Bracketless Invisible Orthosis in the Treatment of Children With Malocclusion : A Protocol of Systematic Review

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Protocol

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Abstract

Background

Malocclusion is a common oral disorder. Childhood is a critical period for the development of malocclusion. This protocol will explore the clinical efficacy and safety of bracketless invisible orthosis (BIO) in the treatment of children with malocclusion.

Methods

This study will search MEDLINE, PUBMED, Cochrane Library, Web of Science, WANGFANG, VIP, CNKI, and CBM from inception to the present. We will not apply any limitations to the language and publication status. All potential randomized controlled trials (RCTs) on the efficacy of BIO for the treatment of children with malocclusion will be considered for inclusion. Two authors will independently carry out study identification, data extraction, and study quality assessment in each study. Any disagreement will be resolved through discussion with a third author. When a number of included studies are sufficient, we will conduct meta-analysis, as well as subgroup analysis and sensitivity analysis. The certainty of evidence will be appraised using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Outcome of interest will be presented in summary of findings tables, and statistical analysis will be performed utilizing RevMan 5.4 software.

Discussion

This systematic study will summarize all available studies to investigate the clinical efficacy of BIO in treating children with malocclusion. Findings of this study will highlight efficacy and safety of BIO for the treatment of children with malocclusion for both clinical practice and future strategies.

Study registration

OSF (<https://osf.io/avpmx>).

Background

What is malocclusion?

Malocclusion is a common oral disease in children [1–2]. It is characterized by the abnormal development of the dental arch and jaw bone, jaw bone and craniofacial deformity due to a variety of causes [3–5]. Its symptoms mainly manifest as disordered teeth and abnormal facial shapes [6–8]. Its etiology comprises of inherited and acquired factors[9]. Children with family history of malocclusion, stimuli during embryonic period, poor oral habits, poor feeding, and systemic diseases are more likely to be affected with malocclusion [10–13]. If children with malocclusion can not be managed timely and effectively, it not only affects their oral function and appearance, but also causes mental and psychological disorders, such as depression and anxiety [14–16].

The prevalence of malocclusion

The prevalence of malocclusion in children varies largely due to the differences in ethnicity, geographic environment, eating habits, and economic levels among regions. It is reported that its prevalence among children population were 46.5% in Japan [17], 83.3% in India [18], 87% in Iran [19], 89.9% in Europe [20], and 36.86–78.48% [21–24] in China.

The effects of bracketless invisible orthosis

Bracketless invisible orthosis (BIO) is a computer-aided design and production of a transparent elastic material movable correction device [25–27]. It is a series of continuous correction devices that achieve the purpose of teeth correction through continuous small-scale tooth movement [25–27]. The appliance can control the magnitude and time of the correction force [25–29]. At different stages, only certain teeth can move, while the other teeth serve as anchors to complete the tooth correction [27–29]. Studies suggested that BIO can treat children with malocclusion [30–40]. However, its efficacy and complications are still inconsistent. In addition, insufficient evidence is available to support the clinical efficacy of BIO for the treatment of children with malocclusion. Thus, this study will systematically assess its efficacy and safety for children with malocclusion.

Study aim and research question

The objective of this review is to systematically synthesize quantitative and qualitative literature that explored the clinical efficacy and safety of BIO in correcting children with malocclusion. To fulfil such aim, we propose the research questions as below:

1. Does BIO benefit children with malocclusion?
2. Is BIO safe for the treatment of children with malocclusion?

Methods

Study registration

This study protocol has been registered on OSF (<https://osf.io/avpmx>). It follows the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Protocol Statement [41–42]. We will record any amendments to this study protocol in OSF and present them in the final manuscript.

Eligibility criteria for study selection

Study design

This study will be limited to randomized controlled trials (RCTs) only for the efficacy and safety of BIO in treating children with malocclusion. Other study designs, such as animal study, descriptive study,

comment, and uncontrolled study will be excluded.

Population

This study will include patients (below 18 years old) who were diagnosed as malocclusion, in spite of gender, race, and region.

Intervention

Studies that are describing or evaluating the efficacy and safety of available BIO to treat children with malocclusion will be included.

Comparators

Comparators will be any managements, such as medication, placebo, and any other therapies. However, we will exclude comparators that involved BIO.

Outcomes

Outcomes include correction time, periodontal health indicators, tilted teeth correction time, transposed teeth twisting time, total treatment completion time, satisfaction level, scores of correction aesthetics, chewing function, and complications.

Information sources

A comprehensive search strategy will be developed to identify the associated studies in electronic databases from inception to the present: MEDLINE, PUBMED, Cochrane Library, Web of Science, WANGFANG, VIP, CNKI, and CBM. No language and publication status restrictions will be applied to this study. The search terms are "Malocclusion", "Deformity", "Poor bite", "Irregular bite", "Crossbite", "Overbite", "Crooked teeth", "Crowded teeth", "Protruding teeth", "Orthosis", "Orthoaidic appliance", "Brace Splint", "Bracketless", "Invisible", "Randomized controlled studies", "Case-controlled study", "Controlled study", "Clinical trial", "Random", "Randomly", "Blind", and "Allocation". We will create a comprehensive search strategy of MEDLINE in a Table 1. In addition, in order to miss potential articles, we will check Google Scholar, reports on related agencies, dissertation/thesis, conference abstracts, and reference lists of included RCTs.

Table 1
Search strategy of MEDLINE

Number	Search terms
1	Malocclusion
2	Deformity
3	Poor bite
4	Irregular bite
5	Crossbite
6	Overbite
7	Crooked teeth
8	Crowded teeth
9	Protruding teeth
10	Or 1–9
11	Orthosis
12	Orthoaedic appliance
13	Brace
14	Splint
15	Bracketless
16	Invisible
17	Or 11–16
18	Randomized controlled studies
19	Case-controlled study
20	Controlled study
21	Clinical trial
22	Random
23	Randomly
24	Blind
25	Allocation
26	Or 18–25
27	10 and 17 and 26

Study selection

Two authors (LSC and XYL) will independently screen titles/abstracts in accordance with the eligibility criteria. Then, we will delete irrelevant records. After that, we will read full-text of potential articles against all inclusion criteria. If there are any divergences between two authors, we will consult a third author (LXG) through discussion. The reasons of excluded studies will be recorded, and the process of study selection will be presented in a PRISMA flow chart.

Data collection and management

Two independent authors (LSC and ZW) will collect data using a standardized data collection sheet. If any disagreement arises between two authors, we will invite a third author to solve it through discussion (LXG). The following information will be collected: title, first author, time of publication, patient characteristics (such as age, sex, race), sample size, study methods, study setting, diagnostic criteria, inclusion and exclusion criteria, details of interventions and controls, all outcome indicators, follow-up information, and conflict of interest. Any unclear or missing data will be requested from original authors by email or telephone.

Study quality assessment

For assessing study methodological quality of included trials, Cochrane Risk of Bias Tool will be utilized. Two authors (XYL and ZW) will independently carry out methodological quality evaluation of all included RCTs, while the raised divisions between two authors (XYL and ZW) will be resolved by discussion with a third author (LXG).

Synthesis of included studies and interpretation

This study will employ RevMan 5.4 software to perform statistical analysis and analyze the data. We will present study information, subject characteristics, intervention and control details, outcomes, and study quality in summary tables. We will convert different types data to facilitate consistent expression and then synthesize the results across eligible trials. We will express appropriate statistics according to the different types of outcome values. The dichotomous values will be calculated by risk ratio and 95% confidence intervals (CIs). The continuous values will be estimated by mean difference and 95% CIs.

The heterogeneity across eligible RCTs will be measured by I^2 statistic [43–44]. $I^2 \leq 50\%$ means acceptable heterogeneity, while $I^2 > 50\%$ exerts obvious heterogeneity. A random-effects model will be used to synthesize the data. We will explore possible heterogeneity via subgroup analysis, that may help to determine whether it is necessary to undertake a meta-analysis. If there is acceptable heterogeneity across trials on the same outcome, we will carry out a meta-analysis by pooling the results of similar interventions and same comparator. If a quantitative synthesis is not possible to conduct because of the insufficient number of eligible trials or remarkable heterogeneity, we will conduct a narrative synthesis by reporting the target patients, description of intervention and controls, and outcomes.

Unit of analysis

The present study will only include RCTs. If there is a crossover eligible trial, we will only collect and analyze the data from the first period [45].

Subgroup analysis

If there are sufficient data and adequate reporting, we will perform the following subgroup analyses:

Geographical location by country/region;

Age groups;

Gender/sex; and

Type of controls.

Sensitivity analysis

In event of a sufficient number of eligible RCTs, we will carry out a sensitivity analysis to check the robustness of study results according to the types of study quality and sample size.

Reporting bias

When RCTs are in sufficient numbers (normally over 10), we will perform a funnel plot and Egger's regression test to examine any potential reporting bias.

Grading the certainty of evidence

We will evaluate the certainty of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [46]. It covers five domains of study limitations, imprecision, inconsistency, indirectness, and other considerations [46].

Dissemination and ethics

We will plan to publish this study on a peer-reviewed journal or conference presentation. This study does not need ethical committee approval, since no primary patient data will be collected.

Discussion

A variety of previous studies suggested the clinical efficacy of BIO in treating children with malocclusion [30–40]. However, inconsistent conclusions regarding its efficacy and safety are far from reached in this topic. In addition, insufficient evidence-based medicine evidence still lacks for its support. Thus, this study will systematically and comprehensively appraise the clinical efficacy and safety of BIO for the treatment of children with malocclusion. Two authors will independently accomplish the process of study selection, data collection and study quality assessment. If any disagreement occur, a third author will be

invited to solve it through discussion, and a consensus decision will be reached. The findings of this study will provide evidence for both clinical practice and further studies.

Declarations

Ethics approval and consent to participate: Not applicable.

Consent for publication: Not applicable.

Availability of data and material: Data sharing is not applicable to this article as no datasets were generated or analyzed during the current protocol.

Competing interests: Not applicable.

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Authors' contributions: LSC and LXG conceived the study. LXG and XYL contributed with the clinical background and expertise. LXG and ZW contributed with the analytical plan and the bias assessment approach. LSC, LYL and ZW performed the literature search plan and drafted the protocol. All authors revised the protocol and approved the final version. LXG supervised the study.

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