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Evaluation of a new adhesive system for orthodontic braces for a 6-month period

Submission date 04/10/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/10/2020	**Overall study status** Completed	
Last Edited 23/06/2023	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Bracket failure (bracket detachment from the tooth) hinders the smooth progress of orthodontic treatment. Thus, a bracket failure rate that is as low as possible is of utmost importance for the clinician as well as for the patient. Recently, a new adhesive system was introduced. This system reduces the steps during bracket placement. Thus, the aim of this study is to evaluate the clinical performance (i.e. bracket failure as well as chair time) of this newly introduced adhesive pre-coated bracket system (PS) compared with a conventional bracket system (CS).

Who can participate?
Patients undergoing orthodontic treatment without tooth extraction

What does the study involve?
Participants receive orthodontic treatment where the mouth is divided into four segments that are randomly assigned to either the PS or CS bracket system. Bracket failure is measured over 6 months.

What are the possible benefits and risks of participating?
The risks of this study are the same as the risks of any routine non-extraction orthodontic treatment. No extra risks are present. The study will give insight concerning the chair time, i.e. the amount of time a patient spends in the chair for treatment, of these systems. Chair time is of great importance, particularly during the COVID-19 pandemic. Furthermore, this study will provide data on whether or not this system (PS) is as reliable as CS.

Where is the study run from?
Ondokuz Mayıs University (Turkey)

When is the study starting and how long is it expected to run for?
June 2018 to June 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
OMÜ KAEK 2018/416

Study information

Scientific Title
Evaluation of the flash-free adhesive system for a 6-month period: a split-mouth trial

Study objectives
The aim of this study was the evaluation of the following parameters:
1. The comparison of the bond failure and survival rates of the APC FF Adhesive Coated Appliance System (3M Unitek) with an OC system (Transbond XT Light Cure Adhesive Paste; 3M Unitek) for a 6-month period.
2. Comparison of the bond failure and survival rates of the upper and lower arches.

3. Comparison of the bond failure and survival rates for incisor, canine and premolar teeth.
4. Comparison of bracket failure and survival rates with respect to gender.
5. Comparison of the ARI scores upon bracket failure.
6. Comparison of the chair time required for each bonding procedure.
The null hypothesis was that there would be no difference in the aforementioned parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/09/2018, Research Ethics Committee at the University of Ondokuz Mayıs (Former Dental School Building, Ondokuz Mayıs University, 55200 Atakum/Samsun, Turkey; +90 (0)362 312 19 19/2782; omutaek@gmail.com), ref: OMÜ KAEK 2018/416

Study design
Single-center randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Orthodontic malocclusion

Interventions
Patients willing to participate in this study receive orthodontic treatment with a split-mouth design, i.e. the mouth is divided into four experimental segments that are randomly assigned to either the pre-coated bracket system (PS) or a conventional bracket system (CS). The observation period for his study is 6 months.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Adhesive pre-coated bracket system, operator-coated conventional bracket system

Primary outcome measure
Bracket failure, i.e. bracket detachment from the tooth, is visually observed. Bracket failure can occur at any timepoint during the observation period. Bracket failure was recorded at the routine monthly controls of the patients.

Secondary outcome measures
Type of failure: the bracket may have detached from the tooth intact with adhesive or without adhesive. Furthermore, the bracket may have fractured. These types of failures can occur at any timepoint during the observation period. These types of failures were recorded at the routine monthly controls of the patients.

Overall study start date
08/06/2018

Completion date
18/06/2019

Eligibility

Key inclusion criteria
1. Willingness to participate in this research project
2. Fully erupted maxillary and mandibular teeth with intact buccal enamel
3. Angle Class I and mild Class II malocclusions
4. Non-extraction patients
5. Normal overbite (1-2 mm)
6. Absence of severe rotations. Severe rotations would have prevented bracket placement or correct bracket placement at the first appointment
7. Absence of pretreatment of teeth with any chemical agents
8. Good oral hygiene, i.e. no bleeding upon probing

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria

1. Patients with skeletal problems
2. Patients with missing teeth
3. Patients with systemic disease
4. Patients with a previous history of orthodontic treatment

Date of first enrolment
17/09/2018

Date of final enrolment
18/12/2018

Locations

Countries of recruitment
Türkiye

Study participating centre
Ondokuz Mayıs University
Faculty of Dentistry
Department of Orthodontics
Samsun
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Sponsor information

Organisation
Ondokuz Mayıs University

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Sponsor type
University/education

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ROR

https://ror.org/028k5qw24

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. All additional documents are available upon request from Dr Selma Elekdağ-Türk. Furthermore, the study protocol and statistical analyses will be available upon the publication of this manuscript.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Tamer Türk (turkset@superonline.com, tamert@omu.edu.tr) and Prof. Dr Selma Elekdag-Türk (elekdagturk@yahoo.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/06/2023	23/06/2023	Yes	No