Direct or indirect placement of fixed braces

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Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON21236

Source
NTR

Brief title
DBB vs IDB

Condition

- Head and neck therapeutic procedures

Synonym
orthodontics; bracket placement, indirect bracket bonding; computer-aided design; chairside time; fixed appliances

Health condition

Orthodontic malformation

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Funded by university

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

- Accuracy of bracket placement

Secondary outcome

- - Immediate and delayed bonding failures
- - Bracket repositioning need
- - Clinician experience
- - Patient satisfaction
- - Patient reported oral health related quality of life

Study description

Background summary

In straight-wire orthodontics, precise and accurate bracket placement is of major importance for the clinical treatment outcomes . In every-day orthodontic practice, brackets are placed with the direct bracket bonding (DBB) technique in most of the cases. Here, the correct bracket position is determined by the clinician during the bonding procedure, based on the clinical situation and treatment goals. Positioning errors with this method are quite frequent, due to e.g., a limited view, anatomical difficulties or saliva contamination, which may result in a prolonged treatment time or a suboptimal treatment result.
In an attempt to overcome the shortcomings of the DBB technique, an indirect bracket bonding (IDB) system was suggested for the first time by Silverman et al. in 1972. With this method, the brackets are placed on a plaster cast model. The advantage of extra-oral placement is that there is a better view of the placement of the brackets, which makes it easier to place them in the correct position. The brackets are then transferred to the dentition of the patient with a transfer tray. This process with several technical steps is quite time-consuming. With the emergence of computer-aided design and manufacturing (CAD/CAM), the number of intermediate steps can be reduced. With current software and intra-oral scanning techniques, the last analogue step in IDB (i.e., impression taking) can also

be digitalized.
IDB is associated with a significantly shorter clinical chair time compared to DBB. However, the total time needed per patient (i.e., including digital bracket placement and transfer tray design) in IDB is longer compared to DBB. Nonetheless, patients may be more satisfied with IDB over DBB since less clinical chair time is needed. This may also have an impact on patients reported oral health related quality of life (OHRQoL), however no studies on OHRQoL and IDB were found in literature.

Study objective

The primary aim of this split-mouth randomized clinical trial is to assess accuracy of bracket positioning of a fully digital IDB workflow compared to a DBB workflow, with IDB bracket planning serving as reference for both methods. The secondary aims are to assess differences between fully digital IDB and DBB, with respect to bracket bonding failures (immediate and delayed), bracket repositioning need (due to malpositioning), clinician experience, patient satisfaction and patient reported OHRQoL.

Study design

The study was designed as a split-mouth randomized clinical trial, with a randomized block design with a 1:1 allocation of IDB and DBB. In every participating patient the first jaw which was planned to be bonded (i.e., upper or lower jaw), was included in the study. The other jaw was also orthodontically treated with fixed appliances but not included in the study. The decision on which jaw had to be bonded first in a particular patient, was based on clinical features and the patient's individual treatment plan, not on randomization. The clinical part of the study could not be blinded due to obvious differences in bracket placement procedures between IDB and DBB. Evaluation of bracket position, bonding failures and repositioning-need was however blinded to the authors. The follow-up period was six months after bonding.

Intervention

Placement of orthodontic fixed appliances, either direct or indirect

Study burden and risks

Burden: not more than standard orthodontic treatment
Risks: more bracket debonding

Contacts

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Eligibility criteria

Age
Children (2-11 years)
Children (2-11 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- - Healthy patient (ASA score I)
- - Permanent dentition present from at least first molar to first molar
- - Vestibular fixed appliances indicated in both jaws
- - Bonding indicated at least from second premolar to second premolar

Exclusion criteria

- -Agenesis (congenitally missing teeth)
- Extractions indicated
- (Pre)molar bands indicated
- Syndromes or enamel abnormalities present

Study design

Design

Study phase: N/A

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2021
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-04-2018
Application type:	First submission
Review commission:	METC Oost-Nederland p/a Radboudumc, huispost 628, Postbus 9101 6500 HB Nijmegen 024 361 3154 commissiemensgebondenonderzoek@radboudumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9411
Other	CMO Arnhem-Nijmegen : CMO: 2018-4032

Study results