

**The impact of multiple caries and its treatment by multiple  
exodontias under GA, on quality of life of children and their  
families.**

**Ibrahim Khalifa Dhahi AIShekaili**

**Submitted in accordance with the requirements for the degree of Doctor of  
Clinical Dentistry**

**The University of Leeds**

**School of Dentistry**

**Division of Child Dental Health**

**December 2017**

**The candidate confirms that the work submitted is his own and that appropriate credit has been given where reference has been made to the work of others.**

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**Dedicated to my family**

*‘Where life begins, and love never ends’*

## ACKNOWLEDGMENTS

I would like to express my sincere thanks and appreciation to my supervisors, Professor Monty Duggal and Professor Jack Toumba, for their invaluable advice and support during the preparation of the dissertation.

I would like to express my gratitude to the staff of the Department of Child Dental Health, and to the many people whose advice and encouragement have helped me reach my goals.

Special thanks to Dr Jianhua Wu, for his help in the statistics.

I would also like to thank all the staff in the One Day Unit (ODU), at Leeds Dental Institute for all their help and support during the data collection.

I would also like to thank Professor Murray Thomson, head of department of Oral Sciences, the University of Otago, New Zealand for providing me the short form questionnaire for the study.

Special thanks to Dr Zoe Marshman, Honorary consultant in Dental Public Health, School of Dentistry, University of Sheffield for providing me with the long form of the questionnaire for this study.

I would also thank my colleague ZuhairAlKahtani for his help and guidance through the research process.

I am also so grateful for my wife, who stood by my side, helped me through the tough times and believed in me, to my two kids, Noor and Osama for filling my life with joy and laughter.

I also would thank my parents for helping me through and standing by my side, for the love, support and encouragement they gave me.



## ABSTRACT

### Aims

To quantify the impact of Early Childhood Caries on the quality of life of children referred to the Day Care Unit, in the Department of Paediatric Dentistry at Leeds Dental Institute (LDI), for extraction of decayed teeth under general anaesthesia. Another aim is to study the change in the quality of life of those children and their families after treatment under general anaesthesia.

### Materials and methods

Parents of 3-7 year old, paediatric patients, attending the ODU at LDI for extraction of carious teeth under general anaesthesia, were given the Child Oral Health-Related Quality of Life (COHRQoL) questionnaire. The COHRQoL questionnaire has two components: the Parent-Caregivers Perceptions questionnaire (P-CPQ) and Family Impact Scale (FIS). The children then were reassessed, 6- 8 weeks later, following completion of treatment under general anaesthesia, using the same questionnaire. Parents answered the follow-up questionnaire by phone

### Results

Showed statistically significant changes in the scores of the P-CPQ and FIS ( $p < 0.05$ ). The effect size was medium (0.32) in the social wellbeing domain of the P-CPQ and large in all of the other domains of both P-CPQ and Family Impact Scale (FIS).

### Conclusions

Early Childhood Caries has a negative impact on the oral health-related quality of life of both, children and their families. The provision of dental treatment under general anaesthesia for young children with Early Childhood Caries resulted in substantial improvement to their oral health-related quality of life as reported by their parents.

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## LIST OF ABBREVIATIONS

LDI	Leeds Dental Institute
ODU	One Day Unit
GA	General Anaesthesia
DGA	Dental General Anaesthesia
ECC	Early Childhood Caries
S-ECC	Severe Early Childhood Caries
dmft	Decayed missing filled teeth
ASA	American Society of Anaesthesiologists
OHRQoL	Oral Health-Related Quality of Life
COHRQoLQ©	Child Oral Health-Related Quality of Life Questionnaire
ITQoLQ	Infantile and Toddler Quality of Life Questionnaire
COHIP	Child Oral Health Impact Profile
ECOHIS	Early Childhood Oral Health Impact Scale
P-CPQ	Parent-Caregiver Perception Questionnaire
FIS	Family Impact Scale
GTRS	Global Transition Rating Scale

## INTRODUCTION

Early childhood caries (ECC) is considered a major public health problem that can have a profound effect on the child and the parent's life. The prevalence of dental caries is decreasing in the developing countries, and that has been attributed to better oral hygiene practice and fluoride product availability within the community. Despite this decline in dental caries prevalence, there is still a substantial number of children presenting with early childhood caries. ECC can have severe effects on the oral health and the wellbeing of young children. The effects include pain, decreased appetite, chewing difficulty, weight loss, sleeping difficulty, changes in behaviour and poor academic performance. The negative impact of dental caries on the quality of life of the family has been documented in the literature (Filstrup et al., 2003, Anderson et al., 2004, Malden et al., 2008, Drummond et al., 2013).

A large number of young children with ECC end up requiring dental treatment under general anaesthesia (GA). This is due to many children being very anxious and refuse treatment under local anaesthesia. Even though treatment under GA has many benefits for the child, parents and the dentist, it still carries some risks and complications.

The term oral health-related quality of life refers to the impact oral health has on the individual day to day general wellbeing or quality of life. It is usually assessed using questionnaires that are comprised of domains such as oral symptoms and functional limitations. Many instruments have been constructed to assess the changes in quality of life of individuals prior to and after treatment.

This study uses the Child Oral Health-Related Quality of Life (COHRQoL<sup>®</sup>) questionnaires to assess the impact of ECC on the quality of life of children and their families, and the changes in the quality of life after dental extractions under GA.



## **Chapter 1 REVIEW OF LITERATURE**

### **1.1 Dental Caries**

#### **1.1.1 What is dental caries**

Dental caries is an infectious disease with multi-factorial cause. It is a process of demineralisation of tooth enamel, leading to destruction of enamel and dentine, with cavitation of the tooth. Oral bacteria convert ingested fermentable carbohydrates into acid. A plaque matrix forms on a susceptible tooth surface and demineralisation of the dental hard tissues results. It is one of the most common chronic diseases and it is of medical, social and economic importance (Rugg-Gunn, 2013). Within the EU in 2011, the cost of dental treatment was estimated to be around 79 billion Euro (Rugg-Gunn, 2013).

#### **1.1.2 Prevalence of dental caries**

Dental caries is considered a major public health problem globally due to its high prevalence and significant social impact. Generally, the prevalence of dental caries in the developed countries is decreasing, while in the underdeveloped and developing countries is on the rise (Farooqi et al., 2015). According to the data available from the World Health Organisation (WHO), caries prevalence among 12-year-old children from many European Union states has decreased considerably from 1970's to 2006. The World Health Organisation (WHO) reports 60-90% of school children have experienced caries, with the disease being most prevalent in Asian and Latin American countries (Petersen et al., 2005).

#### **1.1.3 Prevalence of dental caries in the UK**

Over the last few decades there has been a significant improvement in oral health. This has been attributed to better oral hygiene practice and fluoride product availability within the community. However, despite the declining prevalence of dental caries,

there are still a substantial number of children with ECC (Anderson et al., 2004). A survey of dental health of children in England, Wales and Northern Ireland takes place every 10 years. The survey of preschool children in 2012 reported that 12% of three year old children in England suffered from dental caries with the average dmft score for those children being 3.1 (Public Health England 2014). Moreover, the same survey reported that one-third of those children suffered from a more aggressive form of the disease, affecting their anterior teeth. The results of the 2013 survey showed nearly a third (31%) of 5 year olds and nearly a half (46%) of 8 year olds had obvious decay experience in their primary teeth. According to the state of children's oral health report in England, almost a third of five-year-olds in England are still suffering from tooth decay. Children with decay have at least three teeth affected. The oral health survey of five-year-old children in 2015 found that 75.2% of five-year-old children in England had no experience of obvious dental caries. Among the 24.7% of children with some experience of obvious decay, the average number of decayed, missing, or filled teeth (dmft) was 3.4. The average number of the decayed, missing, or filled teeth (dmft) in five-year-old children in England was 0.8 (PHE, 2015). The findings of the 2013 CDHS suggest that very limited improvement in oral health of five-year-old children has occurred since the earliest comparable survey in 2008, where 31% of five-year-old children were reported to have dental caries with a mean dmft of 3.5.

The results of those two recent surveys might suggest that children's oral health had improved in comparison to the findings of earlier surveys, such as the one in 2003. (Pitts et al., 2006). However, such comparisons are not valid, as the introduction of positive consent as required for recruitment in 2008 had most probably significantly altered the sample of participants. In the 2013 survey, almost one-third of the total number of potential participants did not take part due to the lack of parental consent. This group are possibly from higher risk families and less motivated to take part. According to the 2010 English IMD scores, children from the most deprived quintile

were almost five fold more likely to have developed one or more of the signs of severe caries than those in the least deprived.

#### **1.1.4 Early Childhood Caries (ECC)**

##### **1.1.4.1 Definition of Early Childhood Caries (ECC)**

Early Childhood Caries (ECC) can be defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries) or filled tooth surface (dmfs) in any primary tooth in a child 71 months of age or younger (Drury et al., 1999). Several terminologies were used to describe the condition such as, nursing bottle caries, nursing caries, rampant caries, baby bottle caries, baby bottle tooth decay, milk bottle syndrome, and prolonged nursing habit caries (Anil and Anand, 2017).

##### **1.1.4.2 Clinical Presentation of ECC**

ECC has several unique characteristics in clinical presentation. The lesions develop rapidly and affect a number of teeth soon after they erupt into the oral cavity. It is usually develops on tooth surfaces that are usually at low risk for caries, such as the labial surfaces of maxillary incisors. The anterior teeth are affected first followed by the upper first primary molars, then second primary molars and lastly the canines.

ECC initially presents as dull white or brown spots on maxillary incisors along the gingival margins, which progresses to a complete destruction of the crown leading to root stumps (De Grauwe et al., 2004).

### 1.1.4.3 Classification of ECC

Several research groups have attempted to develop classification systems for ECC. They based their classification on: severity of ECC and aetiology (Table 1) (Wyne, 1999), pattern of ECC presentation (Table 2) (Johnston and Messer, 1994), ECC and severe early childhood caries (S-ECC) (Table 3)(Drury et al., 1999).

<b>Type I (mild to moderate)</b>	The existence of isolated carious lesion(s) involving incisors and/or molars. The most common causes are usually a combination of semisolid or solid food and lack of oral hygiene
<b>Type II (moderate to severe)</b>	ECC was described as 'labio-lingual lesions' affecting maxillary incisors, with or without molar caries, depending on the age of the child and stage of the disease. Typically, the mandibular incisors are unaffected. The cause is usually inappropriate use of a feeding bottle or at-will breast-feeding or a combination of both, with or without poor oral hygiene.
<b>Type III (severe)</b>	ECC was described as carious lesions affecting almost all teeth including the mandibular incisors. A combination of cariogenic food substances and poor oral hygiene is the cause of this type of ECC.

**Table 1 Classification based on the severity of ECC and aetiology**

<b>Type 1</b>	Lesions associated with developmental defects (pit and fissure defects and hypoplasia)
<b>Type 2</b>	Smooth surface lesions (labial-lingual lesions, approximal molar lesions)
<b>Type 3</b>	Rampant caries—having caries in 14 out of 20 primary teeth, including at least one mandibular incisor

**Table 2 Classification based on the pattern of ECC presentation**

Age (months)	Early childhood caries	Severe early childhood caries
<12	1 or more dmfs surfaces	1 or more smoothdmf surfaces.
12–23	1 or more dmfs surfaces	1 or more smoothdmf surfaces.
24–35	1 or more dmfs surface	1 or more smoothdmf surfaces.
36–47	1 or more dmfs surfaces	1 or more cavitated, filled, or missing (due to caries) smooth surfaces in primary maxillary anterior teeth or dmfs score >4.
48–59	1 or more dmfs surfaces	1 or more cavitated, filled, or missing (due to caries) smooth surfaces in primary maxillary anterior teeth or dmfs score >5.

**Table 3 Classification of ECC and Severe Early Childhood Caries (S-ECC)**

Another classification was proposed by Veerkamp and Weerheijm (1995). The classification was based on the stage of development of the dentition and the severity of the dental caries (Veerkamp and Weerheijm, 1995). There are four stages in this classification, initial, damaged, deep lesions and traumatic. During each stage, a different group of teeth are involved and dental caries can range from enamel demineralisation to cavitation.

### **1.1.5 Effect of Early Childhood Caries on quality of life of children**

Early childhood caries (ECC) can have a severe effect on the oral health and wellbeing of young children (Acs et al., 1999) and has been well documented in the literature (Filstrup et al., 2003, Finucane, 2012, Drummond et al., 2013). Parents of children seeking emergency dental care reported that 19% of the children experienced interference with play, 32% with school, 50% with sleeping and 86% with eating (Edelstein et al., 2006). Figure 1 shows a proposed ECC morbidity and mortality pyramid (Casamassimo et al., 2009).



**Figure 1** Early Childhood Caries morbidity and mortality pyramid

Failure to identify, prevent, or treat ECC could result in severe consequences. Table 4 summarises the short and the long term consequences of dental caries if left untreated. In the very rare sequelae, infection related to untreated decayed teeth may lead to sub-orbital cellulitis or brain abscesses (Colak et al., 2013).

**Table 4 Short & long term consequences of dental caries**

Short Term	Long term
<ul style="list-style-type: none"> <li>• Pain</li> <li>• Infection</li> <li>• Sleep disturbance</li> <li>• Difficulty in eating</li> <li>• Loss of school days</li> <li>• Emergency visits and possible hospitalisation</li> <li>• Reduced ability to learn and concentrate</li> </ul>	<ul style="list-style-type: none"> <li>• Poor oral health</li> <li>• High risk of developing new caries in other primary teeth, and in the permanent dentition.</li> <li>• Affect child general health</li> <li>• Increased treatment costs</li> <li>• Premature loss of primary teeth may predispose to malocclusion</li> </ul>

#### **1.1.5.1 Pain**

Pain has been the primary outcome measure used by many studies investigating the effect of ECC on the quality of life of children having treatment under general anaesthesia. Pain is a complex multi-dimensional phenomenon and the objective assessment and reporting of children's pain is a major challenge for health professionals (Franck et al., 2000). Children are often unable to express feelings of pain, besides, variation in children's cognitive ability affects how they understand, remember and report pain (Harbeck and Peterson, 1992). Pain caused by dental caries can manifest in different ways. Children may have difficulty in eating, sleep disturbance and may exhibit negative or disruptive behaviour. Eating and sleeping have been found to be the activities most affected by toothache (Gift et al., 1992). Because children's communication relies on behaviour, indirect methods to assess pain are required.



Low et al. assessed the possible effect of extensive dental caries on the quality of life of 77 young children aged 35 – 66 months over a 5-month period. Parents or caregivers were asked questions about pain, eating habits and social behaviour of the children before and 4-8 weeks after treatment. The results showed that 48% of children had complained of pain before treatment, 43% had problems eating certain foods, 61% had difficulty finishing meals, 35% did not sleep well and 5% had some form of negative behaviour. After treatment, improvement in all of the indicators were found. The major improvement was in pain as 97% of children no longer complained of pain after elimination of caries (Low et al., 1999).

Acs et al. in 2011 evaluated parent's perceptions of their child's quality of life following dental rehabilitation under GA and assessed parental satisfaction with the treatment modality. The parents of 228 children who had comprehensive dental treatment under GA, completed the post-treatment questionnaires out of the 400 parents surveyed. A descending hierarchy of improved treatment outcomes was noted, with improvement in pain being the predominant outcome, followed by improvement in ability to eat and sleep reported by 86, 69, and 41% respectively (Acs et al., 2001).

A study by White et al. examined parental satisfaction with the dental care their child received under GA and the impact of this care on physical and social quality of life of the child. The results showed that 84% of the parents felt that their children were free of pain post-treatment, 69% reported improved masticatory efficiency and 51% of the parents felt their children slept better compared to before treatment (White et al., 2003).

Thomas and Primosch in their study assessed indicators of aspects of quality of life of 50 patients aged 2-7 years old, who were treated for rampant caries under GA. 90% of parents reported a significant improvement in their child's quality of life following treatment (Thomas and Primosch, 2002).

Anderson et al. found that complaints of pain, problems with eating and sleeping and behaviour concerns showed significant improvement, with 100% improvement for children for whom frequent pre-GA problems associated with eating, sleeping and behaviour were reported (Anderson et al., 2004).

El Batawi et al. investigated the perceived clinical outcomes and parental satisfaction after dental rehabilitation under GA with a follow-up period of 2 years. The results showed a dramatic disappearance of symptoms, with none of the 352 children in the study having complained of pain post-treatment. However, only 19.6% of the participants complained of pain prior to treatment (El Batawi et al., 2014).

### **1.1.5.2 Effect on weight and growth**

Growth is a significant indicator for child health and the World Health Organisation (WHO) recognise it as the best single measure for describing the nutritional condition and health of children.

Some studies have reported that ECC inhibited adequate nutrition, thereby adversely affecting the growth of the body (Elice and Fields, 1990, Acs et al., 1998). Acs et al, reported that 115 children with ECC weighed significantly less than age-and gender-matched caries-free children (Acs et al., 1992). Children with ECC had also been noted to be significantly more likely to weigh less than 80% of their age-adjusted ideal weight (Acs et al., 1992). Acs et al. looked at the effect of comprehensive dental rehabilitation under GA on the percentile weight and percentile growth velocity of children with ECC. The results showed that completion of comprehensive dental rehabilitation resulted in a phenomenon of 'catch-up' growth such that children with a past history of ECC were no longer different in percentile weight compared to other children (Acs et al., 1999). The phenomenon of catch-up growth has been reported to occur in children whose growth had been slowed by illness or malnutrition (Prader et al., 1963). Thomas and Primosch, however found that there was a slight, non-

significant increase in the mean percentile weight following dental rehabilitation under GA. Children in their study were not significantly below the 50<sup>th</sup> percentile, whereas previous authors studied children with mean percentile weights between 25<sup>th</sup> and 50<sup>th</sup> percentile (Thomas and Primosch, 2002).

Bhoomika et al. evaluated the relationship between S-ECC and the Body Mass Index (BMI) in the absence of any underlying medical conditions. They included 100 caries-free children, aged 3-6 years and 100 children affected with S-ECC of the same age. They found a positive correlation between the BMI and S-ECC which indicated that caries and obesity possibly shared common risk factors (Bhoomika et al., 2013). However, the relationship between ECC and obesity is controversial. Edalat et al. found no correlation between S-ECC and BMI, height and weight deficiencies (Edalat et al., 2014). The results of the study were in agreement with the results of Sheller et al. where the BMI percentile was not correlated with the dmft or the number of pulp-involved teeth, even after adjusting for confounding factors (Sheller et al., 2009).

In 2006, a systematic review concluded that only one study showed a direct association between obesity and dental caries with a high level of evidence (Kantovitz et al., 2006). Since then, several retrospective studies have shown that overweight children may have less tooth caries than children who are underweight or healthy weight, and other retrospective studies suggested that there was no correlation between dental caries and BMI (Costa et al., 2013).

### **1.1.5.3 Infection**

Infection from an untreated carious tooth could result in pain, facial swelling, pyrexia and even a brain abscess. Carious teeth continue to be responsible for a significant number of child emergency dental presentations. Fleming et al. showed that abscesses are more frequently associated with first primary molars. The study showed that dental abscesses were responsible for 49% of emergency dental

presentations (Fleming et al., 1991). North American studies reported 31% (King and Stallard, 1979) and 22% (Battenhouse et al., 1988) of after-hours dental emergencies in paediatric hospitals were due to painful or infected teeth. Abscesses from an infected primary tooth may spread and cause alteration of the dental germ of a permanent successor and to the surrounding structure (Cordeiro and Rocha, 2005). Untreated dental abscesses may cause spreading cellulitis and Ludwig's Angina, which are potentially fatal conditions and require hospitalisation.

#### **1.1.5.4 Failure to Thrive (FTT)**

Children with very low weight for age or height (below the 3<sup>rd</sup> percentile) and those who do not maintain an appropriate growth pattern may have failure to thrive (FTT) (Homan, 2016). FTT is recognised in 9.6% of the paediatric population and it is on the rise (Elice and Fields, 1990). Some studies have found an association between ECC and disruption of growth and development (Acs et al., 1992, Low et al., 1999, Clarke et al., 2006). However, many of the studies lack a control group to compare with the treatment group. Clarke et al. studied the nutritional status of children aged 2-6 years with S-ECC by using several clinical measurements like height, weight, triceps skinfolds and measurement of upper mid-arm circumference. They also obtained blood samples from the children to assess haemoglobin, serum ferritin and serum albumin levels. The results suggested that S-ECC may be a risk marker for iron deficiency (Clarke et al., 2006). Chronic iron deficiency is associated with impaired brain development and function and can have permanent ill effects.

#### **1.1.5.5 Hospital visits and costs**

Many studies have found that children with ECC were more likely to present to hospital emergency with pain or infection (Rowley et al., 2006, Casamassimo et al., 2009). Many of these cases may require treatment under GA due to the child being uncooperative or the extent of the dental treatment required. In England, dental caries is the number one reason why children aged 5-9 years are admitted to hospitals. The number of children (aged 16 years or under) admitted to hospitals for extraction of teeth due to dental caries under GA has been reported as increased to 66% in England between 1997 and 2006 (Moles and Ashley, 2009). This was considered to be a direct result of the need for all dental GA to be performed in a secondary care setting since the publication of "A Conscious Decision". There were approximately 42,000 hospital admissions of children under 16 years with a diagnosis of dental caries in 2014-2015 (HSCIC, 2015). During 2016-2014, over 62,000 children admitted to hospital for dental extraction under general anaesthesia with an estimated cost of 30 million GB Pounds (de Souza et al., 2017).

#### **1.1.5.6 School performance**

Chronic illness can interfere with the child's ability to succeed at school, and missed school time can lead to a decline in school performance (Wolfe, 1985, Fowler et al., 1985). In a cross-sectional epidemiological study, Maharani et al. studied a sample of 984 children aged 6-7 and 10-11 years old. They found that children with poor oral health were more likely to perform poorly at school and be socially excluded (Maharani et al., 2017). Jackson et al. found that children with poor oral health status were nearly 3 times more likely to miss school as a result of dental pain compared to their healthy counterparts (Jackson et al., 2011). The same study showed that absences caused by pain were associated with poorer school performance, but absences for routine care were not. Guarnizo-Herreno and Wehby in 2012 surveyed more than 40,000 students and assessed the effect of dental health on school performance and

psychological well-being. They found that dental problems were significantly associated with a reduction in school performance and psychological well-being. They also found that children with dental problems were more likely to have problems at school and were less likely to do all required homework (Guarnizo-Herreño and Wehby, 2012). The finding of another study by Garg et al. demonstrated the impact that poor oral health had on school performance in children (Garg et al., 2012). Although many of the studies in the literature have their limitations, they all concluded that improving children's oral health status may be a vehicle to enhancing their educational experience.

#### **1.1.5.7 Cost to the family**

Dental GA is performed in a secondary care unit and the child needs to be admitted in order to provide dental care under GA. Parents or other family members may need to take time off work, thereby interfering with normal daily routines, which is especially difficult in complex family situations (Rashewsky et al., 2012). Holt et al. assessed the cost to the family of 103 children at the Eastman Dental Hospital, London. They found that one or more adults accompanied each child. 79 adults took time off work, 29 of those incurred a loss of salary, and 34 families had to make arrangements for the care of their other children (Holt et al., 1991). However, it is important to note that dental treatment under GA is usually performed in a single visit. Whereas other modalities such as conscious sedation and treatment under local anaesthesia may require more than one visit. Lee et al. used cost modelling to establish that, if a child needs more than three moderate conscious sedation visits, GA is less costly than sedation (Lee et al., 2001). It is also important to compare societal and opportunity costs, in addition to actual medical and dental fees, when evaluating the extent of treatment and behavioural management strategies (Lee et al., 2001).

#### **1.1.5.8 Malocclusion and space loss**

Studies have shown that children who experience early childhood caries will have adverse long term effects on malocclusion, periodontal health and dental anxiety (D'Mello, 2011). Clinical studies of space changes caused by premature loss of primary molars have a wide range of findings including the direction of space change, the amount of space loss and the need for space maintenance (Lin and Lin, 2017). Lin et al. found that premature loss of primary maxillary first molars caused distal drifting of primary canines toward the extraction space and palatal migration of maxillary incisors (Lin et al., 2007). Padma Kumari and Retnakumari evaluated the space changes after unilateral extraction of a lower first molar tooth. The results showed a statistically significant space loss on the extraction side (Padma Kumari and Retnakumari, 2006). Their study challenges the use of space maintenance to prevent space loss. The use of space maintainers may avoid the consequences of premature loss of primary teeth and the need for complex orthodontic treatment at a later stage. Nevertheless, space maintainer appliances are plaque retentive and using them may predispose to dental caries and periodontal problems. There is still little evidence either for or against the use of space maintainers to prevent or reduce the severity of malocclusions (Laing et al., 2009). Moreover, there is a need to evaluate the cost to the healthcare system of managing the consequences of premature primary tooth loss.

#### **1.1.5.9 High risk of developing new carious lesions**

Children with early childhood caries are highly susceptible to develop new carious lesions in the primary dentition after total dental rehabilitation (O'Sullivan and Curzon, 1991, Almeida et al., 2000, Chase et al., 2004, Graves et al., 2004, Amin et al., 2015, Amin et al., 2010, Foster et al., 2006). Amin et al. found that 24 % of children had new caries within 12 months following GA, 53% developed new carious lesions at 13-24 months following GA (Amin et al., 2010). Foster et al. reported more than 50% of children having new carious lesions within two years after GA (Foster et al., 2006). This

suggests the need for a comprehensive and frequent preventive approach to reduce recurrence rates of dental caries following rehabilitation under GA. Furthermore, these children (with ECC) are more likely to develop caries in the permanent dentition (Vanobbergen et al., 2001, Peretz et al., 2003, Skeie et al., 2006, Vadiakas, 2008).

## **1.2 Dental General Anaesthesia (DGA)**

Dental treatment is one of the most common reasons for administering GA to children. It may involve restoration of teeth or extraction of infected or un-restorable teeth. These procedures are often associated with significant amounts of discomfort, pain, and anxiety, for which pharmacological behaviour management is required (Adewale, 2012). Children's perception of pain is related to cognitive development (O'Rourke, 2004). Before the age of two years, the child is unable to distinguish between pressure and pain. Therefore, all forms of dental treatment will usually require GA. Between the age of 2-10 years, the child may be able to understand the sensation of pain. Still, many dental procedures will require GA in this age group. Children over the age of 10 years are more likely to have a better understanding and respond appropriately to explanations. Many children at this age will be able to cooperate with dental treatment under local anaesthesia. A child's ability to cope with dental treatment is also influenced by other factors such as fear, family learning and previous experience of pain (Alison Twycross, 2009).

### **1.2.1 Indications for the use of General Anaesthesia (GA) in children**

The UK National Clinical Guidelines in Paediatric Dentistry states that there are essentially only two indications for using GA in children:

- The child needs to be fully anaesthetised before dental treatment procedures can be attempted.



- The surgeon needs the child fully anaesthetised before the dental treatment can be performed.

The difficulty is neither of these indications are absolute (Davis et al., 2008).

Therefore, there are circumstances and conditions to be considered suitable for GA:

- Severe pulpitis requiring immediate relief.
- Acute soft tissue swelling requiring removal of the infected tooth/teeth.
- Surgical drainage of an acute infected swelling.
- Single or multiple extractions in a young child unsuitable for conscious sedation.
- Symptomatic teeth in more than one quadrant.
- Moderately traumatic or complex extractions e.g. ankylosed or infra-occluded primary molars, extraction of broken-down permanent molars.
- Teeth requiring surgical removal or exposure.
- Biopsy of a hard or soft tissue lesion.
- Debridement and suturing of orofacial wounds.
- Established allergy to local anaesthesia.
- Post-operative haemorrhage requiring packing and suturing.
- Examination under GA, including radiographs, for a special needs child where clinical evidence exists that there is a dental problem which warrants treatment under GA.

ECC followed by behaviour management issues were the most common reasons for referring children for GA (Vermeulen et al., 1991). Severe pulpitis and acute infection were by far the most common conditions treated under GA (Smallridge et al., 1990, Holt et al., 1992). Savanheimo et al. concluded in their study that the most important factors leading to the use of GA, as reported by the parents were dental fear and repeated unpleasant experiences during dental care (Savanheimo et al., 2005).

### **1.2.2 Benefits of using Dental General Anaesthesia (DGA) in children**

DGA has many benefits for the child, parents and dentist. It provides treatment that is safe, efficient and convenient. It offers restoration of dental health in a single visit and with minimal discomfort, requiring little or no cooperation from the child (Savanheimo et al., 2005). It helps in alleviation of pain, anxiety and maintaining stable vital signs allowing adequate conditions for the procedure to be carried out. Confidence in coping with dental care can be rebuilt with preventive programmes afterwards. That will help in minimising the child's future dental treatment requirements (Leagault et al., 1972). For the parents, DGA is an efficient and convenient method of addressing their child's needs and minimises time off work and additional expenses. For the dentist, the immobilisation of the patient with a secured airway can help the dentist to provide high quality dental treatment (Sun, 2010).

### **1.2.3 Risks of Dental General Anaesthesia (DGA) in children**

There are risks and complications associated with GA procedures, and because of these, it has been considered to be a last resort for providing dental treatment (Anderson et al., 2004). When considering the risks associated with GA, mortality is the first problem that 'jumps to mind'. However, death following DGA is relatively unlikely (Krippaehne and Montgomery, 1992), morbidity is a much more common problem (Atan et al., 2004). The risk of death is very minimal in healthy patients, about 1 in 100,000 (Jenkins and Baker, 2003). The dental procedure itself was the main cause of morbidity than the GA (Atan et al., 2004). A study by Holt et al. (1991) found that over 90% of the participants included in the study had symptoms of morbidity at some stage after procedures. Post-operative pain and prolonged bleeding were the most frequently reported oral causes of GA morbidity (Hosey et al., 2006, Atan et al., 2004).

Having said all that the risks and benefits of DGA must be explained to the parents and must be well documented. A written consent should be obtained at the time of treatment planning and updated on the day of the procedure (Davies 2008).

#### **1.2.4 Paediatric dental extractions under general anaesthesia in England.**

A large number of young children with dental caries end up requiring dental extractions under GA. Almost 400,000 children (under 17 years old) were admitted to hospitals for dental extractions under GA in the UK between 1997 and 2006, mostly from deprived areas (Moles and Ashley, 2009). The study reported that almost 22,000 children were admitted more than once. In the worst case, one child received extractions on seven separate occasions over the nine year period (from 1997 to 2006). More recent data on hospital admissions showed that there were about 60,000 children (under 18 years old) admitted for dental extractions in 2013 (Health and Social Care Information Centre 2013). The recent data showed that dental extractions were the most common cause of hospital admission for children aged 5-9 years in England.

#### **1.2.5 Paediatric Dental General Anaesthesia at Leeds Dental Institute**

The Department of Paediatric Dentistry of Leeds Dental Institute is a consultant-led service providing treatment for children and adolescents referred for secondary dental care services. There are two GA waiting lists, the 'exodontia-only list' and the 'comprehensive dental care list'.

There are two 'exodontia-only lists' /week, carried out in the operating theatre in the Leeds Dental Institute. Only children who are ASA grade I and II are seen on these lists. The comprehensive dental care lists are carried in the Clarendon Wing operating theatres, in the Leeds General Infirmary. Three lists are performed each week for healthy children requiring comprehensive dental care or for medically compromised children that are seen on these lists. Because of the high demand on the secondary

dental care for children and the high number of children being referred from different centres, the waiting list time can be between 2 to 3 months in the 'exodontia-only list' and up to 12 months in the comprehensive dental care list.

### **1.2.6 Repeat treatment under general anaesthesia**

Many studies have reported on a high repeat rate of treatment under GA in the UK. Harrison and Nutting reported that 10% of the 3,897 children who had dental treatment under GA in Guy's hospital, had a repeat DGA within the years 1992-1997 (Harrison and Nutting, 2000). In Leeds, 9% of the children who had similar treatment in 1997, had it repeated within the first 6 years, and 72% of the teeth extracted at the repeat GA were caries-free or unerupted at the time of initial treatment (Kakaounaki et al., 2011). In Liverpool, 12% of 278 children treated in 2003 had previous treatment (Albadri et al., 2006). In Manchester, a study showed that 33-59% of the children treated under GA came from families where the child or a sibling had the treatment under GA before (Goodwin et al., 2015). In Scotland, it was reported that as many as 25% of children referred for treatment under GA were repeat cases (Macpherson et al., 2005).

The high repeat rates suggest that the children are from high-risk families and post-operative prevention had failed.

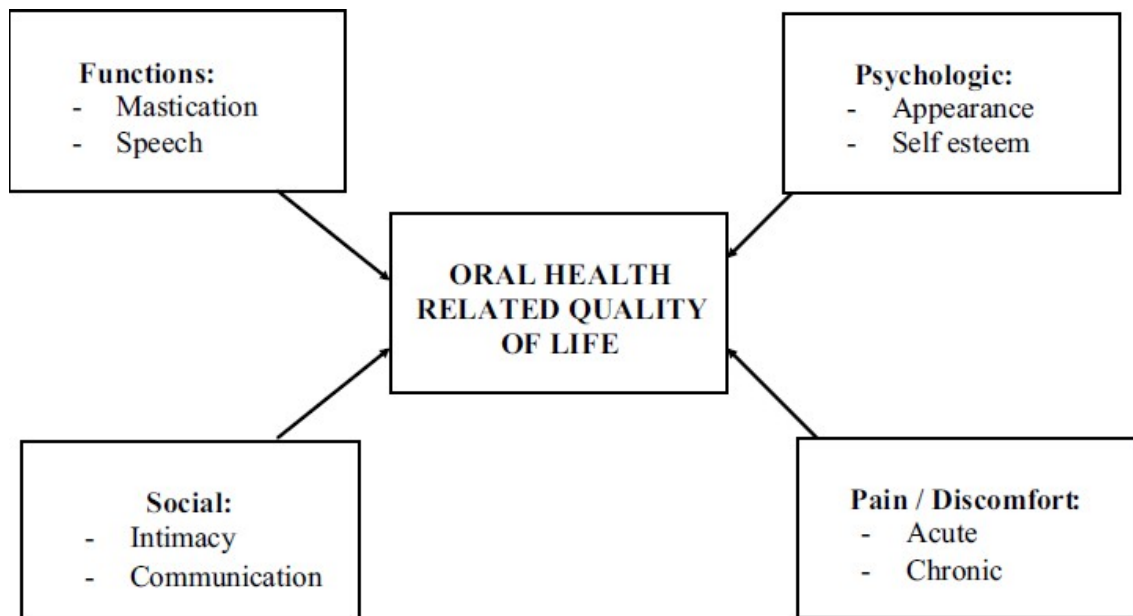
## **1.3 Oral Health-Related Quality of Life (OHRQoL)**

### **1.3.1 Definition of Oral Health-Related Quality of Life (OHRQoL)**

The term oral health-related quality of life refers to the impact that oral health has had on the individual day to day general wellbeing or quality of life (Pahel et al., 2007). It has been described as a multi-dimensional construct comprised of domains such as

the impact of disease on physical oral functions associated with chewing, swallowing and speaking; the absence of discomfort and pain; psychosocial issues such as socialdiscomfort in conversation, or concerns about appearance and social functioning associated with performance of normal roles; self-perceived oral health status and treatment needs; and the survival of the individual (Malden et al., 2008).

There are many variations in the approach to define OHRQoL. Initially, it was defined as ‘the impact of oral conditions on daily functioning’ (Slade, 1998). A few years later, Locker et al. in a paper evaluating OHRQoL outcomes in elderly people, redefined OHRQoL as ‘the symptoms and functional and psychosocial impacts that emanate from oral disease and disorders’ (Locker and Allen, 2002). Other researchers defined OHRQoL as ‘the absence of negative impacts of oral conditions on social life and positive sense of dento-facial self-confidence’ (Inglehart & Bagramian, 2002). From all of the above, OHRQoL can be defined as the persons assessment of how functional factors, psychological factors, social factors and experience of pain affect his or her wellbeing (Figure 2).



**Figure 2 Factors associated with OHRQoL (Inglehart and Bagramain, 2002)**

Oral health has been traditionally assessed based on normative clinical indicators. The indicators can be used as an important tool to assess treatment needs. For example, the indicator dmft can give indication of the success or effectiveness of preventative programs. However, the normative approach has been criticised because they neither catch nor document the full impact of oral disease and disorders on affected individuals (McGrath, 2004). Thus OHRQoL measures have emerged as an important healthcare outcome in clinical trials and healthcare research (Sischo and Broder, 2011). Along with other clinical assessments it allows healthcare professionals to evaluate the efficacy of treatment protocols and the quality of care from the patient perspective. Moreover, professionals are better equipped to accurately weigh the risk and benefits associated with treatment and prioritisation of care (Weintraub, 1998).

### **1.3.2 Children's Oral Health-Related Quality of Life (OHRQoL)**

The majority of OHRQoL questionnaires are most commonly developed for use among adults. More recently, researchers have developed a number of questionnaires designed to assess OHRQoL in children (Jokovic et al., 2002, Locker et al., 2002, Filstrup et al., 2003, Pahel et al., 2007). These questionnaires were designed to measure the impact of the oral condition on the child's daily activities such as speaking, eating, sleeping, smiling, emotional and social wellbeing.

### **1.3.3 Measuring Oral Health-Related Quality of Life (OHRQoL) in children**

There are a number of questionnaires which are specifically designed to assess OHRQoL in children (Filstrup et al., 2003, Jokovic et al., 2002, Pahel et al., 2007). Questionnaires differ in dimensions, age of targeted children, and methods of reporting OHRQoL, either by the children themselves or by the parents/caregivers (Table 5).

**Table 5 Different OHRQoL Tools**

<b>Measure</b>	<b>Author/year</b>	<b>Aim</b>	<b>Dimensions</b>
<b>CPQ11-14</b> Child Perception Questionnaire	Jokovic et al.,2002	The impact of oral and oro- facial conditions	Oral symptoms Functional limitations Emotional well- being Social well-being
<b>FIS</b> Family Impact Scale	Locker et al.,2002	The family impact of oral and oro-facial disorders	Parental/ family activities Parental emotions Family conflict
<b>P-CPQ</b> Parental- Caregivers Perceptions Questionnaire	Jokovic et al.,2003	Parental/care-givers perception of the oral health-related quality of life for children	Oral symptoms Functional limitations Emotional well- being Social well-being
<b>CPQ8-10</b> Child Perception Questionnaire	Jokovic et al.,2004	The impact of oral and oro-facial condition	Oral symptoms Functional limitations Emotional well- being Social well-being
<b>MOHRQoL</b> Michigan Oral Health-Related Quality of Life Scale	Gherunpong et al., 2004	The serious oral impact on children's ability to perform daily activities	Eating Speaking Cleaning mouth Sleeping Emotion Smiling Study Social contact
<b>ECOHis</b> Early Childhood Oral Health Impact Scale	Pahel et al.,2007	The impact of oral health problems and related treatment experiences on the quality of life of preschool age children (3to 5 years old)	Child symptoms Child function Child psychological Child self-image/ social interaction

			Parent distress
<b>COHIP</b> Child Oral Health Impact Profile	Broder et al.,2007	Oral health related quality of life in children with a broad age range (8–15 years) that include positive as well as negative aspects: parallel forms exist for the child and caregiver	Oral health Functional well- being Social-emotional wellbeing School environment Self-image
<b>POQL</b> Paediatric Oral Health-Related Quality of Life	Huntington et al., 2011	A brief measure of oral health-related quality of life (OHQL) in children with a particular focus on input from parents and children from low income or minority populations	Social Role functioning Physical Emotional
<b>SOHO-5</b> Scale of Oral Health Outcomes	Tsakos et al.,2012	Self-reported oral health related quality of life measure for 5-year-old children	Eating Drinking Speaking Playing Smiling (because teeth hurt) Smiling (because of the way teeth look) Sleeping

Children are subjected to numerous oral and oro-facial conditions that can impact their quality of life (Jokovic et al., 2003). One issue that continues to receive a great deal of attention with respect to measuring the OHRQoL of children is that of parent versus child reports (Jokovic et al., 2003).

Until recently, measurement of child health status and OHRQoL were based on proxy reports by parents or caregivers (Canning, 1992, Richards, 1994). The reason for this was the concern regarding the ability of children to provide assessments that met conventional psychometric standards (Pantell and Lewis, 1987). Several questionnaires for parallel parent-child reporting have been recently developed (le Coq



et al., 2000, Varni et al., 2001, Theunissen et al., 1998). These measures have provided the opportunity to examine the extent to which parental assessments correspond to those obtained from their children (Jokovic et al., 2004a). Results from the studies that used parallel reports were conflicting. While one study found a low level of agreement (Vogels et al., 1998), others reported agreement ranging from moderate to high (Theunissen et al., 1998, Verrips et al., 2000, Sawyer et al., 1999). However, these studies showed that the level of agreement depended on the health domain being examined. To date, the extent to which parents understand the effect of ill-health on their children's life remains unanswered (Jokovic et al., 2004a). Jokovic et al. (2004) examined parental knowledge of their children's OHRQoL and the effect of different analytical techniques to manage 'Don't know' responses on the validity and reliability of the questionnaire and the level of agreement between parental and child reports. They found that some parents had limited knowledge concerning their children's OHRQoL. However, the information provided by parents is still useful even if it's incomplete as the parental and child reports measuring different realities (Jokovic et al., 2004a).

A number of (OHRQoL instruments have been designed to assess the impact of oral health problems in children (Farsi et al., 2017). These include the Parental-Caregiver Perception Questionnaire (P-CPQ), the infantile and toddler quality of life (ITQoL), child oral health impact profile (COHIP), child perception questionnaire (CPQ) and Early Childhood Oral Health Impact Scale (ECOHIS)

### **1.3.3.1 The Infantile and Toddler Quality of Life Questionnaire (ITQoLQ)**

The ITQoLQ was developed by Landgraf and designed for children aged 2 months up to 5 years old (Raat et al., 2007). It adopts the World Health Organisation's definition of health and incorporates the results of a review of child health literature and developmental guidelines used by paediatricians together with the feedback of parents

during pilot testing (Raat et al., 2007). There are two versions of the ITQoLQ, the 47 item short form (ITQOL-SF-47) and the 97 item full length version (ITQOL). The questionnaire is completed by parents and covers the physical and psychological aspects of child health and the impact of health problems on family life (Klassen et al., 2003). It measures physical function, growth and development, bodily pain, temperament and moods, behaviour and general health perceptions (Landgraf et al., 2013). The ITQoLQ also includes parent specific scales: emotional and time impact, and the parent's rating of how well the family is getting along with one another.

The ITQoLQ allows for the continuous measurement of health-related quality of life outcomes across the child continuum by utilising items specific to infant development and conceptual framework similar to but not identical to the child health questionnaires (Landgraf et al., 2013). Items on the questionnaire are reverse scored, so that a higher score is better. The questionnaire has been validated and translated into different languages (Raat et al., 2006). It has been successfully used in both large and small-scale studies in the Netherlands (Oostenbrink et al., 2006, van Baar et al., 2006, Raat et al., 2007, Spuijbroek et al., 2011, Oostenbrink et al., 2010). It is also available in English and Spanish. Klassen et al. (2003) found positive parental reports on the ease of use, understanding and acceptability of the ITQoLQ items (Klassen et al., 2003). However, it was anticipated that the length of the questionnaire would not be feasible for clinical use (Landgraf et al., 2013).

### **1.3.3.2 The Child Oral Health Impact Profile (COHIP)**

The COHIP was developed by Broder and Wilson-Genderson (Molek et al., 2016). It is a 34-item questionnaire designed to measure self-reported OHRQoL in children aged 8-15 years (Ruff et al., 2016). The COHIP includes five domains, consisting of oral health (10 items), functional well-being (6 items), socio-emotional well-being (8 items), school environment (4 items) and self-image (6 items). The questionnaire

includes a final global health perception item (Broder and Wilson-Genderson, 2007). The questionnaire was designed to include positive as well as negative aspects of OHRQoL. It was developed for use in epidemiological studies to help instigate potential health policy implications. The COHIP has been previously shown to have good scale reliability, test re-test reliability and discriminance validity (Genderson et al., 2013).

### **1.3.3.3 The Early Childhood Oral Health Impact Scale (ECOHIS)**

The ECOHIS was developed in English by Pahel et al., who demonstrated its validity and reliability (Pahel et al., 2007). It was derived from the Child Oral Health Quality of Life (COHRQoL) instrument developed by Jokovic and Locker (Jokovic et al., 2002, Jokovic et al., 2003, Jokovic et al., 2004a). The ECOHIS tests the impact of oral health problems on both young children and their families. Because preschool children do not have the developmental and psychological abilities that allow them to accurately recall past events and give accurate accounts of personal expression, the questionnaire is designed for adult caregivers who can better relate the impact of oral health on the child's life (Pahel et al., 2007). The questionnaire comprises 13 questions which are divided into two sections, the child and family sections. The child impact section has nine items and is comprised of four domains: child symptoms, function, psychology and self-image and social interaction. The family impact section has four items and is comprised of two domains: parental distress and family function.

The ECOHIS has shown content and construct validity, internal consistency and reliability (Pahel et al., 2007, Martins-Junior et al., 2012, Tesch et al., 2008). Some of the studies have shown that ECOHIS is responsive to treatment-associated changes (Lee et al., 2011, Guedes et al., 2017, Arrow, 2016). Responsiveness refers to the ability of a measure to change in relation to an expected gradient of clinical importance such as global transition ratings of changes in oral health (Arrow, 2016).

Studies have determined that the ECOHIS is valid for assessing the impact of OHRQoL in children between 0-5 years of age and their families (Martins-Junior et al., 2012). The ECOHIS has performed well and has shown good reliability and validity. It has been translated into several languages and tested and validated on diverse populations with good results (Li et al., 2008, Scarpelli et al., 2011, Lee et al., 2009, Bordoni et al., 2012, Martins-Junior et al., 2012, Hashim et al., 2015, Farsi et al., 2017).

#### **1.3.3.4 The Parental-Caregiver Perception Questionnaire (P-CPQ)**

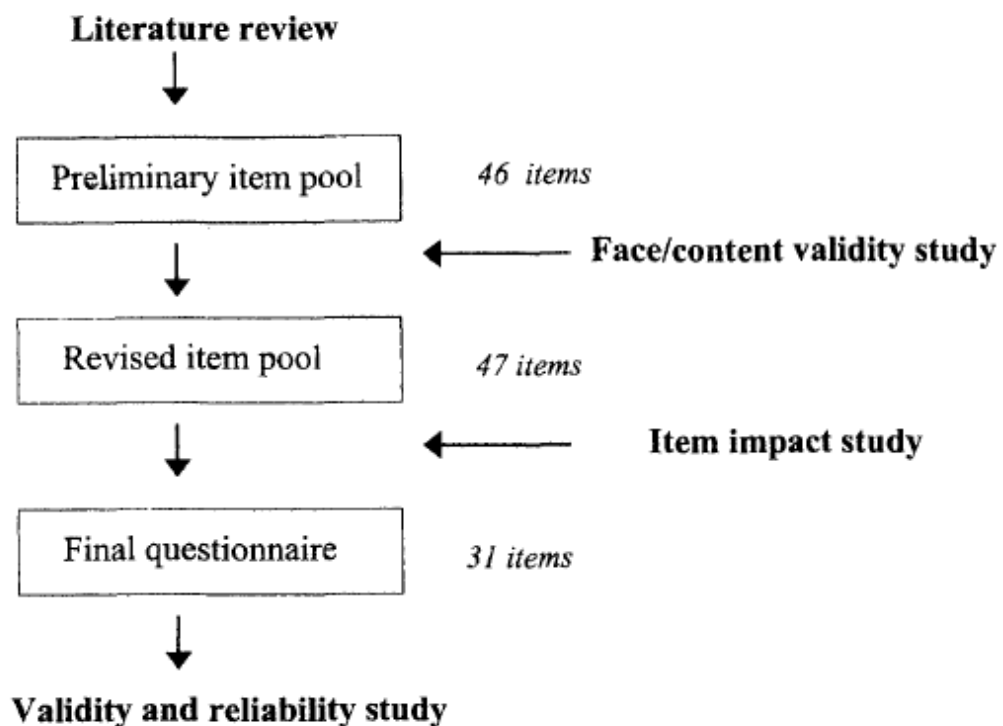
The P-CPQ was developed by a group of Canadian searchers who took into account children's cognitive abilities and lifestyles (Barbosa Tde and Gaviao, 2015). The P-CPQ consists of questionnaires for children aged from 8-10 years (Child Perceptions Questionnaire- CPQ<sub>8-10</sub>)(Jokovic et al., 2004b) and from 11-14 years (CPQ<sub>11-14</sub>)(Jokovic et al., 2002). These questionnaires assess the child's perceptions of the impact of oral disorders on physical and psychological functioning. They also incorporated a questionnaire for parents that evaluates their perception of their child's OHRQoL (Jokovic et al., 2003).

The P-CPQ was constructed according to a process derived from the theory of measurement and scale development (Jokovic et al., 2003). The specific procedures used were those described by Guyatt et al. (Guyatt et al., 1987) and Juniper et al. (Juniper, 1996) for the development and evaluation of health related quality of life measures and are summarised in Figure 3.

The items for the P-CPQ were generated in two stages. In the first stage, a preliminary pool of 46 items was developed by searching the literature and selecting items from existing questionnaires. These items then were subjected to review for its comprehensiveness, relevance and clarity by clinicians who treat children with oral and orofacial conditions, and parents of child patients. Based on the responses and

comments, a modified item pool was developed by excluding irrelevant items, writing additional items and combining items. Items for the final questionnaire were selected from the modified pool using an impact item analysis, which identify the retained and revised items from the initial item pool and measure their importance and relevance to the population.

The studies have confirmed the validity and reliability of the questionnaires. It has been translated and used in different countries such as Australia (Do and Spencer, 2007), UK (Johal et al., 2007, Marshman et al., 2007, Benson et al., 2010), Hong Kong (Zhang et al., 2007), and Netherlands (Klaassen et al., 2008).



**Figure 3** Diagrammatic representation of the developmental process of P-CPQ

### 1.3.3.5 The Child Oral Health-Related Quality of life Questionnaire (COHRQoL<sup>®</sup>)

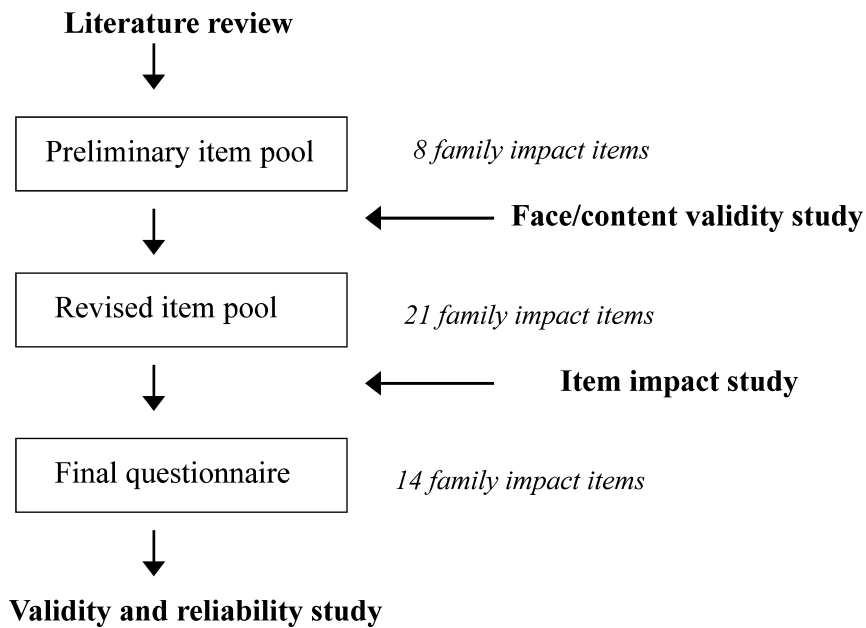
The COHRQoL<sup>®</sup> questionnaire was the first measure of child OHRQoL to be described and validated (Jokovic et al., 2002). It was developed and validated by Jokovic et al.

The COHRQoL<sup>®</sup> was designed to assess the OHRQoL of children aged 6-14 years with oral and orofacial conditions. It consists of two components, the FIS and the P-CPQ. The P-CPQ has two analogues Child Perception Questionnaires, one for children aged 6-10 years and the other for children aged 11-14 years (Locker et al., 2002). Both parental-caregiver and child questionnaires contain domains that include oral symptoms, functional limitations, and emotional and social well-being components.

#### **1.3.3.6 Family Impact Scale (FIS)**

The impact of children's oral health on the family was raised in the early 1980's by Sheiham and Croog. They described the psychosocial impact of dental disease on individuals and societies and found that some of the family life aspects might be affected by the presence of dental disease among its members (Sheiham and Croog, 1981). Evidence has showed that ECC resulted in lost working days for parents/caregivers who had to stay at home to take care of their child, or spend time and money on dental care (Gift et al., 1992). Furthermore, there was strong evidence that the parents or caregivers experienced significant quality of life issues because of their children's health problems and treatment experiences (Locker et al., 2002). The central role played by the family in child health and the likelihood that chronic illness in children would impact on the family, requires the inclusion of the FIS on children's OHRQoL measures. In addition, the fact that health care interventions often address parental needs and concerns as well as the child's needs and the fact that parental reports of a child's health may be influenced by the degree to which the parent is physically or emotionally affected by the child's condition (Rothman et al., 1991).

The FIS questionnaires were developed by the process described by Guyatt et al. (Guyatt et al., 1987). Figure 4 summarises this process.



**Figure 4** Summary of the process used to develop the Family Impact Scale.

## 1.4 Dental General Anaesthesia (DGA) and Oral Health-Related Quality of Life (OHRQoL)

### 1.4.1 Measuring the effectiveness of DGA

The effectiveness of DGA can be measured in many ways. This includes the success of the dental procedure carried out, parental satisfaction, and the overall change in the quality of life of the child, post-operatively. Many studies in the literature have shown a high rate of parental satisfaction following dental rehabilitation under GA to treat their children (Acs et al., 2001, White et al., 2003, Anderson et al., 2004, de Souza et al., 2017, Klaassen et al., 2008, El Batawi et al., 2014, Baghdadi and Muhajarine, 2015).

### 1.4.2 Parent-assessed changes on OHRQoL following DGA

Many studies have used parental perception to demonstrate the change in the oral health-related quality of life following treatment of early childhood caries under GA. Most studies demonstrated improvement in all the domains of the OHRQoL measures (White et al., 2003, Malden et al., 2008), with pain relief being the most reported

improvement in the physical domain followed by improved eating and chewing and sleeping (Acs et al., 2001, White et al., 2003). However, no control groups were included in these studies, so bias cannot be excluded. Klaassen et al. conducted the only randomised controlled trial to test the hypothesis that young children's OHRQoL improves after oral rehabilitation under GA (Klaassen et al., 2009). They used P-CPQ and FIS, and ECOHIS in the study. However, a proper randomised controlled trial will mean that the control group will not get any treatment. Of course treatment cannot be withheld from control groups as this is unethical. Therefore, randomisation groups were created to measure the effect of the pre-test questionnaire rather than treatment under GA itself. The results showed that the pre-test scores of the children examined did not influence the post-test scores, i.e. the improvement to OHRQoL detected were due to the treatment and not because of any influence by the pre-test.

Two systematic reviews were published to assess the change in OHRQoL in children following treatment under GA for the management of dental caries (Jankauskiene and Narbutaite, 2010, Knapp et al., 2017).

Jankauskiene and Narbutaite included 11 articles out of the 69 articles identified initially. All selected articles reported results of clinical trials. 10 studies used a pre-experimental study design and one study used a randomised controlled trial design. The questionnaires in all studies were filled by parents. All the studies concluded that dental treatment under GA led to improvement in the quality of life of children and all aspects considered. The parents pointed out the child's better physical condition, better sleep, appetite and absence of toothache (Jankauskiene and Narbutaite, 2010). Another systematic review by Knapp et al examined 20 studies reported in 22 papers out of 121 titles screened. Most of the included studies were prospective longitudinal studies (n=18). Only one study was a randomised controlled trial (Klaassen et al., 2009), but as mentioned above the randomisation groups were created to measure the effect of the pre-test questionnaire rather than treatment under GA itself. A range of



instruments were employed to measure OHRQoL. Two studies designed their own questionnaires, with the remainder using pre-existing questionnaires. Because of the heterogeneity between the studies included in systematic review, it was not possible to carry out a meta-analysis of the findings which also limits the conclusions that can be drawn. Overall, there were improvements in the proxy-reported OHRQoL. The study highlights the need for further high-quality studies employing validated, child-reported measures of OHRQoL (Knapp et al., 2017)

### **1.4.3 Component of the study questionnaire**

The questionnaires used in this study were composed of the Parent-Caregiver Perception Questionnaire (P-CPQ) and the Family Impact Scale (FIS) which are components of the Child Oral Health-Related Quality of Life (COHRQoL©) questionnaires. These questionnaires were the first measures of child oral health-related quality of life to be described and validated (Jokovic et al., 2002).

#### **1.4.3.1 The Parent-Caregiver Perception Questionnaire (P-CPQ)**

This P-CPQ consists of 12 Items (Questions) that makes up 4 domains: oral symptoms, functional limitations, emotional wellbeing and social wellbeing (see section 1.3.3.4). The questionnaire is proxy reported (Parent/Caregiver) and it is designed to measure the impact of the condition or intervention on the child. It has demonstrated good validity and reliability and was translated into different languages (Jokovic et al., 2003). According to Marshman et al. the P-CPQ was reliable and a valid measure to use in the UK when adjusted for 'don't know' responses (Marshman et al., 2007).

#### **1.4.3.2 The Family Impact Scale(FIS)**

This questionnaire consists of 8 Items (questions), with 3 domains: parent/family activity, parental emotion and family conflict (see section 1.3.3.6). It measures the impact of the child's condition or treatment on the parent and the rest of the family.

### **1.4.3.3 The Global Transition Rating Scale (GTRS) questions**

These are two overall assessment questions that follow the FIS. They ask the parent/care-giver how much their child's overall well-being was affected by the condition (dental caries), and how much was the daily life of the family affected by the child's condition.

Both the FIS and GTRS demonstrated good validity and reliability (Locker et al., 2002, Thomson and Malden, 2011).

## **1.5 Aims and Hypothesis**

### **1.5.1 Aims**

- 1- To quantify the impact of multiple caries on children's quality of life.
- 2- To study the impact of multiple extractions under GA on both the family and the child's quality of life.

### **1.5.2 The Null Hypothesis**

- 1- There is no difference in the effect of multiple teeth extraction under GA on the quality of life of children before and after treatment.
- 2- There is no difference in the effect of multiple teeth extractions under GA on the quality of life of the child's family before and after treatment.

## Chapter 2 MATERIALS AND METHODS

This study was designed to investigate the effect of dental caries on the quality of life of children and their family and the changes in the quality of life after multiple extractions of carious teeth under general anaesthesia. The study was carried out in two parts:

### **Part 1:**

Parents of patients referred to the Day Care Unit at Leeds Dental Institute (LDI), for extraction of carious teeth under General Anaesthesia (GA), were asked to complete the Child Oral-Health Related Quality of Life (COHRQoL) questionnaire.

### **Part 2:**

Involved follow-up of the participants with a phone call, 6-8 weeks after the GA treatment and the same COHRQoL questionnaire was again completed.

## **2.1 Power Calculation**

Statistical advice was sought and the sample size was calculated based on the paper by De Souza et al. 2016. A sample size of 19 achieves 80% power to detect an effect size of 0.7 and with a significance level (alpha) of 0.05 using a two-sided paired t-test. A 20% loss of follow-up was assumed, therefore at least 24 subjects needed to be recruited into the study.

## **2.2 Approvals**

### **2.2.1.1 Ethical approval**

The Health Research Authority (HRA) approval was sought through the national Integrated Research Application System (IRAS) and was gained from the Office for Research Ethics Committees Northern Ireland (ORECNI) (see Appendix A).

### **2.2.2 Local Research and Development (R&D) Approval**

This was gained from the R&D department within the hospital trust in which the study took place.

### **2.2.3 Clinical Service Unit (CSU) approval**

CSU approval was obtained from the Clinical Director of the Leeds Dental Institute.

## **2.3 Subject selection**

Parents of children with dental caries who were referred to the LDI for extraction of multiple carious teeth under GA were considered potential participants for this study. Children with ECC were included in this study. Parents of children, who fitted the inclusion criteria, were approached in the 'new patient' consultation clinics and given an invitation letter (Appendix B), information sheet (Appendix C), and were asked if they would like to participate in the study. On the day of the GA, if the parents agreed to participate in the study, they were asked to sign a consent sheet (Appendix D), then given the pre-operative questionnaire (Appendix E) and asked to complete it while waiting in the waiting area. Any question or inquiry regarding how to complete the questionnaire was answered. The parents were then given a date for the lead investigator to call them and complete the follow-up questionnaire (Appendix F) by telephone.

The age range was selected based on previous studies (Thomas and Primosch, 2002, White et al., 2003, Anderson et al., 2004, Klaassen et al., 2008, Klaassen et al., 2009). Medically compromised children were excluded from the study as they are usually treated in a different list and setting. Moreover, the quality of life of those children and their families is usually affected by their condition.

### **2.3.1 Inclusion Criteria:**

The following were the inclusion criteria:

- Parents of 3-7 year old- paediatric patients attending the ODU at LDI for extraction of carious teeth under GA
- Medically fit and healthy children (ASA I & II)

### **2.3.2 Exclusion criteria**

- Parents who were unable to communicate directly with the person carrying out the research, or did not speak English well enough to communicate with the person carrying out the research
- Parents unwilling to give consent
- Medically compromised children.

## **2.4 Recruitment**

Recruitment took place over a 3 month period (20 September 2016 to 13 December 2016). The primary researcher approached the participants who fitted the inclusion criteria and agreed to take part in the study. Recruitment took place in the Day Care Unit on the day of the GA. A total of 55 parents of patients fulfilled the inclusion criteria. Of these 55, 33 parents consented to take part in the study. Follow-up took place 6-8 weeks post GA treatment. There were 4 parents (12%) that were lost to follow-up as they did not answer the follow-up phone call or did not want to complete the follow-up questionnaire.

## **2.5 Withdrawal of participants:**

Participants were advised that they could withdraw from the study at any time if they wanted. It was decided that any withdrawn participant would still be included for data analysis, unless they expressed otherwise. Withdrawn participants were not replaced.

## 2.6 Blinding

Parents were informed that the study was about oral disease, dental treatment and the quality of life of their children. They were informed that this study was not an experimental study and that there would not be any reduced quality of care. It was hoped that this would not have any negative effect on the participants and bias their responses. Because there was one primary researcher, it was not possible to blind him from the treatment the child received.

## 2.7 Randomisation:

There was no randomisation process involved in this study.

## 2.8 Data Collection

The primary researcher was not involved in the provision of any treatment for the participants under GA.

### 2.8.1 Pre-operative questionnaire

The COHRQoL<sup>®</sup> was used as mentioned before. The questionnaire was comprised of the P-CPQ, the FIS and the GTRS. There were a total of 22 questions. Each item of the questionnaire represented a way in which the condition or the treatment could impact on the child's OHRQoL. Each question had standard responses on a 5 point rating scale.

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
<b>Never</b>	<b>Once or twice</b>	<b>Sometimes</b>	<b>Often</b>	<b>Every day or almost every day</b>	<b>Don't know</b>

The P-CPQ comprised 12 questions in 4 domains. The questionnaire asked: *During the last 3 months, how often has your child:*

**Oral Symptoms domain:**

- Had pain in the teeth, lips, jaw, or mouth
- Had food caught between teeth
- Had bad breath?

**Functional limitation domain:**

- Had difficulty biting or chewing firm foods such as fresh apples, corn on the cob or firm meat?
- Taken longer than others to eat a meal?
- Breathed through the mouth?
- Had trouble sleeping?
- Had difficulty saying any words?

**Emotional Wellbeing domain:**

- Been irritable or frustrated?
- Been upset?

**Social wellbeing domain:**

- Not wanted to talk to other children?
- Missed school or preschool?

The FIS comprised 8 questions in 3 domains. It asked about the effect that the child's condition may have had on the parents or the family members.

**Parental Emotion:**

- Been upset

- Felt guilty
- Required more attention from you or others in the family

**Parent/ family activity:**

- Had sleep disrupted
- Taken time off work (e.g. due to pain, appointments, surgery)
- Had less time for yourself or the family

**Family conflict:**

- Blamed you or another person in the family
- Argued with you or others in the family

The GTRS asked about:

- How much is your child's overall well-being affected by the condition of his/her teeth, lips, jaw or mouth
- How much is the daily life of your family affected by the condition of his/her teeth, lips, jaw or mouth?

The questionnaire were given to the parents/caregivers on the day of the GA and were completed while the parents/caregivers were waiting for their child's pre-anaesthetic check or while their child was in the operating theatre. The primary researcher made sure when getting the questionnaire back from the parent/caregiver that all questions were answered and there was no missing data. The parent/caregiver contact telephone number was taken and they were asked about the best time to call. A date for the follow-up phone call to repeat the questionnaire was given to the parents/caregivers.



### **2.8.2 Post-operative Questionnaire:**

Six to eight weeks after the operation, the parents/caregivers were called by primary researcher, and the same questions were asked. The majority of participants answered the phone from the first call. However, 7 of the participants were called 3-4 times before they answered the phone call. The primary researcher left a voice message stating who is he, why is he calling and when is he going to call again. The phone call took average of 6-7 minutes. Parents/caregivers were asked: since the dental operation, how often has your child had: (then the same questions repeated). At the end of the post-operative questionnaire, one last GTR question asked about the overall quality of life of the child since the operation. A five point scale answer scored the question.

## **2.9 Statistical analysis**

The data were analysed using SPSS statistical software package for windows version 22.0.

- Descriptive statistics were used to calculate the mean, median, range, and standard deviation.
- Mean change score and effect size were calculated for the whole sample using paired t tests, and by domain using Wilcoxon paired tests.

## Chapter 3 RESULTS

### 3.1 Recruitment process

As mentioned in the previous chapter, 33 parents of patients participated in the study. There were 4 patients lost to follow-up as the parent did not answer the follow-up phone call or did not want to answer the questionnaire. Figure 4 illustrates the recruitment process for this study.

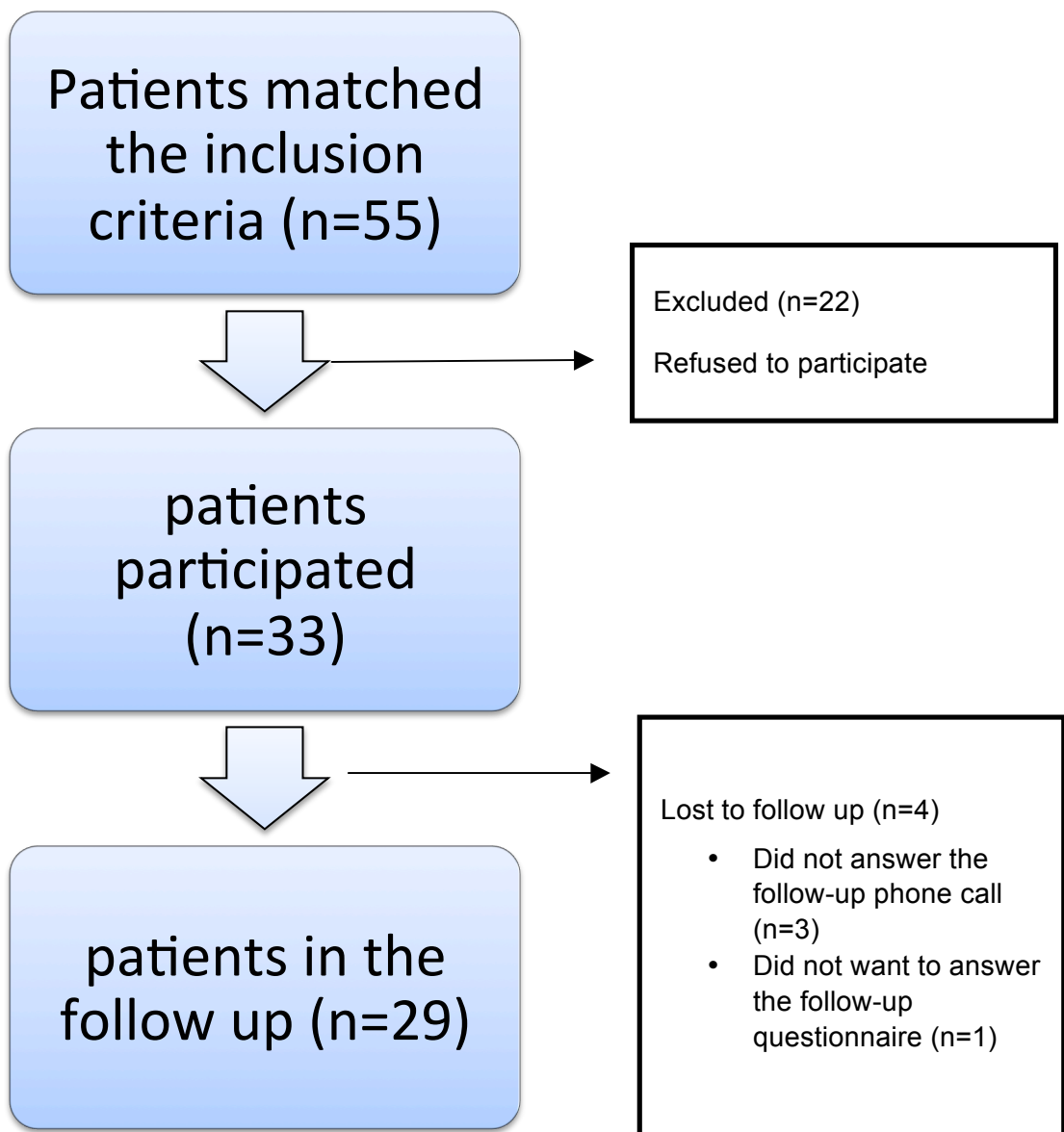


Figure 5 Recruitment process

### 3.2 Age and gender

The mean age of the participants was 5.09 years, with median of 5 and range of 4 years. There were 17 males and 16 females that participated in the study.

### 3.3 Socioeconomic status

The area post code was used to determine the socioeconomic status of each patient. The socioeconomic status was classified into 3 classes, low, middle and high. Table 6 below shows the socioeconomic status of the patients in the study.

**Table 6 Socioeconomic status**

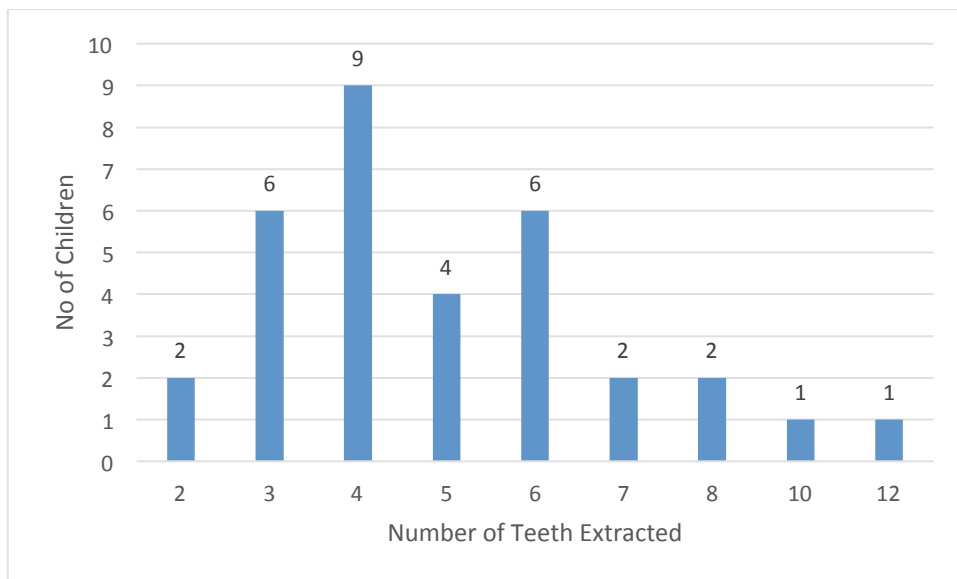
Socioeconomic status	Number of Patients
Low	11
Middle	17
High	5

### 3.4 Treatment Provided

All the children had primary teeth extracted. No permanent teeth were extracted for any of the children. The minimum number of teeth extracted were 2 primary teeth and the maximum number was 12 primary teeth with average of 5 primary teeth for all children. Table 6 gives details on the number of teeth extracted for all children. The majority of the children had 4 primary teeth extracted (9 children). 1 child had 10 primary teeth extracted and another child had 12 primary teeth extracted at the GA session. (figure 6 )

**Table 7 Number of primary teeth extracted for children**

Number of Children	Number of Primary teeth extracted
2	2
6	3
9	4
4	5
6	6
2	7
2	8
1	10
1	12

**Figure 6 Number of primary teeth extraction for children**

### 3.5 The mean scores, change in mean scores, and effect size

The mean scores following treatment were calculated by subtracting the post-operative scores from the pre-operative scores for both questionnaires (P-CPQ & FIS)

and their subscales. A positive score indicated an improvement in the OHRQoL of the child and family and a negative score indicated a deterioration.

The effect size indicated the magnitude of change. It was calculated by dividing the mean change score by the standard deviation of the pre-operative scores. An effect size less than 0.2 indicated a small magnitude of change, 0.2 -0.7 indicated a moderate change, and greater than 0.7 indicated a large change (Malden et al., 2008).

Table 7 presents the mean scores, change in scores and effect size for the domains of the P-CPQ and FIS.

**Table 7 Mean scores, change in scores and effect size for the domains of the P-CPQ and FIS**

	Mean score		Standard Deviation (SD)		Mean change in score	Effect size
	Pre- Op	Post- Op	Pre-Op	Post-Op		
<b>P-CPQ</b>						
Oral Symptoms <b>(Range)</b>	7.73 <b>(1-5)</b>	3.0 <b>(1-2)</b>	3.16	0.310	<b>4.73</b>	<b>1.5</b> (large)
Functional limitations <b>(Range)</b>	10.59 <b>(1-5)</b>	5.23 <b>(1-2)</b>	5.52	0.756	<b>5.36</b>	<b>0.98</b> (large)
Emotional wellbeing <b>(Range)</b>	5.12 <b>(1-4)</b>	2.52 <b>(1-2)</b>	1.825	0.883	<b>2.6</b>	<b>1.42</b> (large)
Social wellbeing <b>(Range)</b>	3.12 <b>(1-3)</b>	2.10 <b>(1-2)</b>	3.179	0.444	<b>1.02</b>	<b>0.32</b> (medium)
<b>Total</b>	26.56	12.85	13.684	2.393	<b>13.71</b>	<b>1.00</b> <b>(Large)</b>
<b>FIS</b>						
Parent/family activity <b>(Range)</b>	6.49 <b>(1-5)</b>	3.03 <b>(1-3)</b>	2.332	0.186	<b>3.46</b>	<b>1.48</b> (large)
Parental emotion <b>(Range)</b>	7.43 <b>(1-4)</b>	3.48 <b>(1-2)</b>	2.865	1.022	<b>3.95</b>	<b>1.38</b> (large)
Family conflict <b>(Range)</b>	3.45 <b>(1-5)</b>	2.03 <b>(1-2)</b>	1.799	0.186	<b>1.42</b>	<b>0.79</b> (large)
<b>Total</b>	17.37	8.54	6.996	1.934	<b>8.83</b>	<b>1.03(Large)</b>

The mean change score between pre-operative and post-operative was positive. That shows that there was an overall improvement in the OHRQoL of the children and their family. The largest change of score was for the oral symptoms domain of the P-CPQ. The smallest change of score was for the social wellbeing domain of the same questionnaire. The effect size was large for all the domains except for social wellbeing, which scored a medium effect size (0.32). The largest effect size was for the parental/family activity of the FIS (1.48). The overall reduction in scores was large for both P-CPQ and FIS questionnaires with large effect sizes for both.

### **3.6 Parent-Caregiver Perception Questionnaire**

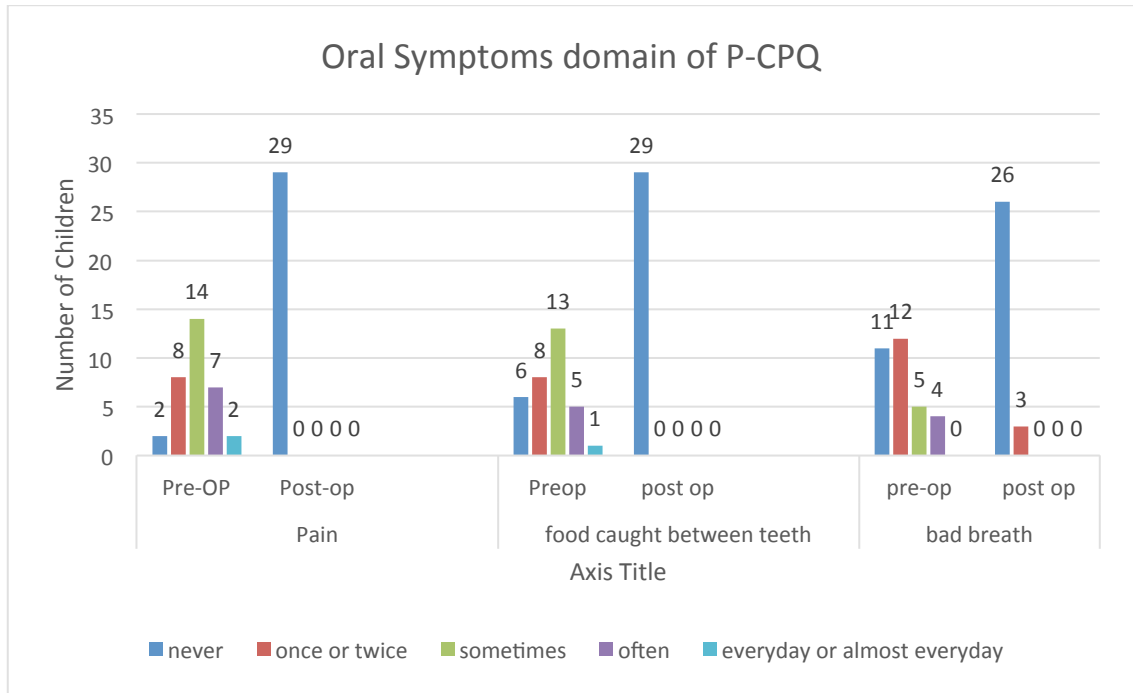
#### **3.6.1 Oral Symptoms Domain (Table 8)**

**Table 8 Oral symptoms domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

	Pain		Food caught between teeth		Bad breath	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	2	29	6	29	11	26
<b>Once or twice</b>	8	0	8	0	12	3
<b>Sometimes</b>	14	0	13	0	5	0
<b>Often</b>	7	0	5	0	4	0
<b>Every day or almost every day</b>	2	0	1	0	1	0
<b>Total</b>	33	29	33	29	33	29

Over 90% of the subjects reported pain in the previous 3 months prior to treatment *once or twice, sometimes, often or almost every day if not every day*. Other oral symptoms, food caught between teeth and bad breath scored over 81% and over 66% respectively. Post-operatively, the score decreased to 0% for both pain and food caught between teeth and to about 10% for bad breath oral symptoms. Figure 7 gives details of the answers of the oral symptoms domain of the P-CPQ per each child. Statistically, these findings were significantly different between the pre-operative and the post-operative scores (Wilcoxon test  $p < 0.05$ ).





**Figure 7 Oral Symptomsdomain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

**3.6.2 Functional limitation domaindomain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

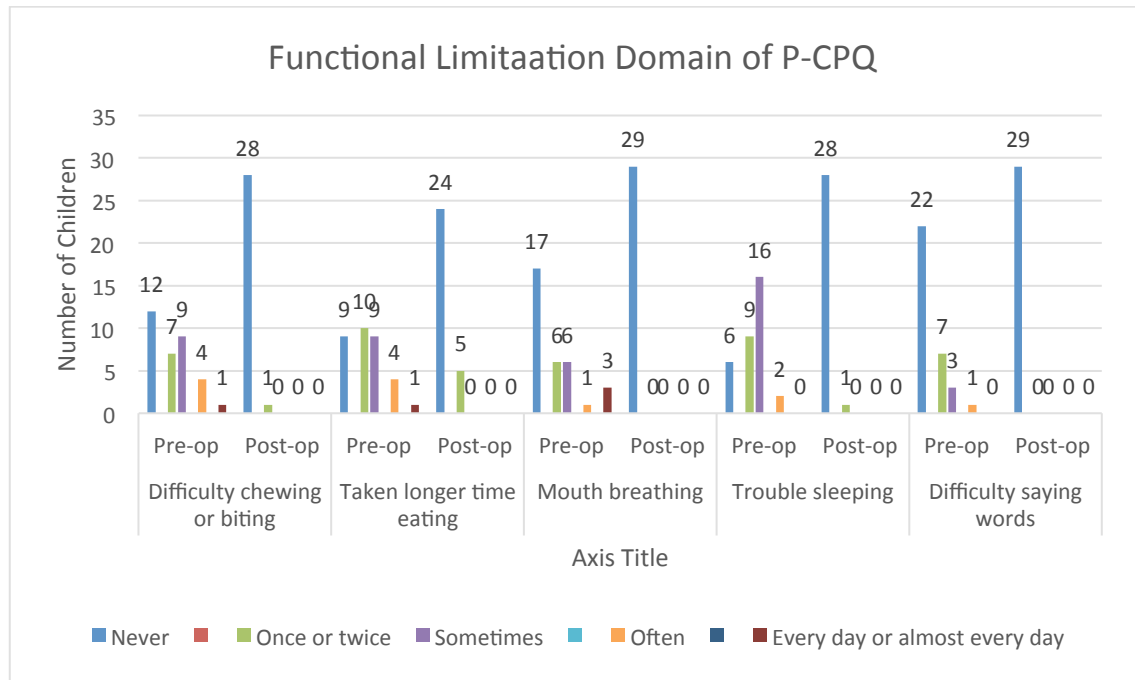
Table 8 shows the reported results of the functional limitation domain of the P-CPQ..

**Table 9 Functional limitation domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

	Difficulty chewing or biting		Taken longer time eating		Mouth breathing		Trouble sleeping		Difficulty saying words	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	12	28	9	24	17	29	6	28	22	29
<b>Once or twice</b>	7	1	10	5	6	0	9	1	7	0
<b>Sometimes</b>	9	0	9	0	6	0	16	0	3	0
<b>Often</b>	4	0	4	0	1	0	2	0	1	0
<b>Every day or almost every day</b>	1	0	1	0	3	0	0	0	0	0
<b>Total</b>	<b>33</b>	<b>29</b>	<b>33</b>	<b>29</b>	<b>33</b>	<b>29</b>	<b>33</b>	<b>29</b>	<b>33</b>	<b>29</b>

Pre-operatively, a number of functional limitations were reported occurring at moderate to high frequencies (*sometimes, often, every day or almost every day*). Almost 82% of the subjects reported having trouble sleeping pre-operatively. The score decreased to just over 3% post-operatively. Some 72% of the participants took longer than others to eat a meal pre-operatively. However, the score dropped to about 17% post-operatively. The percentage of participants having difficulty biting or chewing firm food was about 63% pre-operatively. Only 3% reported the same symptom post-operatively. Other functional limitations reported were mouth breathing and difficulty saying words, which scored 39% and 33% respectively. The score was 0% for both

symptoms post-operatively. Figure 8 shows the answer of each question of the functional limitation domain of the P-CPQ. The scores for the functional limitation component were statistically different for the pre-operative and post-operative results (Wilcoxon test  $p < 0.05$ ).



**Figure 8 Functional limitation domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

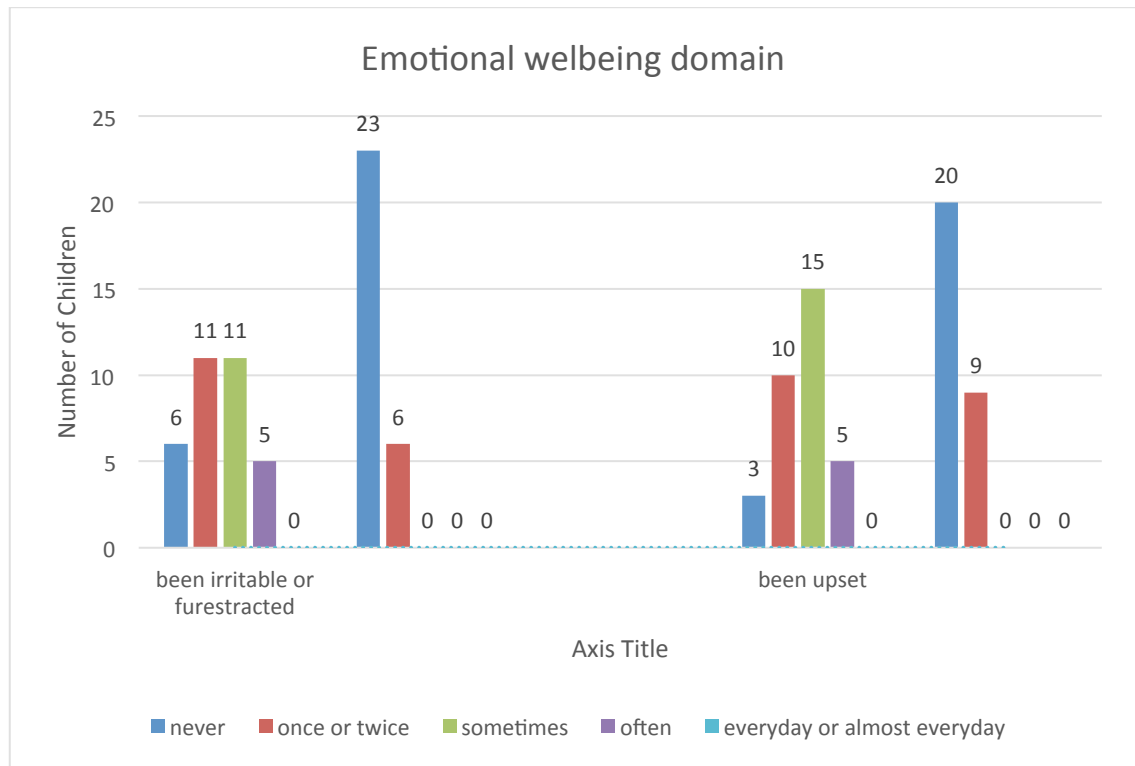
### 3.6.3 Emotional wellbeing domain of Parent-Caregiver Perception Questionnaire (P-CPQ)

Table 9 shows the results of the Emotional wellbeing domain.

**Table 10 Emotional wellbeing domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

	Been irritable or frustrated		Been upset	
	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	6	23	3	20
<b>Once or twice</b>	11	6	10	9
<b>Sometimes</b>	11	0	15	0
<b>Often</b>	5	0	5	0
<b>Every day or almost every day</b>	0	0	0	0
<b>Total</b>	33	29	33	29

Before treatment, over 90% of parents reported that their children were upset And this reduced to 31% post-operatively. About 81% of parents reported that their children were irritable or frustrated before treatmentAnd this decreased to just above 20% post-operatively. Figure 9 shows the change in answer between the pre- and post-operative questions of the emotional wellbeing domain of the P-CPQ. Statistically, there was a significant difference between the scores of the pre- and post-treatment results (Wilcoxon  $p < 0.05$ ).



**Figure 9 Emotional wellbeing domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

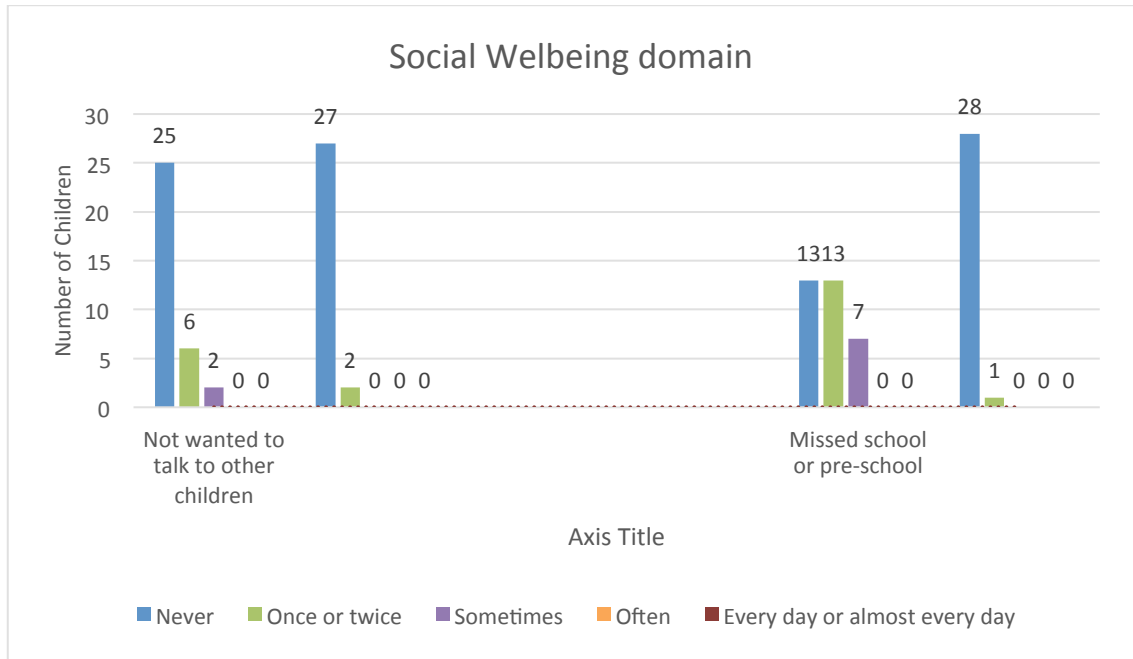
### 3.6.4 Social wellbeing domain of Parent-Caregiver Perception Questionnaire (P-CPQ)

The results of the social wellbeing domain of the P-CPQ are shown in Table 10.

**Table 11 Social wellbeing domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

	Not wanted to talk to other children		Missed school or pre-school	
	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	25	27	13	28
<b>Once or twice</b>	6	2	13	1
<b>Sometimes</b>	2	0	7	0
<b>Often</b>	0	0	0	0
<b>Every day or almost every day</b>	0	0	0	0
<b>Total</b>	33	29	33	29

A large number of parents reported that their children missed school or preschool pre-operatively. Just over 60% of parents said their children missed school or pre-school once or twice, sometimes or often. This decreased to about 3% post-operatively. About a quarter of parents (24%) reported their children not wanting to talk to other children pre-operatively. The percentage decreased to about 7% post-operatively. Figure 10 gives the answers to the social wellbeing domain. Statistically, there was a significant difference between the scores of the pre- and post-treatment results (Wilcoxon  $p < 0.05$ ).



**Figure 10 Social Wellbeing domain of Parent-Caregiver Perception Questionnaire (P-CPQ)**

### 3.7 Family Impact Scale (FIS)

#### 3.7.1 Parental/Family Activity

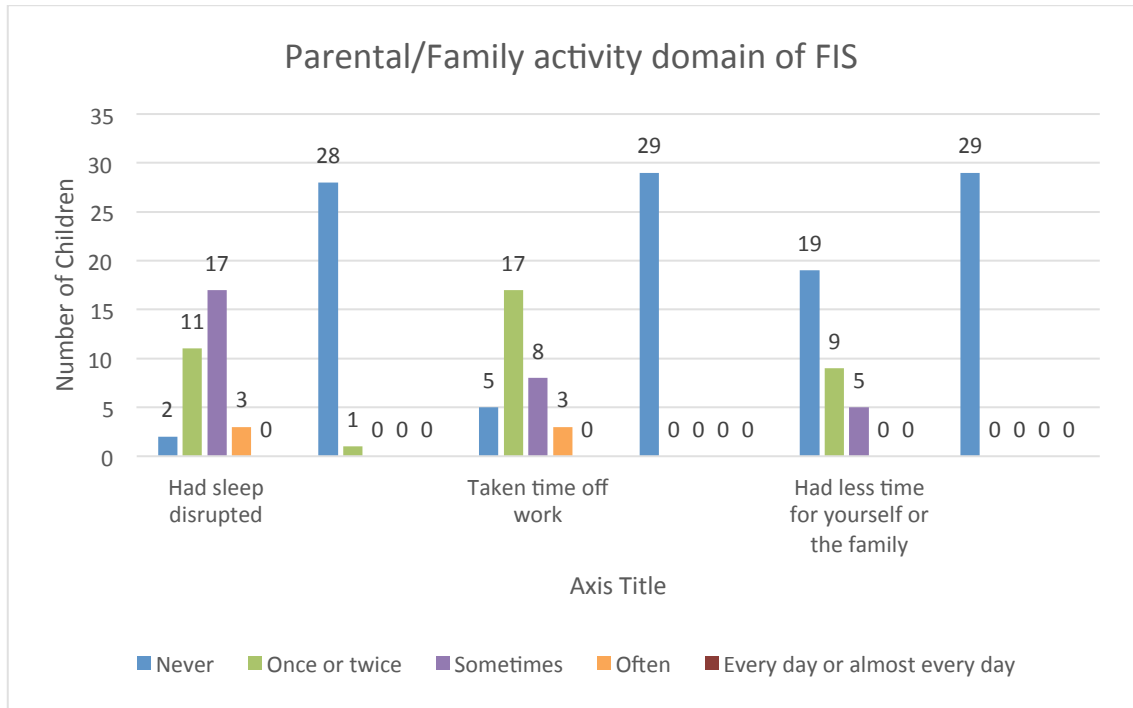
The results of the Parent/Family activity domain of the FIS are presented in Table 12.

**Table 12 Parental/Family activity domain of the Family Impact Scale (FIS)**

	Had sleep disrupted		Taken time off work		Had less time for yourself or the family	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	2	28	5	29	19	29
<b>Once or twice</b>	11	1	17	0	9	0
<b>Sometimes</b>	17	0	8	0	5	0
<b>Often</b>	3	0	3	0	0	0
<b>Every day or almost every day</b>	0	0	0	0	0	0
<b>Total</b>	33	29	33	29	33	29

Nearly 94% of parents experienced sleep disruption, *sometimes*, *once or twice*, *often* as a result of their children's oral status in the last 3 months prior to treatment. Over 84% needed to take time off work and give attention to their child. About 42% thought that they had less time for themselves or their families as a result of a direct or indirect consequence of the oral condition of their children before any treatment. After treatment, only 3% of parents reported having sleep disruption. No parent reported having to take time off work, nor having less time for themselves or the family post-operatively (Figure 11). Statistically, there were significant differences between the scores in the pre- and post-treatment results (Wilcoxon  $p < 0.05$ ).





**Figure 11 Parental / Family activity domain of the Family Impact Scale (FIS)**

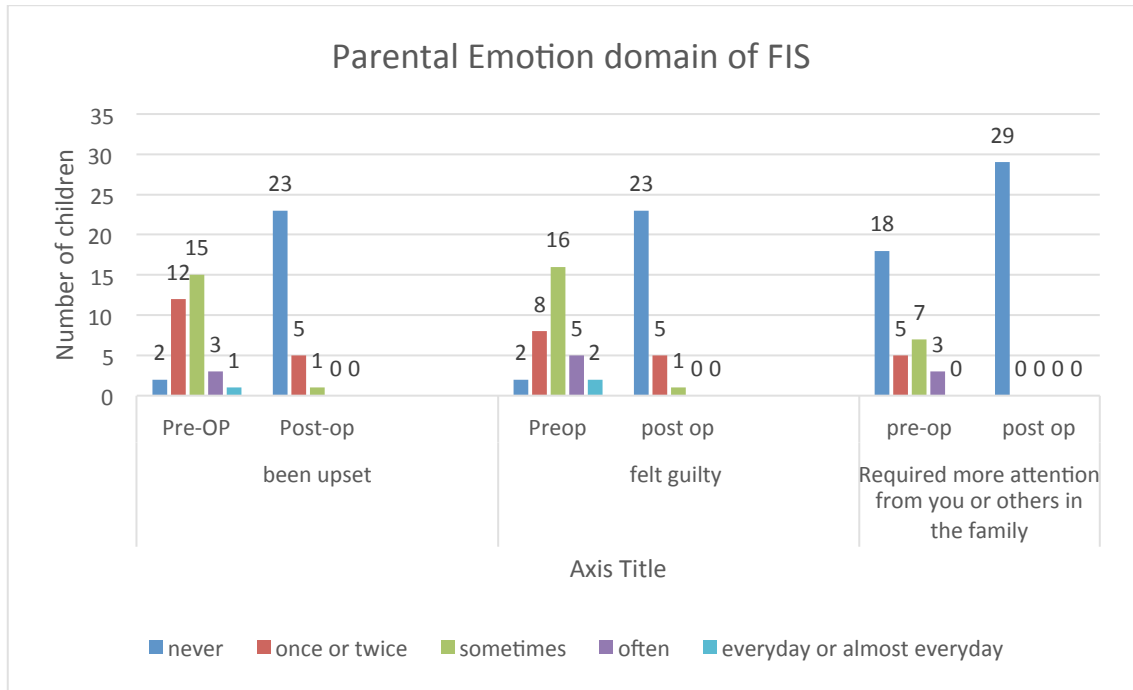
**3.7.2 Parental emotion domain of the Family Impact Scale (FIS)**

Table 13 shows the results of the Parent Emotion domain of the FIS.

**Table 13 Parental Emotion domain of the Family Impact Scale (FIS)**

	Been upset		Felt guilty		Required more attention from you or others in the family	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	2	23	2	23	18	29
<b>Once or twice</b>	12	5	8	5	5	0
<b>Sometimes</b>	15	1	16	1	7	0
<b>Often</b>	3	0	5	0	3	0
<b>Every day or almost every day</b>	1	0	2	0	0	0
<b>Total</b>	33	29	33	29	33	29

Emotional upset and guilt were high impact frequencies for parents scoring about 93% for both pre-operatively. This decreased to about 20% for both factors post-operatively. About half of the parents participated in the study felt that they required more attention from others or a family member prior to treatment. After treatment, no parent recorded any need for any attention from others or a family member (0%) as shown in Figure 12. Statistically, there were significant differences in the scores pre- and post-operatively (Wilcoxon  $p < 0.05$ ).



**Figure 12 Parental Emotion domain of the Family Impact Scale (FIS)**

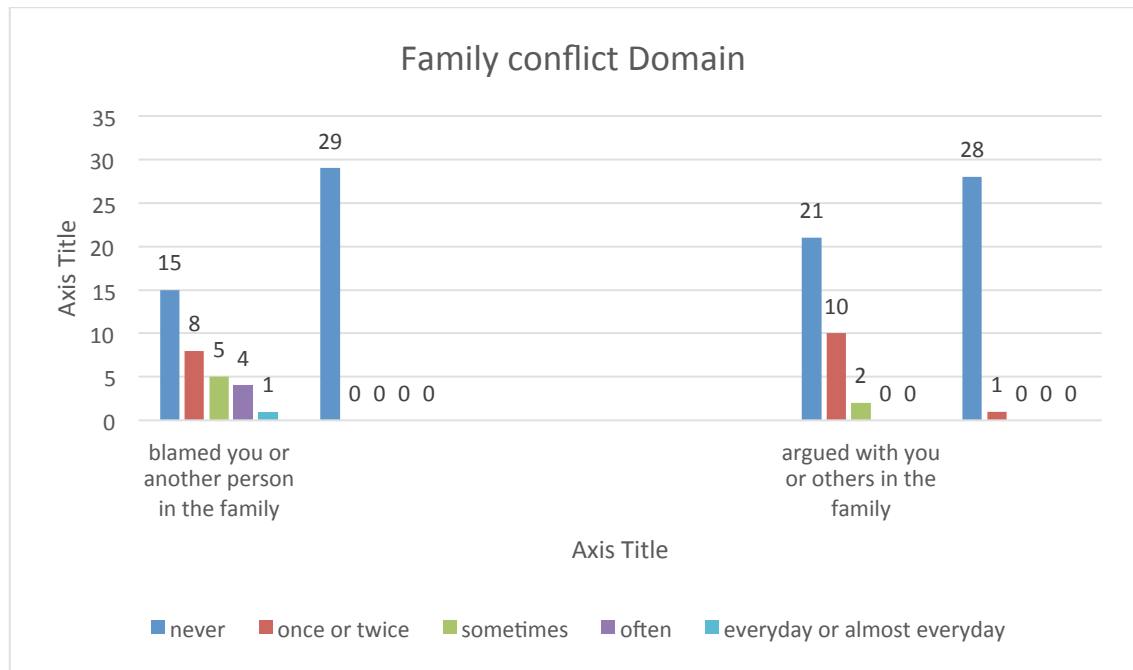
**3.7.3 Family conflict domain of the Family Impact Scale (FIS)**

The results of the family conflict domain of the FIS are shown in Table 14.

**Table 14 Family conflict domain of the Family Impact Scale (FIS)**

	Blamed you or another person in the family		Argued with you or others in the family	
	Pre-op	Post-op	Pre-op	Post-op
<b>Never</b>	15	29	21	28
<b>Once or twice</b>	8	0	10	1
<b>Sometimes</b>	5	0	2	0
<b>Often</b>	4	0	0	0
<b>Every day or almost every day</b>	1	0	0	0
<b>Total</b>	33	29	33	29

Before treatment, 54% and 36% reported that they were blamed by other family members and argued with other family members respectively. After treatment, the percentage decreased to 0% (never) in the case of being blamed by other family members and to 3% in the case of arguing with a family member, as shown in Figure 13. Wilcoxon test showed statistically significant differences between the pre- and post-operative scores (Wilcoxon  $p < 0.05$ ).



**Figure 13 Family conflict domain of the Family Impact Scale (FIS)**

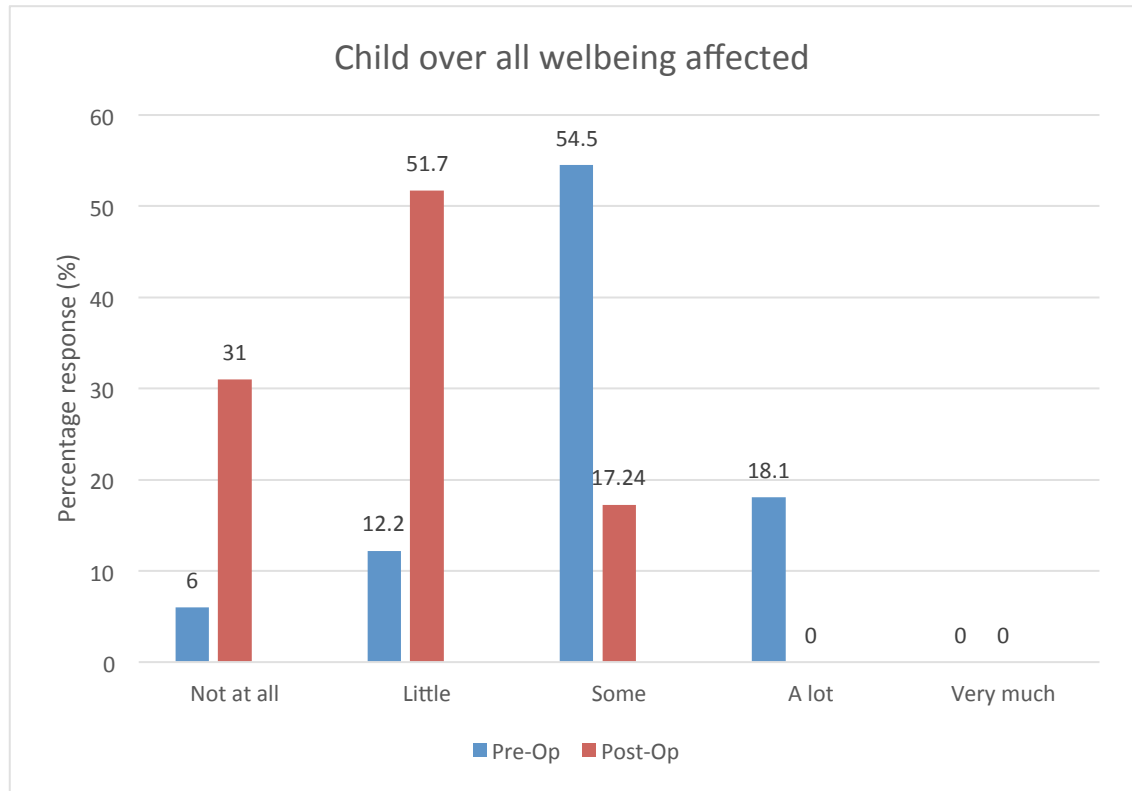
### 3.8 The Global Transition Rating Scale (GTRS)

The GTRS consisted of two questions. They asked about the effect of the oral condition on the overall quality of life of the child and on the quality of life of the family. A third question was added to the post-operative questionnaire, which asked about the overall quality of life of the child after treatment.

#### 3.8.1 Influence of oral status on the child's overall wellbeing

When parents were asked how was the effect of the oral condition on their children, prior to treatment, the majority (54.5%) thought that there was "Some effect". About 18% thought that the oral condition had "A lot of effect on their child's overall wellbeing". Only 6% of the parents thought that there was "no effect" of the oral condition on their child's overall wellbeing. After treatment under GA, on the follow-up questionnaire, the majority of parents answered that the oral condition had a "Little effect" on their child's overall wellbeing. About 17% of the parents thought that the oral condition had "Some effect" on their child's overall wellbeing post-operatively, and

31% reported “no effect” on their child’s overall wellbeing after GA treatment (Figure 14). Statistically, there were significant differences between the effect of the oral condition pre- and post-treatment (Wilcoxon  $p < 0.05$ ).

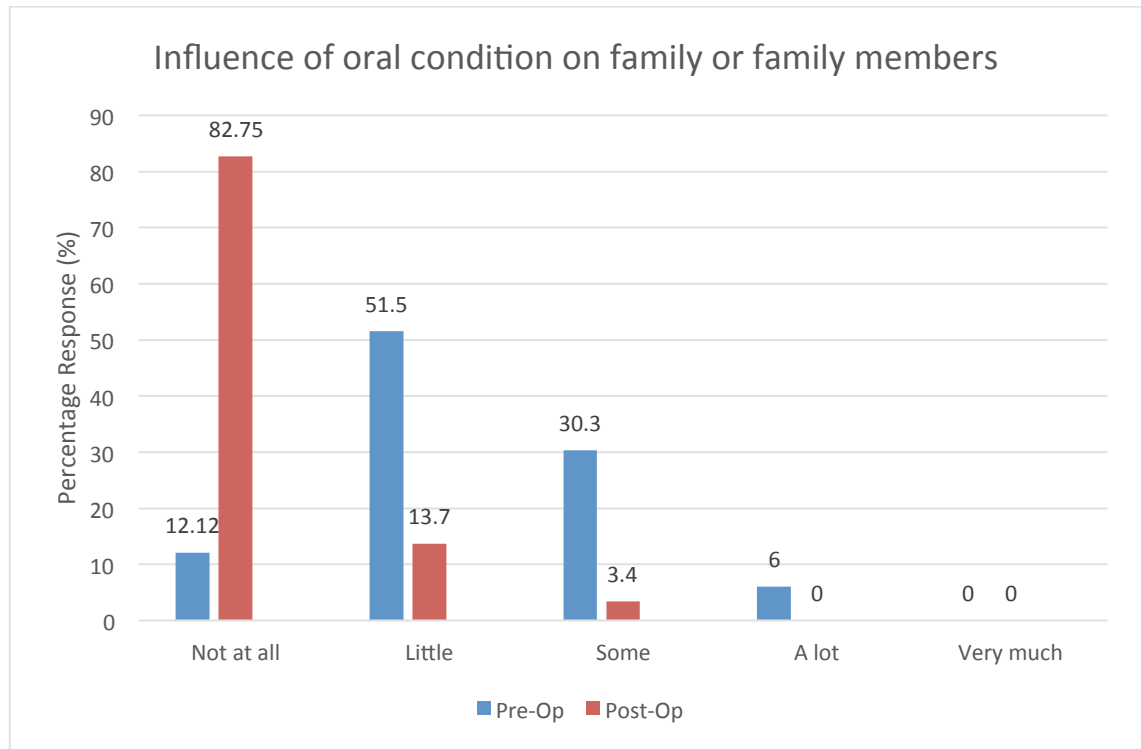


**Figure 14 Child overall wellbeing affected by the oral condition  
For the GTRS**

### 3.8.2 Influence of oral status on family

The second GTRS question asked about the influence of the oral condition the child had on the family and family members. Prior to GA treatment, more than half of the parents thought that the oral condition of their child had a “*Little effect*” on the family or family members. Almost one-third of the parents (30.3%) answered that the oral condition of their child had “*Some effect*” on the family or family members. Only 6% of the parents reported “*A lot of effect*” of the oral condition on the family or family members. About 12% of the parents reported “*no effect*” of the oral condition of

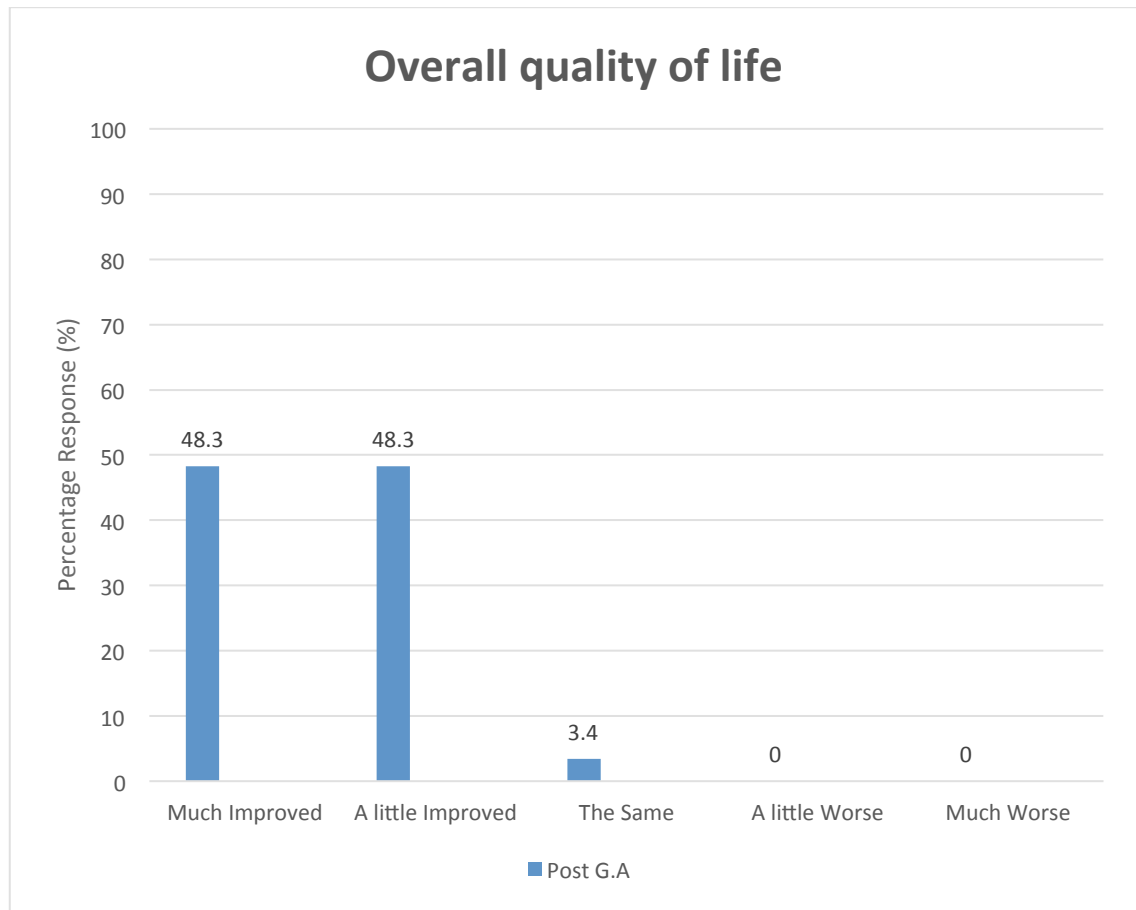
their child on the family or family members prior to GA treatment (Figure 15). Statistical analysis showed significant differences between the effect of the oral condition on the family or family members pre- and post-treatment (Wilcoxon  $p < 0.05$ ).



**Figure 15 Influence of oral condition on family or family members for the GTRS**

### 3.9 Effect on overall quality of life

Following GA almost all the parents reported improvement in their children's quality of life. Almost half of the parents (48.3%) answered "*Much improvement*" to their child's quality of life. The same percentage of parents (48.3%) reported a "little improvement" to their child's quality of life. Only 3.4% (n=1) reported that the quality of life of their child remained the same after GA treatment and that there was no improvement.



**Figure 16 Improvement in overall quality of life**



## Chapter 4 DISCUSSION

This is the second study in the UK to have investigated the impact of ECC on the daily life of young children and their families following dental treatment under GA. The first study was conducted by De Souza (de Souza et al., 2017). Furthermore it is the first study to be carried on in Leeds.

This study was conducted to investigate the effect of dental caries on the quality of life of 3-7 years old children, referred to Leeds Dental Institute for dental extractions under GA. It describes the use of the Parent-Caregivers (P-CPQ) and the Family Impact Scale (FIS), components of the Child Oral Health-Related Quality of Life Questionnaire (COHRQoL©) to assess the quality of life change of those children and their families after treatment of dental caries by extraction under GA. The majority of the children requiring extraction under GA had severe dental caries that caused moderate to severe pain. Provision of treatment was associated with statistically significant improvements in the oral health-related quality of life of the children and their families.

This study is important and adds to the strong evidence of the relationship between treatment of ECC under GA and the improvement of the Oral Health Related Quality of Life of children having the treatment carried on. The results were similar to the studies carried in the UK and other parts of the world.

### 4.1 Sample size and recruitment process

The sample size of this study is low compared to other studies in the same field (Klaassen et al., 2008, Malden et al., 2008, Klaassen et al., 2009). However, there were two previous studies (White et al., 2003, Amin et al., 2006) where they used low sample size and showed that it was representative of the population. The prime investigator discussed the methodology of calculating the sample size with an expert statistician where it was found that this sample size can detect an effect size of 0.7 and with a significance level (alpha) of 0.05 using a two-sided paired t-test. A 20% drop

outs were considered in the sample size calculation as mentioned in section 2.1 in chapter 2. At the end of the study, only 12% (n=4) dropped out of the study. Although data were collected by self-completed questionnaire, there were no missing data. This gives more strength to the study. The fact that there were no significant difference between parents of children who were followed up and others suggest that the group for whom there are complete data should be representative of children who undergo dental treatment under GA in the Leeds population. Children with ECC, who were referred for extractions under GA were included in this study. Because there are different classifications of ECC, we did not include the classification of ECC in the data analysis.

Parents who participated in the study were given the initial questionnaire while waiting for their children to get into the operation theatre for GA. This could have put parents into more pressure and result in questions not been answered in a way to match the current condition of the child as they –certainly- more worried about their children going to GA than filling questions regarding their child's health. A better way could have been done by sending the parents with the questionnaire on the day of initial consultation, then asking them to bring the questionnaire on the day of GA or post them before that to the prime investigator. Or , parents could have been sent home with the questionnaire after their child is finished with his GA, and ask them to post the questionnaire to the prime investigator. The only problem with these two methods is the low questionnaire return that the one would expect in such studies.

The prime investigator acknowledge that the person who filled the initial questionnaire is not recorded, so the investigator did not know if the same person did fill the post-operative questionnaire. This would have cause biased results as perception differ between people, even with parents with the same children.

## **4.2 The mean scores, change in mean scores, and effect size**

Effect size indicates the magnitude of change i.e. provides clinical meaning to an otherwise intrinsically meaningless score. The mean change scores between pre- and post-operative were positive. The results showed similar differences in effect sizes between domains as seen in previous studies (Thomson and Malden, 2011, Malden et al., 2008). The results showed an overall large effect size in both P-CPQ and FIS. These observations are in agreement with the findings of Thomson and Malden (2011) who found a large effect size of the overall FIS in their study, and also in agreement with the findings of Malden et al.(2008) who found an overall large effect size for both P-CPQ and FIS.

### **4.3 Parent-Caregiver Perception Questionnaire (P-CPQ)**

#### **4.3.1 Change in oral symptoms domain**

The oral symptoms domain of the P-CPQ had the largest effect size of all the domains (1.5). The findings for both pre-and post-operatively in this domain were expected, with pain being the highest scoring impact pre-operatively (along with sleep disturbance (Parent/Family activity domain) andhavingbeen upset for the parental emotion domain of the FIS. Malden et al. (2008) found that the highest change in the P-CPQ subscale was in the oral symptoms domain. Low and colleagues reported that less than 50% of the parents in their study felt their children were experiencing pain prior to GA. However, all parents felt their children were pain-free following GA treatment(Low et al., 1999). The results of the study are also in agreement with the findings of White et al. (2013) who found that the highest improvement in dental outcome wasfor the relief of dental pain.

#### **4.3.2 Change in functional limitation domain**

Some parents reported certain functional limitations even after GA treatment. About 17% (n=5) of parents reported that their child took a longer time eating. This could be as a result of extracting multiple teeth and taking a longer time to recover. However,

this did not affect the overall change in the functional limitation domain. This domain had the highest mean change in score and a large effect size (0.98).

The results of this study and similar studies could be of a clinical significance especially in regards to concerns raised by parents regarding post-operative complications after multiple teeth extractions, and their children having some difficulties, for example with chewing food or difficulties in saying words. Thus evidence from this study and similar studies may provide evidence to base reassurance advice to parents that their children will adjust and adapt well following treatment. In fact, some studies, as mentioned previously in the literature review, showed that there was an increase in body weight and resulted in the phenomenon of 'catch-up growth' of children who were below normal weight for age, following dental rehabilitation under GA despite the number of teeth extracted (Acs et al., 1999).

#### **4.3.3 Change in emotional wellbeing**

Many parents appreciated and reported the effect of dental caries on their children's wellbeing. Because of dental caries, as high as 91% and 82% of parents reported that their children felt upset and had been irritable or frustrated respectively. Following treatment, about one third of the parents (31%) still reported that their child felt upset once or twice. The reason for this could be the post-operative pain or discomfort a child might have experienced after extraction.

#### **4.3.4 Changes in social wellbeing**

About 60% of parents reported that their children missed school pre-operatively because of dental caries. Even after treatment, there were still parents reporting their children missing school because of dental caries (3.4%). This could be because some children need more time to recover after multiple dental extractions under GA. This is an important and significant finding that shows the link between dental caries and school performance of children.

The results are in agreement with many of the studies in the literature that looked into dental caries and school performance of children. The missed school time could lead to a decline in school performance as was shown in the literature (Wolfe, 1985, Fowler et al., 1985, Jackson et al., 2011, Garg et al., 2012). A quarter of the parents reported that their children, pre-operatively, did not want to talk to other children.

In my opinion, this impact is negligible as the literature has shown that parental knowledge regarding some aspects of their children's lives (social and psychological wellbeing) is inaccurate and limited (Barbosa and Gaviao, 2008). This highlights the limited usefulness of proxy reporting questionnaires.

## **4.4 Family Impact Scale (FIS)**

### **4.4.1 Parental / Family Activity**

There was a major and significant reduction of the impact of dental caries on the parental/ family activity domain following the GA treatment. The mean change in the score of the domain was 3.46 with a large effect size (1.48). This was not surprising knowing that children at this age are wholly dependent on their parents/caregiver to meet their daily needs. A healthier child meant less time spent requiring health care, less time taken off work, and more time to spend with the family. Many studies have shown that the child's oral condition had a pervasive impact on the family (Locker et al., 2002).

### **4.4.2 Parental Emotion**

Not surprising, a large number of parents (93.9%) felt guilty and been upset because of their children's condition. The author observed many parents, who participated in the study blaming themselves for not taking care of their children's teeth or for allowing them access to frequent sweets. However, there was still some parents (20.6%) who reported that they were upset and felt guilty even after their children had GA treatment. Thomson and Malden observed similar findings in their study (Thomson and Malden,

2011). Following treatment, no parents reported requiring more attention from others in the family.

The parental emotion domain had a large effect size reaching 1.38. Thomson and Malden found in their study that the parental emotion sub-scale performed well and showed an effect size which was of similar magnitude to the observed with the overall FIS.

#### **4.4.3 Family Conflict**

The family conflict domain showed a large effect size (0.79). There was positive change in the scores of the domain with 1.42 as the mean change in score.

More than half of the parents participated in this study reported that they were blamed or blamed another person in the family because of the oral condition of their children. This is not uncommon given that taking care of children is a sharing responsibility of the family. However, after treatment, the score dropped to zero indicating that solving the child's oral health problem could have helped in eliminating the blame between the family members.

One-third (36.3%) of the parents that participated in this study argued once or twice or sometimes with others in the family because of the oral condition of their children. The score decreased to 3.4% after treating the child's dental caries. In my opinion, arguments could have arisen as a result of feeling guilty and not wanting the child to go through the same experience.

### **4.5 The Global Transition Rating Scale (GTRS)**

#### **4.5.1 Influence of oral status on the child's overall wellbeing**

Over two-thirds of the parents reported that the status of oral health had little or some effect on the overall wellbeing of their children prior to GA treatment. However, there was still a high number of parents (51% and 17.24% reported *little* and *some* effect respectively) indicated that the overall wellbeing of their children was still affected even

post-GA treatment. In my opinion, many of the parents might not have understood the question correctly. Some of the parents, when answering questions post-operatively required more clarification about what the question meant and what aspects it intended to cover. For the one-third of the parents who thought that oral status had no effect at all post-operatively, the tangible impact of the treatment might have presented a solution for them, particularly if their child had been visibly suffering and showing a deteriorated quality of life. Acs et al. observed similar findings in their study (Acs et al., 2001). White et al. also reported a positive effect of GA treatment on the children's overall health (White et al., 2003).

#### **4.5.2 Influence of oral status on family**

A large number of parents (87%) reported their family life to be affected by their children's oral condition prior to GA treatment. This is expected especially after the FIS scoring showed a high score prior to GA treatment. After treatment, many of the parents thought that the improvement in their children's oral health resulted in an improvement in the family status with about 83% of parents reporting no effect of the oral condition on the family or family member. This may indicate that parents recognise the interplay between their children's OHRQoL and impact on the wider family.

#### **4.5.3 Effect on overall quality of life**

At the end of the post-operative questionnaire, parents were asked to rate the overall quality of life of their children after treatment. Almost all of the parents reported improvements in their children's overall quality of life after GA treatment. Only 3.4% thought that the quality of life of their children remained the same and the treatment had no effect. The reason behind this could be that the impact of dental caries on their children was mild and treating it did not have an overall change in the quality of life of the child. It must be mentioned that for some children it is the dental treatment rather than the GA itself that could have a negative impact on the child's OHRQoL. Some of

the parents did report that their children had some difficulties immediately or few days after GA. This was expected especially with children who never had any experience of dental extractions. The emotional effect of losing teeth could have been reduced –in my opinion- by preparing the child by the parents and the paediatric dentist to what to expect and how to react to it and by reassuring the child and the parents as well. Amin et al reported that some children had difficulties coping with the consequences of the extractions of their teeth and having some emotional reaction to the loss of their teeth as losing a number of teeth was a shock to come children (Amin et al., 2006)



## 4.6 Limitations of the study

This was an uncontrolled, no-randomised study. However, conducting a randomised controlled study in this area of research is very difficult and can be unethical. A controlled group is needed where no treatment is provided to the children in that group. Of course no ethics will allow such a process or a study to be carried. A convenience sample was used introducing sampling bias. This kind of bias can be difficult to overcome in such a study. The low sample size was acknowledged. A larger sample size similar to the sample size in similar studies should be considered. Another limitation of this study is recall bias. The pre-operative questionnaire asked about events that might have happened in the previous 3 months. Sometimes it is difficult to recall such events that might have happened, Moreover, the parents were filling the pre-operative questionnaire on the day of the GA. With no doubt, they are very anxious and more concerned about their child's GA , than answering a questionnaire on their health. This could be overcome by asking the questionnaire on the day of the consultation appointment or by posting the questionnaire to the parents immediately after the GA. A major limitation is that the questionnaire is proxy reporting not self-reporting, as it is been filled by the parents not the child. The answers may reflect the degree to the which the parent is affected physically or emotionally by the child's condition. However, using these questionnaires has been shown to be a valid approach especially for young children. The exclusion of parents who did not speak English could have caused or contributed to the sampling bias. Including these parents would mean using tested and translated versions of the questionnaires. Those versions should have been teste for validity and reliability. Another major limitation is not collecting the socio-economic demographic data. This would have helped in assessing if the low socio-economic children would have an increased risk of dental caries. It will also allow comparison of change of OHRQoL in different

socioeconomic groups, and to see if OHRQoL improves more with the low socioeconomic groups. Another limitation is not recording the person who is filling the initial (Pre-Op) questionnaire and making sure that the same person is answering the post-op questionnaire. This would have caused information bias as different people have different perception to how or what, for example affect the quality of life of a child and the extent of the effect. For example, what a mother might recognise as causing great effect to a child , a father might think the effect is mild or moderate.

#### **4.7 Suggestions for future research**

The author suggests that further research is needed to develop, evaluate and test self-reporting measure, to directly evaluate the child's perspective in this field. A very simple questionnaire with answers showing happy, sad or crying faces could be used. Moreover a daily or weekly diary with these questions could be used to assess children as it is difficult for them to recall events that happened in the past.

As this research was looking into one group of treatment, the author suggests comparing different treatment approaches on the OHRQoL of children (restorations and extractions vs extractions only). Another suggestion is to evaluate the long term OHRQoL effect on children by following up the children for longer periods (6 months, 1 year, 2 years). Further research is needed to correlate child dental anxiety and fear with OHRQoL and establish if treatment under GA helps to reduce child dental anxiety in relation to provision of treatment.

Finally , the author suggests that more research needs to be done to assess and evaluate the cost-effectiveness of GA treatment in relation to OHRQoL and compare it to other behaviour management techniques, for example sedation.

#### **4.8 Null Hypothesis outcomes**

- 1- The null hypothesis 'There is no difference in the effect of multiple tooth extraction under GA on the quality of life of children before and after treatment' can be rejected as significant difference was observed before and after GA treatment of children.
  
- 2- The null hypothesis 'There is no difference in the effect of multiple tooth extraction under GA on the quality of life of the child's family before and after treatment' can be rejected as significant difference was observed for the quality of life of the child's family before and after treatment.

## CONCLUSIONS

The purpose of this study was to evaluate the impact of ECC on the quality of life of young children and their families, and to examine if the treatment of ECC under GA improves the quality of life of children and their families.

ECC has a negative impact on the quality of life of children and their parents. A significant number of parents reported improvement in the quality of life of their children and the family following the provision of dental treatment under GA. Thus the two null hypothesis that there were no differences in the effect of dental extraction of multiple teeth under GA on the quality of life of children and their families.

A consideration for future research is to construct a child-reported questionnaire to survey the children directly in addition to the parents/caregivers.

Further research is needed to assess the cost-effectiveness of treating young children under GA in relation to OHRQOL measures.

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## APPENDICIES

### Appendix A : HRA ethical approval



Health Research Authority

Mr Ibrahim AIShekaili  
 Post Graduate Student  
 Currently a fulltime student doing a Professional Doctorate  
 degree in Paediatric  
 Leeds Dental Institute  
 Clarendon Way  
 LS2 9LU

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

28 June 2016

Dear Mr AIShekaili,

#### Letter of HRA Approval

<b>Study title:</b>	<b>The impact of multiple caries and its treatment by multiple exodontias under GA, on quality of life of children and their families.</b>
<b>IRAS project ID:</b>	<b>200991</b>
<b>REC reference:</b>	<b>16/N/0107</b>
<b>Sponsor</b>	<b>University of Leeds</b>

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

#### Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

*Appendix B* provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from [www.hra.nhs.uk/hra-approval](http://www.hra.nhs.uk/hra-approval).

### Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

### After HRA Approval

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](http://www.hra.nhs.uk), and emailed to [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net).
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](http://www.hra.nhs.uk).

### Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.



IRAS project ID	200991
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**User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

**HRA Training**

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **200991**. Please quote this on all correspondence.

Yours sincerely

**Miss Lauren Allen**  
**Assessor**

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

*Copy to:*

*Ms Anne Gowing, Leeds Teaching Hospitals NHS Trust Research & Development department (Lead NHS R&D contact)*

IRAS project ID	200991
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### Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover letter]	V.1	08 June 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		22 September 2015
IRAS Application Form [IRAS_Form_16052016]		16 May 2016
Letter from sponsor [Sponsor Letter]	V.1	04 May 2016
Other [COHLQoLQ (Post Op)]	V.1	10 May 2016
Other [Prof Jack Toumba CV]		
Participant consent form	6	23 June 2016
Participant information sheet (PIS)	7	23 June 2016
Research protocol or project proposal [Research Protocol]	V.7	25 May 2016
Summary CV for Chief Investigator (CI) [CV]	V.1	10 May 2016
Summary CV for student [Student CV]	V.1	10 May 2016
Summary CV for supervisor (student research) [Supervisor CV]	V.1	10 May 2016
Validated questionnaire [COHRQoL Q(Pre Op)]	V.3	10 May 2016

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## Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

**For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.**

The following is the sponsor contact for the purpose of addressing participating organisation questions relating to the study: [governance-ethics@leeds.ac.uk](mailto:governance-ethics@leeds.ac.uk), 01133437587

### HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	It has been confirmed that Leeds Teaching Hospitals should be listed as the participating NHS organisation at Part C, IRAS.
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial single NHS site study sponsored by a partner organisation, and the participating NHS site has confirmed that an agreement with the study sponsor will not be required.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this

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Section	HRA Assessment Criteria	Compliant with Standards	Comments
			research study
4.3	Financial arrangements assessed	Yes	No funding will be provided to the participating NHS organisation.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

### Participating NHS Organisations in England

*This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.*

There is one site-type. This is a non-commercial single NHS site study. Participants will complete a questionnaire in clinic. The research team will contact participants 6-8 weeks later to complete a second questionnaire via telephone.

If this study is subsequently extended to other NHS organisation(s) in England, an amendment should be submitted to the HRA, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). The HRA will work with these organisations to achieve a consistent approach to information provision.

### Confirmation of Capacity and Capability

*This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.*

The HRA has determined that participating NHS organisations in England **are not expected to formally confirm their capacity and capability to host this research**, because this is a non-commercial single NHS site study sponsored by a partner organisation where the participating NHS organisation has confirmed that there are previous arrangements in place.

- The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.
- Following issue of the Letter of HRA Approval the sponsor may commence the study at these organisations when it is ready to do so.
- The document "[Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected](#)" provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations. Further study specific details are provided the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this Appendix.

### Principal Investigator Suitability

*This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).*

This is a single NHS site study and the student researcher will act as Principal Investigator (PI), therefore no additional PI or Local Collaborator (LC) is required.

If this study is extended to other NHS organisation(s) in England a further assessment of the need for

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a PI or LC at the additional sites will be made.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

### HR Good Practice Resource Pack Expectations

*This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken*

No access arrangements will be required for study activity conducted by members of the research team who have a contractual relationship with the relevant organisation.

If study activity will be conducted by members of the research team who do not have a contractual relationship with the relevant organisation then letters of access will be needed. Disclosure and Barring Service and Occupational Health checks will need to be in place where a letter of access is required.

### Other Information to Aid Study Set-up

*This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.*

- The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.



Date: 08 June 2016 (V.1)

IRAS Project ID: 200991

**School of Dentistry**

University of Leeds  
Clarendon Way  
Leeds LS2 9LU

T +44 (0) 113 343 6199

F +44 (0) 113 343 6165



## **Invitation letter**

**Research Title:**

**A research to study the effect of dental decay on children's wellbeing and everyday life, and the effects on their families.**

Dear Parents / Guardians

Please be aware that when you arrive at the clinic for your referral appointment you will be asked to sign the consent form to confirm that you are content to take part in the study.

- If you are interested, the project investigator will give you a copy of the information sheet with more information on it.
- Please note the treatment your child has been planned for and receives will be unaffected by this study
- You will be asked to complete a questionnaire (tick box style) with the help of the researcher on the day of the dental operation which asks questions relating to how you think your child's lip, teeth and mouth affects various aspects of their quality of life over the last 3 months prior to the treatment they are to receive that day
- With your consent, the same questionnaire will be conducted with you over the telephone 6- 8 weeks after completion of your child's treatment reviewing your child's quality of life since the dental treatment
- You can stop taking part in the research at any time. This will not affect the care your child will receive

**Thank you for taking the time to read this invitation to take part in this study**

# Appendix C : Parent Information Sheet

Date: 23-June 2016, (V.7)

IRAS Project ID: 200991

## School of Dentistry

University of Leeds  
Clarendon Way  
Leeds LS2 9LU

T +44 (0) 113 343 6199  
F +44 (0) 113 343 6165



## Parents Information Sheet

### Research Title:

A research to study the effect of dental decay on children's wellbeing and everyday life, and the effects on their families.

### Introduction

You are invited to take part in the above research study at Leeds Dental Institute. Before you decide whether or not to take part, please take time to read the following information carefully in order to understand what this research is about and what your participation involves. Please feel free to discuss with other people and ask us if you wish to clarify any matters regarding this research. Taking part in the study will approximately add 5-10 minutes to your appointment.

### Study Purpose

The purpose of this study is to help dentists and dental care providers to identify the effect of dental caries on the quality of life of your child. Additionally, we shall look at the effect of treatment under general anaesthesia on the quality of life of the child and his family. This study will be funded by the Faculty of Medicine and Health, University of Leeds.

### Some Questions You May Have

#### Why have I been chosen?

You have been chosen because your child is having his/her teeth removed under general anaesthesia in One Day Unit at Leeds Dental Institute.

#### Do I have to take part?

You are not obliged to participate **and this won't affect the treatment that your child is going to receive**. We will go through this information sheet and explain this study to you. You are free to withdraw from the study at any time without giving a reason.



Date: 23-June 2016, (V.7)

IRAS Project ID: 200991

**What do I have to do?**

A questionnaire will be handed to you that will ask you some questions about your child and how does he/she feel and how is the dental decay affecting their life. Then 6 to 8 weeks later, a phone call will follow and you will be asked the same questions.

**What are the possible benefits of taking part?**

There are no direct benefits for participants taking part in the study. We hope to understand more about the effect of dental caries on the quality of life of young children. We will also know more about the quality of life changes after the treatment under general anaesthesia.

**What are the possible risks of taking part?**

Your participation will not affect the care we provide for your child both now and if they ever require future treatment. There are no risks to you or your child in taking part in this study.

**What will happen if I decided not to continue with the study?**

You can withdraw from the study at any time; this won't affect your child's treatment in any way. Unless you ask us not to, the information already collected shall be used in the analysis.

**Will my taking part in this study be kept confidential?**

Yes. All information which is collected about you during the course of the research will be kept strictly confidential and anonymous. Collected data will be stored anonymously on a secure, password protected database (on university of Leeds secure server), in keeping with the Data Protection Act 1998. This data will not be accessible to anyone other than the immediate study team. This data will be stored for up to 3 years and may be used in future research and for educating dentists and the dental team.

**What will happen to the result of the research?**

The researchers' intention is to publish the findings of this study. You and your child will not be identified in any report or publication. There will be no disclosure of information to a third party. You may withdraw any data/ information you have already provided up until it is transcribed for use in the final report.

Date: 23-June 2016, (V.7)

IRAS Project ID: 200991

**What if I need to complain?**

The normal complaints process will apply. You can have more information on the NHS Patient Advice and Liaison Service (PALS) website [<http://www.pals.nhs.uk/>]. You can also contact the local PALS office in Leeds; their contact details are as follows:

*Telephone:* 0800 0525270

*Email:* [pals@leedspt.nhs.uk](mailto:pals@leedspt.nhs.uk)

*Office Address:*

Patient Advice and Liaison Service

NHS Leeds

1st floor, North West House

West Park Ring Road

Leeds, LS16 6QG

**Who is organising and funding this research?**

This research is funded by the Faculty of Medicine and Health, University of Leeds.

**Who can I contact for further information?**

If you have further questions, you can contact

- Ibrahim AlShekaili: Email: [dnia@leeds.ac.uk](mailto:dnia@leeds.ac.uk)
- Professor M. Duggal: Telephone: 0113 3436177

Email: [M.S.Duggal@leeds.ac.uk](mailto:M.S.Duggal@leeds.ac.uk)

## Appendix D : Consent Form

Date: 23 June 2016 (V.6)

IRAS Project ID: 200991

### School of Dentistry

University of Leeds  
Clarendon Way  
Leeds LS2 9LU

T +44 (0) 113 343 6199

F +44 (0) 113 343 6165


**UNIVERSITY OF LEEDS**
Patient Identification No: 

### Consent form

#### Research Title:

A research to study the effect of dental decay on children's wellbeing and everyday life, and the effects on their families.

*Please initial the box if you agree with the statement to the left.*

- |   |  |                          |
|---|--|--------------------------|
| 1 | I confirm that I have read and understand the information sheet/letter explaining the above research project and I have had the opportunity to ask questions about the project and I have them answered satisfactory.  | <input type="checkbox"/> |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. | <input type="checkbox"/> |
| 3 | I understand that my child's name will not be linked with the research materials, and we will not be identified or identifiable in the report or reports that result from the research.  | <input type="checkbox"/> |
| 4 | I agree for the anonymous data collected from our participation to be used in future research and for educating dentists and the dental team.  | <input type="checkbox"/> |
| 5 | I agree to take part in the above research project.  | <input type="checkbox"/> |

_____	_____	_____
Name of participant	Date	Signature

*(Or legal representative and relationship)*

_____	_____	_____
Lead researcher Signature <i>the participant.</i>	Date	<i>To be signed and dated in presence of</i>

1 copy for participant and 1 for investigator file.

# Appendix E : Pre-operative COHRQoL<sup>®</sup> Questionnaire

COHRQoL Q's V 3

Date 10/05/2016

IRAS Project ID: 200991

School of Dentistry

University of Leeds  
Clarendon Way  
Leeds LS2 9LU

T +44 (0) 113 343 6199  
F +44 (0) 113 343 6165  
E dentistry@leeds.sc.uk



## Pre-Operative

### CHILD ORAL HEALTH QUESTIONNAIRE: P/CPQ & FIS

#### Section 1:

The following questions ask about symptoms and discomfort that children may experience due to the condition of their teeth, lips, mouth and jaws.

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

<b>Had pain in the teeth, lips, jaw or mouth?</b>					
<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 food caught in or between the teeth?</b>					
<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 difficulty biting or chewing firm foods such as fresh apple, corn on the cob or firm meat?</b>					
<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>Taken longer than others to eat a meal?</b>					
<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>Been irritable or frustrated?</b>					
<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>Been upset?</b>					
<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>Not wanted to talk to other children?</b>					
<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>Missed school or preschool?</b>					
<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 bad breath?</b>					
<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>Breathed through the mouth?</b>					
<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 troubles sleeping?</b>					
<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 difficulty saying any words?</b>					
<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

**Section 2:**

**The following questions ask about effects that your child's oral condition may have on PARENTS AND OTHER FAMILY MEMBERS.**

During the *last 3 months*, because of your child's teeth, lips, mouth or jaws, how often have you or another family member:

<b>Been upset?</b>					
<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>Felt guilty?</b>					
<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 sleep disrupted?</b>					
<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>Taken time off work (e.g. due to pain, appointments, surgery)?</b>					
<input type="checkbox"/> Never	<input type="checkbox"/> Once or twice	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Often	<input type="checkbox"/> Every day or almost every day	<input type="checkbox"/> Don't know
<b>Had less time for yourself or the family?</b>					
<input type="checkbox"/> Never	<input type="checkbox"/> Once or twice	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Often	<input type="checkbox"/> Every day or almost every day	<input type="checkbox"/> Don't know
<b>Blamed you or another person in the family?</b>					
<input type="checkbox"/> Never	<input type="checkbox"/> Once or twice	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Often	<input type="checkbox"/> Every day or almost every day	<input type="checkbox"/> Don't know
<b>Argued with you or others in the family?</b>					
<input type="checkbox"/> Never	<input type="checkbox"/> Once or twice	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Often	<input type="checkbox"/> Every day or almost every day	<input type="checkbox"/> Don't know
<b>Required more attention from you or others in the family?</b>					
<input type="checkbox"/> Never	<input type="checkbox"/> Once or twice	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Often	<input type="checkbox"/> Every day or almost every day	<input type="checkbox"/> Don't know

**GLOBAL TRANSITION RATING SECTION**

**How much is your child's overall well-being affected by the condition of his/her teeth, lips, jaw or mouth?**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all	Very little	Some	A lot	Very much

**How much is the daily life of your family affected by the condition of his/her teeth, lips, jaw or mouth?**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all	Very little	Some	A lot	Very much



# Appendix F :Post-operative COHRQoL<sup>©</sup> Questionnaire

Post-OP Q's V1  
School of Dentistry

Date 10/05/2016

IRAS Project ID: 200991

University of Leeds  
Clarendon Way  
Leeds LS2 9LU

T +44 (0) 113 343 6199  
F +44 (0) 113 343 6165  
E dentistry@leeds.sc.uk



Post-Operative (6-8 weeks)

## CHILD ORAL HEALTH QUESTIONNAIRE: P/CPQ & FIS

### Section 1:

The following questions ask about symptoms and discomfort that children may experience due to the condition of their teeth, lips, mouth and jaws.

Since the dental operation, how often has your child had:

<b>Had pain in the teeth, lips, jaw or mouth?</b>					
<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 food caught in or between the teeth?</b>					
<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 difficulty biting or chewing firm foods such as fresh apple, corn on the cob or firm meat?</b>					
<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>Taken longer than others to eat a meal?</b>					
<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>Been irritable or frustrated?</b>					
<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>Been upset?</b>					
<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>Not wanted to talk to other children?</b>					
<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>Missed school or preschool?</b>					
<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 bad breath?</b>					
<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>Breathed through the mouth?</b>					
<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 troubles sleeping?</b>					
<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 difficulty saying any words?</b>					
<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

**Section 2:**

**The following questions ask about effects that your child's oral condition may have on PARENTS AND OTHER FAMILY MEMBERS.**

Since the dental operation, because of your child's teeth, lips, mouth or jaws, how often have you or another family member:

<b>Been upset?</b>					
<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>Felt guilty?</b>					
<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 sleep disrupted?</b>					
<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>Taken time off work (e.g. due to pain, appointments, surgery)?</b>					
<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 less time for yourself or the family?</b>					
<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>Blamed you or another person in the family?</b>					
<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>Argued with you or others in the family?</b>					
<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>Required more attention from you or others in the family?</b>					
<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

**GLOBAL TRANSITION RATING SECTION**

<b>How much is your child's overall well-being affected by the condition of his/her teeth, lips, jaw or mouth?</b>				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all	Very little	Some	A lot	Very much
<b>How much is the daily life of your family affected by the condition of his/her teeth, lips, jaw or mouth?</b>				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all	Very little	Some	A lot	Very much
<b>Since the operation to treat your child's teeth, has your child's overall quality of life been....</b>				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Much improved	A little Improved	The Same	A little worse	Much worse

*Thank you for taking time to fill the questionnaire.*

## Appendix G : University of Leeds Indemnity Certificate of Liability

**HENDERSON**  
INSURANCE BROKERS

Henderson Insurance Brokers Limited  
Trueman House  
Capitol Park  
Leeds  
LS27 0TS

22 September 2015

Tel 0113 393 6300  
Fax 0113 393 6363

[www.hibl.co.uk](http://www.hibl.co.uk)

**To Whom it May Concern**

Dear Sirs,

**EVIDENCE OF INSURANCE – The University of Leeds &/or Subsidiary Companies**

We are writing to confirm that we act as Insurance Brokers to the above client and that we have arranged liability insurance on their behalf as detailed below:

**EMPLOYERS LIABILITY**

Cover in respect of indemnity for claims made for death, injury or disease to any person arising out of and in the course of their employment.

INSURER	:	Zurich Municipal
POLICY NUMBER	:	NHE-03CA02-0015
PERIOD OF INSURANCE	:	29 <sup>th</sup> September 2015 – 28 <sup>th</sup> September 2016
LIMIT OF INDEMNITY	:	£40,000,000 each occurrence including costs and expenses

**PUBLIC/PRODUCTS LIABILITY**

Indemnity in respect of claims made for death, injury or disease to persons (other than employees) or loss or damage to third party property arising out of and in the course of the business.

INSURER	:	Zurich Municipal
POLICY NUMBER	:	NHE-03CA02-0015
PERIOD OF INSURANCE	:	29 <sup>th</sup> September 2015 – 28 <sup>th</sup> September 2016
LIMIT OF INDEMNITY	:	£40,000,000 each occurrence (and in the aggregate in respect of Products)

**PROFESSIONAL INDEMNITY**

Indemnity in respect of the Legal Liability to Third Parties for breach of professional duty due to negligent act, error or omission in connection with your business.

INSURER	:	Royal & Sun Alliance
POLICY NUMBER	:	RKK665002
PERIOD OF INSURANCE	:	29 <sup>th</sup> September 2015 – 28 <sup>th</sup> September 2016
LIMIT OF INDEMNITY	:	£10,000,000 each occurrence and in the aggregate

Subject to the policy terms, conditions, limitations, exclusions and cancellation provisions.

This document is issued as a matter of information only and confers no rights upon the document holder other than those provided by the policy. This document does not amend, extend or alter the coverage afforded by the policy or policies as described herein.

/Continued.....

Registered Office: Trueman House · Capitol Park · Leeds · LS27 0TS  
Authorised and Regulated by the Financial Conduct Authority (FCA)  
Company Registration Number - 1985767

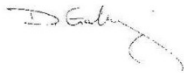


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Notwithstanding any requirement, term or condition of any contract or other document with respect to which this document may be issued or pertain, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions or exclusions of such policy (policies). Limits shown may have been reduced by paid claims.

If you should require any further information or the above please do not hesitate to contact us.

Yours faithfully,



David Galey  
Broking Manager

**Direct Dial:** 0113 393 6825  
**Email:** david.galey@hibl.co.uk



