# INPLASY PROTOCOL

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**Review Stage at time of this submission:** **Formal screening of search results against eligibility criteria.**

**Conflicts of interest:** **No.**

# Effects of the Forsus appliance with temporary anchorage devices on class II malocclusion: A systematic review and meta-analysis

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**Review question / Objective:** **The study focuses on skeletal and dentoalveolar effects of the Forsus appliance with or without TADs. The participants will be adolescent patients with moderate to severe skeletal Class II malocclusion due to a deficient mandible(ANB>5°). They received fixed orthodontic treatment with FFRD in combination with TADs or not. The primary outcomes are the skeletal changes measured on cephalometric radiograph, including the change of SNA, SNB, ANB, Co-Gn and SN-MP. The secondary outcomes include dento-alveolar effects (change of lower incisors inclination and upper incisors inclination) and side-effect( pain, failure of TADs and long-term stability). The studies are randomized clinical trials (RCTs) or pospective controlled clinical trials (CCTs).**

**Condition being studied:** **The Forsus appliance is one of the most commonly used fixed functional appliances nowadays. The results of studies about effects of skeletal anchored FFRDs were controversial in regard to the achievement of actual skeletal correction of the malocclusion, with some of them reporting significant enhancement of mandibular growth and others refuting this effect. To our knowledge, a systematic review evaluating the outcomes of FFRDs with TADs has not been undertaken.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 May 2020 and was last updated on 21 May 2020 (registration number INPLASY202050077).

## INTRODUCTION

**Review question / Objective:** **The study focuses on skeletal and dentoalveolar effects of the Forsus appliance with or without TADs. The participants will be adolescent patients with moderate to severe skeletal Class II malocclusion due to a deficient mandible(ANB>5°). They received fixed orthodontic treatment with FFRD in combination with TADs or not. The primary outcomes are the skeletal changes measured on cephalometric radiograph, including the change of SNA, SNB, ANB, Co-Gn and SN-MP. The secondary outcomes include dento-alveolar effects (change of lower incisors inclination and upper incisors inclination) and side-effect( pain, failure of TADs and long-term stability). The studies are randomized clinical trials (RCTs) or pospective controlled clinical trials (CCTs).**

**Rationale:** To our knowledge, a systematic review evaluating the outcomes of FFRDs with TADs has not been undertaken. The purpose of the present review and meta-analysis was to assess main skeletal and dento-alveolar effects of FFRD combinating with TADs or alone. The fndings of this study can help orthodontists in proper patient selection when using such appliances.

**Condition being studied:** The Forsus appliance is one of the most commonly used fixed functional appliances nowadays. The results of studies about effects of skeletal anchored FFRDs were controversial in regard to the achievement of actual skeletal correction of the malocclusion, with some of them reporting significant enhancement of mandibular growth and others refuting this effect. To our knowledge, a systematic review evaluating the outcomes of FFRDs with TADs has not been undertaken.

## METHODS

**Search strategy:** An electronic search will be undertaken in databases PubMed, EMBASE, CENTRAL, Web of Science, Goole Scholar, CBM, CNKI, and the System for Information on Grey Literature in Europe (SIGLE). MeSH terms will be combined with free-text words optimized for each database. MeSH terms are Orthodontic Appliances, Functional and Orthodontic Anchorage Procedures and Malocclusion, Angle Class II. Free-text words include functional therapy, temporary anchorage device, skeletal class II , and so on.

**Participant or population:** Adolescent patients with moderate to severe skeletal Class II malocclusion due to a deficient mandible(ANB>5°); horizontal or neutral growth pattern.

**Intervention:** Use fixed orthodontic treatment with FFRD in combination with TADs.

**Comparator:** Use fixed orthodontic treatment with FFRD alone.

**Study designs to be included:** Randomized clinical trials (RCTs) or pospective controlled clinical trials (CCTs).

**Eligibility criteria:** The inclusion criteria are the followings: (1) Participants: growing human patients (treatments performed during either the circumpubertal or immediate post-pubertal phase); moderate to severe skeletal Class II malocclusion due to a deficient mandible; horizontal or neutral growth pattern; a full set of erupted permanent teeth, from the first molar to the first molar of the other side. (2) Intervention: treatment carried out using the Forsus appliance with fixed orthodontic appliance; use of FFRD in conjunction with anchorage reinforcement mini screws or mini plates for management of Class II malocclusion(the methods for anchorage reinforcement includes using a stainless steel archwire between the mandibular canine bracket and the miniscrew slot as indirect anchorage and the pushrods inserting into the miniplate heads as direct anchorage). (3) Comparator: treatment carried out using the Forsus appliance with fixed orthodontic appliance and without skeletal anchorage for correction of the skeletal dysplasia. (4) Outcomes: The main outcome measure were the skeletal changes, including SNA, SNB, ANB, Co-Gn and SN-MP; the secondary outcome measures included dento-alveolar side-effects (L1-MP and U1-PP), pain and long-term stability. Cephalometric measurements were carried out before insertion of FFRD (T1) and immediately after active Forsus treatment(T2). (5) Study design: randomized clinical trials (RCTs).

**Information sources:** An electronic search will be undertaken in databases PubMed, EMBASE, CENTRAL, Web of Science, Goole Scholar, CBM, CNKI, and the System for Information on Grey Literature in Europe (SIGLE). A manual search will be carried out for supplemental information. An additional search will be carried out by examining the references of the included articles. In addition, the corresponding authors of included studies will be

contacted asking for further information where necessary or other related studies.

**Main outcome(s):** The primary outcomes are the skeletal changes measured on cephalometric radiograph, including the change of SNA, SNB, ANB, Co-Gn and SN-MP.

**Additional outcome(s):** The secondary outcomes include dento-alveolar effects (change of lower incisors inclination and upper incisors inclination) and side-effect( pain, failure of TADs and long-term stability).

**Data management:** The following information will to be recorded using customized forms: the study characteristics, including author, publication year and country; study design; participant details, including age, gender, sample size; interventions and o treatment duration; and outcomes relevant to the present review, including antero-posterior and vertical skeletal measurements and dento-alveolar measurements. Side-effect, including pain, failure of skeletal anchorage and long-term stability will be reported whenever possible.

**Quality assessment / Risk of bias analysis:** The risk of bias the randomized clinical trials (RCTs) will be assessed using the Cochrane Risk of Bias Tool. Seven domains will be scored separately to quantify the risk of bias in individual studies including random sequence generation; allocation concealment; blinding participants and personnel; blinding of assessors; incomplete outcome data; selective reporting of outcomes and other potential sources of bias. An overall assessment for each included trial will be made (high, unclear or low risk of bias) accordingly. If there is at least one criterion for a high/ unclear risk of bias, the study will be assessed as an overall high/unclear risk of bias.

**Strategy of data synthesis:** Meta analyses will be performed using RevMan 5.3 (version 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). For continuous data including skeletal and dento-alveolar measurements, mean differences (MD) with standard deviation (SD) or standard mean difference (SMD) and 95% confidence intervals (CI) will be used. In order to extract data with CBCT or lateral cephalometric radiographs, standard mean differences (SMDs) and their corresponding 95% CIs will be used instead of the MDs as recommended by the Cochrane Handbook. A random-effect model will be used for the meta-analysis if the heterogeneity is high (I2>50%). Otherwise (ie, I2 ≤50%), a fixed-effect model will be employed. All P values are two-sided with α = 5 per cent. Descriptive qualitative analysis will be performed on data that cannot be meta-analyzed, such as pain, failure of skeletal anchorage and long-term stability. The overall quality of evidence for each outcome will be performed using the GRADE system.

**Subgroup analysis:** We plan to make subgroup analyses to determine the potential sources of heterogeneity from different skeletal anchorage types and measurement means.

**Sensibility analysis:** Sensitivity analyses will be performed to evaluate the robustness of the pooled results through changing analysis model or omitting high risk studies.

**Language:** No.

**Country(ies) involved:** China.

**Keywords:** Dental changes; Forsus appliance; Meta-analysis; Skeletal changes; Skeletal class II malocclusion; Temporary anchorage devices.

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