#### Success Rates of Stainless Steel Crowns vs. Composite Restorations in

#### **Primary 1st Molars**

#### BY

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#### THESIS

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#### LIST OF ABBREVIATIONS

AAPD	American Academy of Pediatric Dentistry
ASA	American Society of Anesthesiologists
DEJ	Dentin Enamel Junction
dmft	decayed, missing or filled (primary) teeth
ECC	Early Childhood Caries
PI	Principal Investigator
S. Mutans	Streptococcus Mutans
SSC	Stainless Steel Crown

#### Summary

Stainless steel crowns (SSCs) and composite resin restorations are restorative options for caries in the primary dentition. The AAPD recommends that stainless steel crowns be the treatment of choice for interproximal caries in primary molars in high caries risk patients (AAPD, 2017). There is limited evidence based research comparing the success rates of SSCs to traditional composite resin restorations.

A retrospective study was carried out using electronic health records of children ages three to six years of age with high caries risk who had SSCs or composites placed on primary first molars at the University of Illinois Post Graduate Pediatric Dental Clinic. Electronic charts and radiographs were evaluated to determine the depth of the carious lesion, type of restoration that was placed and if the restoration failed in a period of 36 months.

The purpose of this study was to determine if there was a statistically significant difference in the success rates of SSCs vs composite resin restorations placed in high risk first primary molars for a period of 36 months.

#### **1. Introduction**

#### **1.1 Background**

The American Academy of Pediatric Dentistry (AAPD) guidelines state that stainless steel crowns (SSCs) are recommended in high caries risk patients (AAPD Guideline on Pediatric Restorative Dentistry, 2017). Stainless steel crowns have been the treatment of choice for interproximal lesions on primary molars in high caries risk children. SSCs are preformed metal crowns that are cemented to teeth using a luting cement. SSCs are indicated in teeth with large caries, where future failure is anticipated, decalcification is present, in patients who grind teeth and following any pulpal treatment. SSCs are the definitive treatment choice for patients undergoing general anesthesia or sedation for completion of dental treatment (Randall, 2002). A Cochrane review of non-randomized, retrospective studies, concluded that SSCs had a longer longevity than amalgam restorations for a period of five years (Innes et al., 2015). Parents have raised questions about the esthetics of SSCs, as they are silver in color. They require more tooth preparation than traditional composite restorations and require the removal of healthy tooth structure in order to achieve proper fit and occlusion. SSCs are the material of choice as they are believed to be more durable than traditional filling material (Innes et al., 2015). Composite restorations are a more esthetically pleasing restorative material and require minimal preparation of the tooth. The drawbacks of composite resins are the failure rates due to secondary caries (Donly and Garcia-Godoy, 2015). Composite resin restorations are considered clinically acceptable restorations if they have a minimum longevity of three years, according to American Dental Association standards for acceptance of restorative material (Donly & Garcia-Godoy, 2015 and AAPD Guideline on Restorative Dentistry, 2017).

The main reason for failures of composite resin restorations is secondary caries caused by a number of different bacteria, including Streptococcus Mutans (*S. Mutans*), which have esterase activity (Bourbia et al., 2013). Inflammatory (cholesterol esterase, CE) and salivary (pseudo-cholinesterase, PCE) enzymes can cause failures of composite resin restorations by affecting the bisphenol-A-diglycidyl dimethacrylate (bisGMA) and triethylene glycol dimethacrylate (TEDDMA) portions of the composite (Finer and Santerre, 2003). The bacteria is able to enter a crack that is formed between the composite and the tooth and cause the composite to breakdown and fail. The amount of breakdown is dependent on the individual patients' salivary make up and amount of esterase present (Finer and Santerre, 2003). When comparing the longevity of SSCs to composite resin restorations, the crowns were less likely to fail than composite resins in the time frame of 12 to 24 months, with a relative risk of 0.18, 95% confidence interval 0.06 to 0.56 (Innes et al., 2015). The AAPD guideline states that SSCs also cause increased gingival bleeding at the time of placement compared to resin restorations (AAPD Guideline on Pediatric Restorative Dentistry, 2017).

On the other hand, Attin et al. (2001) explained that the success rates of composite resin restorations used to treat interproximal caries on primary molars in children, in a private practice setting, was 85.8% after three years. This suggests composites may be an option for restorations. Composite resin restorations are a clinically acceptable treatment option in treating class II carious lesions in primary molars. Therefore, both materials could be used, depending on the situation and we need to determine which one is the best option in terms of longevity in primary first molars.

#### 1.2 Purpose of this Study

The primary aim of this study was to determine if there was a difference in the success rates of SSCs vs. composite resin restorations in primary first molars over a period of 36 months in high caries risk patients.

#### **1.3 Null Hypothesis**

There is no difference in the success rates of SSC's vs. composite resin restorations in first primary molars with interproximal carious lesions extending up to two millimeters in the dentin followed up for a period of 36 months, in high caries risk patients.

#### 2. Literature Review

#### 2.1 Early Childhood Caries

Dental caries is considered the single most common chronic childhood disease (Bagramian et al., 2009). Early childhood caries (ECC) is defined as the "presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled tooth surface in any primary tooth in a child under the age of six years" (AAPD Guideline on Pediatric Restorative Dentistry, 2017). By the age of five years, 60% of children have experienced caries in at least one of their primary teeth (Crall, 2005).

ECC is a preventable disease. The disease process starts with an accumulation of *S*. *Mutans* (Almeida et al., 2000). *S. Mutans* can adhere to the tooth surface, produce acid and survive the oral environment at low pH (Tinanoff and Reisine, 2009). However, its esterase activity can also degrade existing dental resins and adhesives (Bourbia et al., 2013). The initial colonization of MS is usually due to vertical transmission from the parent/primary caregiver to the child and can be seen in the child as early as six months of age (Tinanoff and Reisine, 2009). Vertical transmission can be decreased by eliminating the sharing of utensils and any other habits where saliva can be transferred.

It is extremely important to treat ECC. Primary teeth hold the space for the eruption of the permanent successor. Losing a primary tooth early can cause shifting of teeth, crowding and need for orthodontics in the future (Yengopal et al., 2016). Primary teeth are useful for the development of a child's speech and self poise as well as everyday functions such as biting and chewing (Yengopal et al., 2016).

Leaving caries untreated can decrease a child's oral-health related quality of life (Tinanoff and Reisine, 2009). Untreated caries can lead to dental pain, dental abscess,

destruction of alveolar bone support and spread of dental infection in the bloodstream that can be life threatening (Bagramian et al., 2009). Many hours of school are missed and children have a decreased ability to learn due to untreated dental caries (Edelstein and Reisine, 2015). In the United States, seven million hours of school are lost annually for children ages five to seven due to dental problems/visits (Tinanoff and Reisine, 2009). Parents, caregivers and the children themselves often report likelihood of child to miss school, ashamed to smile and having problems eating due to dental decay (Tinanoff and Reisine, 2009). Parents have to miss days of work to attend to their children's dental needs, which can lead to economic hardship.

Treatment of ECC can be expensive. In 1996, the estimated cost to treat two to five carious teeth in a child in the dental chair, not utilizing oral sedation or general anesthesia, was reported to be \$408 and \$1725 for 16 to 20 teeth. If a child requires treatment to be completed under general anesthesia or conscious sedation due to behavior or the extent of treatment recommended, the cost can increase anywhere from \$1500 to \$6000 (Tinanoff and Reisine, 2009). Since then, the price has increased. In 2018, the cost of five SSCs in a child on private dental insurance is \$2500 (States Employee's Group Insurance Program, 2018).

It has been shown that children in families, who fall under the poverty line (annual income of \$17,000 for a single family of four), have two times the amount of dental caries than non-poor children and many of the caries remain untreated (Bagramian et al., 2009). Although the prevalence of dental caries in non-poor children is less, once the caries is present, the severity is the same between poor and non-poor children (Tinanoff & Reisine, 2009). Children insured by Medicaid had fewer dental visits than children with private dental insurance with only one in five children on Medicaid receiving the preventative dental care they are eligible to receive (Mouradian et al., 2000). From 2010 to 2012, only 29.2% of the children who were Medicaid-

eligible visited a dentist for preventative care, as opposed to 46.1% of the children who had private dental insurance (Berdahl et al., 2016). Poor and non-poor children from the ages of two to five years had 72% of decayed teeth left untreated (Tinanoff & Reisine, 2009).

#### 2.2 Stainless Steel Crowns

SSCs are a prefabricated metal crown which is placed over the entire tooth and cemented using a dental cement (Seale and Randall, 2015). This restoration is preferred for restoring a primary tooth with extensive caries, cervical decalcification, developmental defects (hypoplasia, hypocalcification), high likelihood of failure of other dental restorative options (i.e. large caries extending past the tooth's line angle, child with history of bruxism), teeth following pulpal treatment (pulpotomy or pulpectomy), high-caries risk patients and/or patients requiring dental treatment to be completed under general anesthesia or conscious oral sedation (Innes et al., 2015, AAPD Guideline on Restorative Dentistry, 2017).

SSCs are designed to have the basic anatomy of teeth. They are durable enough to withstand natural chewing forces and flexible enough to allow for adjustments (trimming, crimping and shaping) for a more ideal fit to the tooth (Seale & Randall, 2015). They are cemented to the tooth using a biocompatible luting agent, such as glass ionomer cement (Seale & Randall, 2015, AAPD Guideline on Restorative Dentistry, 2017). Because they encompass the entire tooth, they provide a protective barrier that eliminates the risk of the tooth developing any new or recurrent caries.

SSCs require the entire tooth to be prepared. The recommendation is for 1.5mm of occlusal reduction (or more depending on the extent of the caries), breaking through the mesial and distal contacts with proximal tooth reduction and rounding all line angles (Randall, 2002). After caries removal and proper tooth reduction is complete, a preformed SSC is chosen based

on proper sizing. A good fitting crown will be crimped and seated slightly subgingival up to 1mm and have minimal alterations on patients' natural occlusion (Randall, 2002). According to Randall, a crown can be up to one and a half millimeters high on occlusion, as primary teeth can spontaneously adjust for this amount of occlusal discrepancy over a week or so.

#### 2.3 Composite Resin Restorations

Composite resin restorations are another treatment option for restoring interproximal carious lesions in primary molars. Resin based composites are comprised of bisphenol A-glycidyl methacrylate (Bis-GMA), quartz filler particles and silane coupling. The filler particles combined with silane cause less discoloration and degradation of the resin matrix (Donly and Garcia-Godoy, 2015).

According to Donly and Garcia-Godoy, (2015), when choosing to place a composite resin restoration; many factors need to be addressed:

- Patient cooperation: composites are more technique sensitive and have a longer placement time. Children who are uncooperative may not be ideal candidates for composites.
- 2) Isolation: Composite resins have hydrophobic properties and proper isolation of a rubber dam or IsoDry (Isolite Systems, Santa Barbara, CA, USA) system are needed to prevent contamination. If the adhesive surface is contaminated with saliva (i.e, proper isolation not achieved), the filled composite resin will be unable to bond to the adhesive, which would result in microleakage and failure of the composite.
- Dentin bonding: dentin adhesive bonding must be utilized and light cured prior to composite placement to minimize marginal microleakage.

Composites are a less invasive treatment option than SSC, requiring less tooth preparation, while offering an esthetic outcome. With proper isolation, etching and bonding, the chances of marginal staining and detectable open margins in composites are decreased, thus increasing the success of the composite (Heintze and Rousson, 2012, AAPD Guideline on Restorative Dentistry, 2017). According to Zimmerman et al. (2009), parents preferred "tooth colored" restorations compared with amalgam or SSCs as they see this treatment as less painful and does not require the child to have metal in his/her mouth.

The most common reason for failure of composite resin restorations is recurrent caries (Bernardo et al., 2007, AAPD Guideline on Restorative Dentistry, 2017). Factors considered by pediatric dentists as contraindications for the placement of composite resin restorations are: poor oral hygiene, isolation concerns, high caries risk, deep preparation, pulpotomy, caries extending for more than two surfaces, and large tooth preparation (Zimmerman et al, 2009). Proper patient selection is important in choosing to place a composite resin restoration.

#### 2.4 Composite Resin Restorations vs. Stainless Steel Crowns

SSCs are the preferred treatment choice by pediatric dentists for the restoration of primary teeth affected by moderate to advanced dental caries (Innes et al., 2015). The research to support this is limited and not of high quality evidence. In a systematic review, Innes et al. (2015) concluded there were no randomized control trials that compared the successes of SSCs vs composites after caries removal. Many of the studies completed are of poor to medium quality, consisting of mainly case reports and uncontrolled studies (Innes et al., 2015). It was concluded that SSCs placed on primary teeth after caries removal are less likely to produce a major failure or have post-op complications (i.e. pain) when compared to fillings.

A study by Roberts et al. (2005) compared SSCs to resin-modified glass ionomers for the treatment of class II carious lesions in primary molars in a private practice pediatric dental office. The average age of the patients was 7.48 years for class II and 6.29 years for SSC's (age ranges were 1.96 to 15.41 years), when the restorations were placed. The cavity preparation for class II caries had to be very close to ideal form in order for resin-modified glass ionomer to be placed. If the carious lesion extended on both proximal surfaces or the outline form was larger than the classical form, SSCs were placed. Rubber dam isolation was utilized in 95.7% of the class II restorations and 98% of SSCs. Resin modified glass ionomers had a success rate of 97.3% and SSCs had a success rate of 97%, within a time frame of seven years. Thus it was concluded that SSCs were proven successful for treating large carious class II lesions or caries involving the pulp and resin modified glass ionomers were successful in treating smaller class II carious lesions (Roberts, Attari, & Sherriff, 2005).

The main reason for failures of composite resin restorations is secondary caries caused by *S. Mutans*, which have esterase activity (Bourbia et al., 2013). For children who have ECC or severe early childhood caries (SECC), the levels of *S. Mutans* present in the saliva is elevated. This increases the esterase activity, which causes destruction of the resin-dentin interface, thus causing breakdown of the resin and secondary caries (Bourbia et al., 2013). When comparing the longevity of SSCs to composite resin restorations, SSCs were less likely to fail than composite resins in the time frame of 12 to 24 months, with a relative risk of 0.18, 95% confidence interval 0.06 to 0.56 (Innes et al., 2015). However, SSCs caused increased gingival bleeding at the time of placement compared to resin restorations (Innes et al., 2015).

On the other hand, Attin et al. (2001) explained that the success rates of composite resin restorations used to treat interproximal caries on primary molars was 85.8% after 3 years. This

shows that there is a minimal failure rate of composite resins of primary molars in this study. Composite resin restorations are a clinically acceptable treatment option in treating class II carious lesions in primary molars (Attin et al., 2001).

Hybrid composite resins are recommended in low caries risk patients (Sengul and Gurbuz, 2015). Other restorative materials such as compomer, resin-modified glass ionomer and Giomer composite resin are options for esthetically pleasing restorations for class II carious lesions (Sengul and Gurbuz, 2015). In a prospective, non-blinded, parallel group study of 146 primary molars in 41 high caries risk children from ages five to seven years, giomer composite resin had the lowest failure rate (21.1%), compomer had the highest failure rate of 33.3% and hybrid composite resins had a failure rate of 22.5% after 24 months in a study by Sengul and Gurbuz (2015). These reported differences were not statistically significant.

Therefore, it remains unclear whether composite resin restorations or SSCs should be the preferred restorative choice in treating class II carious lesions in primary first molars.

#### 3. Methods

#### **3.1 Sample Selection**

The target population included children three to six years of age who presented to the UIC post graduate pediatric dental clinic between 2013 to 2017 for a comprehensive dental examination. The American Society of Anesthesiologist's (ASA) classification of physical health was utilized to determine the health status of each child (American Society of Anesthesiologists, 2014). The inclusion criteria included: ASA I (completely healthy), or ASA II (mild systemic diseases), able to sit for dental treatment in the chair with nitrous oxide or conscious sedation, radiographs taken at initial and at least once radiograph taken at follow-up appointments up to three years and radiographically carious lesions on primary first molars extending up to two mm into dentin. Exclusion criteria were: children younger than three and older than six years at the comprehensive examination, ASA III (severe systemic disease that is not debilitating) or ASA IV (systemic disease that is a constant threat to life) (American Society of Anesthesiologists, 2014), treatment completed by pre-doctoral students, caries larger than 2mm into dentin radiographically, patients who failed to return to at least one recall appointment after initial treatment, second primary molars and patients treated under general anesthesia.

#### 3.2 Study Design

After obtaining IRB approval (protocol number 2017-0507), all electronic dental charts of patients from three to six years of age seen in the graduate clinic who had either an SSC or composite resin placed on a primary first molar were audited to determine if the patients met the inclusion criteria. All restorations were placed with utilization of a rubber dam or IsoDry (Isolite Systems, Santa Barbara , CA, USA), as that is the standard of care in the postgraduate dental clinic.

For the purpose of calibration, a pilot study was performed. A random list of 10 teeth, with class II carious lesions, was generated and the principal investigator (PI) measured the depths of each lesion on three different occasions and recorded the results. The primary mentor also measured the same 10 lesions and recorded the results. Lesions were measured utilizing a measuring ruler included on the Dexis (Dexis Digital Diagnostic Imaging, Alpharetta, GA, USA) radiograph software in which radiographs were taken. Each lesion was measured from the dentin enamel junction (DEJ) to the end of the carious lesion. The measurement was then deleted to ensure that no one was able to see the measurement that was previously obtained. Intra-examiner reliability was determined to be >0.9 and the inter-examiner reliability was determined to be >0.75, based on Pearson's Rho Correlation.

Measurement	Canal	Calibrat	ion
Distance		0.8	mm
Angle			•
Density			2
Record Me	asureme	nt	
Show Grid			Done

**Picture 1: Measuring Carious Lesion** 

After determining reliability, an Excel (Microsoft, Redmond, Washington, USA) spreadsheet was created by the PI to organize the data. Each tooth had the radiographic caries measured and recorded. Each tooth was evaluated with radiographs, when available, and clinical notes at 12, 18, 24, 30 and 36 months to determine if the restoration was successful or had failed. The PI and mentor determined that restorations were successful if the restoration was sound, the tooth did not have recurrent caries or the tooth naturally exfoliated. For failed restorations, the time that the failure occurred and type of failure were recorded. Failures included: recurrent caries on the tooth, open margin (based on clinical notes or radiographs), wear facets through occlusal portion (based on clinical notes), abscess, lost restoration and new restoration placed.

#### **3.3 Survey Tool**

The spreadsheet contained electronic chart numbers of the patients, age of patient at initial exam, decayed, missing, and filled teeth (dmft), qualifying tooth, depth of lesion and if tooth failed or was successful at the intervals of 12, 18, 24, 30 and 36 months. The PI kept the spreadsheet on a password secured computer. Once the data were entered into SPSS (IBM Corporation, Armonk, NY, USA), the spreadsheet was destroyed to ensure there were no electronic chart numbers in the data set.

#### **3.4 Statistical Analysis**

Each tooth was followed with clinical notes and radiographs for up to 36 months. SPSS (IBM-SPSS, Armonk, NY) was used to run Chi-square analysis to determine if there was a statistically significant difference in the success rates of composite resin restorations vs SSCs at 12, 18, 24, 30 and 36 months. Chi-square analysis was also used to determine if there was a difference in success rates of restorations dependent on initial dmft scores. Statistical significance was set at p<0.05.

#### 4. Results

#### 4.1 Number of Participants

Initially, 1702 charts were available. A total of 304 teeth (151 SSCs and 153 composite resin restorations) met the study criteria and were entered into the study.

#### **4.2 Sample Information**

Sample information are presented in Table I. The depth of the lesions ranged from 0.1mm into dentin up to 2mm into dentin. Only 2% of the teeth restored with a resin had an initial lesion deeper than 1.1mm into dentin, compared to 35.7% of SSCs. 55% of all restorations were placed on primary mandibular first molars.

	Demographics	
		n (%)
Patient's age at restoration	3	61 (20.1%)
placement (years)		
	4	108 (35.5%)
	5	68 (22.4%)
	6	67 (22%)
Depth of Lesion (mm)	0.1-0.5	SSC: 48 (31.8%)
		Composite: 125 (81.7%)
	0.6-1.0	SSC: 49 (32.5%)
		Composite: 25 (16.3%)
	1.1-1.5	SSC: 39 (25.8%)
		Composite: 3 (2.0%)
	1.6-2.0	SSC: 15 (9.9%)
		Composite: 0 (0%)
Tooth Number	Maxillary right first molar	SSC: 35 (23.2%)
	(B)	Composite: 28 (18.3%)
	Maxillary left first molar (I)	SSC: 30 (19.9%)
		Composite: 42 (27.5%)
	Mandibular left first molar	SSC: 45 (29.8%)
	(L)	Composite: 39 (25.5%)
	Mandibular right first molar	SSC: 41 (27.2%)
	(S)	Composite 44 (28.8%)
Type of Restoration	Stainless Steel Crowns	151 (49.7%)
	Composite	153 (50.3%)

Table I Demographics

#### 4.3 Caries Risk Status

At the time of the comprehensive dental examination, the caries risk status of each patient was evaluated, based on the odontogram, clinical notes and radiographs taken at the initial examination. The dmft scores were recorded and are illustrated in Figure 1. As shown in Figure 1, more than 90% of the subjects had a dmft score of >6. This indicates most children in the study were high caries risk.

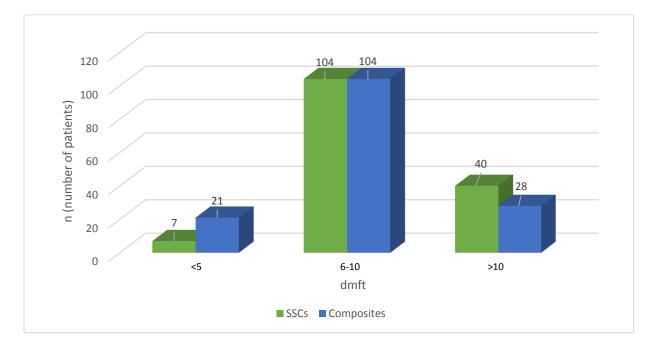


Figure 1. Decayed, missing or filled teeth at comprehensive examination

#### 4.4 Success Rates of SSCs vs Composite Resin Restorations

SSCs and composite resin restorations were evaluated with progress notes and available radiographs at the time frames of 12, 18, 24, 30 and 36 months. The results are outlined in Figure 2. There was not a significant difference ( $p\leq0.5$ ) between the success rates of SSCs compared to composite resin restorations on primary first molars up to 36 months. As shown in Figure 2, the success rates of crowns and composites decreased at each time frame, composites at a higher frequency. At 12 months, a total of 3 SSCs and 6 composites had already failed. By 36 months, the success rates of SSCs was 72% and composite resin restorations 58.7%, (p = 0.23). The majority of failed composites were restored with new composite resin restorations or SSCs. There were three teeth with SSCs that abscessed or had a periapical radiolucency which required extraction, one tooth had a periapical radiolucency that was not extracted due to tooth being asymptomatic per clinical note (Table II). Two stainless steel crowns were replaced due to recurrent caries, according to the clinical notes. In both instances, the crown had become dislodged. When child returned to clinic for new SSC, caries was noted clinically on the previously crowned tooth.

Throughout the study, there was a high patient drop out rate. The drop out rate was consistent in both the SSC and composite resin restoration patients (Table III). After 24 months, 45.7% of SSCs and 56.2% of composites remained in the study. By 36 months, only 21.2% of SSCs and 30.1% of composites remained in the study. This effected the power of the study and thus statistical conclusions can only be made through 24 months.

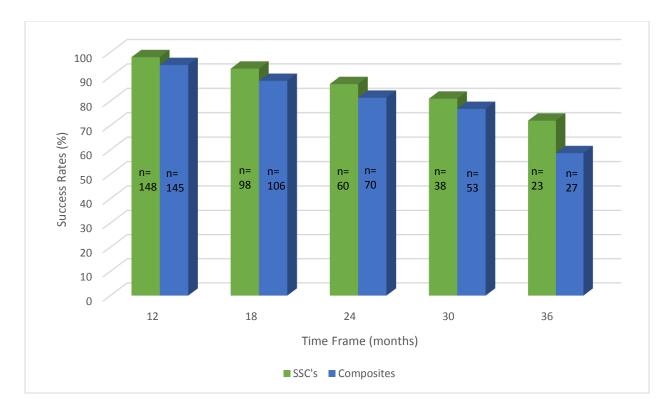


Figure 2. Success rates of SSCs vs composite resins

#### Table II

		<12	12	18	24	30	36
		months	months	months	months	months	months
Failures	Recurrent	SSC: 1	SSC: 0	SSC: 1	SSC: 0	SSC: 0	SSC: 0
(N)	Caries	Comp: 2	Comp: 4	Comp: 7	Comp: 3	Comp: 0	Comp: 2
	Open	SSC: 0	SSC: 0	SSC: 1	SSC: 0	SSC: 0	SSC: 0
	Margin	Comp: 0	Comp: 1	Comp: 0	Comp: 0	Comp: 0	Comp: 0
	Abscess	SSC: 1	SSC: 0	SSC: 1	SSC: 0	SSC: 0	SSC: 0
		Comp: 0					
	Periapical	SSC: 0	SSC: 1	SSC: 0	SSC: 1	SSC: 0	SSC: 0
	radiolucency	Comp: 0					
	Lost	SSC: 0	SSC: 1				
	restoration	Comp: 0					
	Incisal Wear	SSC: 0	SSC: 0	SSC: 0	SSC: 0	SSC: 1	SSC: 0
		Comp: 0	Comp: 0	Comp: 0	Comp: 0	Comp:	Comp: 0

### Types of failures of restorations at different time intervals after initial radiographs

#### Table III

12 months	18 months	24 months	30 months	36 months
151 (100%)	105 (69.5%)	69 (45.7%)	47 (31.1%)	32 (21.2%)
153 (100%)	120 (78.4%)	86 (56.2%)	69 (45.1%)	46 (30.1%)
	151 (100%)	151 (100%) 105 (69.5%)	151 (100%)     105 (69.5%)     69 (45.7%)	151 (100%)     105 (69.5%)     69 (45.7%)     47 (31.1%)

### Number of patients remaining in different time intervals

#### **5.** Discussion

#### **5.1 Early Childhood Caries**

All patients in this study had ECC. The study sample were children all under the age of 6 who had at least 1 interproximal carious lesion, which classified them as having early childhood caries and being of high caries risk (AAPD Guideline on Pediatric Restorative Dentistry, 2017). There were 90.8% of the children who had greater than 6 carious lesions present at the time of the comprehensive examination. This illustrates the majority of the children seen in the study had significant dental restorative needs. It is important to make good clinical and evidence based recommendations in the treatment options for these primary molars in high caries risk children.

#### **5.2 Stainless Steel Crowns vs Composite Resin Restorations**

According to the AAPD guidelines, SSCs are the recommended treatment option for large carious lesions (AAPD Guideline on Pediatric Restorative Dentistry, 2017). This appeared to be true in our study as 78.6% of the lesions greater than 0.5mm into dentin had been restored with SSCs. If the lesion was less than 0.5mm, composite resin restorations were the restorative choice 72.3% and SSCs 27.3% of the time.

The guidelines developed by the AAPD also state that the most common reason for failure of composite resin restorations is recurrent caries (AAPD Guideline on Pediatric Restorative Dentistry, 2017). In this study, the majority of the composite failures were attributable to recurrent caries or a new carious lesion, which developed on the proximal surface that was not restored. As it is the standard practice in the UIC Post-Graduate Pediatric Dental Clinic, all teeth that were restored with composite resins were treated using rubber dam isolation or IsoDry (Isolite Systems, Santa Barbara , CA, USA) to minimize marginal leakage and contamination to the composite resin restoration.

At each time interval, the number of failures increased in both groups. The study performed by Innes et al. (2015) concluded that SSCs were less likely to fail than composite resin restorations at 12 to 24 months post-placement (Innes et al., 2015). In our study, there were more overall failures in the composite resin restorations at each time interval, but was not of statistical significance (Table 2). However, there was a high dropout rate over the 36 months, which diminished the power of the study. Due to the rapidly decreasing sample size, it is impossible to conclude the success rates of SSCs and composite resins were due to chance. If failures follow the same pattern seen at 12 months, it is reasonable to assume that there would have been larger percentage of composite failures at 36 months. At the conclusion of the study, only 21% of SSC's and 30% of composite restoration remained in the study, leaving us to question the status of the majority of the restorations that were placed.

The majority of failures in the study were able to be re-treated with a new restoration. Of the 19 total composite failures, 18 were replaced by either a new composite restoration (two total) or SSC (16 total). One of the 19 failures was monitored due to an open margin, but a new restoration was never placed during the 36 months. Of the nine SSC failures, five were replaced with a new SSC, one was monitored (periapical radiolucency noted but child was asymptomatic and determined to keep exisiting SSC/tooth as a space maintainer) and three were extracted due to abscesses.

The depth of the carious lesion seemed to play an important role in the type of restoration that was placed. Ninety-eight percent of the composites that were placed were on lesions up to 1.0mm into dentin. About 36% of the SSCs that were placed were on lesions greater than 1.0mm into dentin. This is an important factor to take into account as there were more total composite failures in 36 months. Carious lesions which were treated with composite restorations tend to be

smaller in size and still have an more failures seen overall. This shows that composites may be superior in the context of aesthetics and preservation of tooth structure, but inferior in terms of longevity of restoration.

There are many factors in deciding the best treatment choice for restorations in the primary dentition. The practitioner should take into account the age of the patient. If a child is five or six years of age, the average time the primary first molar would remain in the mouth before natural exfoliation is four to six years. If the caries is small, just beyond the DEJ, a less invasive composite resin restoration can be a treatment choice. There still is a chance of failure during the lifespan of the composite, but the practitioner can be confident that if the composite fails, a new composite or a stainless steel crown can be placed.

Another factor to consider is cost to the patient. According to the State Employee's Group Insurance Program (2018), the cost of a two-surface posterior composite resin restoration is \$48.15 and a stainless steel crown is \$73.40. A private insurance fee schedule is closer to \$240 for a two surface posterior composite restoration and \$500 for a primary tooth SSC (State Employees' Group Insurance Program, 2018). This shows that providers charge an increased fee for stainless steel crowns. If the patient is self-pay or has a percentage coverage for restorative work, the cost of treatment may dictate the type of restoration the parent chooses to have. On the other hand, less hours of work and school may be missed if a SSC is placed at the initial restorative visit, as there is less chance for recurrent caries and may be the more definitive restorative option.

Lastly, the diet and oral hygiene of the patient should be considered. In our study, data on diet and oral hygiene were not collected, but would have been useful to compare the diets in successful restorations and failed restorations. It is important to educate children and parents

about the importance of a healthy diet and eliminating foods with high sugar content and reducing the frequency of sugar intake. It is equally important to educate the child and parent on good oral hygiene practices, including brushing twice a day with a fluoridated toothpaste and daily flossing. If the child has a high sugar diet, snacks frequently or has poor oral hygiene with heavy plaque, the likelihood of recurrent caries increases. If the dental provider does not believe the diet and oral hygiene practices will change, the treatment of choice would be stainless steel crowns, as they are the more definitive treatment choice.

#### 5.3 Strengths and Limitations of the Study

A strength of the study was patients were of similar demographics, (i.e. were of high caries risk, who required extensive restorative dental care). Another strength was the lesions were measured at the time of the initial radiograph and successes vs failures were noted based on radiographs and clinical notes.

A major limitation of the study was a high drop-out rate (Table II) over the 36-month time frame. The patient population included in the study, a representation of the population at the UIC Post-Graduate Pediatric Dentistry Clinic, was made up of patients on public aid (97% of the patients seen at UIC are on Medicaid) who were of lower socio-economic status. At 24 months, less than 50% of the SSCs and 56% of the composites remained in the study. The overall drop out rate at 36 months was 74.3% (78.2% for SSC's and 70.1% for composite resins) which could alter the success/fail rates. With a small sample size remaining, it is impossible to make statistical conclusions about the success rates of the restorative materials. It is unknown if the restorations that drop out of the study were successful or had failed and the patient sought follow up treatment with a different dental clinic. Another limitation of the study was proper radiographic follow up. Due to the lack of patient retention, some patients were not seen at each

of the 6 month intervals but would eventually come for a follow up or were re-referred back to the dental clinic for additional restorative care at later time intervals, such as 36 months. There were not radiographs available for every patient at every time interval.

#### **5.4 Future Studies**

Future studies are warranted to expand on this study. Another study should be completed in the same population, high caries risk children three to six years of age and of low SES, with a significantly larger sample size who followed up for at least 36 months to the same dental clinic. This would allow us to make a statistically significant conclusion on the success rates of SSCs compared to composite resins.

Another study should be done to examine the success rates of SSCs vs composite resin restorations in primary molars in other populations. It would be beneficial to compare the success rates in private practice settings that serve a higher socio-economic status to determine if SES has an effect on the success rates of the restorations. Another reason for including private practice settings in the study would be the opportunity for a longer follow up time interval. Private practice settings may have a better retention rate of patients to help the strength of the study.

One recommendation would be to have a split mouth study completed in which SSCs were randomly placed in one-quadrant and composite resins placed in another. This would eliminate the bias that can present with patient compliance with oral hygiene recommendations and other environmental factors. If a patient has a high sugar diet and/or poor oral hygiene, the SSC and composite will be subject to the same environmental factors for the same frequency and duration. This would give the study higher strength as there would be no outside factors that could have contributed to one restoration failing more frequently than another.

Another recommendation would be evaluate the success rates of the two materials on primary second molars. Primary second molars have a different anatomy than primary first molars, which may or may not influence the success rates of the materials.

#### 6. Conclusions

- 1. Based on the findings of our study, there is no statistically significant difference in the success rates of SSCs vs composite resin restorations in primary first molars up to 24 months.
- 2. There were more composite failures in 36 months, even though the initial carious lesions were smaller in depth compared to SSC's.
- 3. SSCs and composite resin restorations are both clinically acceptable treatment options for the treatment of interproximal caries on primary first molars if the tooth is expected to exfoliate within 24 months.

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#### UNIVERSITY OF ILLINOIS AT CHICAGO

Office for the Protection of Research Subjects (OPRS) Office of the Vice Chancellor for Research (MC 672) 203 Administrative Office Building 1737 West Polk Street Chicago, Illinois 60612-7227

#### Approval Notice Initial Review (Response To Modifications)

June 8, 2017

Hilary Habel, DDS Pediatric Dentistry 801 S Paulina M/C 850 Chicago, IL 60612 Phone: (708) 334-0130 / Fax: (312) 413-8006

RE: Protocol # 2017-0507 "Success Rates of Stainless Steel Crowns vs. Composite Restorations in Primary 1st Molars"

Dear Dr. Habel:

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on June 6, 2017. You may now begin your research

Please note the following information about your approved research protocol:

Protocol Approval Period:	June 6, 2017 - June 6, 2018
Approved Subject Enrollment #:	300
Additional Determinations for Research	Involving Minors: The Board determined that this
research satisfies 45CFR46.404, research no	ot involving greater than minimal risk. Therefore, in
accordance with 45CFR46.408, the IRB det	ermined that only one parent's/legal guardian's
permission/signature is needed. Wards of th	e State may not be enrolled unless the IRB grants
specific approval and assures inclusion of ad	ditional protections in the research required under
45CFR46.409. If you wish to enroll Wards	of the State contact OPRS and refer to the tip sheet.
Performance Sites:	UIC
<u>Sponsor:</u>	None
<b>Research Protocol:</b>	

a) Success Rates of SSC's vs Composites, Version #1

Assent:

a) Waiver of child assent for retrospective medical record chart review granted under 45 CFR 46.116(d).

#### Parental Permission:

a) Waiver of parental permission for retrospective medical record chart review granted under 45 CFR 46.116(d).

#### **HIPAA Authorization:**

a) The research meets the regulatory requirements for waiver of authorization as specified at 45CFR164.512(i)(1)(i).

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

#### Please note the Review History of this submission:

Receipt Date	Submission	Review	Review Date	Review Action
	Туре	Process		
05/08/2017	Initial Review	Expedited	05/15/2017	Modifications Required
05/18/2017	Response To	Expedited	06/06/2017	Approved
	Modifications			

Please remember to:

 $\rightarrow$  Use your <u>research protocol number</u> (2017-0507) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements as explained in the following, which are posted on the <u>OPRS website (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/index.shtml</u>): "UIC Investigator Responsibilities, Protection of Human Research Subjects" (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 413-2053. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

#### Sincerely,

Laura Litman IRB Coordinator, IRB # 3 Office for the Protection of Research Subjects

cc: Marcio Da. Fonseca, Pediatric Dentistry, M/C 850 Shahrbanoo Fadavi, Faculty Sponsor, M/C 850 Privacy Office, Health Information Management Department, M/C 772

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