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The impact of dental caries on the oral health-related quality of life in children

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THE IMPACT OF DENTAL CARIES ON THE ORAL HEALTH-RELATED
QUALITY OF LIFE IN CHILDREN

by

Christa Elizabeth Hirleman

A thesis submitted in partial fulfillment
of the requirements for the Master of Science
degree in Dental Public Health in the
Graduate College of
The University of Iowa

May 2018

Thesis Supervisor: Professor John J. Warren

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

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has been approved by the Examining Committee for
the thesis requirement for the Master of Science degree
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To my late father Walter 'Jack' Hirleman, for his unwavering love, support, and encouragement.

Never bend your head. Hold it high. Look the world straight in the eye.

Helen Keller

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ABSTRACT

Objectives: The purpose of this study was to explore the level to which dental caries and socio-demographic factors impact the oral health-related quality of life (OHRQoL) in a sample of Amish children. **Methods:** This cross-sectional study was embedded within a pilot study of medical management of caries in the primary dentition using silver nitrate. Parents were asked to complete a baseline questionnaire which included questions regarding socio-demographics and an OHRQoL questionnaire- a 16-item Parent Perception Questionnaire (PPQ). Parents were also asked to make a global rating of their child's oral health status and its impact on the child's overall wellbeing. Oral examinations were completed by two previously trained and calibrated dentists for the assessment of dental caries experience. Descriptive and bivariate analyses were performed including the Spearman Correlation and Wilcoxon rank sum test. Multivariable linear modeling was used to model the covariate effects on OHRQoL.

Results: 77 children were analyzed. OHRQoL was negatively impacted by caries as per the Oral Domain of the PPQ ($p < .02$) and the global oral health status rating ($p < 0.0001$). There was no significant difference between males and females in the OHRQoL outcome measures ($p > 0.05$). The effect of income on OHRQoL was tenuous as the results were inconsistent. **Conclusions:** According to parents' perceptions, a higher caries experience was associated with a poorer oral health status rating and had a negative impact on oral symptoms as they related to the OHRQoL of the children. Finally, there may be cultural differences regarding the value and/or expectations of oral health.

PUBLIC ABSTRACT

Poor oral health can cause pain and discomfort. It can impact sleeping, eating, socializing, speaking, working, etc. It can affect one's functional, social, and emotional well-being. The personal evaluation of one's oral health as it relates to the factors just mentioned is known as oral health-related quality of life (OHRQoL).

Children in general have high levels of oral disease. Dental caries (cavities) is the most common chronic disease in children. They are affected in many of the same ways adults are. However, children need someone to advocate for them. Parents directly impact the oral health of their children. Therefore, it is important that we not only know how much children are impacted by this disease, but the level to which parents perceive that impact. That was the goal of this study.

There were 77 children in this study, aged 2 to 14. All had moderate to high levels of oral disease. Their OHRQoL, as perceived by their parents, was assessed through a questionnaire. Parents of children with higher disease levels perceived their children's oral health to be poorer compared to parents of children with lower disease levels. However, despite the high levels of oral disease in this study group overall, parents in general perceived that their children's well-being was impacted very little. It is important to note though that this entire study group was comprised of Amish children. Therefore, there may be cultural differences with the value of oral health and the expectations of health in general.

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CHAPTER I

INTRODUCTION

In 1948, the World Health Organization defined health as a “complete state of physical, mental, and social well-being and not merely the absence of infirmity” (Preamble to the Constitution of the World Health Organization, International Health Conference, 1948). Since then, great advancements have been made regarding the understanding of many common diseases, including oral diseases (Bennadi and Reddy, 2013). In 2000 the Surgeon General released a report proclaiming the relevance of oral health as a fundamental element of general health and overall well-being (DHHS,2000). This report placed emphasis on the fact that oral health can be achieved by all, but currently is not. Unfortunately, significant oral health disparities continue to exist, with impoverished and minority children most affected (DHHS,2000).

Oral health and quality of life are related on functional as well as psychosocial dimensions for both adults and children (DHHS,2000). In children, oral pain can affect sleep, eating, social interactions, school attendance, and daily activities (DHHS, 2000). In essence, it influences their emotional well-being and overall quality of life, as well as the quality of life of their families. Oral health-related quality of life (OHRQoL) is a concept which applies to the specific impact of oral disease on day to day functions and overall well-being (DHHS,2000). Young children are a particularly important population in regards to OHRQoL because they are unable to advocate for themselves. Parents and caregivers directly impact the oral health of their children as they are the initial gatekeepers to care children receive. It is important to not only understand more about

how this disease impacts children, but also to understand the extent to which parents and caregivers perceive this impact.

As caries is the most common chronic disease in children (DHHS,2000), it is imperative to have an effective and efficient method of assessing, interpreting, and improving the OHRQoL of children (Locker et al., 2002, Jokovic et al, 2002-4). A better understanding of this concept will help to determine the true burden of this disease, and with that understanding comes the fundamental information needed in order to make appropriate clinical decisions, determine treatment needs, and implement public health programs (Sischo and Broder, 2011; Locker et al., 2002, Jokovic et al, 2002-4).

There are numerous ‘quality of life’ studies which have been undertaken in various other countries, however, published research regarding children’s OHRQoL and caries status in the United States is minimal. While the results from studies based in other countries provide relevant information related to this subject, for obvious reasons these results cannot be entirely relatable to the population of the United States. Therefore, the purpose of this thesis is to explore the level to which dental caries impacts children’s oral health related quality of life.

This cross-sectional study was embedded within a pilot interventional study, ‘Medical Management of Caries in the Primary Dentition Using Silver Nitrate.’ While this trial aimed to provide evidence for the most clinically-effective and cost-effective approach to managing caries in children’s primary teeth, a secondary purpose was to assess patient quality of life.

One can appreciate the heterogeneous nature of the United States. This country is comprised of various populations and it is of great value to obtain as much knowledge as

possible regarding this heterogeneity. The children who have taken part in this particular study are Amish; therefore, this study was one small step in understanding one specific population. However, generalizations must be made with caution.

CHAPTER II

REVIEW OF LITERATURE

Overview

As the purpose of this thesis is to explore the level to which dental caries impacts children's oral health-related quality of life (OHRQoL), the following chapter contains various sections germane to this purpose. Included is a review of dental caries, its risk factors, etiology, and prevention, key definitions related to this subject matter, tools for measuring and assessing OHRQoL, a review of Amish diet and oral health, as well as several other pertinent topics. However, the majority of this chapter will focus on the review of current literature regarding the impact of dental caries on children's OHRQoL as well as children's changes in OHRQoL following dental treatment.

Dental Caries

Dental caries is a common, preventable, progressive, and cumulative oral disease which impacts oral health, and ultimately day to day living (DHHS, 2000). While there have been numerous definitions of dental caries throughout the years, the World Health Organization defines it as a "localized, post-eruptive, pathologic process of external origin involving softening of the hard tissue and proceeding to the formation of a cavity" (World Health Organization Technical Report Series No. 242., 1962). Dental caries of a specific severity in children has its own terminology. When children of 71 months or younger have "1 or more decayed (noncavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth" (American Academy of Pediatric

Dentistry, Council on Clinical Affairs, 2003), they are affected with what is known as early childhood caries.

Burt and Eklund (1999) describe dental caries as a multifactorial bacterial infectious disease; therefore, without bacteria this disease cannot develop. As depicted in Figure 2.1, caries requires a host, cariogenic biofilm, fermentable carbohydrates, and time (Keyes-Jordan, 1963). Accompanying this complex process are primary as well as secondary modifying factors, such as diet, tooth morphology, salivary rate and buffering, genetics, socioeconomic status, etc (Burt and Eklund, 1999). Mutans Streptococci and Lactobacilli are normal components of the oral bacterial flora, but they are also the principle players in this disease process (Burt and Eklund, 1999).

Modified Keyes-Jordan diagram

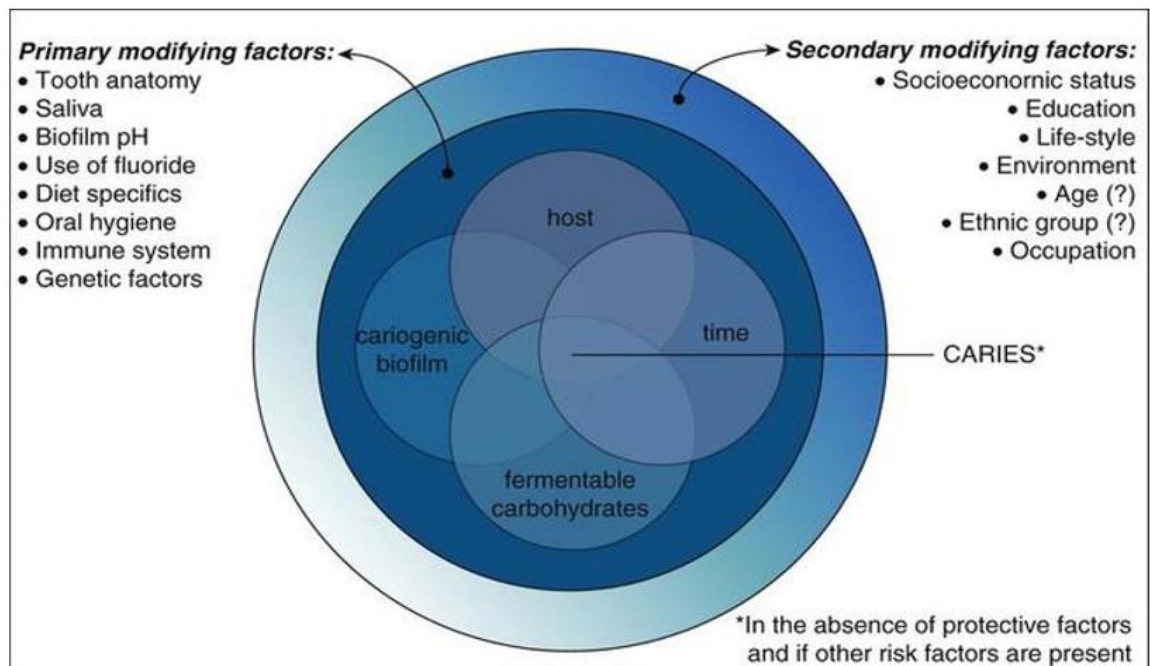


Figure 2.1. Modified Keyes-Jordan Diagram (Burt and Eklund, 1999 as depicted in Keyes Jordan, 1963)

Touger-Decker et al. (2003) described the caries process as a balance between protective and pathologic factors. A cariogenic diet has the ability to impede on this balancing process by promoting demineralization. High sugar diets provide fermentable carbohydrates which are metabolized by the bacteria housed in the plaque (Touger-Decker et al.,2003). This, in turn, creates an acidogenic environment favoring demineralization. Low sugar diets, on the other hand, may favor remineralization (Touger-Decker et al.,2003). Figure 2.2 depicting this balancing process between protective and pathologic factors is below:

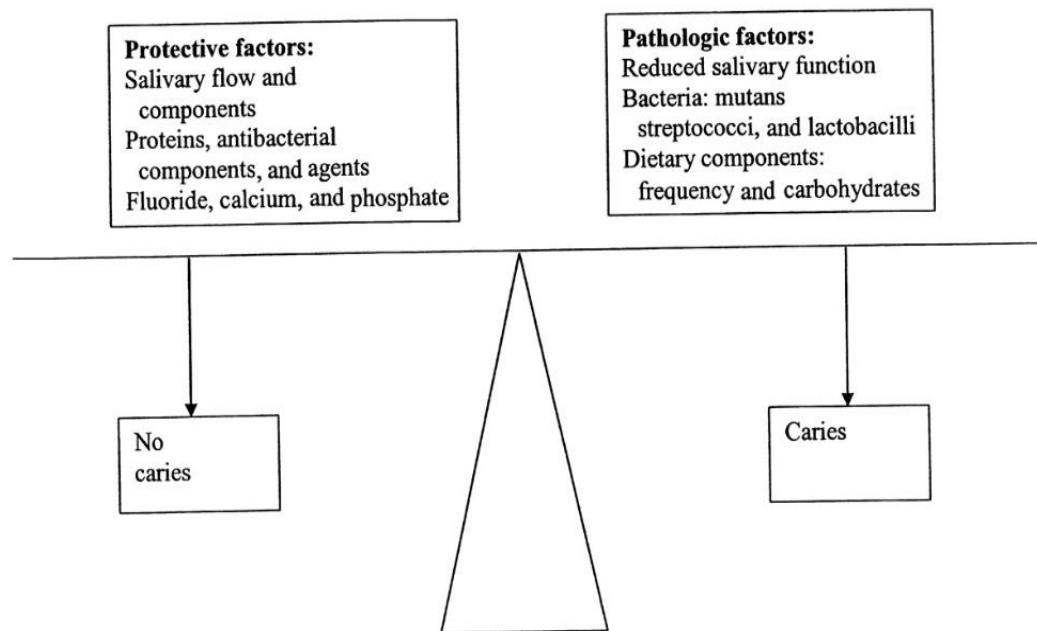


Figure 2.2. The Caries Balance (Touger-Decker et al., 2003, as depicted in Featherstone, 2000)

As diet plays a pivotal role in this process, nutrition does as well (Touger-Decker et al.,2003). There is a complex relationship between diet and nutrition and oral health and disease. Diet has a local effect while nutrition has a systemic effect, and both have

the ability to compromise the health of the teeth (Touger-Decker et al.,2003). Oral health and sugars are associated; however, the relationship between the two is not the same for all, as people have a variety of diets as well as a variety of other impacting factors. This relationship, albeit dynamic, is an integral one which warrants further study (Touger-Decker et al.,2003).

Excluding those who are edentulous, no one is immune to this disease. Regardless of the numerous caries preventive modalities available, oral health disparities still exist across various population groups, and children, unfortunately, face these disparities on a significant level (DHHS, 2000). Due to fluoridated water, dental caries among children began to decline in the 1950s, and by the late 1970s this trend was evident among developed countries as these countries experienced an impressive decrease in caries prevalence (DHHS, 2000; Touger-Decker et al., 2013). However, despite these improvements, dental caries is still the most common chronic disease in children, five times more common than asthma, and seven times more common than hay fever (DHHS, 2000). According to data from the National Health and Nutrition Examination Survey, 2011–2012, the prevalence of caries in the primary teeth of children 2-5 years and 6-8 years is 22.7 and 55.7, respectively. Caries prevalence in permanent teeth for children 6-8 years and 9-11 years is 13.8 and 28.8, respectively (Data from the National Health and Nutrition Examination Survey, 2011–2012, no. 191).

Socioeconomic status as well as race persist as major contributing factors in health disparities among all ages, especially children (DHHS, 2000). One out of every four children born in America is born into poverty, and it is these children who have more untreated, serious dental decay (DHHS, 2000). Regarding specific races and ethnic

groups which disproportionately suffer from oral health disparities; non-Hispanic black and Hispanic children and adolescents have the highest prevalence of untreated dental decay when compared to non-Hispanic white children (Data from the National Health and Nutrition Examination Survey, 2011–2012, no. 191).

Oral Health-Related Quality of Life and Key Definitions

When compared to the concepts of quality of life and health-related quality of life, oral health-related quality of life (OHRQoL) is relatively a new concept and interest in its implications is rapidly increasing (Bennadi and Reddy, 2013). Health, no longer defined as just the absence of disease, has a direct impact on one's quality of life (DHHS, 2000; Bennadi and Reddy, 2013). It is this concept which fulfills the framework of patient assessment, as the World Health Organization defines quality of life as individuals' "perceptions of their position in life in the context of culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns" (WHOQOL, 1995).

In the late 1960s the concept of health related-quality of life (HRQoL) materialized (Bennadi and Reddy, 2013), the assessment of which relied on the relationship between expectations and experiences (Carr et al., 2001). Healthy People 2020 defined HRQoL as a multidimensional concept, in the context of health and disease, the domains of which include mental, physical, emotional, as well as social functioning. This is a parameter which focuses on the influence health status has on quality of life (Healthy People 2020).

In 1976, Cohen and Jago discussed sociodental health indicators for oral health, which referred to the status of oral health and oral health-related delivery of services. According to these authors, the indexes of oral health status, including periodontal disease, dental caries, malocclusion, and oral hygiene, as well as the quality of dental services, needed to be related to social indicators, such as personal lifestyle and cultural factors. Such relationships aided in the assessment of the true impact of dental health on overall health (Cohen and Jago, 1976).

In the early 1980s, the concept of oral health-related quality of life (OHRQoL) emerged, twenty years following the materialization of health-related quality of life (HRQoL) (Bennadi and Reddy, 2013). Clearly there was a delay in the development of OHRQoL, which may be due to the ‘poor perception of the impact of oral disease on quality of life’ (Bennadi and Reddy, 2013). OHRQoL is an individualized concept, one which reflects comfort, self-esteem, and satisfaction with respect to oral health, and similarly to HRQoL, OHRQoL is a parameter which focuses on the influence oral health status has on quality of life (Bennadi and Reddy, 2013; DHHS, 2000). OHRQoL is “a multidimensional construct that reflects (among other things) people’s comfort when eating, sleeping, and engaging in social interaction; their self-esteem; and their satisfaction with respect to their oral health” (DHHS, 2000). It is a subjective and personal concept, one which is associated with functional, psychologic, social and discomfort-related factors (Bennadi and Reddy, 2013). Figure 2.3, depicting these factors, is presented below:

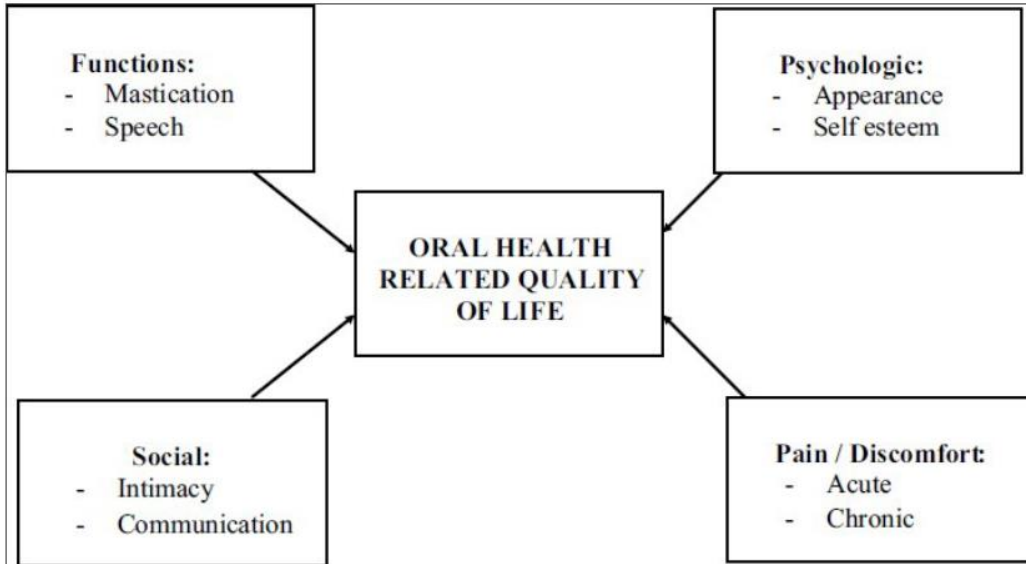


Figure 2.3. Factors Associated with Oral Health-Related Quality of Life (Bennadi and Reddy, 2013)

Similarly, the theoretical model for OHRQoL, adapted from Wilson and Cleary (1995), and discussed by Sischo and Broder (2011), includes biological, social, psychological, as well as cultural factors. The framework of this model incorporates epidemiological findings, and psychological and social science theory. It accounts for the impact access to care and environmental factors have on perceptions of oral health, as well as quality of life. This concept exhibits a subjective viewpoint dependent upon an array of manifestations and experiences (Sischo and Broder, 2011). This theoretical model as well as the dimensions comprising OHRQoL are depicted in Figures 2.4 and 2.5 below, respectively.

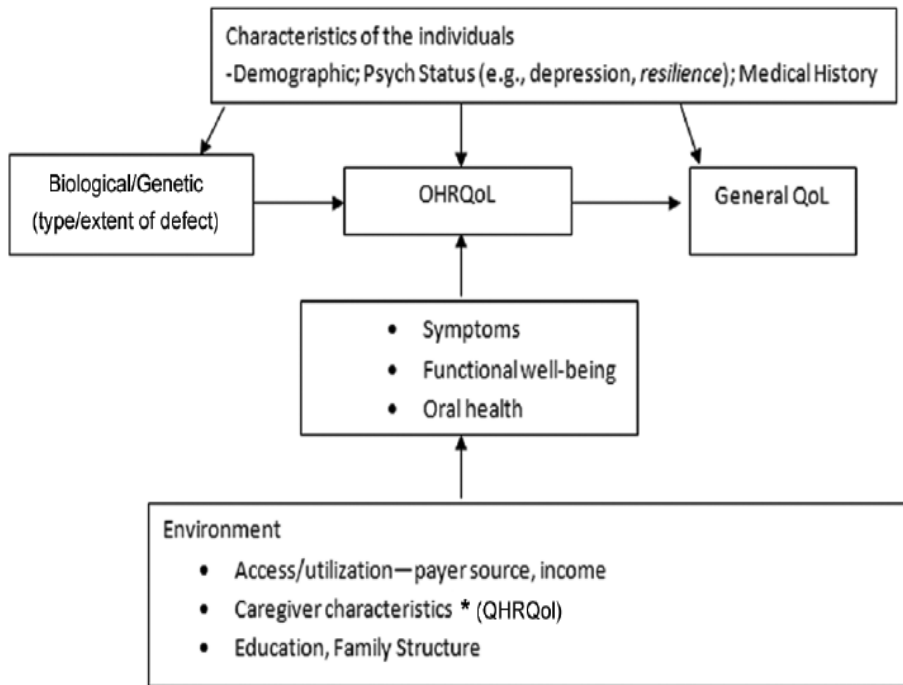


Figure 2.4. Theoretical Model for OHRQoL (Wilson and Cleary, 1995; as depicted by Sischo and Broder, 2011)



Figure 2.5. The five dimensions of OHRQoL (Sischo and Broder, 2011)

As discussed previously, oral health and quality of life go hand in hand. But, how does one define oral health? In 2016, Glick et al. discussed a new definition of oral health, approved by the FDI World Dental Federation General Assembly on September 6, 2016. This new definition, accompanied by its framework in Figure 2.6 below, has the intention of allowing one to understand exactly what oral health encompasses including its associations with oral health policy and clinical practice. It recognizes the aspects of oral health and its multifaceted nature (Glick et al., 2016).

Definition of oral health.
Oral health is multifaceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow, and convey a range of emotions through facial expressions with confidence and without pain, discomfort, and disease of the craniofacial complex.
Further attributes of oral health:
<ul style="list-style-type: none"> ■ It is a fundamental component of health and physical and mental well-being. It exists along a continuum influenced by the values and attitudes of people and communities. ■ It reflects the physiological, social, and psychological attributes that are essential to the quality of life. ■ It is influenced by the person's changing experiences, perceptions, expectations, and ability to adapt to circumstances.

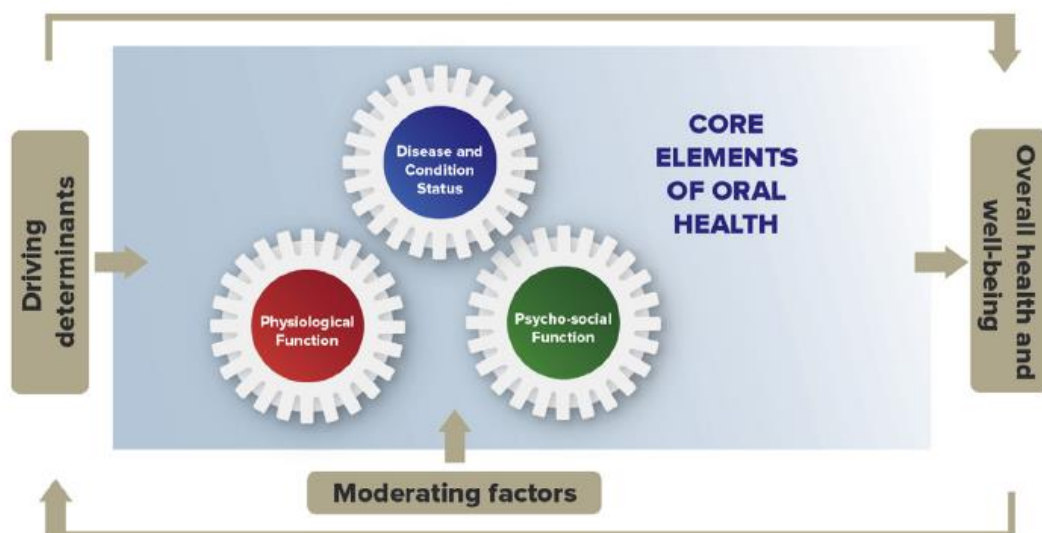


Figure 2.6. Definition of Oral Health; Framework for the Oral Health Definition (Glick et al., 2016)

As one can see, this definition and framework incorporate the full breadth of well-being and health (Glick et al., 2016). They portray the intricacy of the interactions between the three core elements of oral health, including physiological function, psychosocial function, and disease and condition status (Glick et al., 2016). This new definition depicts the factors which determine, influence, and impact oral health; it describes moderating factors, those which determine how one scores his or her own oral health, and finally, it relates these factors to overall health and general well-being (Glick et al., 2016).

Even more recently, Fisher-Owens et al. (2017) presented a conceptual model to explain children's oral health and its influences. As past researchers focused on biological and dietary influences, the purpose of this model was to utilize a much broader framework. This model takes a comprehensive, multidimensional approach to understanding all of the factors which impact children's oral health, as well as the complex interactions among those factors (Fisher-Owens et al., 2017).

This conceptual model contains three levels which influence the oral health outcomes of children: individual, family, and community (Fisher-Owens et al., 2017). Community-level influences include, for example, social environment, physical environment, and the community oral health environment. Family-level influences include factors such as family function, physical safety, social support, and socioeconomic status (Fisher-Owens et al., 2017). The individual child-level influences include the use of dental care, physical and demographic attributes, and development. Five key domains which determine oral health are incorporated within these three levels of influence: genetic and biological factors, social environment, physical environment,

health behaviors, and dental and medical care (Fisher-Owens et al., 2017). Overall, this model embodies the broad range of risk factors as well as the various routes by which they function, which can in turn, assist in the improvement of children's oral health (Fisher-Owens et al., 2017).

As the concept of oral health-related quality of life and various related terms have been reviewed and defined, the following pages describe the common tools utilized for measuring assessing the oral health-related quality of life in children.

Tools for Measuring Oral Health-Related Quality of Life

The endeavor to construct instruments which facilitate the measurement, assessment, and interpretation of OHRQoL has continued since Cohen & Jago first proposed the significance of sociodental health indicators in 1976 (Locker et al., 2002). Until the early 2000's, these instruments were tailored only to adults and the elderly (Locker et al., 2002).

To the defense of the public health community, developing such a tool for children has proven to be an arduous task (Osman and Silverman, 1996; Locker et al., 2002; Jokovic, et al., 2002). Such a tool needs to be tailored to the actions, roles, and daily lives of children, and contain questions which provide the opportunity for parents/caregivers to be reliable proxies and advocates, yet when appropriate, allow children to answer for themselves (Osman and Silverman, 1996; Locker et al., 2002; Jokovic, et al., 2002). Adding to the challenges of a child-version questionnaire, childhood represents a variety of physical, developmental, and emotional stages. A child at age 6 has significant developmental differences from those of a child at age 11;

therefore, these questionnaires must be age specific (Osman and Silverman, 1996; Locker et al., 2002; Jokovic, et al., 2002). Presently, the most common tools utilized to measure the OHRQoL of children include the following:

- Child Oral Health Quality of Life Questionnaire (Jokovic, et al, 2000)
- Michigan Oral Health-Related Quality of Life Questionnaire (Filstrup et al., 2002)
- Child Oral Impacts on Daily Performances (OIDP) (Gherunpong et al., 2004)
- Child Oral Health Impact Profile (Broder et al., 2007)
- Early Child Oral Health Impact Scale (ECOHIS) (Pahel et al., 2007)
- Scale of Oral Health Outcomes (SOHO) (Tsakos et al., 2012)

Each of these tools is described separately in the sections that follow.

Child Oral Health Quality of Life Questionnaire

There are two very important approaches to consider when recognizing the outcomes of various oral conditions in children (Locker et al., 2002). The first is the impact the oral conditions have on the child, while the second is the impact they have on the family (Locker et al., 2002). The Child Oral Health Quality of Life Questionnaire (COHQOL) consists of two types of questionnaires, the Child Perceptions Questionnaire (CPQ) and the Parental-Caregiver's Perceptions Questionnaire (PPQ) (Locker et al., 2002; Jokovic et al, 2002-4). Given the child's age, there are three versions of the CPQ: for children 6 to 7 years of age (CPQ₆₋₇), for children 8 to 10 years of age (CPQ₈₋₁₀), and for children 11 to 14 years of age (CPQ₁₁₋₁₄) (Locker et al., 2002; Jokovic et al, 2002-4).

Both questionnaires, the CPQ and PPQ, measure the OHRQoL of the child, the first from the child's perspective, and the latter from the parent's perspective (Locker et al., 2002, Jokovic et al, 2002-4). These questionnaires represent a multidimensional

system which measure the negative impacts of various oral conditions on the overall quality of life of the child. The included items target functional limitations, oral symptoms, and emotional and social well-being; however, only the parental questionnaire contains the section which measures the impact on the family, entitled the Family Impact Section (FIS) (Locker et al., 2002, Jokovic et al, 2002-4).

Several studies discussed the development and validity of the components of the COHQOL (Locker et al., 2002, Jokovic et al, 2002-4). These studies utilized a process which was mirrored after the process described by both Guyatt et al., (1987) and Juniper et al., (1996). Face/content validity and item impact studies were conducted in order to narrow down the most important items to be included in these questionnaires. The final CPQ and PPQ contain 36 and 31 items, respectively (Locker et al., 2002, Jokovic et al, 2002-4).

The items in both the CPQ and PPQ are organized into the four health domains previously mentioned: oral symptoms, functional limitations, emotional well-being, and social well-being (Locker et al., 2002, Jokovic et al, 2002-4). Questions regard the frequency of events in relation to these items, and answers include ‘never,’ ‘once or twice,’ ‘sometimes,’ ‘often,’ and ‘every day/almost every day.’ These responses are scored as 0,1,2,3,4, respectively. A higher score denotes worse OHRQoL. For example, an oral symptom such as pain while chewing which occurs ‘every day/almost every day’ is scored as a 4, representing worse quality of life than an answer of ‘once or twice’ with a score of 1 (Locker et al., 2002, Jokovic et al, 2002-4).

As mentioned, the version of the CPQ differs depending on the age of the child. Self-concept as well as abstract thinking begin around age 6, the ability to evaluate

various aspects of life increasingly evolves from age 6 through 10, and by age 11 children can experience intricate emotions (Hetherington et al., 1999; Jokovic et al., 2002).

Keeping these concepts in mind, the different forms of the CPQ are designed to target specific ages (Jokovic et al., 2002, 2004).

In 2002, Locker et al. described the development, validity, as well as reliability testing of the Family Impact Section of the PPQ. This section aims to evaluate the ‘caregiver burden’ bias. On some level, for example time off of work or unforeseen health/dental care costs, a child’s chronic illness is likely to impact the family. A parent/caregiver’s report as to the health of the child is in some way motivated by the extent to which the parent is affected. The family plays a pivotal role in a child’s health, and interventions regarding health care recognize the necessities of not only the child, but the parent as well (Locker et al., 2002).

The 14 items of the FIS, are spread through 4 separate factors: parental/family activity, parental emotions, family conflict, and financial burden (Locker et al., 2002). Questions are answered with ‘never’, ‘once or twice’, ‘sometimes’, ‘often’, and ‘every day.’ Scores representing these answers are 0,1,2,3, and 4, respectively. A ‘don’t know’ response was allowed. A higher score indicates a greater impact on the family by the child’s oral condition. Parents are also asked to give an overall account of the child’s oral health and overall wellbeing, known as a global assessment. Responses to the oral health question range from ‘excellent’ to ‘poor’ and are scored from 0 to 4, respectively. A higher score denotes worse oral health. Responses to the overall wellbeing question range from ‘not at all’ to ‘very much’ with scores ranging from 0 to 4, respectively, a higher score denoting worse overall wellbeing (Locker et al., 2002).

The study specific to this thesis utilized a shortened version of the PPQ, which contained 16 items as opposed to 31; however, all four health domains were still represented, including oral symptoms, functional limitations, emotional well-being, and social well-being. This version was developed and validated by Thomson et al., 2013.

Thomson et al. (2013) utilized two studies to validate the PPQ, each conducted in New Zealand, each involving completion of parent OHRQoL questionnaires before and after dental treatment provided to patients with early childhood caries under general anesthesia. The data from one study was utilized for the item impact study as well as preliminary construct validation. Data from the second study was utilized to analyze the responsiveness and validity of the shortened version of the questionnaire. The authors determined that the reliability and validity were adequate, and the responsiveness was acceptable (Thomson et al., 2013).

The final shortened version of the questionnaire utilized in this silver nitrate study contained 16 items, as opposed to the full-length version of 31 items (Thomson et al., 2013). Scoring of the items was on a 5-point Likert Scale. Answers and scores to the items were as follows: 'never'=0, 'once or twice'=1, 'sometimes'=2, 'often'=3, and 'every day or almost every day'=4. Each item also allowed an answer of 'Don't know' which scored as a 0. This was done to prevent the loss of information which would occur if nonresponse items were deleted. A higher score denoted worse OHRQoL (Thomson et al., 2013).

Each item in this questionnaire was in relation to a particular symptom which may have occurred in the past three months (Thomson et al., 2013). For example, parents were asked 'During the last 3 months, how often has your child had pain in the teeth, lips, jaw

or mouth?’ An answer of ‘every day or almost every day’ equated to a score of 4, denoting worse OHRQoL as opposed to an answer of ‘never’ and a score of 0 indicating better OHRQoL. Composite scores, which represented the sum of all 16 individual scores, ranged from 0 to 64. Scores were also categorized into four separate domains: oral symptoms, emotional wellbeing, social wellbeing, and functional limitations, each of which had a score range of 0 to 16. (Thomson et al., 2013).

Michigan Oral Health-Related Quality of Life Questionnaire

The Michigan Oral Health-Related Quality of Life Questionnaire utilizes multidimensional scales to evaluate the OHRQoL of children (Filstrup et al., 2003). It is known as multidimensional because it includes items regarding functional, social, and psychological aspects. For example, questions cover topics such as pain and discomfort of teeth as well as the satisfaction with the appearance of teeth (Filstrup et al., 2003).

This questionnaire consists of child and parent versions (Filstrup et al., 2003). It is intended for children 4 years of age and older. The child version contains 7 items distributed throughout 3 areas, including pain, functional, and psychological aspects. Children answer these 7 questions with a simple ‘yes’ or ‘no.’ Examples of questions include: ‘Do your teeth hurt when you eat something hot or cold?’ ‘Are you happy with your teeth?’ (Filstrup et al., 2003)

The parent/proxy measure provides the ability for parents to answer in a more comprehensive method than children, given their cognitive and perceptive abilities (Filstrup et al., 2003). There are ten items, all of which are answered on a 5-point Likert Scale, ranging from 0 to 5, indicating ‘disagree strongly’ to ‘agree strongly,’ respectively. Example questions include: ‘My child has a toothache or pain currently,’ ‘My child’s

teeth hurt when he/she bites/chews.’ A higher score denotes worse OHRQoL (Filstrup et al., 2003).

Child Oral Impacts on Daily Performances

In 2004, Gherunpong et al. discussed the development of the OIDP, a measurement tool the authors described as a socio-dental health indicator. This is a theoretical model which has three levels of consequences: impairment, intermediate level, and ultimate impacts. These impacts are quantified by the OIDP scoring system, which utilizes both frequency and severity scores. A performance score is calculated by multiplying the frequency score by the severity score (Sheiham and Spencer, 2002; Gherunpong et al., 2004). Addition of the performance scores results in a sum impact score, which when divided by the greatest possible score and then multiplied by 100, provides a percentage score. This scoring system facilitates prioritization (Sheiham and Spencer, 2002; Gherunpong et al., 2004). Those with a higher score are a priority due to the greater impact on quality of life. The use of the total OIDP score allows the calculation of condition-specific scores. This promotes priority treatment for the specific condition causing the impact (Sheiham and Spencer, 2002; Gherunpong et al., 2004).

The child version of the OIDP utilizes the original OIDP, with several modifications (Gherunpong et al., 2004; Yusuf et al., 2006). Given the cognitive and intellectual abilities of children, the wording of the questions of the original OIDP required adjustment (Gherunpong et al., 2004; Yusuf et al., 2006). This questionnaire estimates oral impacts on eight daily performances: eating, speaking, cleaning teeth, smiling, emotional stability, relaxing, doing schoolwork, and social contact. A Likert scale of 0 to 3 is utilized to measure the frequency and severity of the impacts, and scores

are calculated as discussed above. A higher score indicates a greater severity of impact on quality of life (Gherunpong et al., 2004; Yusuf et al., 2006).

Early Child Oral Health Impact Scale

Similar to the COHQOL, the ECOHIS is a tool which measures the impact of oral conditions and its treatment on the quality of life of young children, as well as on families (Pahel et al., 2007, Gomes et al., 2015). It is referred to as a proxy measure because parents/caregivers complete the questions on behalf of pre-school aged children, usually between 3 and 5 years. There are two sections of this questionnaire, the Child Impact Section (CIS) and the Family Impact Section (FIS). There are 13 items and six domains including symptoms, function, psychology, social interaction/self-image, parental distress, and family function (Pahel et al., 2007, Gomes et al., 2015).

The Child Impact Section (CIS) specifically deals with the domains which contribute to the OHRQoL of children (Pahel et al., 2007, Gomes et al., 2015). In this section of the questionnaire, parents/caregivers are asked how often their children have experienced pain, difficulty eating and drinking, trouble sleeping, trouble speaking, etc. Answers include 'never', 'hardly ever', 'occasionally', 'often', and 'very often', and the scores for these answers are 0,1,2,3, and 4, respectively. There are a total of nine items in this section, 4 points maximum per question, resulting in a maximum CIS score of 36, a higher score denoting worse OHRQoL. The Family Impact Section (FIS) specifically deals with the family domains impacted by children's oral health. In this section parents/caregivers are asked how often they, or any members of the family, felt upset, felt guilty, took time off of work, etc. due to children's various oral conditions or dental treatment. There are a total of 4 items in this section, scored the same as the CIS,

resulting in a maximum of 16 points for this section. A greater score in each section represents a greater impact, and in essence a worse OHRQoL for the child, as well as for the family (Pahel et al., 2007, Gomes et al., 2015).

Child Oral Health Impact Profile

In 2007, Broder et al. discussed the development of the Child Oral Health Impact Profile (COHIP). This tool was created with purpose of assessing the oral health-related quality of life of school-aged children through the utilization of both a child report as well as parental proxy report (Broder et al., 2007).

The process used to develop this questionnaire consisted of six phases: development of an initial pool of items, initial assessment of face validity, initial assessment of item impact, a second face validity assessment, a second item impact assessment, and finally a factor analysis (Broder et al., 2007). The factor analysis selected five domains: oral health, functional well-being, social/emotional well-being, school environment, and self-image. The Flesch-Kincaid readability score assessed the readability of the questionnaire, producing a grade level of 3.5. This indicated that this tool was appropriate for children 8 years of age and older, or grade 3 and above. The final questionnaire consisted of 34 items, spread throughout the five domains previously listed, scored on a 5-point Likert Scale, with a higher score denoting worse OHRQoL (Broder et al., 2007).

Scale of Oral Health Outcomes

In 2012, Tsakos et al. discussed the development of the Scale of Oral Health Outcomes (SOHO-5), an oral health-related quality of life measure targeted to children 5 years of age. In this cross-sectional study, a two-phase process was utilized to develop

and assess the reliability and validity of the SOHO-5. These phases consisted of a qualitative and quantitative phase (Tsakos et al., 2012).

The qualitative phase, also known as the development phase, consisted of consultation focus groups (CFGs) which included parents of 5-year-old children (Tsakos et al., 2012). These focus groups discussed concepts and concerns regarding their children's oral health, significant determinants associated with it, and the overall importance of oral health. The CFGs provided valuable input as to the items that should be included in the SOHO-5, as well as the language and overall structure of the questionnaire. The key oral impacts identified by the CFGs included eating, drinking, appearance, sleeping, smiling, and socializing (Tsakos et al., 2012).

The quantitative phase determined the reliability and validity of the questionnaire on a convenience sample of 5-year-old children from Scotland (Tsakos et al., 2012). Overall, 35 schools were selected from various socioeconomic groups, ranging from affluent to deprived. Four trained interviewers administered the questionnaire, and a total of 332 children participated (Tsakos et al., 2012). The authors reported that the questionnaire was able to be administered quickly, within 5 to 6 minutes, and that the children exhibited favorable levels of comprehension. The final questionnaire consisted of 7 questions, all related to difficulties with eating, drinking, speaking, smiling, playing, and sleeping due to oral problems. Answers included either 'no', 'a little', or 'a lot' and scores ranged from 0 to 2 for each response, respectively. When summed a higher score denoted worse OHRQoL (Tsakos et al., 2012).

Overall, the authors reported that the reliability and validity assessment of SOHO-5 produced encouraging results. They declared that this questionnaire had the ability to

be an effective tool for future OHRQoL clinical studies as well as public health programs (Tsakos et al., 2012).

Amish History, Beliefs, and Lifestyle

It is relevant to include a review of Amish diet, culture, and oral care, as all children participating in this study were Amish. Due to the differences in life-style and diet, their oral health habits and disease status may differ from that of the general population. Unfortunately, the number of publications reviewing the oral health, as well as oral health knowledge and practices related to this specific population are almost non-existent. To date, only two articles have been located, both of which are briefly summarized later in this section. For this reason, this thesis will not make any general assumptions regarding their overall health status as it relates to their specific diet, nor will it make any general assumptions regarding their overall oral health literacy levels or practices as they relate to the oral cavity.

This study was conducted within the Amish community of Kalona, Iowa. The history of the Amish begins in Switzerland, as they are a group of traditionalist Christian church followers with origins in the Swiss Anabaptist movement (Schwieder, 1975). They are known for their plain dress and simple lives, as in lives without the use of modern technology (Schwieder, 1975). The first Amish emigration to the United States, Pennsylvania specifically, took place in the late 18th century (Kalona Historical Society; Who are the Amish?). Their need to resettle came from the refusal to answer to European government-controlled churches, as the Amish believe God is the final authority (Woodsmall; Why the Amish and Mennonites Moved to America, 2017). Their

continued persecution led to the decision to accept the invitation of an English Quaker named William Penn who welcomed European religious minorities to his new colony in Lancaster County, Pennsylvania (Woodsmall; Why the Amish and Mennonites Moved to America, 2017).

The Kalona Amish, also known as Old Order Amish, came to Kalona, Iowa in 1846, and as of present day there are 4 additional degrees (divisions) of conservatism in Amish society which include New Order Amish, Beachy Amish, Conservative Mennonite, and Mennonite (Kalona Historical Society; Who are the Amish? 2017; Schwieder, 1975). The most conservative of the Amish, the Old Order Amish, still live with no electricity, phones, or televisions, and use horses and buggies as their primary means of travel (Kalona Historical Society; Who are the Amish? 2017; Schwieder, 1975). Kalona Old Order Amish and Beachy Amish also use tractors with steel wheels (Schwieder, 1975). Old Order Amish have changed little since their arrival in 1846; however, in recent years a greater number of them have opened small businesses. Therefore, it has become more prevalent to see the Amish socializing with the general public (Kalona Historical Society; Who are the Amish? 2017). Old Order Amish generally do not worship in churches. Instead they alternate homes for the services (Schwieder, 1975). Today there are approximately 1,200 Amish living in the vicinity of Kalona, Iowa (Kanellis et al., 2018).

The Amish have their own schools which are overseen by the consolidated district of Mid Prairie Schools (Kalona Historical Society; Who are the Amish? 2017). Old Order Amish are bilingual, speaking a dialect of Pennsylvania Dutch at home, and English in school and during business transactions with non-Amish (Schwieder, 1975).

Children typically do not learn to speak English until they attend school, which is attended until the 8th grade only (Kalona Historical Society; Who are the Amish? 2017; Schwieder, 1975).

Amish homes are typically modest (Schwieder, 1975); however, some may be very large, and the average Amish family has approximately eight children (Kanellis et al., 2018). As children will usually stay on the land and take over the family farm once they are grown adults, it is common for three or four generations to live in the same home (Kalona Historical Society; Who are the Amish? 2017).

Diet is a known dental caries-related factor; therefore, a review of the current Amish diet is germane to this thesis. The Amish diet is not known for being low-fat, but rather very filling; however, over the years it has evolved (Amish America; Exploring Amish Culture and Communities, 2017). It can consist of a variety of homegrown and homemade foods, as well as store-bought foods. Many Amish homes have gardens, dairies, and livestock, all of which provide a steady stream of fresh vegetables, milk, dairy goods, meat, and poultry. The Amish bake an abundant range of desserts, including pies, cakes, cookies, and bread (Amish America; Exploring Amish Culture and Communities, 2017).

The eating habits of the Amish may vary between groups, or just individuals, by community or affiliation (Amish America; Exploring Amish Culture and Communities, 2017). Due to changes in occupation, some Amish will 'eat out' more, making their diet on certain occasions comparable to the American diet, which includes additives, preservatives, and processed foods. Regardless of the variation in their diets, the Amish are well known for their good food, usually advertised as 'Pennsylvania Dutch' or

‘Amish-style’ cooking (Amish America; Exploring Amish Culture and Communities, 2017). While there may be a relationship between the Amish diet, oral hygiene habits, and caries levels in this population, that relationship will not be discussed as part of the study specific to this thesis. It should be mentioned, however, that Amish are more reliant upon self-care and home remedies (Schweider, 1975); therefore, they may not typically practice oral hygiene habits such as brushing and flossing.

As mentioned, two studies related to Amish oral health have been located to date. The first was published in 1988, and the second almost thirty years later, in 2017. The purpose of the study conducted by Bagramian et al., 1988 was to assess the oral health status, knowledge, and behavior among an Amish population in southwest Michigan. 121 subjects, children and adults, from 21 Amish families were included in this study in which caries experience, periodontal health, and oral hygiene status were recorded, as well as data regarding oral health knowledge and practices. Data were collected and assessed via oral exams and face-to-face interviews. Mean DMFS for children younger than 11 was 1.92, while for adults over 35 years it was 34.61(Bagramian et al., 1988). Roughly 25% of the population less than 17 years was free of caries. However, radiographs were not used, therefore caries experiences were most likely underestimated. Periodontal index scores were, on average, quite low for this population, despite the fact that only 1.3% reported brushing twice or more per day. This population, in general, exhibited inadequate oral health knowledge and practices, yet, the majority, 61%, perceived their oral health as good. The authors attributed the low levels of disease to dietary patterns, which reportedly consisted of low-sugar diets and infrequent between-meal snacking (Bagramian et al., 1988).

Heima et al., 2017, assessed oral health and medical conditions among Amish children in Geauga county, Ohio. The authors conducted a retrospective chart review study of all the patients (216 in total) between the ages of 3 and 17 who visited the mobile dental unit in this county from 2011-2012. The charts provided information regarding oral and general health information, while a 5-item questionnaire completed by the parents provided information which addressed parental perceptions of children's oral health. Contrary to the study conducted in 1988, the authors found caries experiences to be significant. It should be mentioned though that Heima et al. utilized radiographs, unlike the 1988 study, which could account for this difference. The average number of untreated decayed teeth was 6.8, 88% of the children had untreated decayed teeth, and only 11 children were caries-free (Heima et al., 2017). Despite the high levels of caries, the majority of parents (87.4%), rated their children's oral health as 'good' or 'very good'. Both of these studies appeared to exhibit limited awareness of oral health; however, caries experiences varied widely, as did the study designs. Additionally, the subjects in both studies were recruited from small Amish communities, providing results which cannot be generalized to the entire Amish population. Therefore, the overall oral health of the Amish population in general is still poorly understood (Heima et al., 2017).

The following three sections include a review of the current literature specific to the study in this thesis. The first section reviews four studies which assessed parental perceptions of children's oral health-related quality of life (OHRQoL). The second section reviews four studies which assessed the changes in OHRQoL for children following dental treatment under general anesthesia. The third section reviews recent

literature assessing the impact of other dental conditions including fluorosis and malocclusion on the OHRQoL of children and adolescents.

Parental Perceptions of Children's Oral Health-Related Quality of Life

Young children do not have the intellectual or emotional capacity to complete quality of life questionnaires themselves (Hetherington et al., 1999). Parents/caregivers must act as proxies. It is important that parents understand the level to which oral disease impacts children (Gomes et al., 2015); therefore, the following four studies to be discussed evaluated parental perceptions of children's oral health-related quality of life.

All four studies were cross-sectional studies conducted in Brazil with a sample of preschool aged children. The first study discussed below was conducted from October 2011 to April 2012 by Gomes et al. These authors published two separate articles regarding this study, one in 2014 and one in 2015. The most recent publication will be discussed first, followed by the article published in 2014.

Gomes et al. (2015) assessed the determinants of parental perceptions regarding the oral health of their children. In other words, the authors aimed to answer the following question: 'what influences parental perceptions of children's oral health?' This cross-sectional study consisted of male and female pre-school aged children from public and private schools in Campina Grande, Brazil (Gomes et al., 2015).

The authors chose a representative sample by stratifying according to the type of institution and administrative district (Gomes et al., 2015). This was a two-phase process. Random selection of preschools occurred during the first phase, and random selection of children occurred during the second phase. Exclusion criteria included

presence of systemic disease, learning disability, and absence of four maxillary incisors due to dental caries or exfoliation (can result in compromised diagnosis of traumatic dental injuries and malocclusion). Inclusion criteria included having a child of pre-school age of either sex, and a parent/caregiver fluent in Portuguese. The estimated minimum sample size was at 720. However, due to the assumption of loss to follow up and noncompliance, the estimated size was increased to 864; however, the final sample size was 843 (Gomes et al., 2015).

In this study, parents/caregivers were asked to complete a questionnaire regarding socio-demographic status and perceptions of their children's oral health (Gomes et al., 2015). The authors utilized the B-ECOHIS, the Brazilian version of the Early Childhood Oral Health Impact Scale. This tool, discussed earlier in this chapter, measures the impact of oral conditions and its treatment on the quality of life of children, as well as on families (Pahel et al., 2007; Gomes et al., 2015). It is referred to as a proxy measure and contains two sections, the Child Impact Section (CIS) and the Family Impact Section (FIS). The CIS specifically deals with the domains which contribute to the OHRQoL of children, while the FIS specifically deals with the family domains which children's oral health has the ability to impact (Pahel et al., 2007; Gomes et al., 2015).

Gomes et al. (2015) reported that three trained and calibrated dentists conducted clinical examinations on the children at the preschools. Children brushed their teeth under supervision prior to the exams. The dentists utilized head lamps, sterile mouth mirrors, sterile probes, and gauze. Diagnosis of caries was facilitated using the International Caries Detection and Assessment System, (ICDAS). Traumatic Dental Injuries (TDI) were classified as one of the following: enamel only fracture, enamel plus

dentin fracture, complicated crown fracture, extrusive luxation, lateral luxation, intrusive luxation, or avulsion (Gomes et al., 2015). Malocclusion classifications included: >2 mm overbite; >2 mm overjet; anterior open bite, anterior crossbite, and posterior crossbite. The statistical analysis consisted of multiple logistic regression with backwards stepwise procedures utilizing the Statistical Package for Social Sciences. The dependent variable was the parental perception of oral health, dichotomized as ‘good’ or ‘poor.’ The independent variables which had a p-value <0.02 were included in the multiple logistic regression model (Gomes et al., 2015).

The authors reported that the majority (84.4%) of the families consisted of less than six members (Gomes et al., 2015). There was a 32.1% prevalence of negative impacts on OHRQoL among children, 26.2% among families. A negative impact is a factor which impacts the quality of life of the child or family, as per the parent, in a negative way. A majority of the parents, (66.5%), perceived that their children’s oral health was good (Gomes et al., 2015). The prevalence of the oral health problems included dental caries at 66.3%, followed by malocclusion at 63.3%, and lastly TDI at 34.2%. The authors determined parental perceptions of poor oral health in children to be significantly associated with caries with a history of a toothache, (p value = 0.035). A toothache not related to caries but to trauma was less likely to be associated with perceptions of poor oral health. In other words, when there was pain associated with decay the parent/caregiver tended to perceive the child’s oral health as poor. When the family suffered from monetary problems and/or distress the parent was more likely to perceive the child’s oral health as poor (Gomes et al., 2015)

The authors concluded that dental caries with pain, as well as older age of the child, influenced parental perceptions of children's oral health, meaning parents tended to perceive children's oral health as poor under these circumstances (Gomes et al., 2015). The authors speculated that the reason older age of children influenced parental perceptions was most likely due to the cumulative effect of oral health problems as age increases. The authors also concluded that parental perceptions of children's poor general health and the impact of the OHRQoL on the family influenced their perceptions of the oral health of their children (Gomes et al., 2015).

The authors of this study discussed several limitations and their methods for combating them (Gomes et al., 2015). Due to the inherent limitations of a cross-sectional study design, the authors took several measures in order to decrease the chance of information bias in the questionnaires, including the use of a validated questionnaire as well as a pilot study. Another limitation was in regards to large confidence intervals for some of the outcomes which the authors felt was due to heterogeneity of the sample (Gomes et al., 2015).

In 2014, Gomes et al. published an article with a slightly different aim from the article they would publish in 2015. The purpose was to assess the impact of various oral health conditions on the OHRQoL of preschool aged children, as well as their families. Parental perceptions were also taken into account (Gomes et al., 2014).

As the same study was utilized for both publications, the sample selection method as well as data collection do not need repeating. Aside from a slightly different purpose, the differences really began with the statistical analysis. The chi-square test assessed the associations between sociodemographic data and oral health conditions (Gomes et al.,

2014). The Bonferroni correction was used for variables with more than two categories. The level of associations between the various oral health conditions and their impact on OHRQoL was assessed utilizing Bivariate Poisson regression with robust variance. The multivariate model followed a hierarchical design for the determinants including socio-demographic data, perceptions of health, and oral health conditions. Finally, the Wald's test evaluated interactions among dental caries, malocclusion, and traumatic dental injuries (TDI) (Gomes et al., 2014).

The authors reported that 81.0% of parents/caregivers perceived children's general health was poor, and 66.5% perceived children's oral health was poor (Gomes et al., 2014). The chi-square test assessed the presence of a relationship between the three oral conditions (caries, TDI, malocclusion) and various socio-demographic factors. The authors reported cavitated lesions were significantly associated with school attended by the child, household income, age of the child, and mother's schooling. TDI and malocclusion were not significantly associated with the socio-demographic factors. The Poisson regression revealed that a negative impact on OHRQoL of children was significantly associated with the birth order of the child (first born), cavitated caries, presence of TDI, and parental perceptions of children's oral health as poor ($p < 0.001$ for all variables) (Gomes et al., 2014).

Parental perceptions of children's oral health as poor ($p < 0.001$), and cavitated caries ($p < 0.001$) were significantly associated with negative impacts on OHRQoL of families (Gomes et al., 2014). A TDI was found to be associated (significantly in some cases) with a negative impact on the OHRQoL of families. For example, enamel and dentine fractures were not significantly associated with a negative impact on OHRQoL

($p = 0.887$), but avulsions and/or luxations were ($p = 0.006$). Parents/caregivers recognized cavitated lesions as an oral health problem when it resulted in pain or became visually evident. In summary, cavitated lesions, parental perceptions of children's oral health as poor, and severe TDIs were significantly associated with a negative impact on OHRQoL of both the families as well as children (Gomes et al., 2014).

To the authors' knowledge, this was the first study which utilized a hierarchical approach (Gomes et al., 2014). This approach stratified the impact of the severity of TDI, various malocclusions, stages of caries, and teeth affected, and it offered an analysis of interrelationships among the factors. The authors discussed limitations of the study, the same listed above in the 2015 article, which included the possibility of information bias in the questionnaires. They also discussed the need for longitudinal studies for further interpretation regarding causality (Gomes et al., 2014).

Abanto et al. (2014) conducted a similar cross-sectional study, the purpose of which was to assess the parental perceptions of the impact of caries and TDI on the OHRQoL of 5- to 6-year-old children utilizing the Brazilian version of the Scale of Oral Health Outcomes (SOHO-5) (Tsakos et al., 2012), an OHRQoL tool discussed earlier in this chapter (Abanto et al., 2014). In addition to parental proxy reports, the authors utilized self-reports in order to assess children's perceptions, as well as agreement between parents and children. The authors hypothesized that caries and TDI would both have negative impacts on the OHRQoL of children when assessing both the parental and child reports, and that there would be a moderate agreement between the two (Abanto et al., 2014).

The authors estimated the minimum sample size to be 327 pairs of parents/children, which was calculated with a standard error of 5%, confidence interval of 95.0%, and 69.3% prevalence of oral impacts (Abanto et al., 2014). This was a convenience (volunteer) sample. All children 5 and 6 years of age who presented to the Sao Paulo Dental School for a dental screening and met the criteria were invited to participate in this study. Children who had received dental care within the last 90 days and those with systemic diseases or developmental disorders were excluded. The final number of pairs of parents and children who agreed to take part in this study totaled 335 (Abanto et al., 2014).

Abanto et al. (2014) reported that both the children and parents completed the SOHO-5 in independent, face-to-face interviews, conducted by four trained and blinded (to the clinical examinations) interviewers. Independent interviews were utilized in order to avoid influence between parent and child. In addition, parents were questioned about their income (Abanto et al., 2014). Three trained and calibrated dentists conducted the dental examinations. Caries were assessed according to the World Health Organization criteria and the outcome was defined in terms of decayed, indicated for extraction, or filled teeth (def-t). The dental examiners categorized TDI as either uncomplicated (no dislocation of tooth, no exposure of pulpal tissue) or complicated (exposure of pulpal tissue and/or dislocation of tooth). Statistical analysis consisted of the Shapiro-Wilk test, Kruskal-Wallis with post hoc Mann-Whitney tests, analysis of covariance using caries as a covariate, and Poisson Regression with robust variance, while utilizing statistical software STATA 8.0 (Abanto et al., 2014).

The authors found that 64.8% of the children experienced caries, whereas 31.0% experienced TDI (Abanto et al., 2014). The most frequently reported items by the children and parents included ‘trouble eating and sleeping’, and ‘avoiding smiling’. However, according to the children, ‘avoiding smiling’ was due to appearance, while for the parents it was due to pain they perceived the children had (Abanto et al., 2014). Overall, 70.5% of parents reported some form of an oral impact on their children’s OHRQoL, whereas 74.6% of children reported an oral impact. Regarding the children with a high caries experience, both children and parents reported worse OHRQoL compared to those with low caries experience ($p < 0.001$). A greater extent of caries and low family income were both associated with higher SOHO scores, meaning worse OHRQoL, for both parent and child versions ($p < 0.05$). TDI was found to be associated with ‘difficulty eating and sleeping’ for the parental version, and ‘difficulty playing’ for the child version. In both the child and parental reports, caries was the only clinical oral condition which caused a negative impact on all items (Abanto et al., 2014).

The authors reported that overall, the quality of life which parents perceived their children had was worse than the quality of life reported by the children themselves ($p < 0.001$) (Abanto et al., 2014). The authors concluded that dental caries was associated with worse OHRQoL, both according to parents and children. TDI, however, was not found to be associated with worse OHRQoL. Also, a better OHRQoL was reported by families who in general had higher incomes, regardless of the presence of oral disease in the children (Abanto et al., 2014).

The authors of this study discussed several limitations (Abanto et al., 2014). They recommended that in the future, the gender of the parent completing the questionnaire

should be accounted for. In this study, both mothers and fathers completed the questions, depending on which parent came to the interview. However, for consistency they suggested that one parent may be best at assessing the child's OHRQoL. The authors also suggested that their convenience sample may not have been representative of the general population because it was comprised of children/parents who were initially seeking dental treatment at the dental school, which may have suggested that their OHRQoL was worse than children not actively seeking treatment. This may have resulted in an overestimation of the results (Abanto et al., 2014).

The fourth study to be discussed was conducted by Scarpelli et al. (2013), the purpose of which was to assess the impact of dental conditions on OHRQoL in preschool based children, as per parents/caregivers via the Brazilian form of the ECOHIS (Pahel et al., 2007). The ECOHIS and its components were discussed previously. This study was conducted in the city of Belo Horizonte, Brazil (Scarpelli et al., 2013).

Scarpelli et al. (2013) estimated the sample size at 941 children. However, due to the use of a multi-stage sampling method and expected loss to follow-up, the target sample size was increased to 1,695. The final participating sample size was 1,632. This study utilized a two-stage random selection sampling method, first preschools randomly selected, followed by random selection of classrooms (Scarpelli et al., 2013). Inclusion criteria included children 5 years of age enrolled in preschool, having one or more primary maxillary incisors, and having parents/caregivers fluent in Portuguese. The authors preferred children with one or more primary maxillary incisors because maxillary incisors are often affected by traumatic dental injuries (TDI). Children with systemic diseases were excluded (Scarpelli et al., 2013).

Parents/caregivers completed the B-ECOHIS, as well as a form regarding socio-demographic information, including caregiver's age, education level, relationship to child, and monthly household income (Scarpelli et al. 2013). The ECOHIS scores were calculated by taking the sum of the response codes, a higher score indicating poorer OHRQoL. Parents/caregivers in this study were also asked specific questions regarding children's general health status, as well as oral health status. They were asked, 'In general, how would you rate the general health of your child?' and 'In general, how would you rate the dental health of your child?' Answers to both questions included very good, good, fair, poor, or very poor (Scarpelli et al., 2013).

Oral examinations were performed by one previously calibrated dentist, who assessed the most prevalent oral health conditions, including dental caries, malocclusion, traumatic dental injuries (TDI), and developmental defects of enamel (Scarpelli et al. 2013). Caries experience was diagnosed utilizing the World Health Organization criteria for decayed, missing, and filled teeth (dmft). Malocclusion was categorized as follows: presence of an overbite (normal, deep, anterior open bite), overjet (ideal, increased, anterior crossbite), and posterior crossbite. The Kolmogorov-Smirnov test evaluated the normality of the distribution of the child impact section (CIS) and family impact section (FIS) scores, which were dichotomized as '0' and 'any value>0' (Scarpelli et al., 2013). Bivariate analysis was utilized to test the associations between the outcome and independent variables. Other statistical analyses utilized in order to determine the interactions between the main variables included the Poisson regression with robust variance and the forward stepwise procedure. The Poisson regression also estimated prevalence ratios and respective 95% confidence intervals between groups, while the

forward stepwise procedure assisted in the inclusion or exclusion of explanatory variables in the fitted models. These analyses were all performed using the Statistical Package for Social Sciences (SPSS). The hypothesis of this study was, 'Children with a better oral health status have better OHRQoL than those with oral health problems' (Scarpelli et al., 2013).

Scarpelli et al. (2013) reported a response rate of 96.3%. There were more negative impacts on OHRQoL in the Child Impact Section (CIS) as opposed to the Family Impact Section (FIS), 36.8% and 31.4%, respectively. This meant that the oral health conditions negatively impacted the children more than the families. There were 63 subjects lost in this study due to refusal of exams by children and children no longer attending that school (Scarpelli et al., 2013). Parents/caregivers most frequently reported 'pain', 'difficulty eating', 'difficulty drinking', and 'irritation' on the child impact scale. In the family impact scale, the most commonly reported items were 'felt guilty' and 'been upset.' Caries experience was the only dental variable regarding clinical disease which was significantly associated with a negative impact on OHRQoL, ($p < 0.05$) (Scarpelli et al., 2013).

Regarding the Child Impact Section, the Poisson regression analysis demonstrated that the following variables had a statistically significant positive impact on OHRQoL: position in family (only child) ($p=0.011$), attended private school ($p=0.004$), household income > 5 times the minimum wage ($p=0.001$), no dental caries present ($p,0.001$), parents between 18 and 33 years ($p=0.009$), and very good or good general health status rating ($p=0.01$) (Scarpelli et al., 2013). Regarding the Family Impact Section (FIS), dmft ($p<0.001$), caregiver's age ($p=0.031$), and monthly household income ($p=0.001$) had

significant impacts on OHRQoL. These values demonstrated that the following variables had a positive impact on OHRQoL: parents between 18 and 33 years of age, monthly household income >5 times the minimum wage, and children with no clinical disease (Scarpelli et al., 2013).

The authors determined that OHRQoL was not influenced by traumatic dental injuries (Scarpelli et al., 2013). However, in this study, the TDIs were not severe. Children from low-income households as opposed to high-income households demonstrated more negative impacts on OHRQoL (Scarpelli et al., 2013).

The authors concluded that personal, social, and environmental factors impacted the relationships between OHRQoL and clinical variables (Scarpelli et al., 2013). The OHRQoL of preschool aged children and their families was influenced negatively by a higher caries experience. Other indicators of negative impacts included lower household income, younger caregivers' age, and poor general health rating. Finally, this study concluded that parents perceived poorer quality of life among children with a poor general health status (Scarpelli et al., 2013).

The authors of this study discussed several limitations, including those specific to cross-sectional study designs (Scarpelli et al., 2013). They concluded that a study design such as theirs may have diminished the ability to establish direction of associations reliably, indicating the need for longitudinal studies. Another limitation was in regards to the severity of TDI in the study sample. Overall, TDIs were not severe, therefore they were not found to be associated with a negative impact on OHRQoL of children and their families. If there had been a larger range of severity of TDIs then the results may have been different (Scarpelli et al., 2013).

Summary

Generally, in these four studies, only when dental caries was accompanied by symptoms such as pain or difficulty eating did parents perceive worse quality of life for their children (Scarpelli et al.,2013; Abanto et al., 2014; Gomes et al., 2014-15). Unfortunately, dental caries, well-known as a disease, did not present in and of itself as an indication of an oral health problem for the majority of parents in these studies. Generally, parents perceived a negative impact on quality of life only when clinical symptoms were present, and/or when the family was impacted in some way (Scarpelli et al.,2013; Abanto et al., 2014; Gomes et al., 2014-15).

Parents and caregivers are an integral piece of the decision-making process regarding children's dental treatment (Locker et al., 2002, Jokovic et al, 2002-4). Therefore, in order to better understand the level to which parents perceive children's oral conditions and overall oral health, more studies of this nature would be beneficial. This is fundamental in order to discern not only the true burden of this disease, but the best way in which to prevent and treat it, on an individual as well as community level (Locker et al., 2002, Jokovic et al, 2002-4).

Changes in Oral Health-Related Quality of Life Following Dental Treatment

Children of a young age who suffer from extensive dental caries may benefit from oral treatment under general anesthesia (Yawary, 2015). Given the young age and necessity for multiple visits, the standard setting in a dental office is not always the best environment in which to treat young children (Yawary, 2015). Dentists may also favor treatment under general anesthesia given the presence of an oral infection, great extent of

caries, anxiety of the child, and distance travelled by the parents/caregivers (Yawary, 2015).

While there are many advantages to oral rehabilitation under general anesthesia, this type of treatment does not come without large financial costs. Therefore, evaluating the benefits for both the child and family are necessary in order to justify these costs (Yawary, 2015). The following paragraphs will discuss four studies which assessed the changes in OHRQoL in children following oral rehabilitation under general anesthesia (GA). These are recent studies; however, all were conducted outside the United States.

Wong et al. (2016) conducted an Australian-based study which assessed the changes in OHRQoL for pre-school aged children requiring emergency dental extractions under general anesthesia (GA). A total of 221 children, 112 males and 109 females, in need of emergency dental extractions under general anesthesia (DEGA) over a 12-month period were recruited. Prior to the procedure, each patient's parent or caregiver completed the Early Childhood Oral Health Impact Scale (ECOHIS) (Pahel et al., 2007), a previously discussed OHRQoL tool (Wong et al., 2016). The parents/caregivers were given the same questionnaire two weeks following treatment. In addition to the questionnaire, information regarding gender, age, primary language, water source, residence, and number of decayed, missing, and decayed, missing, and filled teeth (dmft) was gathered (Wong et al., 2016).

Wong et al. (2016) analyzed the data using IBM SPSS Statistics 19, repeated ANOVA, and the Bonferroni adjustment for multiple comparisons. Significance level was established at $p < 0.05$ and any questionnaire more than 30.0% incomplete was excluded. The effect size, magnitude of change between pre- and post-treatment scores,

was determined by dividing mean change in score by the standard deviation of the score at baseline. An effect size < 0.2 was defined as small, moderate if between 0.2 and 0.7, and large if > 0.7 (Wong et al., 2016).

The authors reported that parents of 126 children completed the questionnaire post-treatment (Wong et al., 2016). There was a large loss to follow-up, despite the attempts made to contact the parents/caregivers via phone and mail. The mean age was 4.02 years and the mean dmft score was 8.27. Overall, the ECOHIS scores had a significant decrease ($p < 0.001$) following the emergency treatment indicating a positive increase in OHRQoL, and a large effect size (Wong et al., 2016). Child impact section scores (CIS) in this study decreased significantly ($p < 0.001$), as did the family impact section scores (FIS) ($p < 0.001$). The effect size for the CIS scores was large, and for the FIS scores, moderate. There was a 32.0% change in the overall ECOHIS scores 2 weeks post-treatment, a 34.0% change in the CIS scores, and a 29.7% change in the FIS scores, all statistically significant ($p < 0.001$) (Wong et al., 2016).

The authors reported that at baseline, the impacts most common for children included difficulty eating, pain, sleep problems, hot/cold drinks, and feelings of irritation (Wong et al., 2016). The impacts most common for the families were financial problems, feeling upset and guilt. The authors determined that the largest decrease in prevalence following treatment was for the following items: pain in teeth, irritation, difficulty drinking, difficulty sleeping, and upset parents (Wong et al., 2016).

Children required this type of treatment due to the fact that parents/caregivers had not sought out dental treatment previously, including preventive and restorative care (Wong et al., 2016). As a result, children eventually experienced pain and infection,

leading to the need for emergency treatment, which is considered a potentially preventable hospitalization (PPH). The authors assessed OHRQoL for these children in particular in order to better understand the quality of life changes following this type of treatment, which ultimately served as a necessary first step in addressing the problem of untreated dental caries in children. Wong et al. (2016) concluded that the OHRQoL of children who presented for emergency dental extractions improved significantly following extractions under general anesthesia. The main limitation of this study included the high non-response rate. It was also impossible to directly compare this study with others. To the authors' knowledge, there were no other studies of this kind which specifically targeted children presenting for emergency dental extractions (Wong et al., 2016).

Erkmen et al. (2014) assessed the changes in OHRQoL following non-emergency dental rehabilitation under general anesthesia, (GA). The purpose of the study was trifold. It aimed to determine if dental treatment under GA improved the OHRQoL of pre-school aged children, assessed the sensitivity and responsiveness of the Early Childhood Oral Health Impact Scale (ECOHIS) (Pahel et al., 2007), and examined the satisfaction of parents in regards to the dental rehabilitation of their child (Erkmen et al., 2014).

This study utilized the Turkish version of the ECOHIS (Erkmen et al., 2014). Children aged 7 and younger from the Kirikkale University Pediatric Dentistry Clinic were recruited over a 16-month period. These were all children who were recommended for comprehensive dental treatment under GA. It was determined that, in order to achieve a statistical power of 90.0%, a sample size of 96 was required (Erkmen et al., 2014).

Therefore, assuming 20.0 % loss to follow-up, the sample size was increased to 120, which by the study's conclusion decreased to 98 due to incomplete questionnaires and loss to follow-up. Children with complex medical problems were excluded. The family/caregivers were asked to complete the questionnaire before treatment, and 4 weeks following treatment (Erkmen et al., 2014). In addition, parents were questioned regarding the assistance they provided the children with at-home dental care. Finally, the parents were asked a global transition judgement question in regards to pre-and post-treatment: 'How has your child's condition changed since dental treatment?' Answers included 'no change', 'got worse,' or 'got better' (Erkmen et al., 2014).

Erkmen et al. (2014) compared scores using the Wilcoxon signed-rank test. Effect-sizes were calculated and categorized so that 0.2 equated to a small magnitude of change, 0.2 through 0.7 indicated moderate change, and above 0.7 related to a large change. McNemar's test was used for the comparison of the parents' help with children's at-home oral care. There were a total of 66 males and 32 females who completed the study, with a mean age of 50.8 months (Erkmen et al., 2014). There was a 54.7% reduction in the total ECOHIS scores post-treatment ($p < 0.001$), which indicated a significant improvement in OHRQoL. There was a 48.4% reduction in the CIS scores and a 67.4% reduction in the FIS scores ($p < 0.001$). The magnitude of change was moderate for child psychology, child self-image, and social interaction (Erkmen et al., 2014). The magnitude of change was large for the remaining four domains. Post-treatment, 87.8% of parents reported children's condition as 'better', while 11.2% reported 'no change' and one parent reported the child as 'worse'. The experience was positive for 91.0% of the parents, whereas 33.0% reported they would not consider

treatment under GA again. This may be due to potential complications associated with general anesthesia (Erkmen et al., 2014). Before treatment, only 24.5% of parents helped their children with oral care at home, and post-treatment that increased to 83.7%. Therefore, it appears treatment had a positive impact on parental perceptions of oral health care for children (Erkmen et al., 2014).

Overall, the authors reported that children's OHRQoL as well as the impact on their families showed a significant improvement following dental treatment under GA, and the Turkish version of the ECOHIS proved to be sensitive and responsive (Erkmen et al., 2014). Finally, the majority of parents concluded this to be a positive experience. The authors discussed one main limitation which was the need for a long-term follow-up, because the significant change in OHRQoL may have only been temporary (Erkmen et al., 2014).

The third study in this category was an Australian-based study conducted by Yawary et al. (2016), the purpose of which was to assess changes in the OHRQoL following comprehensive oral rehabilitation under general anesthesia (GA). There were two groups of study subjects, the first included children less than 6 years of age and the second included children aged 6 to 14 years. For the purposes of this thesis, only the group of children less than 6 years of age will be discussed (Yawary et al., 2016).

This study included children who received comprehensive oral rehabilitation under GA between 1 January 2014 and 31 October 2014 (Yawary et al., 2016). All parents of children were invited to participate. The sample size of preschool aged children totaled 70, 39 males and 31 females, with a mean age of 4.1 years. Parents/caregivers were given the ECOHIS (Pahel et al., 2007) questionnaire to complete

prior to dental treatment (Yawary et al., 2016). Additional information collected included gender, age, ethnicity, language, water source, postal code of residence, as well as decayed, missing, filled teeth due to caries. Exclusions included children with parents who decided to voluntarily withdraw, those not proficient in English, those who failed appointments, and those who did not complete the pre-operative questionnaire (Yawary et al., 2016).

On the day of treatment, all parents were asked to complete the questionnaire (Yawary et al., 2016). The questionnaire focused on children's current oral state as well as well-being over the three months prior to treatment. The parents were then asked to return two weeks and three months post-treatment to complete the follow-up questionnaires. If a parent was unable to return to complete the questionnaire in person, it was mailed to them (Yawary et al., 2016). If the questionnaire was not returned, a follow-up phone call was made by the principal investigator. Incomplete questionnaires, those with more than 30.0% missing answers, were excluded. Data were analyzed using an IBM SPSS Statistics 19, repeated-measures ANOVA, and multiple comparison adjustments using the Bonferroni procedure (Yawary et al., 2016). Significance level was set at 5.0%. The mean change of score divided by the standard deviation of the baseline score determined the effect size. An effect size <0.2 indicated a small change, 0.2-0.7 a moderate change, and >0.7 a large change (Yawary et al., 2016).

The authors reported that 39 participants completed the three-month post-treatment questionnaire, including 23 males and 16 females with a mean age of 4.08 years (Yawary et al., 2016). The majority of children, 92.9%, were Australia-born. The overall scores had a significant decrease post-treatment, ($p < 0.001$), which indicated a

large effect size. In the child impact section, the greatest decreases were for the child oral symptoms and psychology domains, while in the family impact section the domains with the greatest decrease were parental distress and family function (Yawary et al., 2016). The percent change in the overall ECOHIS scores 2 weeks post-treatment had a statistically significant reduction of 30.8%. Scores 3 months post-treatment had a statistically significant reduction of 38.4%. There was not a significant change in scores between the two post-treatment questionnaires, indicating sustained improvement in OHRQoL (Yawary et al., 2016).

The authors reported that the child impact section (CIS) scores at two weeks and three months post-treatment had 30.9% and 37.8% reductions, respectively (Yawary et al., 2016). Similarly, the family impact section (FIS) scores at two weeks and three months reduced by 30.7% and 39.5%, respectively. These reductions were statistically significant ($p < 0.001$). There was not a significant change in these scores between the 2 week and 3 month appointments, indicating sustained improvement in OHRQoL (Yawary et al., 2016). The impacts most frequently reported in the child section included pain, drinking hot/cold beverages, eating problems, pronunciation problems, and feeling of irritation. The impacts most commonly reported in the family section were parents feeling upset and guilty, and the financial impact (Yawary et al., 2016).

The authors determined there to be significant improvements in OHRQoL of these children, as well as a positive impact on the quality of life of the family (Yawary et al., 2016). The authors attributed this to a decrease in the distress experienced by the family, a reduction in the time taken off of work to care for the child, and a decrease in the financial impact on the family. The follow-up period demonstrated sustainment of

this improvement (Yawary et al., 2016). Long term follow-ups were recommended; however, the authors reported a low response rate following the 3-month follow-up, which indicated that a long-term assessment would have been quite difficult. The authors believed this was due to unpaid hospital bills, which prevented those parents from being able to acquire a 3-month follow-up appointment, as per the hospital policy (Yawary et al., 2016).

Over 62,000 children were admitted into England hospitals for dental extractions during 2013/2014, and the most common reason for general anesthesia in England was dental treatment, which cost the National Health Service approximately £30 million in 2012 and 2013 (De Souza et al., 2016). DeSouza et al. (2016) conducted a study which assessed the changes in OHRQoL in children affected with early childhood caries (ECC) following oral rehabilitation under general anesthesia (GA). This study included a convenience sample consisting of parents of children treatment planned to receive oral rehabilitation under GA at Guy's Hospital in London (De Souza et al., 2016). There were a total of 115 eligible participants. However, 32 declined and 5 had time constraints. The authors reported a final sample size of 78, and a mean age of 4.8 years. Inclusion criteria consisted of healthy children who had a minimum of four primary molars affected with caries and who did not yet have erupted first permanent molars. Children who previously had dental treatment under GA were excluded, as were parents who could not speak English fluently (De Souza et al., 2016).

This study split children into two treatment groups, those who received oral rehabilitation (51 children), and those receiving extractions only (27 children) (De Souza et al., 2016). An in-person interview using the questionnaires was administered to the

parents/caregivers just prior to treatment, on the day of treatment. The follow-up questionnaires were completed by telephone a minimum of one month following treatment. The questionnaire utilized was the Chile Oral Health-Related Quality of Life questionnaire (Jokovic, et al, 2000), previously discussed, which contained two sections, the Parent -Caregivers Perceptions Questionnaire (P-CPQ) and Family Impact Section (FIS). Total scores as well as subscale scores for the four domains of the (P-CPQ) were calculated (De Souza et al., 2016). The four domains included oral symptoms, functional limitations, emotional well-being, and social well-being. The four domains of the FIS were parent family activity, parental emotions, family conflict, and economic impact. Global health ratings were included, as the parents and caregivers were asked to ‘rate the overall state of their child’s oral health’ and ‘the extent to which the oral health condition affected their child’s overall well-being’ (De Souza et al., 2016).

Statistical analyses consisted of paired t-tests, log-transformation, and Wilcoxon paired tests, as well as the calculations of effect sizes and minimally important differences (MID) (De Souza et al., 2016). The mean number of teeth with caries in the oral rehabilitation group was 8.8 while in the extraction group it was 10.4. Overall, the changes in the P-CPQ and FIS scores were statistically significant ($p < 0.0001$). The parental emotion and oral symptoms domains had the largest effect sizes while social well-being and family conflict domains had the smallest effect sizes (De Souza et al., 2016). Pre-treatment, 10.0% of parent scored their child’s oral health as good, very good or excellent, and post-treatment that number increased to 90.0%. Prior to treatment only 56.4% of parents felt their children’s oral health was poor. Post-treatment that number

decreased to 0%. It was determined that 43.1% of parents thought their children's overall quality of life improved following treatment (De Souza et al., 2016).

To the authors' knowledge, this study was the first of its kind in the UK (De Souza et al., 2016). It raised the issue of 'limited parental awareness', given the fact that over 40.0% of parents did not perceive their children's oral health as poor prior to dental treatment. Acknowledgement of improved oral health by parents was greater for the group of children who received oral rehabilitation, as opposed to the group who received extractions only. The authors concluded that overall, dental treatment under general anesthesia for children affected by early childhood caries (ECC) greatly improved the OHRQoL of children, as perceived by their parents/caregivers. As for limitations, the authors acknowledged that this was an uncontrolled and non-randomized study, which given the nature of the study could not be avoided. They also discussed the possibility of sampling bias through the use of a convenience sample (De Souza et al., 2016).

Summary

These four studies, with varying study samples, data collection, and results, all had the same underlying purpose, as well as the same overall conclusions. They all aimed to determine if dental treatment under general anesthesia impacted children's OHRQoL, and they all found a decrease in mean overall scores, which indicated an improved OHRQoL following dental treatment. These studies have shown the tremendous impact that dental disease and the appropriate dental treatment can have on children's everyday lives, as well as on the lives of their families (Erkmen et al., 2014; Yawary et al., 2015; Wong et al., 2016; DeSouza et al., 2016).

Any kind of treatment under general anesthesia may raise parental concerns, as there will always be possible complications associated with this approach. However, utilizing dental treatment under general anesthesia for young children with severe oral infections, gross caries, or behavioral problems which preclude standard dental treatment prevents the child from having to return to the dentist several times, thereby expediting treatment, and providing an environment which is not accompanied by multiple, possibly traumatic memories from a dental office (Yawary et al., 2015).

Dental Conditions and Oral Health-Related Quality of Life

While OHRQoL as it relates to children and dental caries is a topic which has had very little assessment in the United States, there is a fairly recent University of Iowa Master of Science thesis, a brief review of which is germane to this chapter (Ahuja, University of Iowa, 2013). This study not only assessed the impact of dental caries on the OHRQoL of adolescents, it also assessed the impact of dental fluorosis as well as malocclusion. Additionally, the perceptions of parents and adolescents on dental esthetics were examined (Ahuja, University of Iowa, 2013).

This study was extracted from the Iowa Fluoride Study. The results suggested that malocclusion severity as well as caries experiences were associated with lower OHRQoL scores (Ahuja, University of Iowa, 2013). Additionally, females as opposed to males were more judgmental of their OHRQoL, and overall, adolescents were more censorious regarding OHRQoL when compared to their parents (Ahuja, University of Iowa, 2013).

Clearly dental caries is not the only oral condition with the capability of impacting one's oral health-related quality of life (OHRQoL) (DHHS,2000). Malocclusion may come with not only functional and esthetic limitations, but also the potential of impacting one's self-esteem, ability to socialize, and overall well-being (Kiyak H, 2008; Onyeaso et al., 2003). It is an oral condition which, similar to dental caries, can influence self-perception (Simoes et al., 2017). The following paragraphs review a recent study which assessed the impact of malocclusion on the OHRQoL of children and adolescents.

In 2017, Simoes et al. assessed the impact of malocclusion on the OHRQoL of children between the ages of 8 and 12 in a school-based cross-sectional study conducted in Southern Brazil. A two-stage cluster procedure was utilized to select children from 20 public and private schools. The first and second stages consisted of random selection of schools and children, respectively. Children not able to answer the questions as well as children with mental or physical disabilities were excluded (Simoes et al., 2017).

Data, collected during the Fall of 2010, consisted of the following: socio-demographic and economic information via parent questionnaires; OHRQoL via the previously discussed Brazilian version of Child Perceptions Questionnaire administered to children during an interview (Jokavic et al., 2002); clinical exam completed by 6 previously calibrated and trained examiners who assessed malocclusion and dental caries via the WHO criteria for the Dental Aesthetic Index (DAI) and decayed, missing, filled teeth (DMFT) index, and dental trauma via the O'Brien criteria (O'Brien M, 1994; Simoes et al., 2017). Statistical analyses, utilizing Stata, consisted of descriptive

statistics, bivariate and multivariate Poisson regression, Pearson's Correlation Coefficient, and Kruskal -Wallis test (Simoes et al., 2017).

The final sample consisted of 1,206 children (Simoes et al., 2017). For analysis purposes, children were categorized as being in either the 'younger group', ages 8 – 10, or the 'older group', ages 11-12. Regarding children in both age groups, those with severe malocclusion presented with worse OHRQoL. Specifically, the younger group and older group presented with CPQ scores 24% and 28% higher, respectively, than those with mild or normal malocclusion. This study also showed that socio-demographic and economic factors had an impact on OHRQoL. Regarding both the younger and older age groups, children who were non-Caucasian, with lower family income, and with less years of maternal education had higher CPQ scores than those without these variables. Following the adjustment for caries, dental trauma, and socio-demographic and economic variables, the authors confirmed the negative impact of severe malocclusion on OHRQoL (Simoes et al., 2017).

In conclusion, the results suggested that severe malocclusion negatively impacts children's OHRQoL, specifically regarding emotional and social well-being, and that those with severe malocclusion overall experience a greater negative impact on OHRQoL than those with mild or normal malocclusion (Simoes et al., 2017).

Chapter Summary

This chapter discussed key definitions germane to this topic. It covered the history of the concept of oral health-related quality of life (OHRQoL) and the tools utilized to measure it. It reviewed Amish history and diet, current literature regarding the impact of

dental caries on OHRQoL, as well as an additional oral condition which has shown to have the ability to impact OHRQoL.

The concept of OHRQoL is relatively new; however, in a short time it has been proven to be a meaningful concept (Sischo and Broder, 2011). The studies discussed in this chapter exhibit the significance of measuring OHRQoL, display the dramatic changes in OHRQoL that children experience following dental treatment, and provide an introduction into the level to which parents perceive children's oral health. The measurement of OHRQoL permits the evaluation of the full impact of oral disease (Inglehart and Bagramian, 2002; Sischo and Broder, 2011; Locker et al., 2002, Jokovic et al, 2002-4). This is of particular importance in regards to children as they are significantly impacted by dental caries (DHHS,2000), and must rely on others to advocate for them.

As this is a fairly new topic, there are many gaps in the literature. The vast majority of studies assessing OHRQoL have been conducted outside the United States, for example Brazil, Australia, Turkey, and England. While these studies provide worthwhile information, they are not always generalizable to the population of the United States. More research in the U.S. regarding OHRQoL can have major implications on oral health care delivery, decision making, program development, and lastly policy, as it can be used as a valuable method of communicating with policymakers the significance of oral health and access to oral health care (Al Shamrany, 2006).

CHAPTER III

MATERIALS AND METHODS

Introduction

The purpose of this thesis was to assess the impact of dental caries on the oral health-related quality of life (OHRQoL) in children. A secondary objective was to determine the influence of socio-demographic factors on parental perceptions of children's oral health status and OHRQoL. This study was embedded within the pilot interventional clinical trial, "Medical Management of Caries in the Primary Dentition Using Silver Nitrate," (NCT#02604134) conducted by researchers at the University of Iowa. This chapter will first focus on the procedures and protocols of the silver nitrate pilot study. Subsequent to that segment, the chapter will discuss the methodology of the OHRQoL study specific to this thesis.

Operational Definitions

Dental Caries

In regards to eligibility for this study, dental caries was defined as a cavitated carious lesion of the primary tooth having extended into the dentin. Caries experience and incidence were measured utilizing the Early Childhood Caries Collaborating Centers criterion, defined in detail in the 'Outcome Measure' section (Warren et al., 2015), while caries activity was described using Nyvad scores (Nyvad et al., 1999), both of which are explained in detail later in this chapter.

Oral Health-Related Quality of Life

Oral health-related quality of life (OHRQoL) was defined through the utilization of the 16-item Parents' Perception Questionnaire (PPQ) (Innes et al., 2013; Thomson et al., 2013) as well as the 11-item Michigan OHRQoL Parent Questionnaire (Filstrup et al., 2002). Answers to questions reflected various scores using the 5-point Likert Scale. When summed, a higher score denoted worse OHRQoL.

Secondary indicators of OHRQoL were the global health ratings, two questions which addressed the parents' rating of the children's oral condition in general, as well as the impact on the overall wellbeing of the children by the condition of the mouth. The questionnaires as well as global health rating questions are discussed in detail in the 'outcome measures' section below.

Procedures for 'Medical Management of Caries in the Primary Dentition'

The following several pages describe the parent study 'Medical Management of Caries in the Primary Dentition Using Silver Nitrate', including its background, purpose, safety, sample, design, and outcome measures. This study was registered at clinicaltrials.gov, (Identifier # NCT02604134), approved by the University of Iowa Institutional Review Board (IRB# #201406792), and funded by Delta Dental of Iowa Foundation. ***It is acknowledged that unless otherwise stated, information contained in these sections was taken from this study's IRB application, grant application (#U54TR001356), published abstract (Owais et al., 2016), and the very recent publication regarding lessons learned from this trial (Kanellis et al., 2018).***

The methods of the cross-sectional study, ‘The impact of dental caries on the OHRQoL in children,’ which this thesis is based on, will be discussed in detail following the discussion of the parent study in which it is embedded.

Background

As mentioned previously, dental caries is a highly prevalent disease in children; odontogenic pain and infection, caused by dental caries, are significant factors in the determination of oral health-related quality of life (DHHS, 2000). The effect of conventional caries preventive measures such as fluoride and sealants are largely limited to lesions which are noncavitated. Many children with high rates of caries do not have the access to this conventional treatment; therefore, there is a need for a treatment modality which instead of serving as a preventive measure for noncavitated lesions, serves to arrest the progression of caries in cavitated lesions. It has been suggested that silver nitrate has the ability to not only arrest the caries process, but to also prevent new caries from forming due to its powerful germicidal effect (Miller, 1905; Howe, 1917; Klein H et al., 1942; Klein U et al., 1999). The following qualities account for the revived interest in silver nitrate: ease of application, control of pain and infection, affordability, minimal training required, noninvasive, and can be utilized in outreach programs (Miller, 1905; Howe, 1917; Klein H et al., 1942; Klein U et al., 1999).

Purpose

There were four goals of this clinical trial (verbatim from grant application #U54TR001356): 1. Compare the clinical effectiveness and cost effectiveness of medically managing caries using silver nitrate and fluoride varnish, with the conventional method of treating dental caries with restorations in primary teeth in children. 2. Compare

the incidence of adverse events such as pain and infection in children treated with silver nitrate/fluoride varnish versus a control group treated with conventional dental treatment.

3. Explore 24-month dental caries incidence and activity in children treated by silver nitrate/fluoride varnish compared to a group of children treated by restoring the carious cavities in the conventional manner. 4. Assess changes in Oral Health-Related Quality of life in children treated by medically managing the caries using silver nitrate and fluoride varnish compared to a control group of conventionally managing caries.

Silver Nitrate Safety

In the presence of silver nitrate, a cavity will turn black. Temporary discoloration of the skin and/or tissue will occur if the silver nitrate makes contact. The National Laboratory Health and Safety Research Division (1992) determined that silver is adsorbed through intact and damaged skin via oral and inhalation routes. A body concentration of greater than 4 grams will result in a condition known as argyria. In this pilot study, one drop of silver nitrate, a 25% solution containing approximately 0.004 grams of silver, was utilized per child, per application. This, in turn, was approximately 0.1% of the amount necessary to produce the toxic effects described above. Therefore, even multiple applications would result in an exposure well below that which is required to produce toxicity.

Sample

Children of Amish families from Kalona, Iowa between the ages of 2 and 14 were recruited to participate in this pilot study. This specific group was targeted because many Amish children have untreated dental decay, minimal exposure to fluoride, as well as parents who may not favor conventional dental treatment. It was also thought that they

would be dependable patients throughout the duration of the study. The co-Principal Investigator of this study approached a Bishop of one of the Kalona Amish's church districts. The Bishop in turn shared the information with Bishops from the other eight church districts and following receipt of a letter of endorsement from the Bishop and IRB approval, families were invited to participate through the utilization announcements and informational sessions in several churches as well as various other public spaces.

An initial screening, which included an eligibility questionnaire completed by the parent, took place in order to confirm qualification for the study. The screening and all subsequent clinical visits for this study took place in a private dental office located in Kalona, Iowa. Inclusion criteria were as follows (verbatim from grant application #U54TR001356): (1) Presence of one or more cavitated carious lesions in the primary dentition, extending into dentin. (2) Absence of any spontaneous or elicited pain due to caries, or signs of pulpal infection in response to any of the carious lesions in the primary dentition. Exclusion criteria included (verbatim from grant application #U54TR001356): (1) Hereditary developmental defects of the teeth such as Amelogenesis Imperfecta and Dentinogenesis Imperfecta. (2) Medical conditions that precluded managing the child in an outpatient setting such as severe bleeding disorders, severe heart problems and mental disabilities. (3) Known allergy/sensitivity to any of the dental materials to be used, including silver nitrate and fluoride varnish. Children with abscessed teeth were enrolled as long as they had other non-abscessed lesions.

Once eligibility was confirmed, parents and children interested in being included in the study were invited to discuss the specifics with the trial manager and another trained member of the research team at the UI College of Dentistry and Dental Clinics.

Before commencement of the study, parents were required to provide written informed consent. If possible, with parental agreement, participating children were also asked to supply written or oral assent. Parents and children were informed of the right to withdraw at any time. There were two options for withdrawal, complete and partial. Complete withdrawal was withdrawal from the study treatment as well as provision of any follow-up data. Partial withdrawal from the study included withdrawal from treatment; however, the provision of follow-up data through attendance of recall visits and completion of questionnaires continued.

Study Design / Detailed Protocol

Children officially enrolled in this study were randomly divided into one of two groups, a control group or study group, in a 1:2 ratio, based on the assumption that more is known about conventional treatment (Kanellis et al., 2017). Two previously trained and calibrated dentists completed the baseline and annual caries examinations. The training and calibration of the examiners took place during the University of Iowa Dental Examiner Training Project, IRB identification # 201408731. The children examined during this calibration training project were between the ages of 1 and 14 and from the patient pool available at Pediatric Dentistry Clinics affiliated with the University of Iowa Department of Pediatric Dentistry. Descriptions of the control and study groups for the silver nitrate intervention are as follows:

Conventional Management of Caries (Control group)

Children in the control group received restorative dental care in accordance with the American Academy of Pediatric Dentistry guidelines as well as local practice within the Department of Pediatric Dentistry at the University of Iowa. This treatment included

local anesthesia, caries removal using rotary instruments and/or hand excavation followed by traditional restoration placement. A pulpotomy was completed if the child presented with symptoms of irreversible pulpitis or if the dental pulp was exposed during caries removal. Teeth described as the following were extracted: nonrestorable, retained root tips, open pulp chamber, or deemed to be the cause of pain and/or infection prior to exfoliation. Preventive procedures were provided to the conventional treatment group in accordance with AAPD guidelines as follows (verbatim from grant application #U54TR001356):

- Prophylaxis, scaling, flossing and regular recall exams, radiographs (if indicated)
- Tooth brushing/topical fluoride
- Dietary investigation, analysis and intervention
- Fissure sealants for permanent teeth
- Fluoride varnish applied to primary and permanent teeth.

Silver Nitrate Management of Caries Group

The protocol for this group included the following: The teeth to be treated were isolated with the appropriate isolation methods, including cotton rolls. The teeth were then dried with gauze or compressed air and while utilizing a liquid micro brush applicator, a 25% silver nitrate solution was placed directly on the carious lesion for five seconds. Finally, a 5% sodium fluoride (NaF) varnish was placed on the tooth surface. Each carious lesion was treated in this manner at monthly intervals for a total of three applications. New carious lesions that developed following the initial treatment were treated by the same regimen. In addition to the silver nitrate protocol, this group also received the same preventive procedures as the conventional group. Pictures illustrating

typical conventional treatment versus silver nitrate treatment are presented below in Figure 3.1:



Figure 3.1 Illustrations of Conventional Versus Silver Nitrate Treatment

Questionnaires

At the initial visit for both groups, parents completed the Parent Baseline Questionnaire. This questionnaire contained various demographic questions regarding age, sex, race, number of children at home, education, work, etc., as well as questions regarding the child's behavior both prior to and following the first baseline appointment. Additionally, embedded within this baseline questionnaire were two questionnaires which measured oral health-related quality of life (OHRQoL) including the 16-item Parent Perception Questionnaire (PPQ) and the parent version of the Michigan OHRQoL Questionnaire. At treatment as well as recall appointments, parents completed the Parent Subsequent Questionnaire. Similar to the baseline questionnaire, it contained various questions related to the child's behavior prior to and following the appointment. The child, if age appropriate (approximately 5 years, but varied child to child), completed the Child Questionnaire with the aid of a parent. This questionnaire assessed the child's anxiety both prior to and during the appointment. A Case Report Form was completed by the practitioner, with the help of a research assistant, at all treatment and recall visits.

This form included all pertinent information related to the appointment, including reason for visit, treatment delivered, treatment recommended, radiographic findings, etc.

If a participant in either group experienced pain and/or infection subsequent to a dental visit, he/she was treated in the Pediatric Dentistry Department at the College of Dentistry. House calls were also made on occasion. If treatment in any way needed to deviate from the original plan due to failure of treatment that had been previously provided, a Treatment Deviation Form was completed. Participants were followed for two years. At 1-year recall visits, parents completed the Parent 1-year Recall Questionnaire which included the same demographic questions in the baseline questionnaire, as well as various questions regarding the treatment delivered during the course of the study, including satisfaction related to it, and child behavior/symptoms following it. Embedded within this questionnaire were the two OHRQoL questionnaires, serving as a way to measure the child's change in OHRQoL following the dental treatment administered during this study. Only the forms/questionnaires utilized in the study specific to this thesis are included in the Appendix. These forms are indicated in the section entitled "Thesis-Specific Methods."

Outcome Measures

1. Caries Prevalence / Incidence in primary teeth:

The number of decayed, missing, and filled surfaces/teeth (dmfs, dmft) represented the measure of dental caries and treatment experience. The EC4 criteria (Warren et al., 2015), discussed in detail in the following paragraph, was utilized for this measure at baseline as well as at bi-annual caries examinations. The baseline measure represented caries prevalence. The comparison of the caries measure taken at annual

examinations with that of the baseline examination facilitated the calculation of caries incidence. The surface-level caries data were collected by two previously trained and calibrated pediatric dentists.

In 2008, with the support of the NIDCR, three research centers which were studying oral health disparities and specifically targeting the reduction of early childhood caries collectively became known as the Early Childhood Caries Collaborating Centers (EC4). The EC4 caries criteria is parallel to the WHO system (d₁-d₄), compatible with the traditional DMF (or dmf) criteria, and distinguishes cavitated from noncavitated lesions (Warren et al., 2015). Tooth and tooth surface status codes are utilized to determine clinical conditions as follows in Tables 3.1 and 3.2:

Table 3.1 EC4 Tooth Status Codes

Code	Clinical Condition
P	Present
R	Partially Erupted
K	Sound (all surfaces)
U	Unerupted
M	Missing due to caries
T	Missing due to trauma
X	Missing due to exfoliation
O	Missing due to other or unknown reason
C	Crown (including stainless steel crown, or other)
Z	Unable to score

(Warren et al., 2015).

Table 3.2 EC4 Tooth Surface Status Codes

Code	Clinical Condition
K	Sound
D	Cavitated decayed lesion (d ₂₊)
W	Demineralized (white spot or d ₁) lesion
A	Filled surface – amalgam restoration

Table 3.2 continued

F	Filled Surface – non-amalgam restoration
S	Sealed Surface
U	Unerupted Surface
Z	Unable to Score

(Warren et al., 2015)

While determining the proper code, there is a hierarchy or priority which takes place. A cavitated lesion takes precedence over a sealant, white spot lesion, or a filled lesion. An amalgam restoration takes precedence over a restoration which is non-amalgam, a white spot lesion, or a sealant. A non-amalgam restoration takes precedence over a white spot lesion or sealant. Finally, a white spot lesion takes precedence over a sealant or sound surface (Warren et al., 2015).

Radiographs were not combined with clinical caries measures to determine caries scores; therefore, caries experiences were likely underestimated. Bitewing radiographs acted as an independent blinded assessment of dental caries and were taken in accordance with American Academy of Pediatric Dentistry guidelines (AAPD, 2015). As caries risk varied among the children, so did the frequency with which radiographs were taken.

Radiographic assessment was as follows:

R0: sound

RF: radiographically filled

R1: caries in the outer half of enamel

R2: caries in the inner half of enamel

R3: caries in the outer half of dentin

R4: caries in the inner half of dentin not encroaching on the pulp

R5: caries encroaching on the pulp

Q: unable to assess

2. Caries activity in primary teeth:

Caries activity measurements, utilizing Nyvad scores (Nyvad et al., 1999) and a blunt perio probe, took place at baseline and annual caries examinations. This visual and tactile measurement was expressed as follows:

S: sound, normal enamel translucency and texture.

A: active enamel caries, surface of enamel is whitish/yellowish opaque with loss of luster; upon probing is soft or rough; presence of small porosity which involves only enamel.

I: inactive enamel caries; brownish or black enamel surface; enamel may appear shiny; upon probing feels hard or smooth; presence of small porosity which involves only enamel.

D: enamel/dentin cavity is easily visible; upon probing surface feels soft or leathery.

P: dentin cavity involving the pulp.

3. Pain and Infection

Pain was assessed at each visit through the utilization of the Dental Discomfort Questionnaire (Versloot et al., 2006), completed by the parents. Based on clinical evidence and patient history, the dentist diagnosed the origination of the pain. If the pain was a result of problems not related to caries, for example pericoronitis, mucosal lesions, exfoliating teeth, etc., this information was excluded from the final study analysis. The outcome measured was the total number of children who experienced any form of tooth (caries) -related pain, as well as the number of episodes of pain for each child during the 2-year follow-up period.

Signs of infection were assessed clinically, at each visit, throughout the length of the trial. Radiographic assessment followed if necessary. The criteria for clinical detection of infection included the presence of swelling, dental abscess, or draining sinus. Regardless of whether or not the infection was symptomatic at the time, it was recorded as an ‘infection.’

The outcomes of pain and infection were recorded at two levels, the tooth level and patient level. At each visit, the number of teeth that either caused or pain or were diagnosed as infected were recorded. Likewise, the total number of children who presented with pain or an infection as well as the total number of episodes of pain for each child were recorded. Tooth level pain/infection had four outcomes:

Outcome 1 - extraction due to pain/infection

Outcome 2 – treatment due to pain/infection (restorations, temporary or permanent, or prescription of antibiotics)

Outcome 3 – treatment due to an asymptomatic infection (restorations, temporary or permanent, or the prescription of antibiotics)

Outcome 4 – symptomless until exfoliation or end of study period

4. Oral Health-Related Quality of Life

This study utilized the shortened version of the Parent Perceptions Questionnaire (PPQ) (Innes et al., 2013; Thomson et al., 2013) and the Michigan OHRQoL Questionnaire (Filstrup et al., 2003), both of which were discussed in detail in Chapter 2. In review, the shortened version of the PPQ contained 16 items, covering four domains: oral symptoms, functional limitations, emotional wellbeing, and social wellbeing. There were four questions in each domain. Questions regarded the parental perception of the

frequency of various events related to the four domains, and answers included ‘never,’ ‘once or twice,’ ‘sometimes,’ ‘often,’ and ‘every day/almost every day.’ The responses were scored as 0,1,2,3,4, respectively; therefore, the composite PPQ score (calculated by the addition of each individual item score) could range from 0 to 64, and each domain score from 0 to 16. A table presenting the domains and their respective items is included in the “Thesis Specific Methods” section of this chapter.

The Michigan Questionnaire contained 11 items and covered two indices: Interference Index and Functioning Index. There were 5 items in the Interference Index and 6 in the Functioning Index. Each question had a score ranging from 1 to 5; therefore, the composite Michigan Questionnaire score (calculated by the addition of each individual item score) ranged from 11 to 55, and the Interference and Functioning Index scores ranged from 5 to 25, and 6 to 30, respectively. In both the PPQ and Michigan Questionnaire, a higher score denoted worse OHRQoL (Filstrup et al., 2003; Thomson et al., 2013).

A secondary indicator of OHRQoL in this study were the global health ratings (GOHR_{1,2}) which consisted of two questions which addressed the parents’ rating of the children’s oral condition in general, as well as the impact on the overall wellbeing of the children by the condition of the mouth (Locker et al., 2002). Parents were asked, ‘How would you rate the health of your child’s teeth, lips, jaws and mouth?’ Answers included ‘excellent’, ‘very good’, ‘good’, ‘fair’, and ‘poor.’ Scores for these answers were 0,1,2,3,4, respectively, a higher score denoted worse health. The second global assessment question was “How much is your child’s overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?” Answers included ‘not at all’, ‘very

little', 'some', 'a lot', and 'very much.' Assigned scores included 0,1,2,3,4, respectively, a higher score denoted worse overall wellbeing (Locker et al., 2002).

5. Silver Nitrate Success / Failure

Each tooth treated with silver nitrate was placed into one of three classifications (Innes et al., 2013):

A. Success – tooth which appeared satisfactory, no symptoms of pulpal pathology, no radiographic pathology, no further treatment necessary; tooth has naturally exfoliated.

B. Minor Failure – tooth presented with new or secondary caries visible clinically or radiographically; reversible pulpitis treatable without pulpotomy or extraction.

C. Major Failure – tooth presented with irreversible pulpitis or dental abscess requiring pulpotomy or extraction; inter-radicular radiolucency; loss of restoration; tooth nonrestorable; internal root resorption.

6. Economic Measures

The two treatments strategies (conventional and silver nitrate) were evaluated economically based on time and cost in order to determine cost effectiveness. The time in the clinic as well as material costs for each procedure completed was used to determine the 'procedure cost.' The 'parental cost' included time off of work, child care costs, and costs of over the counter medications. Data related to the 'parental cost' was collected via the questionnaires completed by the parent at each visit.

The cost effectiveness of each treatment strategy (conventional and silver nitrate) was evaluated by taking into account both the cost per 'pain-free' patient and cost per 'infection-free' patient. The costs for each event of pain/infection and each

new carious lesion was calculated using the conventional caries management as the base case.

7. Treatment Strategy Acceptability / Parent Experiences

Children's dental anxiety was evaluated in order to measure the acceptability of the treatment strategy. This was accomplished with the Modified Child Dental Anxiety Scale (MCDAS), completed by the children themselves at each appointment. This rating scale contained faces (smiling, frowning, crying) as opposed to numbers and it was utilized in order to collect information regarding children's perceptions of dental encounters throughout the course of the study.

A face-based Visual Analogue Scale (VAS) was given to each child prior to each appointment in order to assess the level of anxiety he/she was experiencing prior to dental treatment. The parent was also given a VAS in order to assess the parental perception of the child's anxiety prior to the appointment. Following each appointment each child and parent was given two visual analogue scales. The first scale measured the level of anxiety during the appointment, and the second measured the level of pain experienced during the appointment. Parent and child were both given the VAS in order to assess anxiety and pain from each perspective.

8. Growth Assessment

The dental status (dmft at baseline and follow-up appointments) and gender-specific body mass index were recorded for each child in an attempt to evaluate the impact of caries on growth, as well as any effect silver nitrate may have had regarding this impact.

Data Management

Data were managed in the University of Iowa's REDCap (Research Electronic Data Capture). Each patient in this study was given an individual patient identifier in order to secure confidentiality. This identifier was utilized on all forms and questionnaires throughout the study. Names and addresses did not appear on these forms. Children from the same family were given related identifiers in order to facilitate data analysis within the same family. A limited number of team members had the capability to enter the password protected database which allowed the member to associate the identifiers to names and addresses. The principal investigators were responsible for securing the confidentiality of participants, as well as assuring the compliance with the IRB at the University of Iowa. Publications regarding this study will not include any kind of personal information related to the participants. The 'Results' chapter of this thesis will briefly review the recent publication regarding this study entitled, 'Managing Caries in Primary Dentition with Silver Nitrate: Lessons Learned from a Clinical Trial,' (Kanellis et al., 2018). Figure 3.2 below is a flow chart of the study provided in this publication.

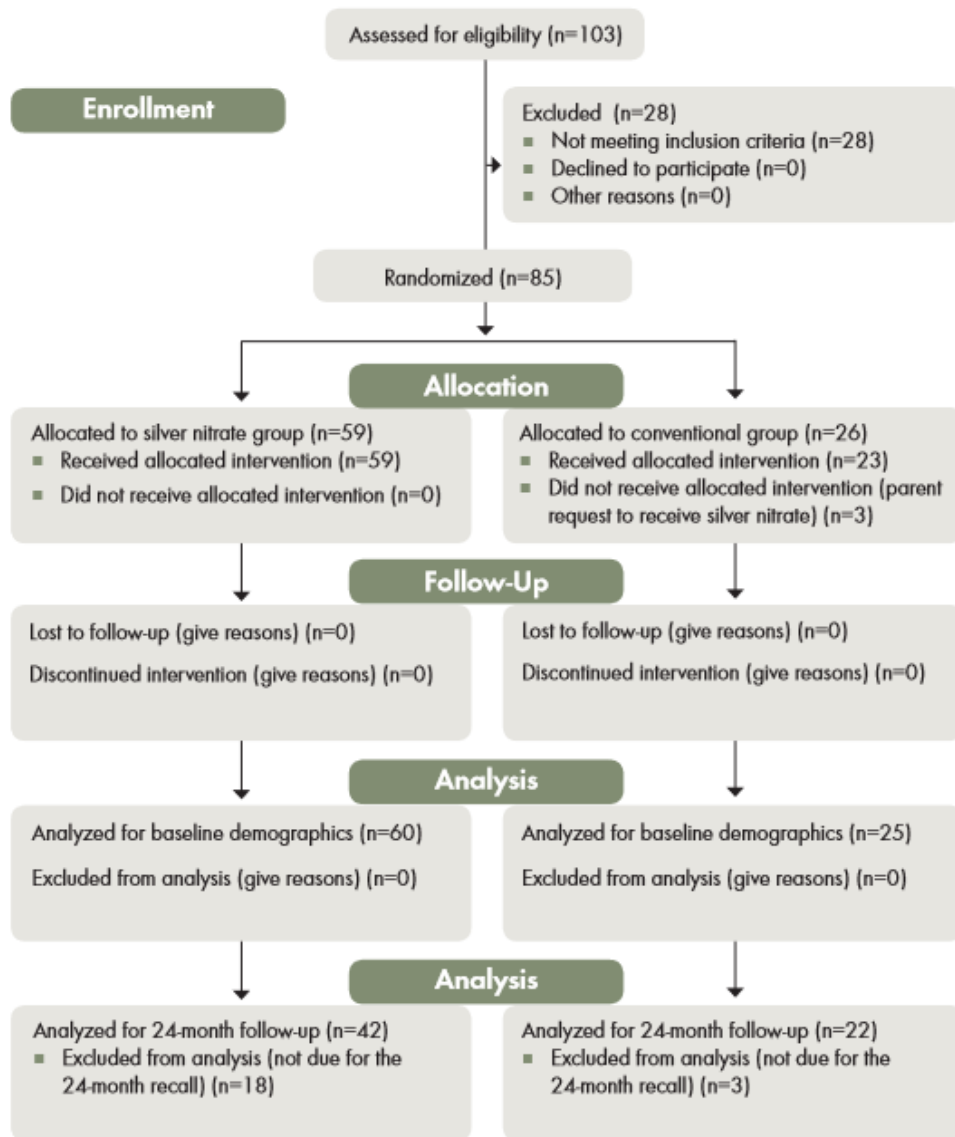


Figure 3.2 Study flow chart (Kanellis et al., 2018)

Thesis-Specific Methods

Problem Statement

The purpose of this thesis is to explore the level to which dental caries impacts children's oral health-related quality of life (OHRQoL).

Research Questions

1. What are the relationships between parental perceptions of OHRQoL of children and caries measurements?
2. What are the relationships between the parental global oral health ratings of children and caries measurements?
3. What are the relationships between the covariates (sex, age, income, parent who completed questionnaire, number of children at home) and parental perceptions of OHRQoL of children?
4. What are the relationships between the covariates (sex, age, income, parent completed questionnaire, number of children at home) and parental global oral health ratings of children?

Hypotheses

Given the purpose of this thesis, the hypotheses are as follows:

1. Children with high caries experience have worse OHRQoL (higher score) than children with lower caries experience.

2. Children with high caries experience have poorer global oral health ratings than children with a lower caries experience.
3. Parents' perceptions of children's overall oral condition as poor is associated with worse OHRQoL (higher score).
4. Children with lower income have worse OHRQoL compared to children with higher income.
5. Male children have worse OHRQoL when compared to female children.
6. Younger children have worse OHRQoL when compared to older children.
7. Fathers in general perceive worse OHRQoL for their children as compared to mothers.

Data and Sample Size

Data utilized for this study included questions from the Parent Baseline Questionnaire and baseline caries measurements from the silver nitrate study. No other data collected during and subsequent to baseline visits were used in this study. The Appendix section of this thesis includes the pre-screening questionnaire to determine eligibility, the EC4 caries exam form, and the Parent Baseline Questionnaire. This study included 77 healthy Amish children between the ages of 2 and 14. These 77 children were members of 32 Amish families in total.

Variables

Dependent/Outcome Variables

The main outcome measure of this study was the oral health-related quality of life (OHRQoL) composite score, acquired via the OHRQoL questionnaire embedded within

the Parent Baseline Questionnaire, the 16-item Parent Perception Questionnaire (PPQ). This 16-item PPQ was utilized in the Fiction dental trial protocol (Innes et al., 2013) and by Thomson et al., 2013. The PPQ, discussed in detail earlier, contained four separate domains (oral, emotional, social, and functional). Therefore, the PPQ score was represented as one composite score, as well as four separate domain scores.

The secondary outcome variables included the global oral health ratings (GOHR_{1,2}) collected via two separate questions. GOHR₁: ‘How would you rate the health of your child’s teeth, lips, jaws and mouth?’ GOHR₂: ‘How much is your child’s overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?’ These ratings were expressed on a five-point Likert Scale. All dependent variables, their types, derivations, and explanations, including Domain and Index subscales, are listed in Table 3.3 below. All question numbers refer to questions in the Parent Baseline Questionnaire.

Table 3.3 Outcome Measures

<u>Dependent Variable</u>	<u>Type</u>	<u>Source</u>	<u>Explanation</u>
PPQ Total Score	Continuous, range 0 through 64	Parent Baseline Questionnaire, Ques.#13, parts a through p.	Composite Parent Perception Questionnaire score
Oral Symptom Domain	Continuous, range 0 through 16	Ques.#13, parts a through d	PPQ Domain score of questions regarding oral symptoms: pain, bleeding, bad breath, food impaction

Table 3.3 continued

Functional Limitation Domain	Continuous, range 0 through 16	Ques.#13, parts e through h	PPQ Domain score of questions regarding functional limitations: trouble breathing, sleeping, chewing, eating/drinking hot/cold foods
Emotional Wellbeing Domain	Continuous, range 0 through 16	Ques.#13, parts i through l	PPQ Domain score of questions regarding emotional wellbeing: frustration, worry about health, worry about difference from other children, embarrassment
Social Wellbeing Domain	Continuous, range 0 through 16	Ques.#13, parts m through p	PPQ Domain score of questions regarding social well-being: unable to spend time with/talking with other children, trouble speaking in class, questioned about his/her teeth
Global Oral Health Rating ₁ (GOHR ₁)	Categorical-Ordinal, ratings 0 through 4	Ques.#11	Rating of the health of the child's teeth, lips, jaws, and mouth
Global Oral Health Rating ₂ (GOHR ₂)	Categorical-Ordinal, ratings 0 through 4	Ques.#12	Rating of child's overall wellbeing as affected by the condition of teeth, lips, jaws, or mouth

Independent Variables / Predictors

The primary independent variable was the baseline caries measurement represented as decayed, missing filled surfaces/teeth (dmfs, dmft) utilizing the EC4 criteria. Radiographs were not utilized. Other covariates included the following: sex of the child, age of the child, parent who completed questionnaire, family income, and number of children at home. The independent variables, including their types, derivations, and explanations are listed in Table 3.4 below. All question numbers refer to questions in the Parent Baseline Questionnaire.

Table 3.4 Independent Variables

<u>Independent Variable</u>	<u>Type</u>	<u>Derivation</u>	<u>Explanation</u>
Caries Experience	Continuous	Clinical examination	dmfs, dmft
Sex	Categorical-Dichotomous	Parent baseline questionnaire, Ques.#1	Sex of the child subject
Age	Continuous	Ques.#2	Age of the child subject in years
Parent	Categorical-Dichotomous	Ques.#20	Parent who completed questionnaire on behalf of child subject (mother or father)
Income	Categorical-ordinal	Ques.#10	Family income, expressed as one of five categories representing income levels between \$0 and greater than \$75,000
# Children	Continuous	Ques.#4	Number of children living at the home

Statistical Methods

Data from this study were entered into the University of Iowa's Research Electric Data Capture, supported by The Institute for Clinical & Translational Science (<https://icts.uiowa.edu/investigators/biomedical-informatics-core/redcap>). Data were then converted into a SAS format data set. Unless otherwise stated, the SAS software for Windows version 9.4 was utilized the data analyses. A statistical significance level of 0.05 was utilized.

Univariate Analyses

In order to obtain a synopsis of all variables, descriptive statistics were conducted, which included the generation of frequency distributions and assessment of outliers.

Bivariate Analyses

The bivariate analyses, which utilized the Spearman Correlation, were conducted in order to evaluate the relationships between the independent and outcome variables. The OHRQoL outcome variables were also compared between the male and female children, as well as between the parents who completed the questionnaire. This assessment utilized the Wilcoxon Rank Sum procedure.

The bivariate analyses continued with the study of the correlations among the independent variables themselves, as well as among the outcome measures themselves, all while utilizing the Spearman Correlation. Given the results of those analyses, the correlation between several of the independent variables (dmfs/t, and age) and the 16 individual PPQ items was assessed.

Multivariable Analyses

These analyses consisted of multivariable modeling of the PPQ total score, its four domains (Oral, Functional, Emotional, and Social), as well as the global oral health rating (GOHR). The normality assumptions were assessed utilizing the Shapiro-Wilk test. The Box-Cox power transformation formulation (Box, 1964) was applied in an attempt to identify suitable normalizing transformations for the purposes of linear modeling, but these attempts were not successful. Therefore, a rank transformation approach (Conover and Iman, 1976 & 1981) was used, a method generally viewed as a bridge between parametric and nonparametric methods. Adjustments for pairwise comparisons was made utilizing the Tukey-Kramer method.

Power transformations were estimated and evaluated using the *lm* and *shapiro* functions, as well as the *boxcox* function from the MASS library (Venables and Ripley, 2002) in R 3.4.1 (R Foundation for Statistical Computing Vienna, Austria: R Core Team, 2017). All other analyses were performed using SAS software for Windows (version 9.4; SAS Institute, Cary NC).

CHAPTER IV

RESULTS

Introduction

This chapter presents the following findings from this study: demographic characteristics of the sample, baseline caries examination findings, descriptive data of OHRQoL outcome measures, bivariate analyses results, and multivariable analyses results.

Demographic Characteristics

This study population was entirely Amish, totaling 77 Amish children from 32 Amish families. Ages ranged from 2 years to 14 years, with a mean age of 6.86 years. There were more boys than girls in this study, 48 versus 29. More fathers completed the questionnaires than mothers, 42 versus 33. The number of children at home ranged from 2 to 12, with a mean of 7.44. Total household income for the majority of the families (50.65%) was greater than \$75,000 per year. The mean household income was 3.85 (a rating of 3 was an income of \$35,001-\$50,000 and a rating of 4 was \$50,001-\$75,000). Frequency distributions and statistics are presented in Tables 4.1 and 4.2 below.

Table 4.1 Distribution of Demographic Characteristics

<u>Variable (number)</u>	<u>Frequency</u>	<u>Percent</u>
Sex (77)		

Table 4.1 continued

Male	48	62.34
Female	29	37.66
Parent (77)		
Mother	33	42.86
Father	42	54.55
Other (not specified)	2	2.60
Age (77)		
2	1	1.30
3	4	5.19
4	10	12.99
5	10	12.99
6	11	14.29
7	7	9.09
8	12	15.58
9	14	18.18
10	4	5.19
11	3	3.90
14	1	1.30
Number of children at home (77)		
2	1	1.30
3	3	3.90
4	6	7.79

Table 4.1 continued

5	13	16.88
6	8	10.39
7	8	10.39
8	7	9.09
9	12	15.58
10	10	12.99
11	3	3.90
12	6	7.79
Total Household Income (72)		
\$0 - \$25,000	12	15.58
\$25,001-\$35,000	4	5.19
\$35,001-\$50,000	4	5.19
\$50,001-\$75,000	13	16.88
More than \$75,000	39	50.65

Table 4.2 Summary Measures of Demographic Characteristics

<u>Variable</u>	<u>Mean</u>	<u>Median</u>	<u>25thile</u>	<u>75thile</u>	<u>Standard Deviation</u>
Age	6.86	7.00	5	9	2.38
# children at home	7.44	7.00	5	9	2.60
Household Income	3.875	5.00	3	5	1.53

Table 4.3 below presents the frequency distribution of the 32 families, which includes the number of children in each family. In this study, the number of children in each family ranged from 1 to 5.

Table 4.3 Distribution of Number of Children in the Study

<u>Family</u> (N=32)	<u>Number of</u> <u>Children</u>	<u>Percent</u>
1	2	2.60
2	4	5.19
3	1	1.30
4	4	5.19
5	2	2.60
6	3	3.90
7	1	1.3
8	3	3.90
9	5	6.49
10	4	5.19
11	2	2.60
12	2	2.60
13	2	2.60
14	1	1.30
15	4	5.19
16	2	2.60

Table 4.3 continued

17	2	2.60
18	3	3.90
19	4	5.19
20	1	1.30
21	3	3.90
22	2	2.60
23	1	1.30
24	3	3.90
25	1	1.30
26	3	3.9
27	3	3.90
28	2	2.6
29	3	3.90
31	1	1.30
31	2	2.60
32	1	1.30

Baseline Caries Examination

The decayed missing filled surfaces (dmfs) ranged from 1 to 64, with a mean of 10.82. The decayed missing filled teeth (dmft) ranged from 1 to 16, with a mean of 4.84.

The dmfs/t frequency distributions are presented in Tables 4.4 and 4.5 below. The dmfs/t descriptive statistics are presented in Table 4.6.

Table 4.4 Distribution of Caries (dmfs)

<u>Variable (number)</u>	<u>Frequency</u>	<u>Percent</u>
dmfs (77)		
1	7	9.09
2	9	11.69
3	4	5.19
4	1	1.30
5	7	9.09
6	7	9.09
7	5	6.49
8	6	7.79
9	4	5.19
10	3	3.90
12	4	5.19
13	2	2.60
14	3	3.9
16	2	2.60
17	1	1.30
18	1	1.30
19	1	1.30

Table 4.4 continued

21	1	1.30
29	1	1.30
32	3	3.90
36	2	2.60
40	1	1.30
42	1	1.30
64	1	1.30

Table 4.5 Distribution of Caries (dmft)

<u>Variable (number)</u>	<u>Frequency</u>	<u>Percent</u>
dmft (77)		
1	10	12.99
2	13	16.88
3	11	14.29
4	11	14.29
5	5	6.49
6	7	9.09
7	2	2.60
8	8	10.39
10	5	6.49
11	2	2.60
12	1	1.30

Table 4.5 continued

15	1	1.30
16	1	1.30

Table 4.6 Caries Descriptive Statistics

<u>Variable</u>	<u>Mean</u>	<u>Median</u>	<u>25th %ile</u>	<u>75%ile</u>	<u>Standard Deviation</u>
dmfs	10.82	7.00	3	13	11.56
dmft	4.84	4.00	2	7	3.41

Descriptive Data of Oral Health-Related Quality of Life Outcome Measures

The main oral health-related quality of life (OHRQoL) outcome measure was the Parent Perception Questionnaire(PPQ) composite score. This score was broken down into 4 domain scores, as well as a score for each of the 16 individual questions. A higher score denoted worse quality of life. The composite score could range from 0 to 64, each domain from 0 to 16, and each individual item from 0 to 4. In this study, the composite PPQ score ranged from 0 to 20, with a mean of 6.10. The domain with the highest mean score was the Oral Domain with a mean of 3.01, followed by Emotional (1.55), Functional (1.53), and Social (.48). The composite and domain scores were calculated only for the children who had complete questionnaires. The frequency distributions for these scores are represented in the tables 4.7 through 4.11 below.

Table 4.7 Distribution of the PPQ Composite Score

<u>PPQ Composite Score</u> (N=62)	<u>Frequency</u>	<u>Percent</u>
0	9	14.52
1	2	3.23
2	6	9.68
3	1	1.61
4	8	12.90
5	3	4.84
6	7	11.29
7	5	8.06
8	4	6.45
9	3	4.84
10	3	4.84
11	1	1.61
12	3	4.84
13	4	6.45
14	1	1.61
15	1	1.61
20	1	1.61

Table 4.8 Distribution of the Oral Domain

<u>PPQ Oral Domain</u> (N=76)	<u>Frequency</u>	<u>Percent</u>
0	20	26.32
1	5	6.58
2	16	21.05
3	6	7.89
4	6	7.89
5	5	6.58
6	9	11.84
7	2	2.63
8	6	7.89
9	1	1.32

Table 4.9 Distribution of the Emotional Domain

<u>PPQ Emotional Domain</u> (N=77)	<u>Frequency</u>	<u>Percent</u>
0	36	46.75
1	5	6.49
2	16	20.78
3	4	5.19
4	12	15.58
5	2	2.60
6	2	2.60

Table 4.10 Distribution of the Social Domain

<u>PPQ Social Domain</u> (N=64)	<u>Frequency</u>	<u>Percent</u>
0	52	81.25
1	1	1.56
2	5	7.81
3	4	6.25
4	2	3.13

Table 4.11 Distribution of the Functional Domain

<u>PPQ Functional Domain</u> (N=76)	<u>Frequency</u>	<u>Percent</u>
0	31	40.79
1	10	13.16
2	20	26.32
3	4	5.26
4	6	7.89
5	2	2.63
6	2	2.63
8	1	1.32

Secondary indicators of OHRQoL were the Global Oral Health Ratings (GOHR_{1,2}). The first (GOHR₁) asked parents to rate the overall health of their child's teeth, lips, jaws and mouth. Scores ranged from 0 to 4, representing answers from 'excellent' to 'poor', respectively. The mean of GOHR₁ was 2.13, a score in between

‘good’ and ‘fair.’ The second rating, GOHR₂, asked parents to rate how much their child’s overall wellbeing has been impacted by the condition of his/her mouth. Scores ranged from 0 to 4, representing answers from ‘not at all’ to ‘very much,’ respectively. The mean of GOHR₂ was .73, a score in between ‘not at all’ and ‘very little.’ Tables 4.12 and 4.13 present the distributions of the GOHR_{1,2}.

Table 4.12 Distribution of the Global Oral Health Rating₁

<u>Global Oral Health Rating₁ (N=77)</u> ‘How would you rate the health of your child’s teeth, lips, jaws and mouth?’	<u>Frequency</u>	<u>Percent</u>
Excellent	2	2.60
Very Good	17	22.08
Good	31	40.26
Fair	23	29.87
Poor	4	5.19

Table 4.13 Distribution of the Global Oral Health Rating₂

<u>Global Oral Health Rating₂ (N=77)</u> ‘How much is your child’s overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?’	<u>Frequency</u>	<u>Percent</u>
Not at all	37	48.05
Very Little	28	36.36
Some	8	10.39
A lot	4	5.19

Table 4.14 below presents the descriptive statistics for all of the outcome measures: the PPQ composite score, each of the four domain scores, as well as the two Global Oral Health Ratings (GOHR_{1,2}).

Table 4.14 OHRQoL Outcome Measures Descriptive Statistics

<u>Outcome Measure</u>	<u>Mean</u>	<u>Median</u>	<u>25%ile</u>	<u>75%ile</u>	<u>Standard Deviation</u>
PPQ Composite Score	6.10	6.00	2	9	4.58
Oral Domain Score	3.01	2.00	0	5	2.69
Emotional Domain Score	1.55	1.00	0	3	1.76
Social Domain Score	0.48	0	0	0	1.08
Functional Domain Score	1.53	1.00	0	2	1.75
GOHR ₁	2.13	2.00	2	3	0.91
GOHR ₂	0.73	1.00	0	1	0.85

Table 4.15 below presents each of the 16 individual PPQ items and their frequency distributions. Each question begins with: “In the past three months, how often has your child.?”

Table 4.15 Distribution of the 16 Individual PPQ Item.

<u>PPQ Item (Number)</u>	<u>Answers</u>	<u>Frequency</u>	<u>Percent</u>
a. Had pain in the teeth, lips, jaw or mouth (N=77)	Never or I don't know	50	64.94
	Once or twice	8	10.39
	Sometimes	15	19.48

Table 4.15 continued

	Often	3	3.90
	Every day or almost every day	1	1.30
b. Had bleeding gums (N=76)	Never or I don't know	59	77.63
	Once or twice	9	11.84
	Sometimes	4	5.26
	Often	4	5.26
c. Had bad breath (N=77)	Never or I don't know	41	53.25
	Once or twice	7	9.09
	Sometimes	26	33.77
	Often	3	3.90
d. Had food caught between the teeth (N=77)	Never or I don't know	32	41.56
	Once or twice	13	16.88
	Sometimes	29	37.66
	Often	1	1.30
	Every day or almost every day	2	2.6
e. Breathed through the mouth (N=76)	Never or I don't know	56	73.68
	Once or twice	7	9.21
	Sometimes	11	14.47
	Often	1	1.32
	Every day or almost every day	1	1.32
f. Had trouble sleeping (N=77)	Never or I don't know	67	87.01
	Once or twice	3	3.90

Table 4.15 continued

	Sometimes	7	9.09
g. Had difficulty biting or chewing firm foods (N=77)	Never or I don't know	57	74.03
	Once or twice	2	2.60
	Sometimes	17	22.08
	Often	1	1.30
h. Had difficulty drinking or eating hot or cold foods (N=77)	Never or I don't know	61	79.22
	Once or twice	8	10.39
	Sometimes	6	7.79
	Often	2	2.60
i. Been irritable or frustrated (N=77)	Never or I don't know	46	59.74
	Once or twice	5	6.49
	Sometimes	26	33.77
j. Worried that he/she is not as healthy as other people (N=77)	Never or I don't know	75	97.40
	Sometimes	2	2.60
k. Worried that he/she is different from other people (N=77)	Never or I don't know	76	98.70
	Sometimes	1	1.30
l. Acted shy or embarrassed (N=77)	Never or I don't know	48	62.34
	Once or twice	6	7.79
	Sometimes	19	24.68
	Often	4	5.19

Table 4.15 continued

m. Not wanted or been unable to spend time with other children (N=77)	Never or I don't know	67	87.01
	Once or twice	2	2.60
	Sometimes	5	6.49
	Often	3	3.90
n. Not wanted to speak or read out loud in class (N=64)	Never or I don't know	63	98.44
	Sometimes	1	1.56
o. Not wanted to talk to other children (N=77)	Never or I don't know	68	88.31
	Once or twice	1	1.30
	Sometimes	8	10.39
p. Been asked questions by other children about his/her teeth, lips, mouth or jaws (N=77)	Never or I don't know	74	96.10
	Once or twice	1	1.30
	Sometimes	2	2.60

Bivariate Analyses

The results from the bivariate analyses utilizing the Spearman Correlation and Wilcoxon Rank Sum are presented in Tables 4.16 through 4.18 below. These analyses assessed the relationships between the outcome measures and independent variables. Significance was set at $p < 0.05$. Significant results are in bold.

Based on the Spearman Rank Correlation test, caries was significantly (positively) associated with the Oral Domain of the PPQ, with p-values of 0.016 and 0.009 for dmfs and dmft, respectively. Caries was also significantly (positively) associated with the first

Global Oral Health Rating (GOHR₁), with p-values <0.0001 for both dmfs and dmft. Therefore, according to parents' perceptions, a higher caries experience was associated with a poorer oral health status rating and had a negative impact on oral symptoms as they related to the OHRQoL of the children. There were no other significant correlations produced from the Spearman Correlation analyses. The Wilcoxon Rank Sum analyses found no significant results regarding differences between sex of the child or parents.

Table 4.16 Spearman Correlation Analyses Results

<u>Outcome Measures</u>	<u>Independent Variable</u>	<u>Correlation Coefficient</u>	<u>P-value</u>
PPQ Composite Score	dmfs	0.168	0.191
	dmft	0.154	0.233
	Age	0.168	0.193
	Number of children at home	0.002	0.988
	Income	-0.041	0.756
PPQ Oral Domain Score	dmfs	0.276	0.016
	dmft	0.300	0.009
	Age	0.180	0.119
	Number of children at home	-0.031	0.790
	Income	-0.162	0.176
PPQ Emotional Domain Score	dmfs	-0.090	0.437
	dmft	-0.141	0.222
	Age	-0.161	0.160

Table 4.16 continued

	Number of children at home	-0.101	0.382
	Income	0.205	0.084
PPQ Social Domain Score	dmfs	0.089	0.486
	dmft	0.112	0.377
	Age	-0.185	0.144
	Number of children at home	-0.120	0.346
	Income	0.132	0.310
PPQ Functional Domain Score	dmfs	0.040	0.731
	dmft	0.009	0.940
	Age	0.042	0.717
	Number of children at home	0.191	0.098
	Income	-0.060	0.622
Global Oral Health Rating ₁ (GOHR ₁)	dmfs	0.460	<0.0001
	dmft	0.435	<0.0001
	Age	0.114	0.325
	Number of children at home	-0.119	0.304
	Income	-0.122	0.307
Global Oral Health Rating ₂ (GOHR ₂)	dmfs	0.152	0.187
	dmft	0.157	0.174
	Age	0.151	0.190
	Number of children at home	0.195	0.089
	Income	-0.141	0.237

Table 4.17 Wilcoxon Rank Sum Analyses Results

<u>Outcome Measures</u>	<u>Independent Variable</u>	<u>P-value (one-sided)</u>
PPQ Composite Score	Parent who completed questionnaire	0.242
	Sex of the child	0.260
PPQ Oral Domain Score	Parent who completed questionnaire	0.354
	Sex of the child	0.478
PPQ Emotional Domain Score	Parent who completed questionnaire	0.089
	Sex of the child	0.140
PPQ Social Domain Score	Parent who completed questionnaire	0.170
	Sex of the child	0.382
PPQ Functional Domain Score	Parent who completed questionnaire	0.251
	Sex of the child	0.187
GOHR ₁	Parent who completed questionnaire	0.388
	Sex of the child	0.158
GOHR ₂	Parent who completed questionnaire	0.125
	Sex of the child	0.357

The Spearman correlation was also utilized to evaluate the relationships between the independent variables themselves, as well as between the main outcome measures themselves. The results for these analyses are presented in Tables 4.18 and 4.19 below. All correlations between the main outcome measures were significantly (positively) correlated. As PPQ scores increased, so did the global oral health ratings. The analyses between the independent variables showed a significant (positive) correlation between

caries (dmfs/t) and age, with p-values of 0.002 and 0.004, respectively. Therefore, as age increased so did caries experience.

Table 4.18 Spearman Correlation Analyses of Independent Variables
Correlation Coefficient
P-value

<u>Variables</u>	<u>dmfs</u>	<u>dmft</u>	<u>Age</u>	<u>Number of children at home</u>	<u>Income</u>
<u>dmfs</u>	1	0.904 <0.0001	0.354 0.002	0.069 0.549	0.059 0.621
<u>dmft</u>	0.904 <0.0001	1	0.325 0.004	0.035 0.764	0.017 0.888
<u>Age</u>	0.354 0.002	0.325 0.004	1	0.360 0.001	-0.033 0.781
<u>Number of children at home</u>	0.069 0.549	0.035 0.764	0.360 0.001	1	0.201 0.091
<u>Income</u>	0.059 0.621	0.017 0.888	-0.033 0.781	0.201 0.091	1

Table 4.19 Spearman Correlation Analyses of Outcome Measures
Correlation Coefficient
P-value

<u>Outcome Measures</u>	<u>PPQ Total Score</u>	<u>GOHR₁</u>	<u>GOHR₂</u>
<u>PPQ Total Score</u>	1	0.305 0.016	0.595 <0.0001
<u>GOHR₁</u>	0.305 0.016	1	0.393 0.0004
<u>GOHR₂</u>	0.595 <0.0001	0.393 0.0004	1

As mentioned above, caries was also the only independent variable which had a significant correlation with any of the outcome measures. Therefore, the correlation between each individual PPQ item and these independent variables (caries and age) was

analyzed. For these analyses, the Spearman Correlation was utilized. These evaluations were purely exploratory. The results are presented in Table 4.20 below.

These analyses produced 10 significant correlations, all highlighted in bold below. The only item which was significantly correlated with dmfs, dmft, and age was the first item, and all three correlations were positive. This question regarded pain in children’s teeth, lips, jaw or mouth, as perceived by the parent. Therefore, as caries experience and age increased, so did the scores for this specific item, indicating more pain in the children’s teeth, lips, jaw or mouth, as perceived by the parent. There were several significant negative correlations. Age was negatively correlated with trouble sleeping, not able to spend time with other children, and not talking to other children. Caries, dmfs/t, was negatively correlated with worry that child is not as healthy as others. Therefore, as age increased, parents perceived their children had less trouble sleeping, spending time with other children, and talking with other children. As caries increased, parents perceived that their children spent less time worrying they were not as healthy as other children, although this may have been a factor of age as well.

Table 4.20 Spearman Correlation Analyses of each PPQ Item

<u>PPQ Item (Number)</u>	<u>Independent Variable</u>	<u>Correlation Coefficient</u>	<u>P-value</u>
a. Had pain in the teeth, lips, jaw or mouth (N=77)	dmfs	0.291	0.010
	dmft	0.297	0.009
	age	0.346	0.002

Table 4.20 continued

b. Had bleeding gums (N=76)	dmfs	0.166	0.152
	dmft	0.126	0.276
	age	0.076	0.513
c. Had bad breath (N=77)	dmfs	0.889	0.444
	dmft	0.128	0.267
	age	-0.003	0.978
d. Had food caught between the teeth (N=77)	dmfs	0.195	0.089
	dmft	0.270	0.018
	age	0.039	0.735
e. Breathed through the mouth (N=76)	dmfs	-0.050	0.666
	dmft	0.012	0.916
	age	-0.053	0.647
f. Had trouble sleeping (N=77)	dmfs	-0.113	0.325
	dmft	-0.107	0.356
	age	-0.249	0.029
g. Had difficulty biting or chewing firm foods (N=77)	dmfs	0.159	0.167
	dmft	0.052	0.653
	age	0.098	0.398
h. Had difficulty drinking or eating hot or cold foods (N=77)	dmfs	0.142	0.217
	dmft	0.098	0.397
	age	0.245	0.032

Table 4.20 continued

i. Been irritable or frustrated (N=77)	dmfs	-0.114	0.322
	dmft	-0.179	0.119
	age	-0.071	0.540
j. Worried that he/she is not as healthy as other people (N=77)	dmfs	-0.228	0.045
	dmft	-0.248	0.030
	age	-0.135	0.241
k. Worried that he/she is different from other people (N=77)	dmfs	-0.036	0.755
	dmft	-0.114	0.322
	age	0.122	0.289
l. Acted shy or embarrassed (N=77)	dmfs	0.010	0.934
	dmft	0.0006	0.996
	age	-0.186	0.106
m. Not wanted or been unable to spend time with other children (N=77)	dmfs	0.132	0.252
	dmft	0.113	0.330
	age	-0.248	0.029
n. Not wanted to speak or read out loud in class (N=64)	dmfs	0.191	0.130
	dmft	0.131	0.304
	age	0.028	0.829
o. Not wanted to talk to other children (N=77)	dmfs	-0.101	0.384
	dmft	-0.107	0.354
	age	-0.304	0.007

Table 4.20 continued

p. Been asked questions by other children about his/her lips, teeth, mouth or jaws (N=77)	dmfs	-0.165	0.150
	dmft	-0.105	0.362
	age	0.079	0.495

Multivariable Analyses

The Box Cox power transformation formulation was unsuccessful in its attempts to identify a normalizing power transformation for the PPQ data. Therefore, the rank transformation approach was utilized. Both the untransformed as well as rank-transformed caries measures were considered. The two caries measures (dmfs, dmft) were highly correlated (Spearman’s rho=0.95, p<0.0001); therefore, only one caries measure was considered in any given model in order to avoid multicollinearity.

When the rank-transform modeling approach was applied to the PPQ total score, as well the Emotional, Functional, and Social Domains, there was no association found between any of the covariates. However, there were relationships between the PPQ Oral Domain score and both family income and caries. The bivariate analyses identified statistically significant relationships between the PPQ Oral Domain and both dmfs/t.

The bivariate analyses did not find a relationship between family income and the PPQ Oral Domain; however, in these analyses family income was an ordinal variable. When income was treated as a nominal categorical outcome, there was in fact a suggestion of a relationship between the two (p=0.0525). The PPQ Oral Domain scores tended to be lowest in income groups 1 (income < \$25,000) and 5 (income >\$75,000),

and highest in income group 4 ($\$50,001 < \text{income} < \$75,000$). This is illustrated in the box plots below.

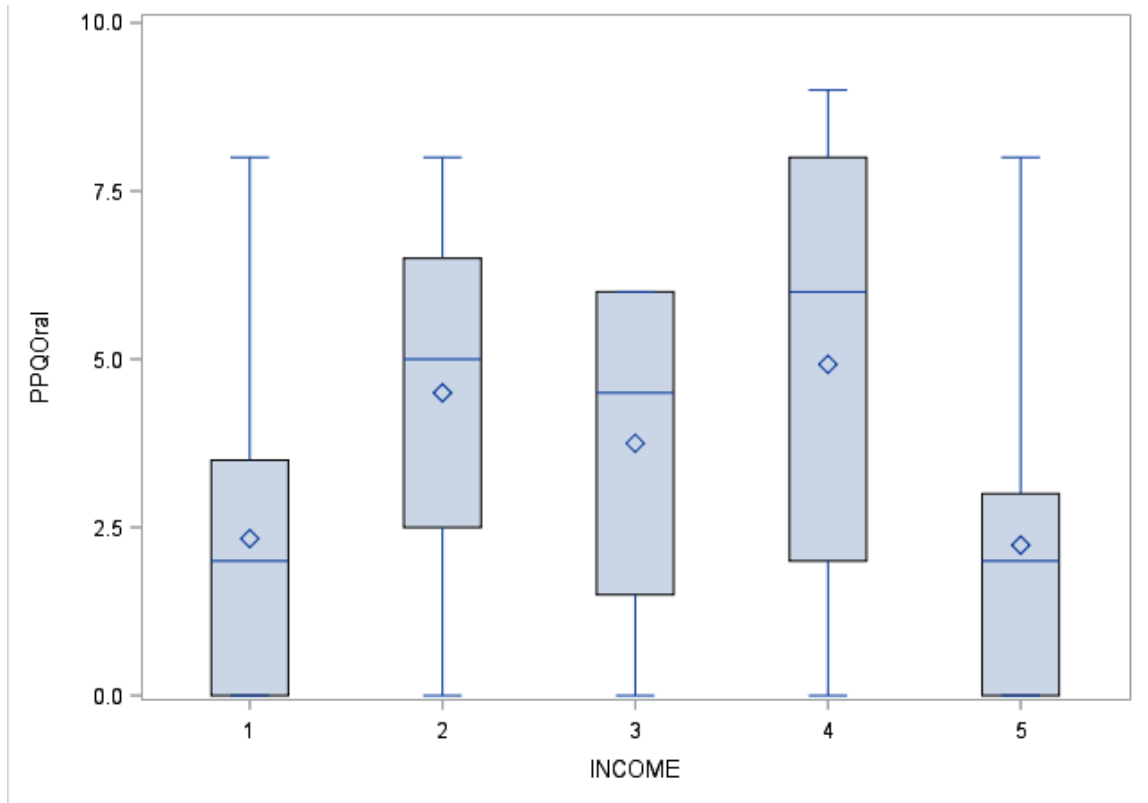


Figure 4.1 Distribution of PPQ Oral by Income

Following rank transformation of the PPQ Oral Domain scores, the data provided evidence of an association with family income after adjustment for caries (dmfs), $p=0.0485$. Family income groups 4 and 5 were found to differ significantly after Tukey adjustment for all pairwise comparisons. Following the adjustment for the effect of income, there was a suggestion of a relationship with dmfs ranking ($p=0.0562$). These modeling relationships are illustrated in Figure 4.2 below.

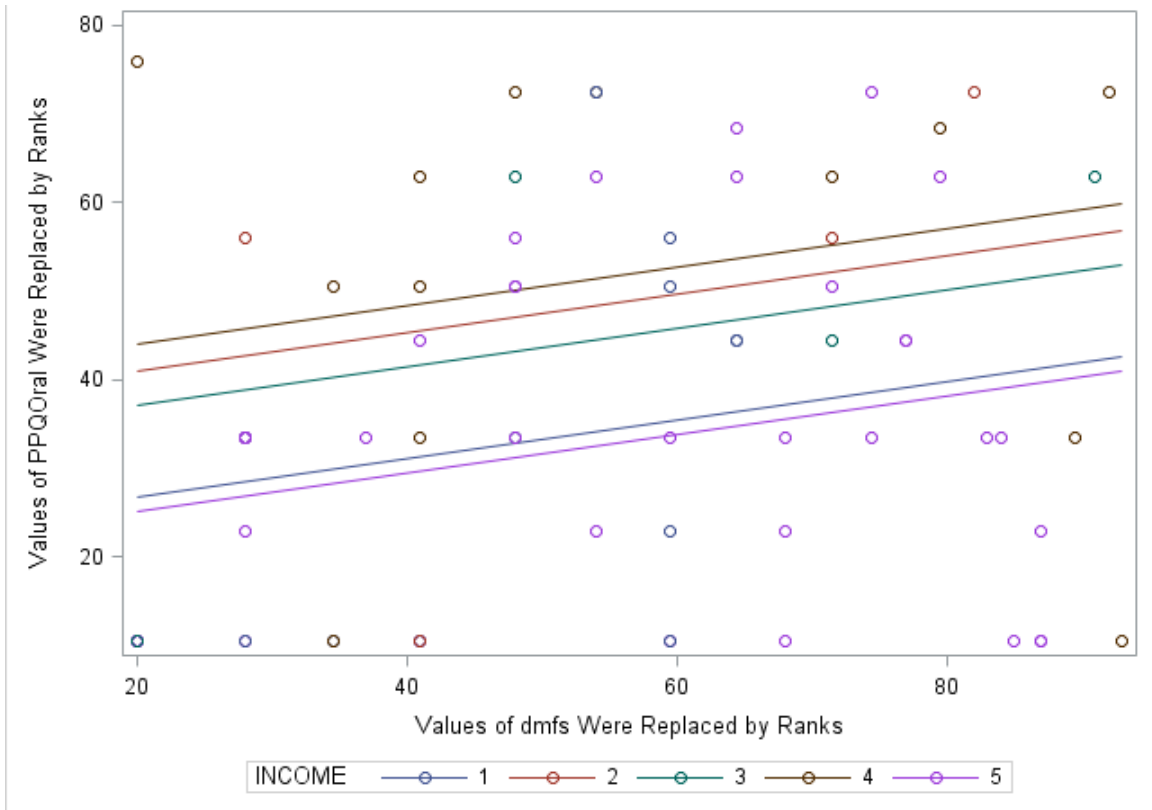


Figure 4.2 PPQ Oral Modeling Relationships of Family Income and dmfs Ranking

Following rank transformation of the PPQ Oral Domain scores, the data provided evidence of an association with family income after adjustment for caries (dmft), $p=0.0452$. Family income groups 4 and 5 were found to differ significantly after Tukey adjustment for all pairwise comparisons. Following the adjustment for the effect of income, there was evidence of a significant a relationship with dmft ranking ($p=0.0214$). These modeling relationships are illustrated in Figure 4.3 below.

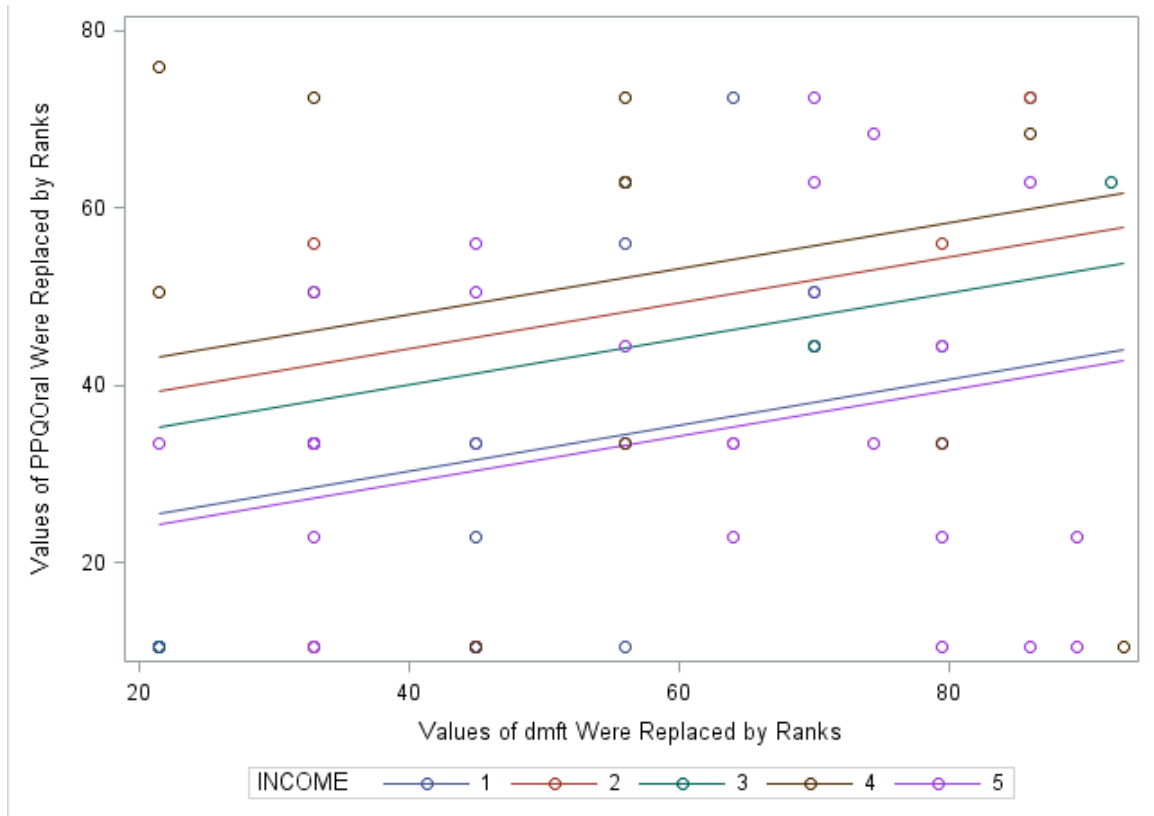


Figure 4.3 PPQ Oral Modeling Relationships of Family Income and dmft Ranking

Secondary quality of life measures were the Global Oral Health Ratings (GOHR_{1,2}). The bivariate analyses showed a significant relationship between caries (dmfs/t) and the first rating, GOHR₁, which asked parents to rate the health of their child's teeth, lips, jaws and mouth. When the rank transformation modeling approach was applied to GOHR₁, there was no association found between any of the covariates; however, after adjusting for dmfs ranking, the data suggested an association with income (p=0.0517). Income was modeled as a nominal categorical income. Following the adjustment for the effect of income, there was evidence of a relationship with dmfs ranking (p<0.0001). This is illustrated in Figure 4.4 below.

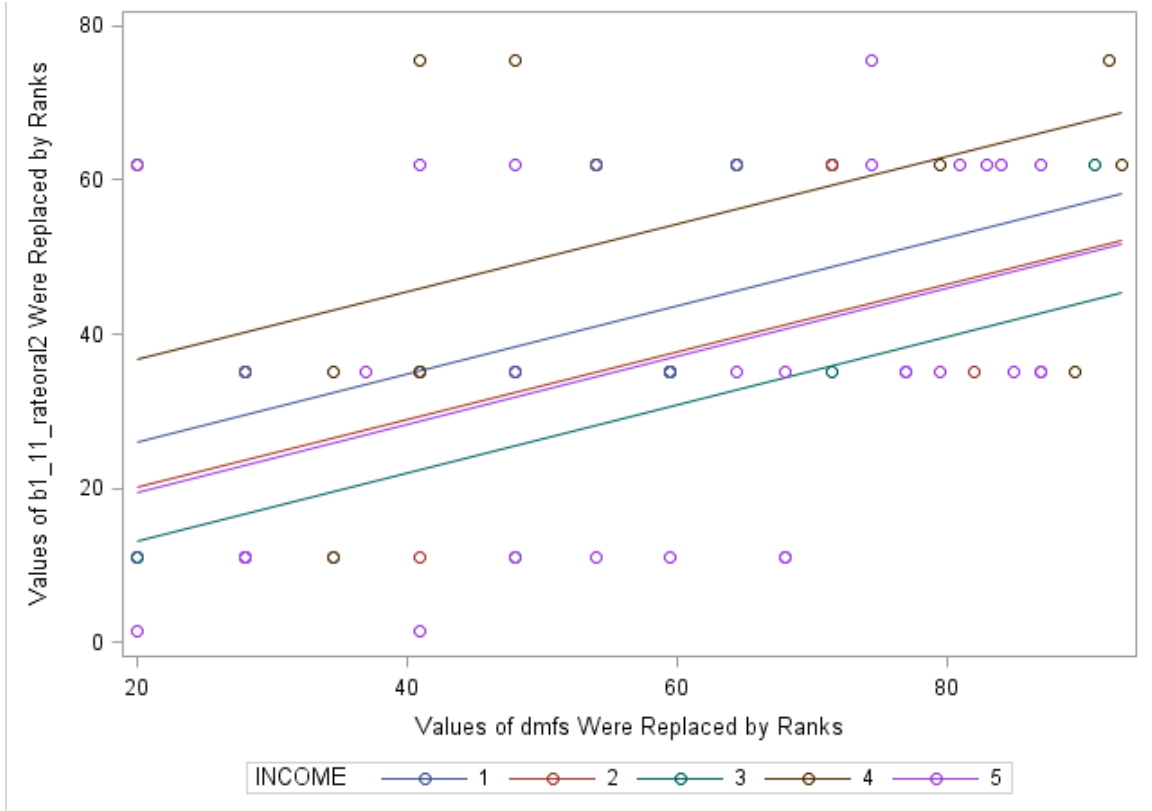


Figure 4.4 GOHR₁ Modeling Relationships of Family Income and dmfs Ranking

Following rank transformation of the GOHR₁, the data provided evidence of an association with family income after adjustment for caries ranking (dmft), $p=0.0421$. Family income groups 4 and 5 were found to differ significantly after Tukey adjustment for all pairwise comparisons. Following the adjustment for the effect of income, there was evidence of a significant a relationship with dmft ranking ($p=0.0214$). These modeling relationships are illustrated in Figure 4.5 below.

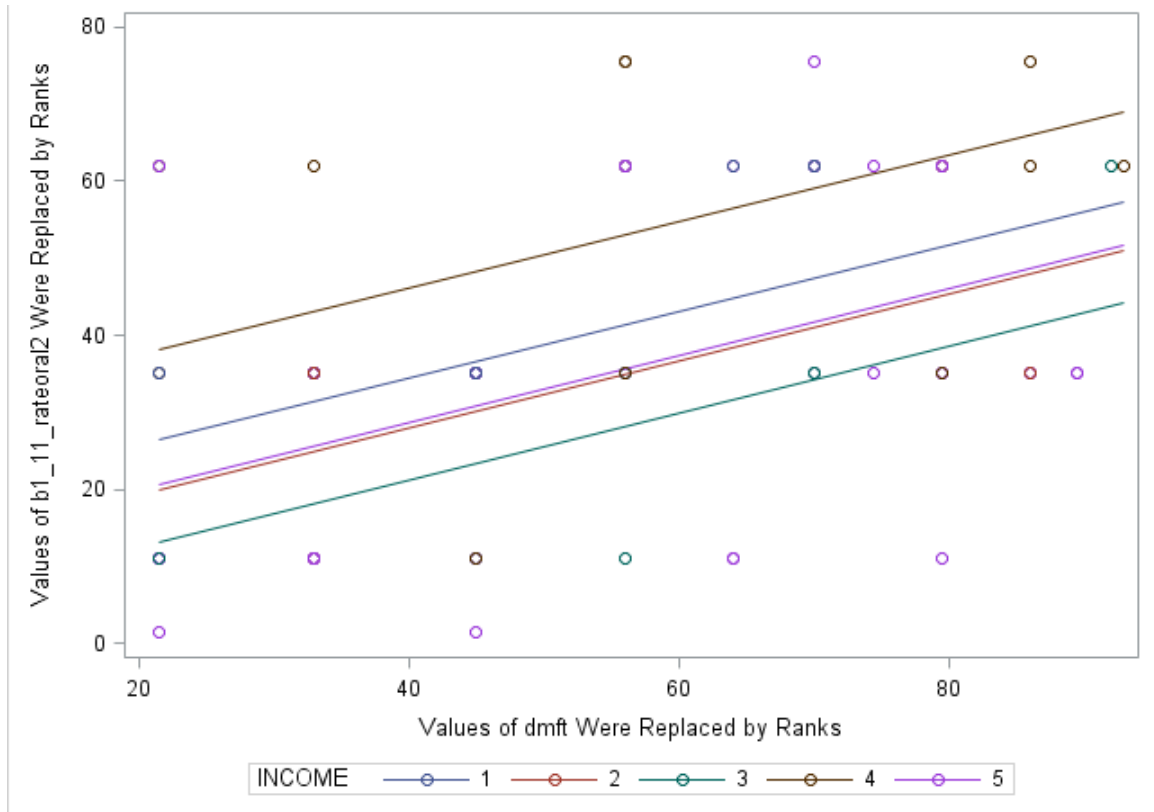


Figure 4.5 GOHR₁ Modeling Relationships of Family Income and dmft Ranking

Lessons Learned

This section briefly reviews the recent publication regarding the parent study to this thesis, ‘Medical Management in the Primary Dentition using Silver Nitrate.’ This publication (Kanellis et al., 2018), discussed some of the key findings as well as lessons learned from this clinical trial which compared conventional restorative treatment to management with silver nitrate. As of this publication, there were no published clinical trials which compare these two treatments. Eighty-five subjects were enrolled in this study, and at the time of the preparation of the manuscript all 85 remained in the study. The majority, 75%, had completed their 24-month follow-up examinations (Kanellis et al., 2018).

The 'lessons learned' as discussed by the authors started with the importance of community engagement in planning and implementing research regarding a conservative study population such as the Amish (Kanellis et al., 2018). This culturally appropriate proposal is what led to the successful recruitment and retention. An approach such as this is crucial with such a unique population (Kanellis et al., 2018).

Next the authors discussed the success of the silver nitrate treatment, which, along with fluoride varnish, proved to be an effective method of medically managing caries in the primary dentition for this group (Kanellis et al., 2018). However, they concluded that silver nitrate does not arrest all caries progression, referring to some lesions which progressed rapidly during the trial. And, in contrast to earlier literature, silver nitrate did not prevent new caries from developing in the study subjects (Kanellis et al., 2018). Radiographs proved to be essential in this trial, as the vast majority of new carious lesions were interproximal and detected radiographically. The location and size of the lesions contributed a great deal to the success of the treatment. All major failures occurred in posterior teeth (Kanellis et al., 2018).

Next the authors reviewed the adjunctive benefits of silver nitrate treatment (Kanellis et al., 2018). Following the application to carious lesions, adjacent teeth benefited; however, they noted that one must be cautious when applying silver nitrate to primary teeth which are adjacent to permanent teeth, as the liquid can seep onto another surface and cause discoloration (Kanellis et al., 2018). The final lesson learned included the challenges associated with interproximal application. Application in these areas using a microfiber brush, unwaxed dental floss, or interproximal picks all proved to be

troublesome, as contamination of the tooth with saliva and/or contamination of the silver nitrate liquid were both risks (Kanellis et al., 2018).

The authors concluded with future plans (Kanellis et al., 2018). Following completion of the study, the authors plan to publish the final results which will include: analysis of the difference between the treatment groups, radiographic progression of carious lesions, treatment satisfaction by both patient and parent, comparison of time and cost by treatment group, as well as the effect of both tooth and surface on the outcomes of treatment (Kanellis et al., 2018).

Chapter Summary

This study included 77 Amish children with an average age of 6.86 from 32 families. In general, caries experiences were rather high, as the mean dmfs and dmft were 10.82 and 4.84, respectively. Income varied a great deal for this group, and its impact on OHRQoL proved to be tenuous as the results were inconsistent. Age and sex of the child, number of children at home, and parent who completed questionnaire all appeared to have no bearing on OHRQoL scores.

Overall, the results of this study indicated that a higher caries experience was associated with a poorer oral health status rating. In addition, according to parents' perceptions a higher caries experience had a negative impact on oral symptoms as they related to the children's OHRQoL. Children with higher PPQ Total scores also had higher Global Oral Health Ratings, indicating a consistency between the two outcome measures. Despite the higher caries experiences, parents in general perceived there to be little impact on children's overall wellbeing.

CHAPTER V

DISCUSSION

Overview

The purpose of this study was to explore the level to which dental caries impacts the oral health-related quality of life (OHRQoL) in a sample of Amish children. A secondary objective was to determine the influence of socio-demographic factors on parental perceptions of children's oral health status and OHRQoL. This cross-sectional study was embedded within a pilot study of medical management of caries in the primary dentition using silver nitrate.

The results from this study indicated that according to parents' perceptions, a higher caries experience was associated with a poorer oral health status rating and had a negative impact on oral symptoms as they related to the OHRQoL of the children. This section will discuss the results of all analyses, compare to past literature, and review the relevance of the results to this unique study population. Following that, this section will cover the strengths and limitations of the study, clinical relevance, and future direction.

Study Sample

Of the 85 children who originally participated in the silver nitrate trial, 77 were included in this OHRQoL study. One child was excluded for not having a calibrated caries exam. An additional 7 children were excluded because they had decay visible radiographically, but not clinically. Inclusion criteria for the silver nitrate trial stated that the child must have one or more cavitated carious lesions extending into the dentin of a

primary tooth. The decay could be visible radiographically or clinically. Dental caries experience was measured as the number of decayed, missing, and filled surfaces/teeth (dmfs, dmft). This was calculated utilizing the data collected during a calibrated exam based on clinically visible decay. Therefore, those 7 children who had decay visible radiographically, but not clinically, technically had a dmfs/t of 0, and were excluded from this study.

Demographics

All 77 participants in this study were Amish children; therefore, this study sample was clearly not representative of children of all ethnic/racial backgrounds in the United States. The majority of the children were males (62.34%). The mean age was 6.86, and the mean number of children at home was 7.44. As one can see, many of the children in this study came from large families, something which was expected as the study sample was comprised of a population known for producing large families (UAB, Encyclopedia of Peaceful Societies, 2017).

In Amish families, the man is known to be the head of the family; however, the responsibility of child-raising usually falls to the woman (UAB, Encyclopedia of Peaceful Societies, 2017). For this reason, one would assume that mothers would be more likely to accompany their children to the dentist office; however, fathers were more likely to complete the questionnaires (54.55%) as opposed to the mothers (42.86%). An ‘unknown guardian’ accompanied two of the children in this sample.

There were a total of 32 families in this study sample. The number of children in each family ranged from 1 to 5. This represented the number of children in that

particular family who participated in the study, not the total number of children in that family. Income varied throughout this sample. While 15.58% of the parents reported a very low total household income of less than \$25,000, the majority (50.65%) reported a total household income of more than \$75,000. Amish economy consists of mainly farming (UAB, Encyclopedia of Peaceful Societies, 2017), however, there are several successful Amish-owned businesses in Kalona, Iowa, the location of this study. It should be noted that Amish incomes do not necessarily translate into similar incomes for non-Amish. Regardless of income, the dress and appearance of the Amish are identical (Kalona Historical Society; Who are the Amish? 2017; Schwieder, 1975). They grow and raise the food they consume. Therefore, they do not have the same expenses as non-Amish families, including cars, houses, or insurance (Kalona Historical Society; Who are the Amish? 2017; Schwieder, 1975).

Univariate Results

Caries Experience

All 77 children in this study had carious lesions, as it was part of the inclusion criteria. Caries experience, high in general for this study sample, was measured by decayed missing filled surfaces/teeth (dmfs/t). Given that radiographs were not utilized for this measurement, an underestimation of overall caries experience was very likely. As discussed in the recent ‘Lessons Learned’ publication regarding the silver nitrate parent study to this thesis, 70.5% of new carious lesions which occurred during the course of the trial in the silver nitrate group were interproximal and diagnosed by radiographs (Kanellis et al., 2018). For the conventional treatment group, 90.9% of the

new carious lesions were interproximal and diagnosed radiographically (Kanellis et al., 2018).

The mean dmfs and dmft for this sample were 10.82 and 4.84, respectively. The majority of the children (54.55%) had a dmfs of 7 or greater, 35.08% had a dmfs of 10 or greater, and 41.55% had a dmft of 5 or greater. As discussed in Chapter II, there are only two known studies which assessed the oral health of the Amish, one published in 1988, the other in 2017 (Bagramian et al., 1988; Heima et al., 2017). Therefore, given the scant literature, comparing the caries experience of this study sample to other groups of Amish children was arduous.

Bagramian et al., 1988, assessed the oral health status, knowledge, and behavior among an Amish population in southwest Michigan. The authors concluded that although they admitted insufficient oral health care knowledge, Amish children had a notably low dental caries prevalence, as the mean dmfs for children younger than 11 was 1.92; however, it must be noted that radiographs were not utilized (Bagramian et al., 1988). This was attributed to a diet low in sugar and infrequent in-between meal snacking (Bagramian et al., 1988).

Heima et al., 2017, assessed oral health and medical conditions among Amish children in Geauga County, Ohio. In contrast to the 1988 study, the authors found that 27.8% of the Amish children in their study had never visited a dentist before, 88% had untreated dental decay, the average number of untreated decayed teeth was 6.8, and only 20% of the children were caries free (Heima et al., 2017). While these results contrasted those from 1988, it must be noted that radiographs were utilized. Given the lack of literature, as well as the considerable differences among the literature that does exist, it is

extremely difficult to make any comparisons or final conclusions regarding the caries experience of the population specific to this thesis and the Amish populations in the two previously discussed studies. It should be mentioned, however, that this particular Iowa Amish community was chosen for this study as it was believed through observation to have high caries rates, a belief which was confirmed.

Oral Health-Related Quality of Life Measures

The primary dependent variable was the PPQ composite score. As a review, questions regarded the parental perception of the frequency of various events related to the four domains, and answers included ‘never,’ ‘once or twice,’ ‘sometimes,’ ‘often,’ and ‘every day/almost every day.’ The responses scored as 0,1,2,3,4, respectively; therefore, the composite PPQ score could range from 0 to 64, each domain score from 0 to 16, and each individual question from 0 to 4. A higher score denoted worse quality of life, as perceived by the parent.

In this study sample, the mean PPQ composite score was 6.10 and had a range of 0 to 20; therefore, the overall OHRQoL for this sample was quite good. However, 20.78% of the subjects had at least one dental impact of ‘often.’ Dental impacts reported as ‘often’ included: oral pain, bleeding, bad breath, food impaction, mouth breathing, difficulty chewing hard food, difficulty chewing/drinking hot or cold foods, embarrassment, and unable to spend time with other children. Two of the 77 subjects reported impacts as occurring ‘everyday,’ and these included oral pain and mouth breathing. Answers which represented a score of 0 were ‘never’ and ‘don’t know,’ indicating that either the impact never happened according to the parent, or the parent was not aware if it happened. The majority of the sample, 94.80%, reported more than

half of the 16 items as occurring ‘never.’ Sixteen of the 77 subjects reported ‘don’t know’ for at least one item, some of which included whether or not the child experienced oral pain, bad breath, mouth breathing, food impaction, difficulty chewing, and feelings of frustration and embarrassment. Nine of the 16 subjects with a report of ‘don’t know’ were reported by the father.

The PPQ domain with the highest mean score was the Oral Domain (3.01), followed by Emotional (1.55), Functional (1.53), and Social (.48). Therefore, parents perceived their children as having more oral symptoms (pain, bleeding, bad breath, food impaction), as opposed to functional, emotional or social symptoms, perhaps due to the expectation of tooth problems as caries was very common among this group.

Secondary dependent variables included the two Global Oral Health Ratings (GOHR_{1,2}). As with the PPQ, a higher rating indicated worse OHRQoL. The first rating, GOHR₁, asked parents to rate the health of their child’s teeth, lips, jaws, and mouth. The mean of GOHR₁ was 2.13, a score in between ‘good’ and ‘fair,’ but closer to ‘good.’ The second rating, GOHR₂, asked parents to rate how much their child’s overall wellbeing has been affected by the condition of his/her teeth, lips, jaws, or mouth. The mean of GOHR₂ was .73, a score in between ‘not at all’ and ‘very little.’ These scores indicated that parents in general perceived their children’s oral health as good, despite the high numbers of caries. And, although parents reported multiple oral symptoms (pain, bleeding, food impaction, etc.), they perceived there was little impact on their children’s overall wellbeing.

These results are consistent with the 2017 Amish study discussed above. The authors found that in spite of the high numbers of untreated carious lesions in Amish

children, parents rated their oral health as ‘good’ or ‘very good’ (Heima et al., 2017). They concluded that while oral and general health disparities exist in this population, there is a general lack of awareness among Amish parents regarding their children’s oral health and its impact on wellbeing (Heima et al., 2017).

While general health disparities were not taken into account for the study sample specific to this thesis, as with the 2017 study, the results suggest a general lack of awareness among Amish parents regarding their children’s oral health and the impact it has on their overall wellbeing. Alternatively, there may be cultural differences with the value of oral health and/or expectations of health, as parents repeatedly reported to the investigators of the silver nitrate trial that if their children presented without pain, they assumed there was no need to visit a dentist. The parents also reported strong beliefs in herbal remedies to treat dental caries such as walnut oil. Therefore, one must appreciate how these OHRQoL ratings in the general population may vary greatly due to cultural differences.

Bivariate Results

The bivariate analyses were utilized to assess the correlations between the outcome measures and independent variables. The Spearman Correlation produced two significant results. Caries (dmft/s) was significantly (positively) correlated with the Oral Domain of the PPQ and GOHR₁. Therefore, according to parents’ perceptions, a higher caries experience was associated with a poorer oral health status rating (GOHR₁) and had a negative impact on oral symptoms as they related to the OHRQoL of the children. In other words, parents of children with higher caries experience perceived more oral

symptoms (pain, bleeding, food impaction, etc.) and poorer oral health overall as opposed to parents of children with lower caries experience.

The Wilcoxon Rank Sum produced no significant results. There was no significant difference between males and females in the OHRQoL outcome measures, and there was no significant difference between parents when it came to perceptions of OHRQoL.

The bivariate analyses continued with the assessments of the correlations between the independent variables themselves, as well as between the main outcome measures themselves. All of the main outcome measures were significantly (positively) correlated with each other. Therefore, the results indicated that scoring was consistent between these two measures. Children with higher PPQ scores also had higher global oral health ratings, both of which indicated poorer OHRQoL.

Regarding the independent variables, caries (dmft/s) was significantly (positively) associated with age. Therefore, as age increased, as did caries experience. This would be expected due to the accumulation effect. Once it was determined that caries was the only independent variable significantly correlated with any of the outcome measures, and that caries and age were significantly correlated, it was decided to assess the correlations between these two independent variables and each PPQ item separately.

Caries and age were both significantly associated with the first item of the PPQ, a question which regarded pain in children's teeth, lips, jaw or mouth, as perceived by the parent. This was to be expected, as this item is part of the Oral Domain, the domain with the highest mean, and the only domain significantly correlated with caries. As caries

experience and age increased, so did the scores for this specific item, indicating more pain in the children's teeth, lips, jaw or mouth, as perceived by the parent.

There were several significant (negative) correlations. As age increased, parents perceived their children had less trouble sleeping, spending time with other children, and talking with other children. This suggests parents perceived socializing and sleeping were not issues for their older children, however, may have been for their younger children. Next it was determined that as caries increased, parents perceived that their children spent less time worrying they were not as healthy as other children. In general, caries experiences were high for this study population; therefore, it could be suggested that parents believed that the children felt they were no less healthy than the other children, as most had similar caries experiences.

When compared to results of the OHRQoL studies discussed in detail in Chapter II, the results of these analyses showed some similarities, but for the most part there were inconsistencies. For example, Gomes et al., 2015 concluded that age of the child influenced parental perceptions of their children's oral health. Gomes et al., 2014 concluded that income was associated with caries. Abanto et al., 2014, as well as Scarpelli et al., 2013 concluded that income was associated with worse OHRQoL, as perceived by the parents. None of these results were consistent with those of this study; however, in this study a higher caries experience was associated with a poorer oral health status rating, a secondary indicator of OHRQoL, as was the case in the four studies mentioned above. One must keep in mind though that these studies did not utilize the same questionnaire that this study did. And as mentioned several times, this study's

population was quite unique, culturally speaking. Therefore, encountering various differences from past studies was to be expected.

Multivariable Results

In the bivariate analysis there was no significant association found between family income level and the various OHRQoL scores; however, in that analysis income was an ordinal variable. In the multivariable analyses, family income was converted into a nominal categorical variable. When treated as such, there was a suggestion of a bivariate relationship between income and the Oral Domain score of the PPQ as well as the GOHR₁ following adjustment for caries.

In child OHRQoL studies discussed previously (Gomes et al., 2014, Abanto et al., 2014, Scarpelli et al., 2013), there were bivariate relationships between income and caries, as well as between income and OHRQoL scores. Lower income was associated with higher a caries experience as well as a higher OHRQoL score, indicating poorer quality of life when compared to someone with a higher income and lower caries experience. This study found very different relationships between income, caries and OHRQoL. There was no bivariate relationship between income and caries, whether income was considered a nominal or ordinal variable. Therefore, income level had no impact on caries experience for this particular study group.

This study contained 5 income groups. Group 1 had the lowest yearly income, \$0 to \$25,000. Group 5 had the highest income, greater than \$75,000. The highest PPQ Oral Domain scores (indicating worse quality of life) tended to be in the group with income between \$50,001 and \$75,000. The scores were the lowest (indicating better quality of

life) in groups with income less than \$25,000 as well as income greater than \$75,000. This is completely inconsistent with the studies discussed previously. The pairwise comparisons also indicated unusual results. Income groups 4 and 5, while having close yearly incomes, could be said to differ significantly regarding PPQ Oral Domain scores.

Overall, the impact of family income on OHRQoL and on caries appeared to be tenuous as the results were inconsistent. As this is a very unique study group, it is difficult to speculate why these particular relationships regarding family income exist. It could be suggested that yearly family income is a proxy for something else, another variable not collected which is in some way impacting the parental perceptions of children's OHRQoL, specifically related to its oral domain. It should be noted; however, that income groups 2 through 4 contained the fewest individuals; therefore, the higher oral domain scores in those income groups could have skewed the results. Finally, it is worth repeating that Amish family incomes do not necessarily translate into similar incomes for the non-Amish. As reported by the investigators of the silver nitrate trial, there was no outward sign of affluence among this group.

Final Conclusions

1. According to parents' perceptions, a higher caries experience was associated with a poorer oral health status rating.
2. According to parents' perceptions, a higher caries experience had a negative impact on oral symptoms as they related to the OHRQoL of the children.
3. Despite the high caries experiences and multiple reported oral symptoms (pain, bleeding, food impaction), parents in general perceived there to be little impact on their

children's overall wellbeing, and they perceived their children's oral health to be good, indicating a lack of awareness among the parents regarding oral health.

4. The effect of income on OHRQoL was tenuous as it produced inconsistent results.

Income may be a proxy for another variable not collected from this sample.

5. There may be cultural differences with the value of oral health and/or expectations of health within this very unique population.

Study Strengths, Limitations, and Future Directions

When interpreting the results of this study and its impact on the dental public health community, one must not discount the relevance of this particular study population. This population, given their culture, life-style, and values, is rather unique. The Amish are known for their quiet, modest lives. Their beliefs include humility, simplicity, obedience, and the serving of others (UAB, Encyclopedia of Peaceful Societies, 2017). They appreciate the danger of pride and live their lives in a way which curtails it (UAB, Encyclopedia of Peaceful Societies, 2017). Some of the greatest purposes of the Amish population include community, family, and hard work (Kalona Historical Society; Who are the Amish? 2017; Schwieder, 1975). Understanding the extent of these cultural differences, one must recognize that their values of oral health as well as their expectations of health in general may vary greatly from those of other nationalities and religions. Therefore, generalizability is one of the main limitations of this study. A second limitation is the small sample size.

As mentioned previously, there are numerous child 'quality of life' studies which have been undertaken in various other countries. Of the OHRQoL studies that were

reviewed in detail Chapter II of this thesis, all concluded that a higher caries experience negatively impacts the OHRQoL in children; however, published research regarding children's OHRQoL and caries status in the United States is minimal.

Dental caries in children has been studied extensively in this country, including its prevalence, susceptibility, rates of progression, and disparities among children of different ages and races. However, the true burden of childhood dental caries lies in the understanding of all possible impacts of this disease, including the impact on quality of life (Sischo and Broder, 2011; Locker et al., 2002, Jokovic et al, 2002-4). Future research of caries in children must account for the concept of oral health-related quality of life, as well as parental perceptions of it in order to truly understand the full burden. With that understanding comes the fundamental information needed in order to make appropriate clinical decisions, determine treatment needs, and implement public health programs (Sischo and Broder, 2011; Locker et al., 2002, Jokovic et al, 2002-4).

While there are multiple limitations, the one main strength of this study lies in that it evaluated a particular area and a specific population, both of which have had very little assessment in the United States. One can appreciate the heterogenous nature of the U.S. This country is comprised of various populations and it is of great value to obtain as much knowledge as possible regarding this heterogeneity. As this study consisted of one very unique group of people, it was one small step in understanding one specific population out of many.

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APPENDIX
FORMS AND QUESTIONNAIRES

Pre-Screening Parent Questionnaire to Determine Eligibility

Please answer the following questions to help us learn whether your child is able to participate in this study. Return this form to the person who gave it to you.

1. Child Name: _____
2. Child Date of Birth: _____ (Month/ day/ year)
3. Does your child have any severe bleeding disorder that prevents his/ her management in the regular dental setting?
 - a. Yes, please specify: _____
 - b. No
4. Does your child have any heart problem that prevents his/ her management in the regular dental setting?
 - a. Yes, please specify: _____
 - b. No
5. Does your child have any medical problem that prevents his/ her management in the regular dental setting (for example, sever bleeding disorders)?
 - a. Yes, please specify: _____
 - b. No
6. Does your child have any allergy to any dental material and / or silver nitrate?
 - a. Yes
 - b. No
7. Does your child have any developmental anomalies in his/ her teeth such as Amelogenesis Imperfecta or Dentinogenesis Imperfecta?
 - a. Yes
 - b. No
8. Does your child have dental decay?
 - a. Yes
 - b. No

Thank you very much

TO BE FILLED BY THE RESEARCH TEAM:	
Based on the information provided, and the initial screening, your child was determined to be	
_____ Eligible	_____ Not eligible
To be part of the silver nitrate study	

Silver Nitrate Study Mixed Dentition Exam Form

1. Study I.D. Number
2. Child's Name
3. Child's Age (years)
4. Date (mm/dd/yy)
5. Examiner
(1=Weber, 2=Kanellis, 3=Owais, 4= Gasparoni)
6. Site
(1=Kalona, 2= Iowa City, 3=Other)
7. Recorder

8. Comments✓

Examiner's Initials _____

Nyvad Criteria (Score for any 2,3 or W surfaces)

Ⓐ Active – For intact surfaces, enamel is whitish opaque with loss of luster and feels rough upon probing with tip of explorer. For cavitated surfaces, cavity feels soft or leathery upon probing.

Ⓘ Inactive – For intact surfaces, enamel is whitish, brownish or black and may be shiny. It feels hard and smooth when probed. For cavitated lesions, cavity may appear shiny and feels hard upon probing. No pulpal involvement.

Silver Nitrate Study Mixed Dentition Caries Exam
 Perm. 1st Molar 2nd 1^o Molar 1st 1^o Molar

		Canine		Lateral		Central		
3 TS <input type="checkbox"/>	4 A TS <input type="checkbox"/>	5 B TS <input type="checkbox"/>	6 C TS <input type="checkbox"/>	7 D TS <input type="checkbox"/>	8 E TS <input type="checkbox"/>			Upper Right
m o d b l	m o d b l	m o d b l	m d b l	m d b l	m d b l			
Q9	Q10	Q11	Q12	Q13	Q14			
14 TS <input type="checkbox"/>	13 J TS <input type="checkbox"/>	12 I TS <input type="checkbox"/>	11 H TS <input type="checkbox"/>	10 G TS <input type="checkbox"/>	9 F TS <input type="checkbox"/>			Upper Left
m o d b l	m o d b l	m o d b l	m d b l	m d b l	m d b l			
Q20	Q19	Q18	Q17	Q16	Q15			
19 TS <input type="checkbox"/>	20 K TS <input type="checkbox"/>	21 L TS <input type="checkbox"/>	22 M TS <input type="checkbox"/>	23 N TS <input type="checkbox"/>	24 O TS <input type="checkbox"/>			Lower Left
m o d b l	m o d b l	m o d b l	m d b l	m d b l	m d b l			
Q21	Q22	Q23	Q24	Q25	Q26			
30 TS <input type="checkbox"/>	29 T TS <input type="checkbox"/>	28 S TS <input type="checkbox"/>	27 R TS <input type="checkbox"/>	26 Q TS <input type="checkbox"/>	25 P TS <input type="checkbox"/>			Lower Right
m o d b l	m o d b l	m o d b l	m d b l	m d b l	m d b l			
Q32	Q31	Q30	Q29	Q28	Q27			

Tooth Status (TS)

- P – Present
- R – Partially Erupted
- K – Sound (all surfaces)
- M – Missing due to caries
- U – Unerupted
- T – Missing due to trauma
- X – Missing due to exfoliation
- O – Missing due to other or unknown reasons
- C – Crown including stainless steel or other
- Z – Unable to score

Surface Scores:

- K – Sound
- W – Demineralized (white spot or D₁) lesion
- 2 – Cavitated Enamel (D₂) lesion
- 3 – Cavitated Dentin (D₃₊) lesion
- A – Filled surface – Amalgam
- F – Filled surface – non-amalgam
- S – Sealed surface
- U – Unerupted surface
- Z – Not examined

CONFIDENTIAL

Participant Study Number

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About your child's teeth

Parent Baseline Questionnaire



Silver Nitrate Trial
S201 DSB
Iowa City, IA 52242-1001
College of Dentistry
The University of Iowa
Pediatric Dentistry Department
Email: dentistry-silvernitrate@uiowa.edu

☎ (319)335-7478

About these questions

In this booklet, you will find some questions about your child's teeth. Some are about your child's teeth in general and some questions are about particular aspects of your child's teeth. We also have some questions about your child's lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are a man.

Are you

A man 1

A woman 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

0	4	1	9	8	0
M	M	D	D	Y	Y

Please answer **every question**, unless the instructions ask you to do something else. You may feel that you are being asked to answer the same questions several times, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

Similar questions will be asked at each of your future visits.

Remember that your name does not appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what you said.

Please now go to the next page

Thank you for helping us with our study. We are asking for your help so we may understand more about the best way to look after children's teeth.

The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

First ten questions about you, your child, and your family:

1. Is your child: (please circle the number that describes your child)

- A boy 1
- A girl 2

2. What is your child's date of birth?

(please write the date in the boxes below)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
M	M	D	D	Y	Y

3. To which of the following ethnic groups does your child belong?

(Please circle the number that best describes your child)

- White 1
- Black..... 2
- Asian..... 3
- Hispanic..... 4
- Native American..... 5
- Other *(please specify)*..... 6

Please now go to the next page

4. How many children live at your house?

Children

5. How many adults live at your house?

Adults

6. Does your child attend school?

Yes1

No.....2 , go to Q8

7. If your child goes to school, How would you rate your child achievement at school?

Below average.....1

Average2

Above Average3

Excellent4

8. On average, how many hours do you usually work outside the house per day?

--	--

Hours/ day

9. On average, how much do you make an hour based on your work?

I do not work1

I make on average US

--	--

 per hour.....2

10. What category best describes the total annual household income? Include salaries, self-employment, alimony, child support, or any other income?

\$0 to \$25,000..... 1

\$25,001 to \$35,000.....2

\$35,001 to \$50,000.....3

\$50,001 to \$75,0004

More than \$75,0005

The next set of questions are about your child's teeth generally

11. How would you rate the health of your child's teeth, lips, jaws and mouth?

- Excellent0
 - Very good1
 - Good2
 - Fair3
 - Poor4
-

12. How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?

- Not at all0
 - Very little1
 - Some2
 - A lot3
 - Very much4
-

The next set of questions are about specific aspects of your child's teeth

Please now go to the next page

The following questions ask about things your children may experience due to the condition of

their teeth, lips, mouth and jaws.

13. During the last 3 months, how often has your child:

a) Had pain in the teeth, lips, jaw or mouth?

- | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Never | Once or twice | Sometimes | Often | Every day or almost every day | Don't know |

b) Had bleeding gums?

- | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Never | Once or twice | Sometimes | Often | Every day or almost every day | Don't know |

c) Had bad breath?

- | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Never | Once or twice | Sometimes | Often | Every day or almost every day | Don't know |

d) Had food caught between the teeth?

- | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Never | Once or twice | Sometimes | Often | Every day or almost every day | Don't know |

e) Breathed through the mouth?

- | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Never | Once or twice | Sometimes | Often | Every day or almost every day | Don't know |

f) Had trouble sleeping?

Never Once or twice Sometimes Often Every day or almost every day Don't know

g) Had difficulty biting or chewing firm foods?

Never Once or twice Sometimes Often Every day or almost every day Don't know

h) Had difficulty drinking or eating hot or cold foods?

Never Once or twice Sometimes Often Every day or almost every day Don't know

i) Been irritable or frustrated?

Never Once or twice Sometimes Often Every day or almost every day Don't know

j) Worried that he/she is not as healthy as other people?

Never Once or twice Sometimes Often Every day or almost every day Don't know

k) Worried that he/she is different from other people?

Never Once or twice Sometimes Often Every day or almost every day Don't know

m) Not wanted or been unable to spend time with other children?

Never Once or twice Sometimes Often Every day or almost every day Don't know

n) Not wanted to speak or read out loud in class?

Never Once or twice Sometimes Often Every day or almost every day Don't know

o) Not wanted to talk to other children?

Never Once or twice Sometimes Often Every day or almost every day Don't know

p) Been asked questions by other children about his/her teeth, lips, mouth or jaws?

Never Once or twice Sometimes Often Every day or almost every day Don't know

**14. Michigan Oral-Health-Related Quality of Life Questionnaire
Parent Version**

Please, tell me for each of the following statements how much you agree with it. Please circle your answer on the 5 point answer scale ranging from 1 = “disagree strongly” and 5 = “agree strongly”.

Statement	Disagree strongly					Agree strongly
	1	2	3	4	5	
a) My child has a toothache or pain currently.	1	2	3	4	5	
b) My child's teeth hurt when he/she eats/ drinks something hot or cold.	1	2	3	4	5	
c) My child's teeth hurt when he/she eats/ drinks something sweet.	1	2	3	4	5	
d) My child's teeth hurt when he/she bites/ chews.	1	2	3	4	5	
e) My child has pain when he/she opens his/her mouth wide.	1	2	3	4	5	
f) My child sometimes wakes up at night with a tooth ache.	1	2	3	4	5	
g) My child sometimes has a tooth ache at school.	1	2	3	4	5	
h) My child sometimes misses a day of school because of a toothache.	1	2	3	4	5	
i) My child has a nice smile.	1	2	3	4	5	
j) My child is happy with his / her teeth.	1	2	3	4	5	
k) My child sometimes complains about his / her teeth.	1	2	3	4	5	

15. When did you fill in this questionnaire?

(please write the date in the boxes below)

M	M

D	D

Y	Y

Please now go to the next page

Please hand this booklet back to a member of staff.
You will need to answer the rest of the questions at the treatment visit.

The following question should be filled out **before** your child has had their treatment.

16. Before seeing the dentist today, do you think your child was?

Not at all worried1

Very slightly worried2

Fairly worried3

Quite worried4

Very worried.....5

These next questions are about your child's behavior.

17. Is your child:

	Never	Sometimes	Often
a. Biting things off with their back teeth instead of their front teeth?	1	2	3
b. Putting sweets away just after starting eating?	1	2	3
c. Starting to cry during meals?	1	2	3
d. Having problems with brushing upper teeth?	1	2	3
e. Having problems with brushing lower teeth?	1	2	3
f. Having problems chewing?	1	2	3
g. Chewing at one side?	1	2	3
h. Suddenly reaching for his/her cheek while eating?	1	2	3

You will need to fill in the rest of the questions after your child has had their treatment. Please wait until after they have had their treatment before completing question 11 onwards.

The following questions should be filled out **after** your child has had their treatment.

18. Thinking about being at the dentist today, do you think your child was?

- Not at all worried 1
 - Very slightly worried 2
 - Fairly worried 3
 - Quite worried 4
 - Very worried 5
-

19. Thinking about being at the dentist today how do you think your child found the treatment?

- Not at all painful 1
 - A little painful 2
 - Somewhat painful 3
 - Painful 4
 - Very painful 5
-

20. Who completed this questionnaire?

(please circle the number that describes you)

- Mother 1
 - Father 2
 - Other (please state who)
..... 3
-

Please now go to the next page

21. Did you attend the appointment with your child?

Yes..... 1

Answer Q15

No 2

Go to Q16

22. Where were you during the visit?

(please circle the number that describes where you were)

In the surgery with my child1

In the waiting room2

23. When did you fill in this questionnaire?

(please write the date in the boxes below)

M	M

D	D

Y	Y

Please make sure you have answered **ALL** questions.

Please hand this booklet back to a member of staff.

THANK YOU
FOR YOUR HELP