Statistical Analysis Plan

Statistical Analysis Plan

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
Version: 1.0
Date: 22/4/2026

1. Introduction

This document outlines the statistical analysis plan for the clinical trial evaluating the combined effect of preheating and high-power light-curing on Class I posterior composite restorations.

2. Study Objectives

2.1 Primary Objective

To compare marginal adaptation between four intervention groups at 12 months using modified USPHS criteria.

2.2 Secondary Objectives

- To compare fracture resistance between groups
- To compare postoperative sensitivity between preheated and non-preheated groups
- To compare color match, surface texture, and anatomical form
- To evaluate restoration survival at 12 months

3. Sample Size Justification

Parameter	Value
Software	G*Power (version 3.1.9.6)
Analysis Type	One-way ANOVA
Effect Size (f)	0.30 (medium effect)
Alpha (α)	0.05
Power (1-β)	0.80 (80%)
Number of Groups	4
Minimum Required	45 patients (180 restorations)

Actual Enrolled	49 patients (196 restorations)

4. Statistical Methods

4.1 Descriptive Statistics

Variable Type	Statistic
Continuous variables	Mean, standard deviation, minimum, maximum, 95% confidence interval
Categorical variables	Frequencies, percentages
Patient demographics	Mean age, gender distribution

4.2 Normality Assessment

Test	Purpose
Shapiro-Wilk test	Assess normality of continuous variables
Levene's test	Assess homogeneity of variances
Q-Q plots	Visual assessment of normality

4.3 Primary Outcome Analysis (Marginal Adaptation)

Comparison	Statistical Test
Between 4 groups at 12 months	Chi-square test
Pairwise comparisons	Chi-square test with Bonferroni correction
Control (G1) vs. Combined (G4)	Chi-square test

4.4 Secondary Outcome Analysis

Outcome	Statistical Test	Time Points
Fracture Resistance	Chi-square test	6, 12 months
Post-operative Sensitivity	Fisher's Exact test	30 min, 24h, 6, 12 months
Color Match	Chi-square test	6, 12 months
Surface Texture	Chi-square test	6, 12 months
Anatomical Form	Chi-square test	6, 12 months
Secondary Caries	Fisher's Exact test	6, 12 months

4.5 Intra-Group Analysis (Temporal Changes)

Analysis	Statistical Test	Time Points
Changes over time within each group	Friedman test	Baseline, 6 months, 12 months
Pairwise time comparisons	Wilcoxon signed-rank test with Bonferroni correction	Baseline vs. 6 months; Baseline vs. 12 months; 6 months vs. 12 months

4.6 Survival Analysis

Analysis	Statistical Test	Outcome
Cumulative survival	Kaplan-Meier	Restoration survival over 12 months
Between-group comparison	Log-Rank test	Overall difference in survival curves

Definition of Failure: A restoration is considered a "failure" if it receives a **Charlie (C)** rating for any criterion OR a **Bravo (B)** rating for marginal adaptation or fracture.

4.7 Effect Size Calculation

Effect Size Measure	Interpretation
Hedges' g	For between-group comparisons (continuous data)
Cramer's V	For between-group comparisons (categorical data)

5. Subgroup Analyses

Subgroup	Analysis
Tooth type	Molar vs. premolar
Patient age	Younger (< 35) vs. Older (≥ 35)
Operator	Operator 1 vs. Operator 2 (if applicable)

6. Missing Data Handling

Situation	Approach
Dropouts	Intention-to-treat analysis; available-case analysis
Pre-test debonded specimens	Recorded separately; excluded from mean μTBS calculation
Missed follow-up appointments	Attempt to reschedule; documented as missing

7. Software

Software	Version	Purpose
IBM SPSS	28.0	All statistical analyses
G*Power	3.1.9.6	Sample size and power calculations

8. Significance Level

Parameter	Value
Alpha (α)	0.05
Confidence Intervals	95%
Statistical Significance	$p \leq 0.05$
Bonferroni Correction	$p \leq 0.017$ (for 3 pairwise comparisons)
Highly Significant	$p \leq 0.01$

9. Reporting Standards

Standard	Compliance
CONSORT	Full compliance (flow diagram included)
USPHS	Modified criteria used for clinical evaluation
Intention-to-treat	Applied for primary analysis

10. Sensitivity Analyses

Analysis	Description
Per-protocol analysis	Excluding protocol deviations
Available-case analysis	Including all available data at each time point

11. Primary Outcome Definition

Outcome	Definition
Success	Alpha (A) rating for marginal adaptation at 12 months
Failure	Bravo (B) or Charlie (C) rating for marginal adaptation at 12 months

12. Statistical Tables

Table	Content
Table 1	Baseline characteristics of patients and groups
Table 2	USPHS scores at all time points (n, %)
Table 3	Comparison between groups (p-values)
Table 4	Intra-group changes over time (Friedman test)
Table 5	Survival analysis (Kaplan-Meier)

13. Data Presentation

Data Type	Presentation
Continuous data	Mean ± standard deviation
Categorical data	n (%)
USPHS scores	n (%) for Alpha, Bravo, Charlie
Survival data	Kaplan-Meier curves with 95% CI
Statistical results	Test statistic, degrees of freedom, p-value

14. Statistical Assumptions

Assumption	Verification
Normality	Shapiro-Wilk test
Homogeneity of variance	Levene's test
Independence of observations	Split-mouth design accounts for patient-level clustering
Proportional hazards	Log-Rank test (for survival analysis)

15. Limitations

Limitation	Mitigation
Dropout rate	Intention-to-treat analysis
Operator unblinded	Standardized protocol; blinded examiner
Single center	May limit generalizability
Single composite material	Results may not apply to other composites

Statistical Analysis Plan Prepared By: Rabeia Jasim Khalil
Date: 25/4/2026

Approved By: Ass.Prof. Faiq Hamza
Date: 30/4/2026