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# Esthetic orthodontic appliance (bracketless orthodontic technique)

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| **Submission date**<br>17/05/2025 | **Recruitment status**<br>Recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>20/05/2025 | **Overall study status**<br>Ongoing | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>20/05/2025 | **Condition category**<br>Oral Health | [ ] Individual participant data<br>[X] Record updated in last year |

**Plain English summary of protocol**

Background and study aims:
This study aims to evaluate the effectiveness of bracketless fixed orthodontics (coated E-wires) in the treatment of mild dental crowding in adults.
The majority of adult patients do not prefer treatment with conventional fixed appliances due to aesthetic concerns, prolonged treatment duration, and the relative difficulty of maintaining oral hygiene in the presence of brackets. Since the available aesthetic alternatives (ceramic brackets, lingual orthodontics, and clear aligners) are relatively expensive for most patients, a bracketless aesthetic orthodontic technique using coated E-wires has been developed for the management of mild crowding cases. This technique is aesthetic, non-intrusive, does not require brackets, and does not rely on patient compliance.

Who can participate?
Adult patients with mild dental crowding often have aesthetics as a primary concern, as they are apprehensive about the visibility of conventional brackets and the potential for prolonged treatment duration. Nevertheless, only patients who meet the inclusion criteria are accepted for treatment.

What does the study involve?
Patients will be randomly assigned to one of two groups:
1. Experimental group: patients are treated with the bracketless orthodontic technique (BOT)
2. Control group: patients are treated with a conventional fixed orthodontic appliance

What are the possible benefits and risks of participating?
The bracketless fixed orthodontic technique may offer patients a shorter treatment duration and better oral hygiene compared to conventional appliances with brackets. It may also help reduce pain and discomfort.

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

Where is the study starting and how long is it expected to run for ?
September 2024 to October 2027

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Nataly Alqaisi, nataly.qaisi@gmail.com

# Contact information

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Public, Scientific, 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
Effectiveness of bracketless fixed orthodontic technique (coated e-wires) for treatment of mild crowding cases in adults: a randomized controlled trial

### Acronym
BOT

### Study objectives

1. Comparison between the two groups regarding the effect on the time required for alignment of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in terms of the effect on the required alignment time.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in terms of the effect on the required alignment time.

2. Comparison between the two groups in Little's Irregularity Index values during the alignment phase of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in Little's Irregularity Index values.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in Little's Irregularity Index values.

3. Comparison between the two groups in changes of overjet, overbite, and arch length and width in mildly crowded dentition:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in overjet, overbite, and arch length and width.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in overjet, overbite, and arch length and width.

4. Comparison between the two groups in changes in the axial inclinations of upper and lower incisors during the alignment of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in the changes of axial inclinations of incisors.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in the changes of axial inclinations of incisors.

5. Comparison between the two groups in levels of pain and discomfort during the alignment of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in pain and discomfort levels.

Alternative Hypothesis ($H_1$): There is a difference in pain and discomfort levels between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group.

6. Comparison between the two groups in oral health-related quality of life during the alignment of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in oral health-related quality of life.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in oral health-related quality of life.

7. Comparison between the two groups in periodontal and gingival tissue health during the alignment of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in periodontal and gingival tissue health.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in periodontal and gingival tissue health.

8. Comparison between the two groups in acceptance and satisfaction levels during the alignment of mildly crowded anterior teeth:

Null Hypothesis ($H_0$): There is no difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in acceptance and satisfaction levels.

Alternative Hypothesis ($H_1$): There is a difference between the bracketless fixed orthodontic appliance group and the conventional fixed orthodontic appliance group in acceptance and satisfaction levels.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 01/10/2024, Biomedical Research Ethics Committee (Faculty of Dentistry, Damascus University, Damascus, 20872, Syria; +963 (0)993303359; president@damascusuniv.edu.sy), ref: DN-01102024-328

## Study design
Two-arm parallel-group single-blind randomized controlled clinical trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)

Other

## Study type(s)
Treatment

## Participant information sheet
See study outputs table

## Health condition(s) or problem(s) studied
Orthodontic tooth movement

## Interventions
Patients will be randomly assigned in a 1:1 allocation ratio to the two groups:
1. Experimental group: patients treated with the bracketless orthodontic technique (BOT)
2. Control group: patients treated with a conventional fixed orthodontic appliance

Randomization will be performed by an independent clinician not involved in the study, using automated computer-generated randomization tables created via the website https://www.randomization.com.

Blinding of either the researcher or the patients during the treatment phase is not applicable. Therefore, blinding will be applied during the measurement recording phase. Measurements will be taken by an independent assessor not involved in the study, and all models will be coded with serial numbers to ensure blinding and minimize detection bias.

Impressions of the upper and lower dental arches were taken using a condensation silicone impression material (Bonasil® C-Silicone Impression Mass Set, DMP Dental, Greece).
The resulting dental cast was scanned for a digital model based on the silicone impression.
The model was imported into the 3Shape Ortho Analyzer software, where the teeth requiring alignment were repositioned according to the necessary amount of interproximal reduction for each tooth to achieve the desired outcome. This process was documented in a specialized form, resulting in a digital setup of both the upper and lower dental arches after the teeth had been aligned.
Subsequently, a 3D printer was employed to create a physical model from this digital representation using resin material.
The wire was positioned on the resin model within the central fossae of the posterior teeth, subsequently aligning it in a neutral manner along the lingual surface of the anterior teeth. The distance between the incisal edge and the wire was recorded for clinical transfer using a Bracket Positioning Gauge with a Marker (Ormco, Switzerland).
Direct Bonding Technique: Interproximal reduction (IPR) was performed using a stripping strip, with the reduction measured using an IPR gauge. The bonding process began with the posterior teeth, where the wire was bonded within the central fossae, followed by the anterior teeth. The bonding points for the anterior teeth were precisely determined based on measured distances from the resin model.
Coated E-wires were sequentially replaced, starting with a 0.012 NITI-coated e-wire and subsequently using a 0.014 NITI-coated e-wire, once the initial wire had sufficiently deactivated and returned as closely as possible to its original shape. (E-wire, Seoul, Korea).

## Intervention Type
Device

## Pharmaceutical study type(s)
Not Applicable

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Coated e-wire

## Primary outcome measure
1. Time required for alignment of mildly crowded upper and lower teeth, measured in days, from the date of appliance placement to the point at which the Little's Irregularity Index reaches zero.
2. Little's Irregularity Index values accompanying the alignment of mildly crowded upper and lower teeth. The percentage of alignment will be determined using the following formula:
[(Little's Index at T0 – Little's Index at the specified timepoint) / Little's Index at T0] × 100
Dental impressions will be taken and casts poured monthly at each archwire change, starting from the beginning of treatment until alignment and leveling are complete, as follows:
T0: before the start of treatment
T1: 1 month after the start of treatment
T2: 2 months after the start of treatment
T3: 3 months after the start of treatment
T4: 4 months after the start of treatment
Tf: the final impression taken when Little's Irregularity Index equals zero
3. Overjet, overbite, and arch length and width resulting from the alignment of mildly crowded upper and lower teeth:
3.1. The overjet will be measured at two timepoints: before the start of treatment (T0) and after the alignment of the anterior teeth is complete (Tf).
The value at T0 will then be subtracted from the value at Tf to determine the change.
3.2. The overbite will be measured at two timepoints: before the start of treatment (T0) and after the alignment of the anterior teeth is complete (Tf).
The value at T0 will then be subtracted from the value at Tf to determine the change.
3.3. Anterior dental arch length = SLux100/160
3.4. Lower dental arch length = Lu-2mm
4. Axial inclinations of upper and lower incisors resulting from the alignment of mildly crowded upper and lower teeth. To calculate the amount of change in the position of the lower incisor axes, the angle formed between the axis of the lower incisor (L1) and the mandibular plane (ML) will be measured at both timepoints (before starting treatment [T0] and after completing the alignment of the anterior teeth [Tf]). The angle formed between the axis of the upper incisor (U1) and the anterior cranial base (S-N) will also be measured, as well as the interincisal angle (U1-L1). Then, the value of the angle before treatment will be subtracted from the value after completing the anterior teeth alignment (Tf - T0).

## Secondary outcome measures
1. Pain and discomfort assessed using a Visual Analogue Scale (VAS) daily for 5 days following the application of any new orthodontic wire
2. Oral health-related quality of life (OHRQoL) measured using the Oral Health Impact Profile (OHIP) questionnaire at five different timepoints:
T0: Before the start of treatment
T1: 1 month after treatment initiation
T2: 2 months after treatment initiation
T3: 3 months after treatment initiation

T4: At the end of treatment
3. Periodontal indices: Plaque Index (PI), Gingival Index (GI), Papillary Bleeding Index (PBI); clinically assessed at the following timepoints:
T0: Before starting treatment
T1: 1 month after treatment initiation
T2: 2 months after treatment initiation
T3: At the end of treatment

### Overall study start date
01/09/2024

### Completion date
03/10/2027

## Eligibility

### Key inclusion criteria
1. Aged between 18 and 28 years
2. Complete dentition except for third molars
3. Mild dental crowding ranging from 1 to 4 mm, not requiring the extraction of any teeth
4. Class I molar and canine relationship according to Angle's classification
5. Skeletal sagittal relationship Class I (1 < ANB < 4), with normal growth pattern according to Björk (396 ± 6)
6. Lower incisor axis angle with the mandibular plane not exceeding 95°, and upper incisor axis angle with the anterior cranial base not exceeding 107°
7. Patients have good oral health: Plaque Index ≤1

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
28 Years

### Sex
Both

### Target number of participants
48

### Key exclusion criteria
1. Patients with systemic health conditions affecting tooth movement
2. Teeth with deep caries or extensive restorations

3. Patients with impacted teeth
4. Patients who have undergone previous orthodontic treatment
5. Smokers

### Date of first enrolment
03/10/2024

### Date of final enrolment
03/10/2025

## Locations

### Countries of recruitment
Syria

### Study participating centre
**Damascus University**
Faculty of Dentistry
Department of Orthodontics
Syria
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## Sponsor information

### Organisation
Damascus University

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### Sponsor type
University/education

### Website
http://www.damascusuniversity.edu.sy

### ROR
https://ror.org/03m098d13

# Funder(s)

**Funder type**
University/education

**Funder Name**
Damascus University

**Alternative Name(s)**
University of Damascus, , DU

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Syria

# Results and Publications

**Publication and dissemination plan**
Planned publication of results article.

**Intention to publish date**
01/10/2027

**Individual participant data (IPD) sharing plan**
The datasets generated and analyzed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Published as a supplement to the results publication

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | | 20/05/2025 | No | Yes |