Long-Term Caries Relapse Following Dental Treatment Under General Anesthesia

by

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Abstract

This retrospective cohort study included 261 patients that received dental treatment under GA at a private pediatric dentistry practice in Southwestern Ontario. Data comprised of patient/caregiver and treatment factors for each subject. Caries relapse over long-term follow-up, along with associations with the collected variables were evaluated. Survival analysis found CR rates of 48% and 71% at 24 months and 48 months post-GA, respectively. Caries relapse was found to be significantly associated with active children, more multisurface composite restorations, and more remaining surfaces available for caries post GA. Patients treated under GA in the mixed dentition were 75% less likely to experience CR compared to those in primary dentition. Caries relapse rates post-GA were high in this sample of children, suggesting that conventional surgical approaches to managing ECC is not controlling the disease process. Identifying risk factors for caries relapse may influence treatment and risk management decisions.

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Table of Contents

List of Tables

List of Figures

List of Abbreviations

ASA: American Society of Anesthesiologists

CR: Caries Relapse

DMFT: Decayed Missing Filled Teeth

ECC: Early Childhood Caries

GA: General Anesthesia

GIC: Glass Ionomer Cement

RMGI: Resin Modified Glass Ionomer

SSC: Stainless Steel Crown

SAC: Surfaces Available for Caries

SAR: Surfaces At Risk

SES: Socio Economic Status

ZOE: Zinc-Oxide Eugenol

List of Appendices

Chapter 1
Introduction

1 Introduction

1.1 Background

1.1.1 Early Childhood Caries (ECC)

Dental caries is the most common chronic disease of childhood. [1,2] The American Academy of Pediatric Dentistry recognizes early childhood caries (ECC) as a significant chronic disease resulting from an imbalance of multiple risk and protective factors over time. [3] It is reported that the best indicator of future caries risk is a history of previous caries. Therefore, one would expect patients with ECC to be at high risk for developing future caries, or experiencing caries relapse after initial comprehensive dental treatment. [1,2,4]

Early childhood caries can substantially affect the child and their family in the following ways: More frequent hospitalizations and emergency room visits, loss of school and work days, poorer oral health-related quality of life, high treatment costs, high future caries risk, and impacts on eating, weight gain, sleeping habits and overall wellbeing. [3,5]

1.1.2 Treatment Options for ECC

Management of children with a history of ECC continues to be a challenge for pediatric dentists. Comprehensive treatment of ECC can be rendered under various treatment modalities, or behaviour facilitation techniques; these include: Local anesthesia, nitrous oxide-oxygen minimal sedation, oral minimal/moderate sedation, and general anesthesia. The treatment modality used is decided based on extent or severity of dental treatment needs, medical history, young age, patient cooperation, dental fear/apprehension, physical, mental, and/or psychological disabilities, preference for number of treatment appointments, patient management challenges and parent preference.

1.1.3 Treatment of ECC Under General Anesthesia (GA)

Management of ECC often requires comprehensive dental treatment under GA as a result of a child's low level of patient cooperation, severity of caries requiring extensive treatment, caregiver preference for single visit comprehensive treatment, and contributory patient medical histories. [4,6-8] The goals of comprehensive dental treatment are to eliminate disease and educate patients and caregivers to manage future caries progression. Comprehensive dental treatment can be defined as the treatment of all dental needs required to eliminate active disease and to restore and maintain oral health.

Indications for dental treatment to be completed under GA include: Young age, limited patient cooperation or communication, extensive dental treatment needs, orofacial trauma or significant surgical treatment, preference for single visit comprehensive treatment, significant medical history, and special health care needs. [4,8,9] Young children commonly have limited communication, comprehension and/or limited reasoning to allow them to cope through regular dental treatment in a clinical setting. Patients with dental fears or phobias can be apprehensive for regular dental treatment. Furthermore, patients with physical, psychological, or intellectual special needs may be treated with greater ease and success under GA. [4]

There are several advantages to comprehensive dental treatment under GA compared to traditional dental treatment with local anesthesia in a clinical setting. Under GA, there is no intraoperative discomfort to the patient, and less stress on the patient and dental staff. Extensive treatment is able to be completed with higher quality in one visit for patients. Additionally, when considering the long-term dental experience of a young patient, initial GA treatment may allow the young patient to mature and build confidence in themselves in a dental setting. In many cases, future treatment needs are well tolerated in the dental clinic without the need for GA. [4]

Conversely, there are a number of risks associated with dental treatment under GA. Escanilla-Casal *et al.* reported post-operative morbidities including: Toothache, cough, nausea, vomiting, fever, bleeding, odynophagia, anorexia, somnolence, insomnia, and psychological changes. [10] Unfortunate rare cases of patient mortality have been reported as well during dental treatment under GA. [11]

Long-term success of restorations may be compromised when attempted under non-ideal conditions in uncooperative children. Treatment with sedation or GA may lead to improved quality of treatment and potentially greater restoration survival rates. [12] Previous studies have reported lower restoration failure rates within one to two years post-op when treated under GA compared to those treated in the dental clinic. [12] Comprehensive dental treatment under GA is commonly utilized to treat ECC in young children and has been shown to result in improvements in children post-GA; including decreased pain experience, improved eating ability, and less disturbed sleep. [5]

Comprehensive dental treatment under GA is an important component of pediatric dentistry, and its efficacy in treating ECC has been studied as far back as 1972 by Legault *et al.* [4] Molding and guiding the pediatric patient to learn to accept dental treatment is a mainstay of pediatric dentistry.

1.1.4 Caries Relapse Following Dental Treatment Under GA

The prevalence of caries relapse following treatment under GA is high. Dental treatment under GA has been reported to have minimal long-term impact on oral *mutans streptococci* levels and professional counseling has been of limited success with regards to changes in oral hygiene and dietary habits. [13,14] As a result, control of caries as an active disease is not easily or frequently achieved.

Reported rates of subsequent caries development, or "caries relapse", range from 7-100% following treatment under GA, with variable study follow-up time, sample size, and caries relapse definitions. [4-9,15-27] Most studies have evaluated caries relapse 6-36 months following GA treatment, many of which use small sample sizes and have high patient dropout rates. Limited literature is available regarding caries relapse with follow-up times greater than 36 months post-GA, or with larger sample sizes. Evaluating and describing caries relapse rates over a greater follow-up time post-GA can provide additional information on caries relapse over time. Most literature available on caries relapse post-GA also only includes subjects of ASA 1 or ASA 2 (mostly healthy) patients. It is apparent that further research on this topic is needed that includes more medically and/or developmentally complex patients. Determining the factors that affect the

risk of caries relapse following treatment under GA is important as well, and they may aid in the management of future caries progression, and the maintenance of long-term oral health.

1.1.5 Caries Relapse Risk Management Considerations

An increased emphasis on caries risk management measures has been advised to manage caries relapse, and maintain good oral health. [4] Caries is reported to be a preventable chronic disease; its progression in children over time is associated with low fluoride exposure levels, unsupervised regular daily tooth brushing, and cariogenic diet patterns. [15] Alternatively, patients with active caries can be considered to be in a state of oral dysbiosis, and the management of dental caries as a disease process should be considered as the management of the patient's dysbiosis. [28]

Antimicrobial treatment used as a caries management adjunct to comprehensive dental treatment and has been suggested for further evaluation for potential effects on clinical outcomes. [6,21] Some potential caries risk management options include use of high fluoride toothpaste, xylitol, povidone iodine, chlorhexidine, more frequent recalls, casein phosphopeptide products, and more frequent fluoride varnish applications. [8,19]

In addition, the challenge of addressing patient/caregiver behaviour change still often remains. [9] Motivational interviewing has shown success in affecting behaviours of caregivers of children with ECC, and may be an effective method to obtain behaviour change to accept caries risk management recommendations. [8,16,29]

1.2 Statement of the Problem

Existing literature on caries relapse post-GA reveals a wide range of reported caries relapse rates. As there were limitations and inconsistencies in the previous studies, determining a reliable estimate of caries relapse post-GA is difficult. There also remains limited literature on long-term caries relapse rates following comprehensive dental treatment under GA. Most studies have follow-up times ranging from 6-36 months post-GA, most of which also have small study sample sizes. Studies on long-term (greater than 36 months) caries relapse rates are lacking. Additionally, literature on factors associated with caries relapse is limited and further research is needed to help understand and improve clinical outcomes. Furthermore, previous literature has

limited the study of caries relapse post-GA almost exclusively to young, relatively healthy patients. Limited research has been done to evaluate caries relapse in patients older than six years of age, or who were treated in the mixed or permanent dentition. Literature is also lacking on caries relapse in patients with more complex medical and/or developmental comorbidities who are often treated under GA in a pediatric dentistry practice.

Most previous cohort studies utilized patient data retrospectively from hospital based dental clinics. Patient dropout is a common limitation of previous studies, often the result of patients returning to their primary community dentist following treatment under GA. Limited research exists on caries relapse post-GA in private pediatric dentistry practices (not hospital-based). Limited patient exclusion criteria in this study allow for the evaluation of caries relapse in more medically and/or developmentally complex patients, not previously studied. In this study long-term caries relapse following treatment under general anesthesia in a unique private pediatric dentistry practice in Southwestern Ontario was investigated.

1.3 Central research question

What is the caries relapse in patients who received comprehensive dental treatment under GA in a private pediatric dentistry practice in Southwestern Ontario?

1.4 Objectives

1. Evaluate caries relapse following comprehensive dental treatment under general anesthesia.

2. Determine any association between caries relapse and patient/caregiver factors, treatment factors, and environmental factors, in patients who received comprehensive dental treatment under general anesthesia.

1.5 Conceptual framework

To illustrate the complexity and multiple factors related caries relapse, a conceptual framework was created (Figure 1). Caries relapse was defined as any new caries or recurrent caries (including any demineralized or non-cavitated lesions) found clinically or radiographically at subsequent recall examinations post-GA. The variables listed have been included based on

findings from the literature review on caries relapse following dental treatment under GA. Independent variables have been categorized into three groups: Patient/caregiver-related factors, treatment factors, and environmental factors. A breakdown of each category can be found in Table 1. Of the variables included in this conceptual framework, most have been considered and evaluated in previous studies related to caries relapse following dental treatment under GA. [4-9,15-27] Some independent variables previously studied have shown statistically significant relationships with caries relapse as highlighted in Table 2. Reviewing previous studies focusing on caries risk assessment provides a broader scope of potentially related factors to consider for caries relapse post-GA. A number of patient/caregiver-related variables, not previously studied specifically with regards to caries relapse post-GA, may play a role or contribute to caries relapse post-GA, and therefore have been included in this conceptual framework. [19,30-56] The conceptual framework acts as a guide or reference when considering factors to be evaluated as potentially associated variables with caries relapse.

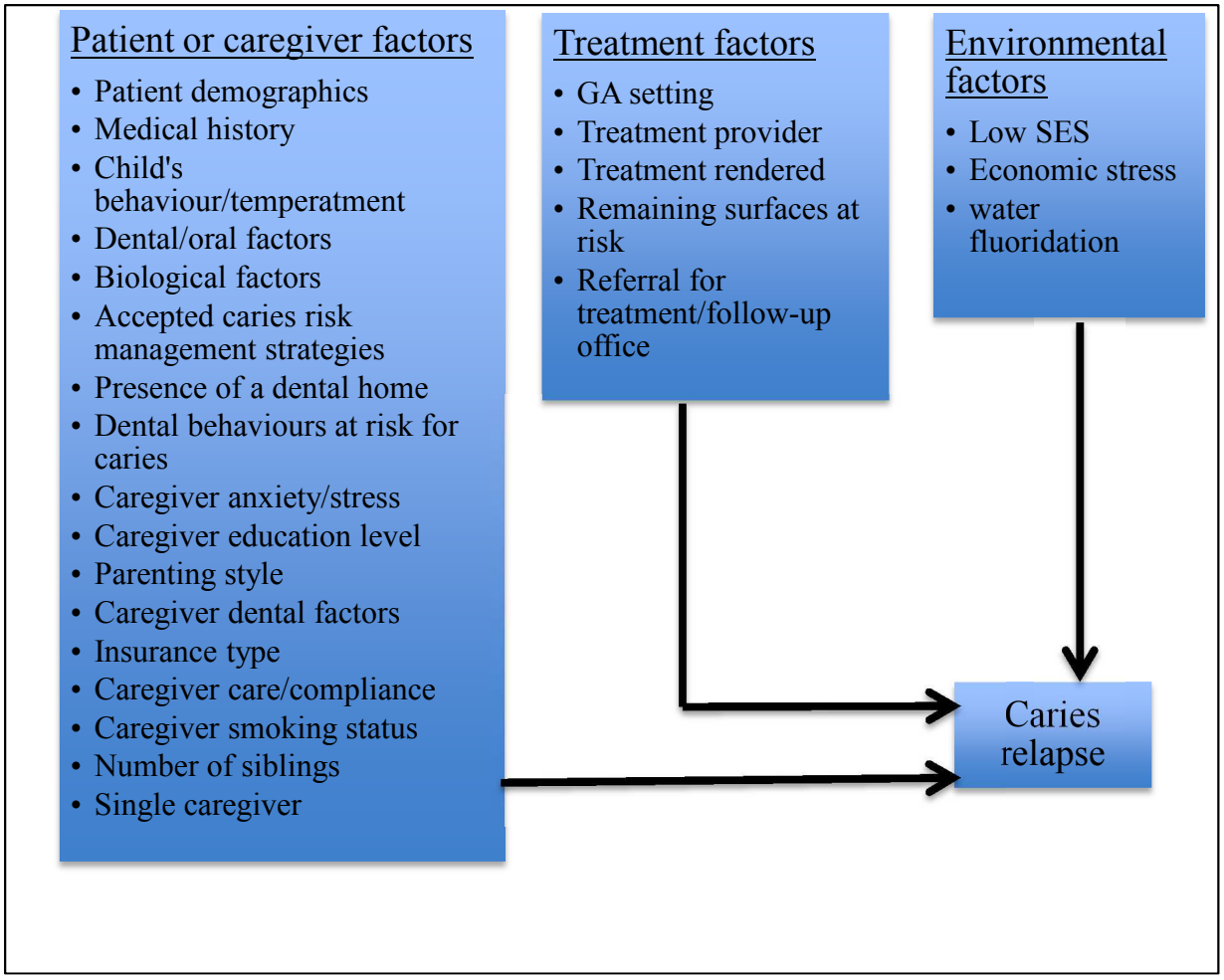

Figure 1. A conceptual framework of caries relapse in patients who received comprehensive dental treatment under general anesthesia.

Table 1. Breakdown of variables within conceptual framework of caries relapse in patients who received comprehensive dental treatment under general anesthesia.

Patient or caregiver-related factors	Demographics • Age at GA • Gender • Race/ethnicity
	Genetics
	Medical history (and special care needs)
	Child's behaviour/temperament
	Dental/oral factors • Oral hygiene (toothbrushing, flossing, toothpaste) • Diet • Dentition at GA • Spaced/non-spaced dentition • Enamel hypoplasia • Saliva • Biofilm/microbiome
	Accepted caries risk management strategies • Recall frequency • Pharmacological caries control (xylitol, casein-phosphopeptide products, high fluoride toothpaste, chlorhexidine, povidone iodine, fluoride varnish applications) • Placement of pit and fissure sealants • Saliva/bacteria testing • Oral hygiene instruction • Diet counselling
	Presence of a dental home
	Dental behaviours at risk for caries • Poor oral hygiene • Cariogenic diet • Poor oral health compliance
	Caregiver anxiety/stress
	Caregiver education level
	Parenting style
	Caregiver dental factors • Oral health literacy • Dental anxiety • Caregiver history of caries (caries risk)
	Type of insurance coverage
	Parent/family dynamics
	Caregiver beliefs system

Patient or caregiver-related factors (continued)	Caregiver care/compliance • Brushing child's teeth • Providing healthy diet • Feeding habits • Compliance to dental recalls
	Compliance/education to risk management programs
	Caregiver smoking status
	Number of siblings
	Single caregiver
Treatment-related factors	GA setting Clinic or hospital
	Treatment provider (pediatric dentist, general dentist, student/resident)
	Treatment rendered under GA Number of extractions, SSCs, pulpotomies, pulpectomies, composite restorations etc.
	Remaining surfaces at risk for caries
	Was patient referred for treatment?
	Regular follow-up with treating office?
Environmental-related factors	Socioeconomic status
	Economic stress
	Water fluoridation

Chapter 2
Literature Review

2 Literature Review

2.1 Overview

A search of the literature was completed using the following databases: COCHRANE, EMBASE, MEDLINE, Proquest Dissertations and Theses Global, and Scopus (Web of Science). The following MESH terms were used for the search: “dental caries”, “tooth demineralization”, “recurrent disease”; “general anesthesia”, “inhalational anesthesia”, “dental anesthesia”; and “dental care for children”, “dental care for the chronically ill”, and “dental care for disabled”. Keywords, “caries recurrence” and “caries relapse” were also included in the search. The initial search generated a total of 1637 articles. After filtering all articles by reviewing titles and/or abstracts, as well as manually reviewing select articles’ references for any missing studies, 20 papers about caries relapse following comprehensive dental treatment under GA were identified. Two of these papers did not have English translated full texts, and one thesis from the United Kingdom was unable to be obtained. [22,27,57] Seventeen English full text papers remained for review. [4-9,15-21,23-26] A summary table of the literature on caries relapse following dental treatment under GA is found in Table 2.

Table 2. Summary of previous studies on caries relapse following dental treatment under general anesthesia.

Study	Location (Practice)	Initial sample size	Final sample size*	Follow-up time (Max) **	Caries relapse rate***	Caries relapse definition	Bias/Errors	Significant findings/notes
Legault *et al.* 1972 [4]	Montreal, Canada (5757 Decelles Ave. Montreal)	300	217	1-57 months (mean 16)	38.6%	Further treatment; time to relapse evaluated (no endpoint)	• Dropout rate • Changed treatment approach over study time	Private practice
O'Sullivan and Curzon 1991 [26]	Leeds, England (Leeds Dental Hospital)	80	60	24 months	65.0%	Further treatment	• Dropout rate • Limited relapse definition	Hospital-based
Berkowitz *et al.* 1997 [18]	Rochester, NY, USA (Ambulatory Surgical Center of the Strong Memorial Hospital)	84	24	6 months	54.2%	Caries into dentin	• Dropout rate • Limited relapse definition	Hospital-based
Almeida *et al.* 2000 [15]	Boston, MA, USA (Franciscan Children's Hospital & Rehabilitation Center)	42	42	24 months	79.0%	New caries (smooth + Pit Fissure)		Had caries-free control group Hospital-based
Chase *et al.* 2004 [21]	Rochester, NY, USA (Ambulatory Surgical Center of the Strong Memorial Hospital)	79	57	6 months	37.0%	Cavitation (as defined by Radike 1972)	• Dropout rate • Limited relapse definition (no recurrent caries)	Hospital-based Aggressive treatment protocol $30 incentive for follow-up
Graves *et al.* 2004 [6]	Rochester, NY, USA (Ambulatory Surgical Center of the Strong Memorial Hospital)	79	57	6 months	37.0%	New caries	• Dropout rate • Limited relapse definition	Hospital-based Introduced SAR measurement
Drummond *et al.* 2004 [5]	New Zealand (University of Otago School of Dentistry)	277	75	48 months	70.7%	New caries	• Dropout rate • Limited relapse definition	University-based Longer follow-up
Foster *et al.*	Buffalo, NY, USA	488	193	24 months	53.4%	New caries	• Dropout rate	Less relapse if

2006 [7]	(Women and Children's Hospital of Buffalo)						• Limited relapse definition • No defined F/U time, ranged from 6-24 months	attended immediate post-op appointment Hospital-based
Jamieson and Vargas 2007 [8]	Iowa city, IO, USA (The University of Iowa Hospitals and Clinics)	217	11	36 months	26.0%	New & recurrent caries	• Dropout rate • Misleading final caries relapse rate (56/217 = 26%), only few returned at full follow-up	Post-op questionnaire to all caregivers Hospital-based Recurrent caries> new caries
Chen *et al.* 2008 [22]	Shanghai, China (China Medical University)	30	30	6-12 months	7.0%	Unknown	English full text not available	University-based Abstract only
Amin *et al.* 2010 [16]	Calgary, Canada (Private pediatric dentistry practice)	269	36	24 months	53.0%	New caries	• Dropout rate • Limited relapse definition	Private practice Relapse with more extensive treatment needs (pulp therapy) Private practice
Berkowitz *et al.* 2011 [19]	Rochester, NY, USA (Ambulatory Surgical Center of the Strong Memorial Hospital, and Eastman Dental Pediatric Clinic)	77	49	12 months	39.0%	Requires restoration	• Dropout rate • Limited relapse definition, • Not full 12 months, ranges 5-12 months	Povidone Iodine applied after GA Hospital-based residency
Borges *et al.* 2012 [20]	Brazil (Private education institution)	1	1	15 years	--	--	• N=1 • 2 week - 2 month recalls, extreme prevention	Educational institution Case report
El Batawi 2014 [23]	Jeddah, Saudi Arabia (Private Medical Hospital, Jeddah)	431	352	24 months	59.0%	Repeat treatment	• Dropout rate • Limited relapse definition, • Not all attended final recall	Hospital based Treatment performed by pediatric dental consultant Relapse associated with: • recall compliance • more GA repeats in special needs

Xia *et al.* 2014 [27]	China (Peking University School and Hospital of Stomatology)	111			215 days until relapse	Unplanned treatment, time until relapse evaluated	• Many teeth exfoliated at recall, • English full text not available	University/Hospital-based Abstract only
Cuadros Fernandez *et al.* 2014 [9]	Barcelona, Spain (Universitat Internacional de Catalunya)	1	1	12 months	Caries relapse present	New caries + white spot lesions	N=1	University-based Case report
EzEldeen *et al.* 2015 [24]	Netherlands (University Hospitals of the Catholic University of Leuven)	98	21	12 years	91% (dentin), 100% (demineralized)	Caries into dentin, Demineralization lesions	• Dropout rate • No information between year 1 & 12	University-based 12 year follow-up available
Amin *et al.* 2015 [17]	Calgary, Canada (Private pediatric dentistry practice in Vancouver, Canada)	278	126	36 months	21.6%	New + recurrent caries, including demineralized lesions	• Dropout rate • Inaccurate final relapse calculation: took # relapsed at final recall out of initial sample	Private practice Relapse associated with: • ASA status • # of teeth at GA • # recalls attended • fewer space maintainers
Lin *et al.* 2018 [25]	Kaohsiung, Taiwan (Children's Dental Clinic of Kaohsiung Chang Gung Memorial Hospital)	92	83	6 months	54.2%	Cavitated lesion, ICDAS ≥3	Limited relapse definition	Hospital-based Relapse associated with: 1.meal-time duration 2.high snack frequency 3.tooth brushing duration

* Final sample size indicates the number of subjects followed until each study's greatest follow-up time.

** Follow-up time (Max) indicates the longest follow-up time post-GA of which subjects were followed.

*** Relapse rate indicates the study's reported relapse rate for remaining subjects included in the Final sample size.

Note: The expanded review of previous studies on caries relapse following treatment under general anesthesia is found in the appendix of this thesis.

2.2 Caries relapse: as reported in previous studies

Reported rates of subsequent caries development, or "caries relapse", range from 7-100% following treatment under GA, with variable study follow-up time, sample size, and caries relapse definitions (see Table 2). [4-9,15-27] Most studies have evaluated caries relapse 6-36 months following GA treatment, many of which use small sample sizes and have high patient dropout rates. The reported relapse rates of the available full English texts with follow-up time ranging from six to 36 months post-GA ranges from 22% to 79%. [4-8,15-19,21,23,25,26] The true caries relapse rate within this follow-up period likely lies within this range. Based on various inconsistencies and biases in the literature, the true caries relapse rate is expected to be on the higher end of this reported range. Caries relapse definitions are inconsistent among studies, as discussed later in this chapter, leading to underestimations of caries relapse in the previous literature. High patient dropout rates also contribute to caries relapse potentially being underestimated. The subset of patients not followed in previous studies may represent a less compliant group of patients/caregivers, which may be at higher risk for caries relapse post-GA than those with routine follow-up care and a dental home, although this remains unknown.

Previous studies' initial sample sizes ranged from as few as one to 488 patients treated under GA. However, most previous studies' initial samples were under 100 subjects. Patient dropout was a common limitation in most previous studies as well. The final sample size relative to the initial sample size in Table 2 illustrates the patient dropout over the full follow-up time of each study. As most studies were based out of hospital tertiary dental practices, a large proportion of patients treated under GA returned to their referring community dentists following comprehensive dental treatment under GA, contributing to significant patient dropout.

Limited literature is available regarding caries relapse with follow-up times greater than 36 months post-GA, or with larger sample sizes. As caries relapse is cumulative over time, it is expected that caries relapse rates will continue to increase with longer follow-up times post-GA. However, due to limited long-term research, it is unknown if or which patients may remain caries relapse-free long-term post-GA.

Most literature available on caries relapse post-GA has been limited to include only ASA 1 or 2 (i.e. mostly healthy) patients. Patient inclusion has often been limited to children under 72

months of age, and to patients with only primary dentition. Pediatric dentists commonly treat patients over six years of age, patients with either primary, mixed and young permanent dentitions, as well as patients with medical and/or developmental comorbidities. Many of these patients may undergo comprehensive dental treatment under GA to manage their dental needs. As a result, further research is needed that includes patients of all ages common to pediatric dentistry, including medically/developmentally complex patients, as well as patients with mixed and permanent dentitions.

2.3 Long-term follow-up

Long-term data on caries relapse, and caries progression patterns in children initially treated under GA is limited. Reported caries relapse rates range from 7% to 79% with 6 to 48-month post-GA follow-up. [4-8,15-19,21,23,26,27] Long-term follow-up (greater than 48 months post-GA) has only been reported twice. [20,24] Borges *et al.* published a case report that followed one patient in Brazil for 15 years following treatment of ECC under GA. [20] The case report presented a patient who received comprehensive dental treatment under GA at the age of four. In order to maximize prevention efforts, the patient was seen every two weeks for the first year, and then every two months to ensure good diet and oral hygiene practices. The patient maintained good oral hygiene for the 15 years followed and had no caries of the permanent teeth. [20] This may seem extreme, and only includes a sample size of one, but illustrates how caries risk management measures may control caries progression long-term.

Only one published cohort study with long-term follow-up to evaluate caries relapse post-GA was found. [24] This Belgian study included 98 healthy children treated under GA between 1995-1996 at the pediatric dental clinic at The University Hospital of the Catholic University of Leuven. Ages of included patients at time of GA ranged from three to nine years. Patients were to return for recall one year after GA, and a second time 12 years after GA. At one year post-GA 60/98 patients returned for recall, while 12 years post-GA 21/98 patients returned for recall. [24] Visible plaque was recorded at 12-year recall in all returning patients. Untreated, active caries were present in 71.4% of patients at 12 years post-GA. [24] In the 21 patients examined, caries relapse at D_3 and D_1 levels 12 years post-GA was 91% and 100% respectively. These results indicate that all remaining patients initially treated under GA have experienced caries relapse within 12 years post-GA. Although, patients that returned for long-term follow-up may have

returned as a result of ongoing caries and dental needs. Therefore the subset of patients who returned long-term may potentially overestimate the caries relapse rate, this complexity creates difficulty in determining the over relapse rate of the initial study. The reported data suggests that patients with a history of ECC remain at high risk for developing caries later in the permanent dentition. When comparing caries relapse rates one-year post-GA, children initially treated for ECC presented relapse rates four to five times greater than non-ECC children evaluated at the same clinic. [24] Long-term follow-up is difficult as patient dropout is common, and presents a limitation of studies such as that by EzEldeen *et al*. Inability to contact patients, refusal to attend follow-up appointments due to distance and time restraints are common reasons for dropout. [24]

2.4 The inconsistent definition of caries relapse

In this literature review of caries relapse following dental treatment under GA, caries relapse is defined as the presence of any clinical or radiographic signs of new or recurrent caries, including signs of demineralization or non-cavitated lesions. New caries defined as any clinical or radiographic signs of caries, including non-cavitated lesions, on a previously non-restored tooth surface. Recurrent caries is defined as any clinical or radiographic signs of caries around or under a restoration of a previously restored tooth surface. The inclusion of both new and recurrent caries, as well as both cavitated and non-cavitated lesions aims to more accurately indicate the presence of any active caries progression post-GA. Previous studies on this topic have used a wide range of inconsistent definitions for caries relapse post-GA, which affects the reported outcome measures. Previous studies on caries relapse following dental treatment under GA have been summarized in Table 2. As outlined below, many studies' definitions of caries relapse have shortcomings, which lead to underestimations of the true caries relapse rates.

In the first study on caries relapse post GA, Legault *et al*. measurement of caries relapse was the requirement for further dental treatment post-GA. [4] Other studies used similar definitions to assess caries relapse, based on additional treatment required. [5,19,23,26,27] This definition does not include signs of caries that do not require surgical intervention, such as demineralized, non-cavitated, white spot or enamel lesions. Therefore caries relapse rates, indicating the presence of a continued caries process, are likely underestimated.

Failing to include demineralized, non-cavitated carious lesions was a common omission from previous studies' definitions. As stated previously, some studies based caries relapse on

additional surgical treatment requirements; however, other studies defined caries relapse as the presence of caries extending into dentin. [18] Therefore, the presence of non-cavitated enamel lesions was not included, leading to a probable underestimation of caries relapse. EzEldeen *et al.* evaluated caries at the DMFT level, using both D_1MFT (enamel level) and D_3MFT (dentin level) to differentiate enamel and dentin lesions. [24] Lin *et al.* used the ICDAS II system for reporting caries, and defined caries relapse as the presence of carious lesions ICDAS II > 3; once again omitting non-cavitated enamel lesions and the underestimation of the presence of active caries. [25]

Many previous studies failed to include recurrent caries in their caries relapse definition, leading to additional underestimations of ongoing caries activity post-treatment. [5-7,15,16] Some studies differentiated caries relapse from restoration failure, although made note that recurrent caries at the margin of an existing restoration was considered restoration failure and not included in caries relapse counts. [5-7,21] As these cases of recurrent caries were noted as restoration failures rather than caries relapse, the reported caries relapse rates were again underestimated.

Caries relapse in the study by Amin *et al.* included both new caries and recurrent caries, including any signs of demineralization. [17] The definition of caries relapse included all signs of caries progression, and would likely be a better estimate of relapse rates. This current study shares its caries relapse definition with the definition only previously outlined by Amin *et al*. [17]

2.5 Variables associated with caries relapse

Some previous studies have evaluated potential associations of patient/caregiver-related, treatment-related, and environmental factors on caries relapse following dental treatment under GA. As caries relapse rates are high post-GA for the management of ECC, research on associated variables may lead to improved clinical outcomes by affecting patient management and dental treatment decisions. A conceptual framework on caries relapse is found in Figure 1 and represents the potential factors that may contribute to caries relapse post-GA. Limited literature exists on the how many of these factors impact caries relapse, therefore further research is still required. However, some studies have reported findings correlated with caries relapse outcomes as outlined below.

There is limited evidence supporting an association of various factors with caries relapse post-GA. Other studies have found factors to be associated with the need for a repeat GA to

manage caries relapse. Factors associated with repeat GA can be broken down into child/caregiver, treatment, and environmental factors. Child factors associated with the need for repeat GA includes: Extensive caries of the maxillary incisors, bottle-feeding at the time of GA, and poor cooperation at follow-up. Caregiver factors include: Not brushing the child's teeth, dysfunctional social situations, and failure to return for follow-up. [8,16,17] Inferences can be drawn from these and suggests a possible association with caries relapse in general, rather than the need for repeated treatment under GA.

Attempts to identify factors that affect caries relapse have been previously reported. [16,17,19,23-25] It remains evident that children with ECC are at high risk for caries relapse in both the primary and permanent dentition as a result of unfavorable persistent oral health habits. Preventive strategies seem to be ineffective as caries relapse is a common outcome. [24]

Patient or caregiver related factors have been previously evaluated as potentially associated with caries relapse. Post-GA recall attendance was previously evaluated with conflicting results. Almeida *et al.* reported that there was no significant association between the number of recalls attended and caries relapse rates. [15] Meanwhile, others reported that a greater number of recalls attended correlated with lower caries relapse rates. [23,33] Attendance to an immediate or two-week post-op appointment was used as another measure of recall compliance, which also has conflicting results. It was hypothesized that those who attend their immediate post-GA appointment would have lower caries relapse rates, as they are more compliant and more likely to practice caries risk management measures. [8] No significant association with caries relapse was found with attendance to an immediate post-op appointment in Graves *et al.*'s study. [6] Another study reported caries relapse rates at two years post-GA of 19.7% and 33.7% in those who attended and those who did not attend a two-week follow-up, respectively; however this was not statistically significant. [7]

Amin *et al.* reported ASA status to be statistically significant associated with caries relapse within 36 months post-GA. [17] Patients who were ASA 2 were 2.7 times more likely to have caries relapse than ASA 1 patients. However, no statistically significant association was found between caries relapse and the number of SSCs placed, consistent with previous studies. [6] Greater caries relapse rates in ASA 2 patients may be the result of parents being more preoccupied with medical needs, thereby delaying or limiting dental preventive care and

treatment needs. With the intake of potential sugar-containing medications, caries risk could increase as well in ASA 2 patients.

Additionally, ethnicity, gender, race, reason for GA, and baseline streptococci mutans levels have not been found to have an association with caries relapse rates following treatment under GA. [5,19,21,27] The age of the patient has been studied as a factor associated with caries relapse, with younger children expected to have higher caries relapse rates. [5] However, previous studies and have found no significant association between age and caries relapse. [19,27] Another measure correlated to the age of young children is stage of dentition at GA. Previous studies have found that children treated under GA with less than full primary dentition rather than a full primary dentition or mixed dentition were 3.1 times more likely to have caries relapse within 36 months. This may be the result of limited oral hygiene at young ages, as well as newly erupted primary teeth post-GA being susceptible to new caries if their caries risk remains unchanged. [17]

Lin *et al.* most recently evaluated a number of independent variables for associations with caries relapse that had not been previously studied. [25] Behaviour related variables such as; mealtime duration, snacking frequency, tooth brushing duration and frequency, child self-brushing, and the use of toothpaste were collected. Additionally, biological variables were collected including *streptococcus mutans* counts, *lactobacillus* counts, and plaque index scores. Bacterial counts were reported to be significantly lower six months post-GA compared to baseline levels. Lin *et al.* also found caries relapse to be associated with tooth brushing duration under two minutes, long (>30 minutes) meal time durations, and high snacking frequency. [25]

Treatment-related factors may potentially influence clinical outcomes and caries relapse in this high caries risk population. Composite strip crowns were reported to be the most common restorations to require retreatment (20%). [5] Consequently, one can often expect a child receiving four maxillary incisor composite strip crowns to require retreatment of at least one incisor within two to four years. Class II amalgam restorations were also noted to have failure rates substantially greater than those of SSCs. [5] These findings on restoration survival promote an aggressive treatment approach with greater use of SSCs rather than Class II or multisurface intracoronal restorations, as well as extraction of heavily decayed primary incisors rather than restoration with composite strip crowns. An aggressive treatment approach should theoretically limit the frequency of new and/or recurrent caries as well as restoration failures.

Previous studies make note of using an aggressive surgical approach, and evaluated the remaining SAR as related to caries relapse. With greater use of SSCs leading to fewer available surfaces for caries, it was expected that caries relapse rates would decrease. Multiple studies reported similar results finding that aggressive treatment and use of a greater number of SSCs and lower SAR did not correlate with a statistically significant decrease in caries relapse. [6,19] Additional studies with larger sample sizes are needed to further evaluate the potential association between SAR and caries relapse. However, caries relapse was reported to be more common in patients who received more extensive treatment (such as pulpotomies), and in patients with a history of previous dental treatment under GA. [6] Furthermore, GA experience did not affect long-term changes in the behaviours of caregivers. [16]

Low socioeconomic status is expected to correlate with greater caries experience and therefore expected caries relapse experience. However, no significant association has been found in the existing literature. [5] No other environmental factors have been studied to date as related to caries relapse following dental treatment under GA. Caries and caries relapse are complex and are affected by multiple factors. Some factors may be within our control, and many are likely out of our control; with additional research, caries relapse may be better understood and may be better controlled and managed.

Chapter 3
Methods

3 Methods

3.1 Study definitions

Caries relapse: Any clinical or radiographic signs of "new caries" or "recurrent caries" (including demineralized, non-cavitated lesions), in a patient with a previous history of treated caries.

New caries: Any clinical or radiographic signs of caries, including non-cavitated lesions, on a previously non-restored tooth surface.

Recurrent caries: Any clinical or radiographic signs of caries around or under a restoration of a previously restored tooth surface.

Failed restoration: The requirement for repair or removal of a previous restoration or previously treated tooth, which is not the result of new or recurrent caries.

3.2 Study design

This study is an observational retrospective cohort study.

3.3 Sample population

This study includes all patients that underwent comprehensive dental treatment under GA at a single private pediatric dentistry practice in Southwestern Ontario between the years of 2001 and 2015. Four-hundred-and-eighty-three patients underwent comprehensive dental treatment under GA. Of those, 222 did not return for recall examination post-GA and were therefore excluded. The remaining sample includes 261 eligible subjects of which data has been previously collected.

This is a private pediatric dentistry practice in Southwestern Ontario. The sample is unique and does not represent the overall pediatric population. This specialty practice has a focus on special health care needs pediatric patients (under 18 years of age), including, but not limited to, medically/developmentally complex patients. There is limited research available on this topic

with the inclusion of more medically/developmentally complex patients. This study will add to the limited existing literature.

3.4 Inclusion criteria

Any subject who underwent comprehensive dental treatment at the private pediatric dentistry practice and returned to the same practice for at least one recall examination following treatment under GA. There was no age or American Society of Anesthesiologists (ASA) physical status restrictions. There was no follow-up time upper limit, or limit to the number of recall examination appointments attended following treatment under GA; this will allow for long-term evaluation.

3.5 Exclusion criteria

Any subject who did not return to the same private pediatric dentistry practice for recall examination post-GA, i.e. subjects who returned to their referring general dentist for ongoing dental management post-GA.

3.6 Data collection

A single previous investigator from the private pediatric dentistry practice had collected and recorded data from patients' dental records that underwent comprehensive dental treatment under GA between years 2001-2015. Patients' data was collected from digital patient records and from hard copy new patient intake forms (patient intake forms have been attached in the Appendix – "Medical History" and "Oral History Evaluation Form"). Collected data included independent variables categorized under patient/caregiver-related factors, or treatment-related factors, as well as the outcome variable caries relapse. A breakdown of collected variables is found in Table 3. The private pediatric dentistry practice assigned each patient a personal identification (ID) number; a separate "identification key" file was stored on the clinic's protected server. Following ethics approval from University of Toronto Health Sciences Research Ethics Board (Protocol #37142), this previously obtained data was offered for analysis and research purposes to evaluate the dental practice's GA treatment outcomes for quality assessment/quality improvement. All collected patients' archival data was recorded under their assigned ID number allowing data records to remain completely anonymous to protect patient confidentiality. Personally-identifiable information (names, addresses, postal codes) was not

used in data collection or analysis. The private pediatric dentistry practice remains confidential to further protect against any patient identification. All collected data was stored on a hardware encrypted, password protected storage device and on the University of Toronto, Faculty of Dentistry protected server. An independent investigator evaluated and recorded data from 50 patient charts for quality assessment of the previously collected data. The 50 subjects were not selected by computer-generated randomization, but by selecting the first patients treated under GA from each year from 2001-2015. Depending on the number of patients treated under GA in any given year, two to four patients per years were selected for evaluation by a second independent investigator. This non-random selection is a limitation of this study.

3.7 Practice protocols

All included subjects underwent comprehensive dental treatment under GA at the private pediatric dentistry practice. The GA treatment protocol undertaken by the single practitioner at the office was as follows:

- All treatment was completed under rubber damn isolation
- Single surface caries lesions were restored with either composite resin restorations, resin-modified-glass-ionomer (RMGI), or glass ionomer cement (GIC)
- Multi-surface (most) primary posterior tooth caries lesions were restored with a stainless-steel crown (SSC)
- Anterior primary teeth with greater than two carious surfaces were restored with composite resin strip crowns, if possible
- Multi-surface permanent tooth caries lesions were restored with composite resin or SSC as indicated
- Vital primary posterior teeth with caries into the pulp received either formocresol or ferric sulfate pulpotomy, zinc oxide eugenol (ZOE) base, and restored with a SSC
- Any tooth with signs of furcational or periapical involvement, necrotic pulps, or deemed non-restorable was extracted
- All patients received scaling as needed, full mouth polishing and topical fluoride application

The pediatric dentistry practice's follow-up protocol/approach suggested a six-week post-GA follow-up appointment to provide diet counseling, oral hygiene instruction, polishing, and topical fluoride application. A three-month recall interval was suggested, but recall interval was

determined by caregiver acceptance. At each recall, patients received a dental examination (by a single operator), scaling, polishing, topical fluoride, and radiographs as indicated. All new and/or recurrent caries (including demineralized lesions or enamel lesions), as well as failed restorations were noted in digital patient charts at each recall examination. Diet counseling, oral hygiene instruction and other caries risk management interventions/suggestions were offered to caregivers through a Motivational Interviewing approach.

3.8 Collected variables

Collected independent variables were categorized under patient/caregiver-related factors, or treatment-related factors. Variables collected and evaluated were based on the conceptual framework for caries relapse, as well as the availability and accessibility to patient information from patients' dental records. The outcome variable, "caries relapse", was collected and recorded at each 6 month recall examination following comprehensive dental treatment under GA, as outlined in Table 3. Caries relapse was defined as, any new caries or recurrent caries (including any demineralized or non-cavitated lesions) found clinically or radiographically at subsequent recall examinations post-GA. New caries was defined as, any signs of caries (including demineralized, non-cavitated lesions) on a previously non-restored tooth surface. Recurrent caries was defined as, any signs of caries at or around a restoration margin of a previously restored tooth surface. Failed restoration was defined as, the requirement for repair or removal of a previous restoration or previously restored tooth, which is not the result of new or recurrent caries. A list of available variables that have been previously collected, along with each variable type and coding to be used for statistical analysis is found in Table 3.

Table 3. Breakdown of patient data previously collected and to be analyzed for descriptive statistics.

Collected Independent Variables			**Variable type**	**Coding**
Patient/caregiver-related factors	Patient ID		Continuous Numeric	
	Age at GA		Continuous Numeric	
	Gender		Categorical	0 = Male 1 = Female
	ASA status		Categorical	1 = ASA 1 2 = ASA 2 3 = ASA 3
	Medical history*		Categorical	0 = Healthy 1 = Medical comorbidity 2 = Developmental disability 3 = Developmental disability + medical comorbidity
	Behaviour style/ temperament	Active	Categorical (for each style)	0 = No 1 = Yes
		Outgoing		
		Emotional		
		Shy		
		High self esteem		
		Low self esteem		
	Dentition at GA		Categorical	0 = Less than full primary 1 = Full primary 2 = Mixed 3 = Full permanent
	Spaced/non-spaced dentition		Categorical	0 = Spaced 1 = Non-spaced
	Presence of erosion/reflux		Categorical	0 = No 1 = Yes
	Presence of hypoplasia		Categorical	0 = No 1 = Yes

Patient/caregiver-related factors (continued)	Oral hygiene at initial recall		Categorical	0 = Poor 1 = Fair 2 = Good
	Number of recalls attended		Continuous Numeric	
	Insurance type		Categorical	0 = None 1 = Government 2 = Private
	Caregiver dental anxiety level		Categorical	0 = Low 1 = Moderate 2 = High
	Caregiver caries history		Categorical	0 = No 1 = Yes
Treatment-related factors	Year of GA		Continuous	
	Treatment provider		Categorical	0 = Operator 1 1 = Operator 2 2 = Operator 3
	Treatment setting		Categorical	0 = Hospital 1 = Private office
	Treatment rendered under GA	# of SSCs	Continuous Numeric	
		# of pulpotomies	Continuous Numeric	
		# of pulpectomies	Continuous Numeric	
		# of anterior composite crowns	Continuous Numeric	
		# of single surface composite	Continuous Numeric	
		# of multi-surface composite	Continuous Numeric	
		# of extractions	Continuous Numeric	
		# of sealants	Continuous Numeric	
	Remaining surfaces available for caries (SAC)**		Continuous Numeric	

Treatment-related factors (continued)	Caries risk management strategy used if accepted by caregiver	Oral hygiene instruction	Categorical	0 = No 1 = Yes
		Use of Xylitol	Categorical	0 = No 1 = Yes
		Use of casein-phosphopeptide products	Categorical	0 = No 1 = Yes
		Use of high fluoride toothpaste	Categorical	0 = No 1 = Yes
		Use of chlorhexidine	Categorical	0 = No 1 = Yes
		Use of povidone iodine	Categorical	0 = No 1 = Yes
		Fluoride varnish application	Categorical	0 = No 1 = Yes
		Saliva/bacteria testing	Categorical	0 = No 1 = Yes
		Future placement of pit and fissure sealants	Categorical	0 = No 1 = Yes
	Follow-up interval		Categorical	0 = 3 months 1 = 6 months 2 = 9 months 3 = 12 months
Outcome variable (recorded at each 6 month recall post-GA)			**Variable type**	**Coding**
Clinical finding			Categorical	0 = Caries free 1 = New caries 2 = Recurrent caries 3 = New + recurrent caries 4 = Failed restoration
Binary outcome (caries relapse)			Categorical	0 = Caries free 1 = Caries relapse
Time to event			Continuous (six month intervals)	

***** Patients were grouped into one of four medical history groups that were mutually exclusive. Those with medical comorbidities only (group 1) include patients with medical conditions only, such as cardiac conditions, asthma or respiratory conditions, GERD, seizures etc. Those with developmental comorbidities only (group 2) include patients with conditions such as Autism spectrum disorder, ADHD etc. without additional medical comorbidities. Those grouped under

medical and developmental comorbidities (group 3) include patients with both a medical comorbidity and a developmental comorbidity, including patients with various syndromes.

** The total number of SAC following GA treatment was calculated based on the following scoring system, as previously used by Graves *et al*.[6] Posterior teeth have five potential surfaces at risk (occlusal, mesial, distal, buccal and lingual) and anterior teeth have four potential surfaces at risk (mesial, distal, labial, lingual). Missing teeth, or teeth with full coverage SSCs will receive a SAC score of zero.

3.9 Sample size calculation

The reported caries relapse rates from previous studies ranges from 7-100% within 6-144 months post-GA.[4-8,15-19,22-27] However, most of the studies that measured caries relapse post-GA had follow-up times ranging from 6-36 months, of which reported caries relapse rates ranged from 21-79% (Table 2).[6-8,15-19,21,23,25,26] Upon reviewing the previous studies' methodologies and definitions, it is suspected that caries relapse rates at 24-36 months post-GA are on the higher end of the reported range. Therefore, we might expect a caries relapse rate of approximately 50% at 24-36 months post-GA. As follow-up time continues beyond 36 months, the available literature becomes limited, however an increase in caries relapse rates is expected to be observed.

A sample size calculation was done using a two-sided Exact (Clopper-Pearson) confidence interval formula for one proportion. With a confidence level of 95%, a sample size of N=104 is needed in order to estimate a confidence interval of 40%-60% (0.4, 0.6), when the true proportion (caries relapse rate) is assumed to be 50% (0.5). When accounting for a 20% dropout rate, the suggested dropout-inflated enrollment sample size is N'=130.

3.10 Data analysis plan

Data was managed and analyzed using SPSS 25 (SPSS Inc.) software. Data from 50 patient charts was collected from two independent examiners to assess inter-examiner reliability for quality assessment of the collected data. A Kappa score of 0.88 was found based on the clinical findings data collected from 50 subjects by two independent examiners.

3.10.1 Descriptive statistics

Descriptive statistics are reported for all collected variables. Categorical variables are reported as frequencies, whereas continuous variables are reported as means with their standard deviation (SD). The investigated outcome of clinical findings following treatment under GA is reported as the frequency of each event. Caries relapse was defined as any new caries or recurrent caries (including any demineralized or non-cavitated lesions) found clinically or radiographically at subsequent recall examinations post-GA. The binary outcome, caries relapse, has been reported as a frequency as well.

3.10.2 Survival analysis

A survival analysis was used to evaluate caries relapse over time. The binary dependent variable in survival analysis is the occurrence of caries relapse as related to time post-GA. The time to event was measured in months post-GA (in six month intervals). Subjects who did not experience caries relapse during their individual follow-up period or until they have dropped out of the study, were right censored. The dependent variable in the survival analysis is composed of two parts: one is the time to caries relapse, and the other is the event status (caries free = 0, or caries relapse = 1). A Kaplan-Meier survival plot and one-minus-survival plot were used to illustrate survival and caries relapse rates. The survival function and one-minus-survival functions were used to describe the distribution of events over time. The one-minus-survival function gives the proportion of subjects who experienced caries relapse over time; illustrating the caries relapse rate over time in our sample. Survival analysis assumes the mechanism for censoring subjects must be unrelated to the probability of event (caries relapse) occurring; this assumption is known as non-informative censoring.

3.10.3 Bivariate analysis

Bivariate analysis was completed to assess any associations between the independent variables and the binary outcome caries relapse. Pearson's Chi square test and t test were used to evaluate associations of caries relapse with categorical variables and continuous variables, respectively. A p-value of <0.05 was considered statistically significant.

3.10.4 Logistic regression

Binary logistic regression was used to evaluate the association of independent variables with the binary outcome caries relapse. Odds ratios were used to describe the association between independent variables and caries relapse. A p-value of <0.05 was considered statically significant.

3.10.5 Determining the final regression model

With a sample size of 261, and a subset of 162 subjects with a positive outcome for the binary outcome variable, 10-15 variables were considered the appropriate number of variables to include in the final regression model. Commonly in biostatistics, one variable per 10-15 positive outcomes is arbitrarily considered adequate to avoid overfitting the regression model. Overfitting a model will poorly describe the relationship between variables and instead describe the random error in the data; leading to misleading results. The final regression model was selected by considering the following:

- Conceptual framework of caries relapse
- Availability of data/variables for collection
- Selecting and eliminating certain highly correlated independent variables
    - To limit collinearity within the model
    - Pearson's correlation coefficient <-0.7 or >0.7
- Previously reported variables associated, or considered to be associated with caries relapse
- Evaluating descriptive statistics to assess variance of outcomes of each variable (excluded if outcome approximately $<10\%$ or $>90\%$)
- Results from bivariate analysis of independent variables' association with caries relapse
- Variables expected to have clinical significance in pediatric dentistry, as related to caries relapse

Modification/combining of some of the categories of certain categorical variables was done in order to limit the degrees of freedom in the final model and further prevent overfitting the model. The breakdown of variables and categories included in the final regression model is found in Table 4. The permanent dentition category of the dentition at GA variable was excluded from the regression analysis as there was only one subject treated under GA in the permanent

dentition. Excluding the permanent dentition category further lowers the degrees of freedom in the regression model.

Table 4. Breakdown of variables and categories included in the final regression model.

Variable in final regression model
Medical History Healthy (reference) Medical comorbidity Developmental & (medical + developmental) comorbidity
Active behaviour type No (reference) Yes Not reported
Dentition at GA 1. Full primary (reference) 2. Less than full primary 3. Mixed
Anterior spaced dentition Spaced (reference) Non-spaced
Oral hygiene at 1st recall Good or fair (reference) Poor
Number of pulpotomies
Number of strip crowns
Number of multisurface composites
Number of surfaces available for caries

Chapter 4
Results

4 Results

4.1 Descriptive results

Of the 483 patients that received comprehensive dental treatment under GA during the study period, 261 were included in the study. A Kappa score of 0.88 was found based on the clinical findings data collected from 50 subjects by two independent examiners, which showed excellent inter-examiner reliability. The mean age of patients included in the study was 4.4 ± 1.8 years, with 79.3% of patients under six years of age. Slightly more males (56.3%) than females were included; the majority of patients were ASA 1 (77%) (Tables 5 and 6). Patients with medical comorbidities included those with asthma, seizures, GERD, and cardiac conditions among others. Patients with developmental comorbidities included those with autism spectrum disorder, developmental delay, attention deficit disorder, visual or hearing impairment among others. Patients with both medical and developmental comorbidities included those with conditions such as Down syndrome, cerebral palsy with a seizure disorder, other various syndromes, or any combination of both medical and developmental conditions. The majority of included patients had a full primary dentition (76.2%) at the time of GA, with approximately half the patients presenting with either spaced (48.7%) or non-spaced (51.3%) anterior dentition. Frequencies of patient and caregiver information, dental status at time of GA, GA provider, GA setting, as well as acceptance of various caries risk management approaches by caregivers post-GA are found in Table 5. Overall, the mean follow-up time post-GA was 49.9 ± 34.9 months, with a range of 6-180 months. Of all the patients treated 37.2% received at least one pulpotomy, while only 9.6% received at least one pulpectomy. Furthermore, 69.3% of patients received four or more SSCs, 22.6% of patients received one or more composite strip crowns, 42.1% received one or more multisurface composite restorations, and 39.1% received one or more extractions. The means ± standard deviation of dental treatment provided under GA, along with remaining number of SAC post-GA are shown in Table 6. Of the 261 patients in this study, 99 (37.9%) remained caries free (no caries relapse) while 162 (62.1%) experienced caries relapse during their individual follow-up period. New caries [97 (37.2%)] was the most common sign for caries relapse, followed by recurrent caries [47 (18%)], and further by both new and recurrent caries [16, (6.1%)] found at

subsequent recall examination post-GA. Frequencies of clinical findings at recall examinations, as well as binary caries relapse outcome frequencies are found in Table 7.

Table 5. Descriptive statistics of collected categorical variables.

Collected categorical variable	N (%)
Gender	
Male	147 (56.3)
Female	114 (43.7)
ASA status	
ASA 1	201 (77.0)
ASA 2	53 (20.3)
ASA 3	7 (2.7)
Medical history	
Healthy	193 (73.9)
Medical comorbidity	40 (15.3)
Developmental comorbidity	19 (7.3)
Medical + developmental	9 (4.3)
Active	
No	96 (36.8)
Yes	119 (45.6)
Not reported	46 (17.6)
Outgoing	
No	113 (43.3)
Yes	102 (39.1)
Emotional	
No	135 (51.7)
Yes	80 (30.7)
Shy	
No	106 (40.6)
Yes	109 (41.8)
High self-esteem	
No	183 (70.1)
Yes	32 (12.1)
Low self-esteem	
No	210 (80.5)
Yes	5 (1.9)
Dentition at GA	
Less than full primary	12 (4.6)
Full primary	199 (76.2)
Mixed	49 (18.8)
Permanent	1 (0.4)
Anterior spacing	
Spaced	127 (48.7)
Non-spaced	134 (51.3)
Dental erosion	
No	193 (73.9)
Yes	68 (26.1)

Dental hypomineralization	
No	228 (87.4)
Yes	33 (12.6)
Oral hygiene at 1st recall	
Poor	191 (73.2)
Fair	53 (20.3)
Good	17 (6.5)
Insurance	
None	48 (18.5)
Government	52 (20.0)
Private	160 (61.5)
Caregiver dental anxiety	
Low	86 (33.0)
Moderate	83 (31.8)
High	37 (14.2)
Not reported	55 (21.1)
Caregiver caries history	
No	20 (7.7)
Yes	156 (59.8)
Not reported	85 (32.6)
GA provider	
Provider 1	226 (86.6)
Provider 2	8 (3.1)
Provider 3	27 (10.3)
GA setting	
Hospital	170 (65.1)
Private office	91 (34.9)
Oral hygiene instruction	
No	47 (18.0)
Yes	214 (82.0)
Xylitol products	
No	240 (92.0)
Yes	21 (8.0)
Casein-phosphopeptide products	
No	203 (77.8)
Yes	58 (22.2)
High fluoride toothpaste	
No	241 (92.3)
Yes	20 (7.7)
Chlorhexidine	
No	246 (94.3)
Yes	13 (5.0)
Povidone iodine	
No	255 (97.7)
Yes	6 (2.3)

Professional fluoride varnish application	
No	5 (1.9)
Yes	256 (98.1)
Saliva/bacteria testing	
No	248 (95.0)
Yes	13 (5.0)
Placement of pit and fissure sealants post-GA	
No	79 (30.3)
Yes	182 (69.7)
Recall interval	
3 months	12 (4.6)
6 months	186 (71.5)
9 months	61 (23.5)
12 months	1 (0.4)

Table 6. Descriptive statistics of collected continuous variables

Collected continuous variable	**Mean ± standard deviation**
Age at GA	4.4 ± 1.8
Number of recall attended	6.5 ± 5.0
Number of stainless steel crowns	4.6 ± 2.6
Number of pulpotomies	0.6 ± 1.0
Number of pulpectomies	0.2 ± 0.8
Number of composite strip crowns	0.7 ± 1.4
Number of single surface composites	1.7 ± 2.0
Number of multisurface composites	1.2 ± 1.8
Number of extractions	1.0 ± 1.7
Number of sealants	0.6 ±1.5
Number of surfaces available for caries (SAC)	62.8 ± 16.5
Total follow-up time (months)	49.9 ± 34.9

Table 7. Descriptive statistics of the outcome variable.

Outcome variable	N (%)
Clinical finding	
Caries free	99 (37.9)
New caries	97 (37.2)
Recurrent caries	47 (18.0)
New + recurrent caries	16 (6.1)
Failed restoration	2 (0.8)
Caries relapse	
Caries free	99 (37.9)
Caries relapse	162 (62.1)

4.2 Survival analysis

Survival analysis using a Kaplan-Meier plot (Figure 2) illustrates the proportion of patients remaining caries free (no caries relapse) over the total follow-up time. A one-minus-survival function plot (Figure 3) illustrates the caries relapse rate over the total follow-up time. From this analysis, a caries relapse rate of 48%, 62%, 71%, and 87% was found in our study sample at 24 months, 36 months, 48 months, and 120 months post-GA, respectively. Caries relapse was seen as early as three months post-GA in five patients, while one subject remained caries free until they were lost to follow-up at 150 months post-GA.

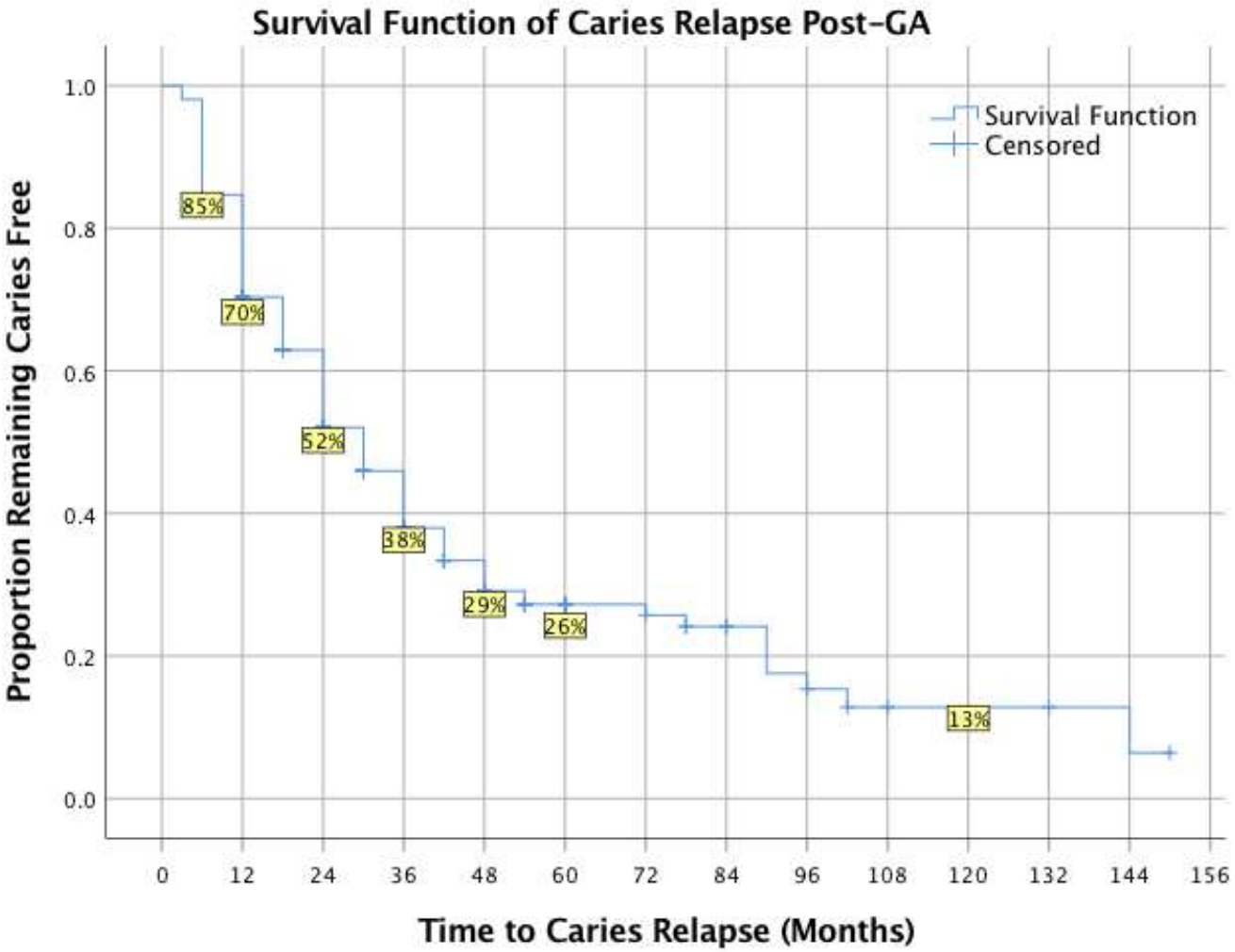

Figure 2. Kaplan-Meier curve illustrating the proportion of patients remaining caries free over the total follow-up period.

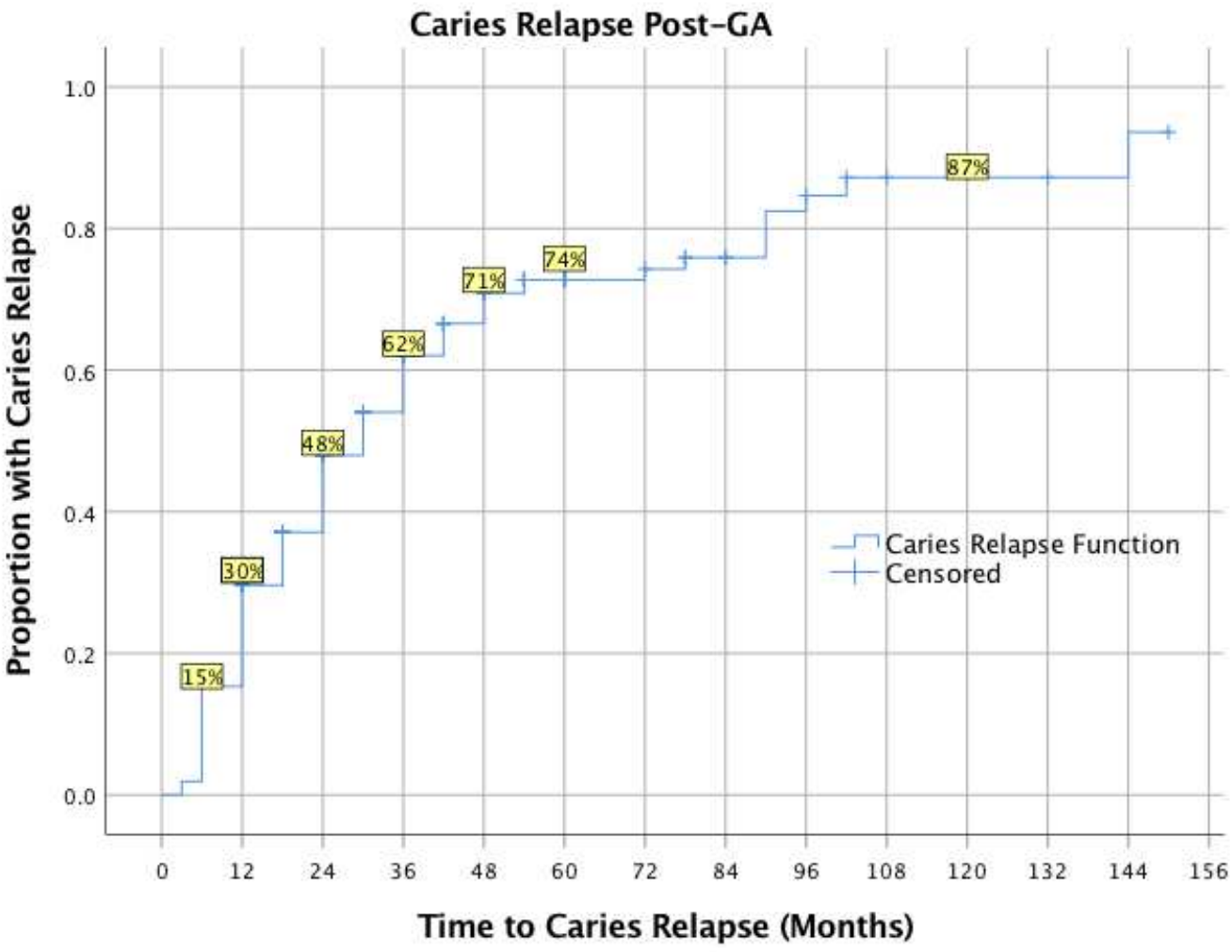

Figure 3. A One minus survival curve illustrating the proportion of patients who experience caries relapse over the total follow-up period.

4.3 Predictors of caries relapse

The relationship of independent variables on caries relapse as determined by bivariate analysis is found in Table 8. Pearson's Chi square test and t-test found several independent variables to be correlated with caries relapse. Of all the variables analyzed with caries relapse, active behaviour status, dentition at GA, anterior spacing of dentition, caregiver level of dental anxiety, caregiver history of caries, GA provider, age at GA, number of recalls attended, and total follow-up time were significantly associated with caries relapse ($p<0.05$). Additionally, the number of pulpectomies, composite strip crowns, multisurface composite restorations, and extractions were found to be significantly associated with caries relapse ($p<0.05$).

In the final regression model, adjusting for the included covariates in a logistic regression, a number of variables were found to be significantly associated with caries relapse ($p<0.05$), as shown in Table 9. Those whose caregivers responded positively for active behaviour status of their child were twice as likely to have caries relapse compared to negative responses for active behaviour (OR = 2.095, 95% CI 1.135-3.865), while those who did not report on child behaviour status were even more likely to experience caries relapse (OR = 2.399, 95% CI 1.007–5.711). Patients treated under GA with mixed dentition were found to be 75% less likely to experience caries relapse compared to patients treated with full primary dentition (OR = 0.252, 95% CI 0.099-0.642). Furthermore, patients who received one additional multisurface composite restoration were found to be more likely to experience caries relapse (OR = 1.289, 95% CI 1.041-1.598). Lastly, with a greater number of remaining SAC post-GA, a greater likelihood of experiencing caries relapse was found in the fully adjusted model (OR = 1.029, 95% CI 1.006-1.053).

Table 8. Variables stratified according to caries relapse outcome during follow-up.

Variables	**Caries Free (N = 99)**	**Caries Relapse (N = 162)**	**p value**
Gender			0.221
Male N (%)	51 (34.7)	96 (65.3)	
Female N (%)	48 (41.1)	66 (57.9)	
ASA status			0.748
ASA 1 N (%)	75 (37.3)	126 (62.7)	
ASA 2 N (%)	22 (41.5)	31 (58.5)	
ASA 3 N (%)	2 (28.6)	5 (71.4)	
Medical history			0.689
Healthy N (%)	71 (37.3)	121 (62.7)	
Medical comorbidity N (%)	17 (42.5)	23 (57.5)	
Developmental comorbidity N (%)	8 (42.1)	11 (57.9)	
Medical + Developmental N (%)	2 (22.2)	7 (77.8)	
Active			**0.008**
No N (%)	48 (50.0)	48 (50.0)	
Yes N (%)	38 (31.9)	81 (68.1)	
Not reported N (%)	13 (28.3)	33 (71.7)	
Outgoing			0.435
No N (%)	48 (42.5)	65 (57.5)	
Yes N (%)	38 (37.3)	64 (62.7)	
Emotional			0.773
No N (%)	55 (40.7)	80 (59.3)	
Yes N (%)	31 (38.8)	49 (61.3)	
Shy			0.504
No N (%)	40 (37.7)	66 (62.3)	
Yes N (%)	46 (42.2)	63 (57.8)	
High self-esteem			0.938
No N (%)	73 (39.9)	110 (60.1)	
Yes N (%)	13 (40.6)	19 (59.4)	
Low self-esteem			1.000
No N (%)	84 (40.0)	126 (60.0)	
Yes N (%)	2 (40.0)	3 (60.0)	
Dentition at GA			**<0.005**
Less than full primary N (%)	2 (16.7)	10 (83.3)	
Full primary N (%)	66 (33.2)	133 (66.8)	
Mixed N (%)	31 (63.3)	18 (36.7)	
Permanent N (%)	0 (0.0)	1 (100.0)	
Anterior spacing			**<0.005**
Spaced N (%)	63 (49.6)	64 (50.4)	
Non-spaced N (%)	36 (26.9)	98 (73.1)	

Dental erosion			0.726
No N (%)	72 (37.3)	121 (62.7)	
Yes N (%)	27 (39.7)	41 (60.3)	
Dental hypomineralization			0.181
No N (%)	83 (36.4)	145 (63.6)	
Yes N (%)	16 (48.5)	17 (51.5)	
Oral hygiene at 1st recall			0.308
Poor N (%)	68 (35.6)	123 (64.4)	
Fair N (%)	22 (41.5)	31 (58.5)	
Good N (%)	9 (52.9)	8 (47.1)	
Insurance			0.088
None N (%)	21 (43.8)	27 (56.3)	
Government N (%)	13 (25.0)	39 (75.0)	
Private N (%)	65 (40.6)	95 (59.4)	
Caregiver dental anxiety			**0.001**
Low N (%)	25 (29.1)	61 (70.9)	
Moderate N (%)	46 (55.4)	37 (44.6)	
High N (%)	13 (35.1)	24 (64.9)	
Not reported N (%)	15 (27.3)	40 (72.7)	
Caregiver caries history			**0.034**
No N (%)	10 (50.0)	10 (50)	
Yes N (%)	66 (42.3)	90 (57.7)	
Not reported N (%)	23 (27.1)	62 (72.9)	
GA provider			**0.006**
Provider 1 N (%)	94 (41.6)	132 (58.4)	
Provider 2 N (%)	2 (25.0)	6 (75.0)	
Provider 3 N (%)	3 (11.1)	24 (88.9)	
GA setting			0.142
Hospital N (%)	59 (34.7)	111 (65.3)	
Private office N (%)	40 (44.0)	51 (56.0)	
Oral hygiene instruction			0.348
No N (%)	15 (31.9)	32 (68.1)	
Yes N (%)	84 (39.3)	130 (60.7)	
Xylitol products			0.987
No N (%)	91 (37.9)	149 (62.1)	
Yes N (%)	8 (38.1)	13 (61.9)	
Casein-phosphopeptide products			0.066
No N (%)	83 (40.9)	120 (59.1)	
Yes N (%)	16 (27.6)	42 (72.4)	
High fluoride toothpaste			0.215
No N (%)	94 (39.0)	147 (61.0)	
Yes N (%)	5 (25.0)	15 (75.0)	
Chlorhexidine			0.082
No N (%)	97 (39.4)	149 (60.6)	
Yes N (%)	2 (15.4)	11 (84.6)	

Povidone iodine No N (%) Yes N (%)	 98 (38.4) 1 (16.7)	 157 (61.6) 5 (83.3)	0.277
Professional fluoride varnish application No N (%) Yes N (%)	 2 (40.0) 97 (37.9)	 3 (60.0) 159 (62.1)	0.923
Saliva/bacteria testing No N (%) Yes N (%)	 95 (38.3) 4 (30.8)	 153 (61.7) 9 (69.2)	0.585
Placement of future sealants No N (%) Yes N (%)	 30 (38.0) 69 (37.9)	 49 (62.0) 113 (62.1)	0.992
Recall interval 3 months N (%) 6 months N (%) 9 months N (%) 12 months N (%)	 4 (33.3) 77 (41.4) 17 (27.9) 1 (100.0)	 8 (66.7) 109 (58.6) 44 (72.1) 0 (0.0)	0.151
Age at GA (mean ± SD)	4.96 ± 1.65	4.13 ± 1.84	**<0.005**
Number of recall attended (mean ± SD)	4.71 ± 4.05	7.65 ± 5.16	**<0.005**
Number of stainless-steel crowns (mean ± SD)	4.97 ± 2.51	4.44 ± 2.59	0.109
Number of pulpotomies (mean ± SD)	0.69 ± .10	0.60 ± 0.99	0.486
Number of pulpectomies (mean ± SD)	0.06 ± 0.28	0.31 ± 0.92	**0.001**
Number of composite strip crowns (mean ± SD)	0.35 ± 1.02	0.96 ±1.59	**<0.005**
Number of single surface composites (mean ± SD)	1.49 ±1.77	1.80 ± 2.07	0.221
Number of multisurface composites (mean ± SD)	0.67 ± 1.21	1.44 ± 2.06	**<0.005**
Number of extractions (mean ± SD)	1.33 ± 1.79	0.86 ± 1.54	**0.030**
Number of sealants (mean ± SD)	0.42 ± 1.19	0.65 ± 1.64	0.192
Number of surfaces available for caries (SAC) (mean ± SD)	60.59 ± 15.90	64.07 ± 16.79	0.098
Total follow-up time (months) (mean ± SD)	35.62 ± 26.27	58.63 ± 36.67	**<0.005**

Table 9. Caries relapse associated variables from binary logistic regression of the final regression model.

Covariate		**p value**	**Odds Ratio**	**95% CI for OR**	
				Lower limit	**Upper limit**
Medical history	Medical vs healthy Developmental ± medical vs healthy	0.267 0.554	0.640 1.332	0.291 0.515	1.408 3.447
Active behaviour	Yes vs no No response vs no	**0.018** **0.048**	**2.095** **2.399**	1.135 1.007	3.865 5.711
Dentition at GA	Less than full primary vs primary Mixed vs primary	0.927 **0.004**	1.083 **0.252**	0.198 0.099	5.921 0.642
Anterior spacing	Non-spaced vs spaced	0.142	1.648	0.846	3.211
OH at 1st recall	Poor vs fair/good	0.103	1.709	0.897	3.257
Insurance Type	Government vs none Private vs none	0.583 0.908	1.316 0.956	0.495 0.448	3.500 2.040
# of pulpotomies		0.713	1.061	0.773	1.456
# of strip crowns		0.159	1.196	0.932	1.535
# of multi-surf composite		**0.020**	**1.289**	1.041	1.598
# SAC		**0.012**	**1.029**	1.006	1.053

Odds ratios are adjusted for other variables in the model. Significant findings ($p<0.05$) are in bold. The odds ratio is the odds of caries relapse relative to the reference covariate group (for categorical variables), or the increased odds of caries relapse for a one unit increase of continuous variables, with all other variables remaining constant. Explained variation in the outcome variable (caries relapse) = 26.2% from the Nagelkerke R Square value.

Chapter 5
Discussion and Conclusion

5 Discussion and conclusion

5.1 Discussion

5.1.1 Caries relapse rates compared to previous studies

Of the 261 subjects included in this study, 62% experienced caries relapse during their individual follow-up time post-GA; which is within the previously reported range of caries relapse. From the 17 full papers and two abstracts on caries relapse post-GA, the reported caries relapse rate ranges from 7-100% with follow-up times ranging from six months to 15 years, and sample sizes ranging from one to 431. [4-9,15-27] Most previous studies report caries relapse with follow-up times of 6-36 months post-GA; of those available full texts the caries relapse rates range from 22%-79%. [5-8,16-19,21,23,25,26] In comparison to previous studies, the current study's sample size of 261 is on the higher end of the range compared to previous studies, and has a considerably longer follow-up period than most previous studies. Subject follow-up time in this study ranged from 6-180 months. As with any retrospective study, patient dropout and loss to follow-up was a limitation. As expected, the number of subjects followed decreased with greater follow-up time post-GA. However, even at relatively long follow-up (e.g. ≥ 36 months) this study has a relatively large remaining sample; at 36 months, 48 months, 60 months, and 120 months post-GA, there were 158, 124, 102, and 22 subjects seen for recall examination, respectively.

Noteworthy caries relapse rates from the study are 15% at 6 months, 30% at 12 months, 48% at 24 months, and 62% at 36 months post-GA. Furthermore, caries relapse rates in the study were found to be 71% at 48 months, 74% at 60 months, and 87% at 120 months post-GA. The caries relapse rate found in this study was on the higher end of previously reported range. Given that the follow-up time is greater than most previous studies, the caries relapse rates are expected to be higher, as caries relapse is cumulative with time following treatment under GA. Notably, not all non-cavitated/demineralized lesions (positive for caries relapse) progressed to cavitated lesions requiring surgical intervention, and instead may have remained stable after being diagnosed.

Another factor contributing to the relatively high caries relapse rate is the stated definition for caries relapse. There is considerable inconsistency in the definition of caries relapse in the previous literature, which could have lead to an underestimation of caries relapse rates in comparison to this study. A number of studies only included new caries in their definition for caries relapse, and excluded those with recurrent caries. Also a number of studies recognized only cavitated lesions, lesions into dentin, or lesions requiring surgical treatment as caries relapse, and did not include the presence of demineralized or non-cavitated lesions in their caries relapse definition. The current study defines caries relapse as, any signs of new caries or recurrent caries (including demineralized or non-cavitated lesions) in a patient with a previous history of treated caries. Only Amin *et al.* [17] reported using the same criteria for caries relapse. Inclusion of both new and recurrent caries as well as both cavitated and non-cavitated lesions allows for a more accurate representation of ongoing caries progression following comprehensive dental treatment, and better indicates the presence of ongoing active disease. Caries relapse rates in this study are expected to be higher than those with less comprehensive caries relapse criteria. Some previous studies' caries relapse rates are therefore underestimated when considering a comprehensive definition.

Of the 162 subjects who experienced caries relapse, 97 (60%) and 47 (29%) were as a result of new caries, and recurrent caries, respectively. This finding is inconsistent with those found by Jamieson and Vargas, [8] who found 73% of subjects with caries relapse to be the result of recurrent caries, while only 27% were as a result of new caries. This difference may be attributed to differences in clinical operator, as well as treatment approaches under GA. The aim of a more aggressive treatment approach is to limit the number of SAC post-treatment, as well as limit the opportunity for recurrent caries. This can be achieved by placing more full coverage restorations (e.g. SSCs), rather than intracoronal composite or amalgam restorations with the potential for recurrent caries. The diagnosis of new caries at follow-up may have been found on previous untreated teeth, or teeth that received intracoronal restorations. Patients that were treated with less than full primary dentition are likely to have new caries on newly erupted primary teeth, while patients treated in the primary or mixed dentition may still experience new caries on newly erupted permanent in their respective follow-up time post-GA. As this study has relatively long-term follow-up post-GA, the incidence of new caries is evident due to the eruption of permanent teeth with longer follow-up in high caries risk patients.

5.1.2 Study sample and patient-related factors to caries relapse

Most research on caries relapse post-GA has limited its sample to healthy children, often under the age of six, and/or is limited to subjects with only a primary dentition. Pediatric dentistry involves the care of patients under the age of 18, including the care of those with more complex medical histories, or special health care needs. Notably, this study includes all pediatric patients treated at a single private pediatric dentistry practice with no age, dentition stage, ASA status, or medical history restrictions at the time of GA. Amin *et al.* [17] reported higher caries relapse rates in ASA 2 patients compared to ASA 1 patients. El Batawi *et al.* [23] found that patients with special health care needs were more likely than healthy patients to undergo subsequent dental treatment under GA, and Lin *et al.* [25] found that patients with preexisting medical problems had higher caries relapse rates. This study did not find a significant association between ASA status or medical history with caries relapse post-GA. However, there were non-significant trends found that are worth noting. Subjects that were ASA 3 showed higher caries relapse rates (71.4%) overall, compared to ASA 1 (62.7%) or ASA 2 (58.5%). Additionally, subjects with both medical and developmental comorbidities were found to have higher caries relapse rates (77.8%) compared to those who were healthy (62.7%), with medical comorbidities alone (57.5%), or with developmental comorbidities alone (57.9%). A larger sample size, or greater proportion of medically and/or developmentally complex patients may produce significant findings. However, likely due to the small sample of ASA 3 and medically and developmentally complex patients, only a non-significant trend was found.

Dentition at GA has been previously reported to be associated with caries relapse post-GA. Amin *et al.* found that patients with less than full primary dentition were more likely to experience caries relapse compared to those treated with full primary dentition or mixed dentition. [17] The results of this study support the findings reported by Amin *et al.* [17] A Chi-square test found a statistically significant association between stage of dentition at GA and caries relapse ($p<0.005$). Of the 12 subjects treated under GA with less than full primary dentition 10 (83.3%) experienced caries relapse in their individual follow-up period. This caries relapse frequency was greater than that experienced by subjects with full primary dentition (66.8%). Meanwhile, caries relapse frequency of subjects treated in the mixed dentition (36.7%) was significantly less than that of subjects with full primary dentition or less than full primary dentition. Logistic regression of the final adjusted model found that subjects treated in the mixed

dentition were 75% less likely to experience caries relapse compared to those treated with a full primary dentition (OR = 0.252). Regression analysis did not find a significant association for caries relapse with subjects with less than full primary dentition, with an odds ratio of 1.082 (95% CI for OR = 0.198, 5.921). The large confidence interval can likely be attributed to the low sample size (N=12) of subjects treated with less than full primary dentition in this study, which is a limitation of this study. However, the trends found between dentition stage and caries relapse support the previously reported findings. Caregivers of children treated with less than full primary dentition often maintain poor oral hygiene and diet behaviours which continue to predispose their high caries-risk children to caries relapse. [37]Typically, within 12 months post-GA these children's second primary molars erupt into the oral cavity, increasing the number of available surfaces for caries, often requiring subsequent treatment under GA due to young age and pre-cooperative behaviour. Results of previous studies as well as the findings from this study, discourage comprehensive dental treatment under GA in children with less than full primary dentition as a result of high caries relapse rates. Interim treatments or caries management may include the use of silver diamine fluoride, or interim therapeutic restorations until comprehensive treatment promises greater success rates. If treatment under GA is undertaken once all primary teeth are erupted, consideration for full coverage restorations with SSCs should be made for non-carious second primary molars that are at high risk for new caries if otherwise left untreated.

Age of the child at GA has not previously been found to be significantly associated with caries relapse post-GA, although it is correlated with dentition at GA, and that has shown to have an association, as stated above. On average, subjects with caries relapse were treated under GA at a statistically significantly younger age (4.13 ± 1.84) compared to subjects who remained caries free (4.96 ± 1.65). As age at GA was found to be highly correlated with dentition at GA, only one variable (dentition at GA) was included in the final regression model. Younger patients are more likely to be treated with less than full primary dentition, or with newly erupted full primary dentition. In either case, the unerupted or newly erupted primary teeth may not have had sufficient exposure time in the mouth to exhibit clinical signs of caries. It is therefore anticipated that these young children will have high caries relapse rates relatively soon after GA treatment if tooth surfaces are still available for caries, and they remain high caries risk children.

Child behaviour and temperament have previously been reported to be associated with caries risk and ECC. [37,47,54,58] Limited literature exists on the relationship between caries relapse and child temperament. Sheller *et al.* reported difficult child temperament as described by the caregiver was associated with repeat dental treatment under GA. [37] Meanwhile, this study was the first to find a significant association between caregiver reported child behaviour and caries relapse. A patient intake questionnaire allowed caregivers to report child temperament as any number of the following temperaments: Active, outgoing, emotional, shy, high self-esteem or low self-esteem. A significant association was found between reported active behaviour and caries relapse. Children of caregivers who reported their child's behaviour to be active were more like to experience caries relapse (68%) than children who were reported as not active (50%). Furthermore, children of caregivers who did not report any response of child temperament were even more likely to experience caries relapse (72%). Logistic regression further supported these results; active children were at 2.1 times more likely than non-active children to experience caries relapse. While children of caregivers who did not report any temperament style were at 2.4 times higher odds of caries relapse compared to non-active children in the regression-adjusted model. These findings suggest that not only does child temperament play a role in caries relapse, but also parenting style. Caregivers who did not report on child's temperament may be an indirect indicator of their level of involvement and responsibility with their children.

Socioeconomic status (SES) and socio-demographic variables have been said to be most important in caries prediction models in young children. [59] Unfortunately, this data was not directly available for collection in this study. However, insurance type may indirectly indicate SES to some degree. Eligibility for government funded dental programs requires patients/caregivers to have a relatively low household income. Subjects with dental insurance that is government funded could therefore be used as an indicator of low SES. This study did not find significant differences between subjects with different insurance types, which is in keeping with previous studies' findings. However, a noteworthy non-significant trend was found. Subjects with government funded insurance types were more likely to experience caries relapse (75%) compared to those without any dental insurance (56%), or those with private dental insurance (59%). The lack of statistically significant findings may be the result of an insufficient sample size to detect a significant difference. The trend supports the expected outcome that

children of low SES are at higher caries risk than others, and are likely at higher risk of caries relapse following treatment under GA.

Two caregiver-related variables that have not been previously studied in relation to caries relapse post-GA are: Caregiver history of caries and caregiver level of dental anxiety. Children of mothers with existing caries have been found to have a greater incidence of ECC. [60] Parental stress, anxiety and depression have also been found to be associated with caries in their children. [61] This study found both caregiver history of caries ($p=0.034$) and caregiver level of dental anxiety ($p=0.001$) to be significantly associated with caries relapse post-GA. An irregular trend was found in relation to caregiver dental anxiety with caries relapse rates of 71%, 45% and 65% in children of caregivers who reported low, moderate and high dental anxiety, respectively. Interestingly, children of caregivers who did not report their level of dental anxiety experienced the highest incidence of caries relapse (73%). Regarding caregiver caries history, only 20 of the 261 caregivers reported "No" history of caries; suggesting the strong familial tendency for caries. Children of caregivers who reported "Yes" for history of caries were slightly more likely to experience care relapse (58%) than children of caregivers who reported "No" (50%). Interestingly, children of caregivers who did not report their caries history were most likely to experience caries relapse (73%). As with the findings from caregiver reported child temperament, a lack of caregiver reporting seems to be associated with a higher incidence of caries relapse. A lack of response to these questions may indicate differences in caregiver personality and parenting styles that may be associated with caries relapse in children following treatment under GA. However, a lack of response to these questions may also have been the result of caregivers not understanding the question, or were potentially uncomfortable answering these personal questions.

Sheller *et al.* previously reported that regular daily brushing of child's teeth by the caregiver following treatment under GA was associated with less frequent repeat GA. [37] Oral hygiene and the presence of plaque on the child's teeth contribute to caries risk. [62,63] This study found a non-significant trend supporting the relationship of oral hygiene and plaque levels with caries relapse. Caries relapse rates of 64%, 59%, and 47% were found in subjects with poor, fair, and good oral hygiene, respectively. It is noteworthy, that even after extensive treatment under GA, only 17 subjects were reported to have "good" oral hygiene at the initial follow-up examination post-GA. Oral hygiene instruction and diet counseling are part of the pediatric

dentistry practice's discussion with caregivers both before and after treatment under GA. However, based on our findings, oral hygiene practices by caregivers did not show much improvement, contributing to the overall high caries relapse rates.

Multiple factors have been suggested for caries risk management, including restorative materials used, recall frequency, use of topical fluoride, antimicrobial agents, remineralizing agents, and additional diagnostic aids.[59] This study is the first to evaluate how caregivers' accepted risk management strategy influences caries relapse rates post-GA. Caries risk management strategies suggested to caregivers included, oral hygiene instruction, use of xylitol products, use of casein-phosphopeptide products, use of high fluoride toothpaste, use of chlorhexidine, use of povidone iodine, professional fluoride varnish application, future placement of pit and fissure sealants, short (three-month) recall frequency, and saliva testing. None of these collected variables were found to be statistically significantly associated with caries relapse post-GA. A limitation of this study was the small number of subjects who accepted various risk management strategies. For example, only 15, 11, 5, and 9 subjects accepted use of high fluoride toothpaste, chlorhexidine, povidone iodine, and saliva testing, respectively. This low acceptance rate may be an indirect indicator of low caregiver motivation. Some degree of caries relapse prevention was optimistically anticipated with the use of some anti-cariogenic products/strategies, however the opposite trend was found. A non-significant trend suggested higher incidence of caries relapse in subjects that used casein-phosphopeptide products, high fluoride toothpaste, chlorhexidine, povidone iodine, and saliva testing. This trend was not expected, however it could be explained as a result of the treating pediatric dentist possibly suggesting the use of various products at recall examination once signs of caries relapse were noted. Use of any of these caries risk management strategies may have been utilized at any time throughout patient follow-up, and not specifically immediately after treatment under GA, creating a bias in the results. Future clinical control trials evaluating the efficacy of various caries risk management strategies on caries relapse post-GA may provide insight into managing caries relapse in these high caries risk patients.

The placement of future pit and fissure sealants after initial treatment under GA was found to have no effect on caries relapse. Tooth-specific clinical findings were not recorded in this study. Therefore it is unknown which teeth experienced new or recurrent caries in patients positive for caries relapse. Even though sealants may have been placed (most commonly

following eruption of first permanent molars), caries relapse may have been evident on any other available tooth surface, as was likely the case given the unchanged caries relapse rates.

Mealtime duration and tooth brushing duration have been previously reported to be associated with caries relapse. [25] Longer meal duration and shorter tooth brushing duration was previously reported to be associated with a higher incidence of caries relapse.[23] Unfortunately, both mealtime duration and tooth brushing duration were not available for data collection in this study.

Compliance to recall examinations post-GA was previously found to be associated with caries relapse. [7,17,23] Patients and caregivers who attended an immediate, two-week, post-op appointment were previously reported to have a lower incidence of caries relapse. [7] Furthermore, patients and caregivers who attended more recall examinations within a 24-36 month post-GA period were previously reported to have a lower incidence of caries relapse. [17,23] A limitation of this study, was that attendance to the suggested six-week post-op exam was not recorded. The pediatric dentistry practice in this study suggested a three-month recall interval to all caregivers following dental treatment under GA. However, the recall interval post-GA was selected by caregiver acceptance. While there were no significant findings between recall interval and caries relapse in this study, there were some noteworthy findings. Subjects who returned for recall on a nine-month recall interval were found to have higher caries relapse (72%) than those on a six-month interval (59%). This supports the previous findings by Amin *et al.*[15] and El Batawi, [23] suggesting more frequent recall and greater recall compliance are associated with a decreased incidence of caries relapse.

Furthermore, even though a three-month recall interval post-GA was suggested to caregivers, only 12 (4.6%) subjects accepted this as part of their management strategy. This speaks to the goals and personalities of caregivers in the study sample. Comprehensive dental treatment under GA is only one behaviour management modality of comprehensive dental treatment. Although it is often selected due to extensive treatment needs and limited patient cooperation; it is also selected based on caregiver preference. [4] Low caregiver motivation and commitment may correspond to selecting GA as the behaviour modality of choice, as well as a less frequent accepted recall interval.

5.1.3 Treatment-related factors: consider an aggressive treatment approach

Graves *et al.* [6] previously suggested a more aggressive treatment approach when managing children with ECC under GA, in hopes of limiting caries relapse outcomes. An aggressive treatment approach intends to limit the number of remaining SAC following comprehensive treatment under GA. Only extractions and placement of SSCs limit the SAC. However, no statistically significant difference has been previously reported between caries relapse and SAC. [6,17,19] Results from this study's Chi-square test indicated a non-significant trend that agrees with Graves *et al.*'s expectations.[6] Overall, subjects with caries relapse had a higher SAC post-GA compared to those who remained caries free. Logistic regression found a significant association between SAC and caries relapse in the adjusted regression model. An odds ratio of 1.029 (p = 0.012) suggests that by increasing the SAC by one, subjects are 3% more likely to experience caries relapse. Although this value seems low, it is important to note that the odds ratio is multiplicative for each increase in SAC (OR = 1.029^difference in SAC). Therefore, with an increase in SAC of 40 surfaces, which corresponds to eight primary molars with five surfaces each, there would be a 3.1 times greater odds of experiencing caries relapse post-GA. Limiting the number of SAC post-GA by utilizing an aggressive treatment approach may limit future caries relapse in these high caries risk patients.

Both Graves *et al.*[6] and Amin *et al.* [17] evaluated the number of SSCs as related to caries relapse post-GA, and found no significant association. This study's findings are in agreement with previous studies, as no significant association was found between the number of SSCs and caries relapse. Given that the treating clinicians in this study, as well as in previous studies have been pediatric dentists or under the supervision of pediatric dentists, one may assume that a similar treatment approaches have been used. Comfort and proficiency in placing SSCs is expected to be greater in specialists in pediatric dentistry compared to most general dentists. Children treated by clinicians who are less aggressive, or prefer to place more multisurface composite restorations rather than SSCs may further suggest the likely superiority of SSCs for limiting caries relapse. Further studies comparing caries relapse rates between different treating clinicians with various treatment approaches may provide better evidence of which treatment approaches lead to better outcomes.

Success rates of multisurface composite restorations have been previously reported to be lower than success rates of SSCs or amalgam restorations. [64] The results of this study support this previous finding, as caries relapse rates were significantly higher in patients with a greater number of multisurface composite restorations. Therefore, one should consider limiting the placement of multisurface composite restorations in children with ECC undergoing comprehensive treatment under GA, and instead consider full coverage restorations such as SSCs to limit the potential for both new and recurrent caries post-treatment.

Patients with more extensive treatment needs at time of GA have been previously reported to have greater caries relapse rates post-GA. [16] Patients that received pulp treatment, either pulpotomy or pulpectomy were noted to experience caries relapse more frequently. This study found the number of pulpectomies performed under GA to be significantly associated with caries relapse, supporting the previous findings by Amin *et al*. [17] However, the number of pulpotomies was not found to be associated with caries relapse, which does not support the findings by Amin *et al*. [17] Pulpectomies are most often performed on primary incisors concurrent with composite strip crown restorations. The association between caries relapse and pulpectomies may actually be confounded by poor success rates, and high caries relapse rates of composite strip crown restorations.

Composite strip crowns on primary incisors have been reported to have lower success rates than most restorations, including SSCs, pit and fissure sealants, single or multisurface anterior composite restorations, single or multisurface posterior amalgam restorations, and class I composite restorations. [64,65] A higher incidence of recurrent caries likely contributes to the reported lower success rate of composite strip crowns. Marginal leakage is a common cause for recurrent caries; unlike stainless steel crowns, composite strip crowns have circumferential resin-bonded margins, which allows for multiple remaining available surfaces for recurrent caries. As previously stated, limiting the SAC was found to decrease the incidence of caries relapse. This study supports these previous findings, as subjects who experienced caries relapse had on average, three times more composite strip crowns placed than those who remained caries free. Limiting the use of anterior composite strip crowns and instead placing SSCs or extracting primary anterior teeth in children under GA may lead to improved clinical outcomes and decreased caries relapse post-GA.

It was previously reported that the number of space maintainers placed under GA was associated with caries relapse. [17] Fewer space maintainers were found to be significantly associated with caries relapse. This previous finding may be correlated with the number of posterior extractions performed under GA, as some cases may be indicated for placement of a space maintainer. Space maintainers were not placed under GA in our study's pediatric dentistry practice, and therefore was not an included treatment-related variable.

Further supporting the role of SAC on caries relapse, the number of extractions performed under GA was found to be significantly associated with caries relapse. The number of extractions is inversely related to SAC. A greater number of extractions, results in fewer available surfaces for caries post-GA, and therefore less potential for caries relapse. Subjects who remained caries free had significantly more extractions than those who experienced caries relapse. Once again, promoting an aggressive treatment approach by limiting the number of surfaces available for caries post-GA as a treatment consideration to limit future caries relapse.

5.1.4 Study strengths and limitations

Compared to most previous studies, this study had the advantage of a relatively large sample size, long-term follow up, a comprehensive caries relapse definition, and a unique patient population with broad subject inclusion criteria. This study included 261 patients treated under GA at a single private pediatric dentistry practice, with a sample size on the higher end of the previous studies' ranges. Follow-up times post-GA ranged from 6 to 180 months post-GA, with over 100 patients followed for at least five years post-GA. A common limitation of previous studies was a limited caries relapse definition that led to underestimations of caries relapse post-GA. In this study the caries relapse definition included both new and recurrent caries as well as cavitated and non-cavitated/demineralized lesions found both clinically and/or radiographically. This complete definition of caries relapse is a more accurate measure of ongoing caries activity post-GA. Inclusion of patients was not restricted based on patients' medical histories, age, or dentition status at the time of GA, which allowed for a broad patient base representative of a private pediatric dentistry practice in Southwestern Ontario.

Caries relapse rates appear to climb fastest within approximately the first four years post-GA, with a caries relapse incidence of 71% at 48 months post-GA in this study sample. Limitation of our study are sample bias and loss to follow-up. Almost half of the subjects

initially treated under GA were excluded, as they did not return to the same pediatric dentistry practice for at least one follow-up exam. This is likely the result of patients returning to their referring general dentists after treatment was completed under GA. The clinical outcomes of these 222 subjects are unknown, and some may not have continued with regular follow-up dental care. Sheller *et al.* previously reported that children undergoing repeat GA for dental treatment were associated with a lack of follow-up dental care. [37] It is expected that the caries relapse rates post-GA in this study are likely an underestimation of the true caries relapse rates in the overall population. Patients that did not maintain regular follow-up dental care at the treating pediatric dentistry practice might have higher caries relapse rates than patients followed in this study. Further studies are needed to evaluate caries relapse patterns in patients who maintain ongoing follow-up dental care at a pediatric dentist's practice compared to at the referring general dentists' practices as well as to those who do not maintain regular follow-up dental care.

The variables included for analysis in this study were selected based on data availability, which poses a limitation of this study. Socioeconomic status (SES) and socio-demographic variables have been said to be most important in caries prediction models in young children. [59] Unfortunately this data was not directly available for collection in this study. Other important variables, such as any environmental factors and other factors included in the conceptual framework of the study were not able to be included. There is still much that could be learned from a study with more rigorous data collection.

5.1.5 Future directions

Eidelman *et al.* compared outcomes following dental treatment completed under GA and treatment completed using oral and nitrous oxide sedation. [12] It was reported that 59% of children treated under GA, and 74% of children treated under sedation required future treatment. The clinical outcomes of treatment related to the quality of restorations, as measured by marginal adaptation, adequate anatomic form, and secondary caries were all found to be worse when completed under sedation compared to under GA. [12] An incomplete preliminary prospective study in the United Kingdom aimed to evaluate caries relapse in children who required dental extractions under GA, inhalational sedation, or local anesthesia. Due to difficulty in recruiting subjects, the study was incomplete. [66] Further studies are needed to compare caries relapse and clinical outcomes of children undergoing comprehensive dental treatment under GA compared to

other (non-GA) behaviour management modalities, such as local anesthesia, nitrous oxide sedation, or oral moderate sedation.

Are children with ECC destined for long-term ongoing caries relapse into the permanent dentition, or can caries progression be slowed or prevented? Studies evaluating caries relapse post-GA as patients transition from the primary to permanent dentition are still needed. Additionally, further studies with tooth-specific data both pre and post treatment are needed to better evaluate long-term prognosis of specific teeth in high caries risk individuals. Hypomineralized and/or hypoplastic teeth are at greater risk for caries and wear, often with irregular presentations; the impact of hypomineralized and/or hypoplastic teeth on caries relapse post-GA is still lacking evidence.

5.2 Conclusion

Caries relapse rates are high in pediatric patients who undergo comprehensive dental treatment under GA. Even with various caries risk management efforts, high caries risk children still often experience caries relapse. Caries relapse was noted as early as three months post-GA, was observed in one out of every two children 24 months post-GA, and observed in seven out of 10 children 48 months post-GA. Early identification of caries relapse risk factors may be useful for guiding treatment and risk management decisions. Caries relapse post-GA was found to be associated with patient or caregiver-related factors, as well as treatment-related factors.

When high caries risk children undergo comprehensive treatment under GA an aggressive treatment approach has shown significant improvements to caries relapse post-GA. Multisurface composite restorations and composite strip crowns have high failure rates in children treated under GA, and lead to higher rates of caries relapse. Aggressive treatment with regular use of SSCs rather than multisurface composite restoration, as well as extraction of primary incisors rather than restorations with composite strip crowns should be considered in order to better control caries relapse post-GA.

Child and caregiver-related factors including child temperament, caregiver history of caries and caregiver level of dental anxiety may provide insight for determining caries relapse risk before treatment is initiated. Questioning caregivers and documentation of these factors should

be considered for inclusion at initial examination prior to treatment under GA to further assess caries relapse risk.

Clinicians should consider a child's stage of dentition at the time of treatment under GA, as it has been repeatedly found to be associated with caries relapse post-GA. Patients with less than full primary dentition have been reported to have higher caries relapse rates than patients with a full primary dentition or mixed dentition. Additionally, patients with a mixed dentition were found to have lower caries relapse rates than patients with a full primary dentition. If initial comprehensive dental treatment under GA can be delayed until the patient is in a more optimal dentition stage, their prognosis and clinical outcomes may be improved by limiting caries relapse experienced. Management of young children with less than full primary dentition with non-invasive interim therapeutic restorations, regular topical fluoride varnish or silver diamine fluoride applications, or urgent extractions with local anesthetic are some interim treatment options that can be considered. These options can be considered to delay comprehensive treatment under GA until the child reaches their full primary dentition when there are improved clinical outcomes post-GA, with lower caries relapse rates.

Poor patient compliance and attendance to follow-up and regular recall examinations have been reported to be associated with caries relapse. Consideration of patients/caregiver compliance and access to regular dental care should be made when treating children under GA or implementing dental public health policies. Patients at greater risk for caries relapse, poor clinical outcomes, and poor compliance or access to regular dental care may benefit from a more aggressive treatment approach.

Furthermore, the conventional surgical approach to managing ECC is not adequately controlling the disease. The high incidence of caries relapse suggests that caries as a disease is still active and progressing after surgical intervention under GA. Dentists should accept the reality of high caries relapse rates post-GA and honestly discuss more realistic expectations and outcomes with caregivers both before and after treatment.

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Appendices

Expanded Literature Review

First studies on caries relapse post-GA: 1972 – 1997

Legault *et al.* [4] was the first to report on caries relapse following dental treatment under GA. These authors analyzed data for 300 children who were treated under GA in Montreal, Canada over a four year period. Indications for GA in 82.4% of all cases were the result of lack of cooperation or extensive caries. The subjects included in this study ranged from 1.5 to 14.7 years of age. It was noted that 54% of cases were between the ages of three and five. Upon completion of GA, patients were told to return for regular dental recall examinations. Follow-up recall exams were done to assess the presence of new caries (caries relapse), and provide further treatment as required. Of the 300 patients treated under GA, 217 (72.4%) returned for follow-up, illustrating the difficulty in maintaining a high sample size in these types of studies as a result of patient dropout. Legault *et al*. reported 84/217 (38.6%) patients required further treatment. The reported range of relapse was 1-34 months post-GA, with a mean time to further treatment at 15.6 months post-GA. Patients that did not require additional treatment within the period of observation were followed from a range of 7-51 months, and mean follow-up time of 16 months. Of the 84 patients with caries relapse, 9 (10.7%) required a repeat GA for treatment to be completed, while 75/84 (89.3%) of patients were able to undergo treatment in the regular dental clinic. This finding suggests that most patients initially treated under GA are able to tolerate future dental treatment needs without the use of GA. Legault *et al.* also reports that the treatment philosophy changed throughout the study, in that later on in the study their treatment approach became more aggressive with greater use of stainless steel crowns (SSCs), and with a greater focus on stressing preventive measures to parents. This change in treatment approach introduced a bias in the study, and it was mentioned that children treated later in the study might have had lower relapse rates. It was then proposed to put greater emphasis on preventive measures, and evaluate how restorative procedures affect the interval until caries relapse. Interestingly, Legault *et al.*'s reported mean of 15.6 months until relapse was said to be indicative of a high standard of care and the authors noted that they were pleased with their results. Future studies do not share

the same opinion on the efficacy of comprehensive dental treatment under GA and caries relapse rates.

O'Sullivan and Curzon were next to report on the efficacy of dental treatment under GA in children. [26] A retrospective chart review was done for patients treated between the years 1984-1987. Patient demographics, initial diagnosis, treatment provided by tooth and tooth surface, operation time and treatment providers were recorded. Follow-up data included: dates of further visits, which restorations required future treatment/replacement, and if subsequent treatment was accepted with local anesthetic or if another GA was required. Eighty children were treated in their study, with an age range of 2-11 (mean age 4.5). Again, most children (55%) were between the ages of 3-5. Treatment under GA included intracoronal restorations - amalgam, composite resin, or glass-ionomer-cement (GIC) - SSCs, formocresol vital pulpotomies, and extractions. Following GA, patients were placed on four-month recall with an emphasis on prevention and behaviour shaping. This included advice on proper oral hygiene practices, fluoride use, and diet counseling. Follow-up rates were similar to Legault *et al.* [4], with 60/80 (75%) of patients presenting for recall. Relapse rates were reported at 65% of cases requiring future treatment at two years post-GA. Eighty percent of these patients tolerated future treatment under local anesthetic, without the use of GA.

O'Sullivan and Curzon also found that success rates of SSCs were significantly more successful than all intracoronal restorations. [26] They reported failed restorations to be primarily the result of recurrent decay, poor retention of class V restorations, and heavy wear of GIC restorations. Full coverage restorations, such as SSCs provides the best success rates in these high caries risk patients who initially present with poor oral hygiene and poor diet; suggesting that increased use of SSCs in high risk patients may decrease caries relapse rates post-GA by limiting the potential of recurrent caries.

In 1997, Berkowitz *et al.* reported on clinical outcomes of ECC treated under GA. [18] The study included 84 Medicaid children, all of low socio-economic-status (SES), ranging from 21-68 months of age were treated under GA for comprehensive dental treatment. [18] Treatment was provided at the Ambulatory Surgical Center of Strong Memorial Hospital in Rochester, NY. Included subjects required a pre-op diagnosis of nursing caries (ECC), which was defined as having caries affecting two or more primary maxillary incisors visible into dentin, as well as a

history of bedtime nursing bottle use after 12 months of age. Following GA, returning patients underwent a follow-up examination at 4-6 months post-GA. Of the 84 children initially treated, only 24 (28.6%) returned for follow-up within 6 months. This is a substantial dropout rate of over 70%, primarily the result of included patients being referred for treatment at this tertiary care center. Tertiary care centers may not promote the best patient relationships or establish long-term preventive behaviours. A study comparing follow-up rates and caries relapse of patients treated in a private practice setting compared to being referred to a hospital setting would be valuable. [8,18]

Berkowitz *et al.* reported caries relapse in 13/24 (54.2%) of remaining patients at 6 months follow-up. [18] The dropout patients were less compliant with follow-up recommendations and therefore may be less compliant with oral hygiene and diet recommendations resulting in potentially greater rates of caries relapse than reported. Berkowitz *et al.*'s definition of caries relapse does not include demineralized, non-cavitated lesions; as a result caries relapse rates would have been greater than reported had these lesions been included.

Caries relapse post-GA: 2000 – 2009

Adding to the limited literature, Almeida *et al.* completed a retrospective study using dental records of children treated under GA at Franciscan Children's Hospital & Rehabilitation Center in Boston, MA. [15] Forty-two healthy patients who underwent dental GA as a result of ECC were included in the study, with ages ranging from 1.9-4.9 years. Within the first 12 months, 57% of patients returned for follow-up, once again demonstrating poor compliance and high drop-out rates, and small sample sizes common in these types of studies. Within 24 months follow-up, 33/42 (79%) of patients from the ECC group were positive for caries relapse, seven of which required retreatment under GA. The study's strategy of increased prevention for high caries risk children was not successful at decreasing caries in these children. The implementation of other methods to reduce or prevent future caries progression is required. Possible approaches to improve caries relapse rates needs further research, including the use of chlorhexidine, and fluoride varnish. [15]

Almeida *et al.*'s study also included a control group of 31 healthy, caries-free children. [15] The ECC groups were given more intensive preventive programs including diet counseling, oral hygiene instruction, and recommendations for fluoride toothpaste. All patients in the ECC group

also presented for a 1-week post-op visit. Both groups were seen at 6-9 month follow-ups over a two-year period. Significantly fewer children from the initially caries-free group developed new caries within the 24 months follow-up, only 9/31 (29%). This further demonstrates the fact that patients with a previous history of ECC are at greater risk for developing new caries in the future compared to initially caries-free patients. Between the two groups, the prevalence of smooth surface caries was greater than pit and fissure caries in the ECC group; however, pit and fissure caries was found to be more prevalent than smooth surface caries in the initially caries-free group.

Chase *et al.* and Graves *et al.* studied a sample of children that received dental treatment under GA at the Ambulatory Surgical Center of the Strong Memorial Hospital at the University of Rochester Medical Center in Rochester, NY.[21] The 79 children included in these studies presented with ECC, were all on government-funded financial support, and only with primary teeth at the time of GA. Treatment under GA utilized an aggressive approach. An aggressive treatment approach to dental surgery was suspected to improve clinical outcomes by limiting the number surfaces available for new caries to develop. The aggressive treatment approach followed the following guidelines:[6]

- Teeth with necrotic pulps or were non-restorable were extracted
- Decayed primary mandibular incisors not able to be treated by stripping were extracted
- Primary maxillary incisors with three or more carious surfaces were extracted
- Single surface caries of primary molars received amalgam restorations
- Primary maxillary incisors and canines with two or less carious surfaces were restored with composite
- Primary molars and canines with pulp therapy received SSCs
- Primary molars with caries of two or more surfaces (including smooth surface, white spot lesions) received SSCs
- Primary canines with caries affecting three or more surfaces received SSCs
- Prophylaxis and topical fluoride applications was performed after all restoration treatment
- All parents received pre-op dietary counseling and oral hygiene instruction

Patients were scheduled for recall examination six months post-GA by two examiners. At six-months follow-up, 57/79 (72%) of patient returned; this also represents a high dropout rate, but is much better than the 28.6% recall rate at six months found by Berkowitz *et al*. [18] In Chase *et al.*'s study, parents were given $30 for returning for follow-up at six months. This small monetary incentive showed dramatic increases in follow-up rates. Caries relapse was reported in 21/57 (37%) patients at six months post-GA. Chase *et al.* states that the current standard of care of ECC is resulting in unacceptable clinical outcomes, which differs greatly compared to the earlier opinions by Legault *et al*. who believed treatment outcomes indicated a high standard of care with positive outcomes. [4,21]

The total number of surfaces at risk (SAR) remaining after treatment under GA was determined for each patient. The SAR scoring system was as follows: primary molars had five potential surfaces at risk (MODBL), and primary incisors and canines had four potential surfaces at risk (MDFL). [6] Surfaces that received intracoronal restorations were not considered at risk, which was inappropriate as teeth with intracoronal restorations can develop (both new or recurrent) caries on any tooth surface. Teeth with SSCs, or missing/extracted teeth received a SAR score of zero. The relapse rate of 37% in six months is an underestimation of caries relapse as the presence of demineralization lesions or presence of recurrent caries were not included in the caries relapse group.[6] Graves *et al.* reported relapse rate was still unacceptably high even with an aggressive surgical approach. Graves *et al.* discusses the need for improvements in clinical outcomes, which may be possible if treatment strategies focus on treating the infectious nature of caries and preventing its progression. The use of topical 10% povidone iodine with treatment of ECC children may be an affective strategy. [6] However, a later study implementing the application of povidone iodine in all cases treated under GA showed no significant improvement in clinical outcomes. [19]

Eidelman *et al.* reported 57% of children treated under GA or conscious sedation required subsequent treatment within 6-24 months. [65] This relapse rate is consistent with relapse rates previously discussed following GA treatment.

Drummond *et al.* reviewed caries relapse two, three, and four years post-GA. Data up to 4 years post-GA was longer than any follow-up previously reported. Relapse was evaluated and assessed relative to fluoride history, SES, age at GA, ethnicity, gender and operator. Records of

277 children treated under GA were reviewed. The new caries rates reported two, three, and four years post-GA were 79/133 (59.4%), 51/69 (73.9%), and 53/75 (70.7%) respectively. The rates of failed restorations (which includes all recurrent caries cases) at two, three, and four years post-GA were, 54/133 (40.6%), 24/69 (34.8%), 18/75 (24%) respectively. If caries relapse had been defined as any signs of caries, including both new and recurrent caries, caries relapse rates would be greater than reported at each year. Follow-up did not include updating bitewing radiographs in all children, which may also underestimate the rate of caries relapse. The remaining sample size of groups at two, three, and four years was 133, 69, and 75 respectively; which is better than previous studies, and with longer follow-up.

Suggested adjunctive preventive measures for high caries risk children following dental treatment under GA include: three-month fluoride applications, use of casein phosphopeptide materials (such as MI paste), and use of antimicrobial agents (such as chlorhexidine, povidone iodine, and triclosan). Although it is suspected that diet and oral hygiene most likely remains unchanged regardless of treatment and counseling efforts.[5] Patient or caregiver compliance is critical to the success of any dental treatment. In children with ECC, diet and oral hygiene are thought to play a serious role in progression of dental caries. Motivating caregivers to change habits can be challenging. Follow-up visits are not only done to examine a child's oral health and provide treatment, but is a valuable opportunity to provide further diet counseling and oral hygiene instruction. Many pediatric dentists will schedule a one to two week post-GA appointment as an opportunity to educate and motivate parents in addition to evaluating the child's recovery and recent treatment.

In 2006, Foster *et al.* reported on children with ECC receiving dental treatment under GA at the Department of Pediatric Dentistry in the Women and Children's Hospital of Buffalo, NY.[7] A retrospective analysis was completed on children who underwent GA treatment that included a non-specified aggressive surgical approach, fluoride application, and parental counseling on diet and oral hygiene. An immediate two-week follow-up appointment was scheduled, as well as regular 6-month recalls. Recalls involved clinical examination and radiographs when feasible to detect new caries and restoration failures, as well as provide diet counseling and oral hygiene instruction. The sample included 448 healthy children, less than 61 months of age at the time of GA. As many patients were referred from private dental practices, many patients did not return for follow-up as a result. 193/448 (43%) patients returned for at least one six-month follow-up.

Within 6-24 months post-GA, 53.4% of patients presented with caries relapse (not including recurrent caries). The reported relapse value at 24 months may be underestimated as not all patients were followed until completion at 24 months.

The relationship between recall frequency and caries relapse was also previously evaluated. [8] This was completed by retrospective chart review of healthy, ASA 1 children aged two to seven treated under GA. The sample included 217 patients, and the following information was recorded: age at GA, referral status, attendance to two weeks post-op visit, frequency of recalls, type of insurance, operative treatment rendered under GA, and answers from a parental questionnaire. Follow-up data was recorded up to 36 months post-GA. Fifty-four percent (118/217) of patients returned for immediate two week post-op visit, greater than compared to Foster *et al.* [7,8] However regular recall rates for Jamieson and Vargas' study were very low; 28/217 (13%) dropping to 10/217 (5%) returning for six-month and 36-month recalls respectively. This unacceptably high dropout rate leads to questionable results that are of limited use. Jamieson and Vargas reported a relapse rate 26% within 36 months, calculated by 56 of 217 patients presenting with caries relapse. However, given the low number of patients who returned for recall examination, the true relapse rate is likely considerably higher. The high dropout rate was attributed to a large proportion of patients coming from referring dentists that returned to the referring dentist after GA treatment. Jamieson and Vargas reported a greater recall frequency by patients with private or no insurance compared to those with government funding. Evaluation of insurance types and recall frequency with a larger sample size is required to make stronger conclusions. It appears that after GA, caregivers do not often appreciate the value or importance of homecare prevention and regular dental visits, contributing to high caries relapse rates in affected children and low recall frequencies. [8]

Additionally, a sample of 30 children that underwent dental treatment under GA in the Department of Pediatric Dentistry of China Medical University was reviewed. [22] Patient ages ranged from 19 months to 14 years and were followed for 6-12 month post-GA. Additional follow-up treatment was required in only five cases. The Chen *et al* paper's abstract was available in English after translation, although the full paper has not been translated and therefore not critiqued in this review.

Caries relapse post-GA: 2010 – present

Xia *et al.* published a paper in 2014 in China as well out of Peking University School and Hospital of Stomatology, however no full English text was available for review. [27] Records of 111 patients under the age of 18 that were treated under GA were reviewed. Patients required at least three-months follow-up post-GA. Failure of restoration was the primary indication for unplanned treatment, and mean time to first unplanned treatment was 215 days. It was mentioned that 23% of treated teeth were not present during the recall period, suggesting that treatments were performed on teeth expected to exfoliate soon. [27]

In Alberta, Canada, another retrospective study was conducted on children with ECC which received dental treatment under GA in a private pediatric dentistry practice with GA facilities. Only healthy patients, six years of age or less at the time of GA, and presenting only with primary teeth were included. A sample of 269 children treated under GA was included. [16] Amin *et al.* recorded a number patient/caregiver, treatment, and environmental factors to be analyzed in relation to caries relapse. Of the 166 patients returning within 12 months post-GA, 40 (24%) presented with new caries. With longer follow-up, the remaining sample dropped considerably; 36 patients attended recalls between 13-24 months post-GA. Of these 36 patients, 19 (53%) were positive for new caries.

As previously suggested, additional preventive measures may improve caries relapse rates. A previous study used an aggressive treatment approach and applied 0.2ml of povidone iodine prior to topical fluoride application at the completion of all treatment under GA. [19] Within 5-12 months post-GA, 19/49 (39%) patients had caries relapse. This reported 12 month caries relapse rate is underestimated as a number of patients were seen for follow-up at less than 12 months. Other studies have reported decreases in *mutans streptococci* levels after povidone iodine applications as an adjunct to GA for up to three months; therefore its use may be promising, but requires more research. [19] Berkowitz *et al.* also suggests evaluating the effect of routine topical fluoride applications two to four times each year on clinical outcomes post-GA. [19]

Further investigation was carried out in Saudi Arabia to determine factors that might affect clinical outcomes of comprehensive treatment of ECC under GA. [23] ECC is reported to be highly prevalent in Saudi Arabia, found in 79% of children. A retrospective chart review was conducted, evaluating children treated for ECC under GA in a private medical facility in Jeddah,

Saudi Arabia. Children aged 2-11 years old, both ASA 1 and ASA 2 were included. Only children who had not previously received an additional dental GA were included. A large sample of 431 children was included in El Batawi's study. The treatment protocol under GA was as follows: [23]

- Small caries were restored with fluoride releasing compomer
- Primary molars with more than two affected surfaces were restored with SSCs
- Primary teeth with pulp therapy received formocresol pulpotomy and SSC
- Extraction was preferred to pulpectomy if questionable prognosis
- All susceptible pits and fissures were sealed
- Topical fluoride application
- Follow-up visit scheduled 7-10 days post-GA, and recalls every six months for two years post-GA which involved: diet and oral hygiene counseling, application of topical fluoride, and detection and treatment of new caries or failed restorations.

Of the 431 patients treated, 352 (81.6%) returned for at least one follow-up. Within two years following GA, 59% of returning patients had caries relapse. Patients were categorized according to follow-up compliance. Of the 38 patients with special health care needs, 23 (60%) showed full compliance to all follow-ups, and 6 (16%) required a repeat GA within two years (the highest of all groups). [23] Preventive measures and good compliance may be even more crucial to the special needs population when it comes to preventing caries progression. Treatment and patient management challenges may also lead to dental treatment requiring repeat GA for patients with special needs.

In 2015, Amin *et al.* conducted another study to help further understand factors contributing to caries relapse, with aims to guide the development of protocols to minimize relapse. [17] This single center, retrospective cohort study reviewed dental records of children treated under GA by one practitioner at a private pediatric dental practice in Vancouver, Canada. Included patients were up to age six at the time of GA, and either ASA 1 or ASA 2. Dental operating guidelines were as follows:

- Teeth with occlusal caries were treated with composite restorations
- Teeth with posterior interproximal caries were primarily restored with amalgam

- Teeth with deep caries (and no pulp exposure) received indirect pulp therapy with resin-modified-glass-ionomer
- Any pulp treated posterior primary tooth was restored with a SSC
- Primary molars with necrotic pulps or furcation involvement were extracted

Following treatment under GA, patients were scheduled for recalls which involved dental examination, prophylaxis, topical fluoride application, updating radiographs as indicated, and other treatment as required. Multiple patient/caregiver, treatment, and environmental variables were recorded and assessed as covariates to caries relapse. The recorded variables included: [17]

- Subject identification number
- Dates and number of follow-up appointments attended up to 36 months post-GA
- Number of teeth at GA
- Age at GA
- Gender
- Type of insurance
- Health status
- History of previous dental GA
- SES – derived from patient's postal code
- Dental procedures provided at GA
- Status of each tooth at follow-ups post-GA

This study sample included 278 children aged 19-71 months of age. Patients were to be followed for 36 months post-GA. At 36 months post-GA, 126/278 (45.3%) of patients returned for all recall appointments. More than half of the sample was not fully compliant with follow-up appointments. Amin *et al.* report a caries relapse rate of 21.6% over 36 months. This is a lower reported relapse rate than most previous studies, and over a relatively long follow-up. However, Amin *et al.* reported caries relapse as 60 out of 278 patients over 36 months. This was a misrepresentation of the true caries relapse rate in that timeframe, as not all 278 patients were followed for the full 36 months. Therefore the reported relapse rate is not a true 36-month caries relapse rate, and is likely underestimated.

Most recently, in 2018, Lin *et al.* evaluated caries relapse post-GA in Kaohsiung, Taiwan. [25] Of the 93 children treated under GA, 83 remained for the full six-month follow-up. The included subjects ages ranged from 27 to 71 months (mean 48.9 ± 10.6 months). Eligible subjects were recruited from the Children's Dental Clinic of Kaohsiung Chang Gung Memorial Hospital. Children under age six with clinical indications for dental treatment under GA and without any preexisting medical condition were eligible. Of the 83 remaining subjects, a caries relapse rate of 54.2% was reported six months post-GA.

An aggressive treatment approach to treatment of ECC under GA has not shown an association with decreased caries relapse post-GA. [6,17,40] It is likely that most pediatric dentists in previous studies have used similar treatment philosophies, leading to similar outcomes. Perhaps most of the children treated in these studies have received aggressive treatment aiming to limit caries relapse and the need for future treatment by controlling treatment variables as much as possible. Had patients received more conservative dental treatment (with fewer SSCs), it is expected, that caries relapse rates would be even higher. [15] Future studies evaluating clinical outcomes of comprehensive treatment provided by pediatric dentists and general dentists may demonstrate the value of the aggressive treatment approach commonly utilized by pediatric dentists during treatment under GA.

MEDICAL HISTORY

Has your child had any of the following? Please circle y (yes) or n (no)

y/n Allergies / Specify _____

y/n Syndrome / Specify _____

y/n ADD/ADHD	y/n Developmental Delay	y/n Leukemia/Cancer
y/n Adopted	y/n Epilepsy/Seizures	y/n Measles
y/n Arthritis	y/n Fainting Spells	y/n Premature Birth
y/n Asthma	y/n History of Malignant Hypothermia	y/n Prone to Car sickness
y/n Autism	y/n Hearing Impaired	y/n Psychiatric Disorder
y/n Bed Wetting	y/n Heart Disease	y/n Recurrent Headaches
y/n Bleeding Disorder	y/n Hepatitis/Liver Disease	y/n Reflux
y/n Cerebral Palsy	y/n History of Ear Infections	y/n Speech Problem
y/n Cleft Palate/Lip	y/n HIV or AIDS	y/n Sleep Disturbances
y/n Diabetes	y/n Kidney Disease	y/n Visually Impaired

Other/Specify _____

- Is your child taking any medications, prescribed or herbal? Please list drugs and dosages below.

  _____

2. Has your child ever had a reaction to any drugs? ___Yes ___No

   If yes, please specify. _____

3. Has your child ever had surgery or hospital procedures? ___ Yes ___ No

4. Has your child suffered any physical, sexual or mental abuse? ___ Yes ___ No

5. Is your child involved in any sports activities? ___ Yes ___ No

   Which ones? _____

- What is your child most interested in? Something to talk about. _____
- Do you consider your child to be:

  __ Advanced in the learning process __ Progressing normally __Slow learner

- How would you describe your child? Please check all that apply.

  __ Shy __Outgoing __ Emotional __Active __ Low Self Esteem __ High Self Esteem

- How would you rank **YOUR** dental anxiety in a dental environment?

  __ High __ Moderate __ Low

  Child's Weight_____ Child's Height_____

I have read and completed this medical history on behalf of my child/ward. I understand that to ensure the best possible treatment for my child I must update ***Pediatric Oral Health & Dentistry*** of any changes to my child/ward's medical and physical condition and any changes in medications.

Date: _____

Signature:_____ Relationship to Patient: _____

ORAL HISTORY EVALUATION FORM

Date:_____ This form is being completed by: Mother Father Grandparent Guardian

Child's Name: _____ Male Female **Age**:

Is this your child's first visit to a dentist? Yes No I

f no; when was the last visit to the dentist? _____

Please describe your child's reaction to previous dental visits._____

Does your family have a history of cavities?

Mother No Yes Less than 4 fillings More than 4 fillings Most cavities were as a child or as an adult

Father No Yes Less than 4 fillings More than 4 fillings Most cavities were as a child or as an adult

Siblings No Yes Less than 4 fillings More than 4 fillings

Were there are difficulties during pregnancy? No Yes Please explain:_____

Did you take any medications while you were pregnant? No Yes Please explain:_____

Was your child premature? No Yes How many weeks?_____

Child's birth weight _____

Was your child intubated? No Yes

Has your child had a history of ear infections? No Yes

Has your child had any ongoing medical conditions requiring treatment by a doctor or medication?

No Yes

Please explain:_____

Please check off any **medications or herbal or homeopathic remedies** that your child has taken on a regular basis.

liquid/chewable Tylenol chewable vitamins antibiotics anti-histamines

iron supplements decongestants asthma puffers other

If other; list medications and reason for taking:

_____

Was your child breastfed? No Yes **Was your child bottle fed?** No Yes

At what age did your child stop bottle or breast feeding? Still 9 months to 1 year 1-2 years 2-3 years

How often did your child fall asleep while nursing or drinking from the bottle? 1-2x per week nightly daytime naps

Did or does your child use a **"sippy"** cup? No Yes What was in the cup?

_____

Which of the following oral habits does your child **have or has had** in the past?

thumb sucking soother mouth breathing teeth grinding nail biting chewing on objects

How often does your child brush his/her teeth? _____ times per day.

Does your child brush his/her teeth; by themselves with help from parent both

When does your child brush? after breakfast after eating before bed after medications

Does your child floss his/her teeth?: by themselves with help from parent does not floss

In which of the following ways has your child had fluoride?

tap water toothpaste flouride rinse or gel at dentist's office does not get any fluoride

Please check off any of the foods your child regularly eats:

chewing gum chocolate crackers candy cookies popcorn raisins

fruit roll-up/chews or snacks dunk-a-roos suckers donuts fruit ice cream

granola bars potato chips vegetable sticks processed cheese sweetened breakfast cereal

What are your child's favourite "**snacks**"?1._____2._____3._____

When does your child have "snacks"?

_____

Please check off any of the following drinks your child has on a daily basis:

milk pop iced tea juice sports drinks water other, list:_____

How many glasses of **juice** does your child drink on a daily basis? _____ glasses.

Which of the following types of **water** does your child drink?

tap water bottled/filtered water well water flavoured water does not drink water

Is your child involved in any sport activities? no yes which ones?

_____

Does your child wear a mouth guard? yes no

Has your child experienced a blow to the mouth? Please describe:_____

Is there any other relevant information you would like to share with us to better allow us to provide the best care possible for your child?

Signed: _____

Date:_____