

Bonding success rate of 2 different composites used for the bonding of attachments for the Invisalign® system

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| Submission date 02/08/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 05/08/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 05/08/2024 | Condition category Oral Health | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

The goal of this prospective study is to compare the bonding success rate of 2 different composites used for the bonding of attachments for the Invisalign® system: the Transbond XT® from 3M Unitek® and the Tetric EvoCeram® from Ivoclar Vivadent®.

Who can participate?

Patients aged 12 - 75 years

What does the study involve?

Patients were assigned randomly between the experimental group with resin composite Tetric EvoCeram® (26 patients) or the control group with resin composite Transbond XT® (25 patients). Attachments were bonded with the given protocol and the number of failed bonding of attachments was registered at T1 (3 months). Patient age and sex influence on bonding failure was also analyzed. Student and 1-factor ANOVA tests were used when the variables were normal, and the non-parametric alternative of the Median Test when not distributed normally. The Chi-square test of independence was used to cross between two categorical variables.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Universidad Alfonso X el Sabio (Spain)

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

September 2021 to August 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

inietsan@yahoo.com

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Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Mr Hugo Patural

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Additional identifiers

Study information

Scientific Title

Bonding success rate of 2 different composites used for the bonding of attachments for the Invisalign® system

Study objectives

There is no difference in attachment loss in the first 3 months of orthodontic treatment between Transbond XT® and Tetric Evo Ceram®

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 07/04/2022, University Alfonso X el Sabio (Avenida de la Universidad s/n., Villanueva de la Cañada, 28691, Spain; +34 918105000; comitedebioetica@uax.es), ref: 2022_3/139

Study design

Single-center prospective randomized clinical trial

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Malocclusion

Interventions

Two composite materials (Transbond and Tetric Ceram) for attachments for orthodontic aligner treatments were used. Once bonded, the attachment loss was registered in the first 3 months. The patients were randomly assigned to only one of the two groups using the software "Research Randomizer" available online at the following link: <https://www.randomizer.org/>. All attachments in the same patients were from the same material, bonding was performed using fabricant recommendations.

Intervention Type

Procedure/Surgery

Primary outcome(s)

The number of debonded attachments on each patient (2 groups: Transbond and Tetric Evo Ceram) measured using a visual inspection at T0 at the appointment when the attachments were bonded, and monthly for 3 months

Key secondary outcome(s)

Differences in the failure rate (debonded attachments) regarding sex and age of the patient using data recorded in patient records at T0 at the appointment when the attachments were bonded, and monthly for 3 months

Completion date

30/08/2023

Eligibility**Key inclusion criteria**

1. Patients in permanent dentition between 12 and 75 years old
2. Men and women
3. Collaborator and with informed consent confirmed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Lower age limit

12 years

Upper age limit

75 years

Sex

All

Total final enrolment

51

Key exclusion criteria

1. Patients in mixed dentition
2. Syndromic
3. Undergoing orthognathic surgery
4. Teeth with porcelain crown or composite restauration.

Date of first enrolment

01/11/2022

Date of final enrolment

30/05/2023

Locations

Countries of recruitment

Spain

Study participating centre

Centro Odontológico de Innovación y Especialidades Avanzadas UAX

Albarracín 35

Madrid

Spain

28037

Sponsor information

Organisation

Universidad Alfonso X el Sabio

ROR

<https://ror.org/054ewwr15>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the main researcher Hugo Patural: hugopatural@icloud.com

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| Participant information sheet | | | 05/08/2024 | No | Yes |