CLINICAL EVALUATION OF CHAIRSIDE CAD/CAM LITHIUM DISILICATE FIXED PARTIAL DENTURES

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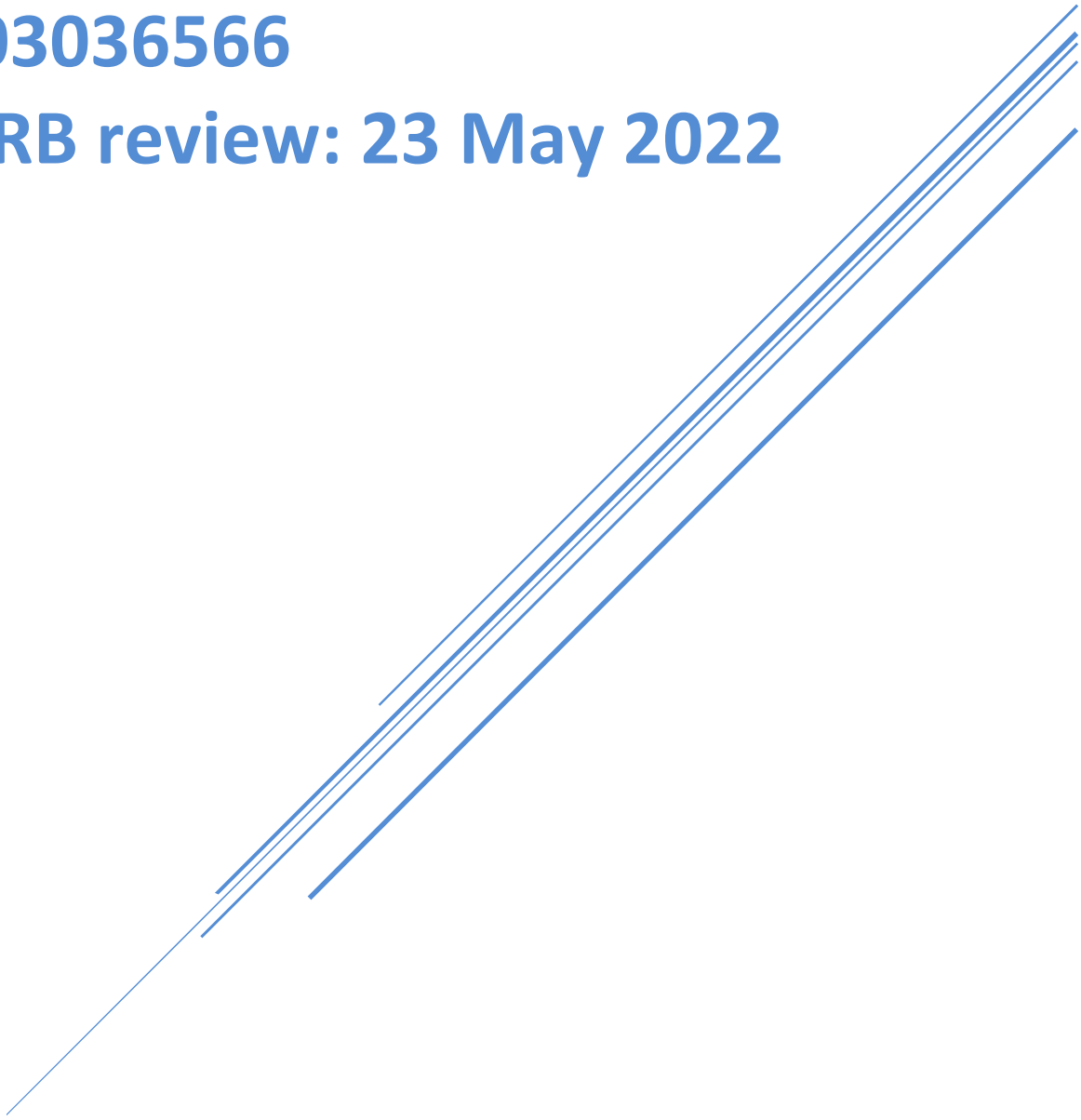

Clinical Evaluation of Chairside CAD/CAM Lithium Disilicate Fixed Partial Dentures

1 Investigation Title

Clinical Evaluation of Chairside CAD/CAM Lithium Disilicate Fixed Partial Dentures

2 Investigators

Dennis J. Fasbinder, DDS
Clinical Professor

Gisele F. Neiva, DDS, MS
Clinical Associate Professor

Donald Heys, DDS, MS
Professor of Dentistry

Joseph B. Dennison, DDs, MS
Professor Emeritus of Dentistry

Ronald Heys, DDS, MS
Associate Professor of Dentistry

Department of Cariology, Restorative Sciences, and Endodontics
School of Dentistry University of Michigan
1011 N. University, Ann Arbor, Michigan 48109-1078 U.S.A.

Phone: (734) 647-4450 e-mail: Dr. Fasbinder = djfas@umich.edu Fax: (734) 936-1597

3 Sponsor

Ivoclar Vivadent, USA

4 Summary of Objectives and Design

This investigation will be a longitudinal clinical trial to study the clinical performance of lithium disilicate (emaxCAD/Ivoclar) for in-office, CAD/CAM generated, full contour fixed partial dentures (FPDs). The fixed partial dentures will be evaluated for clinical performance over a period of three years with an option to extend the study to five years.

5 Specific Aims

The specific aims of this project are:

Evaluate the longitudinal clinical performance of lithium disilicate (emaxCAD) in-office CAD/CAM full contour, fixed partial dentures over five years of clinical service.

Evaluate the clinical workflow for fabricating in-office CAD/CAM FPDs.

6 Significance of the Clinical Investigation

Lithium disilicate (emaxCAD/Ivoclar) has had well documented, long-term success for chairside CAD/CAM full contour single crown applications.[1,2] It has been routinely used for clinical situations requiring high strength and is available in millable block form for single tooth restorations for both the E4D (D4D Technologies) and CEREC (Sirona Dental) chairside CAD/CAM systems. As the CAD/CAM software for the CEREC OmniCam has evolved, full contour, multi-unit restorations are now possible using lithium disilicate.

Pressable lithium disilicate (emax Press/Ivoclar) has been used in dental laboratories to fabricate 3 or 4 unit fixed partial dentures (FPD). Limited published long term results have been favorable.[3] Lithium disilicate FPDs have been limited to replacing premolar or anterior teeth. Multi-unit emaxCAD blocks have been available for laboratory use for stack milling but unavailable for in-office use until recently. The coincidental development of the software capability for full contour FPDs and extended size millable blocks of emaxCAD make the in-office fabrication of full contour FPDs possible.

This three year, optionally five year, longitudinal clinical evaluation will evaluate the clinical effectiveness of using emaxCAD to fabricate in-office, full contour, fixed partial dentures.

Research Plan: Methods and Materials

7.1 Subjects

The patient population will be selected from current patients under clinical treatment at the University of Michigan Dental Clinics. Patients will be over 18 years of age, of either gender, and of any ethnic background. Each patient should have at least one missing premolar or anterior tooth that is appropriate for replacement with a fixed partial denture. The second premolar teeth will be the most distal tooth acceptable for inclusion in the study. Abutment teeth will have healthy periodontal status with at least a 1:1 crown:root ratio. Both abutment teeth must be asymptomatic prior to treatment. Endodontically treated teeth will be acceptable for abutments as long as nonmetallic cores can be placed to retain the FPD since the lithium disilicate will be bonded to the abutments.

No more than one FPD will be placed per patient. If a patient presents with more than one missing teeth acceptable for the study, premolar teeth will be included prior to anterior teeth. Each FPD will be three units and include only one missing tooth.

Exclusion criteria will include:

Sensitive teeth

Teeth with a history of direct or indirect pulp capping procedures

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

Pregnant or lactating women

Patients with allergies to any of the materials to be used in the study

Patients unable to return for recall appointments

7.2 Ethics Approval and Informed Consent

The Health Sciences Institutional Review Board of the University of Michigan must review and approve the investigation protocol prior to initiating the study. Patients can be enrolled in the study as soon as the contract is completed and funding is provided. Patients who are eligible for the study will be screened by one or more of the investigators and 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. Patients will be charged $650 for each FPD. This will fund an incentive fund for patient recalls. As an incentive for patients to be available for the recall examinations, patients will receive $50 for every yearly recall that they return to be examined as well as free parking. Patients will also receive free bitewing radiographs at the two-year (and optionally the five year) recall appointments.

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).

7.3 Study Size

The study will include 30 patients each requiring a single FPD replacing a premolar or anterior tooth.

7.4 Baseline - Restoration Placement

Every patient will be evaluated with a clinical examination and periapical radiographs of the teeth to be included in the FPD. Once the patient is accepted into the study, a series of appointments will be made to complete the FPD.

1st Restorative Appointment

A pre-operative questionnaire will be completed jointly by the patient, Clinical Research Coordinator, and treating doctor (copy enclosed in Appendix). This will establish the baseline information from which to compare the responses at subsequent recall examinations. Abutment 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 as well as the number of caries teeth planned to be restored over the next 6 months. *Low Caries Risk* will be scored for patients having 0 or 1 restoration placed in the previous 12 months or planned to be replaced due to caries. *Moderate Caries Risk* will be scored for patients having 2 or 3 restorations placed in the previous 12 months or planned to be replaced due to caries. And *High Caries Risk* will be scored for patients having 4 or more restorations placed in the previous 12 months or planned to be replaced due to caries. High caries risk patients will not qualify for the study due to the degree of uncontrolled dental disease that is present. The shade of the teeth to be restored will be determined prior to tooth preparation. A Classic Shade guide (Vita) will be used to determine the pre-treatment shade. Digital photographs of the dentition with the selected shade tab(s) will be taken and used as an aid in matching the desired tooth shade. Pre-treatment full arch diagnostic impressions may be made for case evaluation and as an aid in fabricating the temporary FPD should the need arise.

2nd Restorative Appointment - 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 Isolite2 System (Isolite) will be used to isolate the teeth for cavity

preparation, optical imaging, and cementation of the restorations. The abutment preparation will be consistent with the principles for an all-ceramic crown. The crown preparation will be tapered 6-8 degrees towards the occlusal. Occlusal reduction will be 2.0 mm over functional cusps and at least 1.5 mm over nonfunctional cusps and the central fissure area. And the margin will be a rounded internal shoulder design of at least 1.2 mm axial depth without a bevel. The crown margins will be placed at the free gingival margin unless prior restoration, caries, or tooth fracture dictates margin placement subgingivally. If sufficient tooth loss is present to necessitate a core, a composite resin (Multi-core/Ivoclar) will be used. If in the judgment of the operator, less than 1 mm of dentin thickness remains over the pulp, a glass ionomer base may be selectively placed prior to completing the preparation.

FPD Fabrication

After the abutment crown preparations have been completed, gingival retraction will be achieved with a combination of retraction cord, hemostatic agent, and a diode laser as required for the case. The quadrant will be isolated from moisture using an Isolite 2 unit. The CEREC OmniCam (Sirona Dental) will be used to record the preparation quadrant, opposing quadrant, and facial bite registration.

If the case requires a temporary FPD, a bisacrylic material (Telio C&B/Ivoclar) will be used to fabricate a temporary FPD that will be cemented with a eugenol-free temporary cement. The digital impression will be used in the CEREC 4.21 software program for the full contour design of the FPD. The designed FPD will be milled in a MCXL milling unit (Sirona Dental) at fast milling speed.

The milled emaxCAD FPD will be tried in using silicon fit checking material (Fit Checker/GC Amer) and adjusted for delivery. Alternatively, the milled FPD will be tried-in on a replica model of the preparations and adjusted for delivery. The FPD will be crystallized in a porcelain oven under vacuum firing following Ivoclar's recommendations. Esthetic characterization and/or glazing of the FPD will also be done simultaneous with the crystallization process as the esthetic needs of the case dictates. Surface polishing post-crystallization will be done with diamond impregnated polishers, brushes, and diamond polishing paste. Both proximal connectors will be measured in the faciolingual and occlusocervical directions and recorded. Each connector should be no less than 16 mm^2.

3rd Restorative Appointment - FPD Delivery

Once the FPD is ready is for cementation, the internal surface of all abutment crowns will be etched for 20 seconds with 4.9% HFl acid (Ceramic etchant/Ivoclar), rinsed thoroughly, and dried. A silane coupler will be applied for 60 seconds (Monobond Plus/Ivoclar) and gently dried. All FPDs will be cemented with the most current formulation of a self-etching, dual-cure resin cement (MultiLink Automix/Ivoclar) following the manufacturer's instructions. The FPD will be inserted and the excess cement will be removed. Each abutment of the FPD will be light cured for 20 seconds from the facial, lingual and occlusal for a total cure of 2 minutes.

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 paste will be used for removal of excess cement and final adjustment of the occlusion.

Data Collection

8.1 Post-Operative Sensitivity

All patients will be asymptomatic prior to initiating the abutment preparations so the baseline is "no 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 FPD 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 intermittently and it is noticeably uncomfortable

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

8.2 Clinical Evaluation

Two independent evaluators will examine all FPDs in the study. Clinical evaluations will be made at baseline (the appointment the FPD is cemented), six months, one year, two years, three years, and optionally at four years, and five years using written criteria based on modified USPHS criteria for margin discoloration, margin adaptation, proximal contact, recurrent caries, surface finish, connector fracture, and crown fracture (see Appendix for criteria description). Disagreements in evaluations will be discussed between the evaluators and a consensus judgment will be reached and recorded for every criteria. Gingival health adjacent to the abutments and control teeth will be evaluated with a Gingival Score (Loe & Silness Index, 1963) and a Plaque Score (Silness & Loe Index, 1964).

Intraoral digital color images at a 1:1.5 magnification will be taken to document pre-operative, tooth 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 postcementation quadrant impression will be made of the midfacial margin of each abutment and the opposing teeth in a polyvinyl siloxane material and casts will be poured in an enhanced stone. Casts will be made at the baseline, 6 months, 1 year, 2 year, and 3 year, and optionally at the 4 year, and 5 year recall visits. Bite-wing radiographs and periapical radiographs of each test tooth will be available preoperatively and at the two year and optionally at the five year recall.

8.3 Data Management

Case Report Form (CRF)

Data will be entered in the Case Report Form (CRF) by the investigator or prior assigned persons at the study center. 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 and recalls) must be signed and dated by the conducting investigator.

Copies of 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. Data entry will be done by the Clinic Study Coordinator of the Cariology, Restorative Sciences Clinical Research Unit.

9 Statistical Analysis

After the clinical evaluation data is collected for baseline and each recall, the clinical ratings will be entered into a statistical management program and appropriate non-parametric tests will be run to verify significant differences. A Wilcoxon Sign Rank test will be used to determine significant differences in the change of ratings from baseline to a given time period. Each criterion-referenced category will be analyzed independently. At any given time period, significant differences in clinical evaluation ratings will be determined.

10 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 8-10 months to recruit and place the restorations required for the study.

11 Equipment

All 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.

12 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 is also available to provide clinical support. Additional dental materials and instruments as well as personnel support will be provided by the Graduate General Dentistry Clinic as needed.

13 Additional Sponsorships:

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

14 Bibliography

1. Fasbinder DJ, Dennison JB, Heys D, Neiva GF. A clinical evaluation of chairside lithium disilicate CAD/CAM crowns. JADA 2010 141(6 suppl): 10s-14s.

2. Fasbinder DJ, Dennison JB, Heys D, Neiva GF. Clinical evaluation of lithium disilicate chairside CAD/CAM crowns at 4 years. J Dent Res 91(Spec Issue A): abstract #645, 2012.

3. Wolfart S, Eschbach S, Scherrer S, and Kern M. Clinical outcome of three-unit lithium-disilicate glass-ceramic fixed dental prostheses: up to 8 years results. Dental materials 2009 25:63-71.

Appendix

Initial Questionnaire

Clinical Evaluation Criteria

INITIAL QUESTIONNAIRE

Patient: _____ Date:_____

1. Birthdate (month-day-year) _____

2. Gender:male _____ female _____

3. Caries Risk Assessment
   Low _____ 0-1 carious lesions in the last 24 months
   Moderate _____ 2-4 carious lesions in the last 24 month
   High _____ 4+ carious lesions in the last 24 month (disqualifies)

4. Teeth to be restored
   Anterior abutment: _____ Posterior abutment: _____

5. Pre-operative vitality; verify with cold test:
   Abutment tooth: _____ Vital Devital (circle one)
   Abutment tooth: _____ Vital Devital (circle one)

6. Verify pre-operative PAXR for test teeth; less than 6 months old. _____ (initials)

7. Occlusion – at least one centric stop per tooth. _____ (initials)

   lateral guidance location: _____

8. Informed Consent and HIPPA form signed. _____ (initials)

9. Pre-operative Shade: _____ (photograph shade tab/s with control tooth)

   shade details: _____

   _____

10. Opposing Tooth: (photograph opposing teeth; with and without occlusal contacts marked)

    Restorative material present: _____

    Evidence of wear facets: yes no

    Evidence of lateral interferences: _____

CLINICAL EVALUATION CRITERIA

Gingival Index

Gingival score (visual) for gingival area nearest to the crown 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 crown 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

Color Match (with control tooth, indirect lighting, without magnification)	**Rating**
Tooth and restoration have an ideal color match; can distinguish restoration with some difficulty	Alpha
Readily perceptible mismatch in color; general match	Bravo
Obvious mismatch in color between tooth and restoration; unacceptable for cementation	Charlie

Margin Adaptation (margin integrity)

No visible evidence of crevice formation along cavosurface margin explorer does not catch when drawn across the margin	Alpha-1
No visible evidence of crevice formation along cavosurface margin Margin is detectable along less than 50% of cavosurface margin; and less than 1 mm in depth	Alpha-2
No visible evidence of crevice formation along cavosurface margin Margin is detectable along more than 50% of cavosurface margin; and less than 1 mm in depth	Alpha-3
Evidence of crevice formation (penetrable) along less than 50% of the cavosurface margin; greater than 1 mm in depth	Bravo-1
Evidence of crevice formation (penetrable) along greater than 50% of the cavosurface margin; greater than 1 mm in depth	Bravo-2
Evidence of crevice formation exposing dentin to the axial or pulpal floor	Charlie

Margin Discoloration (evaluated with tooth dry)

No evidence of margin discoloration	Alpha
Surface stain along less than 50% of exposed margin	Bravo-1
Surface stain along greater than 50% of exposed margin	Bravo-2
Penetrating discoloration of exposed margin	Charlie

Surface Finish (surface of the restoration as viewed under magnification)

Smooth, highly polished to finely granular	Alpha
Gritty, moderate rough but uniform texture	Bravo
Rough or pitted, visible evidence of significant pits and voids	Charlie
Evidence of surface crazing with no loss of ceramic or mobile pieces	Delta

Caries

No evidence of caries	Alpha
Evidence of recurrent caries at crown margin; repairable without compromise to crown	Bravo
Evidence of recurrent caries at crown margin; not repairable, crown requires replacement	Charlie

Abutment Fracture

No evidence of abutment crown fracture	Alpha
Evidence of restoration fracture with no missing piece or mobility in the pieces	Bravo
Evidence of restoration fracture with a missing piece considered polishable or repairable	Charlie
Fracture of the restoration requiring replacement	Delta

Connector Fracture

No evidence of connector fracture	Alpha
Evidence of connector fracture with no missing piece or mobility in the pieces	Bravo
Evidence of connector fracture with a missing piece considered polishable or repairable	Charlie
Fracture of the connector requiring replacement	Delta

Proximal Contact

Firm resistance to passage of floss with ideal breadth of contact area	Alpha
Light resistance to passage of floss or notable variance in breadth of contact area; shim stock will pass through contact	Bravo
Contact visibly open with passage of one thickness of articulating paper (blue)	Charlie

Pontic Fracture

No evidence of pontic fracture	Alpha
Evidence of pontic fracture without loss of material	Bravo
Pontic fracture with loss of material but repairable or does not require replacement	Charlie
Complete pontic fracture requiring replacement of the crown	Delta

Sensitivity

No sensitivity is experienced at any time	Alpha
Slight sensitivity is experienced occasionally but is not uncomfortable	Bravo
Moderate sensitivity is experienced intermittently and is noticeably uncomfortable	Charlie
Severe discomfort is noted routinely with cold or pressure stimulation	Delta