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Efficiency of clear aligner treatment in orthodontic patient requiring premolar teeth extraction

Submission date
27/10/2022

Recruitment status
No longer recruiting

Registration date
16/11/2022

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Clear aligners are the recent innovation of removable orthodontic appliances which are fabricated from transparent plastic. It applies pressure to correct the malaligned teeth position. The system has provided clinicians with an alternative modality of orthodontic treatment.

Controversy exists as to whether moderate to difficult orthodontic treatment, especially the case that required teeth extraction, can be routinely accomplished with the clear aligners system. So far, clinical research on the accuracy and effectiveness of clear aligners has found several limitations encountered during orthodontic treatment such as posterior open bite, teeth tilting into extraction site, inadequate incisors root movement, etc. Treatment outcome studies have shown some minor discrepancies related to clear aligners which need continual research evaluation for the development of effective treatment in various malocclusion.

The aim of this study is to find out the accuracy of tooth movement: (Comparison of actual vs. virtual tooth movement) of the In-House clear aligner in first premolar extraction cases.

Who can participate?
Adults over 18 years old with upper arch incisor protrusion or bimaxillary protrusion required upper first premolar teeth extraction.

What does the study involve?
Routine pretreatment records which included facial/dental photos, three dimensional radiographs and intraoral scan will be taken for generating treatment plan by 2 orthodontic instructors. Computer-generated tooth movement is used for the fabrication of customized In-House clear aligners appliance for each patient. Space closure of the extraction site would be carried out. In addition, upper canine teeth would be randomly assigned either with accessory attachments called the power arm or the other side with no power arm as control. The patient would be instructed to change the clear aligner every 7 days.
During treatment, intraoral scan recordings of actual teeth movement in the mouth would be done at various stages which are at 12 pieces clear aligners, 24 pieces clear aligners and final

space closure and completion of treatment.
Outcomes measurements are the deviation of distance and angulation. Measurement would be performed using 3D inspection software. The accuracy of teeth movement would be compared between the virtual (computer-predicted 3D model) vs. the actual at various stages of clear aligners use

What are the possible benefits and risks of participating?
Participants will benefit from more than 50% reduced overall treatment fee. The clear aligner laboratory fabrication cost will be sponsored by our research team. The risk may involve minor discrepancies such as teeth moving off-track from clear aligners (1-2 mm), teeth tilting into extraction site, inadequate incisors root movement or posterior openbite. However, these discrepancies are considered reversible which will be continually monitored and can be resolved by orthodontic research team during treatment.

Where is the study run from?
Mahidol University (Thailand)

When is the study starting and how long is it expected to run for?
January 2020 to July 2025

Who is funding the study?
Mahidol University (Thailand)

Who is the main contact?
Prof Nita Viwattanatipa, nitaviw@hotmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Accuracy of orthodontic tooth movement using in-house clear aligners in the first premolar extraction case

Study objectives
Research questions: What is the accuracy of in-house clear aligners in premolar extraction case?
Principal hypotheses:
1. Tooth movement of canine with power arm group is not significantly different from canine without power arm.
2. Actual tooth movement is not significantly different from compuetr generated virtual tooth movement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/04/2020, Faculty of Dentistry/Faculty of Pharmacy, Mahidol University (Chalermphrakiet Building on 11th floor, No. 6, Yothi Road, Ratchathewi District, Bangkok 10400, Thailand; +66 2200-7622; nuthathai.ubo@mahidol.ac.th), ref: COA.No.MU-DT/ PY-IRB 2020/022.1304

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied

Orthodontic treatment using in-house clear aligners appliance in the first premolar extraction patient

Interventions
Participants who met the inclusion criteria underwent orthodontic treatment using in-house clear aligners appliance. A split mouth randomisation technique is used to allocate the side of the maxillary canine teeth (left or right), the experimental canine with power arm attached or without power arm on the other side. Bilateral symmetrical extraction of the upper left and right first premolar teeth were carried out. Canine teeth on both sides were to be moved through the extraction site. Both canine teeth receive pushing force from the clear aligners. However, The experimental canine tooth is subjected to another retracting force on the palatal side using power chain from 1st molar tooth. According to the principle of orthodontic biomechanics, the power arm helps lower the retracting force toward more apical level which hypothetically may help creating bodily tooth movement. The control side of the mouth does not have this power arm extension. Incisors teeth movement will also be concomittantly carried out although at a smaller distance.

The trial cannot be double blinded due to the visibilty of power arm attached on the experimental canine tooth.

Total duration of treatment and follow-up: 4 years

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
In-house clear aligners appliance

Primary outcome measure
Tooth movement measured using 3D inspection software at pretreatment, at various set up stages which are: the 6th clear aligners, at 12th clear aligners and at completion:
1. Mesial/distal teeth movement (distance change in millimeters)
2. Extrusion/ intrusion teeth movement (distance change in millimeters)
3. Rotation / tip/ torque (angulation change in degree)
4. Canine teeth retraction
5. Incisor teeth retraction

Secondary outcome measures
1. Pain level will be measured using visual analogue scale (VAS) at baseline, day 1, day 3 and day 7
2. Teeth off track from clear aligners will be evaluated at pretreatment, at 12th clear aligners, at 24th clear aligners and at completion by observation.
3. Root resorption will be evaluated using periapical radiograph at completion of treatment

Overall study start date
10/01/2020

Completion date
04/07/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Angle Class I or II, with upper anterior teeth proclination/protrusion
3. Crowding less than 6 mm
4. Requiring full therapy of all permanent teeth, with bilateral symmetrical extraction of the upper first premolar teeth.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
18

Key exclusion criteria
1. Presence of systemic illnesses or bone diseases or teeth anomalies
2. Current exposure to any medical or dental condition that could potentially affect study results such as the use of bisphosphonates
3. Pregnancy
4. Plans to relocate or move during the treatment period

Date of first enrolment
14/12/2021

Date of final enrolment
14/06/2023

Locations

Countries of recruitment
Thailand

Study participating centre
Faculty of Dentistry, Mahidol University
6 Yothi Rd

Bangkok
Thailand
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Sponsor information

Organisation
Mahidol University

Sponsor details
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Sponsor type
University/education

Website
https://dt.mahidol.ac.th/en/

ROR
https://ror.org/01znkr924

Funder(s)

Funder type
University/education

Funder Name
Mahidol University

Alternative Name(s)
, , MU

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
Thailand

Results and Publications

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

Intention to publish date
04/07/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	In Thai version 4	01/02/2016	16/11/2022	No	Yes
Protocol file		16/11/2022	16/11/2022	No	No
Results article		28/12/2024	30/12/2024	Yes	No
Results article		14/05/2025	09/06/2025	Yes	No