A comparison of primary maxillary incisor zirconia and composite resin strip crowns: A one-year feasibility study

By

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Abstract

Purpose: The main objectives of this study were to compare the one-year clinical outcomes of primary maxillary incisor composite resin strip crowns (SC) and zirconia crowns (ZC) and the frequency of pulp therapy associated with each technique.

Methods: Children aged 18 to 48 months were randomly assigned to ZC or SC group during treatment under general anesthesia. Raters classified each incisor as intact (I), damaged (D) or requiring treatment (TR), 6 and 12 months following placement.

Results: 76 ZC and 101 SC were placed for 59 participants. ZC were more likely to be rated I than SC at 6 months (OR=4.2; 95% CI, 1.3-13.3; *P*=0.01) or 12 months (OR=4.0 ; 95% CI, 1.2-13.0; *P*=0.02). There was no statistical difference in the frequency of pulp therapy for incisors restored with ZC or SC (OR= 0.8; 95% CI, 0.3-2.1; *P*=0.7). All incisors randomized to the ZC group were restored with ZC.

Conclusions: ZC were more likely than SC to remain intact through time and were not associated with a greater frequency of pulp treatment.

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Chapter 1

1. Background

1.1 Introduction

Primary maxillary incisors are the teeth most commonly affected by early childhood caries (ECC)(Ripa, 1988). Dentists who treat children with ECC are commonly tasked with treating carious primary maxillary incisors. While some children may benefit from non-surgical caries management, such as fluoride application, surgical caries management is indicated for many children. If surgical caries management is indicated, dentists will provide parents with treatment options that include restoration or extraction. Parents prioritize esthetics over other factors such as restoration durability when given treatment options (Zimmerman et al, 2009). As a result, dentists are commonly asked to provide anterior restorations for children (Zimmerman et al, 2009). Restorations for primary maxillary incisors include intra-coronal and full-coverage restorations. Intra-coronal restorations can be used when dental caries is diagnosed early in the disease process. Full coverage restorations are indicated when teeth have large interproximal carious lesions, cervical decalcification, anatomical defects or received pulp treatment (Ram, Fuks, 2006; Casamassimo et al, 2013; AAPD, 2016; AAPD, 2019). Three full coverage restorative techniques are commonly employed by North American pediatric dentists to restore primary maxillary incisors: pre-veneered stainless steel crowns, composite resin strip crowns (SC) and zirconia crowns (ZC) (Oueis et al, 2010; The Handbook of Pediatric Dentistry, 2018; AAPD reference manual, 2020). Children with ECC often have extensive treatment needs that commonly include anterior full coverage restorations. Children with ECC often require general anesthesia to allow surgical management of dental caries due to their limited ability to tolerate

dental procedures (Casamassimo et al, 2009; Sonbol et al, 2018; Waggoner, 2015). General anesthesia carries risks. Therefore, the outcomes of dental treatment done under general anesthesia should be commensurate with the risks of general anesthesia. The benefits of treatment of ECC, such as elimination of pain and improved nutrition, are well known (Acs et al, 1999; Acs et al, 2001; Clarke et al, 2006). On the other hand, the benefits of one treatment option over the other, such as ZC over SC, are not known. As a comparison, longevity of full coverage restorations was found to be greater than that of multi-surface intra-coronal restorations in primary molars (Innes, Ricketts, Evans, 2007; Dhar et al, 2015). Knowledge of the outcomes for each treatment option is required if dentists are to provide parents with accurate information prior to exposing their child to the risks of general anesthesia. Little long-term outcome evidence for primary maxillary incisor full coverage restorations exists in spite of their widespread use by pediatric dentists.

1.2 Management of dental caries in the primary dentition

Dental caries remains a highly prevalent disease among children. In Canada, the 2007-2009 Canadian Health Measures Survey reported that almost half (47.8%) of six- to eleven-year-old Canadians had at least one primary tooth that was decayed, missing or filled (dmft > 0). Children under six years old were not included in the survey (Health Canada, 2009). In the United States, the 2011-2012 National Health and Nutrition Examination Survey (NHANES) revealed that approximately a quarter of two- to five-year-olds experienced dental caries, with a mean decayed or filled surfaces (dfs) score of 2.58 (Dye et al, 2015; National Center for Health Statistics). Untreated dental caries in the primary dentition may progress to pain and infection. A dental abscess can progress into facial cellulitis and, in extremely rare situations, into a brain abscess or

sepsis (Casamassimo et al, 2009; Azenha et al, 2012; AAPD, 2014; Holmberg et al, 2017). Dental pain and infection may prompt parents to bring their child to a hospital to receive care. Every year, hundreds to thousands of children present to hospital Emergency Departments (ED) for dental complaints (Olivia et al, 2008; Friedman et al, 2016; Ferraz dos Santos, Dabbagh, 2020). Dental caries is the chief complaint in approximately half of the children presenting to an ED for dental problems (Olivia et al, 2008; Friedman, 2016; Ferraz dos Santos, Dabbagh, 2020). Dental pain is the presenting complaint for caries-related visits in over fifty percent of participants, followed by facial swelling in over a quarter of patients (Olivia et al, 2008; Friedman, 2016; Ferraz dos Santos, Dabbagh, 2020). The negative socio-economic impact of dental caries on patients, families and the health care system highlights the importance of disease prevention and efficacious treatment.

1.2.1 Non-surgical management of dental caries

Dentists base their clinical decision-making for treatment of dental caries on the available treatment options; the dental and medical history of the patient; the patient's treatment needs and preferences; and the anticipated benefits of treatment (Casamassimo, 2013; Twetman and Dahr, 2015). Historically, treatment of dental caries was limited to surgical intervention. Restoration or extraction of the tooth removed the caries lesions but did not treat the underlying cause. In the past decade, dentists have broadened their focus to include non-surgical management of dental caries. The threshold for non-surgical versus surgical management of dental caries varies among providers. Most dentists agree on the use of non-surgical management for white spot lesions and the use of surgical management for caries lesions extending to the dentin or pulp (Slayton, 2015; Innes, 2017). Management of caries lesions confined to the outer enamel or extending to the

dentin-enamel junction varies between non-surgical and surgical depending on the patient and the dental provider (Slayton, 2015; Innes, 2017). Patient age, caries risk, caries progression and parental motivation influence the choice of caries management strategy. Factors such as past history of dental caries, progression of caries lesions, high frequency of carbohydrate consumption and low parental motivation may guide dentists towards surgical management of enamel caries. Whereas no past history of dental caries, non-progression of caries lesions, use of fluoridated toothpaste and high parental motivation may suggest the utility of non-surgical caries management of enamel caries (Tinanoff, Douglass, 2002; Slayton, 2015; Innes, 2017). Dentists may also recommend non-surgical management for enamel lesions in teeth close to exfoliation.

Non-surgical caries management strategies can also be used to slow caries progression in young children with ECC. Children with ECC often require sedation or general anesthesia to facilitate completion of dental treatment. Non-surgical caries management can be used when pharmacological behavior management strategies are not possible, are not available or if patients have prolonged wait times to access surgical care. Parental preferences may also influence the choice of caries management strategy. For example, parents of young children with enamel caries may opt for non-surgical management of dental caries to delay surgical management under general anesthesia (Tinanoff, Douglass, 2002; Slayton, 2015; AAPD handbook, 2018). The use of fluoridated toothpaste at home and professional application of fluoride varnish for prevention of caries lesions are supported by limited evidence of fair quality (Bader et al. 2001; Twetman, Dahr, 2015). Insufficient evidence exists to support the use of any other strategy for caries prevention or management promoted in the literature (Bader et al, 2001; Twetman, Dahr, 2015). Some examples of those strategies are: application of silver diamine fluoride, use of

chlorhexidine (gel or mouthwash), use of providone iodine, use of casein phosphopeptide amorphous calcium phosphate paste, use of xylitol and placement of sealants or resin infiltration (Bader et al, 2001; Tinanoff, Reisine, 2009; Tellez et al, 2013; Duangthip et al, 2015; Twetman, Dahr, 2015; AAPD, 2019). Study protocols on non-surgical management of dental caries vary widely, for example in participant selection, interventions and assessed criteria. Assessment and comparison of the studies on non-surgical management of dental caries strategies to reach conclusions on the efficacy of any strategy is therefore difficult (Bader et al, 2001). The lack of data on non-surgical management of dental caries strategies results in knowledge gaps among dentists. Those knowledge gaps do not mean that the non-surgical dental caries management strategies are not effective – or that they are effective - but illustrate the need for better insight on the disease process. Better insight on risk factors associated with the disease process would allow dentists to develop better management strategies. Parents and patients should be made aware of the lack of evidence for non-surgical caries management strategies as part of informed consent. Dentists may guide families to make the more appropriate treatment decision to the best of their knowledge. While non-surgical management and prevention of dental caries in the primary dentition has gained prominence despite the lack of supportive evidence, surgical management remains a crucial modality for managing dental caries.

1.2.2 Surgical management of dental caries for primary maxillary incisors

Dental caries is a progressive disease that can be associated with acute sequelae and with chronic systemic problems like low body weight and iron deficiency anemia. The health of children with ECC may be compromised by a combination of factors such as pain, infection, sleep deprivation and loss of appetite that can result in deficient body weight and nutritional deprivation (Acs et

al,1999). Surgical treatment of ECC directly addresses the dental disease. Additionally, surgical treatment of ECC was associated with improvement of compromised growth velocity and reversal of iron deficiency anemia (Acs et al, 1999; Clarke et al, 2006). Healthy two to four year old American children with ECC had lower body weight than caries-free age and sex matched peers (Acs et al, 1999). Close to fourteen percent (13.7 %) of children with ECC weighed less than eighty percent of their age-adjusted ideal weight, meeting one of the criteria for the diagnosis of failure to thrive (Acs et al, 1999). Surgical dental treatment for underweight children with ECC addressed their dental disease and improved their growth velocity. Parents reported their children had improved sleeping patterns and nutrition following surgical dental management. Better sleep and nutrition subsequently were associated with improved growth and development (Acs et al, 1999; Acs et al, 2001). As a result, children with a history of ECC who received surgical dental treatment caught up in growth to their peers with caries free dentitions one to two years after comprehensive treatment of ECC (Acs et al, 1999). The majority of children with severe ECC were also found to have unacceptably low levels of serum ferritin (<22 ug/L), with close to a quarter of the children affected by ECC suffering from iron depletion (serum ferritin level <10 ug/L) (Clarke et al, 2006). Twice as many children with severe ECC suffered from iron deficiency relative to population reference values for iron levels (Looker et al, 1997; Clarke et al, 2006). More importantly, iron deficiency in children was associated with compromised physical growth and produced permanent and irreversible behavioral and cognitive impairments (Lozoff et al 1991; Pollitt, 2000; Saloojee, Pettifor, 2001). For example, Parkin et al (2020) found that infants with higher serum ferritin values scored higher on measures of cognitive function than children with iron deficiency. Close to a quarter of children with ECC suffer from iron depletion (serum ferritin level <10 ug/L). Therefore, treatment of ECC can help

resolve iron deficiency and prevent its negative long-term repercussions on growth and cognitive development.

When surgical treatment is indicated for primary maxillary incisors, dentists proceed to the selection of an appropriate intervention, extraction or restoration (Judd, Casas, 1995; Slayton, 2015). Surgical treatment of ECC by either restoration or extraction of teeth has known benefits, such as resolution of pain and improved growth velocity. However, no clear evidence to recommend one surgical treatment modality over another for primary maxillary incisors exists. For dentists, the decision to restore rather than extract primary maxillary incisors is dictated by the absence of infection and/or presence of adequate tooth structure for restoration (Slayton, 2015). Parental values and preferences will influence the selection of treatment options for primary maxillary incisors. Parents prioritized esthetics over treatment cost, toxicity and durability when faced with the task of dental treatment decision-making for their child (Zimmerman et al, 2009). With parents being involved in decision making regarding dental treatment, and their choice of treatment prioritizing esthetics over durability, "[…] many pediatric dentists follow parental preferences, even when that action is contrary to their initial clinical judgment." (Zimmerman et al, 2009)

Parental guilt may also influence the propensity of parents choosing to restore rather than extract primary maxillary incisors. Parents relate their feeling of guilt to their child's pain, need for general anesthesia and compromised dental esthetics (Isong et al, 2012). Facial attractiveness influences peer perception. The mouth and the eyes are known to be important determinants of facial attractiveness and emotional expression (Baldwin, 1980; Henson et al, 2011; Craig et al,

2015). Children with missing incisors may be perceived by their peers as being more aggressive than children with incisors (Shaw et al, 1981). Teenagers will also make negative psychosocial judgements of peers with enamel differences (Craig et al, 2015). Beyond peers, teachers' judgement and expectations are biased by the physical attractiveness of children (Clifford, Wastler,1973; Ross, Salvia, 1975; Shaw, 1981; Neil Frude, Shaw, 1988; Maag et al,1991). Attractive children are perceived as being more intelligent, social, outgoing, confident and positive leaders (Clifford, Wastler, 1973; Ross, Salvia, 1975; Neil Frude, Shaw,1988; Maag et al, 1991). To respond to the esthetic standards set by our society, dentists are commonly asked by parents to provide esthetic anterior restorations for children. A dentist's ability to restore primary maxillary incisors allows children to return to their initial caries-free state and satisfies parental esthetic demands.

1.3 Intra-coronal restorations for primary maxillary incisors

Carious primary maxillary incisors may be restored with intra-coronal restorations if diagnosed early in the disease process and surgical management is indicated. Class V restorations on the labial or lingual surface of primary incisors and class III restorations may be completed with adhesive materials, such as resin composites or glass ionomer materials. Primary maxillary incisors have disproportionally large pulp chambers, small crowns and thin enamel and dentin compared to permanent maxillary incisors. As a result, intra-coronal preparations in young primary maxillary incisors tend to be small and shallow to avoid iatrogenic pulp exposure. The resulting preparation may not meet the requirements for adequate restoration retention and as a result predisposes the restoration to dislodgement (Piyapinyo, White, 1998; Lee, 2002). Additionally, composite resin has lower bond strength to primary teeth than to permanent teeth,

that can also predispose to dislodgement of the adhesive restoration. Lower bond strength in primary teeth is due to differences in structure and mineral content of the primary enamel and dentin when compared with permanent enamel and dentin (Nör et al, 1997; Piyapinyo, White, 1998). The addition of a dove-tail to a class III preparation was thought to provide mechanical retention of the restoration, but slot and dovetail preparations were found to have overall similar clinical outcomes (Trairatvorakul, Piwat, 2004; Casamassimo et al, 2013; Wagonner, 2015). While small carious lesions can be restored with intra-coronal restorations, several authors recommended that restorable primary incisors with large interproximal lesions, cervical decalcification, pulp therapy or with anatomical defects should receive full-coverage restorations (Ram, Fuks, 2006; Casamassimo et al, 2013; AAPD, 2016; AAPD, 2019).

1.4 Full-coverage restorations for primary maxillary incisors

Dentists who treat children commonly use full coverage restorations for primary maxillary incisors. Pre-veneered stainless-steel crowns, SC and ZC are the preferred full-coverage restorative techniques for primary maxillary incisors by members of the American Academy of Pediatric Dentistry (AAPD) (Oueis et al, 2010; The Handbook of Pediatric Dentistry, 2018; AAPD reference manual, 2020). Despite the introduction of new incisor full-coverage restorative techniques over the years, more recently ZC, little long-term outcome data on any incisor full-coverage restoration exists (Lee, 2002; Waggoner, 2004; Chisini et al, 2018). Each restorative material has its own characteristics, advantages and disadvantages. With limitations in knowledge about any material's efficacy, how does a clinician choose which restoration is best for their patient? As Waggoner (2015) highlighted, "What does the phrase, best restore, mean? Is it the most durable restoration or the most conservative? Is it the least technique sensitive or the

most esthetic?" (Waggoner, 2015). The ideal anterior tooth full-coverage restoration, that would be esthetically pleasing and durable, while being conservative, non-toxic, biocompatible, inexpensive and not technique sensitive, does not seem to exist in the literature. The choice of technique may then be influenced by the dentist and the patient/parent desired outcome for the restoration. As parents prioritize esthetics over other factors such as restoration durability when given treatment options, dentists are commonly asked to provide tooth colored anterior restorations such as SC or ZC, despite the lack of information on their clinical outcomes like restoration longevity (Zimmerman et al, 2009).

Stainless steel crowns, introduced to pediatric dentistry in 1950, were the first full-coverage restorative option for the primary dentition (Humphrey, 1950). Stainless steel crowns were a durable restorative option, but they had poor esthetics when used to restore primary incisors or canines. The poor esthetics of anterior stainless steel crowns influenced some parents in their treatment choices: where esthetic outcomes were important treatment considerations, parents reported a preference for extraction of incisors rather than restoration with stainless steel crowns (Croll, 1998; MacLean et al, 2007). Tooth-colored full-coverage restorative materials were developed later, satisfying parents and dentists desires for esthetic incisor restorations. Open-faced stainless steel crowns were introduced in the 1970s and provided an improvement in esthetic outcomes when compared with classic stainless steel crowns. The technique, however, was time-consuming. Moreover, as metal margins remained visible on the buccal surface of the incisors, the open-faced stainless steel crowns presented some esthetic compromises (Kopel, Beaver, 1967; Stewart et al, 1974; Hartman, 1983; Roberts et al, 2001; MacLean et al, 2007). The polycarbonate crown was introduced during the same decade as the first metal-free full

coverage restorative option for primary incisors (Mink, Hill, 1973). The absence of metal margin on the polycarbonate crown compared to the open-faced stainless steel crown was an esthetic improvement. Polycarbonate crowns became widely popular esthetic restorations despite a high rate of cementation failure and lack of resistance to abrasive forces (Stewart et al, 1974; Mink, Hill, 1973; Stewart et al, 1974; Webber et al,1979). Over ten years later, pre-veneered stainless steel crowns were introduced and the popularity of the polycarbonate crowns waned. Pre-veneered stainless steel crowns remained widely used thirty years after their introduction: as of 2010, half (51%) of surveyed members of the AAPD used anterior pre-veneered stainless steel crowns in their practice (Oueis et al, 2010). Pre-veneered stainless steel crowns are tolerant to moisture contamination and require less chair time compared to other esthetic full-coverage restorations (Gill et al, 2020). On the other hand, dentists report concerns with their durability (Oueis et al, 2010). The durability of pre-veneered stainless steel crowns is commonly compromised by partial or complete loss of the veneer secondary to bonding failure at the interface of the veneer material and metal crown. Loss of the veneer results in compromised esthetics (Croll, Helpin, 1996; Croll, 1998; Roberts et al, 2001; Oueis et al, 2010; Gill et al, 2020). Parents and dentists may prefer metal-free full coverage restorations like SC and ZC to avoid situations in which metal is visible.

1.4.1 Composite resin strip crowns

The SC was first described by Webber in 1979 (Webber et al, 1979). The appellation “strip crown” came from the fact that the celluloid crown form was stripped from the tooth after the resin composite was cured. Thirty years after their first description, SC remained commonly used to restore carious primary incisors: the latest data indicated that, in 2010, the majority of

pediatric dentists used SC as their first choice for full coverage restoration of primary incisors (Oueis et al, 2010; Clark et al, 2016; The Handbook of Pediatric Dentistry, 2018; AAPD reference manual, 2020). The use of SC has many benefits, including the ability to adapt the restoration to space and occlusal requirements, good esthetics, the availability of a variety of shades, and ease of repair (Waggoner, 2002; Waggoner, 2015). Furthermore, parents reported overall good satisfaction with SC - even when they were dissatisfied with color, crown shape and appearance. On the other hand, parents reported overall poor satisfaction only when a SC was completely lost after treatment (Kupietzky, Waggoner, 2004). The use of SC was associated with some important limitations. SC are technique sensitive due to the intolerance of composite resin to moisture contamination from fluids during placement. Fluid contamination can lead to discoloration of the restoration and marginal defects. Additionally, poor shade match, poor crown form, loss of composite resin and marginal gingivitis were identified as potential disadvantages of the SC (Kupietzky et al, 2005; Waggoner, 2002; Waggoner, 2015). The dental literature lacks studies assessing the long-term clinical outcomes of SC such as maintenance of structural integrity, recurrent decay incidence and retention of the restoration, despite the routine use of SC by pediatric dentists. However, some longevity studies in which varying retention rate for the SC were reported are available (Table 1).

Publication (year)	Restoration retention rate (%)	Length of follow-up
Tate AR et al. (2002)	49	6 months
Al-Eheideb A, Herman N (2003)	70	6-27 months
Kupietzky A, Waggoner WF, Galea J (2003)	85	6-24 months
Kupietzky A, Waggoner WF (2004)	88	6-25 months
Kupietzky A, Waggoner WF, Galea J (2005)	78	> 3 years
Walia T, Salami AA, Bashiri R, Hamoodi O, Rashid F (2014)	78	6 months
Gill et al. (2020)	79	12 months

Table 1. Retention rates of SC reported in the literature.

The heterogeneity in survival outcome of the SC among the available studies is related to variations in study protocols. Differences in assessment criteria are one of the contributing factors to the wide variation in reported survival outcomes. For example, failure was defined as restoration requiring replacement due to crown fracture or dislodgement, recurrent decay or infection by Tate et al (2002), whereas failure was defined as partial or complete loss of material by Kupietzky, Waggoner and Galea (2003, 2004, 2005) and Walia et al (2014). Failure was defined as secondary caries, trauma or pulp pathology in Gill et al (2020) (Gill et al, 2020). Al-Eheideb and Herman (2003) had broader failure criteria where recurrent decay; missing, fractured, cracked or poorly adapted restoration; open margins; and extraction due to pathosis were considered a failure of the SC. The criteria to determine whether a SC failed or survived varies between studies and therefore influences the reported outcomes across studies. Another important factor is the wide variation in protocols for restoration placement. SC were placed by

pediatric dentistry residents in some studies while they were placed by a pediatric dentist in other studies. Operating conditions were also different among studies: physical restraint, oral sedation with physical restraint and general anesthesia are some examples of the different behavior management techniques used. Composite resin is a highly sensitive material to moisture contamination: a child's cooperation can affect the quality of the procedure performed and consequently influence the longevity of the restoration.

1.4.2 Zirconia crowns

Just over a decade ago, prefabricated ZC were introduced as an alternative restorative option to SC and pre-venereed stainless steel crowns for full coverage restoration of primary incisors (Clark et al, 2016). Since then, the popularity of ZC amongst dentists has increased (Seminario et al, 2019). The many purported advantages of the ZC probably contributed to the increase in popularity of the restoration. First of all, ZC meet parental preferences for esthetics. Other reported benefits of ZC include color stability, biocompatibility, reduced plaque accumulation, resistance to fracture and potentially less technique sensitivity than SC (Townsend et al, 2014; Waggoner, 2015; Clark et al, 2016; Holsinger et al, 2016; Al Shobber, Alkhadra, 2017; Gill et al, 2020).

The use of ZC provide esthetic restorations that require no manipulation after cementation as a result of their prefabricated nature. This is a compelling advantage of the use of ZC compared to the use of SC, during which dentists are required to adjust and polish the restoration after the composite resin is cured. Adjustment and polishing of the SC are sensitive to the skills and experience of the operator. For this reason, ZC may be considered less technique sensitive than

the SC with regards to the esthetic outcomes of the restoration. Acceptable to excellent esthetics of the ZC were reported by dentists and parents after scoring ZC for color, size and shape. Eighty-nine percent of parents interviewed highly recommended ZC, based on the crown appearance (colour, size and shape) compared with the child's dentition and their children's appearance and oral health improvement following treatment (Holsinger et al, 2016). Over time, the color of the ZC was shown to be stable when visually compared with the color of adjacent natural teeth (Holsinger et al, 2016). Additionally, the polished surface of the ZC leads to less plaque accumulation and consequently less gingival inflammation than pre-veneered stainless-steel crowns and SC (Walia et al, 2014; Holsinger et al, 2016). The ZC is thought to be more biocompatible than other restorations because it was associated with less gingival inflammation following placement.

ZC have esthetic benefits but are also thought to be a durable solution owing to their fracture resistance. The resistance to fracture was measured in vitro, using a uniaxial compressive force at ninety degrees to the incisal edge of the ZC, until fracture. In normal function, however, incisors are used to shear and cut food – actions that are not mimicked by using uniaxial compressive forces applied perpendicular to the incisal edge of the tooth. The mean force to fracture the incisor ZC in vitro was over four times the actual force a primary incisor is submitted to in a child (Moutain et al, 2011; Townsend et al, 2014; Al Shobber, Alkhadra, 2017). This study did not show the resistance to fracture of the primary incisor ZC in normal function: the magnitude and direction of forces applied to the incisor crowns in this model were different from those found in normal masticatory function. Nevertheless, this in vitro study implies the high fracture toughness of the preformed ZC that could be beneficial for the pediatric population, in whom

bruxism – where compressive, tensile and shear forces are applied - is highly prevalent (Dejak et al, 2005; Manfredini et al, 2013).

The use of ZC inherently presents some disadvantages. The placement of ZC requires a proportionally greater amount of tooth reduction than required for SC placement, in order to fit the crown passively on the tooth (Clark et al, 2016). The amount of tooth reduction required for ZC placement was demonstrated in vitro using typodont teeth, that were weighed before and after tooth reduction. Placement of incisor ZC required more than double the amount of tooth structure removal than required for placement of incisor stainless steel crown (Clark et al, 2016). However, the amount of tooth reduction necessary to place ZC may not be a problem in patients with extensively decayed primary maxillary incisors, where considerable tooth structure was lost preoperatively due to the caries process compared with intact incisors. Extensive tooth reduction in intact or minimally decayed young primary incisors may lead to pulp exposure and additional treatment needs as a consequence. No study has yet investigated the frequency of pulp treatment associated with the placement of ZC compared to with the placement of SC. The extensive tooth preparation required for placement of ZC may indirectly compromise the retention of the restoration. Because ZC require a passive fit on the incisor, their retention relies primarily on the quality of the cementation. ZC are cemented with luting cements that are sensitive to moisture contamination - similar to the composite resin used in SC technique. Hemostasis may be difficult to achieve secondary to the subgingival preparation that is required for placement of ZC. As a result, the quality of cementation may be compromised. Cementation-related problems were highlighted in a study where seventeen percent (8 out of 46 crowns) had failed at least once within a six to thirty-seven months period (Holsinger et al, 2016). Additionally, the suggestion

that the adaptability of ZC to space and occlusion requirements may be a problem was seen in previously published randomized control trials, where patients with anterior crowding or deep bite were excluded from the study (Walia et al, 2014; Gill et al, 2020). Limited shade selection, limited potential to alter the shape of the crown, and the cost per crown represent additional disadvantages of ZC (Waggoner, 2015; Clark et al, 2016; Holsinger et al, 2016).

The ability to restore incisors with extensive decay – due to the subgingival extension of the ZC - and the esthetic prefabricated nature of the restoration are potential advantages of ZC. Besides, parents increasing demand for esthetic dental restorations for their children could be an influencing factor in the increased use of prefabricated ZC by dentists (Peretz, Ram, 2002; Zimmerman et al, 2009). Nevertheless, evidence that supports the long-term outcomes for longevity of primary incisor ZC is limited. Some case studies published on anterior ZC reported satisfactory clinical outcomes (Ashima et al, 2014; Planells del Pozo, Fuks, 2014) and only a few retrospective and prospective studies were published.

A retrospective study found that ninety-six percent (44 crowns out of 46 crowns) of assessed ZC were present and intact at six to thirty-seven months following placement. Gingival inflammation, color match, crown contour, opposing tooth wear, marginal integrity and recurrent caries were assessed. Fourteen crowns were assessed at six to eight months after placement. Thirty crowns were assessed at least fourteen months after placement. The authors did not give information on the number of crowns assessed at each time point after placement. Teeth lost due to natural exfoliation (eight), extracted due to pathosis (three) or dislodged (two) were not included in clinical outcome analysis (Holsinger et al, 2016). This study focused on the clinical

outcomes of the ZC at follow-up appointments. The authors did not perform survival analysis of ZC over time.

The survival of primary incisor ZC over thirty-six months was reported in another retrospective investigation. An assessment of dental records belonging to thirty healthy children aged from twenty-four to sixty months who received at least one ZC placed under general anesthesia was undertaken. A total of ninety-four ZC that were placed by a faculty member or resident were included in the study. Failure was defined as a treated incisor requiring any secondary procedure, i.e. replacement of a lost ZC or extraction of a treated tooth, after ZC placement. Reported survival probabilities were ninety-three percent at twelve months after placement of the ZC, eighty-five percent after twenty-four months and seventy-six percent after thirty-six months. It was unclear if each ZC was included in the survival analyses for one, two or all three time points. Statistical analysis that accounted for the lack of independence between crowns from a same patient was performed. A total of eleven (11.7%) crowns failed due to infection and six (6.4%) crowns were lost. If crowns lost due to normal exfoliation of the treated teeth or crowns were lost due to trauma, their time to failure was censored in survival analyses (Seminario, 2019). This retrospective cohort study was the first investigation to assess the survival of ZC with three years of follow-up. It demonstrated that prefabricated ZC offer a clinically acceptable alternative to other full coverage restorations for primary maxillary incisors, with survival probabilities of seventy-six percent three years postoperatively. The study also showed that age, sex, socio-economic status and dmft did not influence the long-term survival of the ZC.

ZC demonstrated an eighty percent (80.2%) survival at twenty-four months in a prospective case series. A single operator restored maxillary primary incisors that were previously deemed non-restorable using conventional restorative techniques (El Shahawy, O'Connell, 2016). Primary maxillary incisors, with and without peri-apical pathosis, were included in the study after parents requested restoration rather than extraction of the affected incisors. Following pulpectomies, a glass ionomer post and core was completed, and the incisors were restored with ZC. The authors reported survival probabilities of ninety-five percent at twelve months after restoration. Survival was defined as the presence of the ZC at the time of follow-up. None of the crowns were fractured and none of the pulp treatments failed. This "unconventional technique" is not commonly used by dentists and therefore limits the applicability of the study to clinical practice. However, the study highlighted the ability to restore primary maxillary incisors with extensive decay. Parents of the children selected for the study all requested that the teeth should be restored instead of extracted, despite extractions being recommended. The primary maxillary incisors were successfully restored and the ZC had satisfactory survival probabilities, but the high parental motivation to care for the restored teeth likely positively impacted the long-term clinical success of this unconventional technique.

The first randomised controlled trial comparing full coronal coverage restorations for primary maxillary incisors (pre-veneered stainless steel crowns, SC and ZC) was published in 2014. The results showed a success rate of one hundred percent for ZC at six months, followed by ninety-five percent for pre-veneered stainless-steel crowns and seventy-eight percent for SC (Walia et al, 2014). Restoration failure was assessed using a graded scale, where 0 = crown appears normal (intact), no cracks, chips or fractures; 1 = small but noticeable area or loss of material; 2 = large

loss of crown material; 3 = complete loss of crown. The grade "0" represented a successful restoration. One hundred and twenty-nine teeth were included in the study and participants were randomly assigned to one of the three treatment groups. Teeth that required pulp therapy, teeth in children requiring sedation, teeth in special needs patients, teeth in patients with a deep bite, teeth in patients with bruxism or presenting signs of attrition on lower incisors were excluded from the study. A total of thirty-nine healthy participants underwent dental treatment, that was performed by three trainees (one per group) of unspecified level of education. Local anesthetic and physical restraint were used to complete treatment. This limited the generalizability of the study, as results may have been compromised by the treatment conditions and clinical experience of the operators. The study participants were followed-up at six months and the clinical evaluations were performed by a single general dentist, who also performed the baseline evaluation. The strict exclusion criteria limited the face validity, or generalizability of the study to patients in clinical practice, as it did not represent the full scope of clinical practice and provided an inadequate picture of the ZC survival. The inclusion of only ideal teeth in ideal patients may have skewed the data towards a more favorable outcome than what is seen in clinical practice as ECC does not present only in ideal situations.

A second randomized controlled trial that compared SC, pre-veneered stainless steel crowns and ZC placed in primary maxillary incisors was published in 2020 (Gill et al, 2020). At twelve months, SC were found to have significantly reduced clinical success in crown retention compared to pre-veneered stainless steel crowns and ZC ($p=0.002$). Additionally, SC had significantly increased partial or complete loss of material ($p < 0.001$) and significantly increased marginal discrepancies and color change versus pre-veneered stainless steel crowns and ZC ($p <$

0.001). One hundred and thirty-five teeth in forty-nine healthy two- to four-year-olds were included in the study. Participants with an ASA greater than one, with anterior dental crowding, with class III occlusion, with primary maxillary incisors that were expected to exfoliate within one year or with primary maxillary incisors that lost over half of the clinical crown after tooth preparation were excluded from the study. Participants were randomized to one of three treatment groups. All treatments were completed under general anesthesia by one of four calibrated pediatric dentists. No pulp therapy was completed on any of the primary maxillary incisors; some of the primary maxillary incisors received SDF application prior to restorative treatment. The majority of interviewed parents (87%) were satisfied with the appearance of the crowns. Most of the dissatisfied parents (83% of dissatisfied parents) were concerned with the color of the crowns, with the majority (52%) dissatisfied with the color match of SC and other parents (31%) dissatisfied with the color of pre-veneered stainless steel crowns ($p=0.005$). The remaining dissatisfied parents (17%) reported the shape and alignment of the ZC as their reason for dissatisfaction ($p > 0.005$). Those findings highlight the importance of esthetics for parents, where as much as a color mismatch or misalignment can influence their overall satisfaction with the appearance of the restorations. This study highlights the higher clinical success rates for ZC compared to SC. Only forty-four percent (44%) of the SC were within an acceptable range of shade and translucency one year after placement. Additionally, seventy-nine percent (79%) of the SC were fully retentive, sixty-nine percent (69%) were intact and sixty-nine percent (69%) had no marginal discrepancies. Whereas for ZC, ninety-eight percent (98%) were within an acceptable range of shade and translucency, ninety-five percent (95%) were fully retentive, ninety-eight percent (98%) had intact facings and ninety-three percent (93%) had no marginal discrepancies. All of those differences were clinically significant ($p < 0.005$). These findings

further outline the challenges of SC placement: results showed SC have lower clinical success than pre-veneered stainless steel crowns and ZC, despite being placed under optimal conditions. The study results are consistent with those of the previously described randomized controlled trial, where SC had significantly more clinical failures than ZC six months after placement ($p=0.004$). (Walia et al, 2014) This study by Gill et al was the first randomized controlled trial that compared the clinical outcomes of three full coverage restorations for primary maxillary incisors twelve months after placement. This study can serve as a basis for comparison in future SC and ZC outcome studies.

1.5 Conclusions

At this time, dentists and parents who opt to surgically treat dental caries affecting the primary maxillary incisors have treatment options that are supported by limited evidence. SC remain widely used by pediatric dentists forty years after their introduction. Since 2008, the prefabricated ZC has gained popularity in pediatric dentistry as an option for full coverage restoration of primary incisors (AAPD, 2018; Seminario et al, 2019). At this time, the literature on ZC and SC demonstrates important knowledge gaps. Differences in participant selection, placement protocols, outcome criteria and assessment protocols are some of the contributing factors to the challenges in the review of clinical outcomes. Additionally, some important outcomes for ZC, such as the impact of tooth reduction on the frequency of pulp treatment compared to other incisor restorations, have not been assessed. Recent data suggests that incisor ZC have significantly better retention and restoration integrity than SC (Walia et al, 2014; Gill et al, 2020). Better knowledge on clinical outcomes of SC and ZC would be beneficial to dentists in order to provide parents with accurate information when discussing treatment options for their

children. Inclusion and exclusion criteria that reflect the reality of clinical setting, long-term clinical assessments done in controlled clinical trials, as well as adequate statistical analyses for survival of the restorations are required in order to have better knowledge of the clinical outcomes of SC and ZC.

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Chapter 2

2.1 Purpose

ZC are increasingly employed in the restoration of carious primary maxillary incisors (AAPD, 2018). At the time of initiation of this investigation, no clinical outcome evidence for ZC longevity was published. The available evidence at the time focused on parental preferences or outcome investigations with narrow inclusion criteria that limited clinical outcome data to a non-representative subset of children with carious incisors. Due to a lack of existing outcome data for ZC, a feasibility study was indicated to establish the basis for a randomized controlled comparison of composite resin SC and ZC. The purpose of this feasibility study is to compare the clinical outcomes of the ZC and SC in primary maxillary incisors at six and twelve months.

Chapter 3

3.1 Objectives

1. To statistically compare the one-year survival of resin composite strip crowns and zirconia crowns in primary maxillary incisors

2. To statistically compare the frequency of pulp therapy associated with placement of resin composite strip crowns and zirconia crowns in primary maxillary incisors

3. To measure the proportion of teeth randomized to receive zirconia crown restorations that cannot be restored with zirconia crowns due to severe attrition, deep bite, crowding or other clinical limitations

Chapter 4

4. Material and Methods

4.1 Compliance with ethical standards

The Research and Ethics Board of The Hospital for Sick Children (REB # 1000062660) and the Research Ethics Board of the University of Toronto (REB # 00037814) approved the study protocol. The investigation was registered with ClinicalTrials.gov Protocol and Registration system (ID NCT03889535).

4.2 Sample size calculation

At the initiation of this investigation, there was inadequate clinical outcome data for SC and ZC to perform sample size calculation for a randomized controlled trial. Hence, a feasibility study was indicated. By establishing the clinical outcomes of SC and ZC with this investigation, a sample size calculation for a subsequent randomized controlled trial could be undertaken. Based on historical clinical activity at the Department of Dentistry of The Hospital for Sick Children and allowing for fifty percent of participants declining to participate, it was anticipated that approximately 150 teeth could be enrolled in the study over a period of one year.

4.3 Participants

4.3.1 Screening

Potential participants were screened by the graduate student and department research coordinator.

4.3.2 Consent

The department research coordinator and the graduate student approached families and obtained consent from prospective participants to participate in the research project. The investigation, procedures, possible risks and benefits were explained to the participant's parents or guardians. The treating pediatric dentists (EJB, MJC, GAG) confirmed continuing consent on the day of the treatment under general anesthesia.

4.3.3 Inclusion criteria

Eligible children met the following inclusion criteria: i) 18 to 48 months of age, ii) ASA I or ASA II scheduled to receive dental treatment under general anesthesia at The Hospital for Sick Children, and iii) one or more carious or fractured primary maxillary incisors that required full coverage restoration based on clinical judgement and criteria listed below.

Inclusion criteria for ZC and SC were the same: (Casamassimo, Fields, McTigue, Nowak, 2013)

1. Incisors with large carious lesions not restorable with intra-coronal restorations
2. Incisors that received pulp therapy
3. Incisors that were fractured and lost an appreciable amount of tooth structure for which a restoration was indicated
4. Incisors with multiple hypoplastic defects or developmental disturbances and carious lesions or fracture
5. Incisors with small interproximal lesions and large areas of cervical decalcification

4.3.4 Exclusion criteria

Incisors were ineligible if i) they had associated signs or symptoms of irreversible pulpitis or clinical evidence of an odontogenic infection or radiographic evidence of pathological root resorption or root fracture secondary to trauma or periapical radiolucency, ii) they lacked sufficient coronal structure to place a full coverage restoration, iii) the participant was ASAIII or higher or iv) the participant's parents did not speak English.

4.4 Training

Three pediatric dentists (EJB, MJC, GAG) completed all restorations. The treating dentists were attending pediatric dentists at The Hospital for Sick Children. Training in ZC technique was provided by the manufacturer of the crowns used in this study: EZCrowns, Sprig Oral Health technologies, Inc, Loomis, California, USA. Two trainers from Sprig Oral Health technologies provided the three investigators with didactic and hands-on trainings. ZC tooth preparation and placement was tried and practiced until all three study treating dentists were comfortable. The hands-on training was supervised by one dentist trainer from Sprig Oral Health technologies. As the SC were the current standard full coverage restoration provided for primary incisors at The Hospital for Sick Children, and the treating dentists all had similar education and experience, additional training for SC was not undertaken.

4.5 Procedures

4.5.1 Randomization

After induction of general anesthesia, following the confirmation of incisor restorability by the treating dentist, each study participant was randomly allocated to either the SC or the ZC treatment group. The assignment was performed using a computer-generated simple random number sequence with a one to one allocation ratio in Excel (Microsoft® Excel 2018, Microsoft Canada Inc, Mississauga, Ontario, Canada). Only one investigator (SL) participated in the generation and implementation of the treatment allocation. Periodic quality assurance checks were performed by the same investigator (SL) to ensure compliance with the randomization protocol. The randomization sequence was concealed until treatment was about to be initiated by the treating dentist. The treatment was consistent for each participant for all eligible teeth, although the experimental unit was the incisor. If any of the incisors in a participant was deemed non-restorable, that incisor was no longer eligible for the study. If all of the incisors in one child were deemed non-restorable, the child was excluded from the study.

4.5.2 Techniques

The restorative techniques were carried out under general anesthesia, in the usual fashion for the SC (3M™ ESPE™ transparent strip crown forms, 3M™ ESPE™ dental products, St. Paul, Minnesota, USA) and following the manufacturer's protocol for the ZC (EZCrown, Sprig Oral Health technologies, Inc, Loomis, California, USA).

4.5.2.1 Strip crown technique

Following the shade selection of composite resin (TPH Spectra® ST, Dentsply Caulk, Milford, DE, USA), the maxillary incisors were isolated with a rubber dam. Primary incisor celluloid crown form (3M™ ESPE™ transparent strip crown forms, 3M™ ESPE™ dental products, St.

Paul, Minnesota, USA) with mesiodistal width similar to the tooth to be restored was selected and trimmed. The incisors were prepped as follows. The incisal edge of the incisor was reduced by 1.5 mm with a no. 888 high speed bur (888 012C FG, NTI New Technology Instruments, Kahla, Germany). Using the same bur, the interproximal surfaces were reduced by 0.5 to 1.0 mm; the buccal surface, by 1.0 mm; and the lingual surface, by 0.5 mm, with a feather edge at the gingival margins. Line angles of the preparation were then rounded. Caries was removed and, if indicated, a MTA pulpotomy was performed. If the pulp was irreversibly inflamed or necrotic, the incisor was extracted and no longer eligible for the study. The preparation was etched (Etch Rite™, Pulpdent corporation, Watertown, MA, USA) for 15 to 20 seconds, then rinsed and air dried. Bond (Adper™ Scotchbond™ multipurpose, 3M™ ESPE™ dental products, St. Paul, Minnesota, USA) was applied to the tooth and polymerised. The selected and trimmed crown form was filled to two-thirds with composite resin (TPH Spectra® ST, Dentsply Caulk, Milford, DE, USA) and seated onto the tooth. Following excess composite resin removal with hand instrument, the composite resin crown was polymerised. The celluloid crown form was then removed with a scaler, and the composite crown was finished and polished.

4.5.2.2 Zirconia crown technique

The maxillary incisors were isolated with a rubber dam. A prefabricated crown (EZCrown, Sprig Oral Health technologies, Inc, Loomis, California, USA) was selected based on the mesiodistal width of the incisor to be restored. The incisal edge of the incisor was reduced by 1.5 mm with a high-speed EZ-Prep 001 donut bur (Sprig Oral Health technologies, Inc, Loomis, California, USA). Circumferential axial reduction of 0.5 to 1.0 mm was done with a high-speed EZ-Prep 002 bur (Sprig Oral Health technologies, Inc, Loomis, California, USA), creating a chamfer

margin at the gingival margin. A thin incisal edge was then created by tapering the lingual surface of the incisal half of the tooth. The lingual surface was reduced by 0.75 to 1.25 mm with the same bur, to create a slightly concave lingual surface. The chamfer was then removed in incremental steps, starting at 0.5 mm subgingivally, with a high-speed EZ-Prep 004 flame bur (Sprig Oral Health technologies, Inc, Loomis, California, USA). Prior to continuing to the next step, the treating dentist assessed restorability with ZC based on their clinical judgement. The treating dentist assessed the participant's occlusion, crowding or other possible clinical limitations to prefabricated ZC. If the incisors were deemed non-restorable with ZC, the incisors were restored with SC and were no longer eligible for the survival and clinical outcomes assessment. If the incisor was deemed restorable with a ZC, and after the chamfer margin was completely removed, the tip of the bur was extended 2 mm subgingivally to finish the preparation. Caries was removed and, if indicated, a pulpotomy was performed. If pulp treatment was determined to be contraindicated, the incisor was extracted and no longer eligible for the study. Hemostasis of the gingiva was then achieved with digital pressure or with 15.5 percent ferric sulfate solution (Astringedent®, Ultradent products Inc, Salt Lake City, Utah, USA) applied for 10 to 15 seconds. The selected ZC (EZCrown, Sprig Oral Health technologies, Inc, Loomis, California, USA) was then cemented with glass ionomer cement (Ketac™ Cem Aplicap™, 3M™ESPE, 3M™ Deutschland, Neuss, Germany).

4.6 Assessment and data collection

4.6.1 Clinical outcomes

Incisors were assessed clinically and photographically at six and twelve months post-treatment. Photographic images of the teeth were acquired at the assessment appointments.

4.6.1.1 Clinical assessment

Clinical assessment was conducted by the graduate student (SL) who did not complete any treatment and did not rate incisors in the photographic assessment (see below). Participants were invited to in-person follow-up assessments at six and twelve months post-treatment. Presence or absence of the restored incisor; presence or absence of the restoration; presence or absence of recurrent decay, presence or absence of discoloration and status of the restoration: intact or damaged were recorded. All follow-up data were recorded on printed data collection sheets and transferred to a REDCap database (REDCap™, Vanderbilt University, Nashville, Tennessee, USA).

4.6.1.2 Photographic assessment

Intra-oral photographs were acquired at six and twelve months postoperatively. All photographs were taken by the graduate student (SL), using a standardized imaging format (Appendix 1). Two photographs per participant were acquired: one extra-oral photograph, encompassing the dental arch from the maxillary right cuspid (tooth 53) to left cuspid (tooth 63); and one extra-oral maxillary occlusal view, limited to the maxillary right cuspid (tooth 53) to left cuspid (tooth 63). (see Appendix1) Photographs were acquired with a Canon Rebel XSi and a Canon ring flash Macro Ring Lite MR-14EX II (Canon, Ota, Tokyo, Japan), using the following settings: shutter speed 1/200, ISO 200 and aperture f25. Photographs were stored in The Hospital for Sick Children's online image database (Apollo EPMM, Apollo PACS inc., USA).

Parents were also asked to take two photographs of their child's treated incisors using their own digital camera or smartphone. Photographs taken by the parents were used for photographic assessment if clinical photographs were unsuccessful at follow-up and if they were of sufficient quality for assessment based on the investigators' judgment. Parents were provided with an example of those photographs, taken with an iPhone X (Apple, Cupertino, California, USA). Parents provided the photographs to the investigators via a secure hospital e-mail. Only the research investigators and the research coordinator had access to the secure e-mail. Pictures sent by the parents were stored on Apollo (Apollo EPMM, Apollo PACS inc, USA). Parents were sent reminders by email to take six and twelve month postoperative photographs.

If the parents and the investigators were unable to obtain photographs of a participant, the incisors were no longer eligible for continuing assessment.

Photographic analysis was conducted by two disinterested experienced staff pediatric dentists. Pedaitric dentist raters assessed the presence or absence of the restored incisor; presence or absence of the restoration; presence or absence of recurrent decay, presence or absence of crown discoloration. In addition, the pediatric dentist raters classified each treated incisor into one of three outcomes based on photographic assessment: I = restoration intact, unchanged from the time of placement; D = restoration damaged but present, clinically acceptable with minor deficiency that does not require immediate intervention; and TR = treatment required, restoration absent or restoration present with major failure or recurrent decay present on restored incisor, re-retreatment or extraction required. Raters were asked to use their clinical judgement to classify each treated tooth into one of the treatment outcome categories. An instructions handout was

provided to the expert raters (Appendix 2). A calibration session was held with both raters prior to each assessment session (Appendix 3). The expert raters were blinded to all participant identifying information, date of treatment and date of photograph. The photographs were randomized by participant and date of follow-up. Photographs were randomly selected for duplication using a random number generator (Google, California, USA) and two assessment sessions were conducted for measure of intra-rater reliability. Photographs were displayed on a MacBook Pro 13.3 inches (2560 x 1600) at maximum brightness (Apple Inc, California, USA). Raters were were not time limited for their assessments. The expert raters were asked to use their clinical judgement to classify each treated tooth into one of the outcome measures. All data were recorded on printed data collection sheets (Appendix 4).

4.6.2 Frequency of pulp therapy

On the day of treatment under general anesthesia, the treating dentist, the dental assistant or the nurse filled out a pre-printed data collection sheet (Appendix 5). Each treated incisor was marked as P = incisor received a pulpotomy; or X = incisor did not receive a pulpotomy.

4.6.3 Deviation from randomization

On the same OR data collection sheet, the randomly assigned treatment and the completed treatment were recorded. Should the operator/investigator deviate from the randomly assigned treatment, the reason for deviation was recorded.

4.7 Statistical analysis

All follow-up data were recorded on printed data collection sheets, entered into a Research Electronic Data Capture data base (REDCap™, Vanderbilt University, Nashville, Tennessee, USA) and exported into an Excel spreadsheet for statistical anaylsis (Microsoft® Excel 2018, Microsoft Canada Inc, Mississauga, Ontario, Canada). Treatment groups were compared for incisor distribution, age, sex and ASA status with chi-square tests. Clinical outcomes were compared using an ordinal logistic regression analysis. Frequency of pulp treatment by treatment group was compared using chi-square test and a generalized estimating equation to account for the lack of independence between incisors.

4.8 COVID-19 pandemic

Participant enrollment and treatment in the operating room ended prematurely in March 2020 due to hospital access restrictions as a consequence of the COVID-19 pandemic. No clinical assessments were provided for the study participants between March and October 2020 due to clinical limitations imposed by the COVID-19 pandemic public health measures. Families were contacted during the period of urgent-only access to the hospital and asked to send photographs of their child's incisors (see section 5.6.1.2) as in-person research assessments were not permitted. Only participants with urgent needs were seen in person. Clinical assessments resumed in November 2020. Families who preferred not to come to their clinical appointment were given the option to send photographs of their child's incisors if they did not present any indication for being seen in person.

Chapter 5

5 Manuscript

5.1 Abstract

Purpose: The objectives of this study were to compare the one-year clinical outcomes of primary maxillary incisor composite resin strip crowns (SC) and zirconia crowns (ZC), to determine the frequency of pulp therapy associated with each restorative technique and to determine the proportion of incisors randomized to ZC restoration not restored with ZC due to clinical limitations.

Methods: In this one-year prospective investigation, children aged 18 to 48 months were randomly assigned to one of two treatment groups: ZC or SC. All restorations were completed under general anesthesia by one of three pediatric dentists. Two disinterested pediatric dentist raters assessed intra-oral photographs of the participants six and twelve months postoperatively. Raters assessed the presence or absence of the tooth and the restoration, integrity of the restoration, discolouration of the restoration and recurrent decay. They also rated each incisor as intact (I), damaged but not requiring treatment (D) or requiring treatment (TR).

Results: A total of 76 ZC and 101 SC were placed for fifty-nine participants. ZC were more likely to be rated I (intact) than SC at 6 months (OR=4.2; 95% CI, 1.3-13.3; *P*=0.01) or 12 months (OR=4.0 ; 95% CI, 1.2-13.0; *P*=0.02). There was no statistical difference in the frequency of pulp therapy for incisors restored with ZC or SC (OR= 0.8; 95% CI, 0.3-2.1; *P*=0.7). All incisors randomized to the ZC group were restored with ZC.

Conclusions: ZC were more likely than SC to be rated as intact at 6 or 12 months after treatment. ZC were not associated with a greater frequency of pulp treatment compared with SC. There were no instances in which a tooth randomized to ZC could not be restored with ZC.

5.2 Introduction

Primary maxillary incisors are the teeth most commonly affected by early childhood caries (ECC)(Ripa, 1988). Parents prioritize esthetics over other factors such as restoration durability when given restorative options (Zimmerman et al, 2009). Dentists who treat children with ECC are commonly tasked with providing esthetic restorations for carious primary maxillary incisors. Two full coverage esthetic restorative techniques are commonly employed by North American pediatric dentists to restore primary maxillary incisors: composite resin strip crowns (SC) and zirconia crowns (ZC) (Oueis et al, 2010; The Handbook of Pediatric Dentistry, 2018; AAPD reference manual, 2020).

Just over a decade ago, ZC were introduced as an alternative restorative option to SC for full coverage restoration of primary incisors (Clark et al, 2016). Since then, the popularity of ZC amongst dentists has increased (Seminario et al, 2019). ZC satisfy parental desires for esthetics, are color stable, biocompatible, demonstrate minimal plaque accumulation and are resistant to fracture. Placement of ZC was reported to be less technique sensitive than SC placement (Townsend et al, 2014; Waggoner, 2015; Clark et al, 2016; Holsinger et al, 2016; Al Shobber, Alkhadra, 2017; Gill et al, 2020). ZC presented potential liabilities. ZC required a proportionally greater amount of tooth reduction than required for SC placement to fit the crown passively on the tooth (Clark et al, 2016). Extensive tooth reduction in intact or minimally decayed young primary incisors may lead to pulp exposure and additional treatment needs as a consequence. No study has yet investigated the frequency of pulp treatment associated with the placement of ZC compared to the frequency of pulp therapy with the placement of SC. Retention of ZC relies primarily on the quality of the cementation: ZC require

a passive fit onto the incisor to avoid fracture of the zirconia during placement. ZC are luted with glass ionomer cements that are somewhat sensitive to moisture contamination. Bleeding as a consequence of the subgingival preparation that is required for placement of ZC may compromise retention of ZC crowns. Retention-related problems were highlighted in a study in which seventeen percent (8 of 46 crowns) were dislodged at least once within a six to thirty-seven months period (Holsinger et al, 2016). In addition, ZC investigations with exclusion criteria such as anterior crowding or bruxism suggested that adaptability of ZC to space and occlusion requirements may be limited (Walia et al, 2014; Gill et al, 2020). Narrow shade selection, inability to modify the shape of the crown, and the cost per crown represent additional disadvantages of ZC (Waggoner, 2015; Clark et al, 2016; Holsinger et al, 2016).

Little outcome evidence for primary maxillary ZC exists in spite of their widespread use by pediatric dentists for more than ten years. It was only recently reported that ZC and pre-veneered SSC had superior retention and favourable clinical outcomes compared to SC at twelve months post-treatment (Gill et al, 2020).

The purpose of this investigation was to compare the clinical outcomes of SC and ZC at six and twelve months after placement; to measure the frequency of pulp treatment associated with placement of SC or ZC; and to measure the proportion of incisors randomized to receive zirconia crown restorations that could not be restored with zirconia crowns due to severe attrition, deep bite, crowding or other clinical limitations.

5.3 Materials and methods

The Research Ethics Board of The Hospital for Sick Children (REB # 1000062660) and the Research Ethics Board of the University of Toronto (REB # 00037814) approved the study protocol. The investigation was registered with ClinicalTrials.gov Protocol and Registration system (ID NCT03889535). Potentially eligible participants were identified during ambulatory clinic scheduling of participants for oral care in the operating room. The investigation, procedures, possible risks and benefits were explained to the participant's parents or guardians. Written consent was obtained at the consultation appointment and confirmed on the day of treatment immediately prior to commencement of treatment.

At the initiation of this investigation, little clinical outcome data for SC and ZC was available to allow sample size calculation for a randomized controlled trial. Hence, a feasibility study was indicated. Based on historical clinical activity in the Department of Dentistry of The Hospital for Sick Children and allowing for fifty percent of participants declining to participate, it was anticipated that approximately one hundred and fifty incisors would be enrolled in the study over a period of one year. Study participants were recruited at the Department of Dentistry of The Hospital for Sick Children between April 2019 and March 2020. Eligible children met the following inclusion criteria: i) eighteen to forty-eight months of age, ii) ASA I or ASA II scheduled to receive comprehensive dental treatment under general anesthesia at The Hospital for Sick Children, and iii) one or more carious or fractured primary maxillary incisors for which a full coverage restoration was indicated. Incisors were ineligible if i) the participant was ASA III or higher, ii) associated with signs or symptoms of irreversible pulpitis and/or clinical evidence of an odontogenic infection, iii) there was radiographic evidence of

pathological root resorption, root fracture secondary to trauma or periapical radiolucency, iv) the incisors lacked sufficient coronal structure to place a full coverage restoration, or v) parents did not speak English.

Three staff pediatric dentists at The Hospital for Sick Children completed all crowns. Training in ZC technique was provided by the manufacturer of the crowns used in this study: EZCrowns, Sprig Oral Health Technologies, Inc, Loomis, California, USA. As the SC were the current standard full coverage restoration provided for primary incisors at The Hospital for Sick Children, and the treating dentists all had similar education and experience, additional training for SC was not undertaken.

Study participants were randomly allocated to either the SC or the ZC treatment group following confirmation of incisor restorability by the operator. The assignment was revealed from a computer-generated simple random number sequence with a one to one allocation ratio created in Excel (Microsoft® Excel 2018, Microsoft Canada Inc, Mississauga, Ontario, Canada). The randomization sequence was concealed until immediately prior to treatment of the incisors. The treatment was consistent for each participant for all eligible incisors. Incisors were restored under rubber dam isolation during general anesthesia. A MTA pulpotomy was performed if a pulp exposure was detected. The incisor was extracted and no longer eligible for the study if the pulp was irreversibly inflamed or necrotic. Incisors randomized to SC were prepared to allow composite thickness of 1.5mm at the incisal edge, 0.5 to 1.0 mm on the interproximal surfaces, 1.0 mm on the buccal surface and 0.5 mm on the lingual surface. A feather edge margin was created and line angles were rounded. A primary

incisor strip crown form with mesiodistal width dimensions approximating the incisor being restored was selected and trimmed to fit. The preparation was etched (Etch Rite™, Pulpdent corporation, Watertown, MA, USA) for fifteen to twenty seconds, then rinsed and air dried. Prime and bond (Adper™ Scotchbond™ multipurpose, 3M™ ESPE™ dental products, St. Paul, Minnesota, USA) was applied to the tooth and polymerised. The trimmed crown form was filled to two-thirds with composite resin (TPH Spectra® ST, Dentsply Caulk, Milford, DE, USA) and seated on the tooth. Following excess composite resin removal with a hand instrument, the composite resin crown was polymerized. The celluloid crown form was then removed with a scaler and the composite crown was finished and polished.

The incisors randomised to receive ZC were prepped and restored following the manufacturer's instructions (Sprig Oral Health Technologies, Inc, Loomis, California, USA). The EZ-prep bur kit (Sprig Oral Health Technologies, Inc, Loomis, California, USA) was used for incisor preparation. The ZC were cemented with glass ionomer cement (Ketac™ Cem Aplicap™, 3M™ESPE, 3M™ Deutschland, Neuss, Germany) as recommended by the crown manufacturer.

Demographic and dental variables collected at the time of treatment included: age, sex, ASA status, treatment allocation (SC or ZC), number of treated maxillary incisor(s), pulp treatment provided (pulp treatment or no pulp treatment), deviation from randomized treatment (yes or no) and reason for deviation from randomization, if applicable. Clinical follow-up and photographs were completed six and twelve months post-operatively by a single investigator who did not complete any treatment and did not participate in the assessment of images.

Participants were provided with an examination and dental prophylaxis during the follow-up appointment if they had an in-person clinical assessment. Clinical images were acquired at each appointment, using a standardized format. If families declined an appointment due to the COVID-19 pandemic, they were invited to send images taken at home using their personal smartphone or camera.

Review of the collected images was conducted by two disinterested experienced staff pediatric dentists. The expert raters were blinded to all participant identifying information, date of treatment and date of photograph. The photographs were randomized by participant and date of follow-up. Thirteen photographs were randomly selected for duplication (thirty-five incisors) using a random number generator (Google, California, USA) and two assessment sessions were conducted for measure of intra-rater reliability. Photographs were displayed on a MacBook Pro 13.3 inches (2560 x 1600) at maximum brightness (Apple Inc, California, USA). Raters were allowed to use as much time as needed for their assessment. A calibration session was held for each rater prior to the assessment sessions. The expert raters were asked to use their clinical judgement to classify each treated tooth into one of the outcome measures. The outcomes assessed were: presence of the treated incisor, presence of the restoration, recurrent decay and discoloration. The expert raters were asked to classify each treated incisor into one of three outcomes based on their clinical assessment: I = restoration intact, unchanged from time of placement; D = restoration damaged but present, clinically acceptable with minor deficiency that does not require immediate intervention; and TR = treatment required, restoration absent or restoration present with major failure or recurrent decay present on restored incisor, re-treatment or extraction required.

All follow-up data was recorded on printed data collection sheets, entered into a Research Electronic Data Capture data base (REDCap™, Vanderbilt University, Nashville, Tennessee, USA) and exported into an Excel spreadsheet (Microsoft® Excel 2018, Microsoft Canada Inc, Mississauga, Ontario, Canada) for statistical analysis. The incisor was the unit of analysis and a generalized estimating equation was used to account for the lack of independence among incisors.

5.4 Results

5.4.1 Participants

Study participants were recruited at the Department of Dentistry of The Hospital for Sick Children between April 2019 and March 2020. One hundred and sixty-six participants were approached during regular ambulatory clinics and were offered inclusion into the study. Fifty-five participants declined participation. Three participants declined participation the day of surgery. Thirty-three participants were excluded by the treating pediatric dentist in the operating room when all incisors received intra-coronal restorations or all incisors were extracted. Sixteen patients consented to the study but did not receive treatment due to clinical closure during the COVID-19 pandemic. A total of one hundred and seventy-seven primary maxillary incisors in fifty-nine participants were enrolled in the study. Participants were randomized to one of two treatment groups. Participant demographics are shown in Table 1.

Participant demographics					
	Number of incisors (number of participants)	**Mean age ± SD (months)**	**Female**	**ASA I**	**ASA II**
ZC	76 (26)	33.0±8.8	14	19	7
SC	101 (33)	32.3±7.0	12	23	10

Table 1. Demographics of participants by treatment group. Chi-square tests demonstrated no differences between groups.

Participant enrollment was terminated early due to clinical closures during the COVID-19 pandemic and limited the number of incisors included in the study. Some delays in assessment were also experienced due to hospital access limitations imposed due to the COVID-19 pandemic. Participants returned to clinic for their first assessment at least six months and up to ten months after placement of the restorations. Participants returned to clinic for their second assessment at least twelve months and up to twenty-two months after placement of the restorations. Participants who declined an in-person assessment appointment were invited to send images of their child's incisors through a secure e-mail. Participant assessment distribution is shown in Table 2. Participants were offered free dental care (recall examination, polishing, fluoride varnish) and a $25 pre-paid Visa card during their assessment appointment. The study suffered a sample wastage of thirty-six percent for the first assessment and thirty-four percent for the second assessment. A total of one hundred and forty-one incisors in forty-eight participants were assessed for clinical outcomes, including eighty-two incisors in twenty-nine participants assessed at both time points.

Participant assessment					
	Number of participants assessed in person	Number of participants who sent photographs	Lost to follow-up		Number of incisors assessed
			Number of participants who declined an appointment and did not send photographs	Number of participants who could not be reached	
6 months	24	14	15	6	109
12 months	32	7	12	8	114

Table 2. Participant assessment distribution at 6 and 12 months.

5.4.2 Clinical outcomes

Times to event (treatment required) could not be recorded for the majority of the crowns that required treatment due to the challenges in assessment experienced during the COVID-19 pandemic. Hence, survival analysis could not be undertaken. Instead, a regression analysis was performed for both time points (six months and twelve months) using a generalized estimating equation. One participant (four incisors restored with ZC) presented eleven months after placement of the restorations for their second assessment. The outcome data was discarded for this participant in the regression analysis. Assessed clinical outcomes are shown in Table 3. Outcomes "damaged" and "treatment required" were grouped to calculate the odds ratio (OR) of ZC being intact compared to SC at six months and twelve months. ZC had an OR of 4.2 (95% CI, 1.3-13.3) times that of SC at six months (P=0.01) and 4.0 (95% CI, 1.2-13.0) times that of SC at twelve months (P=0.02) of being rated as intact. Adjusted OR for sex, age and pulp treatment were 4.3 (95% CI, 1.2-15.0) at six months (P=0.02) and 3.6 (95% CI, 1.0-13.3) at twelve months (P=0.05). Outcomes "intact" and "damaged" were subsequently grouped to calculate the OR of ZC that did not require treatment compared to SC at both time points. ZC

had an OR of 0.5 (95% CI, 0.1-2.4) times that of SC of requiring treatment at six months (*P*=0.4) and 0.4 (95% CI, 0.08-1.6), times that of SC at twelve months (*P*=0.2). Statistically significant differences were not found, possibly due to the small amount of observed "treatment required" outcomes in the ZC group. Measures of inter-rater reliability were substantial for the first session (K=0.70, Cohen's kappa) with 89.1% agreement and for the second session (K=0.70, Cohen's kappa) with 86.4% agreement. Intra-rater reliability was substantial for both raters (K1=0.66, 84.9% agreement and K2=0.77, 89.9% agreement; Cohen's Kappa). (Landis, Koch, 1977) Most of the disagreements occurred between the outcomes "damaged" and "treatment required". This indicated the ability of dentists to differentiate an intact restoration from a non-intact restoration and highlighted the challenge in deciding whether or not a faulty restoration requires additional treatment.

Clinical outcomes			
	Intact (I): number of crowns (%)	**Damaged (D): number of crowns (%)**	**Treatment required (TR): number of crowns (%)**
6 months			
ZC	47 (85.5)	3 (5.4)	5 (9.1)
SC	31 (57.4)	13 (24.1)	10 (18.5)
12 months			
ZC	35 (81.4)	3 (7.0)	5 (11.6)
SC	33 (46.5)	17 (24.0)	21 (29.5)

Table 3. Clinical outcomes for treatment groups

Clinical outcomes		
	Intact (I)	Not intact (D+TR)
6 months [a]		
ZC	47	8
SC	31	23
12 months [b]		
ZC	35	8
SC	33	38

Table 4. Clinical outcomes for treatment groups
[a] ZC had an OR of 4.2 (95% CI, 1.3-13.3) times that of SC of being intact at six months (*P*=0.01)
[b] ZC had an OR of 4.0 (95% CI, 1.2-13.0) times that of SC of being intact at twelve months (*P*=0.02)

5.4.3 Frequency of pulp therapy

A generalized estimating equation was used to account for the lack of independence among incisors. Tooth level factors by treatment groups are shown in Table 5. No statistically significant difference was shown for the frequency of pulp therapy associated with placement of ZC and SC in primary maxillary incisors (OR 0.8 +/- 0.5 (SE), *P*=0.7).

Tooth level factors				
	Central incisor (%)	Lateral incisor (%)	Pulpotomy (%)	No pulpotomy (%)
ZC	44 (57.9)	32 (42.1)	25 (32.9)	51 (57.1)
SC	52 (51.5)	49 (48.5)	34 (33.7)	67 (66.3)

Table 5. Tooth level factors by treatment group. Chi-square tests demonstrated no differences between groups.

5.4.4 Treatment deviation

All incisors randomized to receive ZC were restored with ZC.

5.5 Discussion

Only one randomized controlled trial comparing clinical outcomes of primary maxillary incisor ZC and SC was published prior to the initiation of this investigation. (Walia et al, 2014) This randomized controlled trial had extensive exclusion criteria that limited its generalisability to clinical practice. Incisors that required pulp therapy, children requiring sedation, children with special needs, participants with a deep bite or evidence of bruxism were excluded from the study. These exclusion criteria suggested potential clinical limitations of ZC technique. A second randomized controlled trial was published after the initiation of this investigation. (Gill et al, 2020) Again, participants with an ASA greater than one, with anterior dental crowding, with class III occlusion or with primary maxillary incisors that lost over half of the clinical crown after tooth preparation were excluded from the study. Overly restrictive inclusion criteria limited the applicability of the outcomes of these studies to pediatric clinical practice. The present investigation did not exclude incisors on the basis of potential clinical limitations such as dental crowding or malocclusion and all incisors randomized to receive ZC were restored with ZC. This finding suggests that ZC can be broadly utilized to restore primary maxillary incisors without specific limitations. Malocclusion or crowding was not identified as contributing factor for dislodgement of ZC in the present study. Three of the five ZC rated as "treatment required" were missing at assessment. Biting on a hard object was reported as the reason for the loss of ZC by the parents of two of the participants. Parents of the third participant were unaware of how the ZC was lost. New ZC were cemented for all three

participants. Placement of new ZC was completed in the dental chair for all three participants. New ZC were cemented quickly and without the need for sedation, local anesthesia and restorative steps following cementation of the ZC such as shaping and polishing.

The requirement for greater tooth reduction associated with placement of ZC compared with other full coverage restorations for primary maxillary incisors has been highlighted in several papers (Waggoner, 2015; Clark et al, 2016; Holsinger et al, 2016; Seminario et al, 2019; Gill et al, 2020). The requirement for greater coronal reduction was perceived an increased risk for pulp exposure for incisors restored with ZC crowns. The requirement for greater tooth reduction with ZC relative to SC was demonstrated in vitro using intact typodont incisors. (Clark et al, 2016) Children who present with S-ECC commonly have lost substantial coronal structure prior to restoration of the incisors (Ram, Fuks, 2006; Casamassimo et al, 2013; AAPD, 2016; AAPD, 2019). This investigation found no difference in the frequencies of pulp treatment associated with ZC or SC placement. For grossly carious incisors, restoration technique may not be the most prominent factor as to whether or not pulp therapy is required. Restoration of superficially carious incisors with ZC is analogous to restoration of an intact typodont tooth with ZC. This clinical scenario may potentially result in a higher rate of pulpal therapy due to greater tooth reduction requirements for ZC than for intra-coronal or SC restorations.

Although primary incisor ZC gained popularity since its introduction in 2008, little evidence to support clinical outcomes was available at the initiation of this investigation in 2018. Evidence on clinical outcomes such as longevity of a restoration should be available to dentists and

families to support the informed consent process. One of the objectives of this investigation was to compare the clinical outcomes of ZC to an alternate full coverage restoration that is widely used by pediatric dentists: SC. However, the dental literature lacked studies assessing the long-term clinical outcomes of SC such as longevity, despite the routine use of the SC for the past forty years. The lack of clinical outcome data for ZC and SC did not allow for sample size calculation for a randomized controlled trial. Hence, a feasibility was undertaken. This investigation used a simple assessment protocol that mimicked the clinical practice for pediatric dentists.

This study focused on the clinical relevance of the outcomes: whether or not a restored incisor would require additional interventions. Raters were asked to classify each restored incisor as: intact, damaged or treatment required. ZC were found to have OR of over four times that of SC of being intact at six and twelve month follow-up. Furthermore, age and the presence of pulp treatment did not influence the outcome of the restorations. These findings were consistent with those published by Gill et al in 2020 (Gill et al, 2020). At twelve months, ZC were found to have greater crown longevity compared to SC. Additionally, ZC had fewer instances of partial or complete loss of restorative material and fewer marginal discrepancies and fewer instances of discolouration than SC (Gill et al, 2020). Greater longevity could decrease the need for future treatment to repair or replace a faulty restoration or extract the treated incisor. Lower odds of re-treatment are beneficial to the young participant, for whom cooperation may be difficult to obtain in the dental chair. Greater restoration longevity for ZC could contribute to parental satisfaction with the restorative treatment. Parental preference for long-term appearance of ZC crowns should please parents who were found to prioritize esthetics in the

choice of restorative material. Parental satisfaction with primary anterior ZC and SC was already reported in many investigations prior to the initiation of the present study (Kupietzky, 2004; Kupietzky, 2005; Waggoner, 2014; Salami, 2015; Holsinger, 2016; Acs et al, 2019; Gill et al, 2020). Finally, greater longevity could mean fewer re-treatment appointments for dentists who opt to restore primary incisors with ZC instead of SC.

5.6 Conclusions

1. The current investigation along with recent published data demonstrated superior clinical outcomes of ZC compared with SC up to twelve months post-treatment. Primary incisor ZC were found to have higher odds of remaining intact through the follow-up period when compared with SC. Increased longevity of the restorations can be beneficial to patients, parents and dentists. The greater longevity of ZC may decrease future treatment needs for children with restored maxillary incisors .

2. No difference in the rate of pulp therapy was found for incisors treated with ZC or SC.

3. A ZC was placed for all incisors randomized to ZC. This finding suggests that ZC have broad clinical applicability for children who require full coverage primary incisor restorations.

Appendix 1 : Standardized imaging

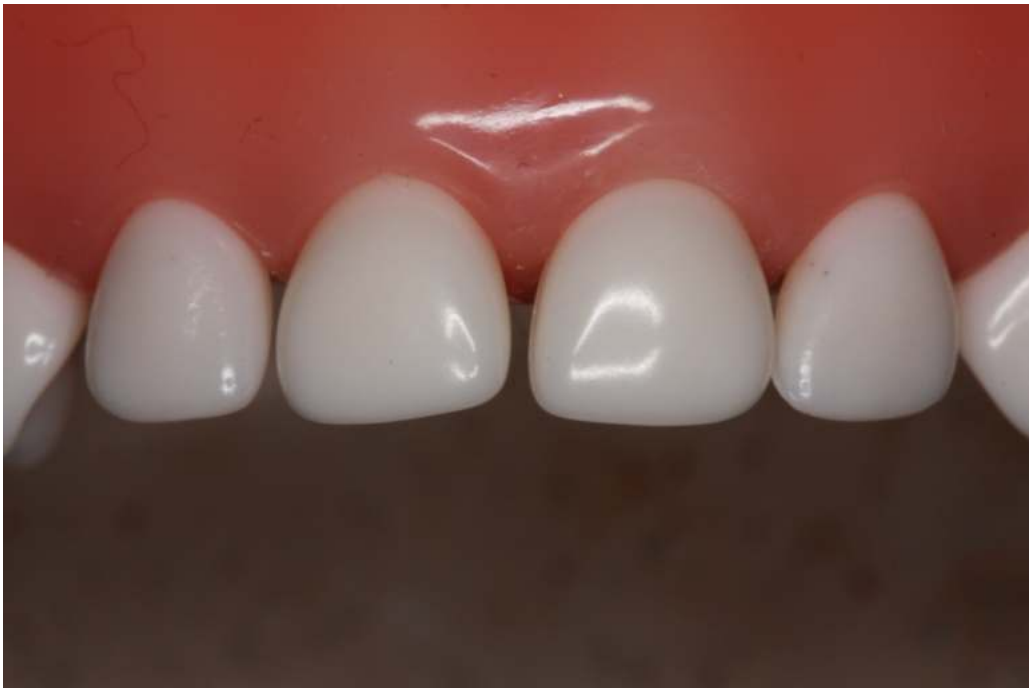


Figure 1.

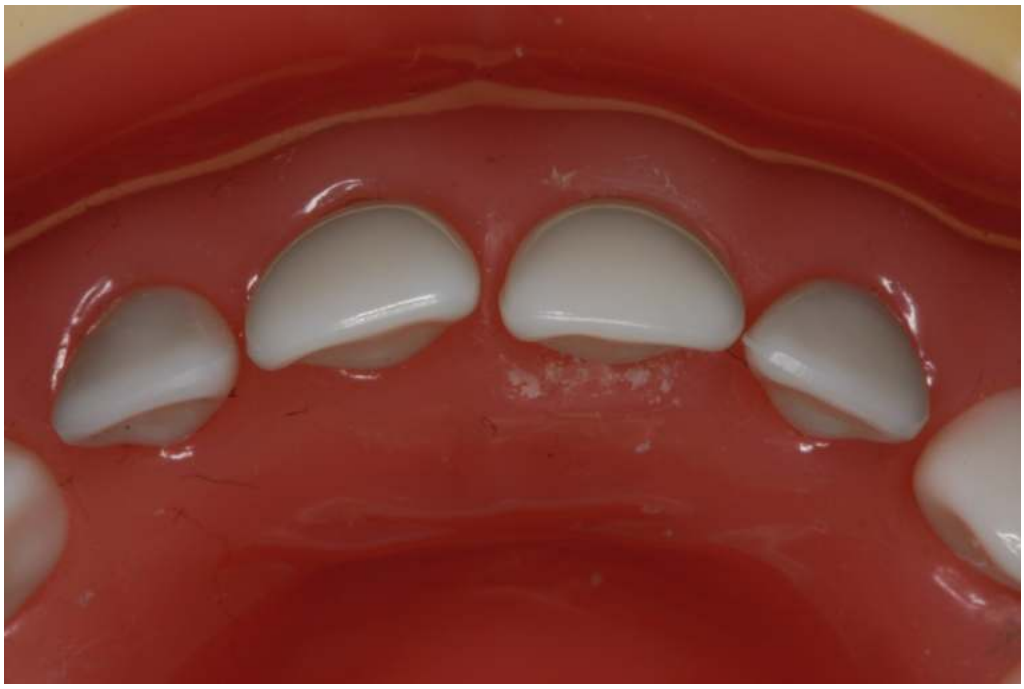


Figure 2.

Appendix 2: photographic assessment instructions handout

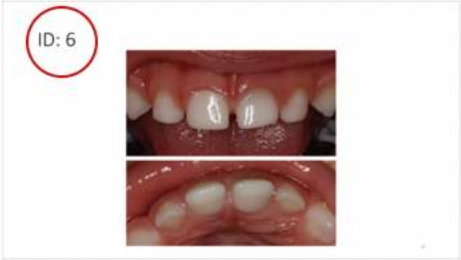
A comparison of primary maxillary incisor zirconia and composite resin strip crowns: A one-year feasibility study

Photographic analysis

1. A calibration exercise will take place in the Department of Dentistry with both raters (staff pediatric dentists) and an investigator (SL).
2. The raters will be provided with the "Photographic analysis handout" and the investigator will give a short presentation on how to conduct the photographic analysis.
3. Raters will proceed to a guided calibration exercise.
4. Once the calibration exercise is completed, the raters will proceed with the study photographic assessment. A total of 90 photographs will be analyzed. Thirteen duplicates will be included for measures of intra-rater reliability.
5. The power point with clinical photographs will be displayed on a single computer screen for both raters and the investigator will be in charge of changing the slides for the raters.
6. Each rater will be provided with paper copies of "Photographic data collection form" and will fill them out as indicated in the "Photographic analysis handout".
7. Once completed, data will be entered in REDcap by the investigator.
8. A second shorter assessment session will take place 2 weeks after the first assessment session for measures of inter- and intra-rater reliability. The raters will proceed to the assessment of 30 photographs with the same fashion.
9. Once completed, data will be entered in REDcap by the investigator.

Photographic analysis - Handout

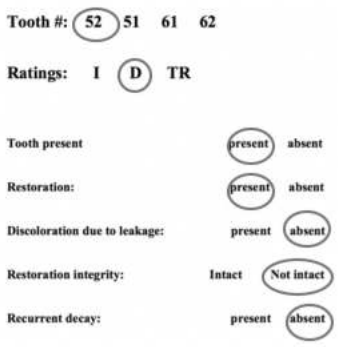
1. Refer to the Power Point presentation "Photographic analysis_final"
2. Use a new data collection form for each participant (1 per slide).
3. On the data collection form, fill out your rater ID (circle 1 or 2) and the ID # found on the power point slide for each participant



PHOTOGRAPHIC EVALUATION FORM: MAXILLARY INCISORS STRIP CROWN VS ZIRCONIA CROWNS STUDY *PLEASE IDENTIFY THE PRESENCE OR ABSENCE OF THE FOLLOWING PHOTOGRAPHIC FINDINGS WITH A CIRCLE*	
Rater: 1 2	Subject Identification #:

4. For each incisor that has received a full coverage restoration (1 to 4 per participant), circle the tooth number (52, 51, 61 or 62).

5. Assess each incisor for the following criteria and circle the appropriate outcome (present or absent; intact or not intact)
   - Tooth presence
   - Restoration presence
   - Discoloration due to leakage
   - Restoration integrity
   - Recurrent decay



6. Use your clinical judgement to classify each treated incisor as:
   - Intact (I)
   - Damaged (D): restoration damaged but present, clinically acceptable with minor deficiency that does not require immediate intervention
   - Treatment required (TR): treatment required, restoration absent or restoration present with major failure or recurrent decay present on restored incisor, re-retreatment or extraction required

Appendix 3: photographic assessment calibration session

A comparison of maxillary incisor pediatric zirconia and composite resin strip crowns: A one-year feasibility study

Photographic analysis

Stéphanie Labbé DMD

MSc Pediatric Dentistry candidate,
University of Toronto

SickKids

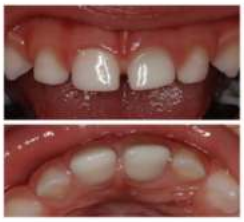
Outcomes

Intact (I)	Damaged (D)	Treatment required (TR)
• Intact	• Restoration present but not intact • Discoloration due to leakage • **Clinically acceptable** • **No treatment recommended**	• Restoration absent or present with major failure or • Recurrent decay • **Re-treatment or extraction**

2

Data collection form

ID: 6



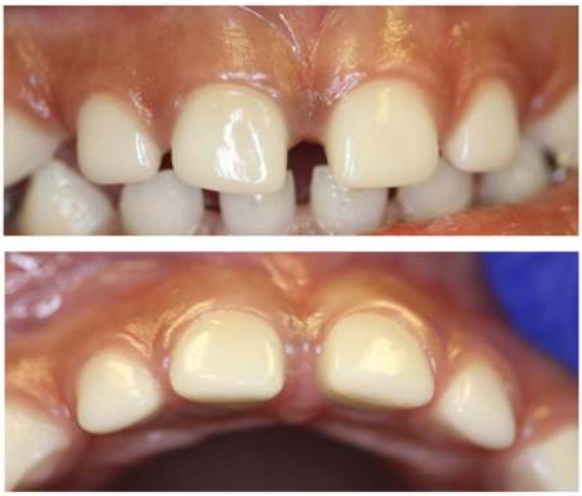
PHOTOGRAPHIC EVALUATION FORM: MAXILLARY INCISORS STRIP CROWN VS ZIRCONIA CROWNS STUDY

PLEASE IDENTIFY THE PRESENCE OR ABSENCE OF THE FOLLOWING PHOTOGRAPHIC FEATURES WITH A CIRCLE

Rater: 1 2	Subject Identification #:
Tooth #: 52 51 61 62	**Tooth #:** 52 51 61 62
Ratings: I D TR	**Ratings:** I D TR
Tooth present present absent	Tooth present present absent
Restoration: present absent	Restoration: present absent
Discoloration due to leakage: present absent	Discoloration due to leakage: present absent
Restoration integrity: Intact Not intact	Restoration integrity: Intact Not intact
Recurrent decay: present absent	Recurrent decay: present absent
Tooth #: 52 51 61 62	**Tooth #:** 52 51 61 62
Ratings: I D TR	**Ratings:** I D TR
Tooth present present absent	Tooth present present absent
Restoration: present absent	Restoration: present absent
Discoloration due to leakage: present absent	Discoloration due to leakage: present absent
Restoration integrity: Intact Not intact	Restoration integrity: Intact Not intact
Recurrent decay: present absent	Recurrent decay: present absent

3

Example 1



4

PHOTOGRAPHIC EVALUATION FORM: MAXILLARY INCISORS STRIP CROWN VS ZIRCONIA CROWNS STUDY

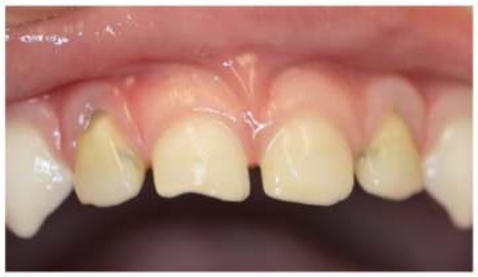
PLEASE IDENTIFY THE PRESENCE OR ABSENCE OF THE FOLLOWING PHOTOGRAPHIC FINDINGS WITH A CIRCLE

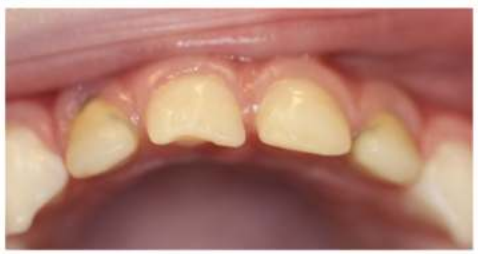
Example 1

Rater: (1) 2	Subject Identification #:
Tooth #: (52) 51 61 62 **Ratings:** (I) D TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: present (absent) Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)	**Tooth #:** 52 (51) 61 62 **Ratings:** (I) D TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: present (absent) Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)
Tooth #: 52 51 (61) 62 **Ratings:** (I) D TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: present (absent) Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)	**Tooth #:** 52 51 61 (62) **Ratings:** (I) D TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: present (absent) Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)

5

Example 2





6

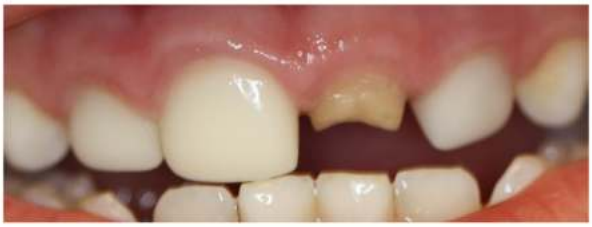
PHOTOGRAPHIC EVALUATION FORM: MAXILLARY INCISORS STRIP CROWN VS ZIRCONIA CROWNS STUDY

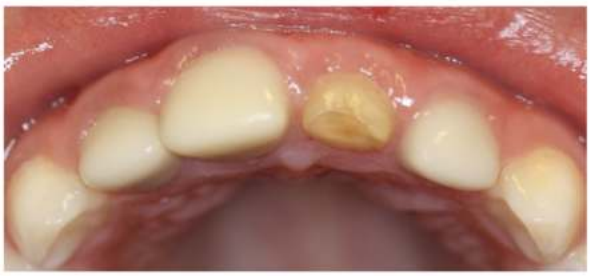
PLEASE INDICATE THE PRESENCE OR ABSENCE OF THE FOLLOWING PHOTOGRAPHIC FINDINGS WITH A CIRCLE

Rater: (1) 2	Subject Identification #: Example 2
Tooth #: 52 (51) 61 62 **Ratings:** I (D) TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: (present) absent Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)	**Tooth #:** 52 (51) 61 62 **Ratings:** I (D) TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: present (absent) Restoration integrity: Intact (Not intact) Recurrent decay: present (absent)
Tooth #: 52 51 (61) 62 **Ratings:** (I) D TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: present (absent) Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)	**Tooth #:** 52 51 61 (62) **Ratings:** I (D) TR Tooth present: (present) absent Restoration: (present) absent Discoloration due to leakage: (present) absent Restoration integrity: (Intact) Not intact Recurrent decay: present (absent)

7

Example 3





8

PHOTOGRAPHIC EVALUATION FORM: MAXILLARY INCISORS STRIP CROWN VS ZIRCONIA CROWNS STUDY

PLEASE IDENTIFY THE PRESENCE OR ABSENCE OF THE FOLLOWING PHOTOGRAPHIC FINDINGS WITH A CIRCLE

Example 3

Rater: (1) 2	Subject Identification #:
Tooth #: 52 51 61 62	**Tooth #:** 52 51 61 62
Ratings: I D TR	**Ratings:** I D TR
Tooth present: present absent	Tooth present: present absent
Restoration: present absent	Restoration: present absent
Discoloration due to leakage: present absent	Discoloration due to leakage: present absent
Restoration integrity: Intact Not intact	Restoration integrity: Intact Not intact
Recurrent decay: present absent	Recurrent decay: present absent
Tooth #: 52 51 61 62	**Tooth #:** 52 51 61 62
Ratings: I D TR	**Ratings:** I D TR
Tooth present: present absent	Tooth present: present absent
Restoration: present absent	Restoration: present absent
Discoloration due to leakage: present absent	Discoloration due to leakage: present absent
Restoration integrity: Intact Not intact	Restoration integrity: Intact Not intact
Recurrent decay: present absent	Recurrent decay: present absent

9

Questions?

10

Appendix 4: photographic assessment data collection sheet

PHOTOGRAPHIC EVALUATION FORM: MAXILLARY INCISORS STRIP CROWN VS ZIRCONIA CROWNS STUDY

PLEASE IDENTIFY THE PRESENCE OR ABSENCE OF THE FOLLOWING PHOTOGRAPHIC FINDINGS WITH A CIRCLE

Rater: 1 2	Subject Identification #:
Tooth #: 52 51 61 62 **Ratings: I D TR** **Tooth present** present absent **Restoration:** present absent **Discoloration due to leakage:** present absent **Restoration integrity:** Intact Not intact **Recurrent decay:** present absent	**Tooth #: 52 51 61 62** **Ratings: I D TR** **Tooth present** present absent **Restoration:** present absent **Discoloration due to leakage:** present absent **Restoration integrity:** Intact Not intact **Recurrent decay:** present absent
Tooth #: 52 51 61 62 **Ratings: I D TR** **Tooth present** present absent **Restoration:** present absent **Discoloration due to leakage:** present absent **Restoration integrity:** Intact Not intact **Recurrent decay:** present absent	**Tooth #: 52 51 61 62** **Ratings: I D TR** **Tooth present** present absent **Restoration:** present absent **Discoloration due to leakage:** present absent **Restoration integrity:** Intact Not intact **Recurrent decay:** present absent

Appendix 5: OR data collection sheet

OR DATA COLLECTION FORM

Participant ID

For SickKids dental staff use only

Circle teeth treated and insert pulp code technique used (bold) as defined:

P: Pulpotomy

X: No pulpotomy

52	51	61	62

Circle teeth treated and insert restorative code technique used (bold) as defined:

ZC: zirconia crown

CRSC: Composite resin strip crown

	52	51	61	62
Randomly assigned treatment				
Treatment completed				

Did the patient receive the restorative treatment randomly assigned? Circle answer.

Yes No

Deviated from randomly selected treatment because:

- Severe attrition (bruxism)
- Deep bite
- Crowding
- Other: _____

Submit this form to Dr. Michael Casas upon completion of treatment