Study Protocol

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

Protocol Version: 1.0
Date: [Insert Current Date]
Registration: ISRCTN (Pending)
Ethical Approval: 2025RJK965 (22 October 2025)

1. Study Identification

Item	Details
Protocol Title	A combined high-power light-curing and preheating protocol for class I posterior composite restorations: A 12-month randomized controlled clinical trial
Short Title	Thermal-Light Protocol for Posterior Composites
Study Design	Prospective, randomized, split-mouth, triple-blinded (patient, examiner, statistician), controlled clinical trial
Study Duration	12 months (with evaluations at 30 minutes, 24 hours, 6 months, and 12 months)
Setting	Operative Dentistry Clinic, College of Dentistry, University of Diyala, Iraq

2. Investigators and Affiliations

Role	Name	Affiliation
Principal Investigator	Rabeia J. Khalil	Department of Clinical Sciences, College of Dentistry, University of Diyala, Iraq
Co-Investigator 1	Hiba Faiq Jumma	Ministry of Health, Diyala Health Directorate.
Co-Investigator 2	Abdulhameed salim Al Taie	Ministry of Health, Diyala Health Directorate.

3. Abstract

Background: Despite continuous improvements in resin composite materials and polymerization methods, achieving ideal marginal adaptation and sustained clinical success in posterior restorations remains difficult. The combination of composite preheating with high-power light-curing may produce synergistic benefits, though clinical trials examining this approach remain limited.

Objective: 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.

Methods: Forty-nine patients received four Class I composite restorations each, randomly allocated to four groups: conventional incremental curing; high-power bulk curing; preheated composite with conventional curing; and preheated composite with high-power curing. Restorations were evaluated at 30 minutes, 24 hours, 6 months, and 12 months.

Expected Outcomes: The combined protocol is expected to demonstrate superior marginal adaptation, reduced postoperative sensitivity, and improved surface characteristics compared to conventional methods.

4. Introduction and Rationale

4.1 Background

Resin-based composites (RBCs) are widely used in restorative dentistry. However, achieving optimal marginal adaptation and long-term clinical success in posterior restorations remains challenging due to polymerization shrinkage, microleakage, and hydrolytic degradation of the adhesive interface.

4.2 Rationale

Preheating composite resin reduces viscosity and improves adaptability to cavity walls. High-power light-curing devices achieve a higher degree of conversion and superior depth of cure in reduced time. The combination of these two techniques may produce synergistic benefits. However, randomized controlled trials evaluating this combined approach are lacking.

4.3 Research Gap

No previous study has evaluated the combined effect of composite preheating (57°C) and high-power curing (Flashmax P3, 4000 mW/cm^2) on the clinical performance of Class I posterior composite restorations using standardized USPHS criteria over a 12-month period.

5. Study Objectives and Hypotheses

5.1 Primary Objective

To evaluate the 12-month clinical performance of Class I posterior composite restorations subjected to a combined preheating (57°C) and high-power light-curing protocol, assessed using modified USPHS criteria.

5.2 Secondary Objectives

1. To compare marginal adaptation between the combined protocol and conventional curing methods.
2. To evaluate postoperative sensitivity in preheated groups versus non-preheated groups.
3. To assess color match, surface texture, and anatomical form retention.
4. To evaluate fracture resistance and secondary caries incidence.
5. To determine the survival rate of restorations at 12 months.

5.3 Hypotheses

Null Hypothesis (H_0): There is no significant difference in the clinical performance of Class I posterior composite restorations between the combined protocol (preheating + high-power curing) and conventional curing methods.

Alternative Hypothesis (H_1): The combined protocol (preheating + high-power curing) results in superior clinical performance compared to conventional curing methods.

6. Study Design

Feature	Description
Design Type	Prospective, randomized, split- mouth, triple -blinded, controlled clinical trial
Randomization	Computer-generated block randomization (block size = 4)
Allocation Concealment	Sequentially numbered, opaque, sealed envelopes
Blinding	Triple-blinded (patient, examiner, statistician); operator unblinded
Control	Active control (conventional incremental curing)
Assignment	Single assignment (split-mouth design)
Unit of Randomization	Each restoration (cavity) within each patient
Primary Endpoint	12 months

7. Study Population

7.1 Target Population

Adult patients aged 18-50 years requiring Class I restorations in permanent molars.

7.2 Sample Size

Parameter	Value
Minimum required (power analysis)	45 patients (180 restorations)
Actual enrollment	49 patients (196 restorations)
Restorations per patient	4
Groups	4 groups
Restorations per group	49

Sample Size Justification: G*Power software (α = 0.05, β = 0.80, effect size = 0.30) indicated 45 patients were required. To account for 10-15% dropout, 49 patients were enrolled.

7.3 Inclusion Criteria

- Age between 18 and 50 years
- Presence of four molars requiring Class I restorations or having primary occlusal caries (ICDAS codes 4 or 5)
- Occlusal contact with antagonist tooth
- Minimum prepared cavity depth of 3 mm
- Vital or endodontically treated teeth with positive prognosis
- Good overall health (ASA I or II)
- Willingness to participate and sign informed consent
- Availability for all scheduled recall visits

7.4 Exclusion Criteria

- Systemic illness, pregnancy, or breastfeeding
- Untreated periodontal disease with tooth mobility
- Severe bruxism (atypical wear patterns, abfractions, dental fractures)
- Caries extending beyond occlusal surface
- Pulp exposure or imminent risk of pulp exposure
- Spontaneous pain or sensitivity to percussion
- Severe occlusal wear

- Refusal to participate
- Prior use of unapproved foundation materials beneath the composite

8. Interventions

8.1 Group Allocation

Group	Description
G1 (Control)	Conventional I ncremental curing (Bluephase G2, 1200 mW/cm^2, 20s per 2mm increment)
G2 (HP)	High-power bulk curing (Flashmax P 3, 4000 mW/cm^2, 3s per 3mm bulk)
G3 (PH)	Preheated composite (57°C) with conventional curing
G4 (PH+HP)	Preheated composite (57°C) with high-power curing (Flashmax P3, 3s)

8.2 Materials

Material	Manufacturer	Composition
Ortho Etching Gel	GC, USA	37% phosphoric acid
ESPE SINGLE BOND UNIVERSAL (5ML)	3M, Germany	MHP Phosphate Monomer, MDP Phosphate Monomer, Dimethacrylate resins
A'CHORD composite resin	G-ænial™, Tokyo, Japan	Full-Coverage Silane Coating (FSC), High Performance Pulverized CERASMART® (HPC) fillers
Blue phase light cure G2	Ivoclar Vivadent, Liechtenstein/Switzerland	1200 mW/cm^2
Flash max P3	CMS dental, Denmark	4000 mW/cm^2

8.3 Clinical Procedure

Step 1: Cavity Preparation

- Local anesthesia (2% Lidocaine, 1:100,000 Epinephrine) as needed
- Rubber dam isolation
- Cavity preparation using diamond burs with copious water cooling
- Standardized Class I cavity (3 mm depth, following fissures and pits)

Step 2: Selective Enamel Etching

- 37% phosphoric acid applied to enamel margins for 15 seconds
- Rinsed thoroughly for 20 seconds
- Gentle air drying

Step 3: Adhesive Application

- Single Bond Universal applied with microbrush for 20 seconds
- Gentle air spraying for 5 seconds
- Light-curing for 20 seconds

Step 4: Flowable Composite Liner

- 0.5 mm layer of flowable composite (G-ænial Flo X)
- Light-cured for 20 seconds

Step 5: Composite Placement

- **G1:** Incremental (2mm layers, 20s cure each) at room temperature
- **G2:** Bulk (3mm, 3s cure) at room temperature
- **G3:** Preheated (57°C) + incremental (2mm layers, 20s cure)
- **G4:** Preheated (57°C) + bulk (3mm, 3s cure)

Step 6: Finishing and Polishing

- Two-step polishing system (pre-polishing and high-gloss silicone rubs)
- Twist brushes (spiral flex brush)
- Occlusal check with articulating paper

9. Outcomes

9.1 Primary Outcome

Outcome	Assessment Tool	Time Point
Marginal Adaptation	Modified USPHS criteria (Alpha, Bravo, Charlie)	12 months

9.2 Secondary Outcomes

Outcome	Assessment Tool	Time Points
Fracture Resistance	Modified USPHS criteria	6, 12 months
Post-operative Sensitivity	Modified USPHS criteria	30 min, 24h, 6, 12 months
Color Match	Modified USPHS criteria	6, 12 months
Surface Texture	Modified USPHS criteria	6, 12 months
Anatomical Form	Modified USPHS criteria	6, 12 months
Secondary Caries	Modified USPHS criteria	6, 12 months
Restoration Survival	Kaplan-Meier survival analysis	12 months

9.3 USPHS Criteria (Modified)

Rating	Meaning
Alpha (A)	Optimal clinical condition (best score)
Bravo (B)	Clinically acceptable
Charlie (C)	Clinically unacceptable (failure)

10. Assessment Schedule

Time Point	Description	Assessments
T_0 (Baseline)	30 minutes after placement	All USPHS criteria
T_1	24 hours	All USPHS criteria (focus on sensitivity)
T_2	6 months	All USPHS criteria
T_3 (Primary Endpoint)	12 months	All USPHS criteria (primary analysis)

11. Statistical Analysis

11.1 Statistical Tests

Outcome Type	Statistical Test
Categorical variables (USPHS ratings)	Chi-square test
Small sample categories	Fisher's Exact test
Intra-group changes over time	Friedman test
Survival analysis	Kaplan-Meier with Log-Rank test
Pairwise comparisons	Post hoc with Bonferroni correction

11.2 Significance Level

$\alpha = 0.05$

11.3 Software

- SPSS version 28.0
- G*Power version 3.1.9.6 (for sample size estimation)

12. Ethical Considerations

- **Ethical Approval:** Institutional Review Committee, College of Medicine, University of Diyala (Approval No. 2025RJK965; dated 22 October 2025)

- **Declaration of Helsinki:** Study conducted in accordance with the World Medical Association's Code of Ethics
- **Informed Consent:** Written informed consent obtained from all participants
- **Confidentiality:** All patient data anonymized and coded
- **Participant Rights:** Participants informed of study goals, methods, risks, and benefits
- **Voluntary Participation:** Participants free to withdraw at any time without consequences

13. Data Management and Monitoring

Aspect	Description
Data Collection	Standardized forms with unique patient codes
Data Storage	Secure, password-protected database
Data Analysis	Performed by blinded statistician
Missing Data	Intent-to-treat analysis for dropouts
Adverse Events	All postoperative complications recorded and reported

14. Dissemination

- **Publication:** Results will be submitted to a peer-reviewed dental journal
- **Presentation:** Findings will be presented at national and international conferences
- **Public Access:** Trial registered with ISRCTN for public transparency

15. Timeline

Phase	Duration
Patient enrollment and baseline assessments	Month 1-2
Restoration placement	Month 2-3
6-month follow-up	Month 9
12-month follow-up	Month 15
D ata analysis and manuscript preparation	Month 15-18

16. Declarations

Conflict of Interest: The authors declare no financial conflicts of interest.

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