

PROTOCOL COVER PAGE

Protocol Official Title	<i>In vivo</i> Assessment of the Tooth-Resin Composite Interface Using Optical Coherence Tomography
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Abbreviations / Definitions

- OCT/ Optical Coherence Tomography
- FDI/ World Dental Federation
- USPHS/ United States Public Health Service
- Class I/ one-surface fissure caries or restoration
- OCT/ Optical Coherence Tomography
- ICDAS/ International Caries Detection and Assessment System
- UMN/ University of Minnesota
- SOD/School of Dentistry
- OHCRC/ Oral Health Clinical Research Center
- CTSI/ Clinical and Translational Science Institute

1.0 Objectives

The study aims to compare the short-term marginal integrity of two preparation techniques for Class I composite restoration using two visual assessment techniques, the FDI World Dental Federation and the US Public Health Service assessment criteria. In addition, Optical Coherence Tomography (OCT) will be used to assess the marginal integrity of the composite restoration.

2.0 Background

2.1 Research Question

A recent review of clinical studies published on the performance of posterior composite restorations that were recalled at least up to 24 months reported that the overall failure rate for studies conducted between 2006-2016 was 13.13% and the two main reasons for failure in these two decades remained the same, i.e. **secondary caries** (25.68% - 29.47%) and **composite fracture** (28.84% - 39.07%).¹ In *in vitro* studies, secondary caries has been attributed to interfacial gap or marginal defect both of which are consequences of polymerization contraction stresses. However, to date, **no clinical study** has been able to directly establish a link between these stresses (and its consequences) to secondary caries.²

World Dental Federation (FDI) and the United States Public Health Service (USPHS) clinical assessment criteria are the two main systems used to evaluate dental restorations in clinical trials.^{3,4} Both systems are designed to evaluate different properties of a restoration and properties about marginal integrity have been reported to be the most frequent properties investigated of a resin composite restoration. The grading descriptions for these properties are subjective and the discrimination between grading and between properties (especially between marginal stains and secondary caries) is problematic.⁵

Reasons for the lack of such a link are the discriminative deficiency of the clinical visual evaluation systems, the FDI and USPHS assessment criteria, and the ethical dilemma of restoration removal to assess for the presence or absence of secondary caries. It has been long acknowledged that an objective clinical measuring tool and new clinical study designs for secondary caries are needed to further the understanding of secondary caries initiation and progression and how these relate to the marginal integrity of dental restorations. This brings forth the need for a sensitive yet clinically applicable assessment method for interfacial debonding and demineralization.

Optical coherence tomography (OCT) is an optical, nondestructive, and clinically applicable technique that uses near-infrared waves to provide cross-sectional images of structures. It is regarded as a standard-of-care equipment in ophthalmology and its clinical application has recently expanded to cardiology and dermatology.^{6,7} In dentistry, it has been used intra-orally in clinical trials to detect and quantify enamel demineralization and to detect mucosal and submucosal lesions.⁸⁻¹¹ Optical coherence tomography has been used to assess the performance of dental adhesives in a 12-month *in vivo* trial on non-carious cervical lesion¹². The authors reported that OCT outcome measures detected significant differences between groups while visual assessments did not. Hence supplementing the two visual assessment techniques with OCT outcome measures is expected to increase the sensitivity of short-term interfacial debonding and demineralization changes.

2.2 Preliminary Data

Figure 1 shows an unpublished *in vitro* 3D scan of a composite restoration placed at the cervical region of a tooth. The walls and floor of the restoration and defects inside the bulk of the restoration can be observed. The top view and various cross-sections (B-scans) of the 3D scan shown in Figure 1 are presented in Figure 2a and Figure 2b – 2d respectively.

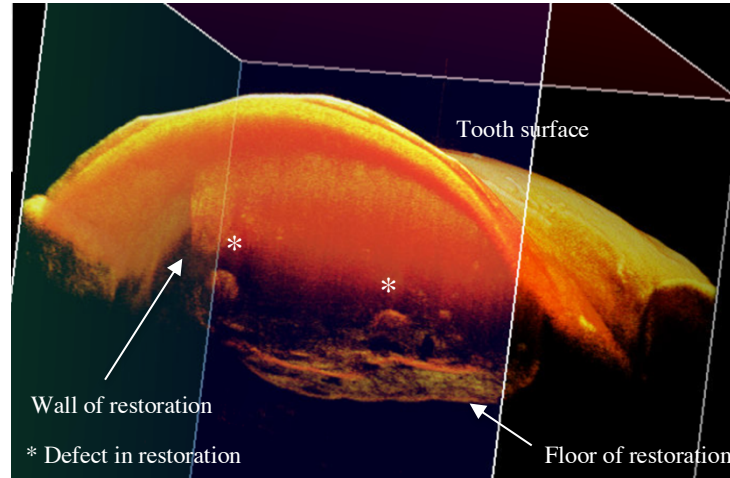


Figure 1 : 3D render of a composite restoration placed at the cervical region of a tooth.

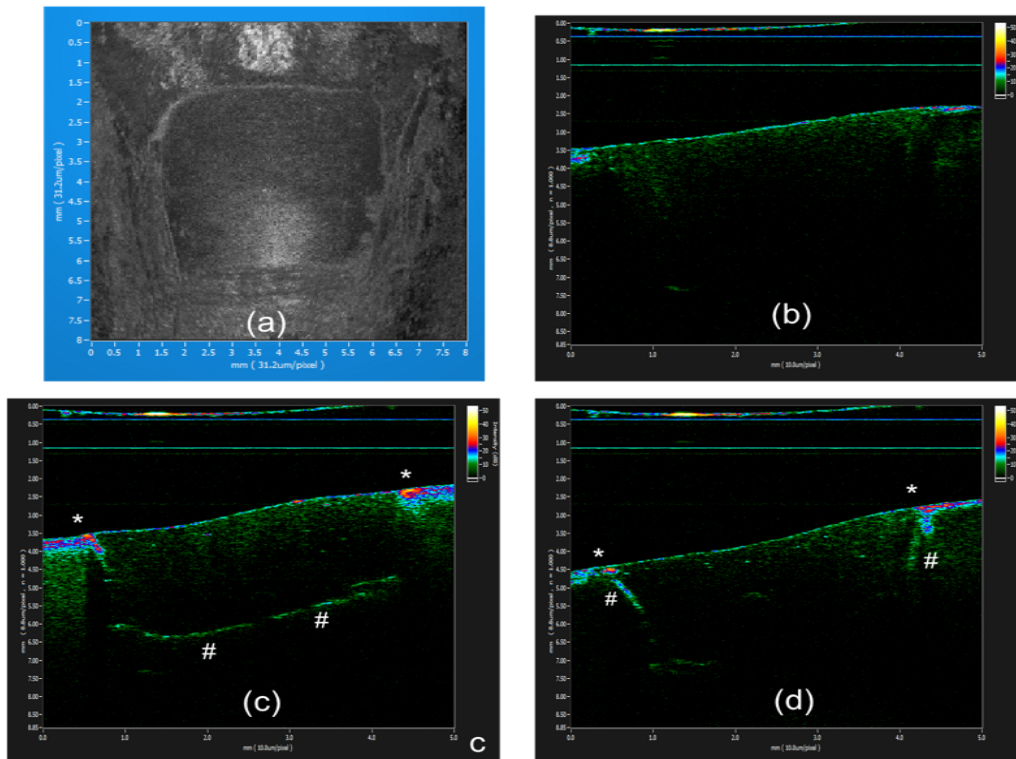


Figure 2: OCT scans of a composite restoration.

(a) is an OCT *en face* view of a composite restoration showing the outline of the restoration. (b), (c) and (d) are OCT cross section views of the composite restoration.

(b) No increased backscatter was observed at margin or the wall of the restoration.

(c) Increased backscatter observed at the margin of the restoration (*) and at cavity floor (#)

(d) Increased backscatter observed at the margin of the cavity (*) and cavity wall (#)

* indicates presence of demineralization and # indicates presence of debonding

2.3 Existing Literature

OCT, attached with a grip-type probe, has been used in dental clinical trials either to identify oral mucosal lesions or to qualitatively measure the extent of demineralization of dental caries.^{9,11,13} The capability of OCT in identifying and quantifying marginal defects and interfacial debonding around resin composite restorations has been demonstrated and verified *in vitro*. Park et al reported that OCT, when validated against light microscopy, detected 79.5% of the total gap lengths at the enamel interface.¹⁴ Bista et al reported a high correlation ($r=0.96$) between OCT and confocal microscopy measurements of sealed tooth-adhesive interface.¹⁵ Tabata et al demonstrated that SS-OCT can be used to detect enamel cracks at the margins of composite restorations noninvasively.¹⁶ It is worth noting too that it was also used to study the development of interfacial gap at the resin-tooth interface in real time. Thus, OCT outcome measures can provide objective and quantitative data for marginal gap and interfacial debonding and demineralization around dental composite restorations *in vivo*.

3.0 **Study Outcome Measures**

3.1 Primary Outcome Measures

The study's primary outcome measures include the following:

Evaluation and comparison of the short-term marginal integrity, up to 18-months, of two Class I composite preparation techniques using the FDI World Dental Federation and US Public Health Service criteria for marginal integrity of dental composite restorations.

Primary assessment endpoints

1. Marginal staining – FDI³ and USPHS⁴ criteria
2. Marginal irregularities – FDI³ and USPHS⁴ criteria

3.2 Secondary Outcome Measures

Evaluation and comparison of the short-term marginal integrity, up to 18-months, of two Class I composite preparation techniques using OCT backscattered intensity outcome measures for marginal integrity.

1. Elevated OCT reflectance of the occlusal cavosurface angle.
2. Elevated OCT reflectance along tooth-restoration interface.
3. Diminished OCT reflectance along tooth-restoration interface.

4.0 **Study Interventions**

The preparation will subsequently be followed with either of the following techniques:

4.1 Group 1

Lesion-specific cavity design with 90° cavosurface angle throughout the cavity margins.

4.2 Group 2

Lesion-specific cavity design with wide bevels throughout the cavity margins.

The cavity preparations in both groups were restored with a bulkfill resin composite (3M Filtek™ One Bulk Fill Restorative)

5.0 Study Population

Convenience sampling of 36 participants that meet study criteria and consent to participate in the study were recruited into the study. Please refer to Section 5.2 for participant recruitment and screening procedures. The participants were randomized into one of the two groups at the stage of restoration placement.

5.1 Inclusion Criteria:

Patient Level Inclusion Criteria

1. 18 years or older
2. Good general health
3. Fair oral hygiene
4. At least 20 teeth in occlusion
5. Available for the duration of the study

Tooth-level inclusion Criteria:

1. Participants with occlusal caries lesion/s in permanent posterior dentition except wisdom teeth
2. Caries lesion can be primary or secondary caries.
3. Caries lesion is in the International Caries Detection and Assessment System (ICDAS) 4 or 5 category.
4. The extent of the caries lesion bucco-lingually is likely not to exceed two-thirds of the occlusal table.
5. The selected tooth must be able to be isolated with either rubber dam or other isolation technique during clinical procedure.
6. The selected tooth must have an opposing antagonist.
7. The selected tooth should be periodontally healthy.

5.2 Exclusion Criteria:

Patient-level exclusion criteria:

1. Signs of bruxism

Tooth-level exclusion criteria:

1. Wisdom teeth
2. Present with irreversible pulpitis.
3. Periodontally compromised tooth that may require extraction.
4. Caries lesions that would require cuspal coverage.

6.0 Study Flow

6.1 Study Design

This study is a randomized single-blind clinical trial and followed the Consolidated Standards of Reporting Trials (CONSORT) statement.

Each participant received only one composite restoration and the participants were blinded to the type of preparation technique used. The study dentist who completed the restoration was not blinded to the preparation technique because the form (shape) of the two types of preparations is distinctly different. However, the restoration evaluators will be blinded to the preparation design.

A HIPAA-compliant and browser-based electronic capture software, REDCap, was used for consent taking and research data recording and storage, including intraoral digital photographs. All data remained within REDCap and access was restricted to authorized personnel only. OCT scans were de-identified prior to uploading into BOX storage and linked to data in REDCap through study participant ID.

6.2 Screening Procedures

A UMN CTSI data pull, housed in a data shelter, was generated as a random query. A preliminary data screening was conducted by the PI using the random order provided and a preliminary list of patients that satisfy the Patient- and Tooth-level inclusion criteria was created. The patients were contacted via telephone to invite them to be a part of the study. If interested, a telemeeting was scheduled with a trained team member.

The telemeetings were conducted via Zoom and study information was shared with the potential participants using Microsoft PowerPoint slides and any arising questions arising were answered. For participants who did not have access to the internet or were able to devise access, they were called on a phone line. At the end of this telemeeting, an in-person screening appointment was scheduled for interested participants, and a packet containing the combined consent/HIPAA form, Guidelines and Consent for Unsecured Email Correspondence for Research Participants, and the study instruction sheet were mailed to them either physically or electronically.

During the in-person screening, consent was attained from the participants. Participants were then screened to ensure that the patient-level inclusion criteria were still met, and the tooth indicated by the data pull for a Class I restoration was examined to ensure the tooth-level inclusion criteria were still met. A screening log was maintained in the data shelter. If both patient- and tooth-level inclusion criteria were still met, relevant medical history was obtained from the participants, a full-mouth dental examination was conducted and an optical impression of the teeth in the same quadrant of the tooth to be treated was taken with an intra-oral 3D scanner.

From these optical impressions, customized guides for OCT scanning were designed and 3D-printed for each participant. These scan guides ensured swift and accurate positioning of the OCT intraorally whereby the buccal, occlusal and lingual surfaces of the tooth are included in the 3D scans and the occlusal surface within the focal range of the OCT. The scan guides also minimized motion artifacts and enabled scanning of the teeth in the same orientation across all time points.

6.3 Dental Restoration Procedure

Participants were randomized into one of two groups using a randomization module incorporated in REDCap. Participants and evaluators were blinded to the assignment, but the study dentist was not.

Prior to scanning with OCT, the participants were instructed to brush their teeth. The fit of the OCT scan guide was then checked and adjusted if needed. Once the scan guide was properly positioned on the tooth that required restoration, excess saliva was removed using pressurized air. Next, the OCT intraoral probe was inserted into place, and pre-operative 3D OCT scans of the tooth were conducted. The scan rate was 20KHz and the scans took approximately 3-5 seconds depending on the size of the tooth. Laser safety glasses were worn by the participant and the operator.

The restorations for both groups were placed by one study dentist. Pre-operative occlusal contacts on intercuspal position and lateral excursions were marked with an articulating film and recorded. Local anaesthesia was then administered, and quadrant isolation was achieved with rubber dam. The Selective Caries Removal method was used in all cases except for cases where caries encroaches into the inner third of dentin, whereby the Partial Caries Removal method was performed. The Partial Caries Removal method was followed by lining of the pulpal floor with a thin layer of Dycal as an indirect pulp-cap material and light-cured glass ionomer (3M Vitrebond).

The cavity preparations were subsequently followed with either of the following techniques:

Group 1 - Lesion-specific cavity design with 90° cavosurface angle throughout the cavity margins; Group 2 - Lesion-specific cavity design with wide bevel throughout the cavity margins was prepared. When cavity preparation is completed, the preparations in both groups were etched a 32% by weight phosphoric acid (3M Scotchbond™ Universal Etchant) on enamel and dentine for 15 seconds. After that, the etchant was rinsed away and an adhesive (3M Scotchbond™ Universal Adhesive) was applied on dentine and enamel with a microbrush for 20 seconds. The adhesive was light-cured for 10 sec with a curing light. Subsequently the preparation was restored in with a pre-warmed (using Bioclear Heatsync Kit) with a bulkfill resin composite (3M Filtek™ One Bulk Fill Restorative) and cured for 20 seconds according to the manufacturer's recommendation. The restorations were finished immediately with fine diamond burs and Sof-Lex XT coarse aluminum oxide disks (3M Oral Care). Polishing was carried out with the Sof-Lex Diamond Polishing System (3M Oral Care).

A post-operative 3D OCT scan of the restoration and the tooth was done using the same method as described above. Marginal integrity and staining of the restorations were evaluated using the FDI SQUACE criteria and the USPHS criteria. An intraoral digital photograph of the restoration was also taken.

6.4 Six-month Evaluation appointment

Marginal integrity of the restorations and post-operative sensitivity were evaluated using the FDI SQUACE criteria and the USPHS criteria. An intraoral digital photograph of the restoration was also taken. A 6-month follow-up 3D OCT scan of the restoration and the tooth was done using the same method as described in Section 6.3.

6.5 Eighteen-month Evaluation appointment

Marginal integrity of the restorations and post-operative sensitivity were evaluated using the FDI SQUACE criteria and the USPHS criteria. An intraoral digital photograph of the restoration was also taken. A 6-month follow-up 3D OCT scan of the restoration and the tooth was done using the same method as described in Section 6.3. In addition to these, a single bite-wing digital radiograph was obtained during the appointment.

7.0 **Withdrawal of Participants**

Participants could withdraw at any time during the study. If the participant wished to withdraw, they were thanked, advised that data already provided was maintained and the participant was withdrawn from the study with no effect on their continued relationship with the UMN and UMN SOD.

8.0 **Risks to Participants**

The dental composite restoration procedure is considered standard of care and includes standard procedures that are involved in the provision of a dental restoration and hence considered of minimal risk. In addition, participant wore a scan guide during OCT scanning and the process took between 3 – 5 seconds.

9.0 **Data Analysis**

9.1 Power Analysis:

Sample size calculation was based on the clinical success rate of posterior class I composite restoration observed in a previous study [16]. Using a significance level of 0.05, power of 80%, and equivalence limit of 15%, the sample size required was 10 restorations per group. However, as the restorative technique of this study is different from the previous study [16], the number of restorations was increased to 15 per group and to account for potential dropouts, the sample size was further increased to 18 per group.

9.2 Statistical Analysis

Descriptive analysis of the FDI criteria, USPHS criteria and OCT outcome measure for marginal defects for each group was performed.

For comparison between groups with FDI and USPHS criteria, the Mann-Whitney test was used, all with $\alpha = 0.05$.

For comparison between groups with OCT outcome measure, the Shapiro-Wilk test was used to determine the distribution of the data and it was found the data was not normally distributed. Hence the non-parametric Mann-Whitney test was used to compare the prevalence of the three OCT outcome measures of the two groups.

10.0 Results

10.1 Descriptive

Thirty-six restorations were placed in premolars and molars. In total, 2 recalls (6-months 18 - months) were performed after baseline assessment. There were 3 dropouts at the 6 months follow up yielding a dropout rate of 8.3%. Reasons for dropping out was moving to another city.

10.2 Marginal Staining (Primary Outcome Measure 1)

No marginal staining was observed with either the USPHS (Table 1) or FDI (Table 2) criteria, in any of the restorations of either group for all three time points (Table 3). Hence statistical analysis was not performed.

Table 1 - USPHS Criteria for Marginal Staining

Score	Criteria
A	None
B	Superficial staining (removable, usually localized).
C	Deep staining (not removable, generalized).

Table 2 - FDI Criteria for Marginal Staining

Score	Category	Criteria
1	Clinically excellent	No marginal staining.
2	Clinically good	Minor marginal staining, easily removable.
3	Clinically satisfactory	Moderate marginal staining, not aesthetically unacceptable.
4	Clinically unsatisfactory	Pronounced marginal staining, major intervention necessary.
5	Clinically poor	Deep marginal staining, not accessible for intervention.

Table 3 – Clinical evaluation of marginal staining at baseline, 6- and 18-months follow-up.

Time point	Group	No of Participant	FDI Criteria (SQUACE)					USPHS criteria		
			1	2	3	4	5	A	B	C
Baseline	1	18	100	0	0	0	0	100	0	0
	2	18	100	0	0	0	0	100	0	0
6 months	1	16	100	0	0	0	0	100	0	0
	2	17	100	0	0	0	0	100	0	0
18 months	1	14	100	0	0	0	0	100	0	0
	2	13	100	0	0	0	0	100	0	0

10.3 Marginal Irregularities (Primary Outcome Measure 2)

With the USPHS criteria (Table 4), the margins of the restorations in both groups were scored as A, i. e., undetectable irregularities, at baseline, 6-months and 18-months follow-up.

With the FDI criteria (Table 5), the restoration margins of both groups were observed to be either excellent or good, i. e., either Score 1 or 2 (Table 6). No restorations were scored higher than 2 at all three time points. At Baseline, both groups have approximately similar percentages of restorations with Score 1 and 2. However, more restorations in Group 2 demonstrated longer lengths of Score 2 (10 - 20% of the perimeter length).

The Mann-Whitney U test was used to compare the prevalence of Score 1, Score 2a (<10% of the perimeter length) and Score 2b (10 – 20 % of the perimeter length) between the two groups. There were no statistically significant differences ($P > 0.05$) of the prevalence of the FDI Scores 1 and 2 between the two groups at baseline, 6-months and 18-months follow-up.

Table 4 - USPHS Criteria for Marginal Adaptation / Irregularities

Score	Criteria
A	Undetectable.
B	Detectable. (V-shaped defect in enamel only or catches explorer going both ways).
C	Detectable. (V-shaped defect to DEJ).

Table 5 - FDI Criteria for Marginal Irregularities

Score	Category	Criteria
1	Clinically excellent	Harmonious outline, no gaps or white lines
2	Clinically good	Slight ditching, slight step, flashes or minor irregularities.
3	Clinically satisfactory	Multiple or major irregularities, ditching, flashes or steps.
4	Clinically unsatisfactory	Larger irregularities or steps. Repair necessary.
5	Clinically poor	Filling is complete- or partially loose but in situ.

Table 6 – Percentage of restoration in each group, with the respective FDI and USPHS scores for marginal irregularities, at baseline, 6- and 18-months follow-up.

Time point	Group	No of Participant	FDI Criteria (SQUACE)						USPHS criteria		
			1	2		3	4	5	A	B	C
				a	b						
Baseline	1	18	38.9	44.4	16.7	0	0	0	100	0	0
	2	18	44.4	33.3	22.2	0	0	0	100	0	0
6 months	1	16	75.0	25.0	0.0	0	0	0	100	0	0
	2	17	70.6	23.5	5.9	0	0	0	100	0	0
18 months	1	14	57.1	42.9	0.0	0	0	0	100	0	0
	2	13	53.8	30.8	15.4	0	0	0	100	0	0

a - <10 % of margin perimeter; b - 10 -20 % of margin perimeter

10.4 Patterns of OCT reflectance at the cavosurface angle and tooth-restoration interface. (Secondary Outcome Measure 1 - 3) at baseline.

Table 7 – Percentage of the perimeter of the restorations at baseline, presenting with the following three patterns of OCT reflectance.

Group	Elevated OCT reflectance at cavosurface angle	Elevated OCT reflectance at Tooth-Restoration Interface	Diminished OCT reflectance at the tooth-restoration interface
1	6.75 ± 6.36	16.20 ± 4.85	14.44 ± 4.36
2	1.56 ± 8.64	7.44 ± 5.29	18.75 ± 4.29

Mann-Whitney tests showed that there were significantly more ($P < 0.05$) elevated OCT reflectance at cavosurface angle and elevated OCT reflectance at tooth-restoration Interface debonding at the margins of the restorations in Group 1 compared to those in Group 2. There were no significant difference of the diminished OCT reflectance at the tooth-restoration interface of gaps between Group 1 and 2.

11.0 References

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