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Effectiveness of 3D-guided piezocision-assisted orthodontic surgery (a minimally invasive surgical technique) in accelerating the correction of severely crowded teeth

Submission date
04/04/2021

Recruitment status
No longer recruiting

Registration date
07/04/2021

Overall study status
Completed

Last Edited
29/03/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Orthodontic treatment uses appliances (usually braces) to correct the position of teeth. The length of comprehensive orthodontic treatment ranges between 18-30 months, depending on treatment options and individual characteristics. In addition, orthodontic treatment time ranges between 25-35 months for extraction therapies. Reducing orthodontic treatment time is one of the main goals for orthodontists due to problems such as root resorption (shortening of the roots), periodontal (gum) disease and caries (tooth decay) that are associated with prolonged treatment time. Many techniques have been introduced to speed up orthodontic tooth movement, both surgical and non-surgical. The surgical approach is the most clinically applied and most tested with known stable results. The invasiveness of these procedures might have limited their widespread acceptance among orthodontists and patients. Therefore, more conservative flapless corticotomy techniques have recently been proposed. These procedures can be accomplished in a reasonably short period that might cause less pain and discomfort, and may improve patient acceptance. Although various techniques of flapless corticotomy have been reported to be successful in practice, scientific evidence for their effectiveness so far has been limited to a few small studies. This study aims to provide evidence about the effectiveness of 3D-guided piezosurgery with a flapless technique to align crowded anterior (front) teeth.

Who can participate?
Healthy adults with severely crowded teeth

What does the study involve?
Participants are randomly allocated to one of two groups. The first group receive conventional orthodontic treatment without any surgery, whereas the second group receive piezocision-assisted orthodontic treatment. The duration of orthodontic treatments differs from one patient to another, and they will all be followed up until the end of the alignment phase.

What are the possible benefits and risks of participating?
The main benefit of participating is faster orthodontic treatment reducing problems such as root resorption, periodontal disease and caries. The risks are limited as 3D-guided surgical cuts will avoid harming teeth and vital structures.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
August 2019 to August 2021

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Omar Gibreal
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UDDS-OMFS-08-2019

Study information

Scientific Title

Evaluation of the efficacy of 3D-guided piezosurgery (a minimally invasive surgical technique) in accelerating orthodontic alignment

Study objectives
3D-guided piezosurgery accelerates orthodontic alignment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2019, scientific research committee in the faculty of dentistry at Damascus University (Mazzeh Highway, Damascus, Syria; +963 (0)113341864; manager@hcsr.gov.sy), ref: 505

Study design
Single-center interventional double-blinded randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anterior teeth severe orthodontic crowding

Interventions
With the aid of a computer-generated list of random numbers, the recruited patients will be assigned to two parallel groups with a 1:1 allocation ratio. The first group receive conventional orthodontic treatment, whereas the second group receive piezocision-assisted orthodontic treatment. The allocation sequence will be concealed using sequentially numbered, opaque, sealed envelopes.

Piezosurgery will be performed on the anterior lower segment of the dental arch in order to accelerate the correction of mandibular anterior crowding. The device tip will be used to create small vertical incisions into the cortex of the dentoalveolar process of the lower anterior teeth guided by a 3D surgical guide. For the control group, traditional orthodontic treatment will be provided to the patients without any surgical interventions.

The duration of orthodontic treatments differs from one patient to another, they will be followed up until the end of the alignment phase.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Duration of tooth alignment measured at the end of treatment by calculating the time required time (in days) to achieve complete alignment of lower anterior teeth from the first day of treatment and up to 120-150 days of observation
2. Change in tooth alignment measured using the Little Index of Irregularity at 30 days after the

onset of treatment
3. Change in tooth alignment measured using the Little Index of Irregularity at 60 days after the onset of treatment
4. Change in tooth alignment measured using the Little Index of Irregularity at last assessment when a complete alignment is achieved; this is expected between 90 to 120 days after the onset of treatment

Key secondary outcome(s))
1. Pain measured using the visual analogue score (VAS) at baseline, 12, 24 and 48 hours
2. Discomfort measured using the visual analogue score (VAS) at baseline, 12, 24 and 48 hours
3. Swelling measured using the visual analogue score (VAS) at baseline, 12, 24 and 48 hours

Completion date
01/08/2021

Eligibility

Key inclusion criteria
1. Adult healthy patients, male and female, age range 15-27 years
2. Severe crowding ≤7 (Little's irregularity index)
3. Permanent occlusion
4. All mandibular teeth exist (except third molars)
5. Good oral and periodontal health:
5.1. Probing depth <4 mm
5.2. No radiographic evidence of bone loss
5.3. Gingival index ≤1
5.4. Plaque index ≤1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Medical problems that affect tooth movement (use of corticosteroid, NSAIDs)
2. Patients have anti indication for oral surgery (medical, social, psychological)
3. Presence of primary teeth in the mandibular arch
4. Missing permanent mandibular teeth (except third molars)
5. Poor oral hygiene or current periodontal disease:
5.1. Probing depth ≥4 mm

5.2. Radiographic evidence of bone loss
5.3. Gingival index >1
5.4. Plaque index >1
6. Patient had previous orthodontic treatment

Date of first enrolment
01/12/2019

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry
Mazzeh Highway
Damascus
Syria
97009

Sponsor information

Organisation
Damascus University

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made 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		11/08/2022	15/08/2022	Yes	No
Results article		28/03/2023	29/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes