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Impact of photobiomodulation on pain associated with orthodontic treatment

Submission date 29/02/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/03/2024	**Overall study status** Completed	
Last Edited 26/07/2024	**Condition category** Oral Health	

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
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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 know 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).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes