# Clinical Performance of Chairside CAD/CAM Restorations using a New Adhesive Cement

**3M ID# CR 19/03**

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## 1 Investigation Title

Clinical Performance of Chairside CAD/CAM Restorations using a New Adhesive Cement

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## 4 Summary of Objectives and Design

A wide variety of restorative materials are available for dental restorations. The most popular current materials include glass ceramics and full contour zirconia. Glass ceramic materials are generally preferred for their high translucency mimicking enamel-like esthetics of natural teeth and zirconia is preferred for high strength applications. Both of these materials are available for clinical treatment using chairside CAD/CAM technology.

The introduction of an induction sintering oven (SpeedFire oven/Dentsply Sirona) opened the opportunity for chairside full contour zirconia crowns by decreasing sintering times for zirconia to under 30 minutes. 3M Chairside Zirconia (3M) was marketed in 2019 and offers improved esthetics and high strength for monolithic zirconia restorations with an efficient processing time.

Chairside CAD/CAM restorations are generally delivered with adhesive resin cements. The cement may or not require pre-treatment of the tooth by etching or a bonding agent. This creates potential confusion for a clinician as to what the optimal material selection and treatment process should be. A new adhesive resin cement (Suglue 3/3M) is the latest generation of dual cured resin cements from 3M with the innovation to use different tooth pre-treatment options, self-etch, selective enamel etch, or total etch depending on the type of restoration. This simplifies the selection process for delivery of restorations by minimizing the amount of different materials required.

This investigation will be a longitudinal clinical trial to study the long-term clinical performance of a new adhesive resin cement for chairside CAD/CAM restorations. Lithium disilicate chairside CAD/CAM onlays (IPS emaxCAD/Ivoclar) will be adhesively bonded using a selective enamel etch technique with a new generation universal adhesive based on Scotchbond Universal Adhesive (3M) and a new generation resin adhesive cement based on RelyX Ultimate (3M). Full contour zirconia crowns (3M Chairside Zirconia/3M) will be cemented using a self-adhesive technique with the new generation adhesive cement. All restorations may be followed up to five years of service.

# 5 Specific Aims

The specific aims of this project are:

1. Evaluate the short-term post-operative sensitivity associated with a self-etching resin cement for adhesive luting of chairside zirconia crowns.

2. Evaluate the short-term post-operative sensitivity associated with the adhesive luting technique for ceramic onlays using a selective enamel etch technique and a universal adhesive and dual cure resin cement.

3. Evaluate the longitudinal clinical performance of lithium disilicate ceramic onlays and full contour zirconia crowns for up to five years of clinical service, for a minimum of 3 years. The onlays and crowns will be evaluated with FDI criteria (Hickel et al., 2007 and 2010) for esthetic properties include surface luster, surface staining, margin staining, color match and translucency; functional properties include anatomical form, material fracture, retention, margin adaptation, occlusal contour and wear, and proximal contact and contour; and biological properties include post-operative sensitivity, recurrence of caries, erosion, abfraction as well as gingival index, and plaque index.

# 6 Research Plan: Methods and Materials

## 6.1 Subjects

The patient population will be selected from current patients under clinical treatment at the University of Michigan Dental Clinics. Patients need to volunteer for the study and must sign the informed consent. Patients will be over 18 years of age, of either gender, and of any ethnic background. Each patient should have at least one carious lesion or defective restoration to be restored on a maxillary or mandibular premolar or molar. Each lesion or defective restoration should exhibit sufficient size to extend at least one-half the intercuspal width of the tooth requiring an onlay or full crown restoration. The onlays may contain between one and three cusps on the selected tooth as long as an occlusal margin will be present. All teeth will test vital and be asymptomatic at the beginning of treatment. No more than two restorations will be placed per patient. If a patient presents with more than two acceptable teeth for the study, molar teeth will be included prior to premolar teeth. Exclusion criteria will include:

Devital or sensitive teeth

Teeth diagnosed with symptoms of incomplete tooth fracture

Teeth with prior endodontic treatment of any kind

Teeth with a history of direct or indirect pulp capping procedures

Subjects with uncontrolled bruxism or parafunctional habits

Subject has known allergies to any product used during this study

Subject will not be available for the study duration of 5 years

Subjects with significant untreated dental disease to include periodontitis and rampant caries

Pregnant or lactating women

### 6.2 Informed Consent

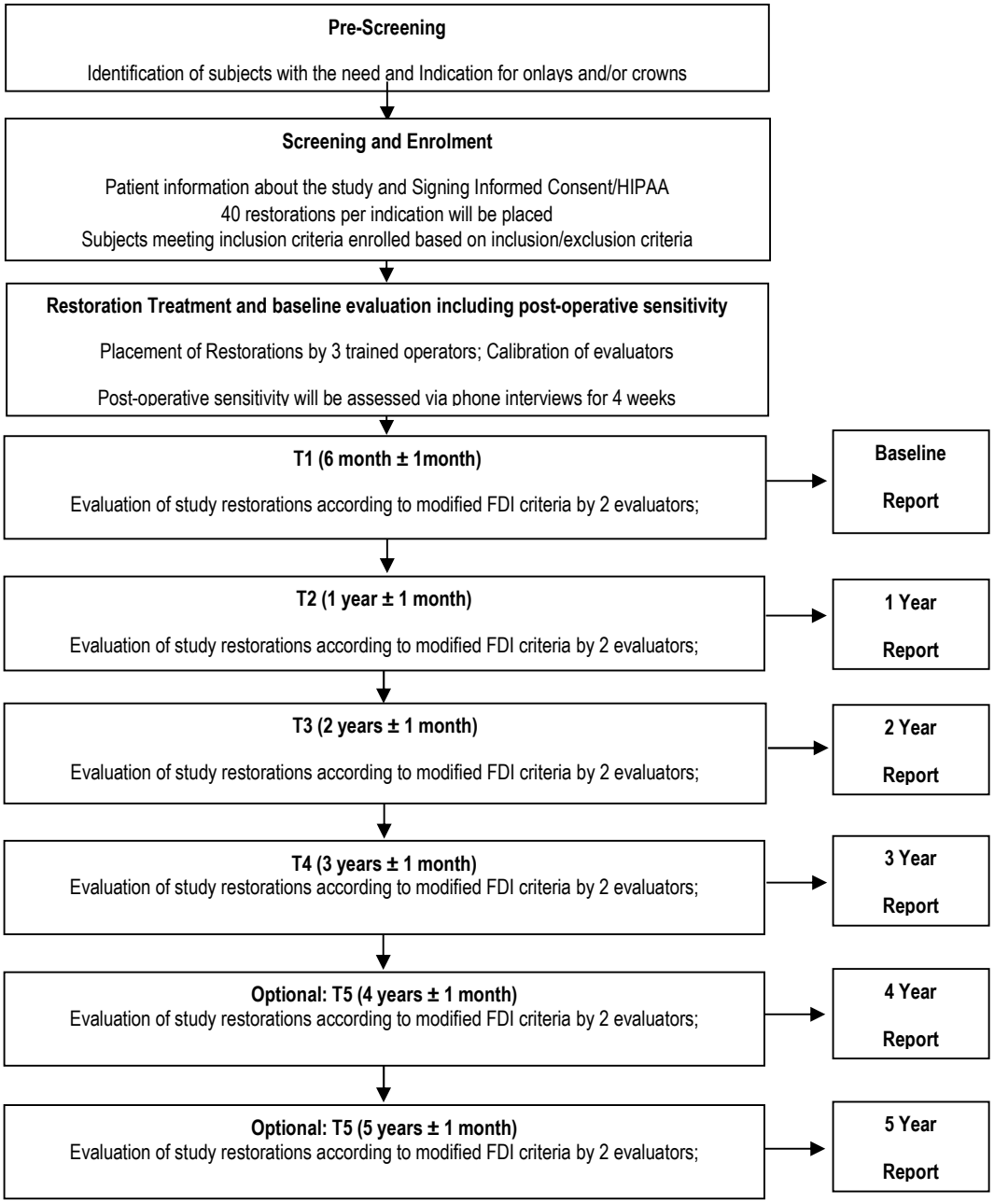
The Health Sciences Institutional Review Board of the University of Michigan must review and approve the investigation protocol. Patients can be recruited to the study as soon as the contract is finalized, and funding is provided. Patients who are eligible for the study will be screened by the Clinical Research Coordinator and fully informed of the nature of the study and the need for long-term availability. Each patient who participates in the study will sign an informed consent agreement and the originals will remain at the University. (A copy is included in the Appendix). [redacted] Patients will also receive free bitewing radiographs at the three-year recall appointment as part of routine, standard of care for monitoring dental restorations. Specific study data is not dependent on the radiographs.

After admission to the study a subject may withdraw at any time for any reason. The right of each subject to withdraw and the right of each subject to confidential treatment of personal data will be respected at all times. The PI will record any subject's withdrawal and the reason(s).

### 6.3 Study Size

There will be 40 zirconia crowns and 40 ceramic onlays placed. The sample size is according to the international standard represented by the criteria of the American Dental Association (ADA, Council on Scientific Affairs: Acceptance Program Guidelines "Restorative Materials", March 1996). 60 patients will be enrolled in the study.

### 6.4 Study Overview



### 6.5 Baseline - Restoration Placement

A pre-operative questionnaire will be completed jointly by the patient, Clinical Research Coordinator, and treating doctor at the restorative appointment (copy enclosed in Appendix). This will establish the baseline information from which to compare the responses at subsequent times. Teeth to be restored will be tested subjectively as described in the Data Collections section to follow. The level of sensitivity will be recorded using a criterion-referenced rating scale. The use of the scale will be explained to the patient prior to beginning the evaluation. A Caries Risk Assessment will be completed for each patient at baseline based on the number of restorations the patient reports having received in the previous 12 months. *Low Caries Risk* will be scored for patients having 0 or 1 restoration placed in the previous 12 months. *Moderate Caries Risk* will be scored for patients having 2 or 3 restorations placed in the previous 12 months. And *High Caries Risk* will be scored for patients having 4 or more restorations placed in the previous 12 months.

*Pre-treatment*

The shade of the tooth to be restored will be determined prior to tooth preparation with a Classic Shade guide (Vita).

*Preparation*

All restorative procedures will be performed under standard local anesthesia with no increased risks incurred by patients participating in the study beyond those involved in routine dental treatment. An Isolite System, or similar device, will be used to isolate the tooth for cavity preparation, optical imaging, and cementation of the restorations. An Optragate may also be used to retract tissues during digital imaging.

*Onlay Preparation*

The occlusal walls of the chairside CAD/CAM onlay preparation will be tapered $10^{o}$ – $12^{o}$ from the cavosurface to the pulpal floor to ensure distinct occlusal margins. The flare of the proximal boxes will conform to standard criteria with proximal walls exposed for convenience in finishing the margins. There will be no bevels on margins and all floors and walls will be relatively perpendicular to the cavosurface. Any additional design modifications will be in accord with the unique parameters of the computergraphic design software. The onlay will have a 1.5 mm

minimal thickness in the central fissure and 2.0 mm minimal thickness over functional cusps. If in the judgement of the operator, less than 1.0 mm of dentin thickness remains over the pulp, a glass ionomer base (Vitrebond/3M) may be selectively placed prior to completing the preparation.

*Crown Preparation*

The occlusal walls of the chairside CAD/CAM crown preparation will be tapered $10^{o}$ – $12^{o}$ with the axial-pulpal angles rounded. There will be no bevels on margins. Any additional design modifications will be in accord with the unique parameters of the computergraphic design software. The crown will have an axial thickness of greater than 0.8 mm, 1.0 mm minimal thickness in the central fissure, and 1.5 mm minimal thickness over functional cusps. If in the judgement of the operator, less than 1.0 mm of dentin thickness remains over the pulp, a glass ionomer base (Vitrebond/3M) may be selectively placed prior to completing the preparation.

*Restoration Fabrication*

The manufacturer's instructions will be strictly adhered to in the imaging, design, and manufacturing of the onlays and crowns using the CEREC system (Dentsply Sirona). Following imaging of the tooth preparation with the CEREC PrimeScan, the onlay or crown will be designed using the CEREC software (5.0). The onlays will be milled from prefabricated blocks of IPS emaxCAD (Ivoclar), a lithium disilicate ceramic. They will be stained, glazed and crystallized per manufacturer's instructions to create the final contour and finished surface. The crowns will be milled from prefabricated blocks of 3M Chairside Zirconia (3M) and then sintered in the SpeedFire oven (Dentsply Sirona) per manufacturers guidelines. The crowns will be hand polished to create the final contour and finished surface prior to restoration delivery.

*Crown Cementation*

Once the crown is ready is for cementation, the internal surface of the crown will be cleaned with air/water spray and air dried with oil-free air.

All of the zirconia crowns will be cemented with a dual cure resin cement, Suglue 3 (3M). Suglue 3 is the latest generation of dual cure adhesive resin cement based on the previously marketed RelyX Unicem 2/RelyX Ultimate adhesive cement chemistry. The internal surfaces of the zirconia crown will be air abraded with 30 μm aluminum oxide (CoJet sand/3M) at a pressure

of 30 psi to create a uniform, matte surface. The crown will be cleaned with alcohol, rinsed with water, and dried with oil-free air.

The cavity preparation will be thoroughly cleaned with water spray for 10 seconds and dried carefully with care taken to prevent over-drying the preparation leaving a glossy surface to the tooth. Suglue 3 Cement will be injected directly into the crown from the automix syringe. The crown will be inserted to complete seating and the excess cement removed. The crown will be light cured for 10 seconds from the facial, lingual and occlusal for a total cure of 30 seconds.

*Onlay Cementation*

The PVS replica technique will not be used for the onlays since onlay preparations are not as uniform as crown preparations with inconsistent areas for measurement between onlays. The internal surfaces of the IPS emaxCAD onlays will be etched for 20 seconds with 4.9% hydrofluoric acid gel, rinsed for 20 seconds, and then air dried with oil-free air. ADH-19 will be actively applied (scrubbed) with the disposable applicator to the etched ceramic surface for 20 seconds then lightly air dried until there is no movement and the solvent has evaporated completely.

The cavity preparation will be etched for 20 seconds with 37% phosphoric acid (Scotchbond Universal Etchant/3M), rinsed thoroughly with water, and lightly air dried leaving a moist surface that is glossy in appearance. ADH-19 is the latest generation of universal bonding agents from 3M based on the Scotchbond Universal Adhesive (3M) chemistry. A thin coating of ADH-19 universal bonding agent will be actively applied (scrubbed) with a disposable applicator and air dried until there is no movement and the solvent has completely evaporated. Suglue 3 Cement will be injected directly into the tooth preparation from the automix syringe. The onlay will be inserted into the cement to complete seating and the excess cement removed. All onlays will be light cured for 10 seconds from the facial, lingual and occlusal for a total cure of 30 seconds.

Finishing and polishing will be initiated after visible light curing of the luting agent. A series of diamond finishing burs, rubber abrasive points and cups, finishing strips, and diamond polishing pastes will be used for removal of excess cement, final contouring of the restoration, and adjustment of the occlusion.

# 7 Data Collection

## 7.1 Post-Operative Sensitivity

To evaluate the immediate post-operative sensitivity, patients will be contacted by telephone once a week after the initial appointment for four weeks or until the restoration is reported asymptomatic. A criterion-referenced rating scale will be used to measure sensitivity. The phone interview will be used as a follow-up procedure to minimize recall loss as the patient is not required to return to the clinic. During the phone interview a criterion-referenced rating will be made of functional tooth sensitivity using the following scale. Patients will only be asked to return for an evaluation if they are having continued discomfort or any indication of premature occlusal contact.

Sensitivity Criteria:

1= No sensitivity is experienced at anytime

2= Slight sensitivity is experienced occasionally but it is not uncomfortable

3= Moderate sensitivity is experienced occasionally, and it is noticeably uncomfortable

4= Severe discomfort is noted routinely with cold or pressure stimulation

## 7.2 Clinical Evaluation

Two independent evaluators will examine all restorations in the study. Clinical evaluations will be made at baseline, six months, one year, two years and three years. If feasible, subjects will return for additional follow-up visits at four and five years. Evaluation criteria are based on FDI criteria (Hickel et al., 2007 and 2010) for esthetic properties include surface luster, surface staining, margin staining, color match and translucency; functional properties include anatomical form, material fracture, retention, margin adaptation, occlusal contour and wear, and proximal contact and contour; and biological properties include post-operative sensitivity, caries, gingival index, and plaque index (see Appendix for FDI criteria description). Disagreements in evaluations will be discussed between the evaluators and a consensus judgment will be reached and recorded for every criteria.

Intraoral digital color pictures at a 1:1.5 magnification will be taken to document pre-operative, cavity preparation, and post-operative conditions. Facial and occlusal views of the tooth will be documented for both the pre-operative and post-operative conditions.

A post-cementation quadrant digital scan will be made of each test restoration using the OmniCam. Digital files will be recorded at the baseline, 6 months, 1 year, 2 year and 3 year. Optionally also at 4- and 5-year recall visits. Bite-wing radiographs and periapical radiographs of each test tooth will be available preoperatively and at the three-year recall for routine, standard of care monitoring of the restorations.

### 7.3 Data Management

#### Case Report Form (CRF)

For this study, all required data will be entered into the electronic CRFs (eCRFs), by the end of each day by [redacted], the Research Clinic Coordinator at the University of Michigan. Approval is required by the principal investigator Dennis J Fasbinder. Up to 50 sets of paper copies of the CRFs may be provided to the site in the event that computer access is limited. If paper CRFs are used, they are the source data and must be entered into the eCRF by the end of each day. If study-related data are recorded for the first time directly into the eCRF, then the eCRF is the source document. Completed paper and eCRFs will be reviewed by the site monitor to ensure accuracy and consistency of subject data. Any discrepancies found during CRF review are to be clarified by the Investigator or designee.

In case paper format would need to be used the entries will be made with blue ball-point pen. In case of necessary corrections, the wrong entry will be crossed out and the new entry will be written beside it. No erasure is allowed for corrections. Changes or corrections will be dated and initialized by the investigator or assigned person(s). The documentation of each patient visit (baseline, follow-ups) must be signed and dated by the conducting investigator. If paper versions would be used the data would be directly entered into Clindex for electronic data capture by [redacted]

The completed CRFs and Adverse Events/Incident Reports will be retained together with the investigator's study file for a period of 10 years after completion of the study at the study center.

3M intends to use electronic data capture (eDC) software (Clindex) for this study. Sites will be trained on the eDC software prior to study enrollment. Each site will be provided with a manual, including instructions on how to complete the CRFs and how to make CRF corrections. Data may be recorded onto data collection sheets (provided by 3M) prior to data entry or may be entered directly into the eDC system. Once the forms are completed, the monitor will review the CRFs to assure accuracy and completeness. The Investigator must review and sign the CRFs for each subject in a timely fashion following completion.

**Adverse Event / Adverse Device Effect Form – Incident/Near Incident form**

In case of occurrence of any Adverse Event or Adverse Device Effect the appropriate form provided by 3M has to be filled in by the investigator. In case of any near incident or any event that could lead or led to any medical hazard for the investigator (user) of the investigational device the Incident/Near Incident form provided by the sponsor has to be filled in by the investigator.

Any adverse reactions to the treatment provided as part of the study will be fully investigated and recorded on the Adverse Event/Adverse Device Effect form (See Appendix), including details of the appropriate clinical action taken. An adverse event is defined as any unintended adverse experience associated with the study materials or study procedures that results in an unplanned medical assessment or treatment or changes the risk to subjects.

*Restoration Failures*

If a crown or onlay fails during the term of the study, the investigator will provide complete information on the manner of the failure and the proposed resolution to the study contact person at 3M. Failures associated with the bonding agent, cement, crowns and onlays that may be expected in this study include:

- loosening or complete loss of the crown or onlay

- fracture and/or chipping of the crown or onlay
- surface roughening or discoloration of the crown or onlay

Upon a determination that the crown or onlay failure did not result from other identifiable causes, and with 3M's prior approval, the Institution will make arrangements to replace the crown or onlay or carry out appropriate alternative treatment (i.e. replacement with a fixed or removable partial denture) at 3M's expense. 3M will not be responsible for any expenses incurred without its prior approval. If a crown or onlay fails after the term of the study, 3M will not be responsible for any costs incurred in its repair or replacement. 3M will have no responsibility for any other treatment a patient may receive during the term of the study or after the study has ended.

**Monitoring**

Monitoring visits will take place at the study center. During these visits, questions on the study conduct will be discussed and the study documentation will be reviewed. The study monitor will check whether the Clinical Investigation Plan was followed and whether the investigational device was applied according to the Instructions for use. The monitor will verify if appropriate patient consent is available for each patient and that it was included before enrolment.

Furthermore he/she will check the availability, completeness, logicalness, accuracy and legibility of certain study documents, the CRFs and the Adverse Event/Incident forms. The occurrence of any new Adverse Event/Adverse Device Effect/(near) incident will be reported in the monitoring report and copies of the forms will be collected. Certain data in the CRFs will be verified with source documents (patient files).

The study will be monitored at appropriate intervals by the study monitor, or his/her designee, by means of visits to the study site to evaluate study data and any photographs. Study monitoring visits will involve review of the study status and any issues pertaining to it. All Informed Consent forms, HIPAA forms will be reviewed for signatures; all CRF's will be reviewed for completeness of data entry and that the study protocol is being followed; the subjects'

profiles will be checked to ensure they meet the inclusion and exclusion criteria. Materials will be checked for adequate storage and sufficient quantity to meet the study needs.

**Data collection and Data corrections**

During monitoring, CRFs will be checked for accuracy, legibility, logicalness and completeness, that all patients have given informed consent, meet selection criteria, and have had treatments randomly allocate in accordance with the study protocol. Resulting changes in the data will be initialized and dated by the person who changed them. If all open questions could be cleared with the investigator, copies of the signed Adverse Event/Incident forms will be provided for the Study Monitor's file. Data entry will be done by [redacted], Research Clinic Coordinator of the Cariology, Restorative Sciences Clinical Research Unit.

## 8 Statistical Analysis

In general, all analyses will be conducted separately by type of restoration; onlay or crown. Means and standard deviations were calculated for all clinical measurements and assessments. Categorical variables were summarized in frequency distributions.

There will be two datasets analyzed at each recall period; (1) one dataset consisting of subjects who were enrolled up to and including that recall period, and (2) one dataset consisting of all subjects with baseline data. In the second dataset (2) primary and secondary outcome variables which are missing will be imputed using the method of last observation carried forward (LOCF), wherein the last observed values for that variable will be carried forward to all remaining timepoints.

The primary analysis for this study will be the percent of intact/surviving restorations from baseline to the end of each recall period. This will be estimated using the Kaplan-Meier method, there will be no direct comparisons within this analysis. The median survival time of a restoration will be presented alongside survival curves.

The secondary analyses for this study will relate to the FDI criteria for esthetic properties including surface luster, surface staining, margin staining, color match and translucency; functional properties including anatomical form, material fracture, retention,

margin adaptation, occlusal contour and wear, and proximal contact and contour; and biological properties including post-operative sensitivity, caries, gingival index, and plaque index (see Appendix for FDI criteria description). The FDI criteria will be assessed at each recall period versus their respective baseline scores for a particular restoration within a particular subject. FDI criteria which are measured in an ordinal-discrete manner will be assessed using the Wilcoxon-signed rank test. Criteria which are measured continuously such as PI and GI will be assessed using the student's t-test, in the event that the PI and GI scores do not appear to be Normally distributed this assessment will shift to be done using the Wilcoxon-signed rank test.

A two-sided alpha of 0.05 will be used for all comparisons. There will be no adjustments made for multiplicity.

All statistical analyses will be performed e.g. using SAS version 9.4 or above (SAS Institute, Cary, NC).

## 9 Project Time Line

The recruitment of patients and clinical placement of restorations will begin immediately upon approval and funding of the project. It is anticipated to take 9-12 months to recruit and place the restorations required for the study.

*Protocol Amendments and Discontinuing the Study*

After approval of the study protocol, any changes to the content of the study documentation must be described in an Amendment Form and be approved by the PI, 3M, and the reviewing IRB prior to implementation. Any decision as to whether to prematurely stop the study will be taken jointly by the PI, 3M, and the IRB. Where early termination of the study occurs, subjects will receive appropriate follow up dental treatment.

## 10 Equipment

A CEREC system including a CEREC OmniCam and PrimeScan, MCX mill, Programmat oven, and SpeedFire oven is available at the University of Michigan for use during the study. All other instrumentation required for placement and clinical evaluation of the restorations is available through the Research Clinic of the Department of Cariology, Restorative Sciences, and

Endodontics at the University of Michigan School of Dentistry. Additional measurement instrumentation to include measuring microscopes, scanning electron microscope, computer analysis, and intraoral imaging equipment is available within the School of Dentistry.

## 11 Facilities

The Graduate General Dentistry Clinic maintains a two chair Clinical Research Unit for clinical research within the department. A full time Clinical Research Coordinator is dedicated to the Clinical Research Unit as well. She will coordinate and schedule all patient appointments, maintain recall schedules, and collate data collected. A Certified Dental Assistant will also provide clinical support as well. Additional dental materials and instruments as well as personnel support will be provided by the Graduate General Dentistry Clinic as needed.

## 12 Additional Sponsorships:

No other sponsorships are presently available or will be applied to this project.

In the event that study restorations should fail and require replacement, patients may elect to have a laboratory-fabricated restoration placed instead of another test restoration. [redacted]

## 13 References

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Löe, H.; Silness, J. Periodontal disease in pregnancy. *Acta Odontologica Scandinavica*, Vol. 21, (December 1963), pp. 533-551, ISSN 0001-6357.

Silness J, Loe H (1964). Periodontal disease in pregnancy 2. Correlation between oral hygiene and periodontal condition. Acta Odontol Scand; 22: 121-135.

## 14 Budget

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# Appendix

**Subject Enrollment**
**Pre-Operative Questionnaire**
**FDI Clinical Evaluation Criteria**
**Adverse Event Records**

# *SUBJECT ENROLLMENT*

3M
Health Care
EM-11-CR 19-03
University of Michigan School of Dentistry

## Inclusion / Exclusion Study Criteria

**Review this document with the subject to confirm the inclusion/exclusion criteria qualification.**

**Inclusion Criteria**

Subjects to whom *all* of these conditions apply will be eligible for enrollment in this study:

1. Subject in need of crown and/or onlay restoration
2. Subject age 18 or above
3. Subject with healthy / treated periodontal status (max. degree of movement 1)
4. Subject agrees to participate in the study and signed informed consent and HIPAA form

**Exclusion Criteria**

Subjects to whom *any* of these conditions apply will be excluded from this study:

1. Devital or sensitive teeth
2. Teeth diagnosed with symptoms of incomplete tooth fracture
3. Teeth with prior endodontic treatment of any kind
4. Teeth with a history of direct or indirect pulp capping procedures
5. Subjects with uncontrolled bruxism or parafunctional habits
6. Subject has known allergies to any product used in this study
7. Subject will not be available for the study duration of 5 years
8. Subjects with significant untreated dental disease to include periodontitis and rampant caries
9. Pregnant or lactating women

3M
Health Care
EM-11-CR 19-03
University of Michigan School of Dentistry

# Enrollment

Site Number ☐☐☐
Subject Number ☐☐

Date ☐☐☐☐ ☐☐ ☐☐ (e.g., 2019-01-23)
Year Month Day

Date consented ☐☐☐☐ ☐☐ ☐☐
Year Month Day

## Inclusion / Exclusion Criteria

Based on the criteria, does this subject qualify for participation in this study? ☐ Yes ☐ No

If no, check all criteria that were not met below:

Inclusion Criteria ☐1 ☐2 ☐3 ☐4

Exclusion Criteria ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

## Demographics

Sex ☐ Male ☐ Female

Age ☐☐ Years ☐ Check if 90 years of age or older

3M
Health Care
EM-11-CR 19-03
University of Michigan School of Dentistry

# Pre-Operative Questionnaire

Site Number ☐☐☐
Subject Number ☐☐

Date ☐☐☐☐ ☐☐ ☐☐ (Year Month Day)

## Caries Risk Assessment (check one)

- ☐ Low (0-1 carious lesions in the last 12 months)
- ☐ Moderate (2-4 carious lesions in the last 12 months)
- ☐ High (4+ carious lesions in the last 12 months)

## Pre-Operative Assessment

1. **Tooth to be Restored:** ☐☐ ☐ Onlay ☐ Crown
2. **Control Tooth Number:** ☐☐
3. **Reason tooth needs restoration:** (check all that apply)
   - ☐ Fractured cusp
   - ☐ Esthetics
   - ☐ Fracture lines
   - ☐ Severe wear
   - ☐ Poor contour
   - ☐ Caries
   - ☐ Fractured restoration
   - ☐ Open margins
   - ☐ Cervical overhang
   - ☐ Open proximal contact
4. **Pre-operative shade:** _____
5. **Opposing restorative material:** _____
6. **Evidence of wear facets on the test tooth:** ☐ Yes ☐ No
7. **Evidence of lateral interference(s) on test tooth:** ☐ Yes ☐ No

## Comments

# *FDI CLINICAL EVALUATION CRITERIA*

**Gingival Index**

Gingival score (visual) for gingival area nearest to the restoration margin; evaluate without disclosing.
(Gingival scores will be based upon the standard Loe & Silness Index, 1963)
score 0 = normal gingiva
score 1 = mild inflammation - slight change in color, slight edema, no bleeding
score 2 = moderate inflammation - redness, edema and glazing, bleeding on probing
score 3 = severe inflammation - marked redness and edema, ulceration, spontaneous bleeding

**Plaque Index**

Plaque score (visual) for facial gingival area nearest to the restoration margin; evaluate without disclosing.
(Plaque scores will be based upon the standard Silness & Loe Index, 1964)
score 0 = no plaque detectable in the gingival area
score 1 = plaque recognized only by running tip of probe across tooth surface at gingival crest
score 2 = moderate accumulation of plaque visible along gingival margin and adjacent tooth
score 3 = abundance of plaque visible along gingival margin and adjacent tooth

| **A. Aesthetic properties** | **1. Surface lustre** | **2a. Surface Staining** | **2b. Margin Staining** |
|---|---|---|---|
| **1. Clinically excellent / very good** | 1.1 Lustre comparable to enamel, Smooth, high gloss surface | 2a.1 No surface stain | 2b.1 No margin stain |
| **2. Clinically good** (after polishing probably very good) | 1.2.1 Slightly dull, not noticeable from speaking distance.<br>1.2.2 Some isolated pores. | 2a.2 Minor surface staining, easily removable by gentle polishing (prophy cup) | 2b.2 Minor marginal staining, easily removable by gentle polishing (prophy cup) |
| **3. Clinically sufficient / satisfactory** (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth) | 1.3.1 Dull surface but acceptable if covered with film of saliva.<br>1.3.2 Multiple pores on more than one third of the surface. | 2a.3 Moderate surface staining that may also present on other teeth, not aesthetically unacceptable. | 2b.3 Moderate marginal staining, not aesthetically unacceptable.(aggressive removal of surface) |
| **4. Clinically unsatisfactory** (but repairable) | 1.4.1 Rough or pitted surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary.<br>1.4.2 Voids. | 2a.4 Surface stain not removed by gentle polishing, penetrates crown surface, major intervention necessary for improvement. (aggressive removal of material + adding material ) | 2b.4 Pronounced margin staining, Deeper penetration of the margin, major intervention necessary for improvement. (aggressive removal of material + adding material ) |
| **5. Clinically poor** (replacement necessary) | 1.5 Very rough, unacceptable plaque retentive surface. | 2a.5 Severe Subsurface staining within the body of the crown, not accessible for intervention, removed only by replacement of crown | 2b.5 Deep and widespread margin staining that penetrates margin, not accessible for intervention removed only by crown replacement |

| A. Aesthetic properties | 3. Colour match and translucency | 4. Aesthetic anatomical form |
|---|---|---|
| **1. Clinically excellent / very good** | 3.1 Good colour match, no difference in shade and/or translucency. | 4.1 Form– comparable to natural tooth anatomy. |
| **2. Clinically good** (after polishing probably very good) | 3.2 Minor deviations in shade and/or translucency | 4.2 Form is only slightly deviated from natural tooth anatomy. |
| **3. Clinically sufficient / satisfactory** (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth) | 3.3 Distinct deviation but acceptable. Does not affect aesthetics:<br>3.3.1 more opaque<br>3.3.2 more translucent<br>3.3.3 darker<br>3.3.4 brighter | 4.3 Form deviates from the natural anatomy but is aesthetically acceptable. |
| **4. Clinically unsatisfactory** (but repairable) | n.a. | 4.4. Form is affected and unacceptable aesthetically. Intervention/correction is necessary. |
| **5. Clinically poor** (replacement necessary) | 3.5 Unacceptable. Replacement necessary. | 4.5 Form is unsatisfactory and/or lost. Repair not feasible / reasonable, replacement needed. |

| B. Functional properties | 5a. Fracture of material | 5b. Retention | 6. Marginal adaptation |
|---|---|---|---|
| **1. Clinically excellent / very good** | 5a.1 No fractures / cracks | 5b.1 Restoration in place | 6.1 Harmonious outline, margins not detectable |
| **2. Clinically good** | 5a.2 Small hairline crack. | n.a. | 6.2 margins detectable: Slight ditching, slight step/flashes, minor irregularities. |
| **3. Clinically sufficient / satisfactory** (minor shortcomings, no unacceptable effects but not adjustable w/o damage) | 5a.3 Two or more or larger hairline cracks and/or material chip fracture not affecting the marginal integrity or approximal contact. | n.a. | 6.3 moderate detectability: Major irregularities, ditching or flash, steps or minor crevice formation |
| **4. Clinically unsatisfactory /** (but repairable) | 5a.4.1 Material chip fractures which damage marginal quality or approximal contacts | n.a. | 6.4.1 major crevice formation<br>6.4.2 Larger irregularities or steps (repair necessary) |
| **5. Clinically poor** (replacement necessary) | 5a.5multiple fractures | 5b.5 Complete Loss of restoration | 6.5 Generalized major gaps/crevice formation or irregularities. |

| B. Functional properties | 7. Occlusal contour and wear | 8. Approximal anatomical form<br>a. contact point<br>b. contour |
|---|---|---|
| **1. Clinically excellent / very good** | 7.1 No evidence of occlusal wear, wear equivalent to enamel | 8a.1 Normal contact point (floss or 25 µm metal blade can pass)<br>8b.1 Normal contour. |
| **2. Clinically good** | 7.2 Evidence of local facet formation < 2.0 mm in diameter, no change in occlusal anatomy, wear only slightly different from that to enamel | 8a.2. Contact slightly too strong but no disadvantage (floss or 25 µm metal blade can only pass with pressure).<br>8b.2 Slightly deficient contour. |
| **3. Clinically sufficient / satisfactory** (minor shortcomings, no unacceptable effects but not adjustable w/o damage) | 7.3 Evidence of local facet formation > 2.0 mm in diameter, slight change in occlusal anatomy, Different wear rate compared to enamel | 8a.3. Somewhat weak contact, no indication of damage to tooth, gingiva or periodontal structures; 50 µm metal blade can pass<br>8b.3 Visible deficient contour |
| **4. Clinically unsatisfactory /** (but repairable) | 7.4 Evidence of generalized facet formation with evidence of generalized wear altering occlusal anatomic form, Wear considerably exceeds normal enamel wear | 8a.4 Too weak and possible damage due to food impaction;<br>100 µm metal blade can pass<br>8b.4 Inadequate contour<br>Repair possible. |
| **5. Clinically poor** (replacement necessary) | 7.5 Generalized, excessive occlusal wear with loss of anatomic form | 8a.5 Too weak and/or clear damage due to food impaction and/or pain/gingivitis.<br>8b.4 Insufficient contour requires replacement |

| B. Functional properties | 9. Radiographic examination (when applicable) | 10. Patient's view |
|---|---|---|
| **1. Clinically excellent / very good** | 9.1 No pathology, harmonious transition between restoration and tooth. | 10.1 Entirely satisfied with aesthetics and function. |
| **2. Clinically good** | 9.2.1 Acceptable material excess present.<br>9.2.2 Positive/negative step present at margin <150 µm. | 10.2 Satisfied.<br>10.2.1 Aesthetics.<br>10.2.2 Function, e.g., minor roughness |

| | | |
|---|---|---|
| **3. Clinically sufficient / satisfactory**<br>(minor shortcomings, no unacceptable effects but not adjustable w/o damage) | 9. 3. 1 Marginal gap < 250 µm.<br>9. 3. 2 Negative steps visible < 250 µm.<br>No adverse effects noticed.<br>9.3.3 Poor radiopacity of the restoration. | 10.3 Minor criticism but no adverse clinical effects.<br>10.3.1 Aesthetic shortcomings.<br>10.3.2 Some lack of chewing comfort.<br>10.3.3 Unpleasant treatment procedure. |
| **4. Clinically unsatisfactory /** (but repairable) | 9.4.1 Marginal gap >250 µm.<br>9.4.2 Material excess accessible but not removable.<br>9.4.3 Negative steps >250µm and repairable. | 10.4 Desire for improvement<br>10.4.1 Aesthetics.<br>10.4.2 Function, e.g., tongue irritation<br>Reshaping of anatomic form or refurbishing is possible. |
| **5. Clinically poor**<br>(replacement necessary) | 9.5.1 Secondary caries, large gaps, large overhangs<br>9.5.2 Apical pathology<br>9.5.3 Fracture/loss of restoration or tooth. | 10.5 Completely dissatisfied and / or adverse effects, incl. pain. |

| **C. Biological properties** | **11. Postoperative (hyper-) sensitivity and tooth vitality** | **12. Recurrence of caries (CAR), erosion, abfraction** |
|---|---|---|
| **1. Clinically very good** | 11.1 No hypersensitivity, normal vitality. | 12.1 No secondary or primary caries |
| **2. Clinically good**<br>(after correction maybe very good)<br>No treatment required. | 11.2 Minor hypersensitivity for a limited period of time, normal vitality. | 12.2 Small and localized<br>1. Demineralization<br>2. Erosion or<br>3. Abfraction. |
| **3.Clinically sufficient / satisfactory**<br>(minor shortcomings with no adverse effects but not adjustable without damage to the tooth) | 11.3.1 Moderate hypersensitivity<br>11.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed. | 12.3 Larger areas of 1. Demineralisation<br>2. Erosion or<br>3.Abrasion/abfraction, dentine not exposed Only preventive measures necessary. |
| **4. Clinically unsatisfactory**<br>(repair for prophylactic reasons) | 11.4.1 Intense hypersensitivity.<br>11.4.2 Delayed with minor subjective symptoms.<br>11.4.3 No clinical detectable sensitivity.<br><br>Intervention necessary<br>but not replacement. | 12. 4.1 Caries with cavitation and suspected undermining caries<br>12.4.2 Erosion in dentin<br>12.4.3 Abrasion/ abfraction in dentin.<br>Localized and accessible can be repaired. |
| **5. Clinically poor**<br>(replacement necessary) | 11.5 Intense, acute pulpitis or non-vital tooth. Endodontic treatment is necessary, and restoration has to be replaced. | 12.5 Deep<br>caries or exposed dentine that is not accessible for repair of restoration. |

3M
Health Care
EM-11-CR 19-03
University of Michigan School of Dentistry

# Adverse Event Record

AE# ☐

Site Number ☐☐☐
Subject Number ☐☐

Date of onset: ☐☐☐☐☐☐☐☐ (Year Month Day)

**NOTICE: Contact 3M Study Monitor ASAP if the adverse event is serious or unanticipated/unexpected.**

**Specify the sign or symptom of the adverse event.**

**Identify study material(s) used at the site of the adverse event.** (check all that apply)

☐ Suglue-3 ☐ ADH-19 ☐ Scotchbond Universal Etchant ☐ Chairside Zirconia
☐ CoJet Sand ☐ Vitrebond Plus Light cure glass ionomer liner/base ☐ Epilar Deep Cure S
Other: _____

| *Severity at Onset (Check one) | Seriousness (Check one) | Anticipated / Expected (Check all that apply) | Related to Study Material (Check one) | Action Taken (Check all that apply) |
|---|---|---|---|---|
| ☐ Mild<br>subject is aware of signs, symptoms but they are easily tolerated<br>☐ Moderate<br>signs, symptoms are sufficient to restrict but not prevent subject's daily activity<br>☐ Severe<br>subject unable to perform daily activity | ☐ Not serious<br>☐ Serious<br>a) led to death,<br>b) led to serious deterioration in health that either resulted in:<br>1) a life-threatening illness or injury, or<br>2) a permanent impairment of a body structure or a body function, or<br>3) in-patient or prolonged hospitalization, or<br>4) medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function,<br>c) led to fetal distress, fetal death or a congenital abnormality or birth defect. | ☐ Anticipated / Expected<br>defined in protocol/ Investigational Plan, Investigator's Brochure or Informed Consent form<br>☐ Unanticipated / Unexpected in nature<br>☐ Unanticipated / Unexpected in severity | ☐ Not related<br>☐ Unlikely<br>☐ Possible<br>☐ Probable<br>☐ Causal relationship | ☐ None<br>☐ Study product discontinued<br>☐ Withdrawn from study<br>☐ Medications (describe below)<br>☐ Other (describe below) |

**Outcome** (Check one)

☐ Recovered
☐ Persistent effect (describe below)
☐ Death (describe below)

Date recovered: ☐☐☐☐☐☐☐☐ (Year Month Day)

**Describe the chronology of events, actions taken and outcome.**

*From onset to outcome, did the adverse event increase in severity? ☐ Yes ☐ No
If yes, to what degree? ☐ Moderate ☐ Severe