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Dentoskeletal effects of clear aligners used to distalize maxillary molars in adult patients

Submission date
23/10/2015

Recruitment status
No longer recruiting

Registration date
12/11/2015

Overall study status
Completed

Last Edited
18/04/2016

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Malocclusion is a problem in the way the upper and lower teeth fit together when biting or chewing. Orthodontic treatment can be used to improve the appearance, position and function of the teeth. In the last few decades increasing numbers of adults have sought orthodontic treatment and expressed a desire for aesthetic and comfortable alternatives to conventional fixed braces. Clear aligners were introduced to answer this request. Cosmetically, invisible aligners are more appealing because they are difficult to notice, making them particularly popular among adults who wish to straighten their teeth without the use of traditional metal braces. Such aligners are also easily removed during eating and tooth brushing. However, little is known about the effects of clear aligners on the teeth and bones of adult patients treated to correct a forwarded position of the upper dental arch. The aim of this study is to find out whether it is possible to correct this type of malocclusion with clear aligners.

Who can participate?
Adult patients (over 18) treated with clear aligners for a forwarded upper dental arch

What does the study involve?
Participants undergo a profile x-ray of the head before and after their orthodontic treatment to assess the position of the teeth, jaws, skull and soft tissues.

What are the possible benefits and risks of participating?
Participants will benefit from the correction of their malocclusion with an aesthetic and comfortable appliance. There are no risks in participating in the study - a large number of patients have previously been treated with the clear aligners used in the study, and x-rays are always needed at the beginning and at the end of any orthodontic treatment.

Where is the study run from?
Two orthodontic private practices in Torino (Italy) and Vancouver (Canada), and the University of Torino (Italy).

When is the study starting and how long is it expected to run for?
March to September 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ATRA2014

Study information

Scientific Title
Dentoskeletal effects of maxillary molars distalization with aligners in adult patients: a retrospective observational trial

Study objectives
The study was conducted in order to test the hypothesis that maxillary molar bodily distalization is not achievable with aligners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending - to be submitted to the ethics board of the City of Health and Science of Torino, Italy in November 2015

Study design
Multicentre retrospective observational trial

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Skeletal Class I or Class II malocclusion and a bilateral end-to-end class II molar relationship

Interventions
Orthodontic treatment with Invisalign aligners, composite attachments and class II inter maxillary elastics. Lateral cephalograms in habitual occlusion obtained before and after treatment of 20 Caucasian subjects were collected. For standardization purposes, the magnification was corrected to 8% for all cephalograms. The digital x-rays were stored in a computer, imported into commercial software ORISCEPH Rx3 (Elite Computer, Vimodrone, Italy), in order to perform landmark identifications and cephalometric tracings. These operations were randomly performed by one investigator blinded about the study, using a customized

digitization set including 47 landmarks and 54 variables chosen from different existing and validated cephalometric analyses. The great number of variables was due to the number of analyzed teeth and to the number of analyzed crown and roots landmarks.

All the cephalograms were traced again after 3 weeks and then after 6 months. If there was a discrepancy between the three cephalograms, a new tracing was obtained by mutual agreement between the researchers involved in the protocol. Statistical analysis was performed using the R statistical package (version 3.0.1, R Core Team, Foundation for Statistical Computing, Vienna, Austria). The normality assumption of the data was evaluated with the Shapiro-Wilk test. According to this evaluation, the differences between before (T0) and after treatment (T1) were compared with the t-test. The level of significance was set at $P<0.05$.

Intervention Type
Device

Primary outcome measure
Maxillary molars distalization movement: on the lateral cephalograms collected before (T0) and after treatment (T1) (mean treatment time was 24.3 ± 4.2 months) crown and roots landmark were identified in order to describe the mean distalization movements on the sagittal plane as well as the vertical and the angular movements. Crowns' centers, obtained as the midpoint between the greatest mesial and distal convexity of the crown, as well as the axis passing through mesial cusps and mesio-vestibular roots' apex were taken as reference points of the maxillary first and second molar as seen on the cephalograms. The movements of these points at T1 with respect to T0 were considered in relation to the reference axes represented by the palatal plane (x axis) and by a perpendicular line to the palatal plane passing through the Ricketts' Pt point (y axis). The palatal plane was used to measure vertical and angular movements, while the y axis was used to measure sagittal movements of the second molar and of the first molar.
The overall craniofacial treatment changes were evaluated by superimposing on the stable structures of the anterior cranial base according to the Structural Method (Björk A. Guide to superimposition of profile radiographs by "The Structural Method" http://www.angle-society.com/case/guide.pdf). Superimpositions were conducted digitally.

Secondary outcome measures
Central incisor retraction movement: the incisal edge point, the root apex point and the crown centre point, the midpoint of the lateral projection of the circumference formed by the root and crown conjunction, were the landmarks considered on the lateral cephalograms to describe the movement of the maxillary central incisor with respect to the reference axes described above.
On the lateral headfilms, the palatal plane/mandibular plane (PP/MP) and the SN/mandibular plane angles were evaluated as indicators of skeletal posterior vertical dimension changes.The overall craniofacial treatment changes were evaluated by superimposing on the stable structures of the anterior cranial base according to the Structural Method (Björk A. Guide to superimposition of profile radiographs by "The Structural Method" http://www.angle-society.com/case/guide.pdf). Superimpositions were conducted digitally.

Overall study start date
18/03/2015

Completion date
21/09/2015

Eligibility

Key inclusion criteria
1. Age over 18 years old
2. Skeletal Class I or Class II malocclusion and a bilateral end-to-end class II molar relationship
3. Normodivergence on the vertical plane (SN/GoGn angle less than 37 degrees)
4. Mild crowding in the upper arch (≤ 4mm)
5. Standardized treatment protocol
6. Good compliance during the treatment (wearing aligners time: ≥20 hours per day)
7. Absence or previous extraction of the upper third molars
8. Good quality radiographs, with adequate landmark visualization and head rotation control

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Transversal dental or skeletal discrepancies
2. Vertical dental or skeletal discrepancies
3. Extraction treatment (except for third molars)
4. Unilateral distalization
5. Signs and/or symptoms of temporomandibular disorders (TMDs) accordingly to Diagnostic Criteria for TMDs
6. Periodontal disease
7. Endodontic treatments of the maxillary molars
8. Prosthodontics rehabilitations of the maxillary molars

Date of first enrolment
01/04/2015

Date of final enrolment
08/04/2015

Locations

Countries of recruitment
Canada

Italy

Study participating centre
Daher Orthostyle
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Study participating centre
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Study participating centre
University of Torino
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Sponsor type
University/education

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We would like to publish a paper reporting the protocol and the results of the study in the first quarter of 2016. The dissemination of the results will be performed also with the presentation of scientific posters or oral communications during orthodontic Congresses in 2016.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No