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Analysis of dental and facial changes and nasal function in adults

Submission date
13/04/2023

Recruitment status
Recruiting

Registration date
02/05/2023

Overall study status
Ongoing

Last Edited
24/12/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Crossbites are a common problem and can affect the bite, breathing patterns, and other dental structures in the mouth. At this age, there are two treatment options for the condition. The first treatment includes the placement of an expansion appliance that attaches directly to the palatal bone. The second treatment involves the separation of the roof of the mouth with surgery and the placement of the expander attached to the teeth or bone. Since at 18 years old, the roof of the mouth is expected to be very hard to separate by just using an appliance attached to the teeth, for this reason, surgery is usually suggested. Presently, appliances attached to the roof of the mouth directly have been demonstrating the capability to separate the roof of the mouth without the need for surgery. There are different types of expanders that attach to the roof of the mouth. The aim of this study is to compare two different types of these appliances, one that attaches to the middle of the roof of the mouth and that attaches to the sides of the roof of the mouth.

Who can participate?
Healthy patients aged between 18-30 years old who require maxillary expansion treatment

What does the study involve?
Complete orthodontic treatment. A series of dental diagnostic tests will be done including radiographs, photos, dental scans, and airway measurements. Measurement of how well the participant breathes through the nose will also be made. Participants will be randomly selected for having the expander that is attached in the middle of the roof of the mouth or on the sides of the roof of the mouth. The attachments would be placed with local freezing. A second minor surgery is required to remove the attachments when the orthodontic treatment is completed. To help track jaw and tooth position changes two additional three-dimensional X-rays will be taken.

The rate of airflow while breathing through the nose and dimensions of the inside of the nose will be measured at each record appointment, being four total (initial, at the end of the expansion, at the end of all the treatment, and 2-year follow-up after treatment is done). The

participant will be asked to blow through the nose into a special mask that fits over the nose. A device that uses sound waves to measure the size of the inside of the nose will be placed close to the nostril and a recording is made.

What are the possible benefits and risks of participating?
The participants will not benefit from the information obtained from this study. The information gained from this study will help the practitioners compare the effects of a bone-anchored upper jaw expander that would help in treating other patients with similar conditions in the future.

The risks associated with the attachments are like those expected with tooth removal and may include a minor risk of infection or bleeding. The attachments are constructed from titanium and stainless steel and will not cause an allergic reaction. The X-rays taken for this study are no different than if the participants were not in the study. There are no risks or discomforts associated with the airflow measurements.

Where is the study run from?
Orthodontic Graduate Clinic, Kaye Edmonton Clinic at the University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
September 2018 to December 2027

Who is funding the study?
Faculty of Medicine and Dentistry, University of Alberta (Canada)

Who is the main contact?
Prof Manuel Lagravere, manuel@ualberta.ca

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Pro00084145

Study information

Scientific Title
Analysis of dentofacial changes and nasal function with two different bone-anchored maxillary expanders in adults

Study objectives
Bone-borne rapid maxillary expansion (RME) appliances with implants were investigated at the University of Alberta without any identified adverse effects. The study hypothesis is that this study will give us an insight into adequate paramedian palatal bone volume for placement of osseous integrated palatal implants in adolescent patients with 3D volumetric digital radiographic (cone beam CT) imaging.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/09/2018, 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 (0)780 492 0459; reoffice@ualberta.ca), ref: none available

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Maxillary deficiency in adults

Interventions
Sample size will be determined with sequential statistical analysis with the cut-off for subject recruitment at 36 months. Experience gained from conducting a previous study at the University of Alberta involving adolescent patients requiring rapid maxillary expansion (RME) suggests that 36 months of recruitment will yield a sample of 66 subjects (33 patients per treatment group, considering a 10% loss during follow-up). It is hoped that the use of sequential statistical analysis will allow the conclusion of the study prior to 36 months and reduce the ultimate sample size.

A randomization list (flipping a coin) will be used to assign patients to receive one of the two study treatment options:
Group A. Treatment with an expansion appliance attached in the middle of the roof of the mouth
Group B. Treatment with an expansion appliance attached at the sides of the roof of the mouth.
Each patient will undergo orthodontic clinical charting and corresponding diagnostic auxiliary exams (digital dental scan (Itero Scan), digital volumetric images (full field of view - cone-beam computed tomography [CBCT]), airway assessment (questionnaire, take home polysomnography and in-office breathing assessment), 3D facial photos and extraoral/intraoral photos).

Group A treatment will consist of a maxillary skeletal expander (Moon design). Model casts will be obtained from the patient and an expansion appliance will be fabricated consisting of bands located on teeth 16 and 26 and soldered to the Moon design screw. The appliance would be inserted in the patient's mouth after a local anesthetic is placed around the palatal suture at the level of the upper permanent first molars. The appliance is cemented on teeth 16 and 26 and then four temporary anchorage devices (TADs) of 11-13 mm in length are inserted (two on each side of the expansion screw. The appliance will be activated four times each day from the day of insertion until there is a presence of a diastema between the upper central incisors (teeth 11 and 21). Once this space is seen, activation will be done twice a day until the upper basal bone is wider than the lower basal bone. Once the complete expansion is obtained, a new set of records will be obtained. Then, full braces will be placed on the patient's teeth and orthodontic alignment will start. The expander is removed once the patient is on a rectangular wire on the braces with a minimum of 6 months in the mouth. Complete records will be taken again at the end of all the orthodontic treatment and 2 years after the removal of all appliances when the patient would be dismissed. In the scenario that the suture does not separate, then the patient would have to proceed with the alternative treatment being the surgical separation of the suture and expansion.

Group B treatment will involve maxillary expansion with the implant-anchored expansion appliance. Model casts will be obtained from the patient and an expansion appliance will be fabricated consisting of implants located between the upper second premolar and first molar with an average of 9 mm away from the palatal suture. The appliance would be inserted in the patient's mouth after the local anesthetic is placed in the palatal area between the upper second premolars and first molars. Once the appliance is inserted, two TADs (one on each side) of 9-11 mm will be inserted to hold the appliance in place. The appliance will be activated two times each day from the day of insertion until there is a presence of a diastema between the upper central incisors (teeth 11 and 21). Once this space is seen, activation will stay the same until a 20% over-expansion of the required one is obtained. Once the complete expansion is obtained, a new set of records will be obtained with the difference that the CBCT would be of the maxilla and mandible only. Then, full braces will be placed on the patient's teeth and orthodontic alignment will start. The expander would be removed once the patient is on a rectangular wire on the braces. Complete records will be taken again at the end of all the orthodontic treatment and 2 years after the removal of all appliances when the patient would be dismissed. In the scenario that the suture does not separate, then the patient would have to proceed with the alternative treatment being the surgical separation of the suture and expansion.

Complete records (digital dental scan (Itero Scan), digital volumetric images (full field of view - CBCT), airway assessment (questionnaire, take home polysomnography and in-office breathing assessment), 3D facial photos and extraoral/intraoral photos) will be taken four times for the two treatment groups.

Once all records are obtained, measurements will be done for every group to determine the ratio between dental expansion and skeletal expansion. This will be done with the use of CBCT images and dental scans. Changes in nasal volume and shape obtained will be obtained from the CBCT images after applying the AVIZO software. Airway resistance and nasal peak airflow will be compared between groups and the association between airway resistance and nasal volume /shape will be determined. Nasal volume determined with CBCT and polysomnography will be compared.

All data will be coded for blinding purposes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Maxillary skeletal expander, implant-anchored expansion appliance

Primary outcome measure
Skeletal and airway changes to measure expansion using cone-beam computed tomography (CBCT) images, dental scan, photos, airway measurements and questionnaires at baseline, 12 months, end of active treatment and end of retention at 2 years. Expansion is measured using CBCT images, and dental scans. Changes in nasal volume and shape obtained will be obtained from the CBCT images after applying the AVIZO software. Airway resistance and nasal peak airflow will be compared between groups and the association between airway resistance and nasal volume/shape is measured using CBCT and polysomnography.

Secondary outcome measures
Dental expansion changes measured using CBCT images, dental scans, photos, airway measures and questionnaires at baseline, 12 months, end of active treatment and end of retentions, questionnaires, etc.

Overall study start date
19/09/2018

Completion date
30/12/2027

Eligibility

Key inclusion criteria
1. Requirement of maxillary expansion treatment for the groups
2. Need for post-expansion orthognathic surgery
3. Full permanent dentition erupted (except 3rd molars)
4. Treatment may involve post-expansion tooth extraction or not
5. No syndromic characteristics or systematic diseases clinically determined or based on previous records
6. Male and female aged 18-30 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
Sample of 66 subjects (33 patients per treatment group, considering a 10% loss during follow-up)

Key exclusion criteria
Patients with palates too narrow for placement of the expander appliance, with large tori and/or asymmetric (canted) maxillary palatal plane

Date of first enrolment
01/06/2019

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Canada

Study participating centre
Kaye Edmonton Clinic
11400 University Ave
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Study participating centre
University of Varese
Varese
Italy
-

Sponsor information

Organisation
University of Alberta

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Sponsor type
University/education

Website
http://ualberta.ca/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
University/education

Funder Name
Faculty of Medicine and Dentistry, University of Alberta

Alternative Name(s)
Faculty of Medicine & Dentistry - University of Alberta, University of Alberta Faculty of Medicine and Dentistry, Faculty of Medicine and Dentistry at University of Alberta, University of Alberta Faculty of Medicine & Dentistry, Faculty of Medicine & Dentistry - University of Alberta, University of Alberta Faculty of Medicine and Dentistry, FoMD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Present the results at conferences in different countries and within Canada

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/05/2023	No	Yes