikely to be attributable to sampling variation under the assumptions of the model, but does not establish that the effect would be perceptible to patients or sufficient to influence clinical decision-making. Moreover, no established minimal clinically important difference was identified for the gingival indices used across the included trials. At the later follow-up, the pooled effect was small and borderline, with the confidence interval extending to the null value. The available evidence does not therefore demonstrate a sustained or clinically meaningful gingival benefit associated with a particular toothbrush head design. In practice, the observed small, short-term difference is unlikely to justify recommending one head design over another without considering patient preference, accessibility, comfort, toothbrushing technique, and adherence(13,14,21).

Substantial heterogeneity was observed in the single-use, 7-day, and 28-day plaque analyses, limiting confidence in the corresponding pooled estimates. Although random-effects models were used, and leave-one-out sensitivity analyses generally indicated that the direction of

the pooled effects was not dependent on any single study, these findings do not resolve the considerable inconsistency among trials. Interpretation of the 7-day estimate requires particular caution, as it was based on only two studies that reported effects in opposite directions. Potential sources of heterogeneity included differences in toothbrushing duration, supervision, technique, baseline plaque levels, participant adherence, plaque indices, and study design. In addition, the evaluated toothbrushes frequently differed in bristle stiffness, filament arrangement, tuft density, end-rounding, and other characteristics beyond head size or shape. The meta-regression did not identify plaque index type as an explanation for the observed variability, suggesting that other clinical and methodological differences contributed to the inconsistency. Consequently, these pooled estimates should be interpreted as broad summaries of heterogeneous trials, rather than as precise estimates of a common treatment effect. The absence of a consistent direction of benefit across studies suggests that no head design has demonstrated clear superiority; however, the very low certainty of evidence prevents definitive conclusions regarding equivalence between designs.

The certainty of evidence ranged from very low to moderate. The single-use, 7-day, and 28-day plaque outcomes were rated as having very low certainty, primarily because of substantial heterogeneity and imprecision. Meanwhile, the 15-day plaque and gingival index outcomes were rated as having moderate certainty. Evidence concerning gingival lesions was rated as very low because events were sparse and inconsistently reported. Accordingly, the absence of a consistent advantage should be interpreted as a lack of demonstrated superiority, rather than proof of equivalence between toothbrush designs. Larger trials using standardized toothbrush characteristics, brushing protocols, outcome definitions, and longer follow-up periods are needed to increase confidence in these findings. The findings of this review suggest that manual toothbrush head size and shape should not be prioritized when selecting a toothbrush for plaque control or gingival inflammation reduction in healthy adults. This interpretation is consistent with broader evidence that demonstrates that behavioral and bristle-related factors play a far greater role in oral hygiene effectiveness than brush head size and shape alone. Numerous clinical studies included in this review emphasize that toothbrushing technique and toothbrushing duration are primary determinants of plaque removal, often explaining more variance than brush design(16,17,41). Similarly, prior work has shown that the quality of bristle end-rounding and filament softness influences both plaque control and gingival safety, with poorly end-rounded or stiff filaments increasing the risk of soft tissue trauma, without providing additional plaque removal

benefits(29,39). The literature also highlights the importance of user adherence, as consistent and properly executed brushing habits routinely outperform mechanical modifications in brush head design(25,26). Given that the differences observed across head geometries were negligible, and smaller than those typically attributed to variations in brushing technique or filament properties, it is reasonable to conclude that patient comfort and personal preference—key predictors of sustained toothbrushing adherence—should guide toothbrush selection without compromising clinical outcomes.

Furthermore, this interpretation aligns with large comparative evaluations of manual and powered toothbrushes, which consistently show that user-related variables outweigh structural differences when evaluating plaque removal and gingival health(53,54). Thus, even though the certainty of evidence remains variable, the overall consistency in effect direction supports a pragmatic clinical recommendation: emphasizing correct toothbrushing behavior and selecting toothbrushes that patients are more likely to use consistently may have greater clinical relevance than optimizing head size and shape.

An important limitation of this review is that toothbrush head size and head shape were analyzed collectively as characteristics of head design. These features are conceptually distinct and may influence oral hygiene outcomes through different mechanisms. For example, head size may primarily affect access to posterior and interproximal surfaces, whereas head shape may influence adaptation to dental and gingival contours. However, most included trials evaluated commercially available toothbrushes, whose size and shape often varied simultaneously; these changes were also typically accompanied by differences in bristle arrangement, tuft configuration, or other design characteristics. Consequently, the available data did not routinely allow the separation of head size and shape as independent effects, without relying on potentially subjective *post hoc* classifications. Pooling these design characteristics may therefore have increased clinical heterogeneity and diluted possible design-specific effects. Accordingly, the present findings should be interpreted as evidence regarding overall differences in manual toothbrush head design rather than definitive evidence that head size and shape have no individual effects. Future trials designed to assess head size or shape should modify only one head characteristic at a time, while also standardizing bristle stiffness, filament arrangement, tuft density, end-rounding, handle characteristics, brushing instructions, and other potentially influential features.

A further limitation is that the included toothbrushes were not always identical apart from head size or shape. Most trials evaluated commercially available products that could also differ in bristle stiffness, filament arrangement, tuft density, filament end-rounding, handle ergonomics, and brushing instructions. These characteristics were inconsistently reported and may independently influence plaque removal, gingival inflammation, and soft-tissue responses. Consequently, any differences observed between groups cannot be attributed exclusively to head size or shape. Indeed, any potential effect of head design may have been obscured or modified by these concurrent differences. The findings should be interpreted as comparisons between complete toothbrush designs rather than as estimates of the isolated causal effects of head size or shape.

Limitations include the substantial variation in toothbrushing protocols, techniques, and toothbrushing times across studies. Many trials used short-term follow-up periods, preventing evaluation of longer-term gingival outcomes and cumulative soft-tissue effects. Variability in plaque and gingival indices may also have introduced measurement inconsistency, although the meta-regression indicated that index type alone did not meaningfully influence effect estimates. Additionally, several RCTs lacked detailed demographic reporting, limiting the ability to assess potential effect modification by factors such as age, sex, baseline oral health conditions, or prior oral hygiene behaviors. In this sense, one should be aware of upcoming literature that may change this tendency. Overall, basing decisions regarding toothbrush design on one or two trials that compared “head to head” might be more beneficial for an individual choice, especially if the available trial was performed rigorously and answers specific questions to support clinical decision-making.

These limitations highlight important methodological gaps that future RCTs should address. Further studies would benefit from standardized toothbrushing protocols, including clear and consistent instructions on toothbrushing duration, technique, force, and supervision. Using longer follow-up periods, beyond four weeks, would allow researchers to capture sustained effects on gingival inflammation and potential cumulative trauma. To reduce measurement variability, studies should adopt uniform, validated plaque and gingival indices, ensure examiner calibration, and report inter and intra-examiner reliability. Future trials should also provide comprehensive demographic and clinical baseline information to enable subgroup analyses and the identification of populations who may respond differently to specific brush head designs. Finally, incorporating

objective measures of brushing behavior, such as pressure sensors or digital adherence tracking, could reduce behavioral variability and help clarify the mechanical contribution of head size and shape. A guideline for toothbrushing studies may be of interest. Together, these improvements would enhance methodological rigor, reduce heterogeneity, and support higher-certainty evidence for future systematic reviews.

CONCLUSION

Current evidence does not demonstrate consistent clinically meaningful differences in plaque removal or gingival inflammation between manual toothbrushes with different head sizes or shapes and standard rectangular-head toothbrushes. However, substantial heterogeneity in several plaque analyses, the combined evaluation of head size and shape, and certainty of evidence ranging from “moderate” to “very low” decreases the confidence in these findings. No consistent short-term association between toothbrush head design and gingival adverse events was identified; however, the small number of events, inconsistent reporting, and short follow-up periods prevent any major conclusions regarding long-term gingival safety or equivalence between designs. Therefore, no particular manual toothbrush head design can currently be considered clinically superior, based on the available evidence.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest related to the present study. Any past

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DISCLOSURE OF AI-GENERATED CONTENT

During the preparation of this manuscript, the authors used Chat GPT Version 5.2 to review vocabulary and grammar. Before adding vocabulary and grammar to the submission, the authors reviewed and corrected it, as required, and take full responsibility for its content.

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Tables:

Table 1. Main methodological characteristics of the selected studies

Author, Year	Country, Type of RCT	Sample Size, Male/Female, Mean Age $\pm$ SD	Assessment	Brushing Time	Toothbrush Technique
Ashwath et al., 2014	India – Parallel	110, N/A, N/A	Plaque Index (Q&H)	2 min	Modified Bass Technique
Biesbrock et al., 2004	USA – Crossover	47, M: 10 F: 37, 44 $\pm$ 6.6	Plaque Index (RMNP) Gingival Lesion (Adverse Effects)	1 min	N/A
Chalas et al., 2015	Poland – Parallel	30, M: 23 F: 7, 25 $\pm$ N/A	Plaque Index (API)	N/A	N/A
Claydon et al., 2001	UK – Parallel	18, M: 5 F: 13, 39.8 $\pm$ N/A	Plaque Index (Q&H)	2 min	N/A
Emling & Yankell, 1994	USA – Parallel	60, N/A, Range: 18–60 years	Plaque Index (Q&H) Gingival Index (Löe-Silness) Gingival Lesion (Adverse Effects)	1 min	N/A
Ghassemi et al., 2016	USA – Crossover	68, M: 16 F: 52, 45.59 $\pm$ 10.42	Plaque Index (RMNP) Gingival Lesion (Adverse Effects)	2 min	N/A
Grimaldi et al., 2022	UK – Crossover	80, M: 28, F: 52, 33.6 $\pm$ 11.00	Plaque Index (RMNP)	N/A	N/A
Grossman et al., 1994	USA – Crossover	109, M: 31 F: 78, N/A	Plaque Index (Q&H) Gingival Index (Lobene)	N/A	N/A
Hanioka et al., 1992	Japan – Crossover	41, N/A, Range 19 and 22 years	Plaque Index (Suzuki Method)	N/A	N/A
Hari et al., 2021	Malaysia – Parallel	104, N/A, N/A	Plaque Index (Q&H) Gingival Lesions (Adverse Effects)	3 min	N/A
Harpenau et al., 2006	USA – Crossover	21, N/A, Range: 18–65 years	Plaque Index (Q&H)	N/A	Bass Technique
Kieser et al., 2005	South Africa – Parallel	60, N/A, N/A	Plaque Index (Q&H)	1 Min	N/A
Kim et al., 2024	Korea – Crossover	57, M: 18 F: 39, 53.21 $\pm$ 14.37	Plaque Index (Silness- Löe)	N/A	N/A
Levin et al., 2012	Israel – Parallel	190, N/A, N/A	Plaque Index (Silness- Löe)	N/A	Horizontal Scrub Technique
McDaniel et al., 1997	USA – Crossover	25, N/A, Range: 19–42years	Plaque Index (RMNP)	90 sec	Patient's Preferred Method

Author, Year	Country, Type of RCT	Sample Size, Male/Female, Mean Age $\pm$ SD	Assessment	Brushing Time	Toothbrush Technique
Mizutani, et al., 1987	Japan Crossover	– 15, N/A, Range: 19–22 years	Plaque Index (Silness- L��e)	4 min	Modified Bass Technique
Nathoo et al., 2004	USA Parallel	– 80, N/A, Range: 18–67 years	Plaque Index (RMNP) Gingival Index (L��e-Silness)	1 minute	Usual Manner
Nieri et al., 2013	Italy Parallel	– 48, N/A, Older than 18 years	Plaque Index (O’Leary)	N/A	N/A
Rosema et al., 2010	Netherlands –Parallel	38, N/A, N/A	Plaque Index (Q&H) Gingival Lesions (Gingival Abrasion)	2 Min	Bass Technique
R��sing et al., 2016	Brazil Parallel	– 70, N/A, Range: 21–70 years	Plaque Index (RMNP) Gingival Lesions (Adverse Effects)	1 min	N/A
Saffarzadeh et al., 2021	Iran Crossover	– 30, M: 18 F: 12, N/A	Plaque Index (Q&H)	2 min	Bass Technique
Sgan-Cohen & Vered, 2003	Israel Parallel	– 112, N/A, Older than 20 years	Plaque Index (RMNP) Gingival Index (L��e-Silness)	N/A	Usual Habits
Sharma et al., 2000	USA Crossover	– 75, M:37, F: 38, N/A	Plaque Index (RMNP)	1 min	N/A
Sharma et al., 2010	USA Crossover	– 50, N/A, Range: 18–70 years	Plaque Index (RMNP)	1 min	N/A
Singh et al., 2001	USA Parallel	– 30, N/A, Range: 18–70 years	Plaque Index (RMNP) Gingival Index (L��e-Silness)	N/A	Usual habits
Sowinski et al., 2008	USA Parallel	– 109, M: 31 F: 78, Range: 18–67 years	Plaque Index (RMNP) and Gingival Index (L��e-Silness)	N/A	N/A
Ter��zhalmy et al., 2005	USA Crossover	– 120, N/A, Range: 23–62 years	Plaque Index (RMNP) Gingival Index (Adverse Effects)	1 min	N/A
Ter��zhalmy et al., 2008	USA Crossover	– 35, N/A, Range: 20–60 years	Plaque Index (RMNP) Gingival Index (Adverse Effects)	2 min	Horizontal Motion Technique
Tirapelli et al., 2006	Brazil Crossover	– 17, N/A, Range: 23–60 years	Plaque Index (Q&H)	N/A	N/A
Vanstraelen et al., 2024	Belgium Crossover	– 21, N/A, Range: 19–26 years	Plaque Index (Q&H) Gingival Index (Adverse Effects)	N/A	Modified Bass Technique

Author, Year	Country, Type of RCT	Sample Size, Male/Female, Mean Age $\pm$ SD	Assessment	Brushing Time	Toothbrush Technique
Yankell et al., 1995	USA – Parallel	28, N/A, Range: 18–60 years	Plaque Index (Q&H) Gingival Index (Löe-Silness) Gingival Index (Adverse Effects)	N/A	N/A
Legend: N/A : Not Available; RMNP : Navy Plaque Index Modified by Rustogi; Q&H : Turesky Modification by Quigley and Hein.					

Table 2. Main results of the selected studies

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)	Main Results for Gingival Index (mean reduction compared to baseline)	Main Results for Gingival Lesions
Ashwath et al., 2014	14 Days	Group A Standard Rectangular: 0.74 $\pm$ 0.495 Small Head Rectangular: 0.64 $\pm$ 0.555 Triangular Head: 0.92 $\pm$ 0.616 Curved Triangular Head: 0.93 $\pm$ 1.15 p < 0.05, one-way ANOVA	N/A	N/A
Biesbrock et al., 2004	Single Use	Standard Rectangular: 0.175 $\pm$ 0.014 Triangular Head: 0.161 $\pm$ 0.015 p < 0.001	N/A	Adverse Effects No adverse effects observed in either group.
Chalas et al., 2015	14 Days	Standard Rectangular: 3.70% Triangular Head: 21.60% Small Triangular Head: 16.60%	N/A	N/A
Claydon et al., 2001	Single Use	Standard Rectangular: 1.2 $\pm$ 0.45 Triangular Head: 1.25 $\pm$ 0.45 Rectangular Small Head: 1.16 $\pm$ 0.14 p > 0.05	N/A	NA
Emling & Yankell, 1994	Single Use	Standard Rectangular Head: 0.45 $\pm$ 0.504	Standard Rectangular Head: 0.18 $\pm$ 0.195	Adverse Effects

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)	Main Results for Gingival Index reduction (mean reduction compared to baseline)	Main Results for Gingival Lesions
Ghassemi et al., 2016	Single Use	Triangular Head: 0.36±0.438 p < 0.01 Standard Rectangular Head: 0.306±0.042 Triangular Head: 0.429±0.048 p = 0.0001 Small Triangular Head: 0.369±0.052	Triangular Head: 0.11±0.25 p < 0.05 N/A	No oral irritation was observed in either group. N/A
Grimaldi et al., 2022	7 Days	Standard Rectangular Head: 49.2% Small Rectangular Head: 56.5% Round Small Head: 50.2% Small Rectangular Head with Tapered Bristles: 59.9% p < 0.0001	N/A	N/A
Grossman et al., 1994	28 Days	Standard Rectangular Head: 0.78±0.506 Triangular Head: 1.02±0.439 Small Rectangular Head: 0.65±0.45 p < 0.05	Standard Rectangular Head: 0.26±0.276 Triangular Head: 0.19±0.327 Small Rectangular Head: 0.24±0.308 p < 0.001	N/A
Hanioka et al., 1992	Single Use	Standard Rectangular Head: 0.67±0.55 V Shaped: 0.78±0.43 p = 0.44	N/A	N/A
Hari et al., 2021	Single Use	Standard Rectangular Head: 36.50% Triangular Head: 41.70% p = 0.673	N/A	N/A
Harpenau et al., 2006	Single Use	Standard Rectangular Head: 0.69±0.332 Curved Toothbrush: 0.65±0.294 p < 0.05	N/A	N/A
Kieser et al., 2005	15 Days	Standard Rectangular Head: 0.408±0.078 Triangular Head: 0.451±0.078	N/A	N/A

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)	Main Results for Gingival Index reduction (mean reduction compared to baseline)	Main Results for Gingival Lesions
Kim et al., 2024	Single Use	Snake-Like Toothbrush: 0.371±0.07 p < 0.05 Standard Rectangular Head: 0.68±N/A Small Rectangular Head: 0.55±N/A p = 0.9607	N/A	N/A
Levin et al., 2012	7 Days	Single Headed: 0.09±0.16 Triple Headed: 0.02±0.145 p = 0.61	N/A	N/A
McDaniel et al., 1997	Single Use	Standard Rectangular Head: 0.163±0.069 Small Head Rectangular: 0.144±0.068 Triangular Head: 0.145±0.063 p = 0.0001	N/A	N/A
Mizutani et al., 1987	Single Use	Standard Rectangular Head: 0.97±0.25 Small Rectangular Head: 1.23±0.28	N/A	N/A
Nathoo et al., 2004	Single Use	Standard Rectangular Head: 0.274±0.074 Triangular Head: 0.238±0.062 p < 0.05	Standard Rectangular Head: 0.143±0.29 Triangular Head: 0.124±0.3 p < 0.05	N/A
Nieri et al., 2013	Single Use	Standard Rectangular Head: 5.4±3.5 Small Head Rectangular: 7.2±2.7 Triangular Head: 6.4±3 Triangular Head: 6±3.2 Round Head Toothbrush: 7±3.2 Small Triangular Head: 5.6±3.2 Triangular Head: 6.7±2.9 Triangular Head: 5.6±3.6 Rectangular Head: 5.5±3.5	N/A	

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)	Main Results for Gingival Index (mean reduction compared to baseline)	Main Results for Gingival Lesions
Rosema et al., 2010	15 Days	Rectangular Head: 6.8±3.2 Triangular Head: 5.9±3.1 p < 0.0001 Standard Rectangular Head: 1.23±0.43 Square Head: 1.32±0.46 p = 0.028	N/A	Gingival Abrasion Reduction (Number of Cases) Standard Rectangular Head: 8.43 Square Head: 8.91 p=0.707
Rösing et al., 2016	7 Days	Standard Rectangular Head: 0.18±0.04 V Shaped Tip: 0.27±0.05	N/A	Adverse effects (Number of Cases) Standard Rectangular Head: 1 Patient presented dental hypersensitivity; V Shaped Tip: 4 patients with gingival sensitivity and redness in the upper arch. N/A
Saffarzadeh et al., 2021	15 Days	Standard Rectangular Head: 1.18±0.605 Triangular Head: 1.2±0.575 Small Head Rectangular Brush: 1.28±0.67 p < 0.05	N/A	N/A
Sgan-Cohen & Vered, 2003	15 Days	Standard Rectangular Head: 12.61±3.791 Triangular Head: 14.32±3.68 p = 0.003	Standard Rectangular Head: 1.63±5.99 Triangular Head: 1.11±5.79 p < 0.05	N/A
Sharma et al., 2000	Single Use	Test 1: Standard Rectangular Head: 0.38±0.08	N/A	N/A

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)	Main Results for Gingival Index reduction (mean reduction compared to baseline)	Main Results for Gingival Lesions
		Triangular Head: 0.36±0.08 p = 0.5136 Test 2: Standard Rectangular Head: 0.37±0.07 Small Triangular Head: 0.25±0.08 p = 1.0000 Test 3 Standard Rectangular Head: 0.45±0.08 Rectangular Head: 0.45±0.08 p = 0.4787 Test 4: Standard Rectangular Head: 0.46±0.08 Triangular Head: 0.28±0.08 p = 0.4139 Test 5: Standard Rectangular Head: 0.44±0.07 Triangular Tip: 0.27±0.08 p = 1.0000 Test 6: Standard Rectangular Head: 0.42± 0.08 Rectangular Head: 0.29±0.08 p = 0.8170 Test 7: Standard Rectangular Head: 0.38± 0.07 Triangular Head: 0.29±0.08 p = 0.8017		

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)	Main Results for Gingival Index reduction (mean reduction compared to baseline)	Main Results for Gingival Lesions
Sharma et al, 2010	Single Use	Standard Head: 0.544 Rectangular Head: 0.549±0.049 Small Triangular Head: 0.599±0.049 Triangular Head: 0.549±0.049 Triangular Head: 0.585±0.049 p = 0.775	N/A	
Singh et al., 2001	Single Use	Standard Head: 0.18±0.28±0.11 Rectangular Head: 0.09 Triangular Head: 0.28±0.11 p < 0.001	Control: 0.37±0.156 Triangular Head: 0.28±0.854	N/A
Sowinski et al., 2008	30 Days	Standard Head: 0.21±0.05±0.085 Rectangular Head: 0.085 Small Rectangular Head: 0.05±0.085 Triangular Head: 0.28±0.085 p < 0.05	Standard Rectangular Head: 0.18±0.13 Small Rectangular Head: 0.05±0.15 Triangular Head: 0.23±0.16	N/A
Terézhalmy et al., 2005	Single Use	Standard Head: 0.196 Rectangular Head: ±0.031 Triangular Head: 0.245±0.031 p < 0.001	N/A	Adverse Effects: No adverse effects were observed in either group.
Terézhalmy et al., 2008	Single Use	Standard Head: 0.215 Rectangular Head: ±0.012 Triangular Head: 0.215±0.012 p < 0.001	N/A	Adverse Effects: No adverse effects were observed in either group.
Tirapelli et al., 2006		Standard Head: 0.475±N/A Rectangular Head: 0.1600±N/A V Shaped: 0.0089±N/A p < 0.0001	N/A	N/A
Vanstraelen et al., 2024	Single Use	Single Headed: 1.42±0.51 Triple Headed: 1.53±0.46 p < 0.05	N/A	Adverse Effects:

Author, Year	Follow Up Time	Main Results for Plaque Index Reduction (mean reduction compared to baseline)		Main Results for Gingival Index Reduction (mean reduction compared to baseline)		Main Results for Gingival Lesions
Yankell et al., 1995	28 Days	Standard Head: 0.09±0.02±0.145 p < 0.05	Rectangular Head: 0.16 p < 0.05	Standard Head: 0.36±0.19 p < 0.05	Rectangular Heads: 0.3±0.23 p < 0.05	Adverse effects could not be verified. Adverse Effects: No oral irritation was observed in either group.
Legend: N/A: Not Available						

Table 3. Meta-regression for single use plaque index. Legend: 95%CI: 95% confidence interval

Meta-regression for single use, plaque			
Index	Estimate (95%CI)	p-value	R ²
O'Leary	0.38 (−0.57–0.33)	0.610	0.00%
Suzuki Method	0.34 (−1.82–2.49)	0.760	
Silness & Loe	1.07 (−1.14–3.27)	0.342	
Turesky Modification by Quigley and Hein	0.09 (−0.97–1.15)	0.863	

Table 4. Sensibility analysis using the methods of “leaving one out”.

Plaque – single use		
	SMD (95%CI)	I ² (p-value)
Biesbrock et al., 2008	−0.03 (−0.40–0.33)	91% (p < 0.001)
Claydon et al., 2001	−0.00 (−0.38–0.38)	91% (p < 0.001)

Emling & Yankell, 1994	0.00 (−0.37–0.38)	91% (p < 0.001)
Ghassemi et al., 2016	−0.12 (−0.47–0.24)	90% (p < 0.001)
Hanioka et al., 1992	−0.01 (−0.38–0.36)	91% (p < 0.001)
Harpenau et al., 2006	−0.00 (−0.37–0.37)	91% (p < 0.001)
McDaniel et al., 1997	0.01 (−0.37–0.39)	91% (p < 0.001)
Mizutani et al., 1987	−0.03 (−0.40–0.34)	91% (p < 0.001)
Nathoo et al., 2004	0.01 (−0.36–0.39)	91% (p < 0.001)
Nieri et al., 2013	−0.05 (−0.46–0.35)	93% (p < 0.001)
Rösing et al., 2016	−0.02 (−0.39–0.35)	91% (p < 0.001)
Sharma et al., 2000	0.42 (0.16–0.68)	73% (p < 0.001)
Sharma et al., 2010	−0.08 (−0.47–0.32)	91% (p < 0.001)
Singh et al.2001	−0.03 (−0.40–0.33)	90% (p < 0.001)
Terézhalmy et al., 2005	−0.06 (−0.41–0.29)	89% (p < 0.001)
Terézhalmy et al., 2008	−0.00 (−0.38–0.37)	91% (p < 0.001)
Terézhalmy et al., 2009	−0.01 (−0.39–0.37)	91% (p < 0.001)
Vanstraelen et al., 2024	−0.01 (−0.38–0.36)	91% (p < 0.001)

Plaque – 15 days

	MD (95%CI)	I ² (valor de p)
Ashwath et al., 2014	0.01 (−0.08–0.10)	61% (p = 0.01)
Emling & Yankell, 1994	0.01 (−0.08–0.10)	51% (p = 0.03)
Kieser et al., 2005	0.05 (−0.05–0.15)	0% (p = 0.59)
Rosema et al., 2010	0.00 (−0.08–0.09)	49% (p = 0.04)

Saffarzadeh et al., 2021	0.01 (−0.07–0.10)	57% (p = 0.02)
Sgan-Cohen & Vered, 2003	0.00 (−0.07–0.06)	29% (p = 0.18)
Yankell et al., 1995	0.02 (−0.08–0.11)	51% (p = 0.03)

Plaque – 28 days

	SMD (95%CI)	I ² (p-value)
Ashwalth et al., 2014	−0.27 (−0.77–0.23)	88% (p < 0.001)
Emling & Yankell, 1994	−0.19 (−0.66–0.28)	85% (p < 0.001)
Grossman et al., 1994	−0.27 (−0.77–0.23)	84% (p < 0.001)
Nathoo et al., 2004	−0.10 (−0.53–0.33)	81% (p < 0.001)
Sgan-Cohen & Vered, 2003	−0.17 (−0.65–0.32)	85% (p < 0.001)
Sowinsky et al., 2008	−0.14 (−0.48–0.19)	67% (p = 0.002)
Yankell et al., 1995	−0.23 (−0.69–0.24)	84% (p < 0.001)

Gingival index – 15 days

Emling & Yankell, 1994	−0.10 (−0.18–0.02)	0% (p = 0.54)
Sgan-Cohen & Vered, 2003	−0.07 (−0.15–0.02)	35% (p = 0.21)
Yankell et al., 1995	−0.01 (−0.13–0.11)	0% (p = 0.60)

Gingival index – 28 days

Emling & Yankell, 1994	−0.16 (−0.36–0.04)	26% (p = 0.22)
Grossman et al., 1994	−0.19 (−0.42–0.04)	37% (p = 0.15)

0% ($p = 0.98$)

27% ($p = 0.21$)

yses.

yses.

of patients		Effect	
Standard rectangular head	Relative (95% CI)	Absolute (95% CI)	

762	-	SM S (0 low 0. high
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132	-	SI 0.74 high (1 low 3. high
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200	-	Medium 0.00 high (0.00 low 0.00 high
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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Different head shape/size	Standard rectangular head	Relative (95% CI)	Absolute (95% CI)		
7	randomized trials	not serious	very serious ^a	not serious	serious ^b	none	378	262	-	SMD 0.19 SD lower (0.61 lower to 0.23 higher)	⊕○○○ ○ Very low ^{b,e}	CRITICAL

Gingival index - 15 days

3	randomized trials	not serious	not serious	not serious	serious ^f	none	113	118	-	MD 0.07 lower (0.14 lower to 0.01 lower)	⊕⊕⊕○ Moderate ^f	CRITICAL
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Gingival index - 28 days

7	randomized trials	not serious	not serious	not serious	serious ^b	none	364	278	-	SMD 0.17 SD lower (0.35 lower to 0)	⊕⊕⊕○ Moderate ^b	CRITICAL
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CI: confidence interval; MD: mean difference; SMD: standardized mean difference

Explanations

a. High heterogeneity was detected ($I^2=91\%$, $p<0.001$)

b. A high 95% confidence interval was observed, and the analysis showed no statistically significant difference between groups.

c. High heterogeneity was detected ($I^2=98\%$, $p<0.001$)

d. A high 95% confidence interval was observed, and the analysis showed no statistically significant difference between groups. Only 260 individuals were involved in this analysis.

e. High heterogeneity was detected ($I^2=83\%$, $p<0.001$)

f. Only 231 individuals were involved in this analysis.

Table 6. Narrative GRADE assessment framework for the outcome gingival lesions

Certainty assessment							Impact	Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			

Gingival Lesions

9	randomized trials	not serious	serious ^a	not serious	very serious ^b	none	The true incidence of gingival lesions may be substantially different from the available evidence due to very low certainty.	 Very low ^{a,b}	CRITICAL
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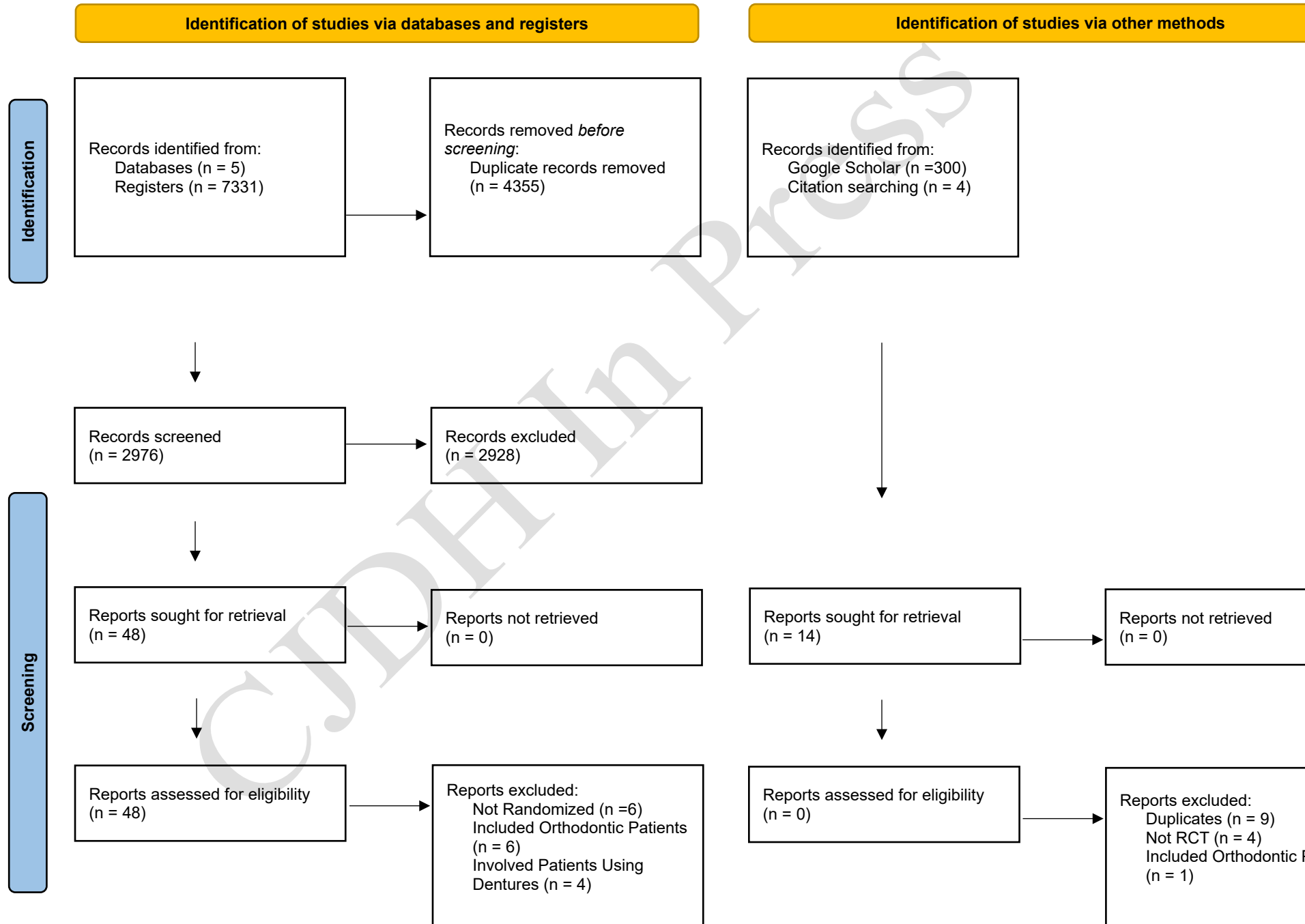
Explanations

a. Only one study reported more gingival sensitivity/redness in the V-shaped design than in the rectangular head, while most studies reported no adverse effects.

b. Gingival lesions were rare across more than 500 participants, and most studies reported no events

Figures

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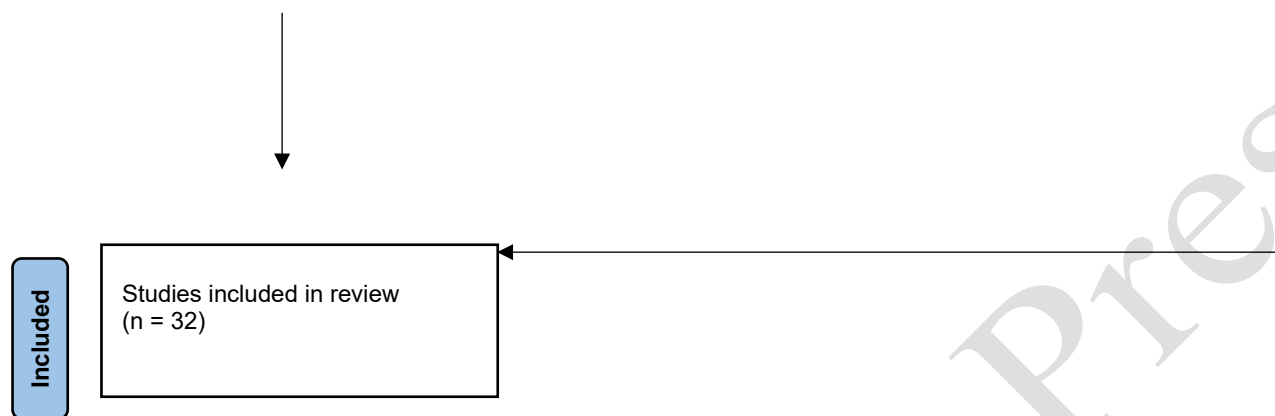


Figure 1. PRISMA Flowchart of Study Inclusion. RCT: randomized clinical trials

Intention-to-treat	Unique ID	Study ID	Outcome	D1	D2	D3	D4	D5	Overall	
	1	Grimaldi 2022	Plaque Index	●	●	●	●	●	●	● Low risk
	2	Ashwath 2024	Plaque Index	●	●	●	●	●	●	● Some concerns
	3	Kim 2024	Plaque Index	●	●	●	●	●	●	● High risk
	4	Sowinsky 2008	Plaque Index	●	●	●	●	●	●	
	5	Terezhalmy 2003	Plaque Index	●	●	●	●	●	●	D1 Randomisation process
	6	Biesbrock 2004	Plaque Index	●	●	●	●	●	●	D2 Deviations from the intended interventions
	7	Hari 2021	Plaque Index	●	●	●	●	●	●	D3 Missing outcome data
	8	Vanstraelen 2024	Plaque Index	●	●	●	●	●	●	D4 Measurement of the outcome
	9	McDaniel 1997	Plaque Index	●	●	●	●	●	●	D5 Selection of the reported result
	10	Rosing 2016	Plaque Index	●	●	●	●	●	●	
	11	Ghessemi 2016	Plaque Index	●	●	●	●	●	●	
	12	Harpensau 2006	Plaque Index	●	●	●	●	●	●	
	13	Terezhalmy 2003	Plaque Index	●	●	●	●	●	●	
	14	Rosema 2010	Plaque Index	●	●	●	●	●	●	
	15	Emiling 1994	Plaque Index	●	●	●	●	●	●	
	16	Grossman 1994	Plaque Index	●	●	●	●	●	●	
	17	Hanioka 1999	Plaque Index	●	●	●	●	●	●	
	18	Singh 2001	Plaque Index	●	●	●	●	●	●	
	19	Cohen 2003	Plaque Index	●	●	●	●	●	●	
	20	Claydon 2000	Plaque Index	●	●	●	●	●	●	
	21	Staudt 2001	Plaque Index	●	●	●	●	●	●	
	22	Kieser 1997	Plaque Index	●	●	●	●	●	●	
	23	Saffarzadeh 2021	Plaque Index	●	●	●	●	●	●	
	24	Chalas 2015	Plaque Index	●	●	●	●	●	●	
	25	Levin 2012	Plaque Index	●	●	●	●	●	●	
	26	Mizutani 1987	Plaque Index	●	●	●	●	●	●	
	27	Nathoo 2004	Plaque Index	●	●	●	●	●	●	
	28	Sharma 2000	Plaque Index	●	●	●	●	●	●	
	29	Sharma 2010	Plaque Index	●	●	●	●	●	●	
	30	Terezhalmy 2003	Plaque Index	●	●	●	●	●	●	
	31	Tirapelli 2006	Plaque Index	●	●	●	●	●	●	
	32	Yankell 1995	Plaque Index	●	●	●	●	●	●	

Figure 2. Risk of bias assessment for plaque index

Intention-to-treat	Unique ID	Study ID	Outcome	D1	D2	D3	D4	D5	Overall	
	1	Emiling 1994	Gingival Index	+	+	+	+	+	+	Low risk
	2	Grassman 1994	Gingival Index	+	+	+	+	+	+	Some concerns
	3	Nathoo 2004	Gingival Index	+	+	+	+	+	+	High risk
	4	Sgan-Cohen 2003	Gingival Index	+	+	+	+	+	+	
	5	Singh 2001	Gingival Index	+	!	+	+	+	!	D1 Randomisation process
	6	Sowinsky 2008	Gingival Index	+	+	+	+	+	+	D2 Deviations from the intended interventions
	7	Yankell 1995	Gingival Index	+	+	+	+	+	+	D3 Missing outcome data
										D4 Measurement of the outcome
										D5 Selection of the reported result

Figure 3. Risk of bias assessment for gingival index

Intention-to-treat	Unique ID	Study ID	Outcome	D1	D2	D3	D4	D5	Overall	
	1	Biesbrock 2004	Gingival Lesions	+	+	+	+	+	+	Low risk
	2	Emiling 1994	Gingival Lesions	+	+	+	+	+	+	Some concerns
	3	Harl 2021	Gingival Lesions	+	+	+	+	+	+	High risk
	4	Rosema 2010	Gingival Lesions	+	+	+	+	+	+	
	5	Rosing 2016	Gingival Lesions	+	+	+	+	+	+	D1 Randomisation process
	6	Terezhalmi 2005	Gingival Lesions	+	+	+	+	+	+	D2 Deviations from the intended interventions
	7	Terezhalmi 2008	Gingival Lesions	+	+	+	+	+	+	D3 Missing outcome data
	8	Vanstraleen 2024	Gingival Lesions	+	+	+	+	+	+	D4 Measurement of the outcome
	9	Yankell 1995	Gingival Lesions	+	+	+	+	+	+	D5 Selection of the reported result

Figure 4. Risk of bias assessment for gingival lesions

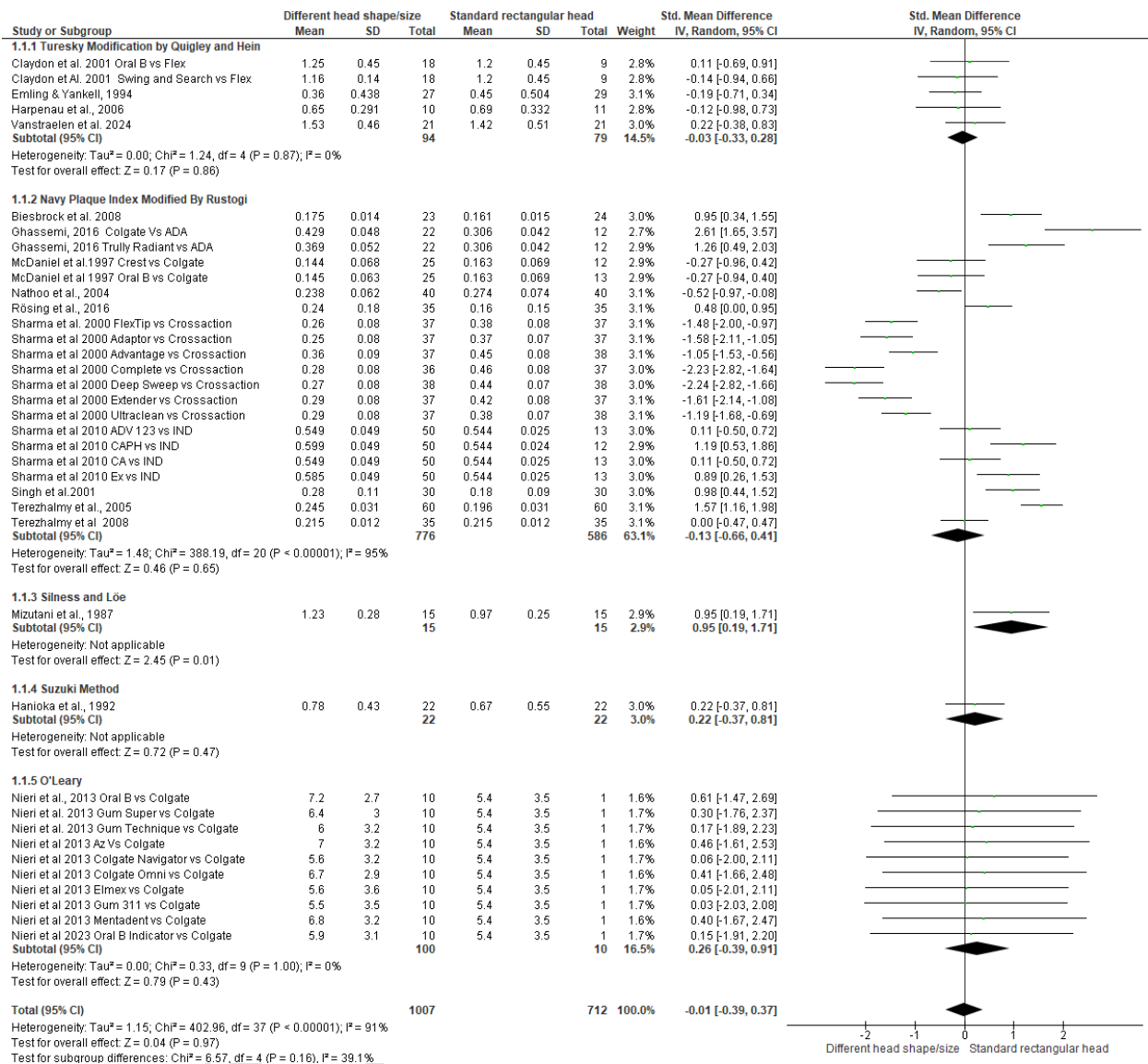


Figure 5. Forest plot for the comparison between toothbrushes of different head shapes and sizes and standard rectangular brushes for plaque index reduction after a single use session

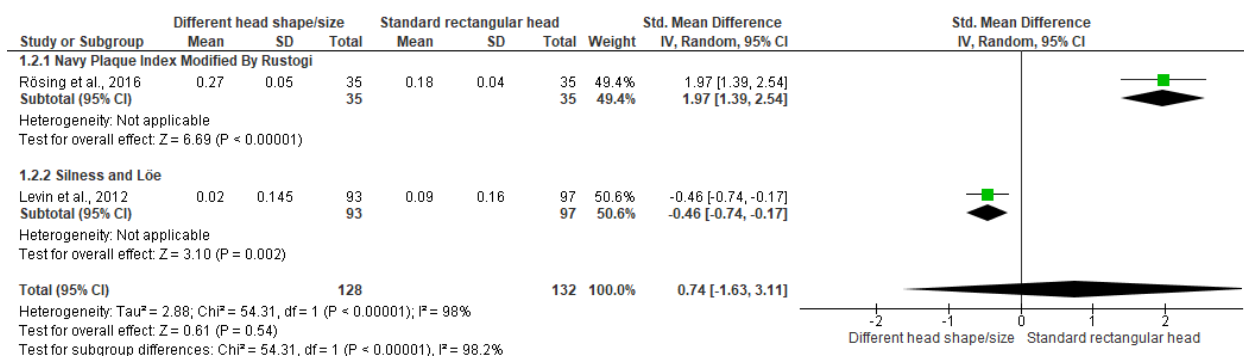


Figure 6. Forest plot for the comparison between toothbrushes of different head shapes and sizes and standard rectangular brushes for plaque index reduction after 7 days of use.

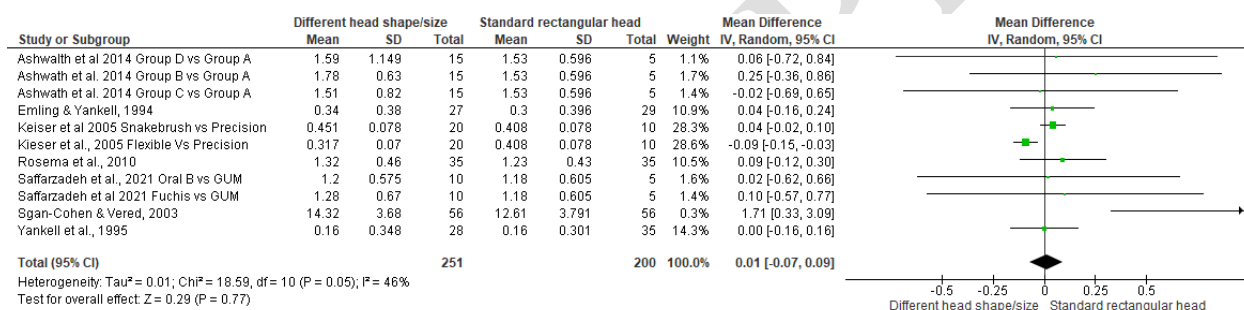


Figure 7. Forest plot for the comparison between toothbrushes of different head shapes and sizes and standard rectangular brushes for plaque index reduction after 15 days of use.

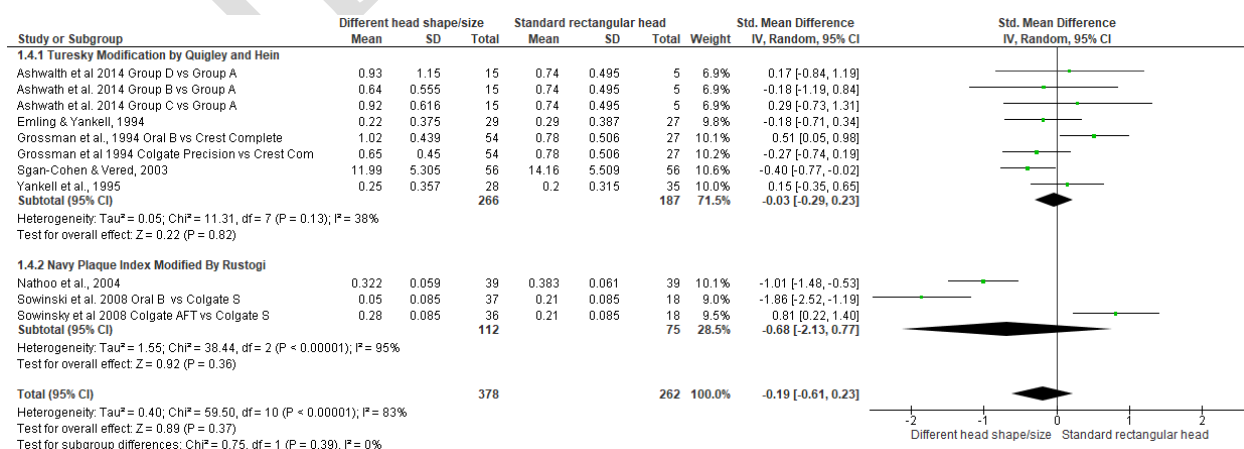


Figure 8. Forest plot for the comparison between toothbrushes of different head shapes and sizes and standard rectangular brushes for plaque index reduction after 28 days of use

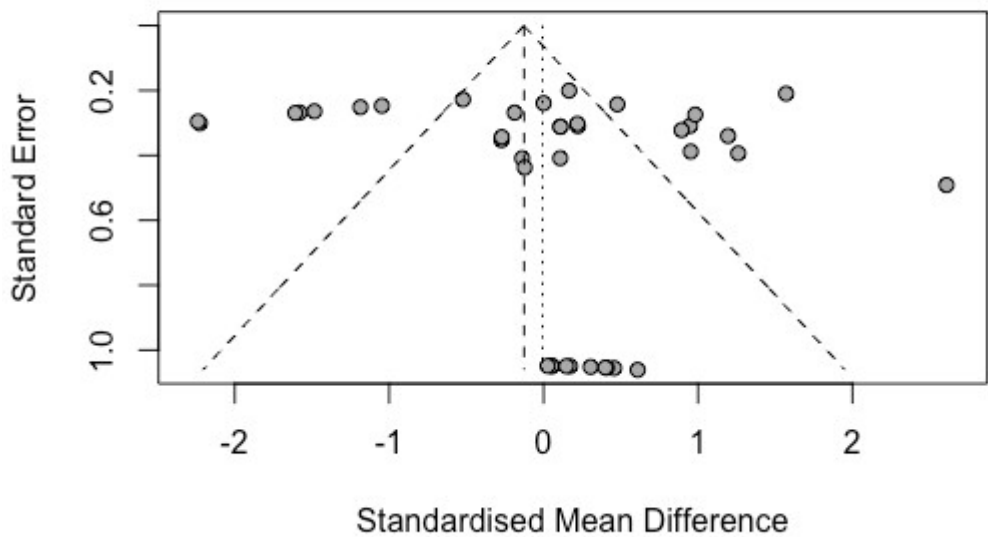


Figure 9. Funnel plot for the single use plaque index meta-analysis

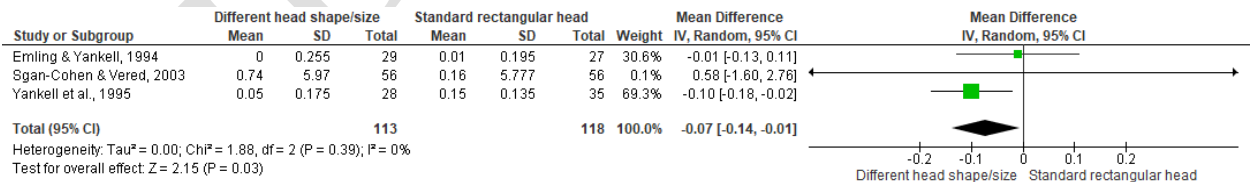


Figure 10. Forest plot for the comparison of toothbrushes of different shapes and sizes with standard rectangular brushes for gingival index reduction after 15-day evaluation.

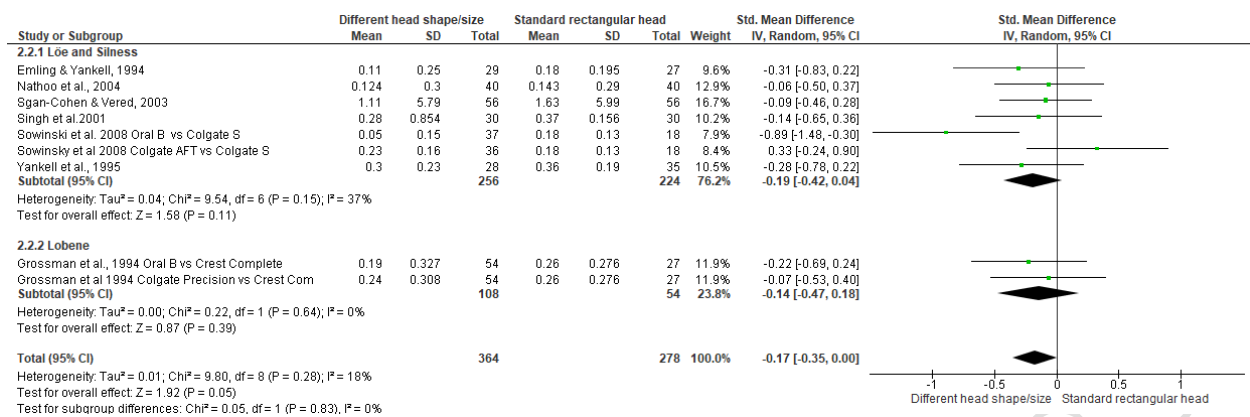


Figure 11. Forest plot for the comparison of toothbrushes of different shapes and sizes with standard rectangular brushes for gingival index reduction after 28-day evaluation

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