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Invisalign - a concept for the prevention of white spot lesions in teenaged orthodontic patients?

Submission date 03/09/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 16/10/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/10/2014	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Wire dental braces (fixed vestibular multi-bracket appliances) are traditionally considered to be the best treatment (gold standard) for correcting misaligned teeth (dental malocclusion) in teenage patients. However, patients wearing wire braces are 5 times more likely to develop dental cavities (caries) and white spot lesions (often an early sign of tooth decay) than people who dont. Such damage to the teeth cannot be reversed. Invisalign is an alternative to the wire brace. It is made out of plastic, using transparent aligners to gradually adjust the affected teeth. It is often used by people who have misaligned teeth but want a more attractive solution to wearing the traditional brace. Here, we want to find out whether wearing Invisalign rather than wire dental braces will result in fewer or more white spot lesions after 6 months and then after 12 months of therapy.

Who can participate?
Patients aged between 13-19 years needing dental (orthodontic) treatment to correct misaligned teeth.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are treated with a traditional multi-bracket appliance for orthodontic treatment. Those in group 2 receive Invisalign therapy. All participants are examined for white spot lesions at the start of the study, after 6 months of orthodontic treatment, and then after 12 months of treatment.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Department of Orthodontics, University Hospital Freiburg (Germany)

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

Who is funding the study?
International Align Research Award of the Align Technology, North America (USA)

Who is the main contact?
Professor Britta A. Jung

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Invisalign - a concept for the prevention of white spot lesions in teenaged orthodontic patients? A prospective controlled clinical trial

Study objectives
The aim of this study is to investigate the incidence of white spot lesions during orthodontic treatment with Invisalign and multi-bracket appliance treatment (the gold standard) in teenaged patients.
The null hypothesis of no difference in the incidence of white spot lesions between teeth undergoing treatment with fixed braces and Invisalign therapy will be investigated. The investigation will be designed as a prospective, bicenter controlled clinical study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Albert-Ludwigs-University of Freiburg, Germany (Ref. No: 406/14 (MPG§23))

Study design

A prospective controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malocclusion

Interventions
Two groups of patients (male and female, aged 13-19 years) will be randomly allocated into one of two arms:
1. Group 1 will consist of 30 patients. All of these patients receive a traditional multi-bracket appliance for orthodontic treatment.
2. Group 2 will consist of 30 patients. All of these patients receive Invisalign therapy for orthodontic treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Macroscopic characterization (presence, frequency, and severity) of white spot lesions at baseline, after 6 months, and after 12 months of orthodontic treatment. The severity of disease will be rated according to Gorelick's classification:
Grade 0: no visible white spot lesions on clinical investigation
Grade 1: minor white spot lesions
Grade 2: severe white spot lesions
Grade 3: white spot lesions with cavitation
2. Determination of fluorescence, size and lesion depth and the bacterial acitivity of white spot lesions by means of quantitative light-induced fluorescence measurement (QLF) at baseline, after 6 months, and after 12 months of orthodontic treatment.

Key secondary outcome(s))
Determination of fluorescence, size and lesion depth and the bacterial activity of white spot lesions by means of quantitative light-induced fluorescence measurement (QLF) after active orthodontic treatment and 6 month later.

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Orthodontic indication for a vestibular multi-bracket appliance or
2. The need and desire to receive Invisalign therapy

3. Persons aged 13-19 years (teenagers) with fully erupted and visible teeth before treatment
4. No white spot lesions at baseline/no caries
5. Good oral hygiene
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
19 years

Sex
All

Key exclusion criteria
1. Patients with cheilognathopalatoschisis or other syndromes associated with craniofacial abnormalities
2. Patients with enamel abnormalities

Date of first enrolment
01/11/2014

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Germany

Study participating centre
Head of the Department of Orthodontics
Freiburg, Germany
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Sponsor information

Organisation
Align Technology, Inc. (USA)

ROR
https://ror.org/005sbaa41

Funder(s)

Funder type
Industry

Funder Name
International Align Research Award of the Align Technology, North America (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes