

# Impact of photobiomodulation on pain associated with orthodontic treatment

<b>Submission date</b> 29/02/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/07/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study investigates how using photobiomodulation (PBM) affects the pain that comes with orthodontic treatment. Photobiomodulation is a therapy that uses light to stimulate biological processes in the body. We're exploring whether this therapy can help reduce the discomfort often experienced during orthodontic procedures.

This study was a retrospective study that collected information and data from the dental charts of patients who provided informed consent/authorization to the dental clinic to use their data for research purposes.

### Who can participate?

Patients at 7 dental clinics in Japan aged 18 - 65 years.

### What does the study involve?

Patients were asked to use an intraoral light therapy device called PBM Ortho and to record their pain level on a scale from 0 to 10 (0 = no pain, 10 = worst pain imaginable) for 7 days at the beginning of orthodontic treatment with either clear aligners or fixed appliances. The device was to be used for 4 minutes per arch, so a total of 8 minutes per day. Other patients were asked to just record their pain levels in the same manner as described, but they did not use any device. The PBM Ortho devices were made by a company called PBM Healing International Limited. This study aimed to investigate the impact of this light therapy device on orthodontic pain.

### What are the possible benefits and risks of participating?

Patients that used the device may have experienced a reduction in pain, but there were no risks with using the device.

### Where is the study run from?

PBM Healing International Limited (Hong Kong)

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

October 2023 to February 2024

Who is funding the study?  
PBM Healing International Limited (Hong Kong)

Who is the main contact?  
Dr Alan Kwong Hing, dr.al@pbmhealing.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Alan Kwong Hing

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Pro00134382

## Study information

### Scientific Title

Impact of photobiomodulation on pain associated with orthodontic treatment with clear aligners or fixed appliances - a retrospective, multicentre study

### Study objectives

Photobiomodulation (PBM) reduces orthodontic pain

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 03/10/2023, University of Alberta Research Ethics Board (2-01 North Power Plant (NPP), 11312 - 89 Avenue NW, Edmonton, T6G 2N2, Canada; +1-780-492-0459; reoffice@ualberta.ca), ref: Pro00134382

**Study design**

Multicenter 7-day case-control retrospective observational study

**Primary study design**

Observational

**Study type(s)**

Treatment

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

Reduction of pain associated with orthodontic treatment in patients undergoing orthodontic treatment

**Interventions**

Upon starting orthodontic treatment with either clear aligners or fixed appliances, some patients were asked to use the PBM Ortho device and to record their pain level every day for 7 days, and some patients were asked to record their pain levels every day for 7 days without using any devices. The PBM Ortho device is an intraoral device with a mouthpiece that produces photobiomodulation, also known as low level laser/light therapy, for 4 minutes per arch.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

PBM Ortho device

**Primary outcome(s)**

Self-reported pain level for 7 days using a visual analog scale form (0 = no pain, 10 = worst pain imaginable)

**Key secondary outcome(s)**

Any report of adverse events measured using patient records throughout the study

**Completion date**

20/02/2024

**Eligibility****Key inclusion criteria**

1. Systemically healthy male and female patients (age 18 - 65), i.e., did not suffer from systemic illness nor require medication during the study period.
2. Permanent dentition, with Little's Irregularity Index (LII) of 2 mm or greater for the upper and lower arch.
3. Orthodontic treatment using clear aligners or fixed appliances via non-extraction therapy.
4. Non-smoker with no use of chewing tobacco.

5. Good oral hygiene.
6. Caries free.
7. No sign of periodontal disease.

**Participant type(s)**

Healthy volunteer, Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

32

**Key exclusion criteria**

1. Systemic diseases
2. Medication use for the past 6 months; especially use of anti-inflammatory (e.g., NSAIDs)
3. Smoking.
4. Active dental caries.
5. Any periodontal problem including bleeding, tooth mobility, bone loss, attachment loss, deep pockets.
6. Sleep apnea and other airway pathologies
7. Photosensitivity or use of drugs that may cause photosensitivity
8. Use of osteoporosis drugs
9. Epilepsy
10. Patients who had an implanted cardiac device unless the device is known to not be affected by magnetic fields

**Date of first enrolment**

03/10/2023

**Date of final enrolment**

20/02/2024

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

Japan

**Study participating centre**  
**IXI Family Dental Clinic**  
Tokyo  
Japan  
183-0015

**Study participating centre**  
**Sawa Dental Clinic**  
Kasugai  
Japan  
486-0806

**Study participating centre**  
**Tsujimura Dental Clinic**  
Tanabe  
Japan  
646-0028

**Study participating centre**  
**Miki Dental Clinic**  
Tokyo  
Japan  
187-0021

**Study participating centre**  
**Bio Dental Clinic Ashiya**  
Ashiya  
Japan  
659-0065

**Study participating centre**  
**Higashimachigran Dental Clinic**  
Kumamoto  
Japan  
830-0032

**Study participating centre**

**Soejima Dental Clinic**  
Kitakyushu  
Japan  
860-0952

## **Sponsor information**

**Organisation**  
PBM Healing International Limited

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
PBM Healing International Limited

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study may be available upon reasonable request from Dr. Jacqueline Crossman ([jacqueline@pbmhealing.com](mailto:jacqueline@pbmhealing.com)).

### **IPD sharing plan summary**

Available on request