Official Title: Clinical Evaluation of Chairside CAD/CAM Resilient Ceramic Crowns

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1 Investigation Title

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3 Sponsor

Ivoclar Vivadent

4 Background

There has been significant interest in computer assisted design/computer assisted manufactured (CAD/CAM)-generated restorations as the technology has evolved. Innovative high strength and resin-based restorative materials have been introduced for a variety of single tooth restoration indications. A limitation of the current high strength ceramic materials is the increased clinical time required for fabrication and processing of the materials to achieve the high strength feature. Resin-based ceramic CAD/CAM materials have been introduced that offer a material that can absorb a greater functional load without chipping as may occur with ceramic materials. This has lead to the general categorization of Resilient Ceramic CAD/CAM blocks to distinguish them from conventional direct composite materials. Another stated advantage of a resin-based resilient ceramic material is a shorter fabrication and processing procedure compared to high strength ceramic materials to allow for a more efficient clinical workflow.

A new resilient ceramic CAD/CAM block has been developed, Tetric CAD (Ivoclar Vivadent). It is a digital restorative material based on the previously documented composite chemistry of Tetric Evoceram (Ivoclar Vivadent) and consists of a highly cross linked dimethcrylate resin matrix with inorganic barium glass and silicon dioxide fillers (71.1% by weight). The blocks are available in two translucencies; High Translucency (HT) recommended for intracoronal restorations such as inlays and onlays and Medium Translucency (MT) recommended for exracoronal restorations such as crowns. The manufacturer reports a biaxial flexural strength of 272 MPa that is significantly greater than adhesive glass ceramic materials currently available for chairside CAD/CAM restorations. It is also reported to have a Modulus of Elasticity of 11 GPa confirming its resilient property.

It is the intent of this investigation to evaluate the clinical application and performance of this new monolithic, resin-based resilient ceramic material for chairside CAD/CAM crowns.

5 Summary of Objectives and Design

This investigation will be a prospective, longitudinal clinical trial to study the clinical performance of a new monolithic resilient ceramic 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 an adhesive luting technique using a total etch process with a universal bonding agent and dual-cured resin cement.

2. Evaluate the longevity of the surface finish and anatomy of the resilient ceramic crowns over five years of clinical service.
3. Evaluate the longitudinal clinical performance of a new monolithic resilient ceramic restorative material for chairside CAD/CAM crowns over five years of clinical service.

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 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 resin cements or composite resin restorative materials

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.

The potential benefits for patients to enroll in the study include receiving a time efficient, long term crown for their tooth at a significantly reduced cost compared to usual and customary private practice fees.

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 50 monolithic, resilient ceramic crowns (Tetric CAD by Ivoclar Vivadent) placed using an adhesive bonding process including a total etch process with a universal adhesive (Adhese by Ivoclar Vivadent) and dual cured resin cement (Variolink Esthetic by Ivoclar Vivadent). It will be a longitudinal clinical study with the outcome data to be benchmarked against published results of other chairside CAD/CAM materials.

7.4 Baseline - Restoration Placement

A Treatment Appointment Checklist will be completed by the Clinical Research Coordinator and treating doctor at the restorative appointment (copy enclosed in Appendix). This will document the baseline information required for delivering the crown. 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 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. 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 adhesive cementation of the crowns.

The crown preparation will be in accordance with the manufacturers guidelines and will have a rounded shoulder design of at least 1.0 mm axial reduction, 2.0 mm reduction over cusps, and a minimum of 1.5 mm reduction in the central fissure area. The maximum thickness of Tetric CAD that will allow complete polymerization of the adhesive bonding agent is 3.0 mm. If defects in the tooth structure would result in a thickness of the crown to be greater than 3.0 mm, a core will be placed replacing some of the missing tooth structure to limit the thickness of the crown to less than 3.0 mm. The core will be placed using a total etch process. The entire cavity preparation will be etched using 37% phosphoric acid for 20 seconds and then thoroughly rinsed with water spray and lightly dried. Adhese Universal (Ivoclar Vivadent) will be applied in an active scrubbing action to the tooth preparation for 20 seconds and lightly air dried. MultiCore (Ivoclar Vivadent) will be injected on the preparation and VLC for 2 minutes. The final crown preparation will be completed based on the previous guidelines.

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 (Dentsply Sirona) using the most current version of the software (4.5.2 as of February 2018). The crowns will be milled from prefabricated blocks of Tetric CAD (Ivoclar Vivadent).

The crown will be tried-in intraorally after milling to verify the proximal contacts, margin fit, and occlusal relationships prior to surface finishing. Cement try-in pastes may be used to verify the shade of the dual cure resin cement with the selected shade of the crown to confirm the desired shade of the tooth to be restored. The crown will be rinsed thoroughly with an air-water spray once the final shade is confirmed to remove any remaining try-in paste and dried with oil-free air. The internal surface of the crown will be air abraded (50 micron aluminum oxide, 1 bar pressure) to create a uniform matte surface. After air abrasion, the restoration will be cleaned in an ultrasonic unit with 70% ethanol for 3 minutes. The crown will be thoroughly rinsed with water spray and dried with oil-free air. Adhese Universal (bonding agent) will be applied to the air abraded surface with an active scrubbing motion for 20 seconds and lightly air dried. It will NOT be light cured prior to cementation.

Adhesive Cementation

Crowns will be adhesively bonded using a total etch process. The entire cavity preparation will be etched using 37% phosphoric acid for 20 seconds and then thoroughly rinsed with water spray and dried with oil-free air. Adhese Universal (Ivoclar Vivadent) will be applied in an active scrubbing action to the tooth preparation for 20 seconds and lightly air dried. It will be cured for 10 seconds using a light intensity of 500 mW/cm². The previously determined shade of Variolink Esthetic (Ivoclar Vivadent) will be injected directly from the automix syringe into the crown. The crown will be inserted to complete seating and light cured for 2 seconds per line angle prior to initial cleaning of the excess cement. Once the margins have been completely cleaned, the margins will be coated with a glycerine gel/air block (Liquid Strip by Ivoclar Vivadent) and the crown will be light cured for 40 seconds from the facial, lingual and occlusal for a total cure of 2 minutes. If necessary the tooth will be cooled with air during polymerization.

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 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 FDI criteria (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 optical scan (CEREC OmniCam) will be made of each test restoration at each recall visit. 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. 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)

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).

All data will be reported through an online software program called “Evaluation”. The data collected through this software will be stored without patient identifiers and the study sponsor will only be able to see the patient ID. Global Information Services (Ivoclar Vivadent Internal IT Department) operates the central data protection for the data to ensure consistent contingency processes and to prevent data loss. Enterprise Backup Solution is used for virtual data backup and restore. All data originating from this study are stored on the servers intended for this purpose. The SPSS Server is stored in the DMZ Zone at the Ivoclar Headquarters in Schaan.

The data is stored in protected directories that are not generally accessible. Access to data deserving protection may only be granted to authorized individuals to ensure the proper task fulfillment. The user management is part of the system, with the proper role, and the permissions are managed. Users can be locked at any time, so no access is possible. At all times an audit trail shows the movements or changes done on the platform. All SPSS data will be stored on the relevant server, there is no dedicated archiving in place, since the data quantity is minimal. Deletion of any data is not foreseen.

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.

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 restoration 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 Ivoclar Vivadent. Upon a determination that the restoration failure did not result from other identifiable causes, and with Ivoclar Vivadent's prior approval, the Investigator will make arrangements to replace the restoration, or carry out appropriate alternative treatment (i.e. replacement with a fixed or removable partial denture) at Ivoclar Vivadent's expense. Ivoclar Vivadent will not be responsible for any expenses incurred without its prior approval. If a restoration fails after the term of the study, Ivoclar Vivadent will not be responsible for any costs incurred in its repair or replacement. Ivoclar Vivadent 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. Ivoclar Vivadent 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.

Ivoclar Vivadent 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. 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, Ivoclar Vivadent, and the reviewing IRB prior to implementation. Any decision as to whether to prematurely stop the study will be taken jointly by the PI, Ivoclar Vivadent, 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, 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.

Appendix

Treatment Appointment Checklist
Clinical Evaluation Criteria

TREATMENT APPOINTMENT CHECKLIST

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?: _____

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. 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. 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. 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

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	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: 3.3.1 more opaque 3.3.2 more translucent 3.3.3 darker 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 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** **a. contact point** **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) 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). 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 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; 100 µm metal blade can pass 8b.4 Inadequate contour 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. 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. 9.2.2 Positive/negative step present at margin <150 µm.	10.2 Satisfied. 10.2.1 Aesthetics. 10.2.2 Function, e.g., minor roughness
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage)	9. 3. 1 Marginal gap < 250 µm. 9. 3. 2 Negative steps visible < 250 µm. No adverse effects noticed. 9.3.3 Poor radiopacity of filling material.	10.3 Minor criticism but no adverse clinical effects. 10.3.1 Aesthetic shortcomings. 10.3.2 Some lack of chewing comfort. 10.3.3 Unpleasant treatment procedure.
4. Clinically unsatisfactory / (but repairable)	9.4.1 Marginal gap >250 µm. 9.4.2 Material excess accessible but not removable. 9.4.3 Negative steps >250µm and repairable.	10.4 Desire for improvement 10.4.1 Aesthetics. 10.4.2 Function, e.g., tongue irritation Reshaping of anatomic form or refurbishing is possible.
5. Clinically poor (replacement necessary)	9.5.1 Secondary caries, large gaps, large overhangs 9.5.2 Apical pathology 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 (after correction maybe very good) No treatment required.	11.2 Minor hypersensitivity for a limited period of time, normal vitality.	12.2 Small and localized 1. Demineralization 2. Erosion or 3. Abfraction.
3.Clinically sufficient / satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	11.3.1 Moderate hypersensitivity 11.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed.	12.3 Larger areas of 1. Demineralisation 2. Erosion or 3.Abrasion/abfraction, dentine not exposed Only preventive measures necessary.
4. Clinically unsatisfactory (repair for prophylactic reasons)	11.4.1 Intense hypersensitivity. 11.4.2 Delayed with minor subjective symptoms. 11.4.3 No clinical detectable sensitivity. Intervention necessary but not replacement.	12. 4.1 Caries with cavitation and suspected undermining caries 12.4.2 Erosion in dentine 12.4.3 Abrasion/ abfraction in dentine. Localized and accessible can be repaired.
5. Clinically poor (replacement necessary)	11.5 Intense, acute pulpitis or non vital tooth. Endodontic treatment is necessary and restoration has to be replaced.	12.5 Deep caries or exposed dentine that is not accessible for repair of restoration.