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Effect of fixed growth modification correctors to treat mild to moderate misaligned bite (malocclusion) in adolescents

Submission date
12/09/2022

Recruitment status
No longer recruiting

Registration date
21/10/2022

Overall study status
Completed

Last Edited
19/05/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Class II malocclusion represents approximately 30% of the reported malocclusions (bite arrangement problems) among the United States population. Treatment of Class II malocclusions is a common challenge for orthodontists. Fixed Class II Correctors (FCCs) (orthodontic devices that are secured inside the mouth to favor the correction of this malocclusion type) have been shown to be relatively effective in Class II malocclusion correction. Compared to removable appliances (orthodontic devices that are inserted and removed by the same patients inside the mouth to favor the correction of this malocclusion type), FCCs are advantageous in terms of eliminating patient compliance concerns and maintaining continuous corrective forces.

Although there is a significant body of data published in this area, the specific data reported about the effects of FCCs on some oral tissues and functions remains unclear. The primary purpose of this study is to assess the impact of Class II malocclusion correction using FCCs on the facial bones, teeth, gingival tissues, jaw functions, and related patients' daily life impacts. All these factors have not been evaluated simultaneously before for this type of orthodontic appliance.

Who can participate?
Adolescents from the Edmonton (Alberta, Canada) region with a diagnosis of mild to moderate Class II malocclusion

What does the study involve?
This study will make use of different imaging modalities, questionnaires, and clinical assessments to evaluate skeletal and dental changes, as well as clinical symptoms. Magnetic resonance imaging (MRI), and orthodontic x-ray images will be used to determine and compare the oral tissues before, during, and after the proposed treatment. Subjects will be enrolled in the Graduate Orthodontic Clinic at the Dental School, University of Alberta. Findings from this study are expected to provide high-quality evidence that may be used to amend routine treatment practices as needed.

What are the possible benefits and risks of participating?
Participants will not receive any direct benefits from this study. This multiple assessment study allows objective assessment of function, structure as well as the impact on the patient's quality of life. Consequently, it will enable a thorough understanding of skeletal and soft tissue remodeling in growing adolescents. The concluded information from this study will significantly benefit future orthodontic patients with similar malocclusions.
The physical risk for the participant is greater than in everyday life for two reasons:
1. Risks present are related to the present COVID-19 pandemic issues
2. The other risk is limited to the scans using harmless non-ionizing radiation imaging (MRI). The orthodontic x-ray is already part of the routine orthodontic practice and the amount of additional risk is debatable and has not been directly linked to any clear harm; no additional radiation will be given to the patient during the study beyond routine clinical requirements. The self-reported questionnaire was developed at the orthodontic department of the University of Alberta to suit North American audiences. This survey has been reported to be well accepted by patients to express their level of discomfort and functional limitations.

Where is the study run from?
University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
March 2014 to March 2024

Who is funding the study?
University of Alberta (Canada)

Who is the main contact?
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Additional identifiers

Protocol serial number
Pro00045191

Study information

Scientific Title
Skeletal, functional and dental changes during treatment of mild to moderate class II malocclusions with fixed class II correctors: A randomized clinical trial

Study objectives
Understanding the role of Class II correction using fixed Class II correctors (FCCs) in bone remodeling, oral functions, and patients' comfort, is an area of high interest among orthodontic clinicians. Magnetic resonance imaging (MRI) will be used to obtain a clear description of soft anatomical change within the articular surfaces of the temporomandibular joint (TMJ). Cone-beam CT (CBCT), which has a much lower radiation exposure than multi-detection computerized tomography (CT), will be used to quantify the skeletal changes. The combination of the data simultaneously will be the methodological novelty of this study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2022, Alberta Research Information Services (ARISE) University of Alberta (Research Ethics Office, Health Research Ethics Board, 2-01 North Power Plant (NPP), 11312-89 Ave NW, Edmonton, Alberta, T6G 2N2, Canada; +1 780 492 0459; no email available), ref: none available

Primary study design
Interventional

Study design
Randomized controlled study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Class II malocclusion

Interventions
The research is designed as a randomized controlled clinical trial to evaluate dentofacial and dentoalveolar changes following mild to moderate Class II malocclusion correction using different fixed Class II correctors (Herbst, Crossbow, and Esprit). This prospective clinical trial

will use different sources of information (imaging, clinic evaluation, and self-reported questionnaire) to objectively assess and monitor related changes over time.
Records and assessments: Assessments will be conducted at 4 points of time;
T1: Baseline records for all groups at enrolment date.
T2: 12 months after T1 (before full bonded orthodontic treatment for all groups).
T3: 18 – 30 months after T2 (after debonding of orthodontic treatment for all groups).
T4: 24 months after T3.
Anatomical assessment:
1) Fused MRI-CBCT images: MRI and CBCT images, from one point of time (before or after treatment phases), will be fused and will be performed to measure the change in the TMJ articular disc position, rotational status, disc displacement- length ratio and disc morphology. This assessment will use images taken at T1, T2, T3 & T4.
2) Fused CBCT-CBCT:. The obtained CBCT images at different treatment times will be superimposed to evaluate the skeletal changes/remodeling in the regions of the maxillofacial, dentoalveolar, glenoid fossa, articular eminence, and condyle. This image assessment will use CBCT images obtained at different assessment times (T1, T2, T3 & T4).
3) Hand-wrist Radiograph: patients will have this radiograph before treatment (T1) only, to detect their skeletal age.
4) 3DMD photograph, Intra-oral scanner: patients will have this routine orthodontic records taken at 4 assessment times (T1, T2, T3, T4).
Clinical assessment:
Routine extra- and intraoral dental, periodontal, and TMJ clinical examinations will be conducted at all assessment time points. Clinical signs and symptoms of TMJ function and muscular tenderness will be examined using a scoring scale to detect the severity of any dysfunction. The dental assessment will be conducted at all time points, whereas the TMJ assessment will be conducted at T1, T2, T3 & T4.
Questionnaire:
Patients will be provided with a self-reported questionnaire to evaluate their overall experience during the FCC treatment. This self-reported questionnaire was developed at the orthodontic department of the University of Alberta to suit North American audiences. This survey has been reported to be well accepted by patients to express their level of discomfort and functional limitations. Patients will be asked to answer this survey at all 4 assessment times (T1, T2, T3, T4).
Participants will be adolescents (10-13 years old for females, 10-14 years old for males) from the Edmonton region with a confirmed diagnosis of mild to moderate Class II malocclusion. Inclusion criteria include overbite ≥ 1mm, first permanent premolars and molars in end-to-end or full class II occlusion, and dental crowding ≤ 6mm. Patients with gingival recession, syndromes or a history of Class II corrective orthodontics will be excluded.

Patients will be randomly assigned into 3 groups;
(G1) Herbst (rigid FCC) group; Patients of this group will undergo 3 phases of treatment; Phase I: Class II occlusal correction using Herbst appliance (treatment and retention take approximately 6 months respectively for a total of 12 months). Phase II: full bonded orthodontic archwires treatment, which starts after Phase I is completed (treatment takes approximately 18 to 24 months). Phase III: post-treatment retention period (takes approximately 12 to 24 months).

(G2) Crossbow (spring FCC) group; Patients of this group will undergo 3 phases of treatment; Phase I: Class II occlusal correction using a Crossbow appliance (treatment and retention take approximately 6 months respectively for a total of 12 months). Phase II: full bonded orthodontic archwires treatment, which starts after Phase I is completed (treatment and retention take approximately 18 to 24 months). Phase III: post-treatment retention period (takes approximately 12 to 24 months).

(G3) Control group; Patients of this group will receive full bonded orthodontic archwires for the first 12 months after enrolment in the study in Phase I. Then in Phase II: patients will receive a Class II Correction appliance (Crossbow or Esprit) directly attached to the archwire (treatment takes approximately 18 to 24 months). Phase III: post-treatment retention period (takes approximately 12 to 24 months).

Intervention Type
Mixed

Primary outcome(s)
1. Evaluating maxillofacial, dentoalveolar bone remodeling, and tooth position changes associated with FCC treatment using fused MRI-CBCT images and fused CBCT-CBCT
2. Evaluate TMJ disc remodeling and disc-condyle relationship changes associated with FCC treatment using Fused MRI-CBCT images.
3. Evaluate TMJ clinical function changes associated with FCC treatment using a scoring scale to detect the severity of any dysfunction.

The dental assessments will be conducted at all time points, whereas the TMJ assessments will be conducted at T1, T2, T3 & T4.

Timepoints:
T1: Baseline records for all groups at the enrolment date
T2: 12 months after T1 (before full bonded orthodontic treatment for all groups)
T3: 18 – 30 months after T2 (after debonding of orthodontic treatment for all groups)
T4: 24 months after T3

Key secondary outcome(s)
1. Evaluating gingival attachment and periodontal condition changes associated with FCC treatment, using Clinical assessment at all 4 assessment times (T1, T2, T3, T4)
2. Evaluate the FCCs impact on participants' quality of life associated with FCC treatment using a self-reported Questionnaire:
Patients will be provided with a questionnaire to evaluate their overall experience during the FCC treatment. Patients will be asked to answer this survey at all 4 assessment times (T1, T2, T3, T4).

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. Females aged 10-13 years old and males aged 10-14 years old, with first premolars and first permanent molars, fully erupted
2. Class II molar relationship or at least ½ cusp on both sides
3. Dental crowding ≤ 6mm
4. Overbite ≥ 1mm

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Child

Lower age limit
10 Years

Upper age limit
14 Years

Sex
All

Total final enrolment
59

Key exclusion criteria
1. Patients with missing/unerupted permanent first premolars and molars
2. Gingival recession (below CEJ)
3. TMJ trauma syndromes
4. History of Class II corrective orthodontics

Date of first enrolment
04/06/2014

Date of final enrolment
20/11/2019

Locations

Countries of recruitment
Canada

Study participating centre
KAYE Edmonton Clinic Orthodontics Graduate Clinic
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Sponsor information

Organisation
University of Alberta

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
University/education

Funder Name
Fund For Dentistry (Internal grant)

Results and Publications

Individual participant data (IPD) sharing plan
A participant's personal information (such as full name, address, phone, and health card number), and CBCT imaging digital files will be stored in a limited access desktop computer at the Department of Dentistry (8th-floor KATZ building). All participants' information except imaging files will be also available at the department of orthodontics, School of Dentistry, University of Alberta. The University of Alberta policies will be followed for sharing the data once the long-term data is collected and analyzed.

Individual participant data (including data dictionaries) will be available. Individual participant data that underlie the results reported will be shared, after deidentification (text, tables, figures, and appendices). The Study Protocol will be made available. Data will be available beginning 9 months and ending 36 months following article publication. Data will be shared with investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose for individual participant data meta-analysis. Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2025	19/05/2025	Yes	No
Participant information sheet	version 1.0	25/03/2014	30/09/2022	No	Yes
Participant information sheet	version 1.0	07/03/2014	30/09/2022	No	Yes
Thesis results		18/11/2024	27/11/2024	No	No