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## Prevention of Enamel Demineralization by Use of K18-smooth Surface Sealant (K18)

This study is not yet open for participant recruitment.

See [▶ \*\*Contacts and Locations\*\*](#)

*Verified October 2017 by University of Colorado, Denver*

Sponsor:

University of Colorado, Denver

ClinicalTrials.gov Identifier:

NCT03306433

First Posted: October 11, 2017

Last Update Posted: October 11, 2017

**⚠** The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Collaborator:

University of Colorado School of Dental Medicine

Information provided by (Responsible Party):

University of Colorado, Denver

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[No Study Results Posted](#)

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[How to Read a Study Record](#)

### ▶ Purpose

This study will evaluate effectiveness of a urethane dimethacrylate (UDMA)-quaternary ammonium methacrylate (K18) resin (UDMA-K18) smooth surface sealant to prevent biofilm attachment to tooth surfaces thereby eliminating the possibility for the tooth to be demineralized. The hypothesis is that UDMA-K18 containing smooth surface sealant will be more effective at reducing enamel demineralization than the UDMA control or no treatment.

<u>Condition</u>	<u>Intervention</u>
Dental Caries	Device: UDMA-K18 smooth surface sealant

**Study Type:** Interventional

**Study Design:** Allocation: Randomized

**Intervention Model:** Parallel Assignment

**Intervention Model Description:**

prospective, paired randomized control trial for which treatment (no sealant, UDMA control, UDMA-K18 sealant) will be applied clinically and evaluated on extracted teeth in laboratory conditions.

**Masking:** Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

**Masking Description:**

The trial design is triple-blinded. The manufacturer will deliver the blinded treatments in identical bottles labelled A and B, therefore, neither the patient nor the clinician will know which treatment is rendered to each tooth. However, the no sealant control will not be blinded. Blinding will continue to be present during the histological portion of the experiment as the assessors will not be aware of which sealant was used to treat each tooth. After a blinded assessment, blinds will be lifted when between-group analysis is performed.

**Primary Purpose:** Prevention

**Official Title:** Prevention of Enamel Demineralization in Fixed Appliance Orthodontic Patients Using UDMA-K18 Sealant to Prevent Microbial Attachment Compared to a UDMA Control and no Sealant, a Randomized Split Mouth Clinical Trial

**Resource links provided by NLM:**

[MedlinePlus](#) related topics: [Tooth Decay](#)

[U.S. FDA Resources](#)

**Further study details as provided by University of Colorado, Denver:**

**Primary Outcome Measures:**

- Change in Mineral density [ Time Frame: 3 weeks, 4 weeks. ]

The mineral density immediately below the surface of the tooth will lower if left unprotected to some extent.

**Secondary Outcome Measures:**

- Change in Lesion depth [ Time Frame: 3 weeks, 4 weeks. ]

The depth of the lesion will increase from 0 (no lesion) to several hundred microns depending on the intensity of the acid attack generated by the biofilm

Estimated Enrollment: 30  
 Anticipated Study Start Date: October 2017  
 Estimated Study Completion Date: October 2018  
 Estimated Primary Completion Date: March 2018 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
Experimental: UDMA-K18 UDMA-K18 smooth surface sealant	Device: UDMA-K18 smooth surface sealant The K18 as part of the UDMA polymer network (UDMA-K18) is hypothesized to prevent microbial attachment to the surface. Other Name: UDMA-control
Placebo Comparator: UDMA-control UDMA smooth surface sealant without K18	Device: UDMA-K18 smooth surface sealant The K18 as part of the UDMA polymer network (UDMA-K18) is hypothesized to prevent microbial attachment to the surface. Other Name: UDMA-control
No Intervention: Negative control No intervention to provide baseline	

#### Detailed Description:

Esthetics is a motivating factor to seek orthodontic treatment. However, if oral hygiene is inadequate during fixed appliance wear, unsightly white spot lesions (WSL) may develop. WSLs are areas of enamel demineralization that develop due to microbial assault that manifest as white, chalky opacity on the enamel. Urethane dimethacrylate (UDMA) can be modified to produce an antimicrobial compound, UDMA-K18, that has been proven to decrease microbial attachment in-vitro. (Sticker 2016) The use of a UDMA-K18 containing sealant may help to eliminate the development of WSLs around orthodontic brackets.

This study will place experimental or control smooth surface resins on teeth that are scheduled to be extracted for orthodontic reasons. These teeth are typically bicuspid teeth that are to be extracted to create room for the orthodontic movement of teeth. These teeth are usually not extracted at the advent of first orthodontic bracket bonding but are extracted about 30 days later. The design of this study is to place sealants on those teeth (or as control, no sealant) and evaluate the teeth after they have been extracted.

**Design:** The study is a prospective, paired randomized control trial for which treatment (no sealant, UDMA-control, or UDMA-K18 sealant) will be applied clinically and evaluated on extracted teeth in laboratory

conditions.

**Procedures:** Before bonding, one premolar per patient will be assigned to a group. The group each premolar is assigned to will be determined by a randomized, computer generated program. The allocation will be concealed in an opaque envelope that will be opened at the time of initial bonding. If a fourth premolar is planned for extraction, a random selection of the treatments will be selected in a 1:1:1 ratio and this treatment will be applied to the fourth premolar.

At the time of initial bonding, the UDMA and UDMA-K18 sealant will be applied to the selected premolar following manufacturer instructions. Briefly, the clinician will isolate the teeth using the NOLA Dry Field System and excess saliva will be removed by drying the teeth with an air-water syringe. In the treatment group, 37 % Phosphoric Acid will be applied to the entire buccal surface for 30 seconds, rinsed, and dried. Next, the assigned sealant will be evenly applied to the entire buccal surface of the premolar and light cured. The sealant which is adhesive will be applied to the bracket pad and the bracket pad will be pushed to place, excess cement will be removed and light cured.

In the control group, 37 % Phosphoric Acid will be applied for 30 seconds strictly to the area where the bracket will be bonded on the buccal surface, rinsed, and dried. No sealant will be applied. The adhesive sealant will be applied to the bracket pad and the bracket pad will be pushed to place, excess cement will be removed and light cured. After 3-6 weeks, the patient will have their premolars extracted. After extraction they will be placed in a Tooth Storage Solution (25 % ethanol, 75 % water with the addition of saturated hydroxyapatite, 20 mg of NaN<sub>3</sub>, and 40 mg Thymol) that is antimicrobial and does not alter the tooth surface. These teeth will be collected by the investigators for histologic study.

The collected, extracted teeth will be sectioned using a water-cooled, Buhler slow speed diamond saw in three 2mm sections through the bracket base. A polarized light microscopy (PLM) digitized photograph of the cross-sectional sample will be analyzed to determine the depth of lesions, if present. The mineral density profile will be analyzed using contact micro radiography (TMR).

## ► Eligibility

Information from the National Library of Medicine



*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).*

**Ages Eligible for Study:** 12 Years to 89 Years (Child, Adult, Senior)  
**Sexes Eligible for Study:** All  
**Accepts Healthy Volunteers:** Yes

## Criteria

### Inclusion Criteria:

- Orthodontic patients at the Department of Orthodontics Clinic, School of Dental Medicine, University of Colorado who agree to consent to this study.
- Orthodontic treatment plans that include fixed appliances from the second premolar to second premolar in both arches.
- Orthodontic treatment plans that include extractions of at least 3 bicuspids at about 1 month after bracket placement.
- The patient has adequate oral hygiene

### Exclusion Criteria:

- Evidence of decalcification or restorations on any of the premolars planned for extraction prior to orthodontic treatment,
- Pregnant women (self reported)
- Any condition that contraindicates orthodontic treatment,
- Not willing to consent to the study.

## ▶ Contacts and Locations

Information from the National Library of Medicine



*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):  
NCT03306433*

### Contacts

Contact: Clifton Carey, PhD    3037241046    [clifton.carey@ucdenver.edu](mailto:clifton.carey@ucdenver.edu)

Contact: Craig Shellhart, DDS    303-724-6993    [craig.shellhart@ucdenver.edu](mailto:craig.shellhart@ucdenver.edu)

### Locations

#### United States, Colorado

University of Colorado, School of Dental Medicine

Not yet recruiting

Aurora, Colorado, United States, 80045

Contact: Clifton Carey, PhD    303-724-1046    [clifton.carey@ucdenver.edu](mailto:clifton.carey@ucdenver.edu)

Contact: Craig Shellhart, DDS 3037246993 [craig.shellhaart@ucdenver.edu](mailto:craig.shellhaart@ucdenver.edu)

Sub-Investigator: Shivani Patel, DDS

Sub-Investigator: Megan Fellows, DDS

### Sponsors and Collaborators

University of Colorado, Denver

University of Colorado School of Dental Medicine

### Investigators

Principal Investigator: Clifton Carey, PhD Professor, Dir Translational Research, University of Colorado, Sci

### ▶ More Information

#### Publications:

[Schmuck BD, Carey CM. Improved Contact X-Ray Microradiographic Method to Measure Mineral Density of Hard Dental Tissues. J Res Natl Inst Stand Technol. 2010 Apr 1;115\(2\):75-83. Print 2010 Mar-Apr.](#)

[Gong SQ, Niu LN, Kemp LK, Yiu CK, Ryou H, Qi YP, Blizzard JD, Nikonov S, Brackett MG, Messer RL, Wu CD, Mao J, Bryan Brister L, Rueggeberg FA, Arola DD, Pashley DH, Tay FR. Quaternary ammonium silane-functionalized, methacrylate resin composition with antimicrobial activities and self-repair potential. Acta Biomater. 2012 Sep;8\(9\):3270-82. doi: 10.1016/j.actbio.2012.05.031. Epub 2012 May 29.](#)

[Liu SY, Tonggu L, Niu LN, Gong SQ, Fan B, Wang L, Zhao JH, Huang C, Pashley DH, Tay FR. Antimicrobial activity of a quaternary ammonium methacryloxy silicate-containing acrylic resin: a randomised clinical trial. Sci Rep. 2016 Feb 23;6:21882. doi: 10.1038/srep21882.](#)

[Wefel JS, Harless JD. Comparison of artificial white spots by microradiography and polarized light microscopy. J Dent Res. 1984 Nov;63\(11\):1271-5.](#)

Responsible Party:	University of Colorado, Denver
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Last Verified:	October 2017

#### Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

**Plan Description:** The COMIRB approval and the consent forms specify that we cannot share PHI except as mandated by law. Therefore we do not intend to share any IPD to other researchers.

<b>Studies a U.S. FDA-regulated Drug Product:</b>	<b>No</b>
<b>Studies a U.S. FDA-regulated Device Product:</b>	<b>Yes</b>
<b>Device Product Not Approved or Cleared by U.S. FDA:</b>	<b>No</b>
<b>Pediatric Postmarket Surveillance of a Device Product:</b>	<b>No</b>
<b>Product Manufactured in and Exported from the U.S.:</b>	<b>No</b>

**Keywords provided by University of Colorado, Denver:**

dental caries

white spot lesion

prevention

smooth surface sealant

**Additional relevant MeSH terms:**

Dental Caries

Tooth Demineralization

Tooth Diseases

Stomatognathic Diseases