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Quality of orthodontic treatment with straightwire or standard edgewise appliances

Submission date	Recruitment status	[ ] Prospectively registered
09/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/05/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/05/2018	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The type of orthodontic appliance (brace) used might have a direct effect on the results and duration of treatment. This study aims to compare two kinds of braces (one pre-programmed and one not) from treated patients' records to assess any differences in the quality of treatment.

Who can participate?
Patients treated with fixed orthodontic appliances (braces) for crooked teeth

What does the study involve?
The study involves assessing routinely-collected anonymized treatment records (stone cast models and x-rays of the teeth) taken before insertion of the orthodontic appliances and directly after their removal (around 18-60 months later).

What are the possible benefits and risks of participating?
All patients have been already treated in the two participating university clinics to have their teeth straightened and before treatment they have signed an informed consent form that their anonymized data can be used for research purposes. No additional risks are imposed on the patients other than risks that are normally included in the average treatment with dental braces. The benefits to be gained are in the form of increased treatment effectiveness with one of the two brace types, which is translated to patients being burdened for less time during treatment by the braces and the subsequent reduction of side effects.

Where is the study run from?
1. University of Zurich (Switzerland)
2. University of Oslo (Norway)

When is the study starting and how long is it expected to run for?
March 2017 to September 2018

Who is funding the study?
University of Zurich (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ABOZUROSL

Study information

Scientific Title
Clinical outcomes of orthodontic extraction treatment with pre-adjusted versus standard edgewise appliances: a retrospective cohort study

Study objectives
There is no difference in the occlusal outcome of comprehensive orthodontic extraction treatment, as measured with the American Board of Orthodontics (ABO) Objective Grading System (OGS), with either pre-adjusted edgewise appliances and standard edgewise appliances.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Committees for Medical and Health Research Ethics, 26/10/2017, ref: 2017/1885
2. Kantonale Ethikkommission Zürich, ID: 2018-00631 - approval pending

Study design
Retrospective non-randomized comparative multi-center observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Most orthodontic malocclusions can be effectively treated with comprehensive fixed appliance treatment, due to the ability of the latter to perform controlled tooth movements in all three planes of space. Often, severe arch length discrepancies or several dental/skeletal malocclusions necessitate the incorporation of dental extractions in the orthodontic treatment plan.

Interventions
Patient clinical documentation is consistently taken by all orthodontists both before insertion of the orthodontic appliances and directly after their removal (around 18-60 months after insertion). This documentation consists of intraoral/extraoral photographs, impressions made with metal trays and alginate to construct dental cast models of the patient’s dentition, and radiographs. These documentation, including each patient’s written log of treatment will be used as material for this study.

Intervention Type
Device

Primary outcome measure
The ABO OGS score will be evaluated using all its 8 components: alignment, marginal ridges, buccolingual inclination, overjet, occlusal contacts, occlusal relationships, interproximal contacts, and root angulation. This is measured from the patients’ post-treatment documentation (stone cast models of the occlusion and x-ray) using a specific checklist/form provided by ABO. The overall cumulative score for all ABO OGS categories will be used as primary outcome. The principal investigator (S.N.P.) has prior to initiation of the study completed the necessary calibration process as instructed by the ABO. All measurements will be obtained using the special ABO gauge provided with the calibration kit. The principal investigator has extensive experience in cephalometric analyses and their assessment for

research purposes. The primary outcome of this study will be the overall ABO OGS score in a continuous scale (expected to be normally-distributed).

Reliability of the method
Descriptive and inferential statistics will be performed to detect both random and systematic errors of the method. Initially, Dahlberg's formula will be used to assess intra examiner repeatability. With the aid of a table of random numbers, 10 patients will be randomly selected and will be re-evaluated 10 days later by the same examiner (S.N.P.) and also by a second examiner. Next, the intraclass correlation coefficient and the Bland-Altman limits of agreement [Bland and Altman, 1986] will be used to evaluate interexaminer agreement.

Secondary outcome measures
The secondary outcomes will include each of the separate components of the ABO OGS score that is used as a summary in the primary outcome.

Additionally, the treatment duration will be also extracted from the patient files and be used together with the ABO OGS to assess treatment efficacy. As treatment durations are expected to differ between the two centers, we might consider normalizing treatment durations within each center with the average duration of each center.

Overall study start date
01/03/2017

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Any ethnicity or race
2. Male or female
3. Class I, Class II, or Class III malocclusion
4. Full complement of teeth excluding the third molars
5. No previous orthodontic treatment
6. No dentofacial deformities or clefts
7. Complete set of diagnostic records

With the following treatment characteristics to control for factors that might influence treatment outcome or duration:
1. One phase treatment with labial fixed appliances in both arches (no two-phase treatment)
2. Bilateral extraction of a premolar in one or two jaws (either 2- or 4-premolars extracted)
3. No temporary anchorage devices of any form
4. No orthognathic surgery
5. No dental trauma
6. No impacted canines
7. Complete set of treatment records

Participant type(s)
Patient

Age group

All

Sex
Both

Target number of participants
A priori sample size calculation has been performed for the primary outcome of ABO OGS based on the previous study of Mislik et al. 2016 (PMID 26827982) using: (i) control mean of 25.7 points, (ii) standard deviation of 8.7 points - assumed common between groups, (iii) a clinically meaningful difference in ABO OGS of 30% of the control mean, (iv) use of an unpaired Student's t-test, (v) alpha of 5%, and (vi) beta of 20%. With these baseline data and assumptions, a needed sample of 22 patients/group (to a total of 44 patients) was calculated. In order to account for patient losses due to eventually excluded radiographs/models this was rounded up to 25 patients/group (to a total of 50 patients).

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2018

Date of final enrolment
01/08/2018

Locations

Countries of recruitment
Norway

Switzerland

Study participating centre
University of Zurich
Zurich
Switzerland
8032

Study participating centre
University of Oslo
Oslo
Norway
0455

Sponsor information

Organisation
University of Zurich

Sponsor details
Plattenstrasse 11
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Switzerland
8032

Sponsor type
University/education

Website
http://www.zzm.uzh.ch/de.html

ROR
https://ror.org/02crff812

Funder(s)

Funder type
University/education

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
The study's protocol, including the Statistical Analysis Plan will be made openly available following ethical approval and prior to study initiation through the Open Science Framework (https://osf.io/).

After study completion a scientific paper will be performed and submitted to a leading scientific journal in the field of dentistry/orthodontics. A list of general dental and orthodontic journals according to submission preference has been made a priori. Additionally, the results of the study will be disseminated through social media and be formally presented in international scientific congresses (like the congress of the European Orthodontic Society in 2019).

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
After study conduct, submission, and acceptance of the paper from a scientific journal, the anonymized dataset of the study will be made openly available through the Zenodo repository (https://zenodo.org/).

IPD sharing plan summary
Stored in repository