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Analysis of gingival fluids of orthodontic patients undergoing different treatments

Submission date	Recruitment status	[_] Prospectively registered
26/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2022	Oral Health	

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 better looking and more comfortable alternatives to traditional metal braces (often referred to as “train tracks”). Clear aligners, also known as “invisible braces”, are removable retainers which apply pressure to teeth, pushing them into the correct position. Many adults choose to use this type of appliance because they are made of a clear material, which make them very difficult to notice. They are also considered to be beneficial for good oral hygiene as they can be removed while eating and during tooth brushing. Previous studies have suggested that the movement of teeth when people use clear aligners is different to the movement of teeth seen with traditional braces, which put continuous pressure against teeth. This study aims to examine the mechanisms of tooth movement on a molecular level, by examining the biochemical make-up of the fluid found along the gum line (gingival crevicular fluid) in patients using traditional braces and clear aligners.

Who can participate?
Adults suffering from malocclusion.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are treated using traditional braces. Participants in the second group are treated using clear aligners. For participants in both groups, before treatment and then after treatment at 1 hour, 7 days and 21 days, samples of fluid from the gum line are taken using special paper strips, which are tested in the laboratory for any chemical markers of tooth movement.

What are the possible benefits and risks of participating?
Participants will benefit from correction of their malocclusion, regardless of which technique is used. There are no risks expected for those taking part in the study.

Where is the study run from?
Dental School, University of Torino (Italy)

When is the study starting and how long is it expected to run for?
May 2014 to April 2016

Who is funding the study?
Align Technology (USA)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
award2014

Study information

Scientific Title
Bio-markers of orthodontic tooth movement in gingival crevicular fluid of patients undergoing treatment with clear aligners or fixed appliances

Study objectives
The aim of this study is to find out if the bone remodeling induced by Invisalign aligners significantly different from the one induced by self-ligating appliances.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Board of The Health And Science City of Turin (Comitato Etico Interaziendale A.O.U. Città della Salute e della Scienza di Torino), 10/04/2015, ref: 373/2015

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

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
Malocclusion

Interventions
The selected subjects will be randomly allocated into two groups (random number list software generated) accordingly to the following treatment protocol:

Group 1: Fixed Appliance group (FA) with 10 subjects who will be treated consecutively with traditional brackets at the Department of Orthodontics of the Dental School of the University of Torino.

Group 2: Clear Aligners group (CA) with 10 subjects who will be treated consecutively with clear aligners at the Department of Orthodontics of the Dental School of the University of Torino.

GCF samples will be collected using periopaper strips (Harco, Tustin, Calif). Samples will be collected at the mesiobuccal and mesiolingual sites of control and test teeth at baseline, at 1 hour, at 7 days, and 21 days after placement of the appliances. Teeth will be isolated with cotton rolls, cleaned of plaque deposits, and dried gently with air before paper strips will be applied 1 mm subgingivally for 30 seconds. The volume of the sample on the paper strips will be measured using a calibrated Periotron 8000 (Harco). The readings from the Periotron will be converted to an actual volume (microliters) by reference to the standard curve calibrated with human serum.

Intervention Type
Procedure/Surgery

Primary outcome measure

Cytokine concentration will be determined from GCF samples using titration and centrifugation at baseline, 1 hour, 7 days and 21 days.

Secondary outcome measures
Identification of the most biologically efficient technique among fixed appliance and clear aligners by analysing concentrations of Interleukin 1-beta, TGF-beta, RANKL, OPG and OPN in GCF at baseline, 1 hour, 7 days and 21 days.

Overall study start date
01/05/2014

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. Dentoskeletal Class I malocclusion (Witts appraisal)
2. Mild crowding (mean crowding 6 mm)
3. Permanent dentition
4. Vertebral maturation as assessed on lateral cephalograms more advanced than CS4 (postpubertal)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20-30

Total final enrolment
10

Key exclusion criteria
1. Smokers
2. Have gingivitis
3. Have probing pocket depths ≥4 mm
4. Have loss of clinical attachment ≥2 mm in the selected or adjacent teeth
5. Had taken anti-inflammatory or antibiotic medications within the previous 6 months

Date of first enrolment
01/05/2014

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
Italy

Study participating centre
Dental School, Department of Orthodontics
University of Torino
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Sponsor information

Organisation
University of Torino (Italy)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Industry

Funder Name
Align Technology

Results and Publications

Publication and dissemination plan
Planned publication of one or more papers, reporting the protocol and the results of the study in 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
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2017	12/01/2022	Yes	No