Clinical Evaluation of Lithium Disilicate Quartz Chairside CAD/CAM Crowns

University of Michigan IRB: HUM00191892

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27 Jul 2021
Date

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 recent interest are newer high strength materials that have been introduced for chairside applications. Lithium disilicate CAD/CAM restorations have been popular due to an esthetic result with high strength. However, a somewhat involved and lengthy fabrication process after the restoration has been milled, including crystallization oven firing under vacuum is required to achieve the desired results. Full contour zirconia crowns have increased in clinical application for a number of reasons including a more conservative preparation, improved fracture resistance of the material, and ease in cementation. However, an oven fired sintering process using the SpeedFire oven (Dentsply Sirona) is required to generate the high strength of the zirconia. And the time required for sintering is similar in length to the lithium disilicate crystallization process. Initial full contour zirconia materials available for chairside CAD/CAM

crowns had high strength (>900 MPa flexural strength), but also were relatively opaque compromising the esthetic results.

An innovative high strength, lithium disilicate ceramic material is reported to offer a more efficient fabrication process resulting in a similar esthetic and high strength crown. Lithium Disilicate Quartz (Ivoclar Vivadent) is a glass ceramic with crystalline phases of lithium disilicate and quartz.

Current glass ceramic materials have a recommended minimum thickness to maintain the maximum strength potential of the material. An occlusal thickness of 1.5 mm is generally recommended. This can be a challenge to achieve in the posterior of the mouth with teeth with limited clinical crown height. In addition, the glass ceramic material should be adhesively bonded to ensure maximum strength of the restoration. Lithium Disilicate Quartz offers an alternative high strength ceramic that may allow a more conservative occlusal reduction resulting in a crown thickness of 1.2 mm, equitable to the recommendation for full contour zirconia crowns. The material may also be sufficiently strong to allow for conventional cementation in addition to adhesive bonding.

Current high strength materials have not been embraced for partial coverage restorations due to the lengthy post-milling firing process. Lithium Disilicate Quartz may also offer a more clinical efficient process to fabricate partial coverage restorations since it does not require post-milling crystallization.

It is the intent of this investigation to evaluate the clinical application and performance of the new high strength, lithium disilicate quartz material for CAD/CAM-generated chair-side crown applications.

5 Summary of Objectives and Design

This investigation will be a randomized, prospective, longitudinal clinical trial to study the clinical performance of a new monolithic, high strength precrystallized lithium disilicate material for chairside CAD/CAM crowns. The restorations 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 cementation techniques using a self-adhesive, self-curing resin cement and a total etch/universal bonding agent with a dual-cured resin cement.
2. Evaluate the resistance to material chipping and fracture of reduced thickness high strength precrystallized lithium disilicate CAD/CAM crowns.

3. Evaluate the longitudinal clinical performance of precrystallized lithium disilicate crowns over five years of clinical service. The crowns will be evaluated with modified FDI criteria for maintaining their esthetic, functional and biological properties.

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 at least 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 tooth. Each lesion or defective restoration should exhibit sufficient size or loss of tooth structure requiring a full crown restoration. The tooth should have at least one opposing tooth in occlusion and one adjacent tooth with an intact proximal contact. 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 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/or rampant caries

Women who self-report that they are possibly pregnant, pregnant, or lactating, as elective dental treatment is not indicated at these times

Patients with a self-reported past history of allergies to the materials to be used in the study including composite resin cements or ceramic restorative materials

Patients unable to return for the recall appointments

7.2 Study Size

There will be a maximum total of 80 monolithic, high strength precrystallized lithium disilicate crowns (Quartz by Ivoclar Vivadent). There will be 2 groups of 40 crowns differentiated by occlusal thickness and type of cement.

Group 1 = occlusal thickness of 1.5 mm delivered with a self-adhesive, self-curing resin cement (SpeedCem Plus/Ivoclar).

Group 2 = occlusal thickness of 1.2 mm delivered with Adhese Universal Adhesive in total etch mode with a dual cure resin cement (Variolink Esthetic by Ivoclar Vivadent).

The study will be a randomized, longitudinal clinical study with the outcome data to be benchmarked against published results of other chairside CAD/CAM materials.

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 FDI criteria (Hickel et al., 2007 and 2010) (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, and post-operative conditions. Facial and occlusal views of the tooth will be documented for both the pre-operative and post-operative conditions including occlusal contacts.

A post-cementation quadrant optical scan (CEREC PrimeScan) will be made of each test restoration at each recall visit. The scan will include the quadrant with the test crown, the opposing quadrant and buccal bite.

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 is not available for review. The use of

radiographs in the study is in compliance with the standard of care for ensuring and maintaining the health of the tooth during treatment and not for research-specific reasons.

8.3 Data Management

Case Report Form (CRF)

Castor EDC is a cloud-based Electronic Data Capture (EDC) platform which will be used to collect data. All changes are tracked by an audit trail. The pictures are stored locally at the University of Michigan. After entering data by a study coordinator the data will be reviewed and approved by the principal investigator

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. 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 10 months to recruit and deliver the restorations required 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 restorations with an additional 9 months needed to complete the data analysis and final report for the project. Additional recall periods beyond the 5 years may also take place following approval by Ivoclar Vivadent.