

Informed Consent Form

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

Principal Investigator: Dr. Rabeia J. Khalil

Institution: College of Dentistry, University of Diyala, Iraq

Please initial each box

	Statement
☐	I confirm that I have read and understood the Participant Information Sheet dated [Insert Date] for the above study.
☐	I have had the opportunity to consider the information, ask questions, and have received satisfactory answers.
☐	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my dental care being affected.
☐	I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from the research team, regulatory authorities, or the ethics committee, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
☐	I agree to my dentist being informed of my participation in this study.
☐	I agree to the collection and use of my data for the purposes of this research study.
☐	I understand that my data will be anonymized and kept confidential.
☐	I agree to attend follow-up appointments as required by the study (at 24 hours, 6 months, and 12 months).
☐	I agree to take part in the above study.

Participant Details

DETAILS	
PARTICIPANT NAME:	
PARTICIPANT SIGNATURE:	
DATE:	
AGE:	
GENDER:	☐ Male ☐ Female ☐ Other
CONTACT NUMBER:	

Researcher Details

DETAILS	
NAME OF PERSON TAKING CONSENT:	
SIGNATURE:	
DATE:	
ROLE:	☐ Principal Investigator ☐ Co-Investigator ☐ Research Assistant

Witness Details (If Applicable)

DETAILS	
WITNESS NAME:	
WITNESS SIGNATURE:	
DATE:	
RELATIONSHIP TO PARTICIPANT:	

Study Information for Participant

What will happen during the study?

Step	Description
1	Examination and X-rays to confirm the need for four fillings
2	Placement of four fillings using one of four methods (assigned randomly)
3	Follow-up at 30 minutes, 24 hours, 6 months, and 12 months
4	Assessment of filling quality at each visit

Treatment Groups:

Group	Description
G1 (Control)	Conventional method (standard filling technique)
G2 (HP)	High-power light curing (faster curing)
G3 (PH)	Preheated filling material
G4 (PH+HP)	Preheated material + high-power light curing

Withdrawal of Consent

I understand that I may withdraw from the study at any time without giving a reason.
If I withdraw, I understand that:

- My dental care will continue as usual
- Data collected up to the point of withdrawal may still be used for the study analysis (unless I request otherwise)

To withdraw from the study, I will:

- Contact the research team at [Phone Number] or [Email Address]
- Inform my dentist that I wish to withdraw

Storage and Use of Data

Aspect	Details
Data Collected	Dental examination findings, X-rays, filling quality assessments, patient-reported sensitivity
Data Storage	Stored securely in password-protected databases and locked filing cabinets
Data Sharing	Anonymized data may be shared with regulatory authorities or published in scientific journals
Data Retention	Data will be stored for 5 years after study completion

Complaints

If you have any concerns or complaints about this study, please contact:

Institutional Review Committee

College of Medicine, University of Diyala

Phone: [Phone Number]

Email: info.med@uodiyala.edu.iq

Copy of Consent Form

☐ I have received a copy of this signed consent form.