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

Submission date	Recruitment status	[ ] Prospectively registered
02/08/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/08/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/08/2024	Oral Health	[ ] 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
hpatu@myuax.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mr Hugo Patural

ORCID ID
https://orcid.org/0009-0007-3840-2960

Contact details
C. de Albarracín, 35, San Blas-Canillejas
Madrid
Spain
28037
+34 63857181
hpatu@myuax.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Medical and other records, University/medical school/dental school

Study type(s)
Treatment, Efficacy

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
01/09/2021

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

Age group
All

Lower age limit
12 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
51

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

Sponsor details
Albarracín 35
Madrid
Spain
28037
+34 914402330
pmartnpa@externos.uax.es

Sponsor type
University/education

Website
https://www.uax.com

ROR
https://ror.org/054ewwr15

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

05/08/2024

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