INPLASY PROTOCOL

Corresponding author:
Song Chen

Songchen882002@hotmail.com

Author Affiliation:
West China Hospital of Stomatology

Support: None.

Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest:
None.

Treatment effect of twin-block appliance on condylar remodeling in patients with Class II malocclusion: a systematic review

Xu, J[1]; Xu, L[2]; Yin, Y[3]; Yin, K[4]; Chen, S[5].

Review question / Objective: The aim of this study is to evaluate the changes of condylar in patients with skeletal class II malocclusion treated with Twin-block appliance. 1. Participants: growing patients with skeletal Class II malocclusion 2. Intervention: growing patients treated with Twin-block appliance, with non-extraction or non-surgical approach to prevent interference of confounding factors 3. Control: growing patients with Class II malocclusion receiving no treatment or fixed appliance treatment 4. Outcome: The displacement and modification of condylar 5. Study: randomized clinical trials (RCTs) and prospective controlled clinical trials (CCTs)

INTRODUCTION

Review question / Objective: The aim of this study is to evaluate the changes of condylar in patients with skeletal class II malocclusion treated with Twin-block appliance. 1. Participants: growing patients with skeletal Class II malocclusion 2. Intervention: growing patients treated with Twin-block appliance, with non-extraction or non-surgical approach to prevent interference of confounding factors 3. Control: growing patients with Class II malocclusion receiving no treatment or fixed appliance treatment 4. Outcome: The displacement and modification of condylar 5. Study: randomized clinical trials (RCTs) and prospective controlled clinical trials (CCTs).

Condition being studied: Skeletal Class II malocclusion is a common dentofacial deformity that greatly affects the facial appearance, oral function and psychological health of patients. Either mandibular deficiency or maxillary excess or even both can be the mechanism of Skeletal Class II malocclusion. For a child or teenager at rapid growth stage, Skeletal Class II functional appliances are recommended to make the best of growth potential and promote skeletal growth modification and tooth movement. Twin-block appliance is one kind of removable Skeletal Class II functional appliances, invented by professor Clark in 1982. Composed of two separate removable acrylic bite blocks and occlusal inclined planes, Twin-block appliance is small and tolerable for patients to wear all day, promising a relatively satisfying treatment outcome. To date, reliable scientific evidence about the effects on the temporomandibular joint (TMJ) of Twin-block appliance is insufficient, with a few articles reporting conflicting results. Some studies reported that Twin-block appliance enables forward movement of the condylar and promotes new bone deposition on the condylar. However, some studies found that the treatment effects of Twin-block appliance on TMJ were small.

METHODS

Search strategy: Electronic databases including PubMed, EmBase, Cochrane library, ClinicalTrials.gov, Chinese Biomedical Literature Database, China National Knowledge Infrastructure and VIP Database are searched without limitations on language. SIGLE is searched for grey literature. The electronic database search is supplemented by a manual search of the reference lists of included articles. The search string is built as follows: ("Angle Class II malocclusion" OR "Class II malocclusion" OR " mandibular retraction" OR "mandibular deficiency") AND ("Orthodontic Appliances, Functional" OR "Functional Appliance" OR "Twin-block appliance) AND ("Temporomandibular Joint" OR "TMJ" OR "Jaw Joint" OR "Condylar").

Participant or population: Growing patients with skeletal Class II malocclusion.

Intervention: Growing patients treated with Twin-block appliance, with non-extraction or non-surgical approach to prevent interference of confounding factors.

Comparator: Growing patients with Class II malocclusion receiving no treatment or fixed appliance treatment.

Study designs to be included: Randomized controlled trials and clinical controlled trials will be included.

Eligibility criteria: 1. Participants: growing patients with Class II malocclusion 2. Intervention: growing patients treated with Twin-block appliance, with non-extraction or non-surgical approach to prevent interference of confounding factors 3. Control: growing patients with Class II malocclusion receiving no treatment or fixed appliance treatment 4. Outcome: The displacement and modification of condylar 5. Study: randomized clinical trials (RCTs) and prospective controlled clinical trials(CCTs).

Information sources: Electronic databases including PubMed, EmBase, Cochrane library, ClinicalTrials.gov, Chinese Biomedical Literature Database, China National Knowledge Infrastructure and VIP Database are searched without limitations on language. SIGLE is searched for grey literature. The electronic database search is supplemented by a manual search of the reference lists of included articles.

Main outcome(s): The displacement and modification of condylar before and after treatment with Twin-block appliance, including measurements of the anterior, superior and posterior space of temporomandibular joint and condylar height, width and length.

Data management: The data extraction form will be developed by two reviewers independently, including the following

items: the first author's name and year of publication; study type; sample size; age and gender of participants; duration of treatment; measurement method; mean observation period; and outcomes. Any obscure or missing data will be obtained by contacting authors. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author.

Quality assessment / Risk of bias analysis: The risk of bias (RoB) of included RCT study will be assessed according to the Cochrane Handbook for Systematic Reviews of Interventions with the software Review Manager. For each article, the following domains will be examined: (1) sequence generation; (2) allocation concealment; (3) blinding of participants, personnel, and outcome assessors; (4) incomplete outcome data; (5) selective outcome reporting; and (6) other sources of bias. Each study will be assigned an overall risk of bias rating: low risk (low for all aspects), high risk (high for ≥1 aspect), or unclear risk (unclear for ≥1 aspect). Meanwhile, a quality score will be calculated by a modified version of the method described by Jadad. The Newcastle-Ottawa Scale will be used for quality assessment of CCTs. For each study, 3 domains will be examined: (1) the selection of the study groups; (2) the comparability of the groups; (3) the ascertainment of the outcome of interest. By this "star system", each study will be evaluated as high quality (its score is ≥6) or low quality (its score is <6). The risk of bias and quality assessment will be performed by two reviewers. Any disagreement will be resolved after consulting another author.

Strategy of data synthesis: RevMan 5.3 was used for the meta-analysis of quantitative data. For continuous data, the mean difference and their 95% confidence intervals were used for statistical pooling. The statistical significance of the hypothesis test was set at P50%). If the data could not be pooled, then they were described. When more than 10 studies were included, Funnel plots and the Begg's rank correlation test would be used to evaluate publication bias.

Subgroup analysis: We will consider subgroups such as age and measurement method.

Sensibility analysis: The sensibility analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies.

Country(ies) involved: China.

Keywords: Twin-block appliance; Class II malocclusion; Temporomandibular Joint.

Contributions of each author:
Author 1 - Jingchen Xu.
Author 2 - Lin Xu.
Author 3 - Yuanyuan Yin.
Author 4 - Ke Yin.
Author 5 - Song Chen.