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Can low-power laser treatment or gentle electrical nerve stimulation reduce pain after orthodontic wires are fitted?

Submission date 10/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/08/2026	**Overall study status** Completed	
Last Edited 11/08/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Fixed orthodontic wires can cause pain, especially during the first two days after they are fitted. This study looked at whether low-level laser therapy (LLLT) or transcutaneous electrical nerve stimulation (TENS) could reduce this pain without medication.

Who could participate?
Patients aged 14–20 years with permanent teeth and mild crowding in both dental arches could take part. Patients with systemic or neurological diseases, poor oral or periodontal health, impacted or missing teeth, or current use of pain-relieving or anti-inflammatory medication were excluded.

What did the study involve?
Participants were randomly assigned to three groups. Group A received LLLT at week 1 and TENS at week 5. Group B received the same treatments in the opposite order. Group C received dummy LLLT at week 1 and dummy TENS at week 5.

Treatment was applied to the right side, while the left side was left untreated for comparison. Participants rated pain on both sides using a scale from 0 to 100 immediately after treatment and at 2, 4, 6, 12, 24 and 48 hours.

What were the possible benefits and risks?
The treatments might have reduced pain, but a direct benefit was not guaranteed. Both treatments were non-invasive. TENS could cause temporary tingling or discomfort, and any unwanted effects were recorded.

Where was the study run?
The study was carried out at the Orthodontic Clinic of Sultan 2. Abdülhamid Han Training and Research Hospital in Istanbul, Türkiye.

When did the study take place?
Recruitment took place between September 2020 and March 2021. Follow-up was completed in April 2021.

Who funded the study?
The study was funded by the University of Health Sciences Türkiye, Scientific Research Projects Coordination Unit (project number 2021/009).

Who was the main contact?
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Study information

Scientific Title
Low-level laser therapy and transcutaneous electrical nerve stimulation for pain control after fixed orthodontic archwire placement: a randomized clinical trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2020, University of Health Sciences Hamidiye Clinical Research Ethics Committee (University of Health Sciences, Mekteb-i Tıbbiye-i Şahane (Haydarpaşa) Campus, Selimiye Mahallesi, Tıbbiye Caddesi No: 38, Üsküdar, Istanbul, 34668, Türkiye; +90 2167779021; hamidiye.kaek@sbu.edu.tr), ref: Protocol reference: 20-76; approval number: 2020.07.10-66

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Pain following fixed orthodontic archwire placement in adolescents and young adults with mild dental crowding.

Interventions
After confirmation of eligibility and written informed consent, 81 participants were randomly allocated in a 1:1:1 ratio to three intervention sequences using sex-stratified, computer-generated permuted blocks and sequentially numbered, opaque, sealed envelopes. All participants received 0.018 × 0.025-inch fixed metal brackets.

During period 1 (week 1), immediately after placement of a 0.016-inch round nickel–titanium archwire, Group A received active low-level laser therapy (LLLT), Group B received active transcutaneous electrical nerve stimulation (TENS), and Group C received sham LLLT. During

period 2 (week 5), immediately after placement of a 0.016 × 0.016-inch rectangular nickel–titanium archwire, Group A received active TENS, Group B received active LLLT, and Group C received sham TENS.

LLLT was delivered using a Solase diode laser (Lazon Laser, Shenyang, China) at 976 nm and 0.5 W in continuous mode through a 1 cm² biostimulation tip. Treatment was applied for 15 seconds per tooth (7.5 J per point; 7.5 J/cm²) at one vestibular point corresponding to the middle third of each root, with the tip in contact with the gingival mucosa.

TENS was delivered using a Medelsan device (Istanbul, Türkiye) with a 200-μs pulse width at 50 Hz for 20 minutes. Extraoral 5 × 5 cm electrodes were positioned near the premolar roots immediately below the zygomatic bone for the maxilla and near the mental foramen for the mandible. Participant-specific stimulation amplitudes were not retained.

The right side was the fixed application side and the left side was the untreated contralateral comparator. Sham LLLT used the same device placement and application procedure without laser emission. Sham TENS used the same electrode placement and duration without electrical current. Pain was recorded separately for the application and contralateral sides for 48 hours after each intervention period.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Solase multifunctional dental diode laser (Lazon Laser, Shenyang, China), Medelsan transcutaneous electrical nerve stimulation (TENS) device (Medelsan, Istanbul, Türkiye)

Primary outcome(s)
1. Orthodontic pain intensity for the right application side and the left contralateral side measured using self-reported 0–100 visual analogue scale (VAS), where 0 indicated no pain and 100 indicated the worst pain imaginable at 0, 2, 4, 6, 12, 24 and 48 hours after the intervention following archwire placement in each study period (week 1 and week 5). The retained protocol materials did not identify a single primary timepoint; all prespecified VAS timepoints are therefore listed.

Key secondary outcome(s)
1. Adverse events associated with LLLT and TENS measured using occurrence and type of any discomfort or unintended event documented in treatment and follow-up records at during each device application and throughout the 48-hour follow-up period after each intervention session at weeks 1 and 5

Completion date
28/04/2021

Eligibility

Key inclusion criteria

1. Male or female participants aged 14–20 years
2. Permanent dentition
3. Dental crowding of 2–4 mm in both the maxillary and mandibular arches
4. No previous orthodontic treatment

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 Years

Upper age limit
20 Years

Sex
All

Total final enrolment
81

Key exclusion criteria
1. Presence of a systemic or neurological disease
2. Use of analgesic or anti-inflammatory medication at enrolment
3. Impacted or missing teeth, except for third molars
4. Requirement for additional anchorage reinforcement
5. Poor oral hygiene
6. Presence of periodontal disease

Date of first enrolment
15/09/2020

Date of final enrolment
20/03/2021

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
University of Health Sciences Türkiye

Funder(s)

Funder type

Funder Name
Health Sciences University Hamidiye Scientific Research Projects Coordination Unit

Results and Publications

Individual participant data (IPD) sharing plan
De identified individual participant data will be available from the corresponding author upon reasonable request, subject to institutional approval and applicable ethical and data-protection requirements.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Adult		11/08/2026	No	Yes
Participant information sheet	Child		11/08/2026	No	Yes
Participant information sheet	Parent/guardian		11/08/2026	No	Yes