Comparison of Three Esthetic Full-coverage Restorations in Primary Maxillary Incisors

Ashley Gill

A thesis

submitted in partial fulfillment of the

requirements for the degree of

Master of Science in Dentistry

University of Washington

2019

Committee:

Ana Lucia Seminario

Mariella Garcia

JoAnna Scott

Program Authorized to Offer Degree:

Dentistry

University of Washington

Abstract

Comparison of Three Esthetic Full-coverage Restorations in Primary Maxillary Incisors

Ashley Gill

Chair of the Supervisory Committee:
Ana Lucia Seminario
Department of Pediatric Dentistry

Purpose: To compare the 12-month clinical outcomes of primary maxillary incisors restored with composite strip crowns (CSCs), NuSmile Preveneered Stainless Steel Crowns (PVSSCs), and NuSmile Zirconia Crowns (ZCs).

Methods: One hundred and thirty-five (N=135) teeth in 49 children two to four years with ECC were randomly assigned to one of the three crown groups. Demographic and tooth-related variables at baseline and 12 months were assessed by calibrated examiners. Fisher's exact or Chi-square tests were used to test associations ($P<.05$).

Results: Children were on average 3.4 years, female (55%), and had mean dmft of 10.6. At 12 months, crown retention was significantly lower for CSCs than PVSSCs or ZCs (79% vs 100% and 95%, $P=.002$). Partial and complete loss of material was significantly higher in CSCs than

PVSSCs or ZCs (29% vs 11% and 0%, P<.001). Teeth restored with composite presented with an increased rate of marginal discrepancies and color change (P<.001).

Conclusions: Clinical outcomes were significantly different among CSCs, NuSmile PVSSCs, and NuSmile ZCs at 12 months. CSCs showed significantly reduced clinical success in regards to retention, durability, marginal adaptation, and color compared to PVSSCs or ZCs. Parental esthetic satisfaction was highest for NuSmile ZCs.

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ACKNOWLEDGEMENTS

I would like to acknowledge everyone who played a role in my academic accomplishments. First of all, my family, who has been most important to me in the pursuit of this project. I would like to thank my parents, Surjit and Paramjit, and my sister, Aman, whose love and guidance are with me in whatever I pursue. I will be forever grateful for your support and dedication to my success.

Secondly, my committee members, each of whom has provided patient advice and guidance throughout the research process. Thank you all for your unwavering support. I would especially like to thank Dr. Ana Lucia Seminario, the chair of my committee. As my teacher and mentor, she has taught me more than I could ever give her credit for here. She has shown me, by example, what a good dentist (and person) should be. Thank you for providing unending inspiration.

DEDICATION

To my brother, TJ Gill.

So many things I never got to say,

I never imagined you'd ever be so far away.

You were my brother,

And I loved you like no other.

In my heart you'll always be,

You'll be my guide and help me see.

Chapter 1. INTRODUCTION

Early childhood caries (**ECC**) is highly prevalent in the 18- to 36-month-old child, who tends to be uncooperative for restorative treatment due to their lack of cognitive skills.[1,2] For this age group, definitive treatment is most typically achieved via immobilization, sedation, or general anesthesia, and clinical failure could pose a problem for replacement.[3] Increased public awareness of esthetics have resulted in greater parental requests for tooth-colored restorations.[4] There are many full-coverage tooth-colored restorative options for primary incisors, each with strengths and weaknesses.

Composite strip crowns (**CSCs**) have long been favored as an esthetic option for restoring primary incisors with the benefit of multiple shade selection, ability to fit in crowded dentitions, and ease of repair.[2] Despite widespread use, CSCs are technique sensitive with difficulty controlling for hemorrhage and saliva.[5] Preveneered stainless steel crowns (**PVSSCs**) are bonded with composite or thermoplastic resin on the roughened or meshwork facial surfaces. Hemorrhaging does not affect the resistance, retention, or color of the crown, and there is less chair time needed when compared with alternative restorations.[6,7] Difficulties include greater tooth reduction due to the thickness of PVSSCs, compromised ability to fit in crowded dentitions, and fracture of the inflexible resin veneer.[7-9] Zirconia crowns (**ZCs**) have proven to be successful in adult dentistry for many years as measured by durability, strength, biocompatibility, and color stability.[10] These crowns are made of high-grade monolithic zirconia ceramic and require nearly twice the force to fracture compared with PVSSCs.[10,11] Benefits include excellent esthetics and no components of the crown that are capable of debonding.[12] The biocompatibility and high polishability of ZCs has been demonstrated to reduce gingival inflammation in comparison with CSCs and PVSSCs.[13] Difficulties include preparing the tooth to fit the crown due to an inability

to crimp the crown margins for mechanical retention,[2] compromised ability to fit in crowded dentitions.[14] There has been one recent randomized controlled trial that compared CSCs, PVSSCs and ZCs placed with basic behavior guidance and physical restraint.[13] Zirconia crowns were found to have better esthetics, retention, and gingival health at six months follow-up.[13]

The purpose of this randomized controlled trial was to compare the 12-month clinical outcomes of CSCs, PVSSCs, and ZCs for carious primary maxillary incisors in healthy children with ECC who received treatment under general anesthesia. We hypothesized that there is no difference in clinical outcomes measured at 12 months.

Chapter 2. METHODS

2.1 STUDY DESIGN

The University of Washington (**UW**) Human Subjects Review Board (STUDY00003980) approved this single-center, single-blinded, randomized controlled clinical trial. Clinical outcomes and parental satisfaction at 12 months were evaluated. The design of this study followed the guidelines published by the Consolidated Standards of Reporting Trials (CONSORT). Prior to enrollment, all study procedures were explained to every child's parent or guardian and a written consent form was provided.

2.2 SAMPLE SELECTION

Patients were recruited from the University of Washington Center for Pediatric Dentistry (UWCPD) in Seattle, Washington, USA between 2015 and 2017. The criteria utilized for inclusion was as follows: patients in general good health (ASA I), aged 5 years old or younger, in need of at least one preformed crown on anterior primary teeth, and undergoing general anesthesia for dental treatment. The criteria for exclusion was as follows: medically compromising condition, teeth with anterior crowding, teeth with complete absence of facial or lingual walls following tooth preparation, teeth that are expected to be exfoliated or extracted within one year, and class III occlusion. Ninety-seven children (299 teeth) were assessed for eligibility and 75 children (220 teeth) fulfilled the above criteria, as shown in Figure 1. The most frequent reason for exclusion was due to extensive caries warranting extraction or teeth near exfoliation.

2.3 STUDY PROCEDURES

Randomization and sample power calculation

All teeth in a single patient were randomly allocated to receive one type of restoration: CSCs (Space Maintainers Laboratory, Chatworth, California, USA), PVSSCs (NuSmile Signature Crowns), and ZCs (NuSmile ZR Crowns). The randomization sequence was created using Stata 12.0 (StataCorp, College Station, TX) statistical software using random block sizes, which were only known to the study statistician. A post hoc sample power calculation was done using the ANZMTG Statistical Decision TreeG-Power. The power of the sample of 135 teeth allocated in 3 groups with an effect size of 0.06 was determined to be 0.875 with an alpha of 0.05.

Calibration

Prior to initiation of the study, four pediatric dentists were calibrated on tooth preparation and crown placement of PVSSCs and ZCs via online training as well as hands on training with extracted or typodont teeth and in vivo cases done under general anesthesia. Initial calibration was led by a pediatric dentist from NuSmile (Houston, Texas, USA) who trained all four operators and one designated operator then critically assessed each tooth preparation and crown cementation throughout the study. Pictures were taken of all tooth preparations and immediately following crown cementation, of which a random sample was viewed by NuSmile to ensure maintenance of calibration for the course of the study. Calibration of CSCs were performed with the same designated operator critically assessing each crown preparation and placement.

2.3.1 OPERATIVE PROCEDURES

Comprehensive restorative treatment was completed with a rubber dam in place and primary maxillary incisors were restored according to manufacturer's guidelines. The original size of the non-carious tooth was approximated and the crown size that appeared most natural in the child’s

mouth was selected. For the NuSmile PVSSCs, the crown size chosen was one to two sizes smaller than the size of an SSC for that tooth. Downsizing compensates for the additional thickness of the esthetic facing.

For CSCs, the tooth was overall reduced by approximately 15-20%. A feather-edge margin was created supragingivally or at the gingival level. The celluloid crown forms were trimmed and pierced on the palatal incisal angle with a high-speed bur. Enamel was etched for approximately 20 seconds, washed and then dried without desiccation of the dental structures. A thin layer of bonding resin was applied and cured for 20 seconds ensuring that all surfaces were bonded equally. The celluloid crowns were filled with the appropriate shade of composite (Filtek Supreme, 3M, St. Paul, Minn., USA) and seated with gentle, even, pressure, allowing excess to exit freely. The labial, incisal and palatal surfaces were light cured and the celluloid crown form was gently removed. Any adjustments and finishing were completed with composite finishing burs or abrasive discs.

For NuSmile PVSSCs, the tooth was overall reduced by approximately 25-30% and prepared to allow a passively fitting crown. A feather-edge margin was created approximately 1-2mm subgingivally. Crimping of the lingual metal was completed as necessary. PVSSCs were cemented with glass ionomer cement (Ketac, 3M ESPE, St. Paul, Minn., USA) according to the manufacturer's directions. Once seated and after allowing enough time for the cement to set, a white stone or composite finishing bur was used in select cases to equilibrate the veneer out of excessive occlusal contact in centric and excursive functions.

For NuSmile ZCs, the tooth was overall reduced by approximately 20-25% and prepared to allow a passively fitting crown. A feather-edge margin was created approximately 1-2mm subgingivally. NuSmile Try-In Crowns were used to test the fit and to avoid saliva or blood contamination of the ZC intaglio surface. If contamination occurred, the internal surface of the

crown was cleaned with Ivoclean (Ivoclar Vivadent, Amherst, NY, USA) or sandblasted with aluminum oxide. ZCs were cemented with resin modified glass ionomer cement (BioCem, NuSmile) according to the manufacturer's directions.

All patients were provided with standard postoperative instructions including oral hygiene instructions and avoidance of sticky foods to prevent debonding of the crowns.

2.4 DATA COLLECTION

Demographic and dental variables collected at the time of crown placement included the child's age, gender, dmft score, parental insurance status, and primary anterior crown (**PAC**) location (central or lateral incisor). Initial dmft score was categorized into three groups, a) low (≤ 9), b) medium (10-13), and c) high (>13). Clinical and radiographic assessments were performed by calibrated examiners. Crowns were photographed at baseline and again at recall visits when possible to aid in clinical assessments.

The crown variables assessed were as follows: fit, position, proximal contact, color, retention, facing integrity, marginal adaptation and gingival status. An evaluation rating system was created similar to the US Public Health Service (**USPHS**) Ryge Criteria,[15] with three scores (A, B, C) for each variable, as shown in Figure 2. Failures were recorded according to the presence of secondary caries as detected visually, trauma as reported by parents, and pulp pathology as detected clinically and radiographically (Figure 2).

Parental satisfaction was assessed using a questionnaire with a 4-point Likert-type scale that asked parents to rate the overall appearance of their child's teeth as very satisfied, somewhat satisfied, somewhat dissatisfied, and very dissatisfied. Characteristics assessed were shape, color, alignment, spacing between teeth, crowding of teeth, and/or a speckled/spotted/streaky/irregular/blotchy appearance.

2.5 DATA ANALYSIS

All data was entered into REDCap and then imported into Stata 15.1 (StataCorp, College Station, TX) for analysis. Descriptive statistics (means, standard deviations, counts, and percentages) were calculated. Fisher's exact or Chi-square tests were used to test associations between PAC type and variables of interest. Missing data was excluded from all tests of association ($P<0.05$).

Chapter 3. RESULTS

3.1 SAMPLE CHARACTERISTICS

Forty-seven children (135 teeth) were enrolled in the study at baseline: 47 teeth were restored with PVSSCs, 40 teeth with ZCs and 48 teeth with CSCs (Figure 1). At baseline, the children were on average 3.4±0.8 years old with mean dmft 10.6±4.0. The majority of children were between 37 and 48 months old (68%), female (55%), and had Medicaid (83%) (Table 1). More than half had a dmft of 10 or more (59%) and had the primary PAC placed on the maxillary central incisor (53%). Although the children were randomized to groups, gender, insurance type, and dmft at PAC placement were significantly different among the three PAC types (Table 1).

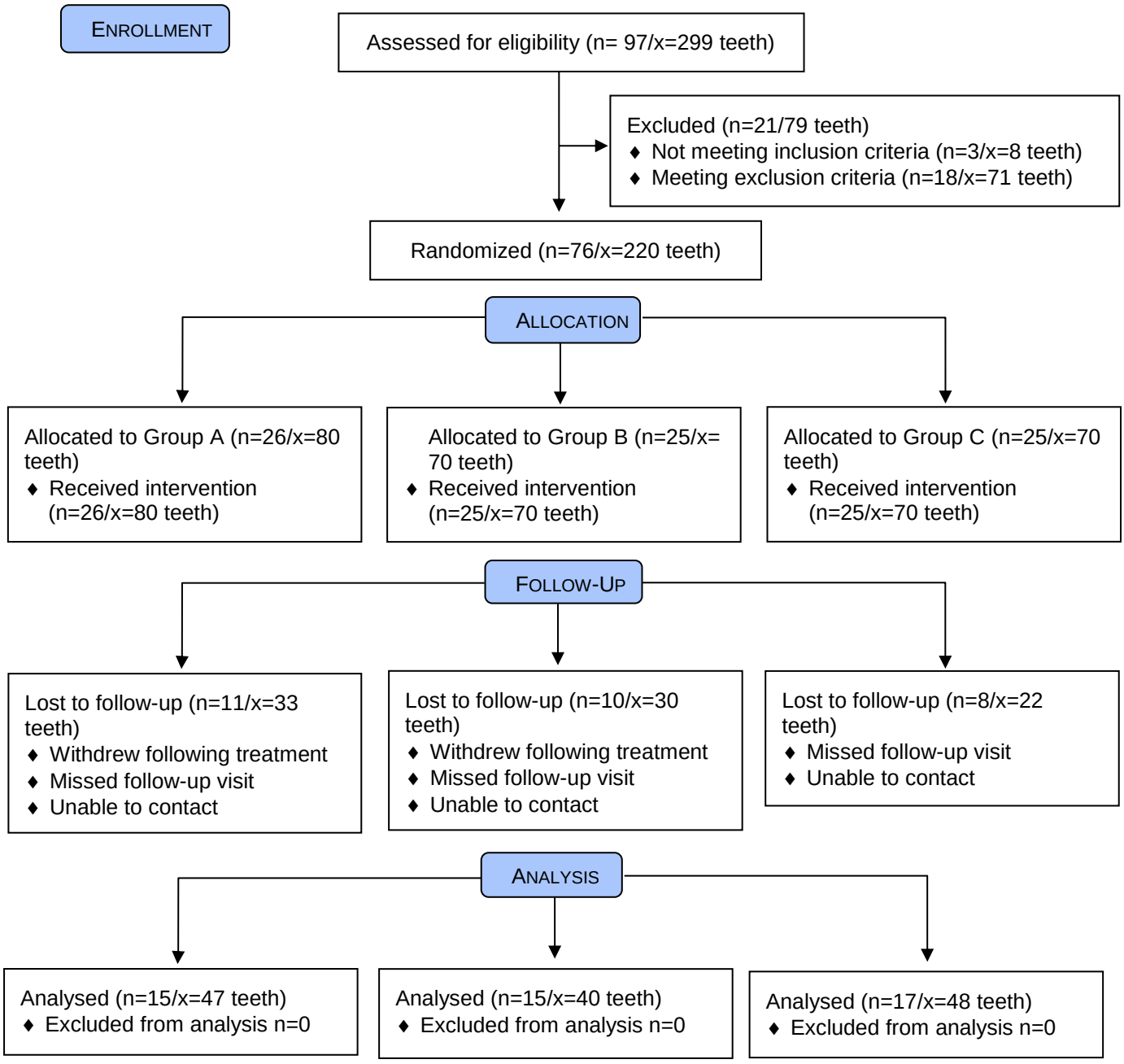

Figure 1: Flow diagram of available, eligible and randomized children, including reasons for loss of follow-up. (Group A= PVSSCs, Group B= ZCs, Group C= CSCs)

Table 1: Demographic and dental variables of primary anterior crowns of the treated study population

	Primary Anterior Crown (PAC) Type				
	Total (N=135)	PVSSC (N=47)	ZC (N=40)	CSC (N=48)	p-value*
Age at baseline					0.53
34-36 months	43 (32%)	12 (26%)	15 (38%)	16 (33%)	
37-48 months	92 (68%)	35 (74%)	25 (62%)	32 (67%)	
Gender					0.004
Male	61 (45%)	12 (26%)	25 (63%)	24 (50%)	
Female	74 (55%)	35 (74%)	15 (37%)	24 (50%)	
Insurance status					0.01
Medicaid	112 (83%)	43 (91%)	35 (88%)	34 (71%)	
Private insurance	23 (17%)	4 (9%)	5 (12%)	14 (29%)	
dmft at PAC Placement					0.001
Low ≤ 9	56 (41%)	19 (40%)	23 (58%)	14 (29%)	
Medium 10-13	48 (36%)	22 (47%)	12 (30%)	14 (29%)	
High >13	31 (23%)	6 (13%)	5 (12%)	20 (42%)	
Tooth Location of PAC					0.82
Maxillary central incisor	72 (53%)	24 (51%)	23 (58%)	25 (52%)	
Maxillary lateral incisor	63 (47%)	23 (49%)	17 (42%)	23 (48%)	

*Chi-square test

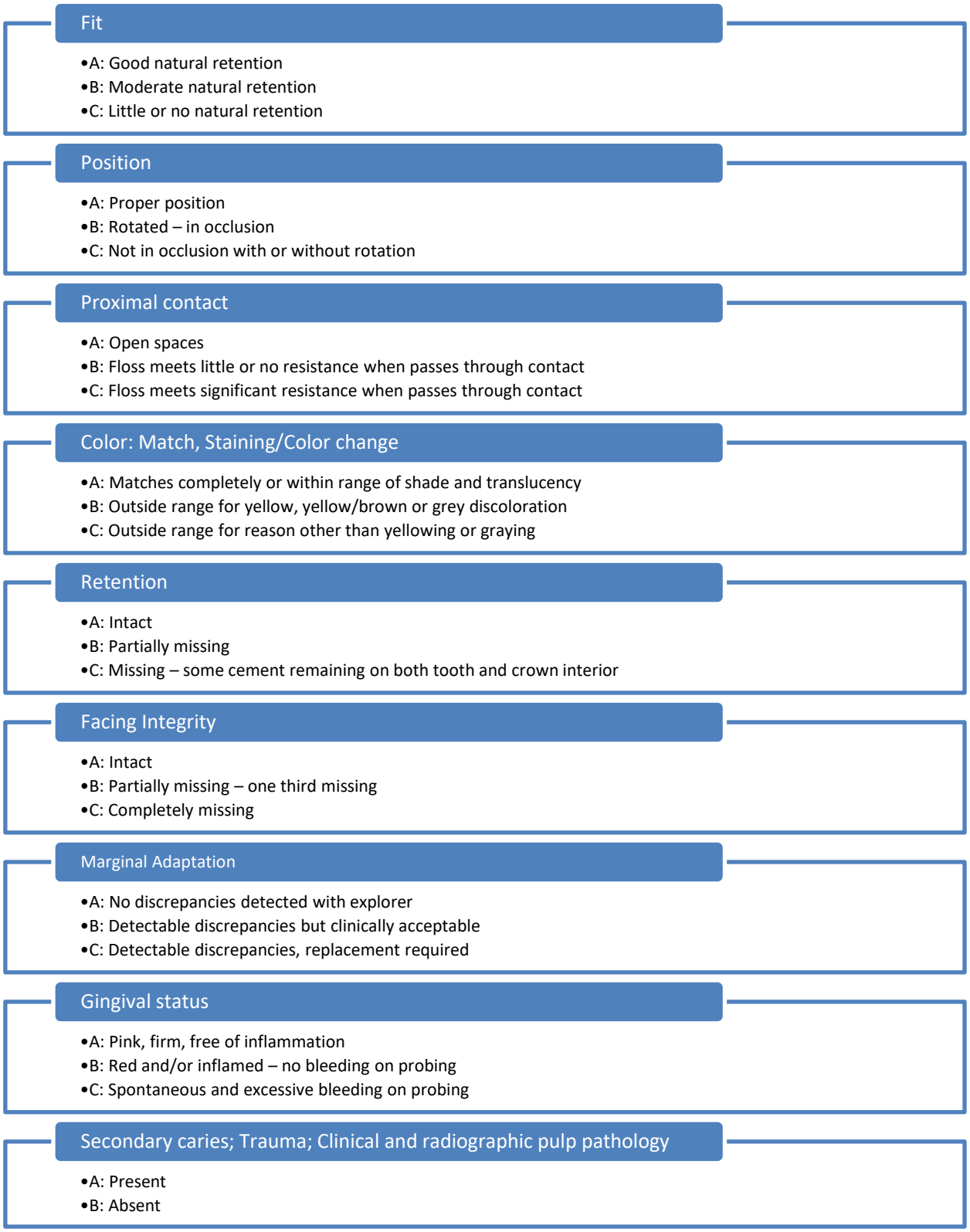

Figure 2: Clinical variables and associated grading system

3.2 CLINICAL OUTCOMES

There was a significant difference between PAC types for color, retention, facing integrity, and marginal adaptation, as shown in Table 2. For all these clinical outcomes, CSCs presented with the lowest clinical success rate. PVSSCs and ZCs matched within the range of shade and translucency of the natural dentition for almost all crowns placed while less than half of the CSCs placed did (100% and 98% vs 44%, $P<0.001$). PVSSCs and ZCs were all or almost all retained while only 79% of CSCs were retained ($P=0.002$). Three crowns were completely missing and these were CSCs. ZCs had the highest success rate for facial veneer integrity at 98%, while PVSSCs and CSCs had 89% and 69% respectively ($P<0.001$). Almost all PVSSCs and ZCs presented without detectable marginal discrepancies, while only 69% of CSCs did ($P<0.001$). Overall, there were three teeth that required retreatment due to inadequate marginal adaptation and these were CSCs.

Table 2: Clinical outcomes of Primary Anterior Crowns at 12 months

		Primary Anterior Crown Type			
	Total	PVSSC	ZC	CSC	
	N = 135	N = 47	N = 40	N = 48	
	N (%)	N (%)	N (%)	N (%)	p-value*
Fit					0.12
A: Good natural retention	119 (88%)	41 (87%)	35 (88%)	43 (90%)	
B: Moderate natural retention	10 (7%)	6 (13%)	3 (8%)	1 (2%)	
C: Little or no natural retention	4 (3%)	0 (0%)	1 (3%)	3 (6%)	
Missing	2 (2%)	0 (0%)	1 (3%)	1 (2%)	
Position					0.22
A: Proper position	119 (88%)	44 (94%)	34 (85%)	41 (85%)	
B: Rotated-in occlusion	11 (8%)	3 (6%)	5 (13%)	3 (6%)	
C: Not in occlusion with or without rotation	3 (2%)	0 (0%)	0 (0%)	3 (6%)	
Missing	2 (2%)	0 (0%)	1 (3%)	1 (2%)	
Proximal Contact					
A: Open spaces	119 (88%)	41 (87%)	37 (93%)	41 (85%)	0.57**
B: Floss meets little or no resistance when passes through contact	12 (9%)	6 (13%)	2 (5%)	4 (8%)	0.44**
C: Floss meets significant resistance when passes through contact	1 (1%)	0 (0%)	0 (0%)	1 (2%)	0.10**
Color					<0.001
A: Matches completely or within range of shade and translucency	107 (79%)	47 (100%)	39 (98%)	21 (44%)	
B: Outside range for yellow, yellow/brown or grey discoloration	23 (17%)	0 (0%)	0 (0%)	23 (48%)	
C: Outside range for reason other than yellowing or graying	3 (2%)	0 (0%)	0 (0%)	3 (6%)	
Missing	2 (2%)	0 (0%)	1 (3%)	1 (2%)	

Retention					0.002
A: Intact	123 (91%)	47 (100%)	38 (95%)	38 (79%)	
B: Partially Missing	7 (5%)	0 (0%)	1 (3%)	6 (13%)	
C: Missing-some cement remaining on both tooth and crown interior	3 (2%)	0 (0%)	0 (0%)	3 (6%)	
Missing	2 (2%)	0 (0%)	1 (3%)	1 (2%)	
Facing Integrity					<0.001
A: Intact	114 (84%)	42 (89%)	39 (98%)	33 (69%)	
B: Partially missing-one third missing	16 (12%)	5 (11%)	0 (0%)	11 (23%)	
C: Completely missing	3 (2%)	0 (0%)	0 (0%)	3 (6%)	
Missing	2 (2%)	0 (0%)	1 (3%)	1 (2%)	
Marginal Adaptation					<0.001
A: No discrepancies detected with explorer	116 (86%)	46 (98%)	37 (93%)	33 (69%)	
B: Detectable discrepancies but clinically acceptable	14 (10%)	1 (2%)	2 (5%)	11 (23%)	
C: Detectable discrepancies, replacement required	3 (2%)	0 (0%)	0 (0%)	3 (6%)	
Missing	2 (2%)	0 (0%)	1 (3%)	1 (2%)	
Gingival Status					0.05†
A: Pink, firm, free of inflammation	96 (71%)	36 (77%)	33 (83%)	27 (56%)	
B: Red and/or inflamed-no bleeding on probing	34 (25%)	11 (23%)	6 (15%)	17 (35%)	
C: Spontaneous and excessive bleeding on probing	1 (1%)	0 (0%)	0 (0%)	1 (2%)	
Missing	4 (3%)	0 (0%)	1 (3%)	3 (6%)	

Missing values excluded, N's won't sum to totals
*Fisher's exact test
**Multiple p-values as more than one option was permitted
†Not significant at the 0.05 level.

3.3 CLINICAL FAILURES

Trauma was found to be significantly different among PAC types ($P<0.001$) (Figure 3). PVSSCs is the only crown type with trauma. Of note, only 50 teeth (37%) had radiographs taken at the 12-month follow-up due to a lack of patient cooperation.

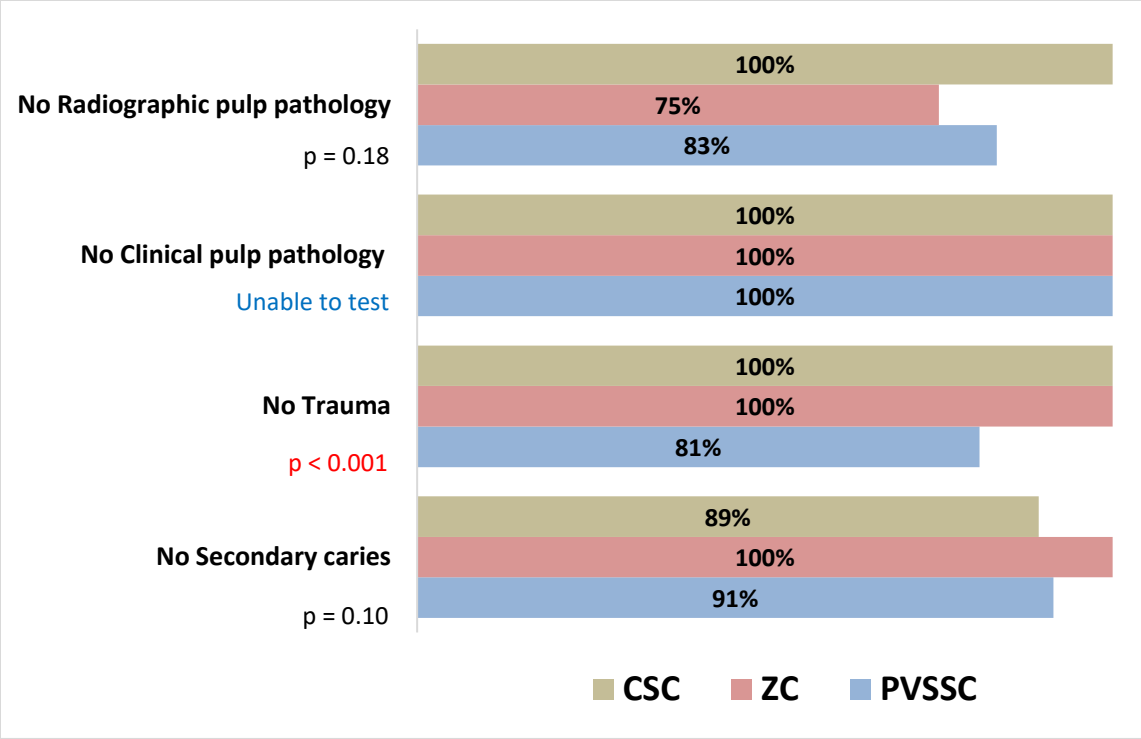

Figure 3: Clinical and radiographic successes of primary anterior crowns at 12 months (Associations tested using Fisher's Exact test)

3.4 PARENTAL SATISFACTION

The majority of parents (87%) were very satisfied with the overall appearance of the crowns. Of the 23 parents dissatisfied with the appearance of the crowns, 19 (83%) were dissatisfied with color. Parental dissatisfaction was significantly different between PAC type for shape, color, and alignment (Figure 4). Examples of color changes in PVSSCs and CSCs, as well as shape and alignment of ZCs are shown in Figure 5. No parents reported concerns with spacing, crowding or a speckled/ spotted/ streaky/ irregular/ blotchy appearance.

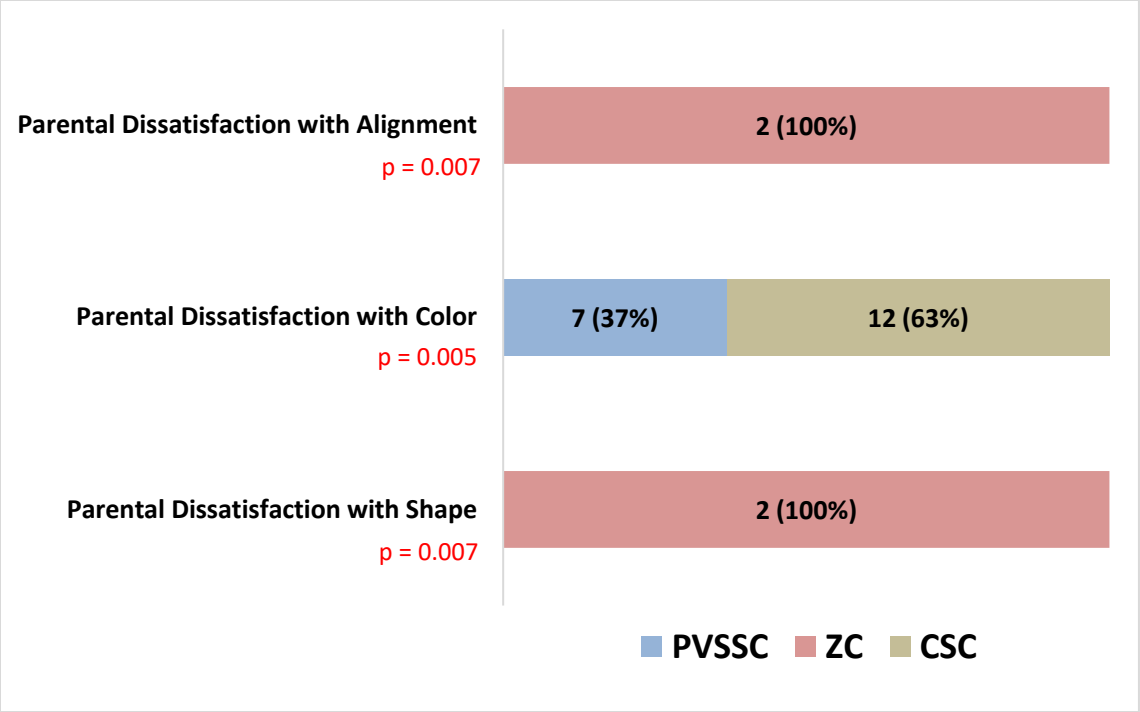

Figure 4: Parental Dissatisfaction with Crown Esthetics at 12 Months (Associations tested using Fisher's Exact test)

Figure 5: Individual cases of restored maxillary incisors at 12 months. Adequate esthetics of A) PVSSCs, B) ZCs, and C) CSC. Inadequate esthetics of maxillary incisors due to A) PVSSC staining, B) ZC misalignment, and C) CSC staining.

Chapter 4. DISCUSSION

The purpose of this randomized controlled trial was to compare the 12-month clinical outcomes of CSCs, PVSSCs, and ZCs for carious primary maxillary incisors in healthy children with ECC who received treatment under general anesthesia. The results of this study demonstrate that CSCs showed overall reduced clinical success in regards to color, retention, facing integrity, and marginal adaptation.

4.1 CLINICAL OUTCOMES

4.1.1 COLOR

Our study found that CSCs were most likely to present with color outside the range of shade and translucency of the tooth, presenting with yellow, brown, or grey discoloration when compared with PVSSCs and ZCs. While CSCs present with the benefit of multiple shades to choose from accounting for a relatively good initial match to tooth structure, concerns arise with discoloration overtime due to the integration of stain into the resin.[16,17] Regarding PVSSCs, several authors have reported difficult color matching and color instability, which has been attributed to minimal shade options (light and extra light) and the accumulation of yellow staining.[2,4,9] Meanwhile, the benefit of ZCs is a highly polished surface preventing staining and plaque accumulation from affecting the color. A study evaluating endodontically treated teeth restored with ZCs over 30 months found that none of the crowns had discolored.[18] Optimal color matching to tooth structure is possible due to a moderate level of translucency that results in a naturally appearing restoration.[4,18]

4.1.2 RETENTION AND FACING INTEGRITY

This study demonstrated high retention rates for PVSSCs and ZCs, compared to CSCs. Facing integrity was found to be highest for ZCs followed by PVSSCs and CSCs. This is consistent with a recent randomized controlled trial where six of 36 CSCs were completely lost and two had loss of material, two PVSSCs had loss of material, and no loss of restoration or material occurred with ZCs.[13]

The retention of CSCs placed with typical behavior guidance or conscious sedation ranges between 80 to 88% at 18 to 74 months of follow-up, with failures including partial and complete loss of composite.[5,16,17] One study demonstrated a much lower success rate of 51% for composite crowns that were placed under general anesthesia.[19] Other studies involving composite crowns placed under general anesthesia have demonstrated success rates ranging from 70 to 100% with follow-up times averaging from 6 months to 24 months.[3,20,21] The variation overall is likely related to differences in material placement technique, moisture, and hemorrhage control. PVSSCs have demonstrated retention rates between 99 to 100% at an average of 17.5 to 21 months, although approximately one third of crowns have lost some or all of the veneer.[7,8] In a more recent retrospective study of NuSmile Signature crowns, 12% of crowns were found to have partial loss of the facing at six months of follow-up.[9] Similarly, this study found 11% of crowns with partial loss of the facing at 12 months of follow-up. Our long retention rates of ZCs compare to existing literature in which at an average of 20.8 months of follow up, ZCs were found to have a retention rate of 96%.[12]

4.1.3 MARGINAL DISCREPENCIES AND GINGIVAL HEALTH

Subgingival preparation is often required for retention of full-coverage restorations in primary teeth and gingival inflammation increases with the depth of the gingival margin.[22] Cementation can further irritate gingival tissues and it can thereby be expected that there will be some level of gingival inflammation following placement of crowns on primary teeth. Although it was not statistically significant, we found that at 12-month follow up, CSCs had a higher rate of gingival inflammation than PVSSCs and ZCs (40% vs 23% and 15% respectively, p=0.052). Previous research has shown gingival index to decrease following placement of ZCs,[13] increase at least mildly around PVSSCs,[7,8] and increase up to two times around CSCs.[16] Increased gingival inflammation with CSCs and PVSSCs may be attributed to increased plaque retention of resin.[13] The biocompatibility of ZCs may be attributed to a polished surface minimizing plaque retention, as has been shown with zirconia fixed partial dentures in the permanent dentition.[13] Further, our study found that CSCs were more likely to present with discrepancies in the crown margin and this may have led to reduced gingival health.

4.1.4 CLINICAL AND RADIOGRAPHIC FAILURES

There was significantly more trauma reported for teeth restored with PVSSCs. This is despite a greater proportion of females receiving PVSSCs (74%), as trauma incidence is higher in males.[23] Further, there was no significant increase in clinical or radiographic pathology nor incidence of fracture reported of PVSSCs, as pathology rates were similar for all crowns. It is unlikely that facial veneer integrity was affected as the incidence of fracture reported in this study is consistent with that previously reported.[7-9,13] The retention of PVSSCs was not affected, as none of the PVSSCs were lost at follow up.

Secondary caries rates were not significantly different among groups, despite significantly higher dmft scores in the CSC group.

None of the crowns presented with clinical pathology at 12 months. Assessment of radiographic pulpal health was not comprehensive, as 63% of crowns did not have new radiographs taken at 12 months due to a lack of patient cooperation. Overall, literature is lacking on the assessment of clinical and radiographic pathology of PVSSCs and ZCs. One study found that five percent of ZCs developed clinical pathology that resulted in extraction at an average of 21 months of follow-up.[12] Radiographic assessment of CSCs have shown minimal teeth presenting with periapical pathosis, of which few have required endodontic treatment (1 to 2%) beyond 18 months of follow-up.[5,16] Radiographic evaluation of CSC margins have shown non-ideal marginal contour in 46% of teeth, including overhangs, under-contour or radiolucencies.[16]

4.1.5 PARENTAL SATISFACTION

Given increased parental involvement in clinical decision making, it is important to consider parental opinion of esthetics, durability and impact on overall health.[4] Further, children as young as four years old have demonstrated negative self and social perceptions regarding altered dental esthetics in the primary maxillary dentition.[24] Parental emphasis on esthetics is further illustrated in that parents prefer treatment to no treatment for primary incisors with dark coronal discoloration.[25] It is no surprise then, that parents were most concerned with the color of the crowns in this study, followed by shape and alignment.

As previously discussed, parents were least satisfied with the color of PVSSCs and CSCs, which is consistent with what has been found previously.[4] Our study found two parents dissatisfied with the shape and alignment of ZCs, while examiners found no significant difference in the position of the crowns at follow-up. In the literature, clinical findings of the size

and shape of ZCs have been found to correlate well between parents and dentists.[12] It is possible that the thickness of ZCs lends to a non-ideal shape and the passivity of fit of ZCs results in rotations at cementation that result in non-ideal alignment, as detected by parents.

4.2 Limitations and Directions for further research

One limitation of this study is the disproportion of gender, insurance status, and dmft score among groups at baseline. Given the limited variability in the results, it was not statistically possible to adjust for these variables. Longer follow-up data and a larger sample may result in increased variability and regression analysis could rule out these potential confounders.

Another limitation of this study is the number of patients who were lost to follow-up. Yet, the post-hoc power calculation provide grounds for the validation for the study. Further, some clinical failures may not be present at 12 months and longer follow-up data is recommended. Our study did not have radiographs for all participants at follow-up due to limited patient cooperation, occasional parental refusal and radiograph necessity per clinical judgement. The standard of care by AAPD for regular follow-up of anterior crowns in young children does not include radiographic evaluation unless clinical manifestation of failure is suspected. In this study, limiting pediatric radiation exposure was a critical component of approval by the UW Human Subjects Review Board.

Chapter 5. CONCLUSION

Based on this study's results, the following conclusions can be made:

1) At 12 months follow-up, PVSSCs and ZCs had better color, retention, facing integrity, and marginal adaptation than CSCs.
2) Differences in position, proximal contact, and gingival status were not significant among groups.
3) The main esthetic concern of parents was crown color and there was most dissatisfaction with CSCs followed by PVSSCs.
4) Selection of an esthetic full-coverage restoration for primary maxillary incisors involves consideration of a multitude of factors (including setting). The preferences of the child and the parent should be taken into consideration given the value of patient-centered care in satisfaction of treatment.

CONFLICT OF INTEREST

The authors of this publication have partial research support from NuSmile (Houston, Texas, USA). The terms of this arrangement have been reviewed and approved by UW IRB in accordance with its policy on objectivity in research.

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APPENDIX A

Subject ID/Initials____ Today's Date_ /____/_____ Visit: Baseline 3 6 12 18 24_

Treatment Group:	Tooth Letter:	Total # Anterior Crowns Placed:	Time Length of Placement:
Clinical Photograph(s)? Yes□ No□ If no please explain_____			Adverse Event? Yes□ No□ (If yes, complete AE form)
Diagnostic Radiographs? Baseline Yes□ No□ N/A□ Date Taken_____			24 Months Yes□ No□ N/A□ Date Taken _____
Parent Esthetic Survey Completed? Yes□ No□			

(mm/dd/yyyy) (Circle Visit Month)

I.Restoration Evaluation

1. Fitting
   - A: Good natural retention
   - B: Moderate natural retention
   - C: Little or no natural retention
2. Positioning
   - A: Proper position
   - B: Rotated—in occlusion
   - C: Not in occlusion with or without rotation
3. Proximal Contact
   - A: Open spaces
   - B: Floss meets little or no resistance when passes through contact
   - C: Floss meets significant resistance when passes through contact
4. Marginal Adaptation
   - A: No discrepancies detected with explorer
   - B: Detectable discrepancies but clinically acceptable
   - C: Detectable discrepancies, not acceptable—replacement required
5. 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
6. Time Placement
   - A: ≤ 30 minutes
   - B: > 30 - ≤ 45 minutes
   - C: > 45 minutes
7. 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
8. 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)

9. 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
10. Secondary Caries
    - A: Absent
    - B: Present
11. Trauma
    - A: Absent
    - B: Present
12. Clinical Pulp Pathology
    - A: Absent
    - B: Present
13. Radiographic Pulp Pathology
    - A: Absent
    - B: Present

II: Failure? Yes□ No□ If failure (please check all reasons that apply below:

Unacceptable margin adaptation	□
Secondary caries	□
Excessive wear/loss of contact	□
Restoration fracture	□
Restoration mobile	□
Restoration missing	□
Unacceptable aesthetics	□
Patient dissatisfied	□
Discomfort/sensitivity	□
Abscess	□
Other (please Specify)	□

Examiner Name_____ Signature_____

APPENDIX B

Subject ID/Initials_____ Today's Date: ____/____/____ Visit: 3 6 12 18 24

Treatment Group:	Tooth Letter:	Total # Anterior Crowns Placed:

(mm/dd/yyyy) (Circle Visit Month)

I. Restoration Evaluation

1. Fitting
   - A: Good natural retention
   - B: Moderate natural retention
   - C: Little or no natural retention
2. Positioning
   - A: Proper position
   - B: Rotated—in occlusion
   - C: Not in occlusion with or without rotation
3. Proximal Contact
   - A: Open spaces
   - B: Floss meets little or no resistance when passes through contact
   - C: Floss meets significant resistance when passes through contact
4. Marginal Adaptation
   - A: No discrepancies detected with explorer
   - B: Detectable discrepancies but clinically acceptable
   - C: Detectable discrepancies, not acceptable—replacement required
5. 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
6. Time Placement
   - A: ≤ 30 minutes
   - B: > 30 - ≤ 45 minutes
   - C: > 45 minutes
7. 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
8. 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)
9. 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

10. Secondary Caries
    - A: Absent
    - B: Present
11. Trauma
    - A: Absent
    - B: Present
12. Clinical Pulp Pathology
    - A: Absent
    - B: Present
13. Radiographic Pulp Pathology
    - A: Absent
    - B: Present
    - N/A: Radiograph not taken

II: Failure? Yes□ No□ If failure (please check all reasons that apply below:

Unacceptable margin adaptation	□
Secondary caries	□
Excessive wear/loss of contact	□
Restoration fracture	□
Restoration mobile	□
Restoration missing	□
Unacceptable aesthetics	□
Patient dissatisfied	□
Discomfort/sensitivity	□
Abscess	□
Other (please Specify)	□

Examiner Name_____ Signature_____

APPENDIX C

Subject ID/Initials_____ Today's Date: ____/____/_____ Visit: Baseline 3 6 12 18 24
(mm/dd/yyyy) (Circle Visit)

Treatment Group:	Tooth Letter:	Total Number of Anterior Crowns Placed:

1. Which of the following best describes your thoughts overall about the appearance of your child's teeth? (Please circle a letter)
   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. Yes2. No
   b. Color1. Yes2. No
   c. Alignment1. Yes2. No
   d. Spacing between teeth 1. Yes2. No
   e. Crowding of teeth1. Yes2. No
   f. Speckled/spotted/streaky/irregular/blotchy appearance1. Yes2. No
   g. Other: _____