ISRCTN70450905 https://doi.org/10.1186/ISRCTN70450905

Effects of thermoplastic dental retainer cleansing agents on the retainer's physical properties and price analysis

Submission date 20/04/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 05/05/2025	**Overall study status** Ongoing	[X] Statistical analysis plan [_] Results
Last Edited 13/02/2026	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

After the completion of orthodontic treatment, when the braces are to be taken off, a patient needs to wear a retainer. The retainers are custom-made appliances used to maintain the teeth's position, and the type of retainer provided in this study is a thermoplastic retainer. The retainer needs to be worn 24 hours except during mealtimes, toothbrushing and sports activities. Without adequate cleansing, retainers can lead to the accumulation of plaque and bacteria in the mouth, and this may also affect the physical form of the retainer. Several studies have investigated the stability and physical form of thermoplastic retainer after being exposed to different cleansers that are commonly used in orthodontic care, but mostly in a laboratory setting. To date, however, very few studies have been performed in a real clinical scenario to investigate the effects of cleansing agents on the physical properties of thermoplastic retainer. This study aims to study the effects of thermoplastic retainer cleansing agents on the physical properties of thermoplastic retainer and to determine the price range of the cleansing agents.

Who can participate?

Adult orthodontic patients who have completed treatment with a fixed appliance and will be fitted with a thermoplastic retainer.

What does the study involve?

Patients who had their braces removed at the UiTM Sungai Buloh dental clinics were informed about the study's goals and procedures. Those who agreed to join were given details about the study and randomly assigned to use one of three cleaning methods: toothpaste, Retainer Brite®, or tap water. They received instructions on dental care and retainer cleaning through demonstrations and WhatsApp messages in English and Malay. Participants were provided with a dental kit and a retainer diary link, along with videos showing proper cleaning techniques. They were reviewed every 6 weeks, and after 6 months, their used retainers were collected for lab evaluation. New impressions were taken to create custom-fitted retainers for nighttime use.

What are the possible benefits and risks of participating?

Information obtained from this research will benefit the individuals, researchers, institutions and

community for the advancement of knowledge and future practice. The results of this research will show the most effective cleansing agent for patients wearing thermoplastic retainers. Besides, it will show us if cleansing agents may affect the physical properties of thermoplastic retainer and finally, to determine the price range of the cleansing agents through market survey.

There is no harm expected from this study in any aspect, physically, mentally or psychologically. Participants will only need to follow specific instructions given to cleanse and wear their retainer and attend review appointments every 6 weeks, till the 6-month follow-up.

Where is the study run from?
Universiti Teknologi MARA (UiTM), Faculty of Dentistry, Malaysia

When is the study starting and how long is it expected to run for?
February 2024 to March 2027

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Wan Salmah binti Yang Mohsin, 2024657312@student.uitm.edu.my, wsym27@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Wan Salmah Yang Mohsin

Contact details
Faculty of Dentistry
Universiti Teknologi Mara (UiTM)
Sungai Buloh
Malaysia
47000
+60122394943
2024657312@student.uitm.edu.my

Type(s)
Public, Scientific

Contact name
Dr Saraswathy Devi Sinniah

ORCID ID
https://orcid.org/0000-0003-1481-2424

Contact details
Faculty of Dentistry UITM
Jalan Hospital
Sungai Buloh, Selangor

Malaysia
47000
+60355448069
saraswathy6153@uitm.edu.my

Type(s)
Public, Scientific

Contact name
Dr Nik Mukhriz Nik Mustapha

ORCID ID
https://orcid.org/0000-0002-6095-993X

Contact details
Faculty of Dentistry UITM
Jalan Hospital
Sungai Buloh, Selangor
Malaysia
47000
+60355448069
nikmukhriz@uitm.edu.my

Type(s)
Public, Scientific

Contact name
Dr Nur Aliana Hidayah Mohamed

ORCID ID
https://orcid.org/0000-0002-4662-9862

Contact details
Faculty of Dentistry UITM
Jalan Hospital
Sungai Buloh, Selangor
Malaysia
47000
+60355448069
alianahidayah@uitm.edu.my

Additional identifiers

Study information

Scientific Title
Effects of thermoplastic retainer cleansing agents on the polymer physical properties and price analysis: a randomised controlled trial

Acronym

Nil known

Study objectives
Thermoplastic retainer cleansing agents (Toothpaste, Retainer Brite, and Tap water) have no significant difference on the effects of physical properties of polymer retainer. There is no significant difference in price analysis between the thermoplastic retainer cleansing agents (Toothpaste, Retainer Brite and Tap water).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/10/2024, Universiti Teknologi MARA (UiTM) Research Ethics Committee (Aras 3, Bangunan Wawasan, Shah Alam, Selangor, 40450, Malaysia; +60355448069; recsecretariat@uitm.edu.my), ref: REC/10/2024 (PG/MR/489)

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Other

Health condition(s) or problem(s) studied
An effective method to cleanse the thermoplastic retainer among debonded orthodontic patients

Interventions
This is a single-centered, randomised controlled trial study which will involve orthodontic patients who have completed their orthodontic treatment, in the Faculty of Dentistry, UITM Campus Sungai Buloh. The conduct of the study will comply with the CONSORT 2010 guidelines for reporting data. The patients will be randomly allocated into the study groups by following the block randomisation in Microsoft Excel. Numbers will be written in sequence based on the total number of samples on each card and then inserted into the opaque sealed envelopes. Patient's treatment allocation will be based on the number on the envelope.

During debond sessions, patients will be recruited and selected based on inclusion and exclusion criteria. The patient will be randomly allocated to 3 groups of cleansing agents (Toothpaste, Retainer Brite and Tapwater). Upon issuing the retainers, thorough instructions will be given in terms of dental care and the thermoplastic retainer. A chairside demo and written instructions will be provided as well via WhatsApp, detailing the assigned cleaning intervention in both English and Malay. The participants will be provided with the dental kit and a link for the retainer diary. A verified MPEG file of pre-recorded video will be shared to demonstrate to patients on how to brush their teeth and clean their retainer correctly. These videos were according to the 3 assigned cleansing procedures. Patients will be reviewed every 6 weeks.

After a period of 6 months, the used retainers will be collected for laboratory evaluation. New alginate impressions will be obtained to create a new set of retainers for the patient. The retainer will be custom-fitted the next day to facilitate its use throughout nighttime wear.

Intervention Type
Other

Primary outcome(s)
Current primary outcome(s) as of 13/02/2026:

1. Changes in translucency of retainer polymer are measured using a spectrophotometer at baseline and 6 months
2. Changes in colour of retainer polymer are measured using a spectrophotometer at baseline and 6 months
3. Changes in surface roughness of the retainer polymer are measured using a profilometer at baseline and 6 months
4. Changes in the flexural strength of the retainer polymer are measured using a universal testing machine at baseline and 6 months
5. Comparison of prices for the thermoplastic retainer cleansing agents (Toothpaste, Retainer Brite, and Tap water) is measured using a monthly price survey. The prices for cleanser products, including over-the-counter, health sectors and virtual through official online purchasing websites, such as Amazon, Shopee and Lazada.

_____

Previous primary outcome(s):

1. Changes in translucency and colour of retainer polymer are measured using a spectrophotometer at baseline and 6 months
2. Changes in surface roughness of the retainer polymer are measured using a profilometer at baseline and 6 months
3. Changes in the flexural strength of the retainer polymer are measured using a universal testing machine at baseline and 6 months
4. Comparison of prices for the thermoplastic retainer cleansing agents (Toothpaste, Retainer Brite, and Tap water) is measured using a monthly price survey. The prices for cleanser products, including over-the-counter, health sectors and virtual through official online purchasing websites, such as Amazon, Shopee and Lazada.

Key secondary outcome(s))
Surface roughness of the retainer polymer is measured by qualitative imaging using scanning electron microscopy (SEM) at baseline and 6 months

Completion date
19/03/2027

Eligibility

Key inclusion criteria
1. Orthodontic patients who have completed treatment with a fixed appliance and are to be fitted with a thermoplastic retainer
2. Patients aged 18 and above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Patients who require a combination of orthodontic and orthognathic surgery
2. Medically compromised or patients who are taking any medication.
3. Patient with cognitive impairment that could affect the comprehension and behaviour
4. Smoker

Date of first enrolment
01/05/2025

Date of final enrolment
10/02/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Orthodontic Postgraduate Clinic
Faculty of Dentistry UiTM, Sungai Buloh,
Jalan Hospital
Sungai Buloh, Selangor
Malaysia
47000

Study participating centre
Orthodontic Specialist Clinic
Faculty of Dentistry UiTM, Sungai Buloh,

Jalan Hospital
Sungai Buloh, Selangor
Malaysia
47000

Sponsor information

Organisation
Universiti Teknologi MARA

ROR
https://ror.org/05n8tts92

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
UNIVERSITI TEKNOLOGI MARA

Results and Publications

Individual participant data (IPD) sharing plan

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?
Participant information sheet	Malay and English		02/05/2025	No	Yes
Statistical Analysis Plan			13/02/2026	No	No