An Exploratory Study of a Contemporary Caries Management Protocol for High-Risk Immigrant Children

by

Carter Kar Tat Ng

D.D.S., University of the Pacific, 2002

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

in

The Faculty of Graduate and Postdoctoral Studies
(Craniofacial Science)

THE UNIVERSITY OF BRITISH COLUMBIA
(Vancouver)

August 2013

© Carter Ng, 2013
Abstract

Objectives: ‘Project Smile-Aid’ (PS-A) was developed as a multi-faceted intervention to manage severe early childhood caries in young low-income, immigrant children attending a public health clinic in Vancouver, Canada. The aims of this pilot study are to: 1) Assess the feasibility and practicality of delivering the PS-A ‘intervention’ in a community setting, 2) Explore the association between the ‘intervention’ and stabilization of dental caries and parent, family, and child quality of life; 3) Assess the acceptance of the ‘intervention’ by the parents.

Methods: PS-A ‘interventions’ included caregiver counselling about diet and toothbrushing employing a motivational interviewing-style approach; interim therapeutic restorations (ITRs); and topical remineralization agents (fluoride varnish and CPP – ACP) applied in clinic and at home. Children aged 1 - 12 years of age with extensive caries were recruited over a 12 month period. One calibrated clinician completed dental assessments using ICDAS, delivered the intervention and recorded measurements at baseline and follow-up visits. Parental satisfaction was rated following the ‘intervention.’ Also, caries status, oral hygiene, child’s behaviour and Early Childhood Oral Health Impact Survey (ECOHIS) scores were compared to baseline at 3, 6 and 9 month intervals.
**Results:** Fifty-two children participated: 22 girls, 30 boys. Child’s age, mean (SD), was 31.9 (10.7) months. Behaviour often impeded placing ITRs, but 27/52 (53%) of children had ≥ 1 ITR, typically on maxillary incisors. The mean (SD) ITR survival time was 5.3 (1.5) months. Plaque scores at follow-up did not demonstrate significant improvement from baseline. Overall, ICDAS scores remained the same, suggesting stabilization of caries. Parental satisfaction with the ‘interventions’ was uniformly positive. Further, decreased mean parental ECOHIS scores suggested improvement in parental quality-of-life over time. However, child-domain ECOHIS scores were challenging to interpret, likely because some items of the instrument did not apply to such young children.

**Conclusions:** PS-A proved feasible in a community setting. As measured by ECOHIS, parental quality of life appeared to improve. A reduction in caries progression was evident. Low-income, immigrant parents welcomed the PS-A strategy as an opportunity to “do something” to improve their child’s dental health.
Preface

Ethical approval for the study was granted by The University of British Columbia and Vancouver Coastal Health Clinical Research Ethics Boards. (Certificate numbers H11-00006 / VC11-13)
## Table of Contents

Abstract ........................................................................................................................................................................ ii
Preface ........................................................................................................................................................................ iv
Table of Contents ............................................................................................................................................................ v
List of Figures ................................................................................................................................................................. vii
Acknowledgements ........................................................................................................................................................ viii
Dedication ......................................................................................................................................................................... ix
1 Introduction ................................................................................................................................................................ 1
2 Dental Caries in the Young Child ......................................................................................................................... 4
   2.1 Definition – Early Childhood Caries ........................................................................................................... 4
   2.2 Etiology ............................................................................................................................................................ 5
   2.3 Dental Caries in Children of British Columbia & Canada ...................................................................... 8
3 Access and Barriers to Dental Care .................................................................................................................. 11
4 Oral Health-Related Quality of Life ................................................................................................................... 15
5 The Management of Severe Early Childhood Caries ..................................................................................... 18
6 Interventions to Control Caries ......................................................................................................................... 21
   6.1 Motivational Interviewing-Style Counselling ....................................................................................... 21
   6.2 Dietary Modification & Feeding Behaviours / Practises ........................................................................ 23
   6.3 Toothbrushing with Fluoride Toothpaste ................................................................................................. 25
   6.4 Casein Phosphopeptide-Amorphous Calcium Phosphate ..................................................................... 26
   6.5 Topical Fluoride Varnish .......................................................................................................................... 31
   6.6 Interim Therapeutic Restoration ............................................................................................................... 33
7 Statement of the Problem ................................................................................................................................. 38
8 Study Aims ............................................................................................................................................................... 39
9 Materials & Methods ............................................................................................................................................ 40
   9.1 Subject Recruitment .................................................................................................................................... 40
   9.2 Baseline Visit and ‘Intervention’ Protocol ............................................................................................... 42
      9.2.1 Caries Risk Assessment & Child’s Behaviour ............................................................................... 43
      9.2.2 Early Childhood Oral Health Impact Scale .................................................................................. 44
      9.2.3 Motivational Interviewing-Style Counselling ............................................................................ 45
      9.2.4 Plaque Score & International Caries Detection and Assessment System .................................... 46
      9.2.5 Interim Therapeutic Restoration ..................................................................................................... 48
      9.2.6 Topical Remineralization Agents: Topical Fluoride Varnish & MI Paste™ ........................................ 49
   9.3 Post ‘Intervention’ Phone Call ..................................................................................................................... 50
   9.4 Follow-up Visits .......................................................................................................................................... 50
   9.5 Statistical Analysis ....................................................................................................................................... 51
10 Results ................................................................................................................................................................. 52
   10.1 Sample ...................................................................................................................................................... 52
   10.2 Caries Risk Assessment & Child’s Behaviour ...................................................................................... 54
   10.3 Early Childhood Oral Health Impact Survey ........................................................................................ 55
   10.4 Caries Progression ................................................................................................................................. 57
10.5 Interim Therapeutic Restoration ................................................................................................................ 58
List of Figures

<table>
<thead>
<tr>
<th>Figure 1</th>
<th>Age Distribution of Sample</th>
<th>53</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 2</td>
<td>Distribution of Subject Ethnicities</td>
<td>53</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Distribution of Caries Risk Factors</td>
<td>54</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Total Mean (SD) ECOHIS Scores</td>
<td>55</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Child Mean (SD) ECOHIS Scores</td>
<td>56</td>
</tr>
<tr>
<td>Figure 6</td>
<td>Parent Mean (SD) ECOHIS Scores</td>
<td>56</td>
</tr>
<tr>
<td>Figure 7</td>
<td>Family Mean (SD) ECOHIS Scores</td>
<td>57</td>
</tr>
<tr>
<td>Figure 8</td>
<td>Tooth Surfaces with Caries Progression</td>
<td>58</td>
</tr>
</tbody>
</table>
Acknowledgements

I am heartily thankful to my co-supervisors, Drs. Karen Campbell and Rosamund Harrison, whose encouragement, guidance and support from the initial to the final level enabled me to develop an understanding of the subject. Without their guidance and persistent help, this thesis would not have been possible.

I would like to thank my committee members, Drs. Pam Glassby and Batoul Shariati for their assistance and guidance.

Lastly, a big thank you to the staff, dentists and families of the Robert & Lily Lee Family Community Health Clinic for their help, support, and enthusiasm for this project.
Dedication

This thesis is dedicated to my parents, Karen Ng and Dr. George Ng, who have supported me all the way since the beginning of my studies. Your love and guidance has always provided me the strength and confidence to pursue my life’s goals.

Also, I lovingly dedicate this thesis to my wife, Cara Yu, who has been a great source of motivation and inspiration.
1 Introduction

Tong Xing is a 2.5 yr old Chinese boy whose family had immigrated to Canada one year ago. He presents with his mother and 4 year-old brother to the Robert & Lily Lee Family Community Health Centre Dental Clinic in Vancouver’s Eastside. His mother is concerned about the brown spots on his upper front teeth and the white spots on the sides of his posterior teeth. She admits that she gives Tong Xing a bottle of milk at bedtime so that he will sleep through the night, and that she brushes his teeth only once a day because he cries and struggles so much. To his mother’s surprise, the dentist advises that Tong Xing requires dental treatment under general anesthesia (GA). The mother is hesitant to proceed with treatment because she had heard from friends that GA’s are very expensive and could be harmful for young children. She is told that the waiting list is long – up to 6 months – and that she should at least get on to the waiting list. She eventually agrees and a referral to BC Children’s Hospital is made immediately. As Tong Xing waits for treatment, it is very likely that the condition of his teeth will deteriorate. One serious consequence is that Tong Xing will experience dental pain and infection, and that these teeth will progress to needing pulp therapy or extraction by the time treatment is rendered. Needless to say, the overall prognosis is poor. In the world of pediatric dentistry, this story is far too common.
Extensive caries in vulnerable young children is a major child health concern. The current management of this infectious disease is largely surgical, involving restoration or extraction of teeth. Because of the limited cooperation of young children, this treatment is often delivered under general anesthesia (GA) in a private or public (hospital) setting. With limited resources and few publicly-funded facilities, GA wait-times can be prolonged which may adversely affect treatment outcomes and quality of life for a young child and his / her family.

It was reported by the British Columbia Provincial Medical Officer in 1997 that the most common reason for a child under 14 years of age to be treated under GA in British Columbia (BC) hospitals was dental surgery (Government of British Columbia 1997). Approximately 60% of these surgeries were for children less than 4 years of age receiving treatment for dental caries. Furthermore, the United States Surgeon General in 2000 reported that dental caries in children is five times more common than asthma (National Institutes of Health 2000).

It is likely that while the child with severe early childhood caries waits for treatment, outcomes will deteriorate as the disease progresses and the prognosis worsens. Teeth which, if treated earlier, could have been easily restored by dental restoration may now require pulp therapy or extraction. In addition to poorer treatment outcomes, the child’s and family’s quality of life may also be compromised because the child may have sensitive teeth and chronic pain. Further, the caregiver may feel guilt and sadness because of the child’s discomfort or appearance.
A need exists to explore how to best address the challenges of early management of extensive dental caries in young, vulnerable children.
2 Dental Caries in the Young Child

2.1 Definition – Early Childhood Caries

‘Early childhood caries’ (ECC) is the accepted term for dental caries affecting the primary dentition of young children or infants. The Canadian Dental Association’s policy statement on ECC has adopted the American Academy of Pediatric Dentistry’s (AAPD) definition of ECC which is “the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries) or filled tooth surfaces in any primary tooth in a preschool-age child between birth and 71 months of age” (AAPD 2012). Although a child with even just one carious tooth surface is troubling, our greatest concern is for children with severe early childhood caries (S-ECC).

As defined by the AAPD, S-ECC is any sign of smooth-surface caries in children younger than 3 years of age (AAPD 2012). S-ECC is also defined as an extremely destructive form of early childhood caries involving multiple teeth, including the maxillary anterior teeth (Drury, Horowitz et al. 1999). S-ECC is a pattern of rampant caries that occurs when the surfaces of primary teeth rapidly develop caries, often soon after eruption. Tooth surfaces that are usually at low risk of developing caries, such as the smooth surfaces of the maxillary anterior teeth, are affected (Harris, Nicoll et al. 2004).
2.2 Etiology

Similar to other forms of dental caries, the etiology of S-ECC is multifactorial. Formerly, S-ECC was thought to be associated with the prolonged use of a nursing bottle (Ismail and Sohn 1999), but poor dietary patterns alone do not account for the severe and extensive nature of this disease.

A varied combination of multiple factors, including social, biologic, environmental, behavioural, and clinical are responsible for dental caries (AAPD 2012). Because of this multifactorial nature, prevention of dental caries is a challenge.

Dental caries is a biofilm (plaque)-induced acid demineralization of enamel or dentin, mediated by saliva. The complex microbiological process involves: 1) cariogenic bacteria, 2) fermentable carbohydrates, 3) a susceptible tooth and host, and 4) time (Harris, Nicoll et al. 2004; Aas, Griffen et al. 2008). Streptococcus mutans, streptococcus sobrinus, and lactobacillus are the major bacterial species implicated (Aas, Griffen et al. 2008; Ly, Riedy et al. 2008). The development of dental caries is mediated by the dynamic balance between pathological factors that lead to demineralization and protective factors that lead to remineralization. Pathological factors include cariogenic bacteria, decrease in salivary function, and frequent ingestion of fermentable carbohydrates. Protective factors include fluoride from extrinsic sources, salivary flow, various salivary components, selected dietary components, and antibacterial agents (Featherstone 2004). Over time, frank cavitation of the tooth surface is the result
of this demineralization process. However, if detected prior to cavitation, the
disease is reversible by a remineralization process that repairs the tooth enamel
surface.

The transmission of cariogenic bacteria from caregiver to child, known as
‘vertical transmission’ has been well documented (Berkowitz 2006). Pathways
for vertical transmission include tasting of food by the mother before feeding the
child or blowing on food to cool it down. Mitchell et al. demonstrated in a sample
of 27 mother / child pairs (all children had S-ECC), 41% were positive for
maternal mutans streptococci (MS) genotypes, while acquisition from non-
maternal sources occurred in 74% (Mitchell, Ruby et al. 2009). This finding
demonstrates the ‘horizontal transmission’ of microbes between members of a
group e.g. siblings of a similar age or daycare playmates (Berkowitz 2006). One
mode of ‘horizontal transmission’, for example, is the sharing of toothbrushes or
utensils. Eliminating saliva-sharing activities may help decrease an infant’s or
toddler’s acquisition of cariogenic bacteria but is a somewhat unrealistic strategy
to implement (Berkowitz 2006).

Evidence from the literature supports a relationship between
socioeconomic status (SES) and general health; there is an inverse relationship
between SES and the incidence and prevalence of disease (Reisine and Psoter
2001). This relationship is true for conditions like caries that are related to
lifestyle factors. The relationship between SES and dental health is also
maintained across individual-level measures such as household income (Vargas,
Crall et al. 1998) and educational attainment (Ismail and Sohn 2001).
A study of 128 Canadian preschool children (mean age 3 years, range 1-5 years) investigated the relative influence of risk factors, alone and in combination, on the severity of ECC (Tiberia, Milnes et al. 2007). Parent survey responses provided information on demographics, SES, and parental education. In this group of children, parents with higher education tended to have children with lower prevalence and severity of caries compared to parents with low levels of education. A major limitation of this cross-sectional study was the volunteer nature of the sample and small sample size.

Anomalies in enamel development i.e. irregularities in composition or structure may contribute to caries development (Caufield and Griffen 2000). A study by Li et al. compared the prevalence and concentration of MS in saliva of 486 Chinese children, aged 3-4 years, with and without enamel hypoplasia (Li, Navia et al. 1994). They demonstrated that high MS counts were correlated with enamel hypoplasia. Another finding was that malnutrition was correlated with hypoplasia. The findings suggest that anomalies in enamel development may also be a contributing factor that fosters increased colonization of MS in young children.

Because dental caries is a result of a varied combination of many factors (AAPD 2012), it is imperative to base the control of caries and caries management strategies on our most current knowledge and understanding of the dynamic interaction between the biofilm and the tooth surface and our ability to engage caregivers in meaningful prevention strategies.
2.3 Dental Caries in Children of British Columbia & Canada

The prevalence of S-ECC varies from population to population; however, economically disadvantaged children, regardless of race, ethnicity or culture, are most vulnerable (Milnes 1996). In 2005, British Columbia’s Ministry of Health in collaboration with the BC Dental Association (BCDA) launched a three-year media awareness and education program on preventing dental caries in young children. They established a province-wide goal that 60% of British Columbia’s kindergarten population would have “no visible decay experience” at the end of the campaign. That is, 3 out of 5 kindergarten children in BC would be “caries-free” based on a standardized survey (Human Early Learning Partnership 2011). The 2009-2010 province-wide dental survey that assessed the dental health of kindergarten-aged children in BC reported a slight improvement (less visible dental caries) compared to a similar survey conducted in 2006-2007. Parents in this 2009-2010 survey would have been key recipients of the 2005-2008 ECC prevention media campaign. The survey found that less than 17% of the sample population of 35,420 children had visible, untreated caries and 63% were caries immune i.e. no visible dental caries and no existing dental restorations. This result exceeded the province-wide goal of 60% that was set in 2005. The survey was conducted by calibrated examiners using tongue blades and flashlights without the use of radiographs, thus early interproximal caries was impossible to assess. Therefore, the collected data were likely an underrepresentation of
actual caries; however, the surveys were conducted using the same methods from one time period to another.

Compared to the survey in 2006-2007, the 2009-2010 survey also found that the percentage of BC children:

- that were caries immune had increased by 2.2%;
- with no visible caries but restorations present had decreased by 2.0%;
- with visible caries had decreased by 0.3%

The Children’s Dental Task Force (CDTF) of the BC Dental Association, whose goals were to recommend strategies and to consult with external groups and government regarding issues of access to care for vulnerable children in BC, concluded that the overall results of the 2009-2010 were cause for cautious optimism (British Columbia Dental Association 2011).

In 2007-2009, the Canadian Health Measures Survey (CHMS) collected data on the oral health of about 6,000 Canadians in 15 communities; the sample was representative of 97% of the general population in Canada. The CHMS reported that 57% of 6-11 year olds had or have had dental caries and that the average number of teeth affected by caries in children aged 6-11 years old was 2.5 (Statistics Canada 2010).

As demonstrated by comparing the 2006-2007 and 2009-2010 “kindergarten” dental surveys, BC’s children appeared to benefit from long-term wide-spread media campaigns on ECC prevention. Although a modest reduction in ECC in BC’s children was reported, it is imperative that we do not remain
complacent. The prevention of ECC, similar to other lifestyle diseases e.g. heart disease and certain cancers, must be an on-going effort.
3 Access and Barriers to Dental Care

The Canadian Academy of Pediatric Dentistry and the Canadian Pediatrics Society promote the concept of a dental home by age one for a healthy child (Canadian Academy of Pediatric Dentistry 2012). The dental home is the ongoing relationship between the dentist and the patient, inclusive of all aspects of oral health care delivered in a continuously accessible, comprehensive, coordinated and family-centered way (American Academy of Pediatric Dentistry 2012). A dental home can be either a private clinic or a public facility.

Definitive dental treatment for BC’s pre-school aged children is customarily delivered by general dentists and pediatric dentists in a private clinic or public setting such as a hospital. For the majority of young children with minimal caries, dental treatment utilizing local anesthesia and behaviour management skills is usually sufficient. However, for some young children with more extensive dental caries and / or those with dental anxiety or fear, pharmacological management may also be required. Minimal sedation techniques such as the administration of nitrous oxide and / or oral sedative adjuncts are commonly utilized to safely deliver invasive dental treatment to young children. In many cases, young children with extensive caries or the inability to cooperate may be best treated under GA in a private or public (hospital) facility. In the Metro Vancouver area, a large number of these children receive treatment at the BC Children’s Hospital (BCCH). From 2007 to 2012, the
average number of dental GA’s at BCCH has been in excess of 1000 per year; this high demand has extended wait-times for treatment under GA to around 6 months\textsuperscript{1}. The eligibility criteria for treatment in the dental operating room at BCCH are as follows (BCCH Dentistry 2012):

- children, 48 months of age and under with extensive or severe caries, and
- children, 17 years of age and under, with a significantly compromising medical condition.

For various reasons, some young children often do not receive dental care in a timely manner. The barriers to care are either environmental (i.e. cost of care, operating room time, accessibility) and / or non-environmental (i.e. child’s behaviour, parent unaware that treatment is needed, or fear of dentist) (Nelson, Getzin et al. 2011). The CDTF (British Columbia Dental Association 2011) concluded that the primary barriers in BC appear to be:

- the child’s behavioural needs which complicate the provision of care;
- challenge of finding a dental provider for ongoing care;
- cost of treatment for those families with no or inadequate dental benefits

According to the CHMS, 62% of Canadians have private dental insurance and 6% have coverage through publicly funded programs. The remainder of the Canadian population (32%) has neither public nor private insurance to help pay for their child’s dental treatment (Government of Canada 2010). For the many families that do not have dental insurance and have limited financial resources, the high cost for their child’s dental treatment may be prohibitive. As such, this

\textsuperscript{1} July 14, 2013: email correspondence with Dr. Karen Campbell, Head, Dental Department, BC Children’s Hospital
segment of the population may suffer the most when faced with this kind of financial barrier.

In BC, most dental offices follow a suggested fee guide that is published annually by the BC Dental Association (BCDA). The majority of private dental plans pay for dental services based on the fee guide, but depending on the dental plan, some require a co-payment i.e. the cost of treatment is not 100% covered by the insurance company. Low-income families in BC who do not have private insurance may be eligible to receive funding from The Healthy Kids Program (HKP). Dependent children under 19 years of age, of families approved for premium assistance by the Medical Services Plan through the Ministry of Health, are eligible for $1400 ($2400 if delivered under GA) of basic dental services every two years under the HKP. The HKP pays for dental services based on the HKP fee guide, which may be 40% less than the current BCDA fee guide. As such, it is known that many dental offices “balance bill” patients who are covered under the HKP to make up the difference between the two fee guides. For the ‘working-poor’ low-income families in Vancouver who have no private insurance or cannot afford their plan’s co-payments, or for families who have dental benefits but whose dental provider “balance bills,” their child’s dental treatment may simply be unaffordable.

The Robert and Lily Lee Family Community Health Centre Dental Clinic (RLLFCHC) is a low-cost dental clinic in Vancouver's east side. Prevention services are offered free of charge for children less than 12 years of age whose families reside in Vancouver and are not able to afford private dental services.
Dental treatment (other than prevention services) is offered at minimal cost for working poor families who do not qualify for the HKP. The RLLFCHC is the only dental clinic of its kind in the province of BC.

A substantial barrier to dental care exists for the segment of the population who simply lack financial resources. Definitive dental treatment may be delayed resulting in poorer treatment outcomes.
As stated by Casamassimo et al., “traditional epidemiologic measures such as the dmft index [a dental caries scale] do not adequately portray the effects of ECC on children, families, society and the health care system” (Casamassimo, Thikkurissy et al. 2009). In the US, the estimated cost for a single admission for dental treatment under GA in 2000 is over $3000 (Casamassimo, Thikkurissy et al. 2009); however, the “costs” are more than financial. The CDTF in 2011 stated that the total cost of having dental caries “must include the immeasurable cost to the child, who is in pain, the family members who are missing work and school, and the overall stress and anxiety for the entire family and care-giving team” (British Columbia Dental Association 2011). Further to this, as explained by Pahel et al., “dental disease and its treatment can negatively affect the oral health-related quality of life (QoL) of preschool aged children and their caregivers” (Pahel, Rozier et al. 2007). S-ECC is a concern because in addition to pain and discomfort, dental caries may interfere with growth and has been implicated in situations of ‘failure to thrive’ (Acs, Lodolini et al. 1992). Although the child is the primary concern, it is clear that the total cost of the disease extends well beyond that of the child.

In any discussion regarding the welfare of a child, it is also important to take into consideration the toll it may have on a child’s parent or caregiver. In addition to a child’s QoL, a parent’s QoL may also be affected when dental treatment is required for a young child because he / she bears the responsibility
for the child’s health. In a study by Gift et al., the social impact of dental problems and visits was assessed. The analysis was based on the 1989 United States National Health Interview Survey with a sample of 50,000 households (117,000 individuals). One hundred and forty-eight thousand hours of work were lost per 100,000 workers and 117,000 hours of school were lost per 100,000 school-age children per year. It was concluded that although the caregiver of a child may be burdened by losing work hours and a child may miss school hours, dental problems may not have a large impact on an individual basis. However, the number of the caregivers’ work hours lost through attending to their child’s dental problems and dental visits on a societal level may be a significant problem in terms of staffing and other workplace policy issues (Gift, Reisine et al. 1992).

Numerous measures have been developed over the years to assess the effect of oral health problems on a young child’s physical, mental and social health and well-being. However, it was only recently that a validated instrument was introduced. In 2007, the Early Childhood Oral Health Impact Scale (ECOHIS) was developed. This survey instrument consists of 13 questions, completed by the child’s parent. These questions assess the impact of oral health problems and related treatment experiences on the QoL of preschool age children and their families (Pahel, Rozier et al. 2007). The instrument has been validated in young children 0-5 years of age in English in the United States (Pahel, Rozier et al. 2007) and in French in Canada (Li, Veronneau et al. 2008).

Assessing parents’ perceptions about how oral health problems, including how signs and symptoms of dental caries and its treatment influence their
children’s QoL, is important. Properly assessing and then addressing these influences may help improve the oral health-related QoL for the child and family.
5 The Management of Severe Early Childhood Caries

For the past 150 years, the “surgical approach” has been the predominant mode of caries management. The usual treatment for a primary tooth with a dental “cavity” is the removal of diseased tooth structure and the placement of an inert material to restore function and form. The management of caries often requires the use of local anesthesia and rubber dam isolation, both of which cause some level of discomfort to the patient. A restoration of a primary tooth can be one of several types depending on the tooth’s location and the size of the lesion. In general, due to esthetic concerns, anterior teeth are often restored with white resin-based composite material. For posterior teeth, where load-bearing is heavy, amalgam or stainless steel crown restorations are usually indicated. When selecting restorative materials, other considerations may include financial considerations, longevity of the restoration, oral hygiene, ease of material placement, and risk profile for future caries (Soncini, Maserejian et al. 2007).

For primary teeth with extensive caries, extraction may be the only option. The consequence of prematurely losing a primary tooth depends largely on its location within the mouth. The early loss of anterior primary teeth may or may not lead to long-term consequences; however, premature loss of posterior primary teeth often results in long-term orthodontic problems for the child. Crowding, crossbite formation, dental impaction, midline discrepancies, and ectopic eruption of the permanent teeth may be the result of the early loss of posterior primary teeth (Laing, Ashley et al. 2009). Therefore, proper space
management by the use of space maintainers may be required when primary molars are lost prior to the eruption of the permanent teeth.

In Canada, tens of millions of health care dollars are spent annually on treating S-ECC (Narvey and Shwart 2007). However, modern-day dentistry is slowly moving toward a more conservative, non-surgical model of caries management. Recently, there has been considerable evidence supporting a minimally invasive approach that includes fluoride treatment and other remineralization products (America ; Cochrane, Cai et al. 2010). Early non-cavitated carious lesions can be reversed and the tooth surface remineralized through appropriate management (Anusavice 2005). The progress of more advanced lesions can be slowed down. ‘Remineralization’ is the process whereby phosphate and calcium ions are supplied from a source external to the tooth to promote ion deposition into crystal voids in demineralized enamel; this process produces a net mineral gain (Cochrane, Cai et al. 2010). With the current knowledge of remineralization potential, a shift in emphasis from “surgical” to “medical” management of caries is an enabled possibility. Such an approach involves assessment of caries risk to identify modifiable external factors, conservative management of the disease, and, in some cases, delayed surgical restoration until the extent of cavitation has increased to a critical threshold (Anusavice 2005).

The multifactorial nature of ECC in young children makes management of this disease challenging. The use of remineralization products to help reverse early lesions in young children, as part of a multi-level approach, holds promise.
Compared to the surgical approach, topical remineralization products are minimally invasive and thus, may be more acceptable to young children and their parents.
6 Interventions to Control Caries

6.1 Motivational Interviewing-Style Counselling

Traditional health education, in other words “advice-giving” sessions, conducted by professionals to parents is common practice for “delivering” preventive advice to parents of young children (Weinstein, Harrison et al. 2006). However, ambivalence about behaviour change is the usual result and little change occurs. Different approaches to encouraging behaviour change have been developed, one of which is known as ‘motivational interviewing.’ This counselling style was first developed in the addictions field for helping people work through ambivalence about behaviour change (Rollnick 1992). Motivational interviewing (MI) is a brief, patient-centered, personalized counselling approach. It is based on the premise of asking open-ended questions and encouraging individuals to talk about their personal goals prior to offering advice or information, and providing choices for individuals that best suit their situation. MI focuses on strategies to move parents from inaction to action; many possible paths to a solution are provided in the form of a ‘menu of options’ (DiClemente 1991).

Weinstein et al. in 2006 compared the effect of a MI counselling visit with traditional health education for Indo-Canadian mothers whose young children were at high risk of developing dental caries. This randomized controlled clinical trial of 240 infants and caregivers was composed of two groups: MI group and
health education (control) group. The control group were mothers that received a pamphlet and video information on preventing dental caries. The MI group received the same pamphlet and video information and an additional 45 minute MI counselling session and six brief follow-up phone calls over 20 weeks. At the end of the 2 year study, it was demonstrated that MI had a protective effect with regard to the development of ECC (Weinstein, Harrison et al. 2006). Additional analysis of the data confirmed that an MI-style intervention shows promise to promote preventive behaviours in mothers of young children at high risk for caries (Harrison, Benton et al. 2007). The study was carefully designed following CONSORT guidelines for a randomized controlled trial and the sample size exceeded the initial sample size determination.

Another group of investigators explored whether an individualized MI approach to oral health education would promote positive changes in ECC risk-related behaviours of mothers. Seventy-two mothers participated (control group N = 32, treatment group N = 40) in a pre-test and post-test four weeks apart. Mothers in the treatment group were given a counselling type session (MI) and follow-up phone calls to promote positive oral health behaviours. MI appeared to have a modest impact on some high-risk parental behaviours that contribute to ECC (Freudenthal and Bowen 2010). This pilot study’s short time period between the pre-test and post-test (4 weeks) may not have been enough time for subjects to significantly change their behaviours. Also, the sample size was too small to draw any meaningful conclusions.
Studies incorporating MI to promote behaviour change show promise; thus a preventive program for high-caries risk children should certainly incorporate a caregiver counselling approach based on MI.

6.2 Dietary Modification & Feeding Behaviours / Practises

Dietary choices affect oral health as well as general health and well-being. Along with increasing caries risk, increased consumption of sugar-sweetened beverages and snack foods also have been linked to obesity (Malik, Schulze et al. 2006). The American Academy of Pediatrics has recommended that children 1-6 years of age consume no more than 4-6 ounces (120-180 mL) of fruit juice per day, from a cup i.e. not a bottle or covered cup as a part of a meal or snack (American Academy of Pediatrics 2001). Bottle feeding with any liquid other than water at night, frequent in-between meal consumption of high-carbohydrate snacks or drinks, and repeated use of a sippy cup increase the risk of caries.

Human milk has been demonstrated to provide the best possible nutrition to infants and has not been associated with caries in population-based studies (Iida, Auinger et al. 2007). Frequent bottle-feeding at night with milk is associated with, but not consistently implicated in development of S-ECC (Reisine and Douglass 1998).

Certainly, poor dietary patterns are a risk factor for the development of S-ECC (Azevedo, Bezerra et al. 2005). Frequent or prolonged day or night use of baby bottles or a sippy cup that contain fermentable liquids (Kreulen, de Soet et
al. 1997), and frequent snacking (Babeely, Kaste et al. 1989) are the most common habits that influence the development of S-ECC (Azevedo, Bezerra et al. 2005). However, for young children who are lulled to sleep with a baby bottle containing a beverage other than water or who have unlimited daytime snacking, change in dietary habits may be a challenge.

Xylitol may have a role in conservative management of caries in young children. This naturally-occurring sugar alcohol has been incorporated into various vehicles such as chewing gum, lozenges, gummy bears, and hard candies (Ly, Riedy et al. 2008). Xylitol has been shown to reduce MS levels in plaque and saliva and to reduce the prevalence of caries. Studies with school children have demonstrated that habitual use of xylitol-containing products decreases the prevalence of dental caries (Ly, Riedy et al. 2008). In a prospective double-blind, randomized controlled trial (154 subjects, mean age 8.4 years) children chewed gummy bears for 6 weeks. The children were randomized into three groups: xylitol 15.6 g / day, 11.7 g / day, or maltitol 44.7 g / day. Maltitol was used as the null-comparison because it is only slowly fermentable (Ly, Riedy et al. 2008). This study demonstrated that xylitol and maltitol gummy bear consumption at therapeutic dose and frequency reduced levels of S. mutans / sobrinus but not Lactobacillus species in plaque after 6 weeks of habitual exposure. Although effective in older children, xylitol gummy bear (or gum) chewing may not be feasible in children less than 3 years of age because of choking hazard. The most common side effect from ingesting high amounts of xylitol is osmotic diarrhea (Ly, Milgrom et al. 2006).
The pH level (measure of acidity or alkalinity) of the oral environment rises and falls throughout the day in the absence and presence of food. A lower pH level (i.e. acidity) is conducive to tooth surface demineralization which may lead to cavitation. Parenting practices such as offering frequent sugary snacks and prolonged use of bottle or training cups with sugar-containing drinks (e.g. acidic beverages, fruit juices) among Aboriginal populations has been found to be associated with ECC (Schroth, Smith et al. 2005; Canadian Academy of Pediatrics 2011). Therefore, limiting the consumption of high-carbohydrate foods to meal times may reduce caries risk by reducing the frequency of acid attacks during the day i.e. allowing the oral environment to be at a neutral pH more often during the day.

6.3 Toothbrushing with Fluoride Toothpaste

Toothbrushing with fluoride toothpaste (those containing 1000 / 1100 parts per million fluoride ion) is a recommended, evidence-based measure to control dental caries (Marinho 2009). Supported by over 50 years of research, the benefits of fluoride toothpaste are firmly established (Marinho 2009). Toothbrushing with fluoride toothpaste serves two purposes: plaque removal and topical fluoride application. It has been demonstrated that children who brush their teeth at least once-a-day with fluoride toothpaste have reduced prevalence of dental caries (Marinho 2009). Twice-a-day toothbrushing has proven to be more effective than once-a-day toothbrushing (Chesters, Huntington et al. 1992;
Gibson and Williams 1999). For young children and children with special health care needs, extra care and parental supervision of toothbrushing are necessary.

However, it has been demonstrated that the toothbrushing behaviour of parents for their toddlers falls well short of professional guidelines. Videotapes of at-home toothbrushing sessions of 18 families reported that the average toothbrushing session was 142 seconds but the actual time spent brushing the teeth was only 23 seconds, despite parents being confident that the toothbrushing was well done. The majority of the time was found to be spent on biting the toothbrush and drinking water (Zeedyk, Longbottom et al. 2005). Despite a small sample size, the study’s conclusion would probably not surprise dentist professionals who treat young children.

Toothbrushing with an appropriate amount of fluoride toothpaste twice-a-day has a place in the recommendations of any dental health counselling program.

6.4 Casein Phosphopeptide-Amorphous Calcium Phosphate

Remineralization products containing the molecular complex CPP-ACP should be considered when developing a contemporary approach towards caries management in young children. Casein phosphopeptide (CPP) is a milk-derived protein that is able to bind calcium and phosphate ions and stabilize them as amorphous calcium phosphate (ACP) without precipitation to ensure the delivery of the ions to the tooth structure before they precipitate. CPP-ACP clusters act
as calcium and phosphate reservoirs that attach themselves to tooth surfaces and dental plaque (Reynolds, Cain et al. 1995). The main action is to supersaturate the biofilm (dental plaque) with calcium and phosphate ions therefore acting as a reservoir. During an acid challenge, the attached CPP-ACP releases calcium and phosphate ions, thus maintaining a supersaturated mineral environment, thereby reducing demineralization and enhancing remineralization (Reynolds, Cai et al. 2003).

Commercial products containing CPP-ACP are available in the form of chewing gum, sports drinks, mouth-rinses, and creams / pastes (Azarpazhooh and Limeback 2008; Yengopal and Mickenautsch 2009). However, despite the wide range of CPP-ACP vehicles, young children with immature swallowing reflexes are most likely to only benefit from the use of CPP-ACP dental paste products. The FDA has approved at-home use of CPP-ACP dental cream products (e.g. “Minimally Invasive Paste” or simply “MI Paste™” (marketed by GC America) containing Recaldent as abrasive prophylaxis pastes for at-home use and secondarily for the treatment of tooth sensitivity (GC 2012). However, the prevention of dental caries by remineralizing dentin and enamel is an ‘off-label’ application (Department of Health and Human Services 2007). According to GC America, CPP-ACP is a useful cariostatic agent for the control of dental caries. Also, it can be used as an adjunct in preventive therapy to reduce caries in high-risk patients, to reduce decalcification in orthodontic patients, to reduce dental erosion in patients with gastric reflux, to repair enamel in cases involving
white-spot lesions, orthodontic decalcification or fluorosis or before and after tooth whitening, and to desensitize teeth, according to GC America².

An advantage that MI Paste™ has over fluoride products as a remineralization agent is that there is no risk in the young child of developing dental fluorosis, which is a developmental disturbance of dental enamel that is caused by excessive exposure to high concentrations of fluoride during tooth development (Ekambaram, Itthagarun et al. 2011). In this regard, GC America claims that MI Paste™ is safe for use in young children who are not allergic to milk protein or benzoate preservatives.

The potential for CPP-ACP to promote remineralization and inhibit demineralization of hard tooth tissue has been demonstrated in clinical studies (Iijima, Cai et al. 2004; Morgan, Adams et al. 2008). Morgan et al. investigated the anticariogenic effect of sugar-free gum containing CPP-ACP on interproximal caries. Subjects were randomly assigned to one of two gums and were instructed to chew their assigned gum for 3 X 10 minutes per day for 24 months. The experimental group chewed sugar-free gum containing CPP-ACP while the control group chewed sugar-free gum. Results of the clinical trial demonstrated that for subjects chewing the CPP-ACP gum the odds of a tooth surface experiencing caries progression were 18% less than those of a surface experiencing caries progression for subjects chewing the control gum. It was concluded that daily chewing of 54 mg CPP-ACP sugar-free gum significantly slowed progression and enhanced regression of interproximal caries relative to a

---

control sugar-free gum (Morgan, Adams et al. 2008). The regressions predominantly involved remineralization of enamel (the superficial layer of teeth) but also a smaller number of dentin lesions (the deeper layer of teeth) (Morgan, Adams et al. 2008).

An in vivo study demonstrated the remineralizing effect of GC Tooth Mousse™ on early dental enamel lesions. Forty volunteers (age range 10-16 years) were divided into experimental and control groups. Two demineralized human teeth enamel specimens were adhered to the buccal surfaces of the right and left first or second upper molars in all subjects. The experimental group was instructed to apply GC Tooth Mousse™ on the right side specimen and a placebo gel on the left side specimen on a daily basis, three times daily for one month. No alterations were made to the subjects’ diet and oral hygiene procedures in the control group for one month. Using scanning electron microscope analysis, it was demonstrated that CPP-ACP was able to depress enamel demineralization and enhance remineralization of early enamel lesions. The results of this study were found to be consistent with other studies showing the anti-cariogenic and remineralization potential of CPP-ACP (Reynolds, Cain et al. 1995; Reynolds 1997; Iijima, Cai et al. 2004).

Although CPP-ACP-containing products have demonstrated anti-cariogenic properties in trials in older children and adolescents, almost no previous studies have explored its effectiveness in preschool children. A 1-year, double-blind, placebo-controlled clinical trial by Sitthisettapong et al. examined the caries-preventive effect of daily application of 10% CPP-ACP paste when
added to regular toothbrushing with fluoridated toothpaste in high caries-risk children aged 2.5 to 3.5 years (Sitthisettapong, Phantumvanit et al. 2012). Two-hundred ninety-six children, similar at baseline, were randomly assigned to two groups: CPP-ACP (N = 150) versus placebo control (N = 146) in addition to fluoride toothpaste. Daily application of 10% CPP-ACP paste on school days, in addition to regular toothbrushing with fluoride toothpaste, appeared to have no significant additional caries-preventing effect. The positive effects of the fluoride toothpaste may have neutralized the additional benefit of CPP-ACP.

For infants and children, GC America recommends that MI Paste™ is applied to the teeth twice daily with a clean finger; rinsing with water is not recommended and any excess amounts may be expectorated or left to slowly dissolve (GC 2012). MI Paste™ is palatable to most young children because it is available in a variety of flavours. It is contraindicated in patients with allergies to milk (casein) protein or benzoate preservatives. The availability of MI Paste™ to the general public is limited to purchase at a dental clinic. Unfortunately, the cost of MI Paste™ is high at approximately $20 (CAD) per 35 mL tube.

Despite these drawbacks, CPP-ACP in the form of a dental cream may have a role in the oral hygiene regimen of a child at high risk to caries because of its ease of application, good taste, and proven ability to promote remineralization.
6.5 Topical Fluoride Varnish

Fluoride is the cornerstone of the non-invasive management of non-cavitated caries lesions (Cochrane, Cai et al. 2010). In North America, professionally applied topical fluoride is available in several forms: foams, gels, rinses, and more recently, varnish. Various concentrations of fluoride are available depending on the vehicle. Compared to other office-applied fluoride modalities, the application of fluoride varnish (FV) takes less time, creates less patient discomfort, and has excellent patient acceptability in preschool-aged children.

FV was developed in the late 1960’s and has been widely used in European countries since the 1980’s. The main advantage of FV over that of other fluoride vehicles is that the contact of the fluoride with tooth enamel is prolonged (Beltran-Aguilar, Goldstein et al. 2000). Duraflor (A.R. Medicom, Inc.) is a 5% NaF (22,600 ppm fluoride ion) varnish that is applied in-office and is approved by Health Canada as an anti-caries agent. One millilitre of FV contains 50 mg of sodium fluoride in an alcohol-based resin suspension. FV’s are not intended to adhere permanently to the tooth surface, but to remain in close contact with enamel for several hours. Due to its concentrated fluoride content, the application of varnish is generally professionally applied and is not intended for home use. Complete drying of the tooth surface is not required because FV sets on contact with intraoral moisture, therefore wiping with gauze or cotton roll is adequate.
FV application every 3 to 6 months in high-caries risk children has been shown to be effective in preventing caries by creating a favourable gradient for inward fluoride diffusion, therefore reducing the porosity of the body of the carious lesion (Beltran-Aguilar, Goldstein et al. 2000). Lawrence et al conducted a 2 year randomized controlled trial of fluoride varnish in addition to customary parent counselling to prevent ECC in young Aboriginal children. The sample consisted of 1275 children aged 6 months to 5 years of age in Northwest Ontario. The subjects were randomized into two groups: the experimental group received FV and caregiver counselling while the no treatment group received caregiver counselling only. At the conclusion of the study, there was an 18% reduction in the 2 year mean ‘net’ dmfs increment for Aboriginal children and a 25% reduction for all children that received the FV treatment. The results of this study support the use of FV at least twice per year, in conjunction with caregiver counselling, to prevent ECC (Lawrence, Binguis et al. 2008).

A 2-year randomized trial of 376 caries-free, low-income Chinese and Hispanic San Francisco families had similar promising results (Weintraub, Ramos-Gomez et al. 2006). All families received counselling, and children (age range 6 – 44 months) were randomized to three groups: no FV, FV once per year, or FV twice per year. The annual counselling protocol followed the AAPD’s anticipatory guidance recommendations (Nowak and Casamassimo 1995). The subjects were recalled at one and two year intervals. The results of this study demonstrated that FV added to caregiver counselling is effective in reducing the incidence of early childhood caries. Unfortunately, the inclusion criteria limited
the study to caries-free children without any signs of demineralization. It would have been interesting to see if FV could have stabilized demineralized teeth surfaces in children with signs of early caries.

Vanish™ 5% sodium fluoride with tri-calcium phosphate (3M ESPE, St. Paul, MN, USA) is a relatively new product that may have superior remineralization potential to that of 5% sodium fluoride varnish alone. The manufacturer claims that Vanish™ continuously releases fluoride and calcium up to 24 hours and provides higher average salivary fluoride levels than regular 5% sodium fluoride varnish (3M 2013). Currently, no clinical studies have been completed to support this claim.

Many studies spanning decades of research have demonstrated that FV is an effective, inexpensive, and safe mode of fluoride delivery to very young children.

6.6 Interim Therapeutic Restoration

Restorative care for infants and young children is a challenge because of the difficulty of patient cooperation. The Interim Therapeutic Restoration or “ITR” procedure is a minimally invasive provisional restorative technique that does not require the use of local anesthetic or rubber dam isolation. It can be used in young and/or uncooperative patients to temporarily restore and prevent further progression of caries because of slow fluoride release from the restorative material. (Deery 2005). The ITR procedure involves the removal of caries using
hand or low speed rotary instruments with caution not to expose the pulp tissues. Its purpose is to remove the ‘infected’ dentin (dead and insensitive tissue) and not the intact ‘affected’ dentin. After the cavity preparation is complete, the tooth is filled with a fluoride-releasing adhesive glass ionomer-based product (Yip, Smales et al. 2001). Follow-up care with topical fluoride treatment and oral hygiene instruction may improve the treatment outcome in high caries-risk dental populations (American Academy of Pediatric Dentistry 2012).

The indications for the use of the ITR procedure include: 1) when circumstances do not permit traditional cavity preparation and placement of traditional dental restorations, 2) when caries control by step-wise excavation in children with multiple open carious lesions prior to definitive restoration of the teeth is necessary prior to placement of definitive restorations, or 3) when definitive treatment needs to be postponed (Vij, Coll et al. 2004; Deery 2005).

The basis of the ITR procedure was pioneered in Tanzania in the mid-1980’s as a part of a community-based primary oral health program; no electricity was available and follow-up visits were not performed (Frencken, Pilot et al. 1996). In undeveloped regions of the world where traditional dental services are not available, this modality of provisional restorations is termed “atraumatic restorative treatment” (ART). This approach, rather than ITR, is endorsed by the World Health Organization (American Academy of Pediatric Dentistry 2012). In short, ITR utilizes similar techniques to that of ART but with different therapeutic goals. ITR is considered a provisional restoration whereas ART is intended to be
a definitive restoration, often delivered under ‘field conditions’ with little likelihood of being revisited.

Only recently have there been studies on the survival rates of ART restorations in the primary dentition. In a study by Honkala et al., the survival rates of ART and amalgam restorations were compared in 35 Kuwaiti children (mean age 5.7 years). Class I, II, and V restorations using high-strength glass ionomer cement and amalgam alloy were compared over a 2 year period. Where possible, the ART and amalgam restorations were placed randomly on comparable pairs of primary molars. Results demonstrated that nearly 90% of all ART restorations were successful and that the failure rate of the comparable pairs of ART and amalgam restorations was similar. It was found that there was no statistically significant difference in the success rate between ART and amalgam techniques. The investigators concluded that class I ART restorations have a high success rate, supporting the appropriateness of the ART approach in primary teeth in industrialized countries (Honkala, Behbehani et al. 2003). Although the success rate of the restorations was high in this study, some reservations should be noted. The study had a small sample size; further, blind assessments and reliability testing of the assessments could not be arranged.

A meta-analysis of survival rates reported positively on ART. It was reported that the survival rates for single-surface ART restorations using high-viscosity glass ionomer cement in primary dentitions were found to be 95% after 1 year to 86% over 3 years. Also, the survival rates for single-surface ART restorations were statistically significantly higher than for those of multiple-
surface ART restorations in primary dentitions (van 't Hof, Frencken et al. 2006). The majority of the subjects in the studies reviewed were older than six years of age at baseline, therefore, compliance and behaviour of the child most likely contributed positively to the promising survival rates for single-surface ART restorations.

Clinical problems with ART over the short-term may include the early loss of restorations from shallow and non-macromechanically retentive preparations, restoration wear, and bulk fracture of multisurface restorations (Smales and Yip 2000). However, recurrent caries with ART has not been shown to be a problem (Smales and Yip 2000). This may be due to the slow release of fluoride from the glass ionomer cement, however, evidence is not conclusive that the fluoride release prevents secondary caries or caries on the adjacent tooth surface (Randall and Wilson 1999).

The use of the ART / ITR procedure on primary teeth in industrialized countries is well justified for several reasons: 1) hand excavation is less uncomfortable than traditional methods of caries removal and seems to offer the best combination of efficacy and effectiveness for caries removal (van Amerongen and Rahimtoola 1999; Banerjee, Kidd et al. 2000), 2) glass ionomer cements possess chemical bonding and fluoride-releasing properties and may act as a rechargeable fluoride-release system by first absorbing fluoride and then releasing it gradually, giving it potential to enhance remineralization (Hatibovic-Kofman and Koch 1991; Kilpatrick 1993; Hatibovic-Kofman, Koch et al. 1997), and 3) single-surface ART restorations have demonstrated similar long-term
survival rates to amalgam in primary teeth (Honkala, Behbehani et al. 2003). Clearly, ITR should be a key part of a conservative multilevel approach to medical management of caries in young children.
Extensive caries in vulnerable young children continues to be a major concern. Surgical treatment involving restoration or extraction of teeth is the predominant approach to management of this disease. Because of the limited cooperation of young children, their treatment is often delivered under GA in a private clinic or hospital setting. With limited resources and few publicly-funded facilities, GA wait-times can be prolonged which may adversely affect treatment outcomes and quality of life (QoL) for a young child and his / her family.

It is likely that while the child waits for treatment, the risk of more negative outcomes increases as the disease progresses and the prognosis worsens. One such negative outcome is that those teeth which could have been restored by dental restorations may eventually require pulp therapy or extraction. In addition to poorer treatment outcomes, both child and family QoL may also be compromised because the child may have sensitive teeth and chronic pain. It would therefore be desirable to stabilize the caries process for those children with S-ECC who are waiting for definitive treatment.

Undoubtedly, the standard ‘watching and waiting’ approach to S-ECC, should be replaced by more pro-active measures. An ‘intervention’ that engages the caregiver, incorporates minimally invasive restorative techniques, and includes the most up-to-date and evidence based approaches to caries management warrants careful investigation.
8 Study Aims

To manage caries in young children, a multi-faceted intervention was developed incorporating parent counselling, remineralization therapies and minimally invasive restorative techniques. The aims of this pilot study are to:

1. Assess the feasibility and practicality of delivering the ‘intervention’ in a community setting;
2. Explore the association between the ‘intervention’ and stabilization of dental caries;
3. Explore the association between the ‘intervention’ and parent, family, and child QoL;
4. Assess the acceptance of the ‘intervention’ by the parents.
9 Materials & Methods

This pilot study (named ‘Project Smile-Aid’ (PS-A)) was supported by a 2010 University of British Columbia (UBC) Dentistry ‘Pilot Project’ Grant #F10-06178. In this thesis, the name ‘PS-A’ will be used interchangeably in reference to both the overall pilot study and to the intervention protocol. A ‘pilot study’ is a feasibility study in which a ‘mini’ version of a full-scale study and specific pre-testing of particular research instruments (e.g. questionnaire) are done in preparation for a larger study.

Ethics approval was granted by the UBC Clinical Research Ethics Board and Vancouver Coastal Health Research Institute.

9.1 Subject Recruitment

Pre- and school-aged children and their parents from culturally-diverse low-income families were recruited at the Robert & Lily Lee Family Community Health Centre Dental Clinic (RLLFCHC) in Vancouver, Canada. The RLLFCHC offers, for a nominal cost, basic dental care for children 12 years and younger whose families, residents of Vancouver, are not able to afford private dental services. The centre also offers emergency dental care for any school-aged or younger child without a dentist and in need of urgent treatment. Aside from dental treatment, the RLLFCHC focuses on prevention and early intervention; preventive dental services are available for children up to about 12 years of age.
This publicly funded clinic was selected for subject recruitment because some of the families and their children were on a long wait list for treatment at BC Children’s Hospital and the clinic staff were interested in providing an alternative to ‘watchful waiting’ for young children with active, extensive caries.

To facilitate subject recruitment, an in-service presentation and engagement of clinic staff and dentists began the project. Advertisements (Appendix A) about the PS-A study were posted in the RLLFCHC reception area and in the dental operatories to attract interested parents. Patients of record at RLLFCHC were screened for caries at their regular dental visits by the dentists. Parents or legal guardians (caregivers) of children that met the inclusion criteria were approached by the clinic staff or dentists to discuss participation in PS-A. All interested parents were contacted by phone by the investigator (CKN) to schedule a 45-minute ‘baseline’ visit. Subjects were recruited on a continuous basis from August 2011 to August 2012. All baseline visits were conducted by the same investigator (CKN) in the same dental operatory at RLLFCHC in the presence of the child’s parent or legal guardian.

Inclusion ‘criteria’ were caries-active pre- and school-aged children (ages 1 to 12 years) that were in good health. “Caries-active” for this study was defined as any visual sign (white spot lesion or frank cavitation) of caries on any tooth surface. Children with acute dental pain and / or infection were excluded. All subjects remained a patient of record at RLLFCHC and were kept on a regular recall schedule in addition to the PS-A 3 month follow-up visits. Any subject that
developed dental pain and/or infection during the study period was immediately referred for treatment, but the subject remained in the study.

9.2 Baseline Visit and ‘Intervention’ Protocol

The ‘baseline’ or first visit began with a verbal and written introduction and explanation of the project (Appendix B). All questions by the parent, legal guardian, or child were answered prior to beginning the ‘Intervention’ and signing the Informed Consent (Appendix C). The first visit usually lasted 45 minutes. At this initial visit, basic demographic information, caregiver responses to the ‘assessment of caries risk’ questions (Appendix D) were recorded and the ECOHIS survey instrument (Appendix E) was completed. Then the protocol for the PS-A ‘Intervention,’ which consisted of the following steps, was administered in the order listed:

1. Caregiver counselling on dietary and at-home oral hygiene; practices using a motivational interviewing-style approach;
2. Recording of dental health status (Appendix D);
3. Placement of ITR(s), where appropriate;
4. Fluoride varnish application;
5. MI Paste™ demonstration and instructions for at-home application;
6. 24-48 hours post-‘Intervention’ phone call (Appendix G);
7. Scheduling first 3 months follow-up visit
9.2.1 Caries Risk Assessment & Child’s Behaviour

A questionnaire was administered to the parent by the investigator to better understand the behaviours that placed the child at high caries risk. This assessment was based on the American Academy of Pediatric Dentistry Caries-Risk Assessment for 0-5 Year Olds (American Academy of Pediatric Dentistry 2012). A general sense of the behaviour was assessed by recording the presence or absence of the following (Appendix D):

1. High (> 3) between-meal fermentable carbohydrate exposure (Kandelman 1997);
2. Poor cooperation during toothbrushing at home;
3. Toothbrushing frequency, if less than twice daily;
4. A night-time bottle containing a beverage other than water;
5. A regular dental home;
6. Use of non-fluoride toothpaste;
7. Use of sugary medication or the presence of dry mouth.

This information helped determine where to focus counselling efforts to help lower the caries risk and served as a reference at follow-up visits.

The child’s overall behaviour during this appointment was recorded using the Frankl Behaviour Rating Scale (Frankl, Shiere et al. 1962).
9.2.2 Early Childhood Oral Health Impact Scale

The oral health-related quality of life of the child, parent, and family were measured using ECOHIS (Pahel, Rozier et al. 2007) (Appendix E). The instrument was administered by the investigator to the caregiver. The responses were recorded as ‘(0) never or doesn’t apply,’ ‘(1) hardly ever,’ ‘(2) occasionally,’ ‘(3) often,’ ‘(4) very often,’ and ‘(5) don’t know.’ Thirteen questions were divided into three domains: ‘Child,’ ‘Parent,’ and ‘Family.’ A grand total and domain totals were calculated. The minimum Total ECOHIS score was ‘0’ and the maximum was ‘52.’ Final ECOHIS scores were inversely related to OHRQoL, i.e. lower scores equate to higher OHRQoL, and vice versa.

The Child domain had four sub-domains:

1. ‘Child symptoms’: whether or not the child has or ever had dental pain;
2. ‘Child function’: difficulties in drinking, eating, speaking, or missed days at daycare, preschool, or school;
3. ‘Child psychological’: trouble sleeping or if the child ever felt irritable or frustrated;
4. ‘Child self-image interaction’: problems with social interactions due to caries.

The Parent domain tested the distress (guilt or sadness) of the parent while the Family domain tested the financial impact (loss of work days or having to pay for treatment) on the family as it related to the child’s caries.
9.2.3 Motivational Interviewing-Style Counselling

Any recommended changes in dietary habits or at-home oral hygiene were discussed with parents using a motivational interviewing-style approach. Potential dietary and oral health-related concerns were discussed and a ‘menu of options’ was suggested to help guide the caregiver towards reducing the child’s caries risk. Open-ended questions helped motivate parents from inaction to action. No consistent script was used. For example, if a child was routinely given a bottle of milk at bedtime, options to reduce and eliminate the habit were to 1) dilute the milk with water over time and to eventually only have 100% water, 2) immediately stop the habit, or 3) offer another form of sleep-time comfort. Another example of a ‘menu of options’ if a child’s oral hygiene was a challenge were: 1) one-person-assisted toothbrushing using a flat surface such as a couch, bed, or floor or 2) two-person-assisted toothbrushing using a knee-to-knee approach. The options presented permitted the caregiver autonomy in the decision as to what home-care methods would work best in their family situation.

To help facilitate understanding, photographs of knee-to-knee tooth brushing technique and recommended toothpaste amounts were presented. Twice-a-day brushing by an adult with a ‘grain of rice-sized smear’ of fluoride tooth paste was recommended for children ≤ 2 years of age and a ‘pea-sized’ amount for children 2-5 years of age (American Academy of Pediatric Dentistry 2012). Children over 6 years of age were advised to be supervised while toothbrushing and to have caregiver assistance.
9.2.4 Plaque Score & International Caries Detection and Assessment System

It was desirable to simulate a non-dental environment in the project to test the feasibility of providing the intervention in a community setting, where a fully functional dental operatory may not exist. Therefore, neither water nor air was used prior to inspecting the teeth nor to remove debris from the prepared surface prior to placement of the ITR material.

Cooperative children were positioned in the supine position in the dental chair. For very young and non-cooperative children, dental exams were conducted using the knee-to-knee position with the parent. Knee-to-knee exams were performed with the aid of a support cushion (Stay N Place® Lap Board (Specialized Care Co., Inc., NH, USA)) for comfort (Appendix H). A regular-sized Open Wide® disposable mouth rest (Specialized Care Co., Inc., NH, USA) was gently used as a mouth prop for non-compliant children.

Plaque score ('0' to '6') was determined by visual inspection: ‘0’ was the complete absence of plaque and ‘6’ was the presence of plaque in all sextants of the mouth (Appendix D). After determining the plaque score and prior to assessing the ICDAS scores, any food debris or heavy plaque obscuring visual inspection was removed by gentle wiping with 2” x 2” dental gauze. The visual presence or absence of gingivitis, defects of enamel, and deep pits / fissures on teeth surfaces were noted (Appendix D).
Presence of caries was assessed visually with the aid of a dental light and mouth mirror. The presence or absence of teeth and caries was recorded on an odontogram (Appendix D). The International Caries Detection & Assessment System (ICDAS) (Ismail, Sohn et al. 2007) was used to assess caries severity. Prior to data collection, the investigator completed the online ICDAS calibration training program to enable accuracy and consistency (ICDAS 2013).

To streamline the results, three modifications to the ICDAS scoring system were made: 1) tooth surfaces were not air-dried (to simulate a community setting where air is not available), therefore, the score of ‘(1) first visual change in enamel – only after drying’ was not used, 2) previously restored teeth were not included in this study, therefore, only one digit was scored for each surface, and (3) ITRs present at recall visits were scored ‘7.’ Therefore, ‘modified’ ICDAS scores for this study were defined as:

- ‘0’ sound tooth surfaces
- ‘2’ distinct visual change in the enamel
- ‘3’ localized enamel breakdown without visual dentin involvement
- ‘4’ underlying dark shadow from dentin
- ‘5’ distinct cavity with visible dentin
- ‘6’ extensive distinct cavity with visible dentin
- ‘7’ ITR present (at follow-up visits)

ICDAS scores for each tooth and surface [(D)istal, (M)esial, (L)ingual, (B)uccal, and (O)cclusal / (I)ncisal] were recorded. ICDAS scores were
categorized into two groups [< 3 (non-cavitated) or ≥ 3 (cavitated)] for statistical analysis purposes and to allow for trends to be seen more easily.

9.2.5 Interim Therapeutic Restoration

ITRs were placed on ‘appropriate’ tooth surfaces only when patient cooperation enabled them to be placed safely. ‘Appropriate’ teeth surfaces were defined as accessible small to medium-sized cavitated lesions, with priority given to the ‘key’ primary teeth (i.e. primary molars and canines), based on subject’s age and stage of dental development. Excluded were small cavitations not accessible to excavation by hand instruments. Gross lesions were excluded because of the high risk of accidental pulpal exposure during caries removal and lack of retention for restorations.

The restorative material used for ITRs in this study was Ketac™ Nano Quick Mix Capsule (3M ESPE, St. Paul, MN, USA), a light-cured resin-modified glass ionomer (RMGI) restorative and the first of its kind to not require trituration (agitation and mixing of RMGI material within a capsule), thus permitting use in a community setting outside of a dental operatory. Teeth with soft carious lesions at least 2 mm in depth and with adequate 3- or 4-walled enamel support were selected for ITR treatment. Gross caries removal was cautiously performed by hand instrumentation using a small spoon excavator (17 Heavy Excavator (Hu-Friedy Manufacturing Co., Chicago, IL, USA)). The deeper caries layer was not disturbed to prevent accidental pulpal exposure. Ketac Nano Glass Ionomer
Primer (3M ESPE, St. Paul, MN, USA) was applied to the prepared tooth surface(s) for 15 seconds with a Microbrush® (Microbrush International, WI, USA) and light-cured for 10 seconds with Elipar™ S10 LED (3M ESPE, St. Paul, MN, USA). The RMGI was immediately applied onto the primed tooth surface and was slightly overfilled to ensure adequate filling. Surface contouring and removal of excess restorative material was performed with a plastic instrument (Composite Instrument (Hu-Friedy Manufacturing Co., IL, USA) prior to light curing for 20 seconds (Yip, Smales et al. 2001).

9.2.6 Topical Remineralization Agents: Topical Fluoride Varnish & MI Paste™

Following ITR placement, topical fluoride varnish (Vanish™ 5% sodium fluoride with tri-calcium phosphate (3M ESPE, St. Paul, MN, USA) was applied on all tooth surfaces prior to sitting the child upright. To maximize fluoride varnish effectiveness, instructions for the child to avoid food for 4 hours and to refrain from toothbrushing until the next day were given to the parents.

Caregivers were instructed to apply a ‘pea-sized' amount of MI Paste™ (GC America Inc., IL, USA) by finger application to all tooth surfaces at home after evening brushing, prior to bedtime. Each caregiver was given a full-sized tube (35 mL) of MI Paste™ at each visit. Prior to dismissal, a reward (sticker), new toothbrush, and sample tube of fluoride toothpaste were given to each child.
9.3 Post ‘Intervention’ Phone Call

Caregivers were telephoned 24-48 hours post-‘Intervention’ by the principal investigator to (Appendix G):

1. Check the status of the child after the ‘baseline’ visit with respect to discomfort or sensitivity of the teeth;
2. Evaluate parental / caregiver satisfaction with the ‘Intervention’;
3. Remind parents of dietary habits and oral hygiene suggestions discussed at the ‘baseline’ visit;
4. Remind parents about the use of MI Paste™ at home;
5. Schedule a 3 month follow-up visit

9.4 Follow-up Visits

Subjects were followed for up to nine months at intervals of three months. A $10 CDN grocery gift card was given as an incentive for attendance at each follow-up visit. Each follow-up visit was conducted in the same dental operatory as the baseline visit and consisted of:

1. Checking the status of the child to see if she / he had any symptoms or signs of worsening dental caries;
2. Counselling on dietary habits and oral hygiene at home using an MI-style approach;
3. Recording of dental health status: plaque score & ICDAS scores (Appendix F);
4. Recording of survival of ITRs (Appendix F) and placement of new or lost ITRs, where appropriate;
5. Application of fluoride varnish;
6. Replenishing MI Paste™ supply;
7. Evaluating parental / caregiver satisfaction with the ‘Intervention;’
8. Scheduling the next three month follow-up visit.

9.5 Statistical Analysis

Baseline measures (ECOHIS scores, ICDAS scores, plaque scores, and Frankl scores) were compared with measures at up to three post-‘Intervention’ intervals. The one sample Kolmogorov-Smirnov (K-S test) was applied to test distribution of the data. Both parametric and non-parametric analyses were performed on the data. Factorial repeated measures ANOVA (for normally distributed data) and Friedman test (for non-normal data) were used to test changes of scores in the repeated measurements. For pairwise comparisons following repeated measures ANOVA, Bonferroni results were reported. Wilcoxon Signed Rank test, using Bonferroni correction, was applied as a post hoc test for ICDAS scores (non-normal data). Kaplan Meier (Log Rank test) was applied for survival analysis of ITR data. Data were analysed using p ≤ 0.05 as the significance level with SPSS version 20 statistical software.
10 Results

10.1 Sample

Fifty-five child / parent dyads were recruited from June 2011 - May 2012. Three children who had received previous dental treatment (restorations and / or extractions) were dropped from the study to simplify analysis of ICDAS data. However, the ‘Intervention’ was still delivered in hopes that it would help halt or slow down the caries progression. Thus, the ‘Intervention’ was delivered to all 55 recruited children but only 52 children [30 boys, 22 girls; mean age (SD): 31.9 (10.7) m; age range: 12 – 68 m (Figure 1)] were included in the analysis. Thirty-nine (39/52) or 75% of children returned for the three-month follow-up visit; 27/52 or 52% of the original sample returned for the six-month follow-up visit; and 13/52 or 25% of the original group of children returned for the nine-month follow-up visit.

The distribution of ethnicities is shown in Figure 2. Thirty-three (63%) of the children were Asian. Four parents did not speak English and required an interpreter, 8 parents spoke Cantonese-only (the investigator was able to speak Cantonese), and 15 parents spoke enough English to not require an interpreter. In total, 27 (52%) parents had limited or no comprehension of English.
Figure 1: Age Distribution of Sample

Figure 2: Distribution of Ethnicities (N = 52)
Thirteen (25%) of the 52 children had their dental treatment completed during the study and did not return for follow-up visits after their treatment; the parents of two children dropped out of the study; and the families of two children moved. Any available follow-up data for these children are reported.

10.2 Caries Risk Assessment & Child’s Behaviour

Because of the active and extensive caries in all participating children, their caries risk was ‘high.’ The distribution of caries risk factors is shown in Figure 3; however, the risk factor “responses” were primarily used to inform the parent during counselling.

Figure 3: Distribution of Caries Risk Factors (N = 52)
The overall behaviour of the children was recorded at each time interval visit using the Frankl Behaviour Rating Scale. Overall, the mode Frankl score at each time interval was 4, i.e. ‘very good.’ The median Frankl score at baseline was 3, i.e. ‘good’, and 4, i.e. ‘very good,’ at all follow-up time intervals.

10.3 Early Childhood Oral Health Impact Survey

Mean ECOHIS scores were compared at all intervals to assess any changes in the OHRQoL. ECOHIS scores were inversely related to OHRQoL. Total Mean ECOHIS scores (Figure 4), Child Mean ECOHIS scores (Figure 5), Parent Mean ECOHIS scores (Figure 6), and Family Mean ECOHIS scores (Figure 7) decreased over time.

Figure 4: TOTAL Mean (SD) ECOHIS Scores
Figure 5: CHILD Mean (SD) ECOHIS Scores

Figure 6: PARENT Mean (SD) ECOHIS Scores
10.4 Caries Progression

All tooth surfaces were scored using ICDAS at all follow-up visits (Appendix I). Increases in tooth surface ICDAS scores suggested caries progression. In general, the ICDAS scores of the maxillary anterior tooth surfaces showed statistically significant changes (p-value < 0.05) over the study period, i.e. caries progressed. Specifically, the tooth surfaces that demonstrated caries progression were: 53B, 52M, 52B, 51D, 62M, 62L, 62B, 61D, 61M, and 61B (Figure 8). ICDAS scores of the posterior and mandibular anterior tooth surfaces demonstrated no statistically significant change over time (p-value > 0.05).
10.5 Interim Therapeutic Restoration

A total of 52 ITRs were performed in 27 subjects: 35 (67%) on anterior teeth and 17 (33%) on molars. Eighteen (67%) of the 27 children received anterior ITRs, 8 (30%) received posterior ITRs, and 1 (3%) received both anterior and posterior ITRs. Amongst the 24 failed ITRs, the majority (20 or 83% ITRs) were placed on tooth surfaces of ICDAS score 5.

ITR survival times are reported in terms of the time that they remained: 15 (29%) ITRs for 3 months, 34 (65%) ITRs for 6 months, and 3 (6%) ITRs for 9
months. The mean (SE) and median (SE) ITR survival times were 5.3 (0.2) months and 6.0 (0.1) months, respectively. Log Rank test revealed that ITR survival time on anterior surfaces [(N = 35, mean (SD) = 5.8 m (1.2)] and posterior surfaces (N = 17, mean (SD) = 4.2 m (1.9)] were significantly different p-value = 0.001).

10.6 Plaque Scores

Plaque scores for each sextant for each child were recorded at each time interval. The median plaque scores were 3, 3, 3, and 2 at baseline, 3, 6, and 9 months post-‘Intervention,’ respectively. A plaque score of ‘3-out-of-6’ demonstrated that the child had plaque on 50% of their teeth. No statistically significant changes in plaque scores were recorded over the study period.

10.7 Post-‘Intervention’ Phone Call & Parent Satisfaction

A 24-48 hours post-‘Intervention’ phone call was made to the parents to inquire about: 1) the status of the child (any signs or symptoms of dental-related problems) after the ‘baseline’ visit and 2) how they (the parent) felt about being in the PS-A study. No parent reported any child with discomfort or any concerns. Using a 4-point Likert scale, the median and mode Parent Satisfaction scores were 4, i.e. ‘very satisfied.’ Forty (73%) parents responded that they were ‘very
satisfied’ with PS-A. Similar inquiries were made at the 3 month recall visit. All parents remained ‘very satisfied.’
11 Discussion

Project Smile-Aid (PS-A) was a pilot study to explore the feasibility, the acceptance by immigrant parents, the stabilization of caries in participating children, and the impact on oral health-related quality of life (OHRQoL) of a protocol that incorporated a variety of caries management approaches. The protocol included parent counselling using a motivational interviewing-style approach, remineralizing agents, and ITR placement (where appropriate). Further, the intervention was delivered in a dental public health clinic, not in a private practice setting.

The ‘intervention’ proved feasible in a community setting. The majority of the dentists and staff at RLLFCHC were supportive of PS-A and appeared to believe that it was a worthwhile effort. PS-A was delivered in a dental operatory at RLLFCHC, but for the majority of the young children in the study a dental operatory was not required because most children were examined and attended to in the knee-to-knee position without the use of a dental chair. Thus, PS-A could have been readily carried out in a “non-dental” setting.

However, the financial implications of a protocol like PS-A need to be kept in mind when the issue of practicality is considered. Because this project was a research study, it was delivered at no cost to the clinic. The salary for the dentist and dental assistant, overhead costs (space and equipment), and the expense of dental supplies and sundries were not insignificant. Cost will always need to be weighed against benefit when public dollars are spent.
The majority of the parents (73%) were ‘very satisfied’ with PS-A. Many parents expressed thanks and gratitude for having their child participate in the PS-A study. Most parents believed that PS-A helped their child even if the child was not in pain as a result of their dental caries.

The parent QoL improved, as demonstrated by the decrease in the Parent Mean ECOHIS scores over time. This improvement was most dramatic in the first 3 months post-‘Intervention.’ Many parents suggested that their guilt and sadness over their child’s dental disease was largely eliminated because they felt that PS-A gave them more ‘control’ over the problem.

11.1 Subjects

The “pre-recruitment” in-service presentation at RLLFCHC was well received by the staff and dentists. PS-A expanded the existing ‘management options’ for the patients and their families and the presentation gave staff an opportunity to comment on and provide input to the project. Recruitment of children was accomplished with the help of the staff and dentists at RLLFCHC, all of whom expressed interest and support of the study. Definitive dental treatment for these children was ‘on hold’ for various reasons: 1) waiting for GA at BCCH, 2) waiting for improvement in child’s behaviour so that the treatment could possibly be performed in the dental chair, 3) parents indecision on best treatment option, or 4) parent’s desire to just monitor the caries. The project offered families ‘non-invasive’ caries management that could potentially halt or
slow down the caries process while the child’s treatment was “on hold”. Thus, PS-A was an attractive option.

The mean age of participating children was about 3 years of age. The young age of the children was expected as this age group of children often exhibit poor cooperation for invasive dental treatment in an ambulatory setting.

The majority (63%) of the subjects were recent Asian immigrants whose mother tongue was not English. In total, one half of parents had limited or no comprehension of English which created challenges in explaining Informed Consent and PS-A protocols. Not only did these explanations lengthen appointment times, it was also uncertain as to whether or not all of the information was fully understood.

As predicted in the planning phase, the majority of the subjects were ethnic Chinese, whose parents spoke only Cantonese or Mandarin. Therefore, the Informed Consent was translated into Traditional Chinese to help facilitate parents’ understanding of PS-A. For many of these parents, their child also did not speak English. Further, a wide variety of languages presented within this cohort, therefore, although the translation of all forms (Poster Advertisement, Parent Information on PS-A, Informed Consent, Caries Risk Assessment, and ECOHIS) for parents would have been ideal, the cost was prohibitive for this pilot study.
11.2 Caries Risk Assessment & Changes in Home Care

The major inclusion ‘criteria’ for children were evidence of caries-activity (white spot lesion or frank cavitation) and young age, hence, all of the children were considered to be high-risk for caries because of their clinical presentation. Parent responses on modifiable caries factors were recorded (American Academy of Pediatric Dentistry 2012) as previously described. The information gathered from the caries-risk assessment was used to inform the parent about dietary and oral care habits using a motivational interviewing-style approach (DiClemente 1991). A discussion with the caregiver about their child’s caries status and risk of future disease was carried out to establish rapport and goals followed by presenting and discussing a ‘menu of options’ for diet and home care (DiClemente 1991). A motivational interviewing-style approach to counselling has previously been demonstrated to shows promise for promoting caries preventive behaviours in immigrant mothers of young children at high risk of caries (Harrison, Benton et al. 2007).

Twice daily toothbrushing at baseline was reported by over three-quarters of subjects; and almost all used fluoride toothpaste. Although these proportions appear promising, cautious optimism must be taken because what was actually being done at home may be very different from what was being reported. For example, some children had multiple caregivers e.g. older siblings, grandparents, or other relatives or lived in various homes e.g. grandparents’ home, separated parent’s home, etc. Therefore, the actual day-to-day oral hygiene practices may
have been inconsistent. In some cases, the caregiver who brought the child to the PS-A visits was not the person responsible for brushing the child’s teeth. For these reasons, it was a challenge to have an accurate verbal confirmation of the actual oral hygiene practices at home.

Fortunately, plaque scores were compared at baseline and all follow-up visits. Overall plaque scores demonstrated that plaque usually covered half of the teeth. Plaque scores did not significantly improve over time, despite constant efforts by the investigator to motivate parents to improve oral hygiene practices. The lack of change in plaque scores over the study period suggests that toothbrushing did not change over the course of the study.

Dietary practices were also a challenge to assess. Parents, siblings, grandparents, other relatives, and preschool instructors were responsible for between-meal snacks to the children. Fortunately, only three parents reported night-time bottle feeding with milk at baseline. The greatest provider of ‘junk food’ was said to be grandparents. When the caregivers were advised to advise the grandparents about the risks of giving their grandchildren too much ‘junk food’ the most common response was that the grandparents’ habits could not be changed. In many Asian cultures, it would be disrespectful to tell elders what to do. The reliability of the answers given by parents about dietary habits at home may also be questionable because some parents may give false statements during an interview to please the investigator. This deference to professionals may also be a demonstration of culturally-related behaviour.
11.3 Child's Behaviour

The behaviour of the children during the delivery of the 'Intervention' was recorded and compared at each visit as measured by the Frankl Behaviour Rating Scale. Surprisingly, the overall behaviour of most of the young subjects was good during the exam and fluoride varnish applications and did not change over the period of the study. The overall 'good' behaviour of the children was somewhat comparable to reports from a behaviour management study of Swedish children. A first dental exam was performed on 273 three-year old children using a mouth mirror and air-drying of the teeth. Similarly, the majority (76%) of the children cooperated well at the dental examination (Holst, Hallonsten et al. 1993).

The children likely behaved so well because they were patients of record at RLLFCHC and had previous experience with the knee-to-knee style of dental exam. Thus, a mouth mirror as used previously for regular dental visits was not perceived as ‘threatening.’ Also, many of the young children had multiple caregivers at home and were perhaps used to having different people brush their teeth and look in their mouth. It emerged at the baseline visit that most caregivers already brushed their child’s teeth in the supine position on the floor, bed, or couch, or using the knee-to-knee position (Appendix H). These brushing techniques are routinely demonstrated to the families of young children at RLLFCHC. All of these previous experiences may have positively contributed to the children’s relative acceptance of the PS-A ‘Intervention.’
When behaviour was a challenge, ‘tell-show-do’ was used to help introduce the procedures to the child. This behaviour management technique proved to be quite effective for slightly anxious young children.

Children receiving ITR treatment, an unfamiliar and more invasive procedure, demonstrated the most uncooperative behaviour. These children may have been less cooperative for toothbrushing at home, which contributed to their advanced caries and need for ITR. The majority of children tolerated the spoon excavation part of the ITR protocol, however, many children did not like having the restorative material placed into the prepared cavity with the large and noisy dispensing ‘gun.’

11.4 Early Childhood Oral Health Impact Survey

The ECOHIS scores measured the oral health-related QoL at baseline and were compared at up to three time intervals post-‘Intervention.’ The Total ECOHIS scores were derived from the summed scores of three domains: Child, Parent, and Family. The ECOHIS score is inversely related to the oral health-related QoL.

The Total Mean ECOHIS scores demonstrated a steady decrease over the study period, suggesting that there was an improvement in overall oral health-related QoL. The greatest decline in Total Mean ECOHIS scores was seen in the first 3 months post-‘Intervention.’ While the Total Mean ECOHIS scores continued to decline at 6 and 9 months, only 52% and 25% of subjects
had a follow-up visit at these time periods so the continuous decline may only be a trend but one that warrants further study. The reasons for this improvement over this study period are many and an explanation may be found by looking at its components: Child, Parent, and Family domains.

The Parent Mean ECOHIS scores demonstrated a statistically significant decrease [3.2, 1.3, 0.9, and 0.9 at baseline, 3m, 6m, and 9m, respectively (p < 0.001)] suggesting an improvement in the parent’s oral health-related QoL. The two Parent domain questions were: ‘How often have you or another family member 1) been upset or 2) felt guilty because of your child’s dental problems?’ Compared to the Child and Family domain questions, the Parent domain questions elicited the most emotional responses. At baseline, many caregivers felt sad and guilty that their child had caries and felt responsible for their child’s dental problems and suffering. Another factor contributing to this high baseline score was the parent’s alarm at their child’s need for extensive dental treatment and the potential risks of treatment under general anaesthesia. Remarkably, there was an improvement in the parent’s oral health-related QoL as demonstrated by the decreasing Parent Mean ECOHIS score over time. When asked why the caregivers felt less upset and guilty about their child’s dental problems, many replied that being a part of PS-A was doubly positive: they felt that it was improving their child’s oral health and they could be more actively involved in the process, rather than just watching things get worse.

The Family Mean ECOHIS scores demonstrated a steady decrease over the study period, suggesting an improvement in the family's oral health-related
QoL. The two Family domain questions were: ‘How often have you taken time off from work because of your child’s dental problems?’ and ‘Has your child had dental problems that had a financial impact on your family?’ Many children were from a single-income family, thus the “unemployed” parent (typically the mother) accompanied the child at each PS-A visit. Therefore, the answer to the first Family domain question was ‘0’ or ‘never’ for the majority of the subjects. Most of the ‘positive’ answers came from the second question regarding financial impact on the family. Keeping in mind that the RLLFCHC serves the working poor families of Vancouver, many families do not have private dental insurance plans nor do they have Healthy Kids coverage; therefore, the majority of the families must pay out-of-pocket for dental services. A reason as to why there was a decrease in Family Mean ECOHIS scores may be that the caregivers felt that PS-A was ‘improving the problem’ and that future treatment (and future financial cost) would decrease. Overall, it appeared that PS-A had given the family better hope for the future.

The Child Mean ECOHIS scores also demonstrated a decrease but this decrease may be more artificial than real and warrants further discussion. The Child Mean ECOHIS score was already very low at baseline. At the 3 month follow-up visit, several parents reported that their child had less or no discomfort compared to the baseline visit. Two possible explanations for this are: 1) placement of ITR(s) or 2) the use of remineralization agents (fluoride varnish or MI Paste™). It is possible that symptomatic cavitated carious lesions treated
with ITR may have become asymptomatic following ITR placement and/or the fluoride varnish/MI Paste™ decreased some sensitivity.

Unfortunately, two of the Child domain questions did not apply to many of the children. For example, some of the very young children (< 2 years of age) did not speak many words, however, one of the Child domain questions was ‘How often has your child had difficulty pronouncing any words because of dental problems or dental treatment?’ Another question that may not have been applicable for very young children was ‘How often has your child avoided smiling or laughing because of dental problems?’ Although the ECOHIS has been validated for use in children aged 0-5 years, these questions did not appear applicable to such young children. Thus, the applicability of ECOHIS to children < 3 years is clearly questionable. For all questions that were ‘not applicable’ a score of ‘0’ was recorded which lowered the Child Mean ECOHIS score.

Unfortunately, a search of the literature for prospective studies using ECOHIS on young children with S-ECC and their families while implementing a caries management protocol did not turn up any results. However, PS-A’s findings for the baseline Parent Mean ECOHIS scores are consistent with an ECOHIS validation study of 247 Brazilian children (mean age 40.5 months, range: 2 - 5 years old) where the most frequently reported items were the parents “feeling guilty” and having “been upset” because of their child’s dental caries (Martins-Junior, Ramos-Jorge et al. 2012). The investigators in the Brazilian study concluded that ECOHIS was significantly correlated with caries experience. Interestingly, the baseline Child Mean ECOHIS scores were higher than those of
our study i.e. the child had experienced dental pain when eating or sleeping. A reason for this might be that the study's mean age was higher than that of PS-A (40.5 months versus 33.1 months in PS-A) and thus the caries lesions were larger and more extensive. This study's purpose was to validate the use of ECOHIS in the Brazilian-Portuguese language. Comparing ECOHIS scores at recall intervals was not an aim of the study.

Carvalho et al. in 2012 assessed the presence of parent guilt and its association with ECC, dental trauma, and malocclusion in 2 to 5 year old children. They concluded that parent guilt is related to ECC but not associated with dental trauma or malocclusion in preschool children (Carvalho, Abanto et al. 2012).

The ECOHIS instrument proved useful in demonstrating an improvement in overall oral health-related QoL, but with this group of children primarily reflected improvement in the QoL of the parent.

11.5 Interim Therapeutic Restoration

Fifty-two ITRs were placed in 27 (53%) children: 35 (67%) on maxillary anterior teeth (central & lateral incisors and canines) and 17 (33%) on the molars. The distribution of ITRs was not evenly distributed as eighteen (67%) of the 27 children received anterior ITRs, 8 (30%) received posterior ITRs, and 1 (3%) received both anterior and posterior ITRs. The fact that the majority of the tooth surfaces with deep caries were anterior teeth is consistent with the young
age group of the subjects. S-ECC affects the teeth in the order of eruption, namely maxillary central incisors followed by maxillary lateral incisors. The last teeth to be affected by caries in a child with S-ECC are usually the second molars, simply because they are the last primary teeth to erupt (20-24 months of age). Therefore, for the majority of the subjects who presented for the PSA-‘Intervention,’ the molars, especially the second molars, were relatively healthy and showed no signs of extensive caries.

For those children who had ITRs placed, behaviour and cooperation were problematic only for the ITR stage of the appointment despite the fact that ITR placement is considered to be non-invasive (Deery 2005). The removal of the infected superficial layers of tooth structure was relatively easy to perform on most subjects. Surprisingly, what appeared to cause most of the poor behaviour during the entire baseline visit was placement of the Ketac™ Nano (RMGI). The Ketac™ Nano dispenser delivery system appeared to cause the children anxiety. The ‘gun-like’ appearance of the shiny metal device and the ‘click-click’ sound it made as the material was extruded from the capsule caused many of the children to become scared and anxious, thereby making it very challenging to place the RMGI properly. Equally challenging was trying to keep the curing light probe tip centered over the RMGI surface for 20 seconds on a ‘moving target.’ What may have also contributed to the displeasure of children during ITR placement was the heat generated by the curing light. To help stabilize a non-cooperative child long enough to complete the ITR placement, the assistant supported the head of the child as the investigator used the bite stick mouth prop
to keep the child’s mouth open. The least difficult tooth surfaces to place ITRs were the buccal surfaces of maxillary anterior primary teeth, which happened to be the most commonly presenting tooth surfaces with caries in this cohort. Despite the challenges and difficulties in placing ITRs in non-cooperative young children, all of the caregivers were very supportive, helpful, and did not report any negative feelings towards this procedure.

ITR failure in this study was defined as any ITR that was completely lost or dislodged at recall. Marginal staining of the ITR was not deemed as failure. The ITR protocol at the beginning of the study was to replace any failed ITRs at the follow-up visit. The investigator replaced several failed ITRs in the first eight subjects, but they too eventually failed. By trial and error, the investigator was able to determine for which tooth surfaces and size of carious lesion the ITRs performed best. Midway through the study, the investigator became more conservative and placed ITRs only on lesions that he felt had a high chance of long-term survival. Of course, this change in methodology created a biased selection of the subjects who received ITR treatment in the latter half of the study.

The ITRs with greatest likelihood of success were on maxillary anterior buccal surfaces with moderately-sized carious lesions (ICDAS 3 & 4). The reasons for success may have been the following: 1) anterior labial surfaces are the most easily accessible on non-cooperative children, 2) moisture control was least challenging in this region of the mouth, 3) sufficient healthy peripheral tooth structure remained to retain the ITR, and 4) the depth of the cavity was sufficient
for adequate bulk of RMGI. Although RMGIs are designed to bond to tooth structure, it is important to keep in mind that the tooth surfaces in these children were not sound and healthy. Therefore, mechanical retention also appeared to play a major role in ITR long-term success. Lastly, although RMGIs are designed to be more moisture-tolerant compared to other dental restorative materials during placement, it was a challenge to maintain moisture control in the small mouth of a less than cooperative child.

The use of ITRs in our protocol was to potentially improve the outcomes of definitive treatment, either by slowing or halting the caries progression. The rationale for future removal of the ITR and complete removal of the remaining carious dentin (i.e. ‘step-wise’ approach) prior to placement of a definitive restoration is not supported by microbiological studies (Ribeiro, de Oliveira Lula et al. 2012). One study has demonstrated that the bacterial count in the carious dentin on the cavity floor is comparable to that of teeth submitted to complete caries removal and no difference in lesion progression was observed (Ricketts, Kidd et al. 2006). Additionally, the one-step approach reduces the risk of pulp exposure caused by cavity reopening and the removal of remaining carious dentin (Ribeiro, de Oliveira Lula et al. 2012). Thus, caries removal in one session and placement of an ITR is more advantageous than removal in stages over 2 visits, provided that the ITR remains sealed.

Although the primary intention of PS-A was not primarily to examine ITR survival times, 37/52 or (71%), remained for 6 months or more. The mean (SD) ITR survival time was 5.3 (1.5) months. There was a significant difference in ITR
survival time on anterior surfaces and posterior surfaces. A likely reason for this is because of the challenge to place ITRs in posterior teeth of non-cooperative young children.

For the purpose of halting or slowing down caries progression in children waiting for a dental GA at BCCH, a mean ITR survival time of 5.3 months may be an adequate amount of time because GA wait times at BCCH are up to 6 months. One possible key to enhance outcomes of definitive treatment may be to help stabilize or slow down caries progression while the child waits for the GA appointment.

In a study by Honkala et al., class I and II ART restoration survival times were measured in 35 children (mean age 68.4 months). The study concluded that after two years, nearly 90% of class I and class II molar ART restorations survived (Honkala, Behbehani et al. 2003). This study’s results differed drastically to PS-A’s ITR survival times most likely because of the following: 1) the age difference of the children (68.4 months vs. 33.1 months in PS-A), 2) the tooth surfaces where ART / ITR were placed (molars only vs. anterior majority in PS-A), and 3) material choice (glass ionomer vs. RMGI in PS-A).

Ketac™ Nano is a RMGI, a hybrid material with properties of both composite resin and glass ionomer. Unlike true glass ionomers that are moisture tolerant, moisture contamination during placement of RMGIs may cause them to fail prematurely. Ketac™ Nano Quick Mix Capsule was chosen for its ease of application.
Certainly, ITRs may have a place in caries management in children awaiting definitive treatment and they warrant further investigation in a future study.

11.6 Remineralization Agents

Professionally applied fluoride varnish with TCP and at-home MI Paste™ were well received by the caregivers and, surprisingly, a large majority of the children. The pastes were quick and easy to use and had an acceptable taste for young children. Prior to the application of fluoride varnish, tell-show-do was performed for fearful or very young children. Overall, all subjects tolerated the application of fluoride varnish very well.

A tube of MI Paste™ was given to parents at the end of each visit. One tube of MI Paste™ was sufficient to last the three month time intervals. Surprisingly, many of the caregivers reported that the child was the one who reminded the parent to apply the MI Paste™ after night-time toothbrushing. The parents explained that the child really liked the taste of MI Paste™, therefore, compliance was rarely an issue. The major disadvantage of MI Paste™ is its high cost (approximately $20 CDN per 35 mL tube) which may therefore be prohibitive at a community dental public health program without demonstrated proven cost-effectiveness.

Regarding the use of remineralization agents, both fluoride varnish and MI Paste™ may have contributed to decreasing tooth sensitivity over time.
Evidence in the literature has demonstrated the effectiveness of fluoride varnish in the treatment of hypersensitive teeth. Fluoride varnish has been demonstrated to have properties equivalent to other dentinal tubule sealants (Arends, Duschner et al. 1997). As for MI Paste™, a much newer dental product compared to fluoride varnish, the current evidence is inconclusive on effectiveness as a dentin hypersensitivity agent (Azarpazhooh and Limeback 2008). A prospective study with 13 adults (range of 23-48 years) tested the effectiveness of CPP-ACP (MI Paste™) as a dentinal hypersensitivity agent and concluded that the efficacy and short-term therapeutic effect of CPP-ACP were inadequate to treat dentin hypersensitivity (Kowalczyk, Botulinski et al. 2006). The study had a small sample size, lacked an appropriate control group, and the evaluators were not masked to the subjects.

Based on what is known about the effectiveness of MI and FV, our protocol may indeed have had a protective effect on the teeth with ICDAS scores of \( \leq 3 \). Other than for the maxillary anterior teeth, ICDAS scores were stable throughout the study.

### 11.7 Caries Progression

One of the aims of PS-A was to explore whether this multi-faceted ‘Intervention’ stabilized active caries over time. ‘Stabilization’ in this study was based solely on clinical criteria. ICDAS was selected as the caries index because it measures the various stages of caries, and not simply its presence or
absence. With the exception of the maxillary anterior teeth, the overall ICDAS scores appeared stable over the study period. Our combination of the preventive protocols appeared to help to slow down the caries progression, despite the lack of improvement in oral hygiene. However, it must be remembered that monitoring of the majority \( [N = 27 \ (52\%)] \) of children was only for a short 6 month interval.

At baseline, many molars had non-cavitated white spot lesions (WSLs) – an early visual sign of caries. The most common location of WSLs was on buccal surfaces near the gingival margin – a common area where plaque accumulation is high when oral hygiene is poor. None of these posterior buccal surfaces with WSLs progressed to frank cavitation during the study.

In contrast, the ICDAS scores of the buccal surfaces of the maxillary anterior teeth (most notably teeth 53, 52, 62, & 61) demonstrated statistically significant worsening of caries scores between baseline and 6 months (\( p \)-values 0.01, 0.015, & 0.01, respectively), that is, there was caries progression. Perhaps these maxillary anterior teeth with the most severe caries at baseline were far too compromised to experience a beneficial effect from any or all components of the ‘Intervention.’

The ‘Intervention’ appeared to stabilize or halt the caries progression of early lesions (ICDAS < 4), however, large carious lesions (ICDAS > 5) progressed. Fluoride varnish studies have demonstrated a redistribution of minerals in active carious lesions and reduction in caries subsurface porosity (Holmen, Ogaard et al. 1986; Beltran-Aguilar, Goldstein et al. 2000) and CPP-
ACP (MI Paste™) releases calcium and phosphate ions, thus maintaining a supersaturated mineral environment, thereby reducing demineralization and enhancing remineralization (Reynolds, Cai et al. 2003). Certainly, these two remineralization agents likely played a role in stabilization of early caries.

While the follow-up period in this study was limited, the combination of interventions included in PS-A hint at longer-term success.

11.8 Parental Satisfaction and Acceptance

Overall, the caregivers were extremely satisfied with PS-A. The ‘Intervention’ gave them the psychological support and motivation and reminders to help deal with their child’s dental problems while they waited for treatment. Based on the decrease in Parent Mean ECOHIS scores over time, it appears that PS-A gave them the ability to take better control of a situation that 1) they perceived to be out of their control and 2) they believed to be the result of their wrong-doing. Another possible reason as to why caregivers were satisfied with PS-A was that it was a free and non-invasive treatment option that was not previously offered at RLLFCHC.

Even though it was stated and discussed with the parents in the Letter of Information that “as a ‘thank you’ for attending your follow-up visit you will receive a $10 CDN grocery gift card,” the “gift” came as a complete surprise. Comments from many of the caregivers were, “Are you serious? I should be the one paying you to help my child!”
There was satisfaction in seeing the majority of parents in PS-A becoming motivated to help deal with their child’s dental problems. Obviously, the involvement of a parent is paramount to the overall welfare of a child. Therefore, the oral health-related QoL of the parent should always be remembered when managing a child with S-ECC.

11.9 Limitations

Limitations of this study included:

1) Any statistically significant changes in outcome measures between baseline and follow-up visits should be viewed as trends. The sample size was insufficient to allow multivariate analysis. Cause and effect were not able to be tested in this pilot study.

2) The ECOHIS instrument was challenging to apply in this young age group because some of the Child ECOHIS domain questions were inappropriate.

3) Bias of self-reporting is always a concern with parent surveys.

4) ITR placement was a challenge in pre-cooperative young children.

5) While the sample size of this pilot study was small, results may permit sample size calculation for a larger study that may provide more definitive results.

6) Loss to follow-up is a reality in studies involving marginalized immigrant families.
12 Conclusions, Future Studies, & Recommendations

12.1 Conclusions

According to the RLLFCHC staff, caregivers were eager to enrol in PS-A. Discussion with the caregivers at the baseline visit revealed that many of them felt guilty and responsible that their child had caries; seeing the caries was a daily reminder of their failure for not safeguarding their child's oral health. During the study, caregivers revealed at follow-up visits that PS-A empowered them to take on a more proactive role in the management of their child’s oral disease; it helped them change a negative situation into a more positive one. Also, the ‘Intervention’ gave the caregivers an option. Overall, it appeared to give the parents a psychological ‘boost’ and a perceived sense of control of their child’s poor dental health.

Results from the Parent ECOHIS Domain scores demonstrated improvement in their oral health-related QoL as early as the first three month follow-up visit. Furthermore, results show that the improvements in the Parent ECOHIS Domain continued with each subsequent three month follow-up visit. However, caution must be used in concluding that it was only the PS-A protocol that led to improved QoL because other issues in the life of the family may have contributed.

The Project Smile-Aid team concludes that:

1) The ‘Intervention’ proved to be feasible in a community setting;
2) ICDAS scores of < 3 may stabilize in children who participate in an ‘Intervention’ like Project Smile-Aid;

3) Parent oral health-related quality of life, as measured by ECOHIS, appears to improve over the duration of the program compared to baseline;

4) Low-income, immigrant parents eagerly participate in and accept a prevention program to stabilize their child's oral disease.

12.2 Future Studies & Recommendations

It was encouraging that the parents and RLLFCHC staff and dentists were supportive and enthusiastic about the study. Future studies with a more robust sample size should explore:

1) Whether such a multi-faceted ‘Intervention’ can slow caries progression at an earlier stage of early childhood caries, i.e. decalcification stage without frank cavitation, or lesions ICDAS ≤ 3;

2) Whether such a multi-faceted ‘Intervention’ can improve the treatment outcomes in a child with S-ECC;

3) The ability of MI Paste™ to control caries in young children;

4) The application of a multi-faceted intervention like Project Smile-Aid in private practice;

5) Revision of the ECOHIS Child Domain questions to enhance its applicability in studies involving children less than 4 years of age;

6) Practicality of placing ITRs on maxillary anterior teeth with ICDAS ≥ 5.
References


Appendices

Appendix A: Poster Advertisement

Volunteers needed for our research study

Your unique ability to support the following:

✓ Is between 16 and 65 years of age
✓ Has problems that you cannot see
✓ Is already on a waiting list for dental treatment with sedation or

with general anesthesia (in hospital)

If you are interested

Please ask reception for more information

Recruitment_V3_17Feb11
Appendix B: Letter of Information

LETTER OF INFORMATION

Title of Research Project: “Project Smile Aid – An exploratory study of a contemporary caries management protocol for caries-active children and youth”

Principal Investigator:
Co-Investigator:

Dear parents/caregivers:
We are concerned about the number of children that still get cavities in their teeth; many of these children are very young and are afraid of the dental treatment. Often, these children are given “sleepy” medicine to calm them during dental work or may be put to sleep in hospital (general anesthetic) to complete the dental work. Both approaches have risks. As well, the waiting lists and the costs of these treatments may delay the treatment. Study Purpose: We are conducting a pilot study to see how we can combine some newer approaches to slowing down the progress of cavities with our current ways of preventing cavities. The goal is to slow down the cavities while your child waits for treatment with “sleepy” medicine or in the hospital, or waits until the time he/she can have the treatment in the usual manner.

Study Procedure: Your child’s special visit with us will take approximately 1 to 1 ½ hours. We will ask you questions and take notes about your child’s medical history, dental home care, snacking/feeding habits, and then examine and make notes about your child’s specific dental needs. From this, a special program will be planned and provided for your child during that visit AT NO ADDITIONAL COST TO YOU. This program may include:

- gently cleaning some of the open cavities with hand instruments placing a protective type of filling to temporarily seal the cavities (no freezing and usually no drilling is required). The filling contains fluoride to strengthen the tooth
- applying cavity-fighting fluoride varnish
- helping you out with the best ways to brush your child’s teeth
- showing you how to apply a special paste to use daily at home to further strengthen the teeth
- following up with you by phone or email to see how your child did after the appointment and how you feel about the appointment and program
• bringing your child back to clinic for follow-up visits with us every three months to check their teeth and measure whether the cavities are staying the same or getting worse. These follow-up visits would also be at NO ADDITIONAL COST. As a ‘thank you’ for attending your follow-up visit you may choose between a grocery gift card or bus fare/parking costs.

Voluntary participation: Participation in this study is completely voluntary. You may choose to participate in all or part of the study; and even if you do, you may withdraw from the study at any time without affecting your child’s future care at the clinic. You do not waive any legal rights by signing the consent form. This letter is for you to keep for your information. We thank you for taking the time to consider participating in this important pilot research study. If you wish to receive the consent form, please see the receptionist at the clinic or contact me personally.
Appendix C: Informed Consent

PARENT INFORMATION & CONSENT FORM

Title of Research Project: “Project Smile Aid – An exploratory study of a contemporary caries management protocol for caries-active children and youth”

Introduction: You are invited to participate in this PILOT STUDY because your child has cavities and may be either very young and/or may need to be “put to sleep” in hospital because of the amount of treatment needed. We want to investigate if putting together some simpler steps can slow down the progress of your child’s cavities, especially if regular treatments have to be delayed for any reason. We are looking for about 50 children and their parents to volunteer to be subjects for this pilot study.

Your participation is entirely voluntary: It is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what this research study involves. This consent form will tell you about the study, why the research is being done, what will happen to your child during the study and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw your child at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any dental care to which your child is entitled or is presently receiving. Subjects do not waive any of their legal rights by signing this consent form.

Please take time to read the following information carefully before you decide.

Background to the study: In many cases, children that have a lot of cavities require treatments that can be difficult for them to tolerate and so many - especially young or worried children - have to be “put to sleep” in hospital or be given “sleepy medicine” by a specialist dentist to have their dental work done. Treatments of this nature are often delayed many months because of added costs and waiting lists for hospital and specialist care.

What is the purpose of the study? We would like to know if we can successfully slow down the progress of your child’s cavities so that their teeth don’t become worse while waiting for specialist or hospital care. In this pilot study we will combine our usual counselling about diet and tooth brushing with additional tooth-strengthening agents and use simplified filling techniques to seal open cavities until they will be properly treated. We will also see your child for more frequent check-ups so that we can monitor your
child’s dental needs closely. In most cases, if your child is required to wait for hospital or specialist care, there is normally few treatments that can be done over the many months of waiting until all planned dental work is arranged.

**Who can participate in the study?** You may be interested in participating if your child is between the ages of 18 months and 12 years, already a registered patient of the clinic and has cavities that you can see but is on a waiting list for hospital or specialist care for their cavities. Children identified with a milk allergy or milk sensitivity will have the “tooth strengthening” (remineralization) paste substituted with another product but may still participate in the study.

**Who should not participate in the study?** If your child already has swelling, uncontrolled pain or infection from their teeth they should not enrol in the study. These urgent needs will require immediate attention by a dentist or dental specialist.

**What does the study involve?** If you wish to participate, you and your child will be given another special visit at the same clinic with the principal or co-investigator of the study. This visit will take about 1 to 1 ½ hours. During this visit, you will be asked some questions about your child’s health, snacking/feeding and tooth brushing habits. Your child will have their teeth checked and our special program for your child will be discussed with you. This program may include:

- applying cavity-fighting fluoride varnish to the teeth
- gently cleaning some of the open cavities with hand instruments placing a protective type of filling to temporarily seal the cavities (no freezing and usually no drilling is required). The filling contains fluoride to strengthen the tooth
- showing you how to use another special toothpaste (“MI paste”) on your child’s teeth at home
- giving you other advice for diet and home care, specific to your child

We will also call or email you 1 to 2 days after this first appointment to ask you some questions about how satisfied you are about our recommendations, how your child did after the appointment and ask if you have any concerns. Then, we will schedule another visit in about 3 months’ time. At this follow-up visit we ask you some questions about how your child’s teeth are feeling and will check the teeth again, including any cavities we sealed (are they still sealed, staying the same or getting worse), reapply fluoride varnish and provide new home care supplies for your child’s specific needs. These follow-up visits will continue every 3 months until your child’s hospital or specialist care is completed.

**Potential Harms, Injuries, Discomforts or Inconvenience:** We expect that your child’s reaction to the type of care provided should be no different than what their usual reaction would be in the dental office. If you are not comfortable with the way your child is reacting to the care provided, you have the right to refuse further participation without compromising your child’s future dental care at the clinic. Participation in the study will require visits that are more frequent than usual, but any public transit or parking costs associated with these extra visits will be reimbursed.
Potential Benefits: We hope that this simpler approach can be used for children even if they are very young or anxious but we do not know if your child may benefit directly from participating in this pilot study. The individual steps of this study are known to be effective and safe, but what is not known is how effective they will be when combined in a “package” designed for a specific child. The results will help us to plan better strategies for managing cavities in children, and the information gained may help us to plan future, larger studies. Your child may also benefit from the more frequent dental check-ups as any changes will be detected earlier than usual. All dental care procedures supplies that we specifically recommend for your child as part of the study will be provided to you at NO EXTRA COST. Also, as a thank you for coming to your follow-up visits you may choose from a grocery gift card or reimbursement for public transit/parking.

Alternatives to participating in the study: Your child may have their regular dental care as a patient of the clinic even if he/she does not participate in this research study. If it was decided that your child be referred for specialist or hospital care, they will remain on the waiting list until their treatment is booked, and may receive any emergency care if required during that waiting period.

What happens if I decide to withdraw from the study? You do not have to provide any reasons for your decision to withdraw from the study. Your child may continue to have their regular dental care as a patient of the clinic. We will retain any data collected up to the point of the subject’s withdrawal from the study.

Confidentiality: Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and dental records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

Who do I contact if I have questions about the study during my participation? The person who may be contacted about the research is:

Phone:
Email:

Who do I contact if I have questions or concerns about my rights as a subject during the study? If you have any concerns about your/your child’s rights as a research subject or experiences, you may telephone the Research Subject Information Line in the UBC Office of Research Services at: or contact by email at:

Consent: I acknowledge that the research procedures described above have been explained to me and that any questions that I have asked have been answered to my satisfaction.
I have been informed of the alternatives to participation in this study, including the right not to participate and the right to withdraw without compromising future dental care for my child. As well, the potential harms and discomforts have been explained to me and I also understand the benefits (if any) of participating in this research study.

I know that I may ask now, or in the future, any questions I have about the study or the research procedures.

I have been assured that records relating to my child and my child’s care will be kept confidential and that no information will be released or printed that would disclose personal identity without my permission unless required by law.

I also understand that I do not waive any of my legal rights by signing this consent form.

I am aware that I will receive a signed and dated copy of this consent form.

I hereby consent for my child ________________________________ to participate.

Printed Name of parent:__________________________________________

Signature of parent:_____________________________________________
Date:_________

Printed name of
Principal Investigator/designate:_________________________________

Signature of
Principal Investigator/designate:_________________________________
Date:_________
# Appendix D: Data Capture Worksheet - Initial

**Project Smile-Aid**

<table>
<thead>
<tr>
<th>Data Capture Worksheet - Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID: __________</td>
</tr>
<tr>
<td>Medical Hx summary: ___________________</td>
</tr>
<tr>
<td>Caries Risk Indicators: ___________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>History</th>
<th>Y (1)</th>
<th>N (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special needs/poor co-op</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent use of sugary meds/dry mouth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular use of dental home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child has decay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High between-meal exposure ( BF, demand bottle, sippy cup, juice, pop)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of fluoride toothpaste</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily brushing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visible plaque</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gingivitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enamel Defects: (list tooth #)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep pits &amp; fissures: (list tooth #)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Clinical**

<table>
<thead>
<tr>
<th>Y (1)</th>
<th>N (0)</th>
</tr>
</thead>
</table>

**Urgent conditions noted:** unprovoked pain (1) abscess/draining sinus (2) swelling (3) other (4)

- [ ] ITRs required: [Tooth #/surface]
- [ ] ITRs placed: [Tooth #/surface]
- [ ] Vanish (reg) / Vanish (TCP)
- [ ] Counselling: [ ] Dietary/feeding
- [ ] Mi paste application
- [ ] TB demo
- [ ] Follow up OK’d & correct contact info:
  - [ ] Phone
  - [ ] Email

**Plan for further definitive care:**

1. Emergency tx req’d now
2. on WL for sed/GA - anticipated date:__________
3. prefers to post-pone tx
4. other:_______________________

- [ ] Next recall:

---

Notes:

DC_initial_14Mar11

Page 1 of 2
Project Smile-Aid          Data Capture Worksheet - Initial

Circle teeth present/Chart 2-digit codes on surfaces (see ICDAS II codes below)

Plaque Score: /6

<table>
<thead>
<tr>
<th>First Number</th>
<th>Meaning</th>
<th>Second Number</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Sound, unexcised</td>
<td>0</td>
<td>Sound</td>
</tr>
<tr>
<td>1</td>
<td>Sealant, partial</td>
<td>1</td>
<td>1&quot; visual change in enamel – only after drying</td>
</tr>
<tr>
<td>2</td>
<td>Sealant, full</td>
<td>2</td>
<td>Distinct visual change in enamel</td>
</tr>
<tr>
<td>3</td>
<td>Tooth-colored restoration</td>
<td>3</td>
<td>Localized enamel breakdown (w/o visual dentin involvement)</td>
</tr>
<tr>
<td>4</td>
<td>Amalgam restoration</td>
<td>4</td>
<td>Underlying dark shadow from dentin</td>
</tr>
<tr>
<td>5</td>
<td>SRC</td>
<td>5</td>
<td>Distinct cavity with visible dentin</td>
</tr>
<tr>
<td>6</td>
<td>Porcelain/Gold/PFM/Veneer</td>
<td>6</td>
<td>Extensive distinct cavity with visible dentin</td>
</tr>
<tr>
<td>7</td>
<td>Lust/Discolored restoration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Temporary restoration 20K/G1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Missing/Unerupted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ICDAS 2-digit Codes: (e.g., 00, 13-45)  codes in bold are more likely to apply
Appendix E: Early Childhood Oral Health Impact Survey

Preamble:
“Problems with the teeth, mouth or jaws and their treatment can affect the well-being and everyday lives of children and their families. For each of the following questions, tell us which response best describes your child’s experiences or your own”.

Response options:
1-Never  2-Hardly ever  3-Occasionally  4-Often  5-Very Often  6-Don’t Know
(If question doesn’t apply, circle 1 (‘Never’)

Child symptoms domain
1. How often has your child had pain in the teeth, mouth or jaws? 1 2 3 4 5 6

Child function domain
2. Had difficulty drinking hot or cold beverages ....... 1 2 3 4 5 6
3. Had difficulty eating some foods........ 1 2 3 4 5 6
4. Had difficulty pronouncing any words........ 1 2 3 4 5 6
5. Missed preschool, daycare or school........... 1 2 3 4 5 6

Child psychological domain
6. Had trouble sleeping........ 1 2 3 4 5 6
7. Been irritable or frustrated......... 1 2 3 4 5 6

Child self-image interaction Domain
8. Avoided smiling or laughing when around other children...... 1 2 3 4 5 6
9. Avoided talking with other children......... 1 2 3 4 5 6

Parent distress domain
10. Been upset................... 1 2 3 4 5 6
11. Felt guilty................. 1 2 3 4 5 6

Family function domain
12. Have you or another family member taken time off from work....... 1 2 3 4 5 6
13. Has your child had dental problems or dental treatments that had a financial impact on your family? 1 2 3 4 5 6

Total Score ___________
Appendix F: Data Capture Worksheet - Recall

Project Smile-Aid

Data Capture Worksheet - Recall

Patient ID: M F Pt age: Date: / / 
Medical Hx summary & update:
RECALL #: 

<table>
<thead>
<tr>
<th>Tooth Number</th>
<th>New ITR (surface)</th>
<th>Previous ITR surface for each add: intact (2) partial loss (1) complete loss (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ Vanish (req) / Vanish (TCP)
☐ Counselling:
  ☐ Dietary/feeding
  ☐ MI paste application
  ☐ TB demo
☐ OH aids given: MI paste TB info
☐ Follow up OK’d & correct contact info:
  ☐ Phone
  ☐ Email
☐ Incentives given:
☐ Next recall:

Notes/Comments:

Plan for further definitive care:
- emergency tx req’d
- ex WLI for sed/GA - anticipated date: 
- prefers to post-pain tx
- other: 

DC_Recall_V1_14Mar11
Project Smile-Aid          Data Capture Worksheet - Recall

Circle teeth present/Chart 2-digit codes on surfaces (see ICDAS II codes below)  

Plaque Score: /6

ICDAS 2-digit Codes: (eg. 06, 13, 45) Codes in Bold are more likely to apply

<table>
<thead>
<tr>
<th>First Number</th>
<th>Meaning</th>
<th>Second Number</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Sound, unerupted</td>
<td>0</td>
<td>Sound</td>
</tr>
<tr>
<td>1</td>
<td>Sealer, partial</td>
<td>1</td>
<td>Suscept visual change in enamel</td>
</tr>
<tr>
<td>2</td>
<td>Sealer, full</td>
<td>2</td>
<td>Distinct visual change in enamel</td>
</tr>
<tr>
<td>3</td>
<td>Tooth colored restoration</td>
<td>3</td>
<td>Le点缀ed enamel breakdown (w/ visual dentin involvement)</td>
</tr>
<tr>
<td>4</td>
<td>Amalgam restoration</td>
<td>4</td>
<td>Underlying dark shadow from dentin</td>
</tr>
<tr>
<td>5</td>
<td>SSC</td>
<td>5</td>
<td>Distinct cavity with visible dentin</td>
</tr>
<tr>
<td>6</td>
<td>Porcelain/gold/PM/Sealer</td>
<td>6</td>
<td>Extensive distinct cavity with visible dentin</td>
</tr>
<tr>
<td>7</td>
<td>Lost/Broken restoration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Temporary restoration 206/01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Missing/Unerupted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix G: 24-48 Hours Post-'Intervention’ Parent Phone Interview

Project Smile Aid:

Script for Parent Phone Interview @ follow up 24-48 hours post-appointment

(Optional of having parent providing answer by email if they so choose)

Start with an open-ended question:

“Could you tell me how your child was after the appointment?” (you could test this question in the first few subjects and then maybe you will come up with a list of options e.g. “no problems” “complained of pain” “no different than usual”, etc. or just leave as a simple open-ended question)

If the parent says “no problem” then they could be asked specifics, any problems with:

eating Yes / No Explain

drinking Yes / No Explain

sleeping Yes / No Explain

chewing Yes / No Explain

pain Yes / No Explain

Make note of any specific comments – positive or negative.

“How happy were you with the way your child was during and after the appointment?”

During: 1-very unhappy 2-a bit unhappy 3-happy with it 4-very happy with it

After: 1-very unhappy 2-a bit unhappy 3-happy with it 4-very happy with it

Follow-up question, for when patient returns after period of 3 months:

“Could you tell me how your child has been doing with since their last visit... Are they?”

- Eating better, sleeping better etc.?

- Problems with brushing?

- How have the teeth been feeling?

“How happy have you been with the special program we suggested for your child?”

1-very unhappy 2-a bit unhappy 3-happy with it 4-very happy with it

Parent_Ques_V2_18Apr11
Appendix H: Photo of Knee-to-Knee Positioning
## Appendix I: Summary of ICDAS Scores

<table>
<thead>
<tr>
<th>Variables</th>
<th># of study subjects</th>
<th>p-value</th>
<th>Test used</th>
</tr>
</thead>
<tbody>
<tr>
<td>55Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>55Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>55Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>55Lb, 3m, 6m</td>
<td>13</td>
<td>N/A; almost all=0</td>
<td>Friedman</td>
</tr>
<tr>
<td>55Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>55Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; almost all=0</td>
<td>Friedman</td>
</tr>
<tr>
<td>55Ob, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Mb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Bb, 3m, 6m</td>
<td>13</td>
<td>N/A</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Ob, 3m, 6m</td>
<td>27</td>
<td>0.78</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A</td>
<td>Friedman</td>
</tr>
<tr>
<td>54Ob, 3m, 6m</td>
<td>27</td>
<td>0.11</td>
<td>Friedman</td>
</tr>
<tr>
<td>53Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>53Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>53Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>All 0 but subject #4, 11, 40, 42 which were 2</td>
<td>Friedman</td>
</tr>
<tr>
<td>53Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>53Bb, 3m, 6m</td>
<td>13</td>
<td>0.29</td>
<td>Friedman</td>
</tr>
<tr>
<td>53Bb, 3m, 6m</td>
<td>27</td>
<td>0.005</td>
<td>Friedman; Post Hoc test shows 53Bb and 53B 6m differ significantly (p-value=0.01)</td>
</tr>
<tr>
<td>53Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Db, 3m, 6m, 9m</td>
<td>13</td>
<td>0.73</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Db, 3m, 6m</td>
<td>27</td>
<td>0.22</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.43</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Mb, 3m, 6m</td>
<td>27</td>
<td>0.024</td>
<td>Friedman; No significant results in pairwise comparisons</td>
</tr>
<tr>
<td>52Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>0.33</td>
<td>Friedman</td>
</tr>
<tr>
<td>Variables</td>
<td># of study subjects</td>
<td>p-value</td>
<td>Test used</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------</td>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td>52Lb,3m,6m</td>
<td>27</td>
<td>0.05</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Bb,3m,6m,9m</td>
<td>13</td>
<td>0.48</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Bb,3m,6m</td>
<td>27</td>
<td>0.005</td>
<td>Friedman; Post Hoc test shows 52Bb and 52B 6m differ significantly (p-value= 0.015)</td>
</tr>
<tr>
<td>52Ib,3m,6m,9m</td>
<td>13</td>
<td>0.47</td>
<td>Friedman</td>
</tr>
<tr>
<td>52Ib,3m,6m</td>
<td>27</td>
<td>0.024</td>
<td>Friedman; No significant results in pairwise comparisons</td>
</tr>
<tr>
<td>51Db,3m,6m,9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Db,3m,6m</td>
<td>27</td>
<td>0.022</td>
<td>Friedman; Post Hoc tests revealed no pairwise significant differences (considering p-value for Bonferroni correction)</td>
</tr>
<tr>
<td>51Mb,3m,6m,9m</td>
<td>13</td>
<td>0.1</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Mb,3m,6m</td>
<td>27</td>
<td>0.12</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Lb,3m,6m,9m</td>
<td>13</td>
<td>0.13</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Lb,3m,6m</td>
<td>27</td>
<td>0.47</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Bb,3m,6m,9m</td>
<td>13</td>
<td>0.93</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Bb,3m,6m</td>
<td>27</td>
<td>0.87</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Ib,3m,6m,9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>51Ib,3m,6m</td>
<td>27</td>
<td>0.22</td>
<td>Friedman</td>
</tr>
<tr>
<td>65Db,3m,6m,9m</td>
<td>13</td>
<td>N.A; All 0</td>
<td></td>
</tr>
<tr>
<td>65 Mb,3m,6m,9m</td>
<td>13</td>
<td>All but sub ≠ 38 are 0</td>
<td></td>
</tr>
<tr>
<td>65Lb,3m,6m,9m</td>
<td>13</td>
<td>All but sub ≠ 0 &amp; 30 are 0</td>
<td></td>
</tr>
<tr>
<td>65Bb,3m,6m,9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>65Bb,3m,6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>65Ob,3m,6m,9m</td>
<td>13</td>
<td>N.A (all but sub≠1, 30,34,40 are 0)</td>
<td></td>
</tr>
<tr>
<td>64Db,3m,6m,9m</td>
<td>13</td>
<td>N.A; All 0</td>
<td></td>
</tr>
<tr>
<td>64 Mb,3m,6m,9m</td>
<td>13</td>
<td>All but sub ≠ 25 are 0</td>
<td></td>
</tr>
<tr>
<td>64Lb,3m,6m,9m</td>
<td>13</td>
<td>N.A; All 0</td>
<td></td>
</tr>
<tr>
<td>64Bb,3m,6m,9m</td>
<td>13</td>
<td>0.73</td>
<td>Friedman</td>
</tr>
<tr>
<td>64Bb,3m,6m</td>
<td>27</td>
<td>0.45</td>
<td>Friedman</td>
</tr>
<tr>
<td>Variables</td>
<td># of study subjects</td>
<td>p-value</td>
<td>Test used</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------</td>
<td>---------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>64Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>NA (due to data scarcity)</td>
<td>Friedman</td>
</tr>
<tr>
<td>64Ob, 3m, 6m</td>
<td>27</td>
<td>0.22</td>
<td>Friedman</td>
</tr>
<tr>
<td>63Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A: All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>63Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A: All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>63Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A: All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>63Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A (due to data scarcity)</td>
<td>Friedman</td>
</tr>
<tr>
<td>63Db, 3m, 6m</td>
<td>27</td>
<td>0.097</td>
<td>Friedman</td>
</tr>
<tr>
<td>63Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A: All 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>62Db, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>62Mb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>62Mb, 3m, 6m, 9m</td>
<td>13</td>
<td><strong>0.015</strong></td>
<td>Friedman; Post Hoc tests revealed no pairwise significant differences (considering p-value for Bonferroni correction)</td>
</tr>
<tr>
<td>62Lb, 3m, 6m</td>
<td>27</td>
<td><strong>0.014</strong></td>
<td>Ditto</td>
</tr>
<tr>
<td>62Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.2</td>
<td>Friedman</td>
</tr>
<tr>
<td>62Bb, 3m, 6m, 9m</td>
<td>13</td>
<td><strong>0.032</strong></td>
<td>Friedman; Post Hoc tests revealed significant differences between baseline and 6 month scores (P=0.01)</td>
</tr>
<tr>
<td>62Bb, 3m, 6m</td>
<td>27</td>
<td><strong>0.005</strong></td>
<td>Ditto</td>
</tr>
<tr>
<td>62Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>62Lb, 3m, 6m</td>
<td>27</td>
<td>0.16</td>
<td>Friedman</td>
</tr>
<tr>
<td>61Db, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>61Db, 3m, 6m</td>
<td>27</td>
<td><strong>0.05</strong></td>
<td>Friedman; Post Hoc tests revealed no pairwise significant differences</td>
</tr>
<tr>
<td>61Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.19</td>
<td>Friedman</td>
</tr>
<tr>
<td>61Mb, 3m, 6m</td>
<td>27</td>
<td><strong>0.011</strong></td>
<td>Friedman; Post Hoc tests revealed no pairwise significant differences (considering p-value for Bonferroni correction)</td>
</tr>
<tr>
<td>61Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.33</td>
<td>Friedman</td>
</tr>
<tr>
<td>61Lb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>Variables</td>
<td># of study subjects</td>
<td>p-value</td>
<td>Test used</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------</td>
<td>---------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>61Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>61Bb, 3m, 6m</td>
<td>27</td>
<td>0.015</td>
<td>Friedman; Post Hoc tests revealed no pairwise significant differences (considering p-value for Bonferroni correction)</td>
</tr>
<tr>
<td>61Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>61Lb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variables</th>
<th>Study subjects</th>
<th>p-value</th>
<th>Test used</th>
</tr>
</thead>
<tbody>
<tr>
<td>75D6, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All but 1 (sub≠32) are 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>75Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>Ditto</td>
<td></td>
</tr>
<tr>
<td>75Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>Ditto</td>
<td></td>
</tr>
<tr>
<td>75Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>75Bb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>75Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A due to data scarcity and 0 data</td>
<td>Friedman</td>
</tr>
<tr>
<td>75Ob, 3m, 6m</td>
<td>27</td>
<td>0.72</td>
<td>Friedman</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variables</th>
<th>Study subjects</th>
<th>p-value</th>
<th>Test used</th>
</tr>
</thead>
<tbody>
<tr>
<td>74Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All but 1 (sub≠32) are 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>74Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All but 1 (sub≠25) are 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>74Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>74Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>74Bb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>74Ob, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A due to data scarcity and 0 data</td>
<td>Friedman</td>
</tr>
<tr>
<td>74Ob, 3m, 6m</td>
<td>27</td>
<td>0.05</td>
<td>Friedman; No significant results in pairwise comparisons</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variables</th>
<th>Study subjects</th>
<th>p-value</th>
<th>Test used</th>
</tr>
</thead>
<tbody>
<tr>
<td>73Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>73Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All but 1 (sub≠8) are 0</td>
<td>Friedman</td>
</tr>
<tr>
<td>73Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>73Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>73Bb, 3m, 6m</td>
<td>27</td>
<td>0.22</td>
<td>Friedman</td>
</tr>
<tr>
<td>73Lb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variables</th>
<th>Study subjects</th>
<th>p-value</th>
<th>Test used</th>
</tr>
</thead>
<tbody>
<tr>
<td>72Db, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>72Mb, 3m, 6m, 9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>Variables</td>
<td># of study subjects</td>
<td>p-value</td>
<td>Test used</td>
</tr>
<tr>
<td>-------------------</td>
<td>---------------------</td>
<td>---------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>72Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>72Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>72Bb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>72Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>71Db, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>71Mb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All but 1 (sub=12) are 0</td>
</tr>
<tr>
<td>71Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>71Bb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All but 1 (sub=3,11,12) are 0</td>
</tr>
<tr>
<td>71Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>85Db, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All but sub # 32 are 0</td>
</tr>
<tr>
<td>85Mb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All but sub # 32 are 0</td>
</tr>
<tr>
<td>85Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All but sub # 32,38 are 0</td>
</tr>
<tr>
<td>85Bb, 3m, 6m, 9m</td>
<td>13</td>
<td>0.39</td>
<td>Friedman</td>
</tr>
<tr>
<td>85Bb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>85Ob, 3m, 6m, 9m</td>
<td>12</td>
<td></td>
<td>N/A due to data scarcity and 0 values in data</td>
</tr>
<tr>
<td>84Db, 3m, 6m, 9m</td>
<td>1</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>84Mb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>84Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>84Bb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All but sub # 34,36,46 are 0</td>
</tr>
<tr>
<td>84Ob, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A due to data scarcity and 0 values in data</td>
</tr>
<tr>
<td>84Ob, 3m, 6m</td>
<td>27</td>
<td>0.99</td>
<td>Friedman</td>
</tr>
<tr>
<td>83Db, 3m, 6m, 9m</td>
<td>131</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>83Mb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>83Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>83Bb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A due to data scarcity and 0 values in data</td>
</tr>
<tr>
<td>83Bb, 3m, 6m</td>
<td>27</td>
<td>0.37</td>
<td>Friedman</td>
</tr>
<tr>
<td>83Lb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>82Db, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>82Mb, 3m, 6m, 9m</td>
<td>13</td>
<td></td>
<td>N/A; All 0</td>
</tr>
<tr>
<td>Variables</td>
<td># of study subjects</td>
<td>p-value</td>
<td>Test used</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------</td>
<td>------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>82Lb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>82Bb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All but sub # 14.46 are 0</td>
<td></td>
</tr>
<tr>
<td>82Lb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>81Db,3m,6m,9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>81Mb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All but sub # 12 are 0</td>
<td></td>
</tr>
<tr>
<td>81Lb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
<tr>
<td>81Bb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All but sub # 3.12 are 0</td>
<td></td>
</tr>
<tr>
<td>81Lb,3m,6m,9m</td>
<td>13</td>
<td>N/A; All 0</td>
<td></td>
</tr>
</tbody>
</table>