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Small pinhole perforations created in the bone around the teeth to accelerate the rate of tooth movement during orthodontic alignment

Submission date
29/11/2019

Recruitment status
No longer recruiting

Registration date
04/12/2019

Overall study status
Completed

Last Edited
17/01/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
The use of braces to realign teeth (orthodontic treatment) is time-consuming and usually will take around 2 to 3 years to complete. Lengthy orthodontic treatments will expose patients to several risks such as gum problems, root resorption, and caries. Small pinhole perforations created in the bone around the teeth to accelerate the rate of tooth movement during orthodontic treatment (Micro-osteoperforations [MOP]) is a new method to accelerate orthodontic tooth movement which could probably shorten the braces treatment time. The main purpose of this study is to compare the overall time taken for alignment of upper front teeth crowding with micro-osteoperforations (MOPs) and to evaluate its effectiveness in reducing the duration of braces treatment. This is anticipated that participants may experience no pain or little discomfort after the procedure.

Who can participate?
Persons aged 18 – 45 years who require orthodontic treatment.

What does the study involve?
Participants who fulfil all the criteria will be allocated into trial and control groups. Both groups will be receiving similar orthodontic treatment. Additionally, for the trial group, small indentations will be performed under local anaesthesia at monthly visit. X-rays will be taken at the start and end of the treatment. Participants will also need to mark their pain level on the diary given as per instruction. Dental impressions are taken several times to evaluate the alignment improvement.

What are the possible benefits and risks of participating?
Benefits: Information obtained from this study will benefit the researchers, Government of Malaysia, doctors and individuals for the advancement of knowledge and practice of medicine in future.
MOPs therapy could be as an adjunct modality to reduce the overall orthodontic treatment length without adverse effect on root resorption and pain if proven in this study and vice versa. Shorter treatment duration would benefit the patients.

Risks: It is anticipated that participants may experience no pain or little discomfort after the procedure. Orthodontic treatment itself can elicit pain for the few days after appliance manipulation. Therefore antiseptic mouthwash is prescribed.

Where is the study run from?
Faculty of Dentistry, Universiti Teknologi MARA, Malaysia

When is the study starting and how long is it expected to run for?
October 2017 to October 2019

Who is funding the study?
Faculty of Dentistry, Universiti Teknologi MARA, Malaysia

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
REC/297/17

Study information

Scientific Title
Accelerating alignment of maxillary anterior crowding with micro-osteoperforations: a randomised clinical trial

Acronym
MOPs

Study objectives
The study aims to answer the following questions:
1. What is the efficacy of micro-osteoperforations (MOPs) in accelerating orthodontic alignment of maxillary anterior crowding compared to conventional methods with fixed appliances alone?
2. What is the difference in the alignment improvement percentage between MOPs and the control group?
3. What is the difference in the degree of apical root resorption with and without MOPs?
4. Do the MOPs procedures increase patients' pain perception in the trial group compared to the control group?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2017, UiTM Research Ethics Committee (Institute of Research Management and Innovation, Universiti Teknologi MARA, Aras 3, Bangunan Wawasan, 40450 Shah Alam, Selangor, Malaysia
+603 5544 2094; irmiuitm@salam.uitm.edu.my), ref: REC/297/17

Study design
Prospective randomised single-blind single-centre two-arm parallel controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
The domain of this study involves the localised minimally invasive surgical procedures known as MOPs in facilitating the first phase of fixed appliances treatment of alignment anterior maxillary arch crowding. This is built on the finding of a clinical trial on the rate of canine retraction that the extension of the surgical intervention did not seem to affect the tooth movement velocity.

During the alignment stage, the intervention group received surgical perforation (MOPs) within the attached gingiva to 1 mm apical to the mucogingival junction (MGJ). Two holes were made at 3 mm apart on alveolar bone equidistant between the anterior teeth from upper right three to upper left three except in the midline alveolar bone.

The control group will continue orthodontic treatment as usual.

The total duration of treatment was until the orthodontic alignment was completed, indicated with Little's Irregularity Index of 0. However, intraoral radiographs were taken six months into treatment. Participants were reviewed every four weeks.

Randomisation process:
All potential participants were screened and selected by the principal investigator (AAS) and the trial coordinator (NHN) by purposive sampling. All patients that met the criteria were included sequentially. Participants were allocated randomly to the MOPs group or control group with 1:1 allocation ratio. Sequentially numbered, sealed, opaque envelopes (SNOSE) were used for concealed randomisation of group allocation to minimise the risk of bias with regards to participant selection. Block of six (three odd and three even numbers) was used to ensure even subjects in each group. Odd numbers were allocated to MOPs and even numbers to control group.

Intervention Type
Procedure/Surgery

Primary outcome measure
Overall time taken for alignment of maxillary anterior crowding measured from patient records.

Secondary outcome measures
1. Alignment improvement percentage assessed monthly for six months: Little’s irregularity index (LII) was used to assess the overall changes and to measure the change of tooth alignment on the casts. Measurement of dental casts were calculated by using digital Vernier calliper
2. Degree of root resorption measured using long cone intra-oral periapical (IOPA) radiographs at baseline and six months
3. Pain perception measured using VAS monthly for six months

Overall study start date
17/05/2017

Completion date
01/10/2019

Eligibility

Key inclusion criteria

1. Age range 18-45 years old
2. Moderate crowding of maxillary arch (5-8mm)
3. Canine relationship between class III ¼ unit up to class II ½ unit
4. Extraction of upper first premolars with or without anchorage reinforcement
5. Healthy periodontal status with probing depth of lesser or equal to 3 mm, full-mouth plaque score lower or equal to 20 per cent, and full-mouth bleeding score lower or equal to 20 per cent (within 15 seconds after pocket depth probing)
6. All permanent maxillary teeth were present at least up to second molars
7. Undergoing conventional orthodontic treatment with McLaughlin, Bennett and Trevisi (MBT) brackets

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Previous orthodontic treatment either removable or fixed appliances
2. Patients with systemic diseases and compromised periodontal oral health
3. Taking medications which could interfere with tooth movement, such as anti-inflammatory drugs, systemic corticosteroids, or calcium channel blockers
4. Dental (e.g. hyperdontia, hypodontia) or craniofacial anomalies (e.g. Cleft lip and palate)
5. Smoker
6. Evidence of bone loss and root resorption on the dental panoramic tomography
7. History of dental trauma
8. Pregnant

Date of first enrolment
01/10/2017

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Teknologi MARA
Faculty of Dentistry
Centre of Paediatric Dentistry and Orthodontics Studies
Sungai Buloh
Malaysia
47000

Sponsor information

Organisation
Universiti Teknologi MARA

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Sponsor type
University/education

ROR
https://ror.org/05n8tts92

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Faculty of Dentistry, Universiti Teknologi MARA

Results and Publications

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

Intention to publish date
30/12/2019

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?
Results article		24/08/2021	01/09/2021	Yes	No
Results article		25/03/2021	17/01/2023	Yes	No