THE CENTER FOR PEDIATRIC DENTISTRY
University of Washington

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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1. BACKGROUND, EARLY CHILDHOOD CARIES

Early Childhood Caries (ECC) is a pandemic in the US, particularly within poor minority populations where ECC rates are as high as 90%.[1] The etiology of this disease is thought to include bedtime bottle feeding and vertical transmission of cariogenic bacteria (i.e. Strep. Mutans) from mother to child. Mandibular incisors are generally protected from the cariogenic bacteria and carbohydrates because of the resting position of the tongue over the lingual surfaces of those teeth, leaving maxillary incisors exposed to both bacteria and carbohydrates.[2] Treatment for ECC is expensive, ranging from $1,000 or more. In addition, ECC's have a large impact on the child's health like low weight gain.[3]

Historically, stainless steel crowns (SCC) have been the most reliable and predictable in longevity. However for the anterior teeth, it is unattractive because of the display of metal. Demand for more esthetic restorations has been on the rise. A procedure was presented exploring an open faced crown technique, where the operator cements a traditional SSC, opens a window on the facial aspect of the crown to fill and shape the tooth colored resin material. This procedure demands more chair time and is also technique sensitive.[4] By the 1990's, pre-veneered stainless steel crowns (PVSSC) had been on the market with names such as NuSmile crowns, Kinder Krowns and Cheng Crowns. NuSmile crowns have shown success by having the strongest veneer facing against shear forces, parental acceptance of esthetics, and are less technique sensitive.[5-7]

PVSSC are SSC bonded with thermoplastic composites on the roughened or meshwork facial surfaces. It is made from the same SSC used by dentists for many years. Many advantages of these crowns are noted. Parents find the PVSCC's to be esthetically acceptable, hemorrhaging does not affect the resistance or retention, or color of the crown, and there is less chair time needed when compared with alternative restorations.[6] Nevertheless, no system is without disadvantages. The operator is limited to crimping only on the lingual surface of the crown because crimping the facial may cause the veneer to chip off. This leads to limited adaptability of the crown to the tooth surface. In addition, there are only two shades available, making exact colors matching very difficult for a single tooth. Overall, the PVSCCs cost more money than SCCs or direct resin restorations.[8] Recently, NuSmile introduced a new type of anterior crowns, the NuSmile *ZR*. It is made of high grade monolithic zirconia ceramic which provides strength, durability and esthetics characteristics to these crowns.

With the variety of options for restoring anterior primary teeth, it is of interest to evaluate the long term success of PVSCC, zirconia and composite in terms of durability, esthetics and cost effectiveness for the treatment of anterior primary teeth.

2. PURPOSE

Notably literature has focused on individual operator experience with the product and comparing bonding strengths of the PVSCC's composite surface, as well as autoclavability of PVSSCs[8], clinical success with NuSmile crowns[9], and their failure strengths.[10] However, most of the literature mentioned early in dealing with resistance, retention and shear forces of the PVCCs are done on bench top or operator experience

describing clinical cases. Very few randomized control trials were done on the clinical success of PVSCCs and zirconia ceramic crowns.
The purpose of this pilot study is to evaluate the clinical performance of PVSCC and zirconia crowns compared to composite crowns as definitive treatment for multi-surfaced affected anterior primary teeth.

3. OBJECTIVES

The objective of this pilot study is to assess the clinical performance of NuSmile's Pre-Veneered Stainless Steel Crown – NuSmile Signature and NuSmile *ZR* compared with composite crowns - Success Essentials esthetic temps/strip crowns - at the Center for Pediatric Dentistry, Seattle, Washington.

4. STUDY DESIGN

This pilot study is a single-center, non-blinded, controlled clinical trial with evaluations at baseline; follow up assessments at months 3, 6, 12 and 18; and a final assessment at the end of study visit occurring at 24.

5. SAMPLE SIZE

As this is a pilot study, a sample size of 90 (30 in each arm) subjects will be chosen as a convenience sample. This is the number estimated to enroll in a 24 week period.

6. STUDY POPULATION

Ninety (90) subjects contributing to approximately 120 to 200 crowns on primary teeth will be recruited from the patient pool of the Center for Pediatric Dentistry who receive care under general anesthesia and enrolled into the study. A maximum of four crowns will be placed in any subject. It is estimated that it will take approximately 24 weeks to place all crowns and complete the baseline examination.

6.1 Inclusion Criteria

- Patients of record at the University of Washington's Center for Pediatric Dentistry
- Patients in general good health (ASA I)
- Patients aged 5 years old or younger
- Patients in need of at least one preformed crowns, on anterior primary teeth
- Patients undergoing general anesthesia for dental treatment
- Parent or guardian of patient able and willing to provide informed consent

6.2 Exclusion Criteria

- Medically compromising condition
- Teeth with proximal space closures of sufficient magnitude to preclude placement of crown
- Teeth with complete absence of facial or lingual walls following tooth preparation
- Teeth that are expected to be exfoliated/extracted within one year will not participate in the study
- Anterior crowding
- Occlusion class III

7. STUDY PROCEDURES

7.1 Training

All research study team members will obtain clinical research and HIPAA training prior to start of study. All pediatric dental (PEDO) clinician team who work at the Dental Surgery Center (DSC) and are willing to participate in this study will train with the NuSmile crowns by preparing extracted or typodont primary teeth and cementing the crowns and at least six in vivo cases done under general anesthesia for each crown type in the study. Intra and inter-reliability assessment will be obtained (Kappa >0.8). Training and calibration will be performed by a representative from NuSmile and Dr. Garcia from the Center for Pediatric Dentistry.

7.2 Informed Consent

All study procedures will be explained to every subject and their parent/guardian, and every parent/guardian will provide written consent to participate in this study prior to the performance of any study procedures.

7.3 Recruitment and Subject Screening

All patients at the Center for Pediatric Dentistry that meet the inclusion/exclusion criteria will be given the opportunity to participate in this research study. Each subject will be screened for compliance with the inclusion/exclusion criteria specified in section 6 prior to enrollment in this study.

7.4 Treatment Randomization

Restorations will be randomly allocated to a patient; all teeth in a single patient will be randomly allocated to receive one of the restoration treatments: 1) NuSmile Signature crowns (thirty patients in the intervention group 2) NuSmile *ZR* crowns (thirty patients in the intervention group and 3) and composite strip crowns (thirty patients in control group).

The randomization sequence will be created using STATA 12.0 (StataCorp, College Station, TX) statistical software using random block sizes, which are known only to the study statistician. The randomization list will be created and placed in the order determined above into opaque sealed envelopes prior to trial start. The envelopes will be kept in a secure place known only to the study coordinator, research assistants, and statistician.

Each patient will be assigned a random treatment when they arrive at the treatment appointment and after they have been determined eligible and have signed the consent form. The clinician will be told the treatment assignment immediately prior to the treatment appointment.

7.5 Operative Procedures

After the subject's parent/guardian has provided informed consent for participation in the study, patient's sedated procedure will be accomplished. This study will be executed within a comprehensive restorative treatment. A rubber dam will be placed and the crowns will be placed following manufacturers' guidelines, see below.

7.5.1 Crown Selection

The crown size is selected prior to prepping the tooth. The original size of the non-carious tooth is approximated and the crown size that appears most natural in the child's

mouth will be selected. For the NuSmile PVSSC Signature crowns, it is recommended to choose one to two sizes smaller than the size of a stainless steel crown (SSC) that would be deemed if used. Downsizing compensates for the additional thickness of the esthetic facing.

7.5.2 Preparation of the tooth

A) For NuSmile PVSCC Signature Crowns:
The tooth should be prepared to fit the crown so that the crown fits the tooth passively without using pressure. The incisal length of the tooth is reduced by approximately 2mm with the interproximal contacts opened. A feather-edge margin is created as far subgingivally as possible (approximately 1-2mm). The tooth is overall reduced by approximately 25-30%. For preparing the tooth subgingivally, and refining the preparation, tapered diamond burs may be used, proceeding from coarse to fine as the preparation is completed.

B) For NuSmile ZR Crowns:
The tooth should be prepared to fit the crown so that the crown fits the tooth passively without using pressure. The incisal length of the tooth is reduced by approximately 1.5-2mm with the interproximal contacts opened. With a course tapered bur, the tooth is overall reduced supragingivally by approximately 20-25%, or 0.5-1.25mm on all planes of the tooth. Reduction should follow the natural contours of the clinical crown and meet in a thin, tapered incisal edge. Carefully extend and refine the preparation margin to a feather-edge approximately 1-2mm subgingivally with a thin tapered diamond bur (green stripe 6852-012). Check that no subgingival ledges remain. Round all line angles and point angles of prepared teeth.

C) For Strip Composite Crowns:
The celluloid crown is selected based on the mesiodistal width of the tooth. The incisal length of the tooth is reduced by approximately 2mm with the interproximal contacts opened. A feather-edge margin is created supra or at gingival level. The tooth is overall reduced by approximately 15-20%. For preparing the tooth, and refining the preparation, tapered diamond or tungsten carbide burs may be used.

7.5.3 Crown Fitting, Adjustment and Cementation

A) For NuSmile PVSCC Signature Crowns:
In some cases, shortening the crown from the gingival margin may be necessary to achieve the desired results. The NuSmile Shortening Bur may be used at low range speed with a water spray to circumferentially reduce and feather the crown margins. After shortening, the composite polisher may be used to restore a polished surface to the esthetic facing.

A properly fitted crown will have a passive fit and be seated with finger pressure only. A “snap fit” is both undesirable and counter-productive as it may result in failure of the veneer. If the crown does not fit passively, the preparation must be refined to fit the crown. Crimping is not necessary, but if needed, excessive crimping or crimping near the facing must be avoided.

Clean the teeth of saliva, blood or debris and control gingival hemorrhage. NuSmile’s Bio-active Resin Modified Glass Ionomer Cement will be used to cement the crowns according to the manufacturer’s directions for use.

Once seated and after allowing enough time for the cement to set, a white stone or composite finishing bur may be used to equilibrate the veneer out of excessive occlusal contact in centric and excursion functions. The opposing teeth may be slightly adjusted, if needed.

It may be desirable to trim the veneer flush with the incisal edge if the patient demonstrates bruxism patterns or end-on occlusion. The distal point angle may be rounded to shape the crown for a right or left anterior.

B) For NuSmile *ZR crowns:*

Use NuSmile *Try-In* Crowns to test the fit and to avoid contamination with saliva or blood of NuSmile ZR Crown's prepared internal surface. If contamination with saliva or blood occurs, clean the internal surface of the NuSmile ZR Crown with Ivoclean or sandblast with aluminum oxide.

A properly fitted crown will have a passive fit and be seated with finger pressure only. A "snap fit" is both undesirable and counter-productive as it may result in fracture of the crown. If the crown does not fit passively, the preparation must be refined to fit the crown.

NuSmile *ZR* Crowns should only be adjusted with burs specifically designed for adjusting zirconia restorations taking care to use a light touch and a copious water spray. The NuSmile *ZR* Adjustment Burs can be used to circumferentially reduce and feather the crown margins when shortening a crown is necessary. The crown walls are very thin and should not be adjusted any more than 0.5mm in the incisal ½ of the proximal area as necessary. No other areas of the crowns should be adjusted. If adjustments are made, the *ZR* polishers should be used to restore a smooth surface to the crown.

Clean the teeth of saliva, blood or debris and control gingival hemorrhage. NuSmile's Bio-active Resin Modified Glass Ionomer Cement will be used to cement the crowns according to the manufacturer's directions for use.

C) For Strip Composite Crowns:
Trim the crown form and pierce one hole in the palatal incisal angle with a high-speed bur. Etch the enamel for approximately 20 seconds, wash and dry without desiccation of the dental structures. Apply a thin layer of bonding resin cure for 20 seconds ensuring that all surfaces are bonded equally. Fill celluloid crown with the appropriate shade of composite and seat with gentle, even, pressure, allowing excess to exit freely. Light-cure each tooth surface (labially, incisally and palatally) equally. Remove celluloid crown gently and adjust form and finish with either composite finishing burs or abrasive discs.

7.5.4 Failure to Fit

Teeth randomized for treatment will be included in the study even if they cannot accommodate the crown and therefore a composite crown is placed instead (intention-to-treat principle). The investigator will keep record of the teeth for further adjustment in the analysis. The reason for the fitting failure will also be recorded (See Appendix 2). If the tooth needs to be extracted (not matching inclusion/exclusion criteria), it will be excluded from the trial.

8. CLINICAL ASSESSMENTS

Clinical Assessments for both groups will be done at post crown placement (baseline); and months 3, 6, 12, and 18; and end of study visit occurring in range of 24 to 30 months from baseline. Please see Appendix 3 for scoring Criteria for the following:

- Fit
- Positioning
- Proximal Contact
- Marginal Adaptation
- Color: Match, staining/color change
- Gingival Status
- Retention of the crown
- Integrity of the veneer/composite
- Secondary Caries
- History of trauma
- Clinical pulp pathology
- Radiographical pulp pathology
- Parents' esthetic satisfaction

9. HUMAN SUBJECTS PROTECTION

Adverse Events (AE) will be documented as to onset, severity, duration, remedy, and relatedness to the test device and will be recorded on source documents and on case report forms. Any study staff member becoming aware of an AE must bring it to the attention of the Principal Investigator as soon as possible, and the Principal Investigator is responsible for reporting the Adverse Event, as needed, to the appropriate agencies and the study sponsor. AE reporting will follow the Western Institutional Review Board (WIRB) guidelines as below.

Adverse Events (AE) are any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Report to WIRB only AE that in the opinion of the investigator may **represent unanticipated problems involving risks to the other subjects in the research, as defined:**

- Event is **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied,
- **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research **places subjects or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the adverse event is clearly not related to the study drug, device, procedures, or washout process, it would not represent a risk to other subjects in the research or a "problem" for the study and, therefore, does not have to be reported to WIRB.

10. STUDY ASSESSMENTS

Clinical Assessments will be done at baseline post crown placement; at months 3, 6, 12 and 18; and end of study visit occurring in range of 24 to 30 months from baseline.

Assessments and documentation required at each assessment interval:

• Photographs of selected teeth	Baseline
• Photographs of tooth preparations	Baseline and when possible
• Photographs of cemented crowns	Baseline
• Photographs of occlusal and frontal views	Baseline and when possible
• Assessment of fit	All intervals
• Assessment of positioning	All intervals
• Assessment of proximal contact	All intervals
• Assessment of marginal adaptation	All intervals
• Assessment of color: match , staining/color change	All intervals
• Assessment of time placement	Baseline
• Assessment of gingival status	All intervals
• Assessment of retention	3, 6, 12, 18 and 24 mo
• Assessment of veneer/composite integrity	3, 6, 12, 18 and 24 mo
• Assessment of secondary caries	3, 6, 12, 18 and 24 mo
• Assessment of trauma	3, 6, 12, 18 and 24 mo
• Assessment of clinical pulp pathology	3, 6, 12, 18 and 24 mo
• Assessment of radiographic pulp pathology	24 mo
• Assessment of tooth	All intervals
• Assessment of parents' esthetic satisfaction	All intervals (baseline at 3-month follow up)

Non-recall assessment to be done at the time of tooth/crown lost to study due to trauma. If this was to occur, the patient would be discontinued from study and the justification recorded.

11.0 DATA ANALYSIS

Descriptive statistics (means, standard deviations, counts, and percentages) will be calculated for all variables. To evaluate if the primary efficacy variables differ by the three treatment groups (NuSmile PVSCC Signature Crowns, NuSmile *ZR*, and Strip composite crowns), ANOVA or Chi-square tests of association will be performed.

All subjects evaluated at the 6-month interval or beyond and subjects who have lost crowns or teeth will be considered for efficacy. All enrolled subjects defined here as those who have had at least one crown placed will be evaluated for safety. Any missing, unused or false data will be omitted from data analysis.

The primary efficacy variables in this trial are fit, positioning, proximal contact, marginal adaptation, color match, gingival status, crown retention, veneer/composite integrity, secondary caries, occlusal integrity, history of trauma, clinical pulp pathology, parents' esthetic satisfaction. Scores for efficacy variables will be summarized and displayed using descriptive statistics (means, standard deviations, counts, and percentages).

Inferential statistics will be used to detect significant differences in the primary efficacy variables by the treatment status at baseline and at 6, 12, 18, and 24 month follow-up. Statistical differences will be calculated using logistic regression models accounting for within cluster variance using generalized estimating equations (GEE).

Safety variables include Adverse Events and Unanticipated Adverse Device Effects. All subjects that have had crowns placed will be evaluated for safety. Descriptions of occurrences, incidence, severity and required treatments for
Adverse Events and Unanticipated Adverse Device Effects Will be summarized and tabulated where appropriate.

12.0 STUDY TERMINATION/SUBJECT WITHDRAWAL

12.1 Study Termination

This study may be terminated for the following reasons:

• Discovery of unforeseen risk that could jeopardize the dental/physical well-being of subjects

• Enrollment or recall rates those are not likely to produce sufficient data for evaluation of safety and efficacy

• Non-compliance with the study protocol, the Investigator Agreement, applicable FDA regulations or conditions of approval imposed by the reviewing IRB

• Withdrawal of IRB approval

In the event of study termination, the Principal Investigator will determine whether subjects are in need of additional treatment and/or follow-up observation as a result of participation in this trial.

12.2 Subject Withdrawal

Subjects may be withdrawn from this study for the following reasons.

• Concurrent illness

• Unanticipated Adverse Device Effect

• Unwillingness to further participate

The Principal Investigator will determine whether withdrawn subjects are in need of additional treatment and/or follow-up observation as a result of participation in this trial.

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APPENDIX 1: FITTING

FITTING	
A=	Good natural retention
B=	Moderate natural retention
C=	Little or no natural retention

APPENDIX 2: POSITIONING

POSITIONING	
A=	Proper position
B=	Rotated – in occlusion
C=	Not in occlusion with or without rotation

APPENDIX 3: PROXIMAL CONTACT

PROXIMAL CONTACT	
A=	Open spaces
B=	Floss meets little or no resistance when passes through contact
C=	Floss meets significant when passes through contact

APPENDIX 4: MARGINAL ADAPTATION

MARGINAL ADAPTATION	
A=	No discrepancies detected with explorer
B=	Detectable discrepancies but clinically acceptable
C=	Detectable discrepancies, not acceptable –replacement required

APPENDIX 5: COLOR: MATCH, STAINING/COLOR CHANGE

COLOR: MATCH, STAINING/COLOR CHANGE	
A=	Matches structure
B=	Does not completely match but within range of shade and translucency
C1=	Outside range with yellow to yellow/brown discoloration
C2=	Outside range with light gray to dark gray discoloration
C3=	Outside range for reason other than yellowing or graying

APPENDIX 6: TIME PLACEMENT

TIME PLACEMENT	
A=	≤ 30 min
B=	>30 - ≤ 45 min
C=	> 45 min

APPENDIX 7: GINGIVAL STATUS

GINGIVAL STATUS	
A=	Pink, firm, free of inflammation
B=	Red and/or inflamed – no bleeding on probing
C=	Red – bleeding on probing
D=	Spontaneous and excessive bleeding on probing

APPENDIX 8: RETENTION

RETENTION	
A=	Intact
B=	Partially missing
C1=	Missing – no cement remaining on tooth or crown
C2=	Missing – some or all cement remaining on tooth
C3=	Missing – some or all cement remaining on crown interior (if crown available)
C4=	Missing – some cement remaining on both tooth and crown interior (if crown available)

APPENDIX 9: VENEER/COMPOSITE INTEGRITY

VENEER/COMPOSITE INTEGRITY	
A=	Intact
B1=	Partially missing – one third missing
B2=	Partially missing – two thirds missing
B3=	Partially missing – more than two thirds missing
C4=	All veneer/composite missing

APPENDIX 10: SECONDARY CARIES

SECONDARY CARIES	
A=	Absent
B=	Present

APPENDIX 11: TRAUMA

TRAUMA	
A=	Absent
B=	Present

APPENDIX 12: CLINICAL PULP PATHOLOGY

CLINICAL PULP PATHOLOGY	
A=	Absent
B=	Present

APPENDIX 13: RADIOGRAPHIC PULP PATHOLOGY

RADIOGRAPHIC PULP PATHOLOGY

A=	Absent
B=	Present

APPENDIX 14: PARENTS' ESTHETIC SATISFACTION

1. Which of the following best describes your thoughts overall about the appearance of your child's teeth?
   a. Very satisfied
   b. Somewhat satisfied
   c. Somewhat dissatisfied
   d. Very dissatisfied

2. If not "very satisfied", which of the following are you concerned about? (circle "yes" or "no" for each subcategory)

a.	Shape	1. Yes	2. No
b.	Color	1. Yes	2. No
c.	Alignment	1. Yes	2. No
d.	Spacing between teeth	1. Yes	2. No
e.	Crowding of teeth	1. Yes	2. No
f.	Speckled/spotted/streaky/irregular/blotchy appearance	1. Yes	2. No
g.	Other: _____		