RETREATMENT OF CLASS II RESTORATIONS IN PRIMARY MOLARS

A. **Specific Aims**

The overall goal of this study is to examine the longevity of Class II amalgam and composite restorations in the primary dentition. The study will focus on treatment rendered by undergraduate dental students in the department of pediatric dentistry at the UNC School of Dentistry (referred to as "UNC" hereafter). The specific aims of this study are: (1) to describe the rates and trends of placement of amalgam and composite restorations in Class II cavities in primary molars over the past ten years at UNC; (2) to compare the rates of retreatment for Class II amalgam and composite restorations in primary molars over the past ten years at UNC; and (3) to examine and compare predictors of retreatment for Class II amalgam and composite restorations in primary molars over the past ten years at UNC.

B. **Significance**

Silver amalgam has been the standard for restoring large carious lesions on posterior primary and permanent teeth for more than 100 years (1). However, composite resin is increasing in popularity as a restorative material in the primary dentition because of better esthetics and concerns among some quarters about the ill-health effects of mercury in amalgam (2). Although research has established the safety of amalgam as a restorative material, controversy about mercury in amalgam continues (3). Nevertheless, the continued improvement in composite resin's handling characteristics and clinical performance have made it an attractive alternative to amalgam for restoring Class II cavities in primary molars (2).

The American Dental Association's Council on Scientific Affairs has established that both amalgam and composite resin are safe and effective permanent restorative materials (4). Guidelines from the department of pediatric dentistry at the UNC School of Dentistry (5)

recommend that amalgam should be the material of choice for Class II restorations in primary molars when there are concerns about: 1) lack of moisture control, since amalgam is more forgiving than composite resin to the presence of moisture in the operating field; 2) the child has extensive caries and/ or is at high risk for caries; 3) the child is four years or younger; or 4) when the child is uncooperative, because it can take upto 35% more time to place a composite restoration versus an amalgam on a molar in a child aged 7-9 years old (6). Further, the same guidelines recommend composite resin to restore Class II cavities in primary molars when there are parental concerns about mercury, including its environmental effects and when esthetics are a concern for the parent or child.

Although composite resin is being used increasingly to restore Class II cavities on primary molars (7), little research has examined the frequency with which Class II composites require retreatment compared to amalgam in primary teeth. A Cochrane systematic literature review published in 2009 examined the effectiveness of all types of restorations in primary teeth (8). Of the 26 studies reviewed, the final review included only three randomized controlled trials that compared (1) esthetic crowns versus conventional stainless steel crowns, (2) Class II resin-modified glass ionomer (Vitremer) versus amalgam over a 36-month period and (3) Class II Dyract (Compomer) versus Tytin (amalgam). No study included in the systematic review compared amalgam to composite resin for restoring carious primary teeth. A recent study compared failure rates of occlusal amalgam and compomer/composite restorations in primary and permanent teeth among 6-10 year olds (2). The authors found no statistically significant difference in retreatment rates for amalgam and composite/ compomer restorations. However, compomer restorations needed retreatment significantly more often for recurrent caries; and

composite restorations needed to be repaired seven times more often than amalgam restorations in that study.

Evidence for the longevity of Class II restorations in primary molars placed by undergraduate dental students is even more limited than that available for licensed dentists and pediatric dentists. Two recent studies investigated the clinical performance of composite restorations placed by undergraduate dental students in Brazil and the Netherlands. Opdam et al. (2004) included all Class I and II composite restorations placed by second to fourth year dental students from September 1993-September 1995 (9). The authors report the annual failure rate of restorations to be 2.8%. Moura and colleagues (2011) report that at the end of three years, the highest failures occurred for Class II restorations (38% restorations failed) (10). To the best of our knowledge, however, no studies have compared retreatment of Class II amalgam and composite restorations placed by dental students in primary molars.

In summary, amalgam remains the material of choice for restoring Class II carious lesions in primary molars. However, composite resin is increasing in popularity as a posterior restorative material for primary teeth because of better esthetics and its lack of mercury as a reactant. Limited research has examined retreatment rates of class II amalgam and composites in primary molars. There exists almost no evidence for retreatment rates of these materials in primary molar teeth in a dental school setting, or for how years in dental school affects longevity of these restorations. This study will attempt to fill this gap in the literature and should provide new knowledge about factors that influence retreatment rates for amalgam and composite restorations in a dental school setting. This study also is likely to provide information about using electronic patient records to study clinical outcomes in dental schools. Such information should assist dental school faculty in addressing issues related to teaching of Class II restorations

on primary molars in dental schools. Finally, lessons learned from this project will help inform future research on designing studies to evaluate the clinical performance and outcomes of other restorative procedures performed by undergraduate dental students.

C. **Preliminary Studies:**

Table 1 presents preliminary information about the total number of two-surface amalgam and composite resin restorations completed in the undergraduate pediatric dentistry clinic at UNC over the past ten years. Note that these data include mesio-occlusal (MO), disto-occlusal (DO), occluso-lingual (OL) and occluso-buccal restorations (OB). For the current study however, we will only include MO and DO restorations. OL and OB restorations will be excluded because, relative to MO and DO preparations, they provide easy visual access to the affected area of the tooth and are therefore easier to perform.

Table 1. Frequency of posterior restorations in primary teeth in the UNC undergraduate pediatric dentistry clinic

	From 1/1/2002 to present
Two-surface amalgam on a primary tooth (D2150)	214
Two-surface resin on a posterior primary tooth (D2392)	474

With respect to retreatment rates, we know from a recent systematic review of the literature that in a controlled clinical environment the need for retreatment of amalgam restorations ranges from 0-22% (11). As mentioned above, data from one study in a dental school in the Netherlands that included Class I and II composite restorations reported that at the end of 5 years 23% of those restorations failed (9). Another more recent study from Brazil reported that at the end of three years about 38% of Class II composite restorations were viewed as failures (10). Finally, although resin-modified glass ionomer also is used as a restorative material for Class II restorations in primary molars, it will not be included in this study because students do not have the option of restoring Class II cavities with that material at UNC.

D. **Methods**

We will access UNC School of Dentistry's Electronic Patient Record system to extract data for this study. The data will be entered into a password protected database. The study sample will include children 1 to 9 years of age who had a primary 1st or 2nd molar restored with an MO or DO amalgam or composite and were followed every 6 months after receiving the MO or DO restoration for at least 3 years. Primary molars begin emerging around 12 months of age and remain in the mouth until 12 years of age. The length of follow-up may be modified depending on the average follow-up time for children in the sample. It is possible that the study sample will include children who had multiple Class II amalgam and/or composite resin restorations placed and retreated during the study period. To simplify the analysis we will only select the

Table 2. Description of study variables

Outcome variables	***Description***	***Categories***
Class II composite restoration	Restorations with code D2150 on MO/DO tooth surfaces	
Class II composite restoration	Restorations with code D2390 on MO/DO tooth surfaces	
Explanatory variables	***Description***	***Categories***
Chronological age in months	Child's age calculated using time between date of birth and placement of class II restoration	Continuous variable
Dental age in months	Child's age calculated using mean of age range for erupted primary and permanent teeth using a standard eruption chart	Continuous variable
Sex	Child's sex	Male, Female
% Tooth surfaces with caries experience	[(DFS/#permanent teeth present) + (dfs//#primary teeth present)] * 100	Continuous
Insurance	Indicator for how patient paid for the Class II restoration	Medicaid, Private pay
Child behavior at restorative appointment	Frankl scale	Definitely uncooperative, uncooperative, cooperative, definitely cooperative
Isolation method	Isolation technique used during the operative appointment	Rubber dam, Isolite

first Class II restoration that was placed for children with multiple Class II restorations. All analyses will be conducted using Stata (Stata Corp., College Station, TX).

Data analysis

Aim 1: To describe the rate and trends of placement of amalgam and composite restorations in Class II cavities in primary molars over the past ten years at UNC.

To describe the rate of Class II amalgam and composite restorations in primary teeth we will identify all restorations with codes D2150 and D2392, respectively. As mentioned above, the analysis will only include DO and MO amalgam and composite restorations. To examine trends, we will use graphs to chart the rate of Class II amalgams and composite resins by year. Bivariate analyses will examine differences in rates of Class II amalgam and composite restorations with respect to a number of explanatory variables (see Table 2). For example, we will document differences in children receiving Class II amalgam and composite restorations based on chronological and dental age of children in the sample, and based on their caries risk status. Caries risk assessment forms developed by the American Academy of Pediatric Dentistry for 0-5 and ≥6 year old children and adapted by the department of pediatric dentistry at UNC (see Appendix) will be used to categorize children as high vs. moderate or low risk for caries.

Aim 2: To compare the rates of retreatment for Class II amalgam and composite restorations in primary molars over the past ten years at UNC.

Patient records and clinic progress notes occurring after the date of initial placement of those restorations will be examined for any documented evidence of need for retreatment including, secondary caries, fractured restoration, and/ or the restoration was lost, or there was a recommendation that the tooth be restored again, either with another Class II amalgam or composite restoration or with a stainless steel crown. Alternatively, if there is a progress note

indicating that the tooth was re-restored then it will qualify as a retreatment. For this aim we will test the following hypothesis: *Class II composite restorations in primary molars are more likely to require retreatment than Class II amalgam restorations in primary molars*.

We will conduct survival analysis to examine differences in retreatment rates for composite and amalgam restorations. For example, the hazard function for retreatment will be estimated using a kernel smoother applied to the Nelson-Aalen cumulative hazard function estimator. The smoothed hazard function plots thus generated also will allow us to test the assumption of proportional hazards for the amalgam and composite resin groups. If the hazards are found to be proportional, the analysis in Aim 3 will use this to advantage by estimating Cox models to assess retreatment rates more efficiently (12).

Aim 3: to examine and compare predictors of retreatment for Class II amalgam and composite restorations in primary molars over the past ten years at UNC.

The final aim of this study will identify risk factors for retreatment of Class II composite and Class II amalgam restorations in the primary dentition. We will estimate separate survival models such as Cox proportional hazards models to identify these risk factors with covariates presented in Table 2. Caries risk will be modeled both, using a continuous variable capturing the % of tooth surfaces with caries experience (Table 2) and using the Caries Risk Assessment approach described above and presented in the Appendix. Based on results from the Cox models we will generate a table comparing risk factors that predict retreatment of Class II composite restorations and factors predicting retreatment of Class II amalgam restorations in the primary dentition. This will allow assessment of similarities or differences in factors that determine retreatment of Class II composite and amalgam restorations in primary molars. Because we will

follow patients over 3 years, this analysis will provide a long-term follow-up of the determinants of restoration success.

Study limitations

The decision to place an amalgam or composite on a tooth may have been dictated by the parent. It also is possible that Class II amalgams were placed in teeth with less extensive decay than teeth restored with composite resin. We are unable to control for these variables in our study.

Anticipated work schedule

Activity	May'12	June'12	July'12	Aug' 12	Sept' 12	Oct'12	Nov'12	Dec'12
Write IRB application and apply for IRB approval								
Data extraction from UNC School of Dentistry's Electronic Patient Record system								
Data analysis								
Writing the manuscript								
Developing the conference presentation for Dental Research and Review Day/ AADR								

Research Personnel

Dr. Jessica Lee (Faculty mentor): will oversee and monitor progress of the project, and help with interpretation of results and developing the manuscript.

Bhavna Pahel (Student investigator): will write and submit application for IRB approval, assist research assistant with data extraction from UNC School of Dentistry's Electronic Patient Record System, analyze data and interpret results and develop the research presentation and manuscript for publication.

Summer Research Assistant (Undergraduate student): will extract data for the project.

E. **Human Subjects:** IRB application in the process of being submitted.

G. **Literature Cited:**

1. **Roberson TM, Heymann H, Swift EJ.** *Sturdevant's art and science of operative dentistry.* St. Louis, MO : Mosby Elsevier, 2006.

2. **Soncini JA, Maserejian NN, Trachtenberg F, Tavares M, Hayes C.** *The longevity of amalgam versus compomer/composite restorations in posterior primary and permanent teeth: Findings From the New England Children's Amalgam Trial.* JADA, 2007. Vol. 138(6):763-72.

3. **Bellinger DC, Trachtenberg F, Barregard L, et al.** *Neuropsychological and renal effects of dental amalgam in children: a randomized clinical trial.* JAMA, 2006. Vol. 295(15):1775-83.

4. **ADA Council on Scientific Affairs.** *Direct and indirect restorative materials.* JADA, 2003. Vol. 134. 463-72.

5. **UNC Department of Pediatric Dentistry.** *Pediatric Dentistry Clinical Syllabus.* Chapel Hill, NC : UNC School of Dentistry, 2011.

6. **Dilley DC, Vann WF Jr, Oldenburg TR, et al.** *Time required for placement of composite versus amalgam restorations.* ASDC J Dent Child., 1990. Vol. 57(3):177-83.

7. **Pair RL, Udin RD, Tanbonliong T.** *Materials used to restore Class II lesions in primary molars: a survey of California pediatric dentists.* Pediatr Dent, 2004. Vol. 26(6): 501-7.

8. **Yengopal, V, et al., et al.** *Dental fillings for the treatment of caries in the primary dentition.* s.l. : Cochrane Database Syst Rev, Issue 2. Art. No.: CD004483, DOI: 10.1002/14651858, 2009.

9. **Opdam NJM, Loomans BAC, Roeters FJM, et al.** *Five-year clinical performance of posterior resin composite restorations placed by dental students.* J of Dent, 2004. Vol. 32: 379-383.

10. **Moura FRR, Romano AR, Lund RG, et al.** *Three-year clinical performance of composite restorations place by undergraduate dental students.* Br Dent J, 2011. Vol. 22(2): 111-116.

11. **Kilpatrick NM, Neumann A.** *Durability of amalgam in the restoration of class II cavities in primary molars: a systematic review of the literature.* Eur Arch Paediatr Dent, 2007. Vol. 8(1):5-13.

12. **Cleeves MA, Gould WW, Gutierrez RG.** *An introduction to survival analysis using Stata.* College Station, TX : Stata Press, 2004.

APPENDIX

Caries-risk Assessment Form for 0-5 Year Olds			
Factors	**High risk**	**Moderate risk**	**Protective**
Biological			
Mother/ primary caregiver has active caries	Yes		
Parent/ caregiver has low socioeconomic status	Yes		
Child has >3 between meal sugar containing snacks or beverages per day	Yes		
Child is put to bed with a bottle containing natural or added sugar	Yes		
Child has special health care needs		Yes	
Child is a recent immigrant		Yes	
Protective			
Child receives optimally-fluoridated drinking water or fluoride supplements			Yes
Child has teeth brushed daily with fluoridated toothpaste			Yes
Child receives topical fluoride from health professional			Yes
Child has dental home or regular dental care			Yes
Clinical findings			
Child has >1 decayed/missing/filled surfaces (dmfs)	Yes		
Child has active white spot lesions or enamel defects	Yes		
Child has elevated mutans streptococci levels	Yes		
Child has plaque on teeth		Yes	

Caries-risk Assessment Form for ≥6 Year Olds			
Factors	**High risk**	**Moderate risk**	**Protective**
Biological			
Parentis of low socioeconomic status	Yes		
Patient has >3 between meal sugar containing snacks or beverages per day	Yes		
Child has special health care needs		Yes	
Child is a recent immigrant		Yes	
Protective			
Child receives optimally-fluoridated drinking water			Yes
Patient brushes teeth daily with fluoridated toothpaste			Yes
Patient receives topical fluoride from health professional			Yes
Additional home measures (e.g., xylitol, MI paste, antimicrobial)			Yes
Patient has dental home or regular dental care			Yes
Clinical findings			
Patient has ≥1 interproximal lesions	Yes		
Patient has active white spot lesions or enamel defects	Yes		
Patient has low salivary flow	Yes		
Patient has defective restorations		Yes	
Patient wearing an intraoral appliance		Yes	