PROTOCOL

"Clinical Evaluation of an Experimental Urethane Dimethacrylate Resin Based Composite"

NCT0201882

Purpose: This double blind randomized, controlled prospective clinical trial will compare the clinical success of two tooth colored resin composite dental filling materials- TPH3 (Dentsply Caulk) and an experimental urethane dimethacrylate resin based composite resin (Dentsply Caulk) for wear resistance, staining and marginal seal using modified Ryge criteria to evaluate the posterior restorations for 24 months in duration.

Study Objectives

The purposes of this clinical trial is to evaluate two composite resins used to restore Class I and Class II cavities in teeth of adults. The clinical study will evaluate the resin composite restorations placed in Class I and Class II cavity preparations for anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, gingival index, staining,wear, and thermal response for 24 months..

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Study Design

The study will be double blind randomized, controlled clinical evaluation of similar sized class I and class II with both dental restorative materials placed in a single patient. Both esthetic restorative materials will be bonded with a single bonding agent Prime and Bond Elect (Dentsply Caulk).

Randomization: teeth that require restorations and satisfy the inclusion criteria parameters will be randomly selected. Code R will be assigned to the most anterior tooth or located on the right. Code T will be assigned to the most posterior tooth or located on left. See randomization scheduled (appendix 3). Sponsor will blind both esthetic bonding materials and label them code R and code T.

The study will be conducted in the Division of General Dentistry at Eastman Institute for Oral Health University of Rochester. The study will evaluate the pair of composite resin restorations over a two year period.

50 adult patients aged 18 - 85 yearsold will be recruited into the study. Based on previous clinical trials, the average attrition rate for a two year clinical trial is approximately 10% per year. To assure that 30 restorations per material are available at the three year recall, 100 restorations (50 of each material) will be placed assuming a 20% attrition rate.

Investigators

Dr Hans Malmstrom is the Principal Investigator. Drs Malmstrom will conduct the screening examinations and Dr. Malmstrom and members of the study team will obtain consent.. Experienced sub-investigators will place the tooth colored restorations.. Two of the study team investigators who have not placed the restorations will complete the baseline, 6 month, 12 months and 24 months recall examinations of the restorations. Investigators will not evaluate the restorations they placed. Baseline evaluations will be conducted one week after the restorations are placed.

Background and Significance.

Posterior resin composites are used by 80% of the dentists practicing in the United States [1]. The results of the first clinical trial of posterior composites were published in 1971 [2]. Subsequent recalls of the same restorations revealed that the resin composite restorations had poor wear resistance [3, 4]. Early reviews recommended that these materials be limited to conservative bicuspid and first molar restorations where esthetics was critical [5]. In spite of improvements in resin composites, material limitations exist which restrict the use of resin composite as a posterior restorative material. Clinically, resin restorations are difficult and require more placement time than a similar sized amalgam restoration [6]. Interproximal contacts are difficult to obtain since composite is a paste material that shrinks during polymerization; two clinical investigations reported weak or defective contacts in 20% of the posterior composite restorations [7, 8].

Resin-based composite consists mainly of a resin matrix surrounding inorganic filler particles. The primary constituents of the resin matrix are resin monomers and an initiator/catalyst system for polymerization. The first dental RBC monomer developed in the 1960's is still used today. Based on the reaction product of bisphenol-A and glycidyl methacrylate (bis-GMA) it is a bulky monomer with methacrylate groups at each end of the molecule (dimethacrylate). Polymerization occurs through a free radical addition reaction. The double bonded carbons of the methacrylate groups at each end of the active site on the monomer cross-links during the polymerization process initially producing a linear polymer, then, by reacting with the second site a highly cross linked polymer is produced [35]. Since bis-GMA is quite viscous, it must be thinned by using shorter, more flexible diacrylate monomers, e.g., ethylene glycol dimethacrylate (EGDMA) and triethylene glycol dimethacrylate (TEGDMA). In the 1970's another diacrylate monomer, urethane dimethacrylate (UDMA) was adopted for dental use, the molecular weight is similar to bis-GMA, but more flexible. UDMA may be used alone or in combination with other diacrylate monomers [36]. Other base monomers are utilized besides bis-GMA and urethane dimethacrylate, however, none has been proven to be clinically superior; these two monomers still predominate.

Adhesives bond the composite resin into the cavity preparation. The entire bonding technique requires isolation from salivary contamination, although the newest dentin bonding agents are more moisture resistant than older generation agents, and blood contaminants are detrimental to bond strength [9, 10].

Although accurate measurement of posterior composite wear is difficult and many different methods have been used to measure wear, most studies have concluded that composite resins exhibit greater loss of anatomic form in occlusal contact areas than in contact free areas [17]. The wear of early composites ranged from 12-105 microns per year, while in the same studies, amalgam wear ranged from 6-58 microns per year and enamel wear ranged from 3-54 microns per year [17-21]. As composite resin materials have improved, so has wear resistance. The current generation of composite resin has wear rates from 4.9 microns for Clearfil Photoposterior [22] and 7-8 microns for Heliomolar [23] which compares favorably to enamel. Additional wear has been shown with composite resin restorations with increased size, in more posterior teeth and in patients with fewer remaining teeth.

Other developments of composite resin with more wear resistance and adhesive systems with stronger bonds to tooth structure are needed. This study will evaluate the clinical success of two composite resins with different chemistries.

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Materials:

Experimental Composite: experimental urethane dimethacrylate, triethylene glycol dimethacrylate, camphorquinone, photoinitiator, co-initiator, butylated hydroxytoluene (BHT), UV stabilizer, fluorescing agent. Fillers are barium aluminum fluoro borosilicate glass, strontium alumino fluorosilicate glass, silicon dioxide nano filler, iron and titanium oxide pigments.

Control Material: TPH[3] resin matrix a Bis-GMA adduct, Bis-EMA, triethylene glycol dimethacrylate camphoroquinone, photoinitiator, stabilizer, pigments. Fillers are a mixture of barium alumino boro silicate glass and barium fluoro alumino boro silicate glass with a mean particle size below 1μm and nanofiller silica (particle size 10-20nm).

Duration of the investigation: 24 months

Number of restorations:
100 restorations will placed to ensure a minimum 60 restorations (30/group)

Class of restorations:
Restorations will be placed in separate preparations in Class I and Class II in upper and lower jaw in bicuspids and molars. All teeth will have natural teeth or crowns of bridgework as antagonists. For the clinical evaluation of the resin, specific criteria (table 1 and 2) will be used to evaluate the restorations directly and indirectly.

Distribution of restorations:
Each patient must need at least 2 restorations so one restoration of each material can be placed in each patient. Restorations will be placed in sets of two for each patient. A maximum of 25% of the restorations will be class I the remainder will be class II restorations.

Size of cavities:
Moderate-large cavities with an isthmus width greater than or equal to 1/3 the intercuspal distance (1/3 the distance between the cusp tips) will be selected for this study.

Subject Population:
Subjects for this investigation will be selected from patients of the University of Rochester at Eastman Institute for Oral Health. Fifty subjects who are generally seeking routine dental care, need two restorations on asymptomatic posterior teeth and aged 18-85 will be recruited.

Inclusion Criteria:

- must have given written consent to participate in the trial
- must be in need of at least two restorations in natural tooth
- replacement restorations with or without caries are acceptable
- must be available for the required post-operative follow-up visits
- restorations to be in bicuspids, 1st or 2nd molars

- restorations to be in contact with opposing natural or crowned teeth
- class II restorations must have at least one proximal contact
- restorations must have a buccal to lingual/palatal width equal to or greater than 1/3 the distance from buccal to lingual/palatal cusp tips
- 75% of the restorations must be Class II
- all restorations must have at least one occlusal contact in habitual closure

Subjects may be excluded for this study if they:

- have severe medical complications (organ transplants, long term antibiotic or steroid treatment, cancer or immunocompromised) or disabilities who may not be able to tolerate the time required to complete the restorations or to provide adequate oral hygiene
- have xerostomia either by taking medications known to produce xerostomia or those with radiation induced or Sjogren's syndrome patients
- have chronic periodontitis, rampant caries or poor oral hygiene which may require extraction of the teeth to be restored
- have a history of chronic bruxism and those unavailable for long term recall
- can not tolerate the rubber dam required for tooth isolation during preparation and restoration.
- do not meet all inclusion criteria
- present with any systemic or local disorders that contra-indicate the dental procedures included in this study
- have an unstable occlusion
- have severe bruxing or clenching or need of TMJ related therapy
- have teeth with periapical pathology or expected pulp exposures
- have teeth that are non-vital or that exhibit signs of pulpal pathology
- Pregnancy
- Known sensitivity to methacrylates and/or acrylates

Screening

Each subject will be screened for compliance with the inclusion/exclusion criteria specified above.

Risks to the patient:

Patients will wear lead aprons as a protective measure during the radiographic procedure to minimize risk. Patient data will be monitored and if, during the course of the study, it becomes apparent that any restorative material is significantly poorer, the patient will be informed and, if needed, the restorations replaced at no cost to the subject.

Other potential risks associated with restorations' study and standard procedures are as follows:Impressions – subjects may experience gag reflex as the soft paste hardens in their mouth.

Photographs – stretching of lips and buccal tissues to allow tooth visibility.

Gingival index – subjects may experience some discomfort around the gingival margins of the two restored teeth as a dental instrument (probe) stimulate the gingival tissues.

Sensitivity test – a cotton swab embedded with a cold solution is placed on the tooth surface to assess sensitivity. Subject may experience a cold sensation that may last 2-3 seconds (same as eating ice cream).
Vitality test – Subject may experience a tingling sensation as the device measures nerve vitality.

Consent:

Consent for this study will be obtained prior to the initial examination and the initiation of any portion of the study. The PI or sub-investigators and study coordinator will explain the consent to the patient and answer questions they may have. The consent forms and all records associated with this study will be maintained in the clinical research office under lock to ensure the records are confidential. Each subject will provide written consent to participate in this study in accordance with Federal regulations (21 CFR Parts 50 and 56).

Materials and Methods:

Two light-cured resin composites: (TPH 3, Dentsply Caulk and an Experimental urethane dimethacrylate resin based composite resin, Dentsply Caulk) will be used to restore teeth with moderate-large size class I or class II cavity preparations. Each composite resin will be used with Prime and Bond Elect bonding agent. All restored teeth will be in occlusion with at least one proximal contact for each class II restorations with an adjacent tooth. Cavity preparations will be prepared for all restorations following rubber dam isolation unless it is not possible due to abnormal anatomic considerations.

Cavity preparation design. To be included in this study restorations must have a buccal to lingual isthmus width equal to or greater than 1/3 the distance from buccal to lingual/palatal cusp tips, 75% of the restorations must be Class II.

All prepared margins will be placed ninety degrees to the external tooth surface. Any tooth with a carious or mechanical pulpal exposure will be excluded from the study. Any cavity preparation judged to be within 1mm of pulpal tissue either clinically or radiographically will be lined with Dycal (Dentsply Caulk, Milford, DE) a calcium hydroxide containing liner. Palodent Plus (Dentsply Caulk) or other sectional matrix will be used with class 2 restorations; however a Toffelmire matrix may be used with large preparations. The composite will be photoinitiated with a curing light (Smart Lite, Dentsply Caulk) with an output of at least 750 mW/cm^2. Output will be recorded for each restoration placed. The resin composite will be placed using an incremental filling technique, beginning with an initial increment in the gingival floor. Subsequent increments will be placed to fill the box. No increment will exceed 2mm.

Investigators will insert 100 restorations. Carbide finishing burs (Midwest 7402, OS 1,OS 2) will be used to remove gross excess, followed by finishing strips and disks (Sof-Lex, 3M, St Paul, MN), and the Enhance system (Dentsply Caulk, Milford, DE). All polishing will be done at slow speed with water spray. After removing the rubber dam the occlusion will be adjusted. Each restoration will be evaluated directly and indirectly at . The direct clinical evaluations will be made using the checklist in table one, a modification of the United States Public Health Services (USPHS) guidelines.
Each restoration will be evaluated for anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, gingival index. Indirect wear measurements will be made on casts from impressions made at each recall and baseline.
Two of the trained evaluators (Drs Malmstrom, Ren, Yunker and Romero) who have not placed restorations, will perform post-restorative evaluation at baseline, 6 months, 12

months and 24 months. A consensus will be reached if both evaluators disagree on the restorations' direct assessment. Dr Malmstrom will provide retraining any time throughout the study upon evaluator's request.

Study Visits

Subjects will be evaluated at the Eastman Institute for Oral Health General Dentistry Department. Study visits at 6, 12 and 24 months may be combined with routine dental care visits.

Screening:

Subjects will be screened for study eligibility. Two bitewing radiographs will be taken of teeth in need of restorations.

If a subject is eligible, the informed consent process will initiate. Subject will be given a consent form by a member of the study team and discuss study procedures. Subjects will be informed about the option of taking the consent form home and schedule an appointment at their convenience as well as that their participation is strictly voluntary and participation will not affect their care.

If the subject wishes to participate in the study a copy of the consent form will be given and pre-operative assessments indicated on schedule of events (appendix 1) will be administered. If the subject satisfies inclusion criteria for the study and wishes to receive the restoration at this visit, the study coordinator will assign products code according to subject number listed on the randomization list (appendix 3) and restorations will be placed by one of the sub-investigators. Subject can choose to schedule a separate appointment for restorations placement and no additional study procedure will be required at the restorative visit.

Baseline (one week after the restorations)

Study procedure:

Subject's restorations will be evaluated by two investigators other than the investigator who placed the restorations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- sensitivity
- Gingival index – (a dental probe will gently stimulate gingival tissues around the two restored teeth).
- Impressions for wearing and contact assessments will be taken. – A soft material is placed on the subject's upper or lower dentition or both (depending on the location of restored teeth). As the material hardens will leave a negative print of the subject's dentition. A stone material is then poured into the impression resulting in a cast which will allow restorations' wearing and contact measurements.
- Two radiographs will be taken.. These radiographs are taken in addition to the screening radiographs as they will provide a post-restorative baseline.

- Photographs of both restorations will be taken with a digital camera. Subjects will be identified according to their assigned subject number.

Standard of care: Patient is scheduled a week after a restoration is placed for follow up. Radiographs may be taken for possible overhang and/or patient's complaints.
Patients will be asked to report complaints and possible adverse events.

6 months follow-up

Study procedure:
Subject's restorations will be evaluated by two investigators other than the investigator who placed the restorations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- Photographs of both restoration
- Gingival index score will be collected.

- Vitality – an electrical pulp tester is placed on the tooth in need of restoration and an adjacent tooth to evaluate level of vitality. A drop of toothpaste or the subject's saliva is used as a conductor of electricity. Subjects may experience a tingling sensation.
- Sensitivity - (a cotton swab embedded with a cold solution will be placed on the tooth surface to assess sensitivity response)

Standard of care:.
Patients will be asked to report complaints and possible adverse events.

12 months follow-up

Study procedure:
Subject's restorations will be evaluated by two investigators other than the investigator who placed the resforations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- Sensitivity

- Gingival index score will be collected.
- Vitality test
- Impressions for wearing and contact assessments will be taken (See Baseline)
- Photographs of both restorations will be taken
- 2 periapical radiographs of restored teeth will be taken to evaluate possible apical pathology.

Standard of care
Bitewing in addition to the two periapical radiographs will be taken for annual dental caries screening.
Subjects will be asked to report complaints and adverse events.

24 months follow-up

Study procedure:
Subject's restorations will be evaluated by two investigators other than the investigator who placed the resforations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- Sensitivity
- Gingival index score will be collected
- Vitality test
- Impressions for wearing and contact assessments will be taken (See baseline).
- Photographs of both restorations will be taken
- 2 periapical radiographs of restored teeth will be taken to assess apical pathology.
- Patients will be asked to report possible adverse events.

Standard of care
Bitewing in addition to periapical radiographs will be taken for dental annual screening.
Subjects will be asked to report complaints and adverse events.

Cost

Subjects and/or dental insurance will be responsible for the cost associated with standard of care of diagnostic procedures. In the event that alternative treatment is indicated, such as replacing a failed restoration, sponsor will be responsible for the cost associated with the procedure. Diagnostic radiographs for study requirements will be taken at no charge to the subjects.

9. **Payment for Participation.**

Subject will receive the following payments.

baseline - $20

6 months – $40

12 months – $50

24 months – $70

Subjects will receive a total of $180.00

Evaluators will be calibrated.

Dr Malmstrom will conduct preclinical sessions to train clinicians by preparing and restoring at least two extracted teeth mounted in stone. Each tooth will be prepared and restored according to the guidelines above and will also standardize restoration placement among the clinicians (Drs Malmstrom, Yunker, Ren and Romero). Dr Malmstrom will also conduct a clinical training session to train clinician evaluators (Drs Malmstrom, Yunker, Ren and Romero)to conduct baseline and recall measurements using the standards, appendix 1. Scores for each evaluator will be compared to other evaluators and inter-evaluator comparisons made. The trained evaluators will independently evaluate each restoration in our clinical study and a forced consensus obtained if necessary. A kappa value of 0.8 of all criteria is expected after calibration of the examiners

Data Analysis:

Restorations placed using each composite will be analyzed. The categorized clinical assessment data (color, marginal discoloration, secondary caries, anatomic form, marginal adaptation) will be summarized by computing percentages for each category and used to describe any trends noted in the performance of the groups. In the analysis of categorical data of anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, and gingival index, the frequency distribution over various categories will be calculated and reported. A sample size of 100 restorations in 50 subjects is not based on a statistical plan, but rather on guidelines put forth by the American Dental Association for obtaining approval as an amalgam replacement for posterior restorations. The guidelines specifically call for an evaluation of a minimum of 30 restorations in a minimum of 20 subjects at 18 months. Taking subject attrition into account that forms the 2 and 3 year requirements.

The primary efficacy variables are based on ADA guidelines for acceptance and include the direct assessments of anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, and gingival index, and periapical pathology. Scores for primary efficacy variables will be summarized and displayed using descriptive statistics. The success criteria for the primary efficacy variables for passing the ADA requirements for acceptance at 18 months, namely;

Color Match – no more than 10% scores of C

Marginal Discoloration – no more than 10% scores of C

Marginal Integrity – no more than 10% scores of C – no scores of D

Caries – an incidence of no greater than 5%

Proximal Contour – not less than 95% showing no observable evidence of broadening of contact

Wear– no more than 50 microns

The ADA guidelines do not specify requirements for Proximal Contacts, Vitality, Sensitivity or Periapical Pathology. Success criteria for these parameters will be based on comparisons to incidences reported in the literature. Secondary efficacy variables include direct assessments of Anatomic Form and the Gingival Index, and the indirect assessment of occlusal contact. Scores will be summarized and displayed using descriptive statistics. Success criteria will be based on comparisons to reports in the literature. Safety variables include adverse events, unanticipated adverse device effects, and complaints. Descriptions of occurrences, incidence, severity and required treatments will be summarized and tabulated where appropriate.

Criteria for evaluation:
Modified USPHS criteria will be used to assess individual restorations.

Times of evaluation: Baseline, 6 months, 12 months, 24 months

Unanticipated Adverse Device Effects
Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

MONITORING The sponsor may monitor this trial at timely intervals for compliance with this protocol, applicable FDA regulations and any conditions of approval imposed by reviewing the IRB. This trial will also be monitored for safety related issues to determine whether any unreasonable risk to subjects develops.

ACCESS TO RECORDS
Investigators will permit monitoring, audits and regulatory inspections and will provide direct access to study related documentation.

REPORTING REQUIREMENTS

- Unanticipated Adverse Device Effects will be reported to the sponsor and the reviewing IRB as soon as possible, but no later than within 10 working days.
- Withdrawal of IRB approval will be reported to the sponsor within 5 working days. Any use of the device in humans without informed consent will be reported to the sponsor within 5 working days. Upon request, reports of complaints and adverse events will be provided to the sponsor.

Problem cases
Where a study restoration has failed this will be recorded on the Failed Restoration An alternative treatment (of a different composite resin restorative and bonding system, or other direct restorative system, at the discretion of the clinician) will be offered to the patient and a record made in the patient's notes. Neither the patient, nor the clinician will pay for this further treatment. Dr. Nick Conte, Director of Clinical Research at Dentsply Caulk must be notified that an alternative treatment has been necessary and requires payment by the sponsor. Factors determining restoration failure or success will be the result of evaluators' assessment criteria listed on Appendix 2.

Both restorative materials will have the same tooth color, consistency and odor.

Adverse Events

Any adverse reaction to the treatment provided as part of the study will be fully investigated and recorded on the Adverse Event Record Form including details of the appropriate clinical action taken, and promptly reported to the Investigational Review Board. Dr. Nick Conte, Director of Clinical Research, Dentsply Caulk will be the contacted at (302-430-7303). In the event of an adverse reaction to the restorative material, any indemnity will be borne by Dentsply Caulk, in accordance with the research contract. Any decision as to whether to prematurely stop the study will be taken jointly by the PI, IRB and Dentsply Caulk. The IRB will be updated by the PI regarding adverse events according to the IRB reporting guidelines.

Reports to sponsor

The PI will prepare and submit a report to the sponsors following completion of the 6 month, 12 month and 24 month recalls

Publication of findings

The investigators will be entitled to publish the findings of the evaluation; the data may also be presented as an abstract or oral presentation at an appropriate Dental Research meeting. Any manuscript, abstract or other communication prepared for submission or public presentation should be submitted to the sponsors for comment as stated in the contract. The data will also be communicated internally at Caulk to appropriate members of the Business Team and Professional Services, Marketing, Regulatory and R & D personnel.

"Clinical Evaluation of an Experimental Urethane Dimethacrylate Resin Based Composite"

APPENDIX 1 - SCHEDULE OF EVENTS

Procedure	screening	Restoration	Baseline one week after restoration	6 months	12 months	24 months
Preoperative radiographs	X *					
Patient assignment # / randomization		X				
Preoperative tooth vitality	X					
preoperative sensitivity testing	X					
preoperative gingival index	X					
treatment		X				
photograph with occlusal marking	X					
direct assessment						
anatomic form			X	X	X	X
color match			X	X	X	X
marginal intergrity			X	X	X	X
marginal discoloration			X	X	X	X
proximal contacts			X	X	X	X
polishability			X	X	X	X
caries			X	X	X	X
sensitivity			X	X	X	X

gingival index			X	X	X	X
vitality				X	X	X
indirect assessment						
impressions - wear and proximal contact assessments			X		X	X
caries – radiograph (bitewings)			X		X*	X*
occlusal contact - photographs			X	X	X	X
periapical pathology - radiograph			X		X	X
Complaints			X*	X*	X*	X*
adverse events			X*	X*	X*	X*
unanticipated adverse device events			X*	X*	X*	X*

* standard of care

APPENDIX 2
SCORING CRITERIA FOR DIRECT ASSESSMENTS

Anatomic Form	
A =	The restoration is continuous with existing form.
B =	The restoration is discontinuous with existing anatomic form, but the existing material is not sufficient to expose dentine.
C =	Sufficient material lost to expose dentin or lining material.

Color Match	
A =	The restoration appears to match the shade and translucency of adjacent tooth structure.
B =	The restoration does not match the shade and translucency of adjacent tooth structure, but the mismatch is within the normal range of tooth shades and translucency.
C =	The restoration does not match the shade and translucency of the adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.

Marginal Integrity	
A =	No visible evidence of a crevice along the margin into which the explorer will penetrate.
B1 =	Explorer clicks on the margin
B2=	Visible evidence of a crevice.
C =	Explorer penetrates into crevice, and dentin or base is exposed.
D =	Restoration is mobile, fractured or missing.

Marginal Discoloration	
A =	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color the adjacent tooth structure.
B =	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction.
C =	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction.

Proximal Contacts	
A =	Tight proximal contacts evaluated with dental floss.
B =	Proximal contacts are weak but present.
C =	No proximal contacts but not visibly open.
D =	Visibly open contacts.

Polishability	
Alpha=	Smooth & highly shiny, similar to enamel
Bravo 1=	Smooth & satin, highly reflective
Bravo 2=	Smooth & shiny but not highly reflective
Charlie =	Rough & shiny, satin, somewhat reflective
Delta=	Rough & dull or satin, not reflective
Eta=	Unacceptable polish

Caries	
A **=**	Absent
B =	Present

Sensitivity-Visual analog will be measured on 10 cm scale
Visual Analog Scale (VAS) ■_____■ No Pain Maximum pain

Gingival Index	
0 =	Normal gingival.
1 =	Mild inflammation, slight change in color, slight edema, no bleeding on probing.
2 =	Moderate inflammation, redness; edema and glazing; bleeding on palpation.
3 =	Severe inflammation, marked redness and edema, ulceration, tendency to spontaneous bleeding.

Appendix 3

Randomized list

Subject #	Code R	Code T
1	T	R
2	R	T
3	R	T
4	R	T
5	T	R
6	T	R
7	R	T
8	R	T
9	R	T
10	R	T
11	R	T
12	T	R
13	T	R
14	T	R
15	T	R
16	T	R
17	T	R
18	R	T
19	R	T
20	R	T
21	R	T
22	T	R
23	T	R
24	R	T
25	R	T
26	T	R
27	R	T
28	T	R
29	T	R
30	R	T
31	T	R
32	R	T
33	R	T
34	T	R
35	R	T

Place code **R** on most anterior tooth or on the **left** side of the mouth

Place code **T** on most posterior or on the **Right** side of the mouth

36	T	R
37	R	T
38	T	R
39	R	T
40	T	R
41	R	T
42	R	T
43	T	R
44	R	T
45	R	T
46	R	T
47	T	R
48	T	R
49	T	R
50	T	R

PROTOCOL Addendum

"Clinical Evaluation of an Experimental Urethane Dimethacrylate Resin Based Composite"

Purpose: This addendum protocol is a controlled prospective clinical trial to evaluate and compare the clinical success of an additional investigational tooth colored resin composite dental filling material, EsthetX HD (Dentsply/Caulk), to TPH3 (Dentsply Caulk) and to an experimental urethane dimethacrylate resin based composite resin (Dentsply Caulk). Comparison of EsthetX HD (Dentsply/Caulk) to the resin composite materials used in the original protocol is necessary in order to evaluate its clinical performance. Using the modified Ryge criteria, EsthetX HD (Dentsply/Caulk) restorations will be evaluated for wear resistance, staining and marginal seal during a 24 month period.

Study Objectives

The purpose of this clinical trial is to evaluate and compare an additional composite resin material used to restore Class I and Class II cavities in teeth of adults. The clinical study will evaluate the resin composite restorations placed in Class I and Class II cavity preparations for anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, gingival index, staining,wear, and thermal response for a 24 months period.

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Study Design

The study will be a controlled clinical evaluation of similar sized class I and class II with dental restorative materials placed in a single patient. The esthetic restorative materials will be bonded with a single bonding agent Prime and Bond Elect (Dentsply Caulk).

The study will be conducted in the Division of General Dentistry at Eastman Institute for Oral Health University of Rochester. The study will evaluate the composite resin restorations over a two year period.

Fifty adult patients aged 18 - 85 years old will be recruited into the study. Based on previous clinical trials, the average attrition rate for a two year clinical trial is approximately 10% per year. To assure that 30 restorations per material are available at the two year recall, 50 restorations will be placed assuming a 20% attrition rate.

Investigators

Dr Hans Malmstrom is the Principal Investigator. Drs Malmstrom will conduct the screening examinations and Dr. Malmstrom and members of the study team will obtain consent.. Experienced sub-investigators will place the tooth colored restorations.. Two of the study team investigators who have not placed the restorations will complete the baseline, 6 month, 12 months and 24 months recall examinations of the restorations. Investigators will not evaluate the restorations they placed. Baseline evaluations will be conducted one week after the restorations are placed.

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Material:

Experimental Material: EsthetX HD improvement composite made by Calk using three lots of the glass filler, which were silanated in a production Resodyn unit at Calk. The raw material, unsilanated glass (also called TPM filler) was provided by TPM company in a production scale. The TPM filler was designed to reduce the stickiness of current EsthetX HD composite.

Duration of the investigation: 24 months

Number of restorations:
50 restorations will placed to ensure a minimum 30 restorations

Class of restorations:
Restorations will be placed in separate preparations in Class I and Class II in upper and lower jaw in bicuspids and molars. All teeth will have natural teeth or crowns of bridgework as antagonists. For the clinical evaluation of the resin, specific criteria (table 1 and 2) will be used to evaluate the restorations directly and indirectly.

Distribution of restorations:
EsthetX HD material will be placed on patients who need at least one tooth restored, with a maximum of two restorations per each patient. A maximum of 25% of the restorations will be class I the remainder will be class II restorations.

Size of cavities:
Moderate-large cavities with an isthmus width greater than or equal to 1/3 the intercuspal distance (1/3 the distance between the cusp tips) will be selected for this study.

Subject Population:
Enrollment for subjects who received composite restoration TPH3 Spectra HV (Dentsply Caulk) and an experimental urethane dimethacrylate resin based composite resin (Dentsply Caulk) is complete and currently on the follow-up phase. An additional 50 subjects for this investigation will be selected from patients of the University of Rochester at Eastman Institute for Oral Health. Fifty subjects who are generally seeking routine dental care and need one or two restorations on asymptomatic posterior teeth and aged 18-85 will be recruited.

Inclusion Criteria:

- must have given written consent to participate in the trial
- must be in need of at least one restorations in natural tooth
- replacement restorations with or without caries are acceptable
- must be available for the required post-operative follow-up visits
- restorations to be in bicuspids, 1st or 2nd molars
- restorations to be in contact with opposing natural or crowned teeth
- class II restorations must have at least one proximal contact

- restorations must have a buccal to lingual/palatal width equal to or greater than 1/3 the distance from buccal to lingual/palatal cusp tips
- 75% of the restorations must be Class II
- all restorations must have at least one occlusal contact in habitual closure

Subjects may be excluded for this study if they:

- have severe medical complications (organ transplants, long term antibiotic or steroid treatment, cancer or immunocompromised) or disabilities who may not be able to tolerate the time required to complete the restorations or to provide adequate oral hygiene
- have xerostomia either by taking medications known to produce xerostomia or those with radiation induced or Sjogren's syndrome patients
- have chronic periodontitis, rampant caries or poor oral hygiene which may require extraction of the teeth to be restored
- have a history of chronic bruxism and those unavailable for long term recall
- can not tolerate the rubber dam required for tooth isolation during preparation and restoration.
- do not meet all inclusion criteria
- present with any systemic or local disorders that contra-indicate the dental procedures included in this study
- have an unstable occlusion
- have severe bruxing or clenching or need of TMJ related therapy
- have teeth with periapical pathology or expected pulp exposures
- have teeth that are non-vital or that exhibit signs of pulpal pathology
- Pregnancy
- Known sensitivity to methacrylates and/or acrylates

Screening

Each subject will be screened for compliance with the inclusion/exclusion criteria specified above.

Risks to the patient:

Patients will wear lead aprons as a protective measure during the radiographic procedure to minimize risk. Patient data will be monitored and if, during the course of the study, it becomes apparent that any restorative material is significantly poorer, the patient will be informed and, if needed, the restorations replaced at no cost to the subject.

Other potential risks associated with restorations' study and standard procedures are as follows:

Impressions – subjects may experience gag reflex as the soft paste hardens in their mouth.

Photographs – stretching of lips and buccal tissues to allow tooth visibility.

Gingival index – subjects may experience some discomfort around the gingival margins of the two restored teeth as a dental instrument (probe) stimulate the gingival tissues.

Sensitivity test – a cotton swab embedded with a cold solution is placed on the tooth surface to assess sensitivity. Subject may experience a cold sensation that may last 2-3 seconds (same as eating ice cream).
Vitality test – Subject may experience a tingling sensation as the device measures nerve vitality.

Consent:
Consent for this study will be obtained prior to the initial examination and the initiation of any portion of the study. The PI or sub-investigators and study coordinator will explain the consent to the patient and answer questions they may have. The consent forms and all records associated with this study will be maintained in the clinical research office under lock to ensure the records are confidential. Each subject will provide written consent to participate in this study in accordance with Federal regulations (21 CFR Parts 50 and 56).

Materials and Methods:
A light-cured resin composites: EsthetX HD will be used to restore teeth with moderate-large size class I or class II cavity preparations. Each composite resin will be used with Prime and Bond Elect bonding agent. All restored teeth will be in occlusion with at least one proximal contact for each class II restorations with an adjacent tooth. Cavity preparations will be prepared for all restorations following rubber dam isolation unless it is not possible due to abnormal anatomic considerations.

Cavity preparation design. To be included in this study restorations must have a buccal to lingual isthmus width equal to or greater than 1/3 the distance from buccal to lingual/palatal cusp tips, 75% of the restorations must be Class II.

All prepared margins will be placed ninety degrees to the external tooth surface. Any tooth with a carious or mechanical pulpal exposure will be excluded from the study. Any cavity preparation judged to be within 1mm of pulpal tissue either clinically or radiographically will be lined with clinically successful Surefil SDR flow plus in up to 4mm increments leaving atleast 2mm for Esthet-X HD improvement material on exposed occlusal surface. Palodent Plus (Dentsply Caulk) or other sectional matrix will be used with class 2 restorations; however a Toffelmire matrix may be used with large preparations. The composite will be photoinitiated with a curing light (Smart Lite Focus, Dentsply Caulk) with an output of at least 750 mW/cm^2. Output will be recorded for each restoration placed. The resin composite will be placed using an incremental filling technique, beginning with an initial increment in the gingival floor. Subsequent increments will be placed to fill the box. No increment will exceed 2mm for Estet-X HD improvement, TPH 3 Spectra HV and 4mm when Surefil SDR flow is used as liner

Investigators will insert 150 restorations. Carbide finishing burs (Midwest 7402, OS 1,OS 2) will be used to remove gross excess, followed by finishing strips and disks (Sof-Lex, 3M, St Paul, MN), and the Enhance system (Dentsply Caulk, Milford, DE). All polishing will be done at slow speed with water spray. After removing the rubber dam the occlusion will be adjusted. Each restoration will be evaluated directly and indirectly at The direct clinical evaluations will be made using the checklist in table one, a modification of the United States Public Health Services (USPHS) guidelines.
Each restoration will be evaluated for anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, gingival index. Indirect wear measurements will be made on casts from impressions made at baseline, 12 and 24 month recall visit

Two of the trained and calibrated evaluators (Drs Malmstrom, Ren, Yunker, DeRosa and Alejandro Murguia-Sanchez) who have not placed restorations, will perform post-restorative evaluation at baseline, 6 months, 12 months and 24 months. A consensus will be reached if both evaluators disagree on the restorations' direct assessment. Dr Malmstrom will provide retraining any time throughout the study upon evaluator's request.

Study Visits

Subjects will be evaluated at the Eastman Institute for Oral Health General Dentistry Department. Study visits at one week, 6, 12 and 24 months may be combined with routine dental care visits.

Screening:

Subjects will be screened for study eligibility. Two bitewing radiographs will be taken of teeth in need of restorations.

If a subject is eligible, the informed consent process will initiate. Subject will be given a consent form by a member of the study team and discuss study procedures. Subjects will be informed about the option of taking the consent form home and schedule an appointment at their convenience as well as that their participation is strictly voluntary and participation will not affect their care.

If the subject wishes to participate in the study a copy of the consent form will be given and pre-operative assessments indicated on schedule of events (appendix 1) will be administered. If the subject satisfies inclusion criteria for the study and wishes to receive the restoration at this visit a restoration or two restorations will be placed by one of the sub-investigators. Subjects can choose to schedule a separate appointment for restorations placement and no additional study procedure will be required at the restorative visit.

Baseline (one week after the restorations)

Study procedure:

Subject's restorations will be evaluated by two investigators other than the investigator who placed the restorations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- sensitivity
- Gingival index – (a dental probe will gently stimulate gingival tissues around the two restored teeth).
- Impressions for wearing and contact assessments will be taken. – A soft material is placed on the subject's upper or lower dentition or both (depending on the location of restored teeth). As the material hardens will leave a negative print of the subject's dentition. A stone material is then poured into the impression resulting in a cast which will allow restorations' wearing and contact measurements.
- Two radiographs will be taken. These radiographs are taken in addition to the screening radiographs as they will provide a post-restorative baseline.

- Photographs of restoration(s) will be taken with a digital camera. Subjects will be identified according to their assigned subject number.

Standard of care: Patient is scheduled a week after a restoration is placed for follow up. Radiographs may be taken for possible overhang and/or patient's complaints.
Patients will be asked to report complaints and possible adverse events.

6 months follow-up

Study procedure:
Subject's restoration (s) will be evaluated by two investigators other than the investigator who placed the restorations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- Photographs of both restoration
- Gingival index score will be collected.

- Vitality – an electrical pulp tester is placed on the tooth in need of restoration and an adjacent tooth to evaluate level of vitality. A drop of toothpaste or the subject's saliva is used as a conductor of electricity. Subjects may experience a tingling sensation.
- Sensitivity - (a cotton swab embedded with a cold solution will be placed on the tooth surface to assess sensitivity response)

Standard of care:
Patients will be asked to report complaints and possible adverse events.

12 months follow-up

Study procedure:
Subject's restoration(s) will be evaluated by two investigators other than the investigator who placed the restorations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- Sensitivity

- Gingival index score will be collected.
- Vitality test
- Impressions for wearing and contact assessments will be taken (See Baseline)
- Photographs of both restorations will be taken
- 2 periapical radiographs of restored teeth will be taken to evaluate possible apical pathology.

Standard of care
Bitewing in addition to the two periapical radiographs will be taken for annual dental caries screening.
Subjects will be asked to report complaints and adverse events.

24 months follow-up

Study procedure:
Subject's restoration(s) will be evaluated by two investigators other than the investigator who placed the restorations for the following:

- anatomic form,
- color match,
- marginal integrity,
- marginal discoloration,
- proximal contact,
- polishability
- caries.
- Sensitivity
- Gingival index score will be collected
- Vitality test
- Impressions for wearing and contact assessments will be taken (See baseline).
- Photographs of both restorations will be taken
- 2 periapical radiographs of restored teeth will be taken to assess apical pathology.
- Patients will be asked to report possible adverse events.

Standard of care
Bitewing in addition to periapical radiographs will be taken for dental annual screening.
Subjects will be asked to report complaints and adverse events.

Cost

Subjects and/or dental insurance will be responsible for the cost associated with standard of care of diagnostic procedures. In the event that alternative treatment is indicated, such as replacing a failed restoration, sponsor will be responsible for the cost associated with the procedure. Diagnostic radiographs for study requirements will be taken at no charge to the subjects.

9. **Payment for Participation.**

Subject will receive the following payments.

baseline - $20

6 months – $40

12 months – $50

24 months – $70

Subjects will receive a total of $180.00

Evaluators will be calibrated.

Dr Malmstrom will conduct preclinical sessions to train clinicians by preparing and restoring at least two extracted teeth mounted in stone. Each tooth will be prepared and restored according to the guidelines above and will also standardize restoration placement among the clinicians (Drs Malmstrom, Yunker, Ren and Alejandro Murguia-Sanchez). Dr Malmstrom will also conduct a clinical training session to train clinician evaluators (Drs Malmstrom, Yunker, Ren and Alejandro Murguia-Sanchez) to conduct baseline and recall measurements using the standards, appendix 1. Scores for each evaluator will be compared to other evaluators and inter-evaluator comparisons made. The trained evaluators will independently evaluate each restoration in our clinical study and a forced consensus obtained if necessary. A kappa value of 0.8 of all criteria is expected after calibration of the examiners

Data Analysis:

Restorations placed using each composite will be analyzed. The categorized clinical assessment data (color, marginal discoloration, secondary caries, anatomic form, marginal adaptation) will be summarized by computing percentages for each category and used to describe any trends noted in the performance of the groups. In the analysis of categorical data of anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, and gingival index, the frequency distribution over various categories will be calculated and reported. A sample size of 100 restorations in 50 subjects is not based on a statistical plan, but rather on guidelines put forth by the American Dental Association for obtaining approval as an amalgam replacement for posterior restorations. The guidelines specifically call for an evaluation of a minimum of 30 restorations in a minimum of 20 subjects at 18 months. Taking subject attrition into account that forms the 2 and 3 year requirements.

The primary efficacy variables are based on ADA guidelines for acceptance and include the direct assessments of anatomic form, color match, marginal integrity, marginal discoloration, proximal contact, polishability, caries, sensitivity, and gingival index, and periapical pathology. Scores for primary efficacy variables will be summarized and displayed using descriptive statistics. The success criteria for the primary efficacy variables for passing the ADA requirements for acceptance at 18 months, namely;

Color Match – no more than 10% scores of C

Marginal Discoloration – no more than 10% scores of C

Marginal Integrity – no more than 10% scores of C – no scores of D

Caries – an incidence of no greater than 5%

Proximal Contour – not less than 95% showing no observable evidence of broadening of contact

Wear– no more than 50 microns

The ADA guidelines do not specify requirements for Proximal Contacts, Vitality, Sensitivity or Periapical Pathology. Success criteria for these parameters will be based on comparisons to incidences reported in the literature. Secondary efficacy variables include direct assessments of Anatomic Form and the Gingival Index, and the indirect assessment of occlusal contact. Scores will be summarized and displayed using descriptive statistics. Success criteria will be based on comparisons to reports in the literature. Safety variables include adverse events, unanticipated adverse device effects, and complaints. Descriptions of occurrences, incidence, severity and required treatments will be summarized and tabulated where appropriate.

Criteria for evaluation:
Modified USPHS criteria will be used to assess individual restorations.

Times of evaluation: Baseline, 6 months, 12 months, 24 months

Unanticipated Adverse Device Effects
Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

MONITORING The sponsor may monitor this trial at timely intervals for compliance with this protocol, applicable FDA regulations and any conditions of approval imposed by reviewing the IRB. This trial will also be monitored for safety related issues to determine whether any unreasonable risk to subjects develops.

ACCESS TO RECORDS
Investigators will permit monitoring, audits and regulatory inspections and will provide direct access to study related documentation.

REPORTING REQUIREMENTS
- Unanticipated Adverse Device Effects will be reported to the sponsor and the reviewing IRB as soon as possible, but no later than within 10 working days.
- Withdrawal of IRB approval will be reported to the sponsor within 5 working days. Any use of the device in humans without informed consent will be reported to the sponsor within 5 working days. Upon request, reports of complaints and adverse events will be provided to the sponsor.

Problem cases
Where a study restoration has failed this will be recorded on the Failed Restoration An alternative treatment (of a different composite resin restorative and bonding system, or other direct restorative system, at the discretion of the clinician) will be offered to the patient and a record made in the patient's notes. Neither the patient, nor the clinician will pay for this further treatment. Dr. Nick Conte, Director of Clinical Research at Dentsply Caulk must be notified that an alternative treatment has been necessary and requires

payment by the sponsor. Factors determining restoration failure or success will be the result of evaluators' assessment criteria listed on Appendix 2.
Restorative materials will have the same tooth color, consistency and odor.

Adverse Events

Any adverse reaction to the treatment provided as part of the study will be fully investigated and recorded on the Adverse Event Record Form including details of the appropriate clinical action taken, and promptly reported to the Investigational Review Board. Dr. Nick Conte, Director of Clinical Research, Dentsply Caulk will be the contacted at (302-430-7303). In the event of an adverse reaction to the restorative material, any indemnity will be borne by Dentsply Caulk, in accordance with the research contract. Any decision as to whether to prematurely stop the study will be taken jointly by the PI, IRB and Dentsply Caulk. The IRB will be updated by the PI regarding adverse events according to the IRB reporting guidelines.

Reports to sponsor

The PI will prepare and submit a report to the sponsors following completion of the 6 month, 12 month and 24 month recalls

Publication of findings

The investigators will be entitled to publish the findings of the evaluation; the data may also be presented as an abstract or oral presentation at an appropriate Dental Research meeting. Any manuscript, abstract or other communication prepared for submission or public presentation should be submitted to the sponsors for comment as stated in the contract. The data will also be communicated internally at Caulk to appropriate members of the Business Team and Professional Services, Marketing, Regulatory and R & D personnel.

"**Clinical Evaluation of an Experimental Urethane Dimethacrylate Resin Based Composite**"

APPENDIX 1 - SCHEDULE OF EVENTS

Procedure	screening	Restoration	Baseline one week after restoration	6 months	12 months	24 months
Preoperative radiographs	X *					
Patient assignment # / randomization		X				
Preoperative tooth vitality	X					
preoperative sensitivity testing	X					
preoperative gingival index	X					
treatment		X				
photograph with occlusal marking	X					
direct assessment						
anatomic form			X	X	X	X
color match			X	X	X	X
marginal integrity			X	X	X	X
marginal discoloration			X	X	X	X
proximal contacts			X	X	X	X
polishability			X	X	X	X
caries			X	X	X	X
sensitivity			X	X	X	X
gingival index			X	X	X	X
vitality				X	X	X
indirect assessment						
impressions - wear and proximal contact assessments			X		X	X
caries – radiograph (bitewings)			X		X*	X*
occlusal contact - photographs			X	X	X	X
periapical pathology - radiograph			X		X	X
Complaints			X*	X*	X*	X*
adverse events			X*	X*	X*	X*
unanticipated adverse device events			X*	X*	X*	X*

* standard of care

APPENDIX 2

SCORING CRITERIA FOR DIRECT ASSESSMENTS

Anatomic Form	
A =	The restoration is continuous with existing form.
B =	The restoration is discontinuous with existing anatomic form, but the existing material is not sufficient to expose dentine.
C =	Sufficient material lost to expose dentin or lining material.

Color Match	
A =	The restoration appears to match the shade and translucency of adjacent tooth structure.
B =	The restoration does not match the shade and translucency of adjacent tooth structure, but the mismatch is within the normal range of tooth shades and translucency.
C =	The restoration does not match the shade and translucency of the adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.

Marginal Integrity	
A =	No visible evidence of a crevice along the margin into which the explorer will penetrate.
B1 =	Explorer clicks on the margin
B2=	Visible evidence of a crevice.
C =	Explorer penetrates into crevice, and dentin or base is exposed.
D =	Restoration is mobile, fractured or missing.

Marginal Discoloration	
A =	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color the adjacent tooth structure.
B =	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction.
C =	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction.

Proximal Contacts	
A =	Tight proximal contacts evaluated with dental floss.
B =	Proximal contacts are weak but present.
C =	No proximal contacts but not visibly open.
D =	Visibly open contacts.

Polishability	
Alpha=	Smooth & highly shiny, similar to enamel
Bravo 1=	Smooth & satin, highly reflective
Bravo 2=	Smooth & shiny but not highly reflective
Charlie =	Rough & shiny, satin, somewhat reflective
Delta=	Rough & dull or satin, not reflective
Eta=	Unacceptable polish

Caries	
A **=**	Absent
B =	Present

Sensitivity-Visual analog will be measured on 10 cm scale
Visual Analog Scale (VAS) ■_____■ No Pain Maximum pain

Gingival Index	
0 =	Normal gingival.
1 =	Mild inflammation, slight change in color, slight edema, no bleeding on probing.
2 =	Moderate inflammation, redness; edema and glazing; bleeding on palpation.
3 =	Severe inflammation, marked redness and edema, ulceration, tendency to spontaneous bleeding.