Official Title: Celtra Duo Computer Assisted Design/Computer Assisted Machining (CAD/CAM) Dental Crown Study

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Clinical Evaluation of Chairside CAD/CAM Zirconia-reinforced Lithium Silicate Ceramic Crowns

1 Investigation Title

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4 Background

There has been significant interest in computer assisted design/computer assisted machining (CAD/CAM)-generated restorations as the technology has evolved. Of particular

interest are newer high strength materials for crowns and onlays. Popular ceramic materials with high strength are primarily limited to fabrication by a dental laboratory that requires at least two dental appointments for completion of the restoration. A recently introduced zirconia-reinforced lithium silicate material is designed to provide a high strength alternative to laboratory fabricated high strength ceramics for crowns and onlays.

This new glass ceramic material is three times stronger than currently marketed ceramic materials for CAD/CAM chair-side applications and equal in strength to the only other high strength ceramic material available for chairside CAD/CAM restorations, that being lithium disilicate (emaxCAD by Ivoclar). Celtra Duo is provided in a precrystallized block form allowing for the option of either polishing the crown after it is milled or oven-firing it depending on the specific needs of the clinical case. This is a potential clinical advantage in that the post-milling processing is simpler and more streamlined compared to the lithium disilicate high strength material resulting in a more efficient delivery process for the patient. The chair-side process using the CEREC 3D system also avoids the final impression process, temporization process, and second dental appointment generally required to complete high strength all-ceramic crowns from a dental laboratory.

It is the intent of this investigation to evaluate the clinical application and performance of the new high strength zirconia-reinforced lithium disilicate material (Celtra Duo by Dentsply) for CAD/CAM-generated chair-side restorations in single crown applications.

5 Summary of Objectives and Design

This investigation will be a prospective, longitudinal clinical trial to study the clinical performance of a recently introduced zirconia-reinforced, lithium silicate material (Celtra Duo by Dentsply) for CAD/CAM generated restorations. Celtra Duo crowns will be evaluated for a period of five years.

6 Specific Aims

The specific aims of this project are:

1. Evaluate the short-term post-operative sensitivity associated with the adhesive luting technique of crowns using a self-etch universal adhesive and a dual-cured resin cement.
2. Evaluate the longitudinal clinical performance of both polished and oven-fired zirconia-reinforced lithium silicate crowns
3. Evaluate the longitudinal clinical performance of zirconia-reinforced lithium silicate crowns over five years of clinical service. The crowns will be evaluated with modified USPHS criteria for margin discoloration, margin finish, margin adaptation, proximal contact, wear of opposing cusps, anatomical form, surface finish, and recurrent caries.

7 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 carious lesion or defective restoration to be restored on a maxillary or mandibular bicuspid or molar. Each lesion or defective restoration should exhibit sufficient size to extend more than one-half the intercuspal width of the tooth requiring a full crown restoration. 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 bicuspid teeth. Exclusion criteria will include:

Devital or sensitive teeth

Teeth with prior endodontic treatment of any kind

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 a history of allergies to any of the materials to be used in the study

Patients unable to return for the recall appointments

7.2 Informed Consent

The Medical 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 completed and funding is provided. Patients who are eligible for the study will be screened by the Investigators and 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 $350 for each restoration. As an incentive for patients to be available for the recall intervals, patients will receive $50 for every yearly recall that they return to be examined. Patients will also receive free bitewing radiographs at the three-year recall appointment.

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 Investigator or Clinical Research Coordinator will record any subject's withdrawal and the reason(s).

7.3 Study Size

There will be a total of 100 Celtra Duo crowns placed. The first 50 crowns will be placed consecutively using Celtra Duo in an oven-fired, glazed finish technique. The second 50 crowns will be placed consecutively using Celtra Duo in a hand polished finish technique. 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)

	Celtra Duo > glazed	Celtra Duo > polished
Crowns	50	50

7.4 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

A pre-treatment periapical radiograph (PAXR) will be used to evaluate the health of the tooth prior to initiation of treatment. A new PAXR will be exposed at no cost to the patient if an existing PAXR dated within 1 month of the evaluation is not available for review. 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.

Full crown preparations will have a rounded shoulder design of at least 1.2 mm axial reduction, 2.0 mm reduction over functional cusps, and 1.5 mm reduction in the central fissure area. If in the judgement of the operator, less than 1 mm of dentin thickness remains over the pulp, a flowable compomer resin (Dyractflow Compomer Flowable Restorative by Dentsply) may be selectively placed prior to completing the preparation.

Restoration

The manufacturer's instructions will be strictly adhered to in the imaging, design, and machining of the crowns using a CEREC OmniCam and MCX milling unit (Sirona Dental Systems) using the most current version of the software (4.31 as of December 2014). The crowns will be milled from prefabricated blocks of Celtra Duo (Dentsply), the zirconia-reinforced lithium silicate ceramic.

The crown will be tried-in intraorally after milling to verify the proximal contacts, margin fit, and occlusal relationships prior to surface finishing. The first 50 crowns to be completed will be glazed used an oven firing process for surface finishing. The second group of 50 crowns to be completed will be hand polished with a series of diamonds abrasives, polishing wheels, and ceramic polishes for surface finishing.

Crown Cementation

The internal surfaces of the Celtra Duo crowns will be etched for 30 seconds with 4.9% hydrofluoric acid gel, rinsed for 20 seconds, and then air-dried with oil-free air. Calibra silane coupler (Dentsply) will be applied to the prepared internal surface of all crowns for 60 seconds and dried for 5 seconds.

All the crowns will be cemented using the most current marketed version of the manufacturer's adhesive resin cement (SmartCem2/Dentsply) in two adhesive techniques. All of the oven-fired, glazed crowns will be cemented using the self-etching, self-adhesive resin cement technique (Calibra Universal Cement/Dentsply. This is the new product name for SmartCem2 used in a self-adhesive technique.). The cavity preparation will be cleaned with a slurry of pumice and rinsed thoroughly for 10 seconds and dried carefully with care taken to prevent over-drying the preparation. Calibra Universal 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 40 seconds from the facial, lingual and occlusal for a total cure of 2 minutes.

All of the hand polished crowns will be cemented using an adhesive bonding technique using Prime & Bond Elect (Dentsply) with the most current version of the resin cement, SmartCem2 (Calibra Ceram/Dentsply is the new product name for SmartCem2 used with a separate bonding agent). Prime & Bond Elect will be applied in an active scrubbing action to the tooth preparation for 20 seconds and lightly air dried. The most current version of SmartCem2

Cement, Calibra Ceram, 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 40 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 pastes will be used for removal of excess cement, final contouring of the restoration, and adjustment of the occlusion. A post-cementation periapical radiograph will be taken to document completion of the all-ceramic crown.

8 Data Collection

8.1 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 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 crowns in the study. Clinical evaluations will be made at baseline, six months, one year, two years, three years, four years, and five years using written criteria based on modified USPHS criteria for margin discoloration, margin finish, margin adaptation, proximal contact, wear of opposing cusps, anatomical form, surface finish, and recurrent caries (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.

Intraoral digital color pictures at a 1:1.5 magnification will be taken to document pre-operative, cavity preparation, restoration try-in, 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 each test restoration in a polyvinyl siloxane material and casts will be poured in an epoxy die material. Casts will be made at the baseline, 6 months, 1 year, 2 year, 3 year, 4 year, and 5 year recall visit.

Bite-wing radiographs (BWXR) of each test tooth will be reviewed at the three year recall. A new BWXR will be taken at the recall appointment at no cost to the patient if BWXR dated within 6 months of the three-year recall are not available for review.

8.3 Data Management

Case Report Form (CRF)

Data will be entered in the Case Report Form (CRF) by the investigator or 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).

Copies of the completed CRFs and Adverse Events/Incident Reports will be retained together with the investigator's study file for a period of 2 years after completion of the study at the study center.

8.4 Study Reports

Progress reports on the investigation shall be submitted to the sponsor and the IRB at regular intervals. Progress reports to the sponsor will follow each recall evaluation period. A final study report shall be submitted to the sponsor 9 months following termination or completion of the study. Study completion for purposes of this requirement will be defined as completing assessments on the last subject.

9 Adverse Events

Any untoward effects either observed or volunteered by the subject during the course of the study either caused by or associated with the use of the test device will be documented as to onset, severity, duration, remedy and relatedness to the test device. Adverse events will be recorded in source documents and on case report forms. Any study staff member becoming aware of an adverse event must bring it to the attention of the PI as soon as possible. Adverse events will also be reported to the University of Michigan IRB as current guidelines indicate.

9.1 Restoration Failures

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

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. This would incur a significant cost to the investigators that is not included in the budget. Replacement restorations would be fabricated in the Graduate General Dentistry Clinic at the prevailing charge per unit. Dentsply will pay the cost of these replacement restorations as described above.

9.2 Monitoring

The sponsor will monitor this trial at timely intervals for compliance with this protocol, applicable FDA regulations and any conditions of approval imposed by the reviewing IRB. This trial will also be monitored for safety related issues to determine whether any unreasonable risk to subjects develops. Quality control measures include inspection of case report forms and source documents for accuracy and completeness. The Principal Investigator is ultimately responsible for the accuracy and completeness of case report forms, source documents, raw data listings and data tabulations. Between monitoring visits, the Sponsor must be updated by the site as to study status by phone, fax or email.

Dentsply may monitor the study at appropriate intervals 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.

10 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 Wilcoxin 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.

11 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 12 months to recruit and place the restorations required for the study. An additional 5 years will be required to complete the five year recall examinations with an additional 9 months to complete the data analysis and final reports.

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, Dentsply, and the reviewing IRB prior to implementation. Any decision as to whether to prematurely stop the study will be taken jointly by the PI, Dentsply, and the IRB. Where early termination of the study occurs, subjects will receive appropriate follow up dental treatment.

12 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.

13 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.

14 Additional Sponsorships:

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

15 Budget

Insertion Phase – 100 crowns (50 crowns per 2 groups) **Placement and Baseline Evaluation**	**Requested**
Supplies and Equipment	**$6,850**
CEREC OmniCam System –supplies included milling diamonds, milling chamber lubricant, milling chamber filters	
Clinical supplies/materials for crown placement and baseline evaluation.	
Cementation kits and supplies to include XP Bond, Calibra cement, and Calibra Ceram cement kits and dispensers	Provided by Dentsply
Celtra Duo blocks (all shades; I10, I12, I14 sizes)	Provided by Dentsply
emaxCAD blocks (all shades; I12, I14 sizes)	
Impression materials, mixing guns, and mixing tips/intraoral tips light body fast set & regular body	Provided by Dentsply
Model fabrication	
Personnel	**$67,000**
Operator – clinical treatment required to complete the onlays	
Dental Assistant - chairside assisting, protocol compliance, data recording, maintain materials and supplies, infection control maintenance	
Clinical Research Coordinator - organize study, recruit and appoint patients, order supplies, manage data and consent forms, catalogue photos, data verification and computer entry, train dental assistant, manage recall, monitor compliance to protocol	
Dr. Fasbinder - evaluator, principal investigator Oversee study, develop data and consent forms, recruit patients, clinical evaluations, data analysis, model analysis, prepare reports	
TBD Faculty (3) - evaluator, co-investigators Review study, recruit patients, clinical evaluations, statistical analysis, model analysis, review prepared reports	
Sub-Total	**$73,850**
University overhead (30%)	$22,155
Total	**$96,005**

Recall Phase – 100 crowns **6 months, 1 year, 2 year, 3 year**	**Requested**
Supplies and Equipment	**$2,000**
Clinical supplies/materials for recall evaluation	
Impression materials and mixing tips/intraoral tips light body fast set & regular body	Provided by Dentsply
Model fabrication	
Bitewing radiographs (**year 3 only**)	
Personnel	**$20,500**
Dental Assistant	
Clinical Research Coordinator	
Dr. Fasbinder - evaluator, principal investigator	
TBD Faculty (3) - evaluator, co-investigators	
Sub-Total	**$22,500**
University overhead (30%)	$6,750
Total	**$29,250**

Proposed Study – Project budget for CROWNS	**Requested**
Placement of 100 crowns	$96,005
6 month recall	$29,250
1 year recall	$29,250
2 year recall	$29,250
3 year recall	$29,250
Total	**$213,005**

Funding for years four and five recalls are to be negotiated after the second year recall has been completed.

Budget time-line
It will take 12 months to recruit the patients and deliver the crowns for the study. The 1 year recall will occur in the second year of the study, and similarly for future recalls in that the 2 year recall will occur in the third year of the study and continuing. This will result in a total time of 6 years required to place and complete the 5 year recall of the crowns with an additional 6-9 months needed to complete the data analysis and final report for the project.

Appendix

Patient Questionnaire
Clinical Evaluation Criteria

INITIAL QUESTIONNAIRE

Patient: _____ Date:_____

1. Birthdate (month-day-year) _____

2. Gender: male _____ female _____

3. Has there been any sensitivity on the tooth to be restored? yes ____ no ____

4. 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)

6. Tooth/Teeth number to be restored (crown): _____

7. Pre-operative vitality; verify with cold test: Vital Devital (circle one)

8. Reason tooth needs restoration:

fractured cusp	_____	caries	_____
esthetics	_____	fractured restoration	_____
fracture lines	_____	open margins	_____
severe wear	_____	cervical overhang	_____
poor contour	_____	open proximal contact	_____

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

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

11. Informed Consent form signed. _____ (initials)

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

13. Opposing Tooth: (photograph opposing teeth; with and without occlusal contacts marked)
    Restorative material: _____
    Evidence of wear facets: yes no
    Evidence of lateral interferences: _____
    Is patient a bruxer?: _____

CLINICAL EVALUATION CRITERIA

Gingival Index (for crowns)

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 (for crowns)

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 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

Anatomic Form (general contour)	
Restoration is continuous with existing anatomic form	Alpha
Restoration is discontinuous with existing anatomic form but missing material is not sufficient in size to expose dentin	Bravo
Restoration is discontinuous with existing anatomic form and missing material is sufficient in size to expose dentin	Charlie

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

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

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

Restoration Fracture

No evidence of restoration fracture	Alpha
Evidence of restoration fracture with a missing piece considered polishable	Bravo
Evidence of restoration fracture with a missing piece considered repairable	Charlie
Fracture of the restoration requiring replacement of the restoration	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