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Brighter smiles, stronger fillings: how heating and high-power light improve dental restorations

Submission date 16/06/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/06/2026	**Overall study status** Completed	
Last Edited 17/06/2026	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Public, Principal investigator

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Additional identifiers

Study information

Scientific Title

A combined high-power light-curing and preheating protocol for class I posterior composite restorations: a 12-month randomized controlled clinical trial

Study objectives
This 12-month randomized controlled clinical trial aimed to assess whether Class I posterior composite restorations subjected to preheating and high-power curing would demonstrate superior clinical performance based on USPHS criteria.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/11/2025, Scientific and Ethical Committee in University of Diyala, College of Medicine (College of Dentistry, University of Diyala Baquba P.O. Box 78, Diyala Governorate, 32001, Iraq; +964 07721863978; info.med@uodiyala.edu.iq), ref: 2025RJK965

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Clinical performance of a specific dental restorative protocol in Class I posterior composite restorations.
From a WHO perspective, the primary conditions being addressed are:
1. Dental Caries (Tooth Decay).
2. Defective Dental Restorations (Failed or failing fillings)

Interventions
Method of Randomization:
Randomization was performed using computer-generated block randomization sequences created using Random Allocation Software (version 1.0, by Dr. Mahmoud Saghaei). The block size was fixed at four, with each block containing an equal number of participants allocated to each of the four treatment groups (1:1:1:1 ratio).

Allocation Concealment:
Allocation was concealed using sequentially numbered, opaque, sealed envelopes. The envelopes were prepared by an independent researcher who was not involved in the clinical procedures. Each envelope contained the group assignment for a specific cavity (tooth). The envelopes were opened by the operator immediately after cavity preparation and before adhesive application, ensuring that the allocation sequence remained concealed until the intervention was assigned.

Study Design:
The study employed a split-mouth design, where each patient received four Class I composite restorations in different posterior teeth. Each restoration was randomly allocated to one of four intervention groups:
• G1 (Control): Conventional incremental curing (Bluephase G2, 1200 mW/cm², 20 seconds per 2 mm increment).
• G2 (HP): High-power bulk curing (Flashmax P3, 4000 mW/cm², 3 seconds per 3 mm bulk).
• G3 (PH): Preheated composite (57°C) with conventional curing.
• G4 (PH+HP): Preheated composite (57°C) with high-power curing (Flashmax P3, 3 seconds).

Randomization Sequence Generation:
The randomisation sequence was generated using a computerized random number generator with a fixed block size of four. The sequence was exported to SPSS version 28.0 for verification of randomness using a runs test.

Restorations were evaluated for seven parameters at 30 minutes, 24 hours, 6 months, and 12 months using the Modified United States Public Health Service (USPHS) criteria (marginal adaptation, fracture resistance, post-operative sensitivity, color match, surface texture, anatomical form, and secondary caries). Each parameter was rated Alpha (optimal), Bravo (acceptable), or Charlie (unacceptable). Statistical comparisons between groups employed Chi-square and Fisher Exact tests, while intra-group temporal changes were analyzed using the Friedman test at 1. T_0 Baseline (30 minutes), 2. T_1 24 hours (1 day), 3. T_2 6 months (180 days) and 4. T_3 12 months (365 days) (Primary endpoint).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Marginal adaptation measured using the Modified United States Public Health Service (USPHS) criteria at at baseline, 24 hours, 6 months, and 12 months

Key secondary outcome(s)

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Patients aged 18–50 years
2. With at least four molars requiring Class I restorations or presenting primary occlusal caries (ICDAS codes 4 or 5)
3. Occlusal contact with the antagonist tooth

4. A minimum prepared cavity depth of 3 mm
5. Vital or endodontically treated teeth with a positive prognosis
6. Good overall health (ASA I or II)

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
47

Key exclusion criteria
1. Systemic illness
2. Pregnancy
3. Breastfeeding
4. Untreated periodontal disease with mobility
5. Severe bruxism
6. Caries extending beyond the occlusal surface
7. Pulp exposure or imminent risk thereof
8. Spontaneous pain or tenderness to percussion, severe occlusal wear
9. Refusal to participate
10. Prior use of unapproved foundation materials beneath the composite

Date of first enrolment
20/02/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Iraq

Sponsor information

Organisation

University of Diyala

ROR
https://ror.org/01eb5yv70

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			17/06/2026	No	No
Participant information sheet			17/06/2026	No	Yes
Protocol file	version 1.0	22/10/2025	17/06/2026	No	No
Statistical Analysis Plan	version 1.0	22/04/2026	17/06/2026	No	No