UNIVERSITY OF WASHINGTON
PARENTAL PERMISSION

A CLINICAL TRIAL OF NUSMILE'S PRE-VENEERED STAINLESS STEEL CROWNS AND NUSMILE ZR CROWNS COMPARED WITH STRIP COMPOSITE CROWNS IN ANTERIOR PRIMARY TEETH – PILOT STUDY

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Researchers' statement

We are asking you to enroll your child in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether your child to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask your child to do, the possible risks and benefits, your child's rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want your child to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Stainless steel crowns (SCC) have been the most common treatment for large cavities in baby (primary) teeth until recently. These crowns are silver in color, and esthetically are not a good option for restoring front (anterior) teeth. Several tooth-colored options have been developed to meet the growing demand for more esthetics on anterior teeth.

Many practitioners use composite resin material to custom make tooth colored crowns. NuSmile Signature crowns have been in use since the 1990's. They are pre-veneered stainless steel crowns (PVSSC), with tooth-colored facings placed on a traditional stainless steel crown. More recently, NuSmile ZR crowns, made of zirconia, were developed to provide an option that enhances esthetics, strength and durability of the crown.

With the variety of options for restoring anterior primary teeth, we would like to evaluate the long-term success of all three of these tooth-colored restoration options: NuSmile Signature crowns, NuSmile ZR, and composite crowns. We are interested in looking at the outcomes of these three restoration types, in terms of durability, esthetics and cost effectiveness for the treatment of anterior primary teeth.

The purpose of this pilot study is to evaluate the clinical performance of two types of NuSmile crowns compared to composite crowns in treating large multi-surfaced cavities on front baby (anterior primary) teeth.

STUDY PROCEDURES

Upon agreement to participate in this study, your child will be randomly assigned to one of these three treatment groups: 1) composite crown; 2) NuSmile classic; and 3) NuSmile ZR as outlined in the "Purpose of the Study" section above. Which crowns your child will receive will be determined completely by chance, like flipping of a coin. A computer program will do the randomization. This is for research purposes for only. If your child were not enrolled in this research study, the clinician usually decides which crowns s/he would get.

The treatment will be provided while your child is under general anesthesia. Your child would undergo these restorative procedures regardless of whether they participated in research or not as part of standard of care. A non- latex rubber dam will be placed and the teeth will be prepared to receive the type of crown to which they have been randomized to restore the anterior primary teeth. In addition, all dental treatment necessary will be completed on the same treatment day.

Your child will undergo extra clinical assessments as part of being in the research study. The following characteristics will be carefully assessed and recorded on research case report forms. There will be clinical photographs taken of your child's teeth. Only their teeth will be shown in the photo, and they will not be identifiable. This is done for research purposes only and will take approximately 5-10 minutes. Characteristics to be assessed are:

- Fit
- Positioning
- Proximal Contact (contact to adjacent tooth)
- Marginal Adaptation (how well is the crown covering the tooth)
- Color: Match, staining/color change
- Gingival Status
- Retention of the crown
- Integrity of the veneer/composite

- Secondary Caries (second cavity under the crown)
- History of trauma
- Clinical and radiographic(when possible) pulp pathology (examination of health of the tooth internally)
- Parents' esthetic satisfaction

These assessments, along with clinical photos only of your child's teeth , will be performed at months 3, 6, 12, and 18; and at the final study visit occurring in the range of 24 to 30 months from placement of restorations.
Your child will be exposed to one periapical dental x-ray at the end of the assessment period (24 months to rule out any dental and bone pathology. You will not be charged for this x-ray if your insurance does not cover this cost.
Your child's dental records will be accessed periodically to see when she/he is coming in for the next visit. This will be done in order for the researchers to perform the assessments outlined above, following the timeline as closely as is possible.
Your child's dental records without any identification, including x-rays and photographs, will be shared with the sponsor of this study and will be used for research and education

RISKS, STRESS, OR DISCOMFORT

Your child may experience some stress during the clinical assessments or clinical photos. They may discontinue from the study at any time without any negative consequences.
If your child is treated with Nu Smile Zirconia Crown there will be more tooth structure being reduced compared to the teeth receiving composite crowns. If your child is treated with Nu Smile Signature crowns there is risk for an allergic reaction for individuals highly sensitive to nickel.
Your child's crown may not be successful .Your child's dental condition may not get better or may become worse while you are in this study. Any of the types of crowns used in this study may fall off, break, decay or the teeth may become infected regardless of participating on this study. These are all standard outcomes and risks of conventional dental treatment. If any of this occurs, your child will have a failed treatment and crown and you will be provided with alternatives for clinical treatment by the investigators. There may be unanticipated or unknown side effects of the crowns at this time.
There is a slight risk of a breach of confidentiality. To ensure participant confidentiality, information about your child will be numbered and linked to your child's name only on a master list that is password protected and will be kept until the study ends and data analysis is complete. Study records are kept in a locked room in a locked cabinetThere are some risks from the dental x-rays used during your treatment and follow-up. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called "background radiation." A "millisievert" (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from all of your x-rays will be less than 0.1 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up.

ALTERNATIVES TO TAKING PART IN THIS STUDY

There are other options for restoring cavities in anterior teeth. These include stainless steel crowns without esthetic facings. In addition, as stated previously, your child may have their anterior teeth restored with any of the three crown options being studied whether they participated in research or not. The researcher will discuss these with you. Your child does not have to take part in this study to have their anterior teeth restored.

BENEFITS OF THE STUDY

Your child will benefit from an esthetic restoration of their anterior teeth for participating in this study. However, they would have access to the same crowns whether they participated in research or not.
The information developed in this study may help patients with deciding on restorations in anterior teeth in the future.

SOURCE OF FUNDING

The sponsor of this study, NuSmile Crowns, is paying the study team and/or the University of Washington for the conduct of this study. They are providing all Nu Smile crowns for this study The principal investigator for this trial, Mariella Garcia DDS, is receiving payment from the study sponsor, NuSmile Crowns, for the time spent completing study-related duties outside of the dental procedure. The Institution is receiving payment to cover the costs of the research staff and study related tests and procedures not billed to insurance.

CONFIDENTIALITY OF RESEARCH INFORMATION

The study data will be confidential but not anonymous. Research team members will keep track of your child's dental electronic record number (Axium number). This is necessary to follow up with your child's crowns during the research period of up to two years. Only research team members will be accessing your child's records, and only for research purposes. The data will be retained for up to two years after study completion (destruction date: August 31st 2018). Data will be used in analysis to determine success rates of the various restoration techniques. Data may be used as preliminary information for other research studies and grants in the future by the study team. Your child's identity will not be revealed in any publications or other information disseminated from this study.
Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

OTHER INFORMATION

The costs for the whole dental treatment performed under general anesthesia, periodic exams, dental x-rays will be the same regardless of your child's participation in the study. In the same way, the costs of all three types of crowns will be equal regardless of which one is placed. There will be no costs for any necessary crown replacement during the course of the study.
You may refuse to have your child participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

There are no additional costs immediately or ultimately as a result of participating in this study.

Subjects may receive up to $120 compensation in gift cards as a token of gratitude for participation in this study. A $20 gift card to either Target or Safeway will be dispensed upon completion of the study visit at the baseline treatment appointment, and at the 3 month follow up, 6 month follow up, 12 month follow up, 18 month follow up, and 24 month follow up appointments.

RESEARCH-RELATED INJURY

If you think you have an injury or illness related to this study, contact Dr. Mariella Garcia, 206 599-9466 right away. Dr. Garcia will treat you or refer you for treatment.
To pay these medical expenses, NuSmile Crowns may need to know some information about your child or the guarantor of your child's insurance, like the first six letters of their last name, date of birth, and social security number. This is because NuSmile Crowns may have to check on insurance information. NuSmile Crowns will not use this information for any other purpose.
No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any of your or your child's rights by signing this consent form.

We will bill you or your insurer for treatment of problems that result from your dental conditions or from standard clinical care.
If the sponsor pays for treating a research-related injury, you may be asked to provide your Social Security number or Medicare Identification number to give to the sponsor. The sponsor requires this information because of a federal regulation.

If you think you have a medical problem or illness related to this research, contact Dr. Mariella Garcia at 2064693287 right away. She will treat you or refer you for treatment.

What to do. For a life-threatening problem, call 911 right away or seek help immediately. Contact Dr. Mariella Garcia at 2064693287 when the medical emergency is over or as soon as you can. For all other problems: contact The Center for Pediatric Dentistry at 2065435800 right away. They will treat you or refer you for treatment.

Who will pay.
If you get sick or hurt in this study, you will receive medical treatment or a referral for medical treatment. Costs will typically be charged to you, the study sponsor or other third party, to the extent these parties are responsible for paying for medical care you receive. If you think your health insurance would pay for any uncovered expenses, you will be responsible for submitting those expenses to your health insurer. Since this is a research study, some health insurance plans may not pay for the costs. The UW does not offer funds to pay for the costs of a research-related

injury. This includes any treatments, added medical costs, loss of a job, or other costs to you or your family. However, you may nonetheless ask the researcher to submit a request for the costs of an uncovered treatment expense.

The law may allow you to seek payment for these expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Other problems. If you have no health insurance or your insurance refuses to pay, we will bill you.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098I will receive a copy of this consent form.

I give permission to the researchers to use my child's medical/dental records as described in this consent form.

Printed name of subject Date

When subject is a minor:

Printed name of parent Signature of parent Date

Relationship of representative to subject

Copies to: Researcher
Subject