

Title:

Clinical Evaluation of Enamel Microhardness Using At-Home and
In-Office Tooth Whitening Agents

NCT#

07165366

Informed Consent Statement:

April 21. 2024

UIC Informed Consent Statement

Study: Effect on the Enamel of At-Home Tooth Whitening Agents With and Without Potassium Nitrate and Fluoride and an In-Office Tooth Whitening Agent: *In-Vivo*.

Part one: The identification, bleaching, and extraction of bicuspids.

Purpose of the study:

You are invited to be part of this study because your orthodontist recommended the extraction of four of your premolar teeth. Your orthodontist will treat your case better if they are removed. In this study, two of the four teeth that have been recommended to be extracted will be whitened with different tooth-whitening agents before extraction. The third tooth might be etched before extractions; we will inform you if you are one of the six selected to have this done. The fourth tooth will not be treated with any tooth whitening or etching material. All of the products used in this study are in common use in dental offices worldwide. After your teeth are extracted, they will be sent to a testing center to determine if there is a change in the top layer of your teeth, the surface of the enamel. If you agree to participate in this study, you will be one of 40 subjects.

Study procedure:

The examiner will review the medical history taken by your orthodontist that determined your eligibility to participate in this study on the first appointment. If the examiner determines that the position and condition of your teeth meet the inclusion and exclusion criteria for participation in this study, we will enroll you to participate in the study. Once accepted, a small area (1 mm) of the premolars will be flattened and polished. Next, your upper teeth will be scanned to make an impression, and the bleaching tray will be made on it. None of these procedures are painful, nor do they require anesthesia. This first appointment will last about 60 minutes. At the second appointment, the initial color of the upper premolar to be bleached will be taken. You will also be given a personalized whitening tray, a container to store the tray when not in use, a tube of low-concentration teeth whitening agent, and a toothbrush and toothpaste.

The examiner will show you how to place the tray on the upper arch. You will wear it through the night for fourteen nights. You will be given a chart for you to mark every night when you put the tray in your mouth and brush your teeth. She will call you the next day and in 7 days to see if you have had any problems putting the gel in the tray and using it. This appointment will last approximately 30 minutes. The third appointment will consist of the examiner isolating one of the lower premolars that will be extracted. Some gel will be applied to that tooth three times; each time, the gel will stay on your tooth for 20 minutes. If the soft tissue or tooth is sensitive, a soothing gel will be applied to relieve the discomfort. This appointment will last approximately 90 minutes. The fourth appointment will be 14 days after the at-home bleaching was done and the in-office bleaching was accomplished. During this appointment, a lower premolar might be etched for 15 seconds. At this appointment, the oral surgeon your orthodontist recommends will extract your teeth. That will be the final appointment. During these 14 days, you must keep cleaning your teeth every day at least twice a day.

Risks of participating in the study:

Your soft tissues or teeth may become sensitive during the use of tooth-whitening agents. If your soft tissues are sensitive during the placement of the teeth whitening agent, we will place a soothing gel in the area. If other teeth become sensitive, we will give you an agent that has been shown to relieve some of the sensitivity. We will use the teeth whitening gel only on the teeth that your orthodontist has recommended for extraction. There is a risk of infection from the instruments, but this is unlikely as all instruments used in the mouth will be sterilized before being used during these appointments. If you have questions after extractions, contact the dentist who removed the teeth.

Compensation for participation:

All procedures are at no cost to you. The compensation you will receive is \$300. This entire compensation will go directly to credit for your orthodontic treatment. The study sponsor will also cover the cost of extractions for the four premolars removed.

People to contact:

If you have any questions about this study, you can contact the examiner or dentist who referred you to the study, your orthodontist, or the dentist who extracted your teeth. If you have any questions about your rights as a research participant or complaints about this research study, please contact the UIC Bioethics Committee at 55-5487-1300 (UIC) or Dr. _____ (for private practice) at 55-5414-9984.

If, for whatever reason, you lose, break, or tear the bleaching tray, you must contact Dr. _____ immediately at 1+206-708-0429 through WhatsApp by call or text to replace it at no cost. Missing a day will jeopardize the study's outcome and, therefore, be a reason to withdraw you from the study.

Thank you for your participation in this study.

Principal Investigator

Clinical Coordinator

Patient consent:

The study has been explained to me, and I agree to participate in this research study. I understand that I may withdraw or be withdrawn from the study due to the dentist's concern for my oral health or not being compliant with the instructions. If I withdraw from this study, I understand that it will not affect future treatment or the quality of care of the doctors participating in this study, but I won't receive the compensation.

I acknowledge receipt of a copy of this Statement of Informed Consent.

Patient Signature

Date

Signature of parent or guardian

(if the patient is under 18 years of age)

Date

Signature of witness

Date