KC IRB
Protocol Summary

Protocol Number: 1403626552A004

Status: Submitted to IRB

Expiration Date: 04/30/2015

Last Approval Date:

Investigator: Platt, Jeffrey A.

Protocol Details

Type: Full Board

Description:

Application Date: 02/17/2015

Reference Num 1:

Reference Num 2:

FDA Application No:

Title: CLINICAL EVALUATION OF A UNIVERSAL ADHESIVE IN NONCARIOUS CERVICAL LESIONS

Organizations

Type	Organization
Performing Organization	Indiana University (UA)
Performance Site	Indiana University

Funding Source

Type	Number/Code	Name/Title
Sponsor	053500	IVOCLAR NORTH AMERICA, INC.
Institutional Proposal	00346994	CLINICAL EVALUATION OF A UNIVERSAL ADHESIVE IN NONCARIOUS CERVICAL LESIONS
Award	064329-00001A	CLINICAL EVALUATION OF A UNIVERSAL ADHESIVE IN NONCARIOUS CERVICAL LESIONS
Award	064329-00002B	CLINICAL EVALUATION OF A UNIVERSAL ADHESIVE IN NONCARIOUS CERVICAL LESIONS

Subjects

Subject	Count
Total	33

Areas of Research

Code	Description
000001	All Research Areas

Personnel

Person Name	Units		Role	Affiliate	Training Flag
Platt, Jeffrey A.	IN-DSRD	DENTISTRY-RESTORATIVE DENT	PI	IU	Y
Rouse, Matthew Adam	IU-UNIV	UNIVERSITY LEVEL	CO-PI	IU	Y

Study Personnel

PersonName	Role	Affiliation	Training
Adams, Brooke N	Key Personnel	IU	Y
Capin, Oriana Reis	Key Personnel	IU	Y
Carlson, Timothy J.	Non-Key, Not Interacting	IU	Y
Cook, Norman Blaine	Key Personnel	IU	Y
Diefenderfer, Kim Edward	Key Personnel	IU	N
Eckert, George J.	Non-Key, Interacting	IU	Y
Jackson, Richard D.	Non-Key, Interacting	IU	Y
Kirkup, Michele Lee	Key Personnel	IU	Y

Roles

Protocol Aggregator

User Id	User Name	Unit Name
	Kelly, Sue Antionette	

Study Manager / Correspondent

User Id	User Name	Unit Name
	Tran, Jennifer L	

Attachments

Description	Attachment Type	Last Updated	Updated By
dated Jan 21, 2014	HIPAA & Recruitment Checklist	03/28/2014 13:52:18	sakelly
dated january 21, 2014	HIPAA Authorization Form (Non-VA)	04/21/2014 13:21:56	efelde
dated March 4, 2014	Informed Consent Statement	04/21/2014 13:17:46	efelde
ICS - Final Stamped	Informed Consent Statement	05/23/2014 11:19:37	shream
medicl device form 1 of 1	Medical Device Form	04/21/2014 13:18:42	efelde
amendment 4	Protocol	02/17/2015 14:59:53	mbjork
telephone interview form amendment 3	Recruitment Materials	01/29/2015 12:17:17	mbjork
pamphlet amendment 3	Recruitment Materials	01/29/2015 12:17:17	mbjork
amendment 4	Summary Safeguard Statement	02/17/2015 14:59:53	mbjork

Other Attachments

Description	Last Updated	Updated By
510k 1	03/28/2014 14:00:33	sakelly
510k 2	03/28/2014 14:01:20	sakelly
CITI proof	01/14/2015 12:05:06	sakelly

Amendment/ Renewal

Type	Version	Status	Created Date	Summary
Amendment	004	Submitted to IRB	02/16/2015	amendment 4 - remove saliva inclusion criteria

Amendment/Renewal Summary

Summary	Editable Modules
amendment 4 - remove saliva inclusion criteria	Add / Modify Attachments and Notes,

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IRB APPROVAL

This research project, including all noted attachments, has been reviewed and approved by the Indiana University IRB.

☐ Exempt Category(ies), if applicable:

☒ Expedited Category(ies), if applicable: (900)

Authorized IRB Signature: Annette Head IRB Approval Date: 02/19/2015

Printed Name of IRB Member: Annette Head

Appendix G-3

Indiana University School of Dentistry
Graduate Student Research Proposal Abstract Form
(for review by the IUSD Research Subcommittee)

Project Title: Clinical Evaluation of a Universal Adhesive in Non-Carious Cervical Lesions

	Name	Signature**
Principal Investigator:	Dr. Jeffrey Platt	
Co-investigator (student):	Dr. Matt Rouse	
Research Committee:	Dr. N. Blaine Cook	
	Dr. Timothy Carlson	
	Dr. Bruce Matis	
	Dr. Richard Jackson	
Project Biometrician:	Mr. George Eckert	

Department/Program: Operative / Preventive

Cost of Project: $40,532 Dates of Project: Feb 2014 - May 2016

Use of: Human Subjects or Tissues: ✓ Animals: _____ Biohazards or rDNA: _____

Reviewed by Sue Kelly (IRB, only if human subjects involved) ✓

Reviewed by Melissa Mau (Good Clinical Practice, only if human subjects involved) _____

Reviewed by Rebecca Dixon (Research Billing Compliance, only if human subjects involved) _

**Signature indicates that the proposal has been read and approved.
Place Abstract on separate page and attach prior to remainder of proposal.

Table of Contents

Clinical Evaluation of a Universal Adhesive in Non-Carious Cervical Lesions

Background/Relevance: For decades, resin adhesives have been used to restore non-carious cervical lesions for esthetics and/or patient comfort. New "universal adhesives" claim to simplify the process of bonding resin composites to tooth structure while maintaining or exceeding the quality of previous adhesive systems. Since dentin and enamel substrates are vastly different with respect to composition and therefore require different bonding protocols, some have advocated a "selective etch" procedure in which the enamel and dentin are etched differently but may still be bonded using a similar bonding agent. The purpose of this study is to determine whether or not a selective etch protocol used with a universal adhesive provides significantly improved results in comparison to a self-etch protocol when restoring non-carious cervical lesions.

Rationale: In vitro studies have shown statistically significantly superior marginal adaptation and color stability with a selective etch technique, but there are currently no prospective in vivo studies greater than 6 months comparing the efficacy of selective vs. self- etch techniques in conjunction with a universal adhesive.

Methods: Thirty-three patients with at least two non-carious cervical lesions (NCCLs) will receive one restoration utilizing the self-etch universal adhesive (Adhese Universal, Ivoclar Vivadent) with no separate enamel etching and another restoration utilizing the universal adhesive and a selective etch protocol in which enamel is etched with 37% phosphoric acid. The adhesive and Tetric composite will be provided by Ivoclar and manufacturer's instructions will be followed for placement of the restorations.

Alternate Hypothesis: Selective-etch restorations will show superior retention rates, marginal adaptation, and color stability after 2 years compared to self-etch restorations.

Relevance: With so many different types of resin adhesives and numerous proposed methods, this study could provide evidence supporting one protocol and eliminate some of the confusion associated with resin bonding protocols.

Clinical Evaluation of a Universal Adhesive in Non-Carious Cervical Lesions

Background:

Non-carious cervical lesions (NCCLs) have been well documented in the dental literature for over a century[1,2]. Differing opinions exist concerning the etiology of NCCLs, but many agree that the etiologies differ and include abrasion, erosion, attrition, and abfraction, a term coined in 1991[3,4]. Although a few patients may not experience adverse effects from the presence of NCCLS, many patients experience sensitivity ranging from mild to severe. The esthetics of the dentition may also be compromised by the presence of NCCLs. For decades, resin adhesives have been used to restore non-carious cervical lesions for esthetics and/or patient comfort; restoration of these lesions with a bonded resin restoration has been shown to be more effective than no treatment or topical treatment with a desensitizing dentifrice[5]. Since the advent of "fourth generation" (also referred to as "3-bottle") resin bonding agents in the 1990s, the primary focus in the development of resin adhesives has been simplifying the components and thus the protocol for placing resin composite restorations. New "universal adhesives" claim to simplify the process of bonding resin composites to tooth structure while maintaining or exceeding the quality of previous adhesive systems. Since dentin and enamel substrates are vastly different with respect to their composition and therefore require different bonding protocols, some have advocated a "selective etch" procedure in which the enamel and dentin are etched differently but may still be bonded using the same bonding agent. An *in vitro* study by Hanbusa et al (2012) indicated that use of a universal adhesive with selective etching of enamel with phosphoric acid provides better bonding efficacy than when the adhesive is used as a

self-etch alone[6]. An *in vivo* study performed by Mena-Serrano et al (2012, 2013) has also shown similar results[7,8], but since significant hydrolysis of the dentin-resin interface continues to occur after six months or even twelve months, a longer clinical trial is indicated which more accurately depicts longer term clinical success[9]. Conversely, a 3-year study was previously conducted by Can Say, et al (2013) to compare self-etch and selective-etch techniques, but with a two-step bonding system instead of a one-step system[10].

Purpose/Specific Aims:

The purpose of this prospective clinical trial will be to evaluate the efficacy of a newly formulated "universal" dental adhesive formulation in adult noncarious cervical lesions using self-etch and selective etch approaches; the aim is to determine whether or not selective etching provides significantly improved retention and/or better resistance to enamel margin discoloration in comparison to self-etching over a 24 month period.

Hypothesis:

The alternate hypothesis is that the restorations placed utilizing a selective etch method will yield superior retention, marginal adaptation, and less marginal discoloration than restorations placed with the self-etch method.

The null hypothesis is that there will be no significant differences with respect to retention, marginal adaptation, or marginal discoloration when comparing restorations placed with selective etch and self-etch methods.

Materials and Methods

1.0 Inclusion/Exclusion Criteria

A total of 33 patients ranging in age from 20 to 75 years of age will be recruited for this study. Roughly 10 patients will be in the following age groups: 20-39, 40-59, and $\geq$60.

The study population will be targeted to be comparable in terms of the ratio of men to women. Subjects will be selected that meet the following criteria:

1.1. Inclusion criteria

1. Willing to provide written consent and authorization for participation.
2. Be between 20 and 75 years of age at the time of recruitment
3. Have at least two non-carious cervical lesions present in canine or premolar teeth;
4. Anticipates availability for recalls (roughly 6 month, 12 month, and 24 month) through the two-year study period
5. The lesions selected will be at least 1 mm in depth (measured with a perio probe) and contain both enamel and dentin margins.

1.2. Exclusion criteria

1. Severe medical complications (organ transplants, cancer, immunocompromised, long term antibiotic or steroid therapy);
2. Active caries on study teeth;
3. Bleeding on probing of study teeth;
4. Generalized severe periodontitis;
5. Patient reported symptoms (burning mouth, loss or diminished taste, saliva amount too little, needs liquids to eat dry foods) or clinical signs (erythematous tongue, chelitis, lack of pooled saliva) associated with dry mouth;

6. Patients determined to be at a high risk of caries as determined by a Caries Risk Assessment

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2.0 Enrollment/Randomization

The clinical design will use each technique (self-etch and selective etch & rinse) in each of thirty-three subjects. Each subject will have at least two teeth selected for inclusion in the study. The first tooth to be treated will be randomly assigned to one of the two treatment groups using a randomization table. The second tooth will be placed in the second group. If a third tooth is included, a randomization table will determine which treatment it receives.

3.0 Study Procedures

3.1 Subject Recruitment

Subjects for this investigation will be selected from patients of record at Indiana University School of Dentistry Clinics that meet the inclusion/exclusion criteria. Dental students, dental hygiene students, and faculty will be briefed on the study criteria to assist in identifying potential subjects. When a potential subject is identified who dentally appears to meet the criteria, the student or faculty member will either contact the principal investigator or student investigator to visit the patient chairside in real time or ask the patient if they would be willing to complete an IRB approved recruitment brochure to allow the investigators to contact them by phone later about the study.

For those expressing interest in the project, the student investigator will complete the IRB approved telephone interview with the potential subject and schedule them for their study screening/restorative appointment, as applicable.

3.2 Screening/Restorative Visit

3.2.1. Consenting

The Principal Investigator or Student Investigator will complete the consenting process with the subjects. Potential subjects will attend a screening visit in which they will be given the IRB approved informed consent and authorization for the release of health information for research form. Upon reading the documents, subjects will be asked if they have any questions. The purpose, procedures, risks and benefits of the study will be reviewed with the subject and the subject will again be asked if they have any questions. If the subject feels they would like to participate, they will be asked to sign and date the consent and authorization forms after having his/her questions answered to his/her satisfaction and feeling he/she has had enough time to make a decision about participating. The person who completed the consenting process with the subject will also sign and date the consent. Copies of both documents will be given to the subject.

3.2.2. Study Screening Procedures

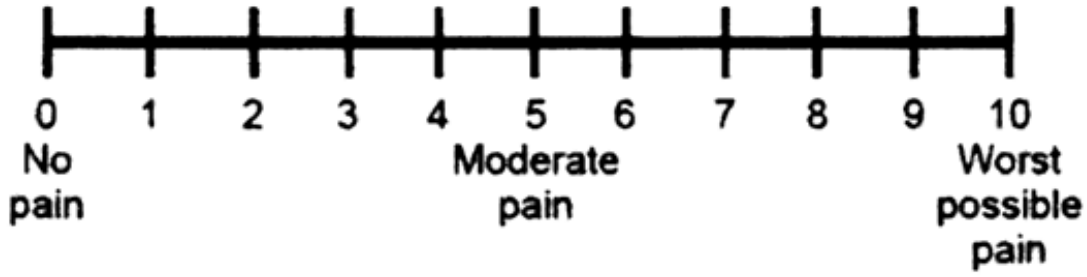
After informed consent has been obtained, the Principal Investigator or Student Investigator will review the subject's on file medical record to ensure accuracy (Axium files), ask the inclusion/exclusion questions and perform an exam of the mouth. If the

subject qualifies to participate, the teeth involved in the research study will be identified and randomized to product as described under section 4.

3.2.3. Restorative Procedures

Prior to the placement of restorations, the following information will be recorded in the format of the table below:

- Evidence of sclerosis (as determined by glossy appearance and glassy feel when examined with explorer; percentage will be visually estimated)
- The lesion morphology (predominantly saucer-shaped or predominantly notch-shaped)
- Evidence and location of occlusal facets
- Pre-operative sensitivity to a blast of air (from approximately 1cm for 1s[12]) using the "0-10 Numeric Pain Scale"



Patient #: xx
Age: xx

	#	Sclerosis	Lesion Morphology	Occlusal Facets	Pre-Op Sensitivity
Self-Etch Tooth					
Selective etch Tooth					
Tooth # ( )					

Legend:	
Sclerosis:	0= no sclerosis 1= <50% sclerotic 2= ≥50% sclerotic
Lesion Morphology	S= saucer shape V= "V" shape
Occlusal Facets	Yes No
Pre-Op Sensitivity	0-10

Intraoral digital photographs will be obtained. Restorative procedures will be performed by a single provider on each tooth following standard of care procedures for a Class V restoration. Any x-rays needed will be taken as standard of care and not specifically for research purposes. All teeth will be cleaned with pumice in a rubber prophy cup prior to treatment. The subject (patient) will read and sign the Indiana University School of Dentistry's consent for treatment. Standard of care treatment will include:

- No mechanical preparation or beveling of the tooth surface will occur for either treatment group.
- Local anesthetic will be offered to each subject and its use guided by the patient response.
- Rubber dam isolation using a 212 clamp will be used for each restoration.

3.2.4. Placing of the Etching Materials and Restorative Materials

At the point in the restorative procedure where the etching and restorative material placement occurs, the operator will follow procedures for each tooth as identified by the randomization schedule and as described below:

a. Self-etch placement

The universal adhesive (Adhese Universal; Ivoclar Vivadent) will be applied utilizing the following instructions from the manufacturer:

> *Starting with enamel, thoroughly coat the tooth surfaces to be treated with Adhese Universal. The adhesive must be scrubbed into the tooth for at least 20 seconds. This time must not be shortened. Disperse Adhese Universal with oil and moisture free compressed air until a glossy, immobile film layer results. Light-cure Adhese Universal for 10 seconds using a light intensity of ≥ 500mW/cm^2*

If the lesion is greater than 2 mm in any dimension, incremental placement of Tetric EvoCeram composite (Ivoclar Vivadent) will occur with the first increment being placed against enamel. Instructions are described below:

> *Apply Tetric EvoCeram in increments of max 2mm and adapt with a suitable instrument. Sufficient exposure to light prevents incomplete polymerization. Remove excess material with suitable finishers or fine diamonds after polymerization. Use silicone polishers as well as polishing disks and strips to polish the restoration to a durable high gloss.*

Each increment will be light-cured using the intensity and duration prescribed by the manufacturer; the curing light will be calibrated at the beginning of each clinic session.

Final restorations will be finished and polished with fluted composite finishing burs and flexible abrasive disks, respectively.

b. Selective etching placement

Total Etch (37% phosphoric acid; Ivoclar) will be placed on the enamel margin with no intentional placement on the dentin within the lesion. The adhesive (Adhese Universal) will then be applied as instructed by the manufacturer. Tetric EvoCeram composite will be placed, light-cured, finished, and polished in the same manner as for the self-etch group.

Materials Table

Adhese Universal
Solvent: 25.0%
Ethanol (64-17-5*) Water (7732-18-5*)
Monomer mixture: 67.1%
HEMA (868-77-9*) Bis-GMA (1565-94-2*) Decandiol dimethacrylate (6701-13-9*) Methacrylated phosphoric acid ester (85590-00-7*) Methacrylated polyacrylic acid (9003-01-04; 106-91-2*)
Filler: 4.0%
Fumed Silica (7631-86-9*)
Initiators: 3.8%
Ethyl p-Dimethylamino-benzoate (10287-53-3*) Campherquinone (10373-78-1*) Dimethylamino ethylmethacrylate (2867-47-2*)
Stabilisers: 0.1%
Butyl hydroxy toluene (128-37-0*) Hydroquinone monomethylether (150-76-5*)

* CAS No.

3.2.5 Post Procedure Images and Impressions

Post-operative intraoral images will be obtained and impressions made using polyvinyl siloxane and poured in epoxy for future SEM marginal analysis. Each restoration will have a baseline evaluation to document retention, marginal discoloration, and marginal adaptation.

3.3. Follow Up Visits

Recall examinations will be conducted by two IUSD faculty members (Dr. Blaine Cook, Dr. Jeff Platt, Dr. Oriana Capin, Dr. Michele Kirkup, Dr. Brooke Adams, Dr. Kim Diefenderfer) at approximately 6, 12, and 24 months from the screening/restorative visit. The subject's medical history will be updated in Axium and the subject will answer questions to assure continued eligibility in the study. Evaluation of sensitivity and modified USPHS criteria to include retention, marginal discoloration, and marginal adaptation will occur and recorded in the table (below). In addition, an overall determination of clinically acceptable or not clinically acceptable will be made at each evaluation visit. Intraoral digital images and impressions will be made at each recall appointment. The subjects will be compensated with checks in the amounts of $25, $50, and $75 at 6,12, and 24-month follow-up visits, respectively. Restorations deemed to be not clinically acceptable within the timeframe of the study will be replaced using normal dental school protocol at no cost to the patient.

Baseline	#	Retention	Marginal Adapt.	Marg. Discoloration	Sensitivity	Clinically Acceptable?
Tooth # (SfE)						
Tooth # (SelE)						
Tooth # ( )						
6 Month Recall	#	Retention	Marginal Adapt.	Marg. Discoloration	Sensitivity	Clinically Acceptable?
Tooth # (SfE)						
Tooth # (SelE)						
Tooth # ( )						

12 Month Recall	#	Retention	Marginal Adapt.	Marg. Discoloration	Sensitivity	Clinically Acceptable?
Tooth # (SfE)						
Tooth # (SelE)						
Tooth # ( )						
24 Month Recall	#	Retention	Marginal Adapt.	Marg. Discoloration	Sensitivity	Clinically Acceptable?
Tooth # (SfE)						
Tooth # (SelE)						
Tooth # ( )						

USPHS Criteria

Marginal Discoloration	A: There is no discoloration between the tooth and the restoration
	B: Discoloration is present without axial penetration
	C: Discoloration is present with axial penetration
Retention	A: Present
	B: Partial loss of restoration
	C: Absent/complete loss of restoration
Marginal adaptation	A: Excellent continuity at resin–enamel interface; explorer exhibits no catch or one way catch when drawn across margin
	B: Explorer exhibits a two-way catch, indicating a crevice, when drawn across margin
	C: Marginal crevice present; exposes base or dentin

3.4 Lost Restorations

For any restoration that is lost during the 24-months of follow-up, an offer will be made to replace the restoration using normal IUSD techniques and materials at no charge.

4.0 Statistical Considerations

The two techniques will be compared for differences in sensitivity, retention, marginal discoloration, marginal adaptation, and clinical acceptability at each follow-up visit using Cochran-Mantel-Haenszel tests for stratified, ordered categorical outcomes. The study subjects are considered the 'strata' in this method so that the comparisons properly account for the use of both techniques in each subject. This method also easily extends to having multiple teeth receiving each technique for each patient.

With a final sample size of 30 subjects, the study will have 80% power to detect a 35% difference between the two treatment methods, assuming two-sided tests of paired proportions and a 5% significance level. To account for attrition the study will enroll 33 subjects.

5.0 Investigator Responsibilities and Regulatory Requirements

This study will be conducted in accordance with the applicable GCPs, 21 Code of Federal Regulations (CFR) 50, 56, and 312; International Conference on Harmonization (ICH) Good Clinical Practice published in the Federal Register: 9-May-97 (volume 62, number 90), pages 25691–25709.

The Principal Investigator will perform or directly supervise the performance of all the study procedures in accordance to the highest standards of medical and clinical research practice. Delegation of any study responsibility will be documented in writing. The Investigator and Student Investigator will follow the protocol as written and to ensure that all members of the assisting staff also understand and follow the protocol. If

changes to the protocol are needed, an IRB approved amendment will be gained prior to initiation of any new or changed procedures.

5.1 Advertising

Advertisements including brochures and telephone interview text for subject recruitment will be approved by the IRB prior to study initiation.

5.2 Institutional Review

The protocol, informed consent, and all other pertinent documents for this study will be approved by:

Human Subjects Office

Office of Research Administration

Indiana University

Lockefield Village, 3rd Floor

980 Indiana Avenue

Indianapolis, Indiana 46202

The study will not begin until the IRB approval for the study has been granted in writing.

5.3 Subject Consent

Written informed consent will be obtained from also subjects prior to their participation in any research procedure. This consent form will comply with all applicable regulations governing the protection of human subjects. The elements of informed consent and the documentation of informed consent will follow specifications in 21 CFR 50.25 and 50.27 and/or ICH GCPs chapter 4.

Each subject will sign and date an informed consent prior to participation in the study. A signed copy of the consent form will be given to the subject and the original will be retained by the Investigator. Subjects may withdraw from participation in the study at any time. Additionally, the Investigator may withdraw subjects from the study if it is in the best interest of the subjects. The reason for all subject withdrawals from the study will be documented on the appropriate CRF.

5.4 Data Collection

The Investigator will ensure that all source documents (i.e., study and/or medical records) and Case Report Forms (CRFs) are completed and maintained according to the study protocol.

5.4.1. Case Report Forms

The Investigator will supply the paper and/or electronic CRFs to be used in this study. It is the responsibility of the Investigator to maintain accurate CRFs. All hard copy CRFs will be filled out legibly in ink.

For paper CRFs, if an entry requires correction, a single line will be placed through the entry so as not to obscure the original record, the corrected entry will be initialed and dated by the individual making the change. There will be no whiteouts or erasures. For electronic CRFs, if an entry requires correction, the change is made directly to the CRF in the database, the user is prompted to provide a reason for the change, and the correction is logged in by an electronic audit trail. If, for any reason, the subject does

not complete the study, an explanation will be entered on the Subject Accountability CRF.

5.4.2. Source Documents

All source documents (i.e., study and/or medical records) and CRFs will be completed and maintained according to the study protocol. Any CRF used as a source document must be identified as such in the Investigator's Study Notebook.

5.5 Study Device Dispensing, Storage, and Accounting

The study device to be used in this study will be supplied by Ivoclar. Upon receipt of the study devices, the Investigator will store them in a secured area. Records of all study devices will be maintained by the Investigator's staff using a Device Dispensing Record. The dispensing of the study devices will be under the Investigator's supervision, and only administered to those subjects who meet the entry criteria.

5.6 Adherence to Protocol

The Investigator will adhere strictly to the protocol (See Section 3.7 for preparing protocol amendments). The Investigator will ensure that all protocol deviations are documented, as they occur, in the Investigator's Study Notebook.

5.7 Adverse Event Reporting

Any adverse events spontaneously expressed by the panelists or observed by the Study Dentist or Investigator will be recorded giving full details including: date of onset, duration, severity, treatment given, final resolution, and will include the investigator's assessments. The Investigator will determine the need for further examination. Should

a serious adverse event occur, the Investigator will instruct the subject to report back to the study site at appropriate intervals until remission has occurred. All such visits will be documented. The Investigator will prepare a written statement describing the serious adverse event and the medical management of the adverse event. All Adverse Events will be reported to the IRB in the annual report. Serious Adverse Events that are directly related to the study will require IRB notification within 3 working days. A serious event is defined as an event that suggests a definite hazard or handicap to the subject. Serious events are any events resulting in death, decreased life expectancy, life-threatening situation, permanent disability, hospitalization, drug overdose with study medication, or congenital anomaly.

5.8 Records Retention

Study records will be stored for a minimum of 7 years after the last regulatory approval has been received or the discontinuation of the study. Study records will be made available for inspection and copying upon the request of authorized personnel.

References:

1. Miller WD. Experiments and observations on the wasting of tooth tissue variously designated as erosion, abrasion, chemical abrasion, denudation, etc. Dental Cosmos 1907;XLIX(1):1–23;XLIX(2):109–124;XLIX(3):225–47.
2. Black GV. A work on operative dentistry. Pathology of hard tissues of the teeth. Vol. 1. 1st ed. Chicago (IL):Medico-Dental Publishing; 1907, pp. 39–59.

3. Grippo J, Simring M, Coleman T. Abfraction, Abrasion, Biocorrosion, and the Enigma of Noncarious Cervical Lesions: A 20-Year Perspective. Journal of Esthetic and Restorative Dentistry 2012; 24(1): 10-23.
4. Grippo J. Abfraction: a new classification of hard tissue lesions of teeth. J Esthet Dent 1991;3:14–8.
5. Veitz-Keenan A, Barna J, Strober B, Matthews A, Collie D, Vena D, Curro F, Thompson V. Treatments for hypersensitive noncarious cervical lesions: a Practitioners Engaged in Applied Research and Learning (PEARL) Network randomized clinical effectiveness study. J Am Dent Assoc. 2013 May;144(5):495-506.
6. Hanabusa M, Mine A, Kuboki T, Momoi Y, Van Ende A, Van Meerbeek B, De Munck J. Bonding effectiveness of a new 'multi-mode' adhesive to enamel and dentine. J Dent. 2012 Jun;40(6):475-84. doi: 10.1016/j.jdent.2012.02.012. Epub 2012 Feb 28.
7. Mena-Serrano A, Kose C, De Paula EA, Tay LY, Reis A, Loguercio AD, Perdigão J. A new universal simplified adhesive: 6-month clinical evaluation. J Esthet Restor Dent. 2013 Feb;25(1):55-69. doi: 10.1111/jerd.12005. Epub 2012 Nov 15.
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9. Hashimoto, M. (2010), A Review—Micromorphological evidence of degradation in resin-dentin bonds and potential preventional solutions. J. Biomed. Mater. Res., 92B: 268–280. doi: 10.1002/jbm.b.31535
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carious cervical sclerotic lesions. Clin Oral Investig. 2013 Nov 22. [Epub ahead of print]

11. Chen A, et al. Using the modified Schirmer test to measure mouth dryness: a preliminary study. J Am Dent Assoc. 2005 Feb;136(2):164-70
12. Sharma D, McGuire JA, Gallob JT, Amini P. Randomised clinical efficacy trial of potassium oxalate mouthrinse in relieving dentinal sensitivity. J Dent. 2013 Jul;41 Suppl 4:S40-8
13. Fontana M[1], Zunt S, Eckert GJ, Zero D. A screening test for unstimulated salivary flow measurement. Oper Dent. 2005 Jan-Feb;30(1):3-8.

Budget:

Anticipated Start Date: February 1, 2013

	Requested from Research Committee		Supplied "in kind" from Other Sources		
Category	Description	Amount	Description	Amount	Source
Personnel:		$ 0	Calibrators, Evaluators, Assistant	$ 28,762	Ivoclar Vivadent
Equipment:		$ 0	Clinical equipment	$ 750	Ivoclar Vivadent
Supplies:		$ 0	Adhesive, composite	$ 3,000	Ivoclar Vivadent
Panelist Payments		$ 0		$	
Bio-statistics		$ 0	Statistical analysis	$ 320	IUSD
Other		$ 0	Patient Incentives, IRB Fee	$ 7,700	Ivoclar Vivadent
			Cost of Procedures	$ 3,201	Ivoclar Vivadent
Total Requested from		$ 0	Total of funds provided		$ 43,733

Research Committee		from other sources:	

Total Cost of Proposed Project: $ 43,733