

# Do light emitting diodes (LED) enhance orthodontic tooth movement?

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<b>Registration date</b> 14/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/11/2018	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A light emitting diode (LED) is a type of light that has been introduced into the orthodontic field with the claim of increasing the speed of orthodontic tooth movement (movement of teeth as a result of force being placed on them). LED devices are very expensive, which therefore increases the cost of orthodontic treatment for both orthodontists and patients. Little research has been done into their use and the results of what research there is has been controversial.

The aim of this study was to look at the effects of an LED light on orthodontic tooth movement compared to a placebo.

### Who can participate?

Patients with maxillary protrusion who require upper first premolar teeth extraction as part of their orthodontic treatment

### What does the study involve?

After 1st premolar teeth extraction, canine tooth movement were carried out through extraction site in orthodontic treatment. This study involved application of intraoral LED curing light (with 430-480 nm wavelength) as intervention upon maxillary canine movement. LED exposure was carried out around 12 points of canine teeth, 5 seconds each point, every 3 weeks for 7 times, during the period of canine movement for 4.5 months. Major outcome collected was the rate of tooth canine movement which was measured from the Panorex films at 2 intervals, 9 weeks apart.

We found that, with this protocol, the intraoral LED curing light device with 430-480 nm wavelength could not accelerate the rate of canine tooth movement into extraction site. No complications were found during our clinical experiment.

All participants will undergo the same treatment; however, one side of their mouth will be randomly allocated to receive LED treatment, whilst the other will receive the control. After extraction of the first premolar teeth, participants will receive canine tooth movement treatment. On one side of the mouth, the LED light will be used during the movement process at 12 points around the teeth for 5 seconds, every 3 weeks for a total of 7 times. The other side of the mouth received treatment as usual. X-rays were taken twice throughout the study to track tooth movement

What the possible benefits and risks of participating?

The possible benefit to participants taking part in this study is that use of the LED light could potentially reduce orthodontic treatment time. There are no known risks to participants taking part in this study.

Where is the study run from?

Faculty of Dentistry, Mahidol University, Bangkok (Thailand)

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

January 2015 to May 2018

Who is funding the study?

Faculty of Dentistry, Mahidol University, Bangkok (Thailand)

Who is the main contact?

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## Contact information

**Type(s)**

Public

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

**Scientific Title**

Randomized controlled trial: Light emitting diodes (LED) with 430-480 nm wavelength versus placebo upon rate of tooth movement in orthodontic patients

**Study objectives**

The rate of canine tooth movement into upper first premolar extraction with the intraoral LED curing light of 430-480 nm wavelength is faster than the control groups

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Faculty of Dentistry/Faculty of Pharmacy, Mahidol University, 11/02/2016, COA.No.MU-DT/PY-IRB 2016/011.1102.

**Study design**

Interventional single-centre double-blind split-mouth randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

[https://1drv.ms/w/s!Apf2A25n-S5lhWTTWp1yd\\_x8GLTw](https://1drv.ms/w/s!Apf2A25n-S5lhWTTWp1yd_x8GLTw)

**Health condition(s) or problem(s) studied**

Angle Class 1 bimaxillary dento-alveolar protrusion

**Interventions**

Participants who met the inclusion criteria underwent orthodontic treatment using an LED device. A split mouth randomisation technique was used to allocate the side of the maxillary teeth (left or right) to the LED or placebo sides.

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. On the LED side of the mouth, the experimental canine tooth was subjected to LED exposure using the LED dental curing light device (Elipar™ S10, 3M ESPE, USA) with energy output 1200 mW/cm<sup>2</sup>, Energy intensity 6 J/cm<sup>2</sup> and wavelength range 430-480 nm. The LED application was made around the canine root at 6 points buccally and 6 points lingually, with 5 seconds per point and a distance of 3 mm from the gingiva. The LED intervention was applied every 3 weeks for 7 times during the period of 4.5 months. The follow-up was 21 weeks after the first LED application.

A placebo LED was used for the control side of the mouth. The LED probe was covered with a foil sheath on the placebo side (in the LED side, the foil sheath was exposed). To ensure the trial

was double-blind, the operator used LED protective eye glasses to prevent identification of the method used on each side.

## **Intervention Type**

Device

## **Primary outcome measure**

Distance and rate of canine movement, assessed using a synapse program on 3 digital panorex taken at the start of retraction and after retraction every 9 weeks. The rate of canine tooth movement was gathered at the end of phase 1 (week 3 - week 12 after start of orthodontic treatment), phase 2 (week 12 - week 21 after the start of orthodontic treatment) and over the total time (week 3 - week 21 after the start of the orthodontic treatment)

## **Secondary outcome measures**

1. Canine angulation change, measured using Panorex film taken at the week 3 and week 21
2. Pain level score after application of LED curing light, measured through self-reported pain rating on the Numerical Rating Scale (NRS) (0 indicates "no pain", 1-3 indicates "mild pain", 4-6 indicates "moderate pain" and 7-10 indicates "severe pain") after every visit (weeks 0, 3, 6, 9, 12, 15 and 18)
3. Complications:
  - 3.1. Tooth vitality, assessed using Electric Pulp Vitality Testing (EPT) at week 0 and week 21
  - 3.2. Root resorption, assessed using parallel films at pre-treatment and post-treatment

## **Overall study start date**

01/01/2015

## **Completion date**

30/05/2018

# **Eligibility**

## **Key inclusion criteria**

- Adult patients age  $\geq 18$  years old
- Angle's Class I or II, with upper anterior teeth proclination/protrusion
- Crowding less than 2 mm.
- Treatment required full fixed edgewise appliance therapy of all permanent teeth, with bilateral symmetrical extraction of upper first premolar teeth.

1. Aged 18 years or older
2. Angle Class I or II, with upper anterior teeth proclination/protrusion
3. Crowding less than 2 mm
4. Requiring full fixed edgewise appliance 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

**Key exclusion criteria**

1. Presence of systemic illnesses or bone diseases
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**

01/03/2015

**Date of final enrolment**

01/08/2017

**Locations****Countries of recruitment**

Thailand

**Study participating centre**

**Faculty Dentistry, Mahidol University**

Faculty of Dentistry

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Bangkok

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10400

**Sponsor information****Organisation**

Mahidol

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.dt.mahidol.ac.th/en/about-us/about-our-dental-school/>

**ROR**

<https://ror.org/01znkr924>

## Funder(s)

**Funder type**

Not defined

**Funder Name**

Faculty of Dentistry Mahidol University

## Results and Publications

**Publication and dissemination plan**

We intend to submit to a Pubmed/Scopus listed journal in 2018

**Intention to publish date**

01/09/2018

**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?
<a href="#">Results article</a>	results	25/10/2018		Yes	No