Impact of Toothbrush Age on Clinical Indicators of Oral Health, a Protocol for a Systematic Review

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Protocol

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Abstract

Background: Dental caries is the most common chronic untreated disease worldwide. The simplest and most important factor in preventing dental caries is maintaining oral hygiene and removing microbial plaque using a toothbrush. Despite the relationship between toothbrush filament wear and plaque removal effectiveness as a potentially important factor in maintaining oral health, there is little objective standard evidence as to 1) what constitutes a worn-out brush and 2) the degree of loss in plaque removal effectiveness due to brush wear. Contradictions in the results of studies on toothbrushing and the loss of its effectiveness in removing plaque based on the time spent using the toothbrush have led to conflicting recommendations for changing toothbrushes after different periods. While some studies generally question the relationship between toothbrush age and effectiveness. The lack of comprehensive evidence in this area necessitates a structured review study.

Methods: We will search the electronic databases ISI, Scopus, and PubMed to find related articles. Our main inclusion criterion is Clinical trial and observational studies investigating manual toothbrush longevity in the natural toothbrush-worn model on each objective indicator of oral health (including plaque removal and gingival indices ...). All funded citations are entered into the Endnote software. the full texts of potentially relevant studies are prepared. study selection and extracting the data will be performed by two reviewers. Also, the studies quality will be assessed. The findings will be displayed using figures, summary tables and narrative summaries. If the similarity of studies and their quality is desirable, meta-analysis will be performed. We will assess the heterogeneity on the bias of the magnitude of heterogeneity variance parameter. We are also going to conduct subgroup analysis and sensitivity analysis if needed.

Discussion: The final systematic review highlights the gaps in the available evidence about the effectiveness of toothbrush longevity on each oral indices to provide the best recommendation for toothbrush renewal periods.

Registration: The review subject has been submitted in PROSPERO database

Background

Dental caries and periodontal disease are the most prevalent oral diseases caused by supra- and sub- gingival plaque microorganisms (1). Regular and effective daily plaque removal plays an essential role in the long-term preservation of oral health. A manual toothbrush is still the most widespread mechanical and affordable means of personal plaque control (2, 3). Toothbrushes are over-the-counter oral hygiene products, and no particular recommendation is given to consumers on the appropriate time of changing the toothbrush, which makes them confused (2). It is well documented that toothbrush bristles become subject to noticeable wear during daily use. Most dental professionals identify bent and splaying bristles as the main indicator of toothbrush wear (4). However, the effect of toothbrush wear on the capacity to remove plaque has been supported by limited published data (5, 6). To our knowledge, only a few studies

were conducted for periods exceeding three months of utilizing toothbrushes (7). Lack of firm scientific evidence leads to contrasting recommendations for toothbrush renewal period from less than one month to more than six months (8, 9).

There is also a large discrepancy concerning the results of current studies regarding the appropriate time of replacing the toothbrush (10). Some studies have generally questioned the relationship between the duration of toothbrushes usage and their efficacy (5, 11–15). In contrast, other studies showed that worn toothbrushes had lower plaque removal efficiency than new ones (2, 3, 16–19). Differences among studies can be attributed to diverse objective methods, duration of use, measuring outcomes indicators, and other variables such as frequency, brushing force, and technique used (20). For example, McKendrick et al. Found no correlation between toothbrush age and the Oral Debris index and the periodontal indices(21).

On the contrary, Tangade et al. suggested that old brush users had higher Quigley and Hein plaque index after 70 and 100 days (2). Moreover, some studies that confirmed the loss of worn toothbrush effectiveness, were performed by artificially worn toothbrushes in the laboratory; the point is, artificially worn toothbrushes aren't clinically appropriate tools for evaluating the effectiveness of plaque removal (7, 22). It's important to note the duration of toothbrush usage and associated reduction in efficiency is not necessarily regarded as marked clinical changes in oral health indicators. The American Dental Association (ADA) identifies a minimum difference of 15% in plaque scores as a clinical threshold of toothbrush superiority. So, there is no exact clinical justification for the time of toothbrushes replacement (3). up to now, no systematic review has summarized the studies, so it's difficult to conclude comprehensive and robust evidence on the toothbrush renewal periods. WHO emphasizes the affordability of oral hygiene products, including toothbrushes and toothpaste containing fluoride. Keeping in mind that the cost of replacing toothbrushes at frequent intervals may not be applicable, especially in some underdeveloped countries (14, 23, 24). Evidence based and accurate advice for toothbrush renewal period will prevent financial constraints and the extra cost of providing oral hygiene products to disadvantaged communities. Systematic reviews summarizing studies will help to define more solid recommendations for the replacement of toothbrushes.

Objectives:

This study aims to determine the mean time interval before discarding manual toothbrushes on plaque removal efficacy. Since patient education about self-performed plaque control is considered an essential aspect of dental treatment, the purpose of this study was to obtain an evidence-based instruction for toothbrush renewal periods.

Methods

1. Protocol development

This protocol draws on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) guidelines (25). A completed PRISMA-P checklist for the protocol is attached as an additional file (Additional file). The review subject has been submitted in the International Prospective Register of Systematic Reviews (PROSPERO) database (26). all updates and amendments will be tracked in PROSPERO.

2. Ethics and Dissemination

Because the data will be retrieved from previously published studies, ethical approval is not required. The results of this study will be widely disseminated through publication in a peer-reviewed journal. Any modifications to the protocol will be stated in the systematic review article.

3. Data sources and search strategy.

Search strategies will be performed on electronic databases: ISI, Scopus, and PubMed. Study selection and data collection will be performed independently by two reviewers. Search concepts include toothbrush age, toothbrush worn, and toothbrush replacement. Systematic searches will be conducted by applying every possible combination of keywords related to these concepts. Oral health index key terms will not limit the searches to reach as many as possible articles. All the reference lists of the included studies will be checked to identify the potentially eligible studies. The search strategy has been shown in Table.

Table 1
Search terms used in literature search in PubMed

Searching strategy
((“old toothbrush”[Title/Abstract] OR “new toothbrush”) [Title/Abstract] OR (wear [Title/Abstract] OR worn) [Title/Abstract] OR “tooth brush renewal” [Title/Abstract] OR “tooth brush replacement” [Title/Abstract] AND “toothbrush” [Title/Abstract])

4. Eligibility criteria

4-1. Types of studies:

The Clinical trial and observational studies in humans will be included in this study.

4-2. Participants:

There was no restriction concerning the characteristics of the study population,

4-3. Intervention/exposure:

Studies that investigated the effectiveness of manual toothbrush longevity in the natural toothbrush-worn model will be included. We will not apply any restrictions on the duration of the toothbrush utilization.

4-4. phenomena of interest:

Studies that assessed each clinical objective Oral health indices such as gingival index, plaque index, periodontal index and etc, will be included.

Publication language:

We will consider only publications in the English language.

Time and location:

No restrictions will be applied concerning the time and location of the publication.

Table 2

Study inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Study design	Clinical trial and observational studies	All other types of study
Participants	humans	None
Intervention/exposure	manual toothbrush longevity in the natural toothbrush-worn model	an artificially worn toothbrush model
Intervention/exposure period	No limitations	None
phenomena of interest	any types of objective oral health indices (Quigley Hein plaque index (QHI), papilla bleeding index (PBI), and gingival index (GI), ...)	1. Subjective evaluation of toothbrush efficacy 2. Non-clinical indices like laboratory determined wear of toothbrush
Publication language	Full articles in English	papers in non-English languages
Study Time	No limitations	None
setting	No limitations	None

5. Data extraction and quality assessment

5-1. Selection of studies.

All the potentially eligible studies will be imported into EndNote X20 literature management software (Thomson Reuters [Scientific] LLC, Philadelphia, PA). Then Duplicates of individual studies will be

deleted. Two reviewers will Screen all the records based on title and abstract against the eligibility criteria independently. Following this, selected papers' full-text will be studied to find final eligible studies by two reviewers. Different opinions will be resolved through discussion or by a third author. The selection process will be summarized according to the PRISMA flow diagram.

5-2. Data extraction and management.

two reviewers will independently extract data from each study using a piloted data extraction form. If necessary, the forms shall be continually modified until the final data extraction form is complete. If clarification on details of included studies is needed, the study authors will be contacted for more information.

The following items will be extracted:

5-2-1. Study information:

author, year of publication, the country where the study was performed.

5-2-2. Participant characteristics:

Total number, age, sex, sociodemographic details.

5.2.3. Descriptive information about variables:

Exposure related variables:

Toothbrush utilization period will be extracted as an essential variable. Then other comorbid conditions and interventions will be extracted such as the measure of bristle splaying (wear index), the brand of toothbrush, the force of brushing, method of brushing, frequency and duration of brushing, use of oral health aids such as mouthwash and type of toothpaste, and other conditions may affect the outcomes.

Outcomes related variables:

Any objective Oral health index such as gingival index, plaque index, periodontal index, etc.

1. Assessment of risk of bias

We will assess all clinical trial studies included in the review for risk of bias independently by using Cochrane Risk of Bias Tool 2 (27). For observational studies, we will follow the Newcastle-Ottawa Quality Assessment Scale (28). Studies will be categorized as being at low, high, or unclear risk of bias.

6. Management of missing data.

We shall contact the corresponding author via email to deal with relevant missing data in included studies. If the data are still not available, we will perform data synthesis through existing information and

address the potential impact of missing data in the Discussion section or impute missing standard deviations.

6-1. Quality of evidence.

The results of the main outcomes will be summarized in the findings tables. To assess the quality and strength of evidence, we will follow The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach (29). Levels of evidence quality will be classified into four groups: high, moderate, low, or very low.

7. Data synthesis

The findings and conclusions from the included studies will be presented in narrative form, including tables and figures to aid in data presentation. We will provide summaries of the intervention effects for each study by calculating dichotomous data by using odds ratio (OR) with 95% confidence interval (CI) and continuous outcomes using weighted mean differences (with 95% CI) or standardized mean differences (95% CI). We will conduct meta-analyses if enough homogeneity between studies will found. Studies that are unadjusted for potential confounders for our data synthesis will include sensitivity analyses.

7-1. Assessment of heterogeneity

To evaluate statistical heterogeneity in effects between included studies, we will use Cochran's Q test and I-squared statistic as the magnitude of heterogeneity variance parameter (30). In case of high unexplained heterogeneity ($P < .05$ for Q test or $I^2 > 50\%$ for I^2), we will explore sources of heterogeneity by subgroup analysis. If no heterogeneity was identified ($P > .05$ for Q test or $I^2 < 50\%$ for I^2 test), the Mantel-Haenszel fixed effect model will be employed.

7-2. Subgroup analysis.

we are going to conduct subgroup analyses if meta-analyses have high heterogeneity by using the following variables:

children versus adult

professional method of brushing versus self-performed.

7-3. Sensitivity analysis.

Sensitivity analysis will be conducted to assess the robustness of the study conclusion and the impact of methodological quality, sample size, analysis methods, type of outcomes, intervention variations, and various statistical aspects on the meta-analytical results. The influence of the individual dataset on the pooled ORs will be assessed. The results will not be substantially changed when any study is excluded if the pooled ORs are robust.

7-4. Publication bias.

If more than ten studies with the same outcome measure are available for review, a funnel plot (a plot of effect estimates against sample sizes) will be used to explore the potential of publication bias.

Discussion

The vast majority of various recommendations periods advocated for worn toothbrush replacement are based on limited evidence. It is also unclear that the associated reduction in efficiency of a worn toothbrush is considered as a significant clinical threshold. Hence, toothbrush renewal at frequent intervals seems not to be cost-effective. This provided the first motivation for this study. On the other hand, to date, there is a lack of systematic reviews summarizing studies that have investigated the determinants of worn toothbrush efficiency. We aimed to fill this gap. In addition, we will assess the quality of studies on this topic. A main strength two reviewers will conduct study selection and data extraction. We will include three main electronic databases for our search and won't apply any restrictions concerning the time and location. However, we will limit the searches to studies published in English.

Conclusion

This review protocol outlines the process to carry out a systematic review that will look at the existing studies on plaque removal efficacy of toothbrushes over time to compare and contrast their findings. Our systematic review will provide an objective base for health policy decision-makers and guideline developers to recommend the best recommendation for toothbrush renewal periods.

Abbreviations

PBI: papilla bleeding index

GI: gingival index

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

PRISMA-P: Preferred Reporting Items for Systematic review and Meta-Analysis Protocols.

QHI: Quigley Hein plaque index

Declarations

Conflict of interest

The authors declare that they have no conflict of interests.

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Competing interest

The authors declare that they have no competing interests

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There was no funding source for this review protocol.

Authors' contributions

ZY proposed the idea and led the design of the protocol. KH and SZ wrote the manuscript and revised it. All authors read and approved the final manuscript.

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