

**Changes in Oral Health Related Quality of Life in Children  
Following Dental Extractions Under a General Anaesthetic  
Using Two Child Self-Report Measures**

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

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### III

## **Dedication**

To my parents, Haya and Tareq, for their endless support and encouragement throughout my education.

To my Sulaiman.

## Abstract

**Title** Changes in oral health related quality of life in children following dental extractions under a general anaesthetic using a child self-report measure

**Aims and Objectives** The main aims of the present study were firstly to measure changes in OHRQoL using a child self-report measure before dental extractions under a general anaesthetic and after one and three months. Secondly, to elicit children's experiences of dental extractions under a general anaesthetic using an interview topic guide.

**Method** Children aged five to eight years seen at the Leeds Dental Institute for dental extractions under a general anaesthetic were invited in this study. This study was constituted of two phases. The first phase included a quantitative prospective longitudinal study, which involved measuring status and changes in OHRQoL in children seen at the Leeds Dental Institute for dental extractions under a general anaesthetic. Changes in OHRQoL status was measured using the CARIES-QC questionnaire, prior to commencing the treatment and then followed at one and three months after the treatment. The second phase was a qualitative study; semi-structured qualitative interviews were undertaken with children who underwent dental extractions under a general anaesthetic. Participants were all selected from the One Day Unit, an outpatient clinic. The interviews were recorded and transcribed verbatim. Data was analysed using the framework analysis method.

### Results:

**Phase 1** : In total, 35 children were recruited, and 28 were followed-up. There was a statistically significant improvement in OHRQoL following dental extractions under general anaesthesia ( $p < 0.005$ ). The effect size was large at one-month (0.93) and three-months (1.66). There was a statistically significant moderate correlation between

total number of teeth extracted and follow-up CARIES-QC score,  $r = 0.453$ ,  $p < 0.05$ .

However, there was no statistically significant difference between total number of teeth extracted and difference in CARIES-QC score between baseline and follow-up,  $r = 0.15$ ,  $p = 0.45$ .

**Phase 2:** Five, dentally anxious, children who underwent dental extractions under general anaesthesia were included in this study. The interviews were carried out at a range of 10-15 weeks following their procedure. The main themes explored in the interviews were: pre-operative events, general anaesthesia experience, post-operative events, and treatment preference. All children reported they would prefer to have dental extractions under general anaesthesia as opposed to other treatment approaches.

**Conclusion** Dental extractions under general anaesthesia resulted in substantial improvement in OHRQoL in children with dental caries. Children with higher numbers of teeth extractions had poorer OHRQoL at baseline and follow-up. Children interviewed in this study demonstrated a variety of immediate and delayed impacts of dental extractions under general anaesthesia. Although some negative impacts were mentioned, the overall dental general anaesthesia experience was positive.

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**Abbreviations**

<b>CARIES-QC</b>	Caries Impacts and Experiences Questionnaire for Children
<b>CPQ</b>	Child Perceptions Questionnaire
<b>COHIP</b>	Child Oral Health Impact Profile
<b>COHRQOL</b>	Child Oral Health Related Quality of Life
<b>C-OIDP</b>	Child Oral Impacts on Daily Performances Index
<b>DMFT</b>	Decayed Missing Filled Teeth in permanent dentition
<b>dmft</b>	decayed missing filled teeth in primary dentition
<b>ECC</b>	Early Childhood Caries
<b>ECOHS</b>	Early Child Oral Health Impact Scale
<b>FIS</b>	Family Impact Scale
<b>GA</b>	General Anaesthesia
<b>HRQoL</b>	Health Related Quality of Life
<b>OHRQoL</b>	Oral Health Related Quality of Life
<b>MID</b>	Minimal Important Difference
<b>MOHRQoL</b>	Michigan Oral Health-Related Quality of Life scale
<b>P-CPQ</b>	Parental-Caregiver Perception Questionnaire
<b>PROMs</b>	Patient Reported Outcomes Measures
<b>POQL</b>	Paediatric Oral Health-Related Quality of Life Measure
<b>SOHO-5</b>	Scale of Oral Health Outcomes for 5-year-old children

## Chapter 1 Introduction

There has been a shift towards involving children in research, however, the gap between proxy-centred and child-centred research remains. A common strategy used to study the impact of dental disease and treatment is through the use of quantitative measures, such as questionnaires. Other less common strategies are through the use of qualitative research methods, such as interviews and focus groups. Well established evidence proved that dental treatment under general anaesthesia (GA) improved oral health related quality of life (OHRQoL). However, the majority of studies which have explored the changes in OHRQoL in children who received dental treatment under GA used proxy reports. In this study children's accounts were taken by use of both, quantitative and qualitative approaches in the investigation of children's experience following dental extractions under GA.

## **Chapter 2 Literature review**

### **2.1 Dental caries**

Dental caries occurs due to demineralisation of enamel and dentine that occurs due to the action of organic acids formed by bacteria within dental plaque. The production of the acids following consumption of sugars or other fermentable carbohydrates increases the solubility of the dental hard tissues and demineralisation occurs. Dental caries is a multifactorial disease influenced by the susceptibility of the tooth, the bacterial profile, quantity and quality of the saliva, low levels of fluoride, and the frequency of sugar intake.

Severe dental caries can impair quality of life. For example, dental caries may cause difficulties in eating and sleeping, and in its advanced stages (abscesses), it may result in pain and chronic systemic infection. Dental caries is also associated with adverse growth patterns. Further, dental caries is a frequent cause of absence from school or work (WHO, 2017).

#### **2.1.1 Prevalence of dental caries in England**

Dental caries is a major public health problem globally and is the most widespread non-communicable disease. It is also the most prevalent condition included in the 2015 Global Burden of Disease Study (Vos et al., 2016), ranking first for caries of permanent teeth (2.3 billion people) and 12th for primary teeth (560 million children) (WHO, 2017).

Although the prevalence of dental caries has reduced worldwide, it still remains a global burden. Almost 25% of five-year old children in the UK have dental caries, rising almost up to 50% in 8-year olds (Steele et al., 2015). According to the Oral Health Survey of five-year old children carried out in 2017, the proportion of children in England with experience of obvious caries showed a gradual reduction from 30.9% in

2008 to 23.3% in 2017. This represents a decrease of nearly eight percentage points and a percentage change of 24.6% since 2008. The average number of teeth affected by caries per child was 0.8. Severity has also decreased over this time with the mean dmft (decayed, missing or filled teeth) reducing from 1.1 in 2008, to 0.8 in 2017. This represents a reduction of 0.3 dmft, a decline of 29.0% between 2008 and 2017. The proportion of five-year-old children with experience of dental extractions across England was 2.4% (Dental Public Health Intelligence Team, 2018). Dental caries is the number one reason why children aged five to nine are admitted to hospital in England (Royal College of Surgeons, 2015).

### **2.1.2 Clinical consequences of untreated dental caries**

Untreated dental caries and its clinical consequences can have a considerable impact on the oral health-related quality of life (OHRQoL) of school children (Mota-Veloso et al., 2016). In fact, untreated dental caries with associated discomfort or toothache has been found to have a negative impact on weight gain, growth and quality of life as well as the cognitive development of young children. Following treatment of affected decayed teeth there is more rapid weight gain and growth velocity in the treated children (Sheiham, 2006). One study was carried out to determine the effect of comprehensive dental rehabilitation on the percentile weight and percentile growth velocity of children with early childhood caries found that there was a 'catch-up growth' period following comprehensive dental treatment, which indicated that the previous oral condition compromised nutritional intake (Acs et al., 1999). Conversely, Thomas and Primosch recorded change in weight, but found no significant difference 18 months post-treatment; the slight gain in percentile weight following dental rehabilitation under general anaesthesia was not indicative of a "catch-up growth" phenomenon (Thomas and Primosch, 2002).

### **2.1.3 Care pathways for management of dental caries**

Multiple approaches are available for treatment of dental caries. While some children are able to cope to have dental treatment carried out under a local anaesthetic or sedation, others could find it challenging. Delivery of dental treatment to children can be difficult, particularly where extensive treatment is required and, for example, when the child is unable to cope due to dental anxiety. Where other behavioural or pharmacological management techniques fail, a GA may be required to deliver effective treatment for dental caries (Baghdadi, 2014). In the UK, the majority of centres provide exodontia services under GA, and so dental GA is mostly used for extractions only (Moles and Ashley, 2009). The main reasons for dental treatment under GA are the following: uncooperative behaviour, multiple extractions, extensive dental caries in a young child and dental treatment for all age groups of children with special needs (Macpherson et al., 2005). Parents of children who undergo dental treatment under GA prefer this option for two reasons: (i) failure of previous dental appointments carried out under local anaesthesia, due to the child's dental fear and (ii) lack of associated pain with procedures carried out under GA. (Klaassen et al., 2009). Nevertheless, the clinician may favour GA for a number of other reasons such as the presence of a dental infection, poor attendance record, distance travelled to receive the treatment, and the extent of the work required (Yawary et al., 2016). According to the UK National Clinical Guidelines in Paediatric Dentistry there are essentially only two indications for 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 dental treatment can be performed.

The difficulty is that neither of these indications are absolute. Both require a degree of judgement on the part of the dental surgeon (Davies et al., 2008).

## **2.2 Oral health related quality of life**

The concept of OHRQoL relates to the impact which oral health or disease has on the individual's daily functioning, well-being or life quality. It has been described as a multidimensional 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 social discomfort 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). OHRQoL measures are subjective indicators based on information provided by individuals about their oral health status and its impact on various aspects of their life (Gherunpong et al., 2006).

### **2.2.1 Effect of treatment of dental caries under general anaesthesia on oral health related quality of life**

Multiple studies have reported an improvement in OHRQoL after dental treatment under GA. A study which employed the use of the Child Oral Health-related Quality of Life (COHQoL) questionnaire have found the provision of dental treatment under GA was associated with substantial and highly statistically significant improvements in the OHRQoL of children who had severe dental caries (Malden et al., 2008). One study reported an immediate improvement in oral health and aspects of QoL following treatment in a single session under GA for children who present with a high caries experience. Complaints of pain, problems with eating and sleeping, and behaviour concerns showed were investigated through telephone interviews of parents of children receiving comprehensive dental treatment under GA. There was 100% improvement in

oral health of children for whom frequent pre-GA problems associated with eating, sleeping and behaviour (Anderson et al., 2004). Another study found that the provision of dental treatment under GA for young children with early childhood caries (ECC) and their families resulted in substantial improvements to their OHRQoL as reported by their parents (de Souza et al., 2016). The OHRQoL of preschool children, who presented to the emergency department with the consequences of untreated dental caries, was significantly improved following emergency dental extraction under GA. The biggest decrease in prevalence at the 2-week follow-up was observed for the items of pain in teeth, trouble sleeping, being irritated or frustrated, difficulty drinking food, and parents being upset (Wong et al., 2017).

One of the earliest systematic reviews carried out included studies which report OHRQoL in children undergoing dental treatment under GA confirmed oral rehabilitation under GA results in the immediate improvement of children's oral health and physical, emotional and social quality of life (Jankauskiene and Narbutaite, 2010). However, no quality assessment of included papers was carried out. As a result Knapp et al. carried out an updated systematic review and assessed the quality of the papers included (Knapp et al., 2017a). In the time span between the two systematic reviews more than 10 studies were carried out, however, none of the studies used a child self-report measure. Their findings confirmed all included studies reported improved OHRQoL overall, however, some sub-scales showed changes which were not significant or worsened OHRQoL (Knapp et al., 2017a). With regards to the outcome of the quality assessment, they concluded some quality criteria such as the fit between the research question and method of data collection and analysis were well addressed by the included studies, however, sample size estimation and assessment of validity of the measurement tools used were less well addressed. A meta-analysis of 22 studies on changes in OHRQoL in children following dental treatment under GA identified a favourable outcome in OHRQoL in all included studies with evidence to support that the OHRQoL of children was improved, with large effect size, in the short-term

following dental GA (Park et al., 2018). However, this meta-analysis excluded studies which used child self-report measures and only included studies that have employed validated proxy-report QoL instruments, the Early Child Oral Health Impact Scale (ECOHIS) and COHQoL, to evaluate the OHRQoL changes in their children following dental GA. This is possibly the case due to the scarcity of studies using child self-report measures to assess changes in OHRQoL following dental GA.

### **2.2.2 Quality of life measures**

There has been a shift towards self-reported measures, which are also referred to as patient reported outcome measures (PROMs). PROMs are reports coming directly from patients about how they feel or function in relation to a health condition and its therapy without interpretation by healthcare professionals or anyone else (Higgins and Green, 2011).

The proposed benefits of such an approach to patient care are (Black, 2013):

1. patients themselves are in the best position to assess the improvement in their symptoms or quality of life
2. involving patients in their healthcare
3. observer bias can be reduced
4. consideration of patients' views increases public accountability.

PROMs were initially developed for use in research and following this further developed by clinicians to allow evaluation of individual patients. The increasing prioritisation of this approach to patient care allows the patient's perception of the effects of clinical intervention to be understood by both clinicians and researchers (Bevans et al., 2010). As many dental conditions have psychological and social implications, the use of such instruments in dentistry is particularly appropriate (Cushing et al., 1986).

To date, the most popular line of enquiry into caries-related impacts has been through the use of OHRQoL measures. These questionnaires seek self-reported quantitative data relating to oral symptoms, functional limitations, and social and emotional well-being (Gilchrist, 2015).

Multiple measures have been produced for use with children or in most instances using parents or caregivers as proxies. These generic questionnaires are designed to cover a variety of oral conditions such as dental caries, malocclusion and craniofacial anomalies. The most commonly used self-completed questionnaires include Child Perceptions Questionnaire (CPQ)(Jokovic et al., 2002; Jokovic et al., 2004; Jokovic et al., 2006), the Child Oral Impacts on Daily Performances Index (C-OIDP)(Gherunpong et al., 2004), and the Child Oral Health Impact Profile (COHIP) (Broder et al., 2007). Other less frequently used measures include the Scale of Oral Health Outcomes for 5-year-old children (SOHO-5) (Tsakos et al., 2012), the Pediatric Oral Health-Related Quality of Life Measure (POQL) (Huntington et al., 2011). Other measures that have been developed to be completed by a proxy report are the Parental-Caregiver Perceptions Questionnaire (P-CPQ) (Jokovic et al., 2003), Family Impact Scale (FIS) (Locker et al., 2002), Early Child Oral Health Impact Scale (ECOHis) (Pahel et al., 2007) and the Michigan Oral Health-Related Quality of Life scale (MOHRQoL) (Filstrup et al., 2003).

### **2.2.3 Child self-report measures**

Oral health related quality of life measures assess the extent to which oral diseases and disorders affect functioning and psychosocial well-being (Locker and Allen, 2007). Multiple measures have been developed, with some being specifically developed for children. As mentioned previously the most frequently used measures of OHRQoL that have been developed for children are the Child Perceptions Questionnaire (CPQ) (Jokovic et al., 2002; Jokovic et al., 2004; Jokovic et al., 2006), the Child Oral Impacts

on Daily Performances Index (C-OIDP) (Gherunpong et al., 2004), and the Child Oral Health Impact Profile (COHIP) (Broder et al., 2007).

A recent systematic review was carried out to assess the methodological quality and measurement properties of the measures using standards proposed by the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) group (Gilchrist et al., 2014).

Assessment of the development and testing of these three measures concluded that reliability and construct validity appear to be adequate for all three measures. Children were not fully involved in item generation which may compromise their content validity. Internal consistency was measured using classic test theory with no evidence of modern psychometric techniques being used to test uni-dimensionality of the measures included in the COSMIN analysis (Gilchrist et al., 2014). The rating system proposed by Terwee and colleagues (2007) (Table 1) was used to assess the quality of the instruments using the results of the studies evaluated by the COSMIN checklist (Terwee et al., 2007).

**Table 1 Measurement properties**

Content validity:	The degree to which the items in the questionnaire are a reflection of those important to the study population.
Construct validity:	The extent to which scores relate to other measures of a similar concept under scrutiny and should be tested using predefined hypotheses to avoid bias
Internal consistency:	The extent to which items in the questionnaire are correlated thus measuring the same concept
Test-retest reliability:	The ability of the measure to produce reproducible results in a stable population over time
Responsiveness:	The ability of a questionnaire to detect clinically important changes over time

### 2.2.3.1 Child Perception Questionnaire

CPQ was one of the earliest child self-report measures developed. Jokovic et al. developed the CPQ 11-14 as a self-report measure of the impact of various oral and oro-facial conditions in children aged 11 to 14-years as until then no children OHRQoL measures were developed (Jokovic et al., 2002). CPQ has been most widely used and therefore has the most evidence of its reliability and validity (Jokovic et al., 2002; Jokovic et al., 2004; Jokovic et al., 2006). Currently there are versions for 11-14 year-olds, 8-10-year-olds and four short forms based on the measure for 11-14 year-olds. This instrument includes 37 questions asking about the frequency of events in the past three months. Questions for the CPQ8-10 were selected from the CPQ11-14. The child development literature and judgments of a child psychologist, grades 3 and 4 teacher, and group of parents provided the basis for this selection. The measure was

constructed by adults with little involvement from the children themselves and this may account for its less than ideal properties. Gilchrist et al. assessed the methodological quality of this questionnaire and concluded it is unclear how the scores can be generalised or their clinical significance. Inclusion of clinical data relating to the population under scrutiny, mean and subgroup scores and floor or ceiling effects is recommended in future studies to aid interpretability. Short forms are available, however, there are varying results with these versions as to their reliability and validity (Gilchrist et al., 2014).

### **2.2.3.2 Child Oral Health Impact Profile**

COHIP was developed to assess oro-facial well-being among children aged 8-15 years old through child reports. The questionnaire was produced using the same initial item pool as CPQ. There were multiple phases to the development of the questionnaire including review of the measure by healthcare professionals, face validity, development of positive items, and removal of redundant questions by factor analysis. There was extensive involvement of children in interviews and item impact studies. The final questionnaire contained 34 items across five domains (oral health, functional well-being, social-emotional well-being, school environment and self-image). Similar to the CPQ11-14 (Jokovic et al., 2002) measure, participants are asked to report on the frequency of events over the past three months on a five-point Likert scale which is scored from ranging from 0=never to 4=almost all the time. It differs from the CPQ11-14 (Jokovic et al., 2004) in which it includes positively worded items. Based on a systematic review on child self-report measures COHIP (Broder et al., 2007) has employed a rigorous development strategy, however, it was the least reported measure in the literature. It has been tested the least but results are promising. However, it contains 34 questions which may constitute significant participant burden. The 19-item version may reduce this but further testing in different populations is required (Gilchrist et al., 2014).

### **2.2.3.3 Child Oral Impacts on Daily Performances Index**

The C-OIDP index (Gherunpong et al., 2004) is one of the child self-report measures used in assessing OHRQoL. Eight items are considered: eating, speaking, cleaning teeth, relaxing, emotion, smiling, studying, and social contact. The impact on each activity is assessed in terms of frequency and severity, using a scale of 0-3. Similar to the CPQ11-14 it asks for a recall period of three months. C-OIDP, in contrast to CPQ, was developed to assess dental needs in child populations. C-OIDP has been successfully used to assess oral impacts in epidemiological surveys. This measure also differs from CPQ in that it is designed to be administered by interview rather than self-completed. The original index was used and face validity assessed by 513, 11-12-year-old children from schools in Thailand. The final version was tested using a sample of 110 children aged 11-12 years. This measure consists of 8-items in addition to pictures to help in understanding.

Although the creators of this measure have stated that the index is a valid, reliable and practical measure of oral health-related quality of life in 12 year old Thai children (Gherunpong et al., 2004), however limited positive evidence was available to support construct validity; there was limited evidence of positive reliability and interpretability and no evidence for internal consistency (Gilchrist et al., 2014).

## **2.3 Caries Impacts and Experiences Questionnaire for Children (CARIES-QC)**

CARIES-QC is a caries-specific measure of quality of life designed for children aged 5-16 years. It has been developed following recommendations suggested by a recent systematic review on measures of OHRQoL that have been developed for children, the review concluded that there is a lack of evidence that the existing measures are responsive longitudinally which strengthens the rationale for the development of a disease-specific measure. It is important to consult children prior to testing the measure

to ensure that the items are relevant and that the response format is based upon their description of the impacts of the disease (Gilchrist et al., 2014). CARIES-QC measure is intended to be used for longitudinal evaluation of interventions for dental caries. It contains 12 items and one global question with a 3-point response format. It is currently available in English and Dutch.

### **2.3.1 Development of CARIES-QC measure**

The item pool was generated following interviews with 20 children with caries experience and reduced following further discussions with another 22 children with dental caries. Ten children helped with the layout, design and formulation of the response format. The draft measure was further refined following testing of face and content validity with another group of 29 children with active caries. The resulting questionnaire took approximately 2-5 minutes to complete depending on the reading ability of the child, with some younger children requiring assistance to read it (Gilchrist, 2015).

### **2.3.2 Validation of CARIES-QC measure**

Two hundred participants with a mean (range) age of 8.1 (5-16) years took part in the evaluation of CARIES-QC. The measure was tested for validity, reliability and responsiveness using both Classical Test Theory <sup>1</sup>and Rasch analysis<sup>2</sup>. Four items, which did not fit the Rasch model, were removed from further analysis. The remaining

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<sup>1</sup> The main purpose of Classical Test Theory within psychometric testing is to recognise and develop the reliability of psychological tests and assessment.

<sup>2</sup> Rasch analysis describes procedures that use a particular model with mathematical properties for the analysis of data from tests and questionnaires in psychology, education, and other fields.

12 items demonstrated good internal consistency ( $\alpha=0.9$ ) and the total score showed significant correlations with the number of decayed teeth, presence of pain, pulpal involvement, the Child Perceptions Questionnaire (16-item short form) and the global score ( $p<0.01$ , Spearman's rho). Responsiveness was tested in 42 children who had completed treatment of their dental caries. Thirty-three (78.6%) reported an improvement since baseline, 6 (14.3%) reported no change and 3 (7.1%) reported a deterioration in their oral condition. The mean difference in CARIES-QC interval score between baseline and follow-up for those who felt they had improved was minus 4.46 (range= -12.45 – 2.76), thus indicating a MID of 4.46 points. There was a statistically significant difference between the mean score at baseline and follow-up in those who reported an improvement ( $p=0.00$ , paired t-test). A strong statistically significant correlation ( $p=0.01$ ) was found between the global transitional judgement score and the CARIES-QC interval score change score ( $r=0.601$ , Pearson correlation) (Gilchrist, 2015).

### **2.3.3 Scoring of CARIES-QC**

Uni-dimensionality is an important property where measures are intended to assess change, as this allows conversion of the raw ordinal score into an interval scale. In this case CARIES-QC has been developed to measure change following interventions for the management of dental caries and this can only be evaluated accurately where an interval scale can be created. The conversion to an interval scale allows accurate calculation of change scores. This transformation allows more meaningful interpretation of the original ordinal data, as all raw scores are non-linear and therefore the values at the margins of the curve cover a wider part of the underlying trait than those at the centre.

These values are expressed in logits (log odds probability units), which allows the scores achieved by participants to be evaluated as an interval scale, rather than the

ordinal scores obtained from the raw data. Thus, change scores can be accurately calculated using the interval scale produced (Gilchrist, 2015).

CARIES-QC consists of 12 items and one global question. The 3-point response format is scored for the items as follows:

Not at all=0    A bit=1    A lot=2

This results in possible raw scores of 0-24 obtained by simple addition of the individual item scores. The global score is presented separately (Gilchrist, 2015).

To calculate change following treatment, the conversion table (Table 2), produced following Rasch analysis, should be used to convert the ordinal raw score to an interval scale score. This allows more accurate calculation change at all points along the scale. Both raw and interval score should be presented (Gilchrist, 2015).

**Table 2 Transformation of raw (ordinal) score to interval score**

<b>Raw score</b>	<b>Interval score</b>	<b>Raw score</b>	<b>Interval score</b>
<b>0</b>	0	<b>13</b>	13.03
<b>1</b>	2.63	<b>14</b>	13.62
<b>2</b>	4.50	<b>15</b>	14.22
<b>3</b>	5.84	<b>16</b>	14.84
<b>4</b>	6.90	<b>17</b>	15.48
<b>5</b>	7.80	<b>18</b>	16.17
<b>6</b>	8.60	<b>19</b>	16.92
<b>7</b>	9.32	<b>20</b>	17.76
<b>8</b>	10.00	<b>21</b>	18.75
<b>9</b>	10.64	<b>22</b>	19.96
<b>10</b>	11.26	<b>23</b>	21.65
<b>11</b>	11.86	<b>24</b>	24.00
<b>12</b>	12.45		

## 2.4 Qualitative research in dentistry

Evidence based dentistry is mainly derived from scientific evidence obtained utilising quantitative research methods with randomised control trials, cross-sectional studies and questionnaire-based surveys being the most common research approaches used. However, there are circumstances in which qualitative research may be the sole or principal method needed to address a research question. These are centrally related to the nature of the information or evidence required (Ritchie and Lewis, 2003).

Qualitative methods, such as interviews, can offer dentistry a unique insight into peoples' personal perspectives, providing a more comprehensive understanding of their beliefs, knowledge and attitudes as well as offering greater depth and methodological flexibility than quantitative research methods such as structured questionnaires (Stewart et al., 2008). Qualitative methods can also overcome literacy problems and are, therefore, particularly useful in obtaining detailed information directly from young children and/or those who have difficulty with reading or writing. Qualitative methods may be used as an adjunct to explore the meaning of information obtained using quantitative research methods. In order to further understand the child's perspective on dental extractions under GA qualitative interviews should prove to be a valuable source of information.

A common strategy used to study the impact of dental disease and treatment is through the use of quantitative measures. Other less common strategies are through the use of qualitative research methods, such as interviews and focus groups. Although the application of qualitative methodology is becoming more common in the investigation of HRQOL in children and adolescents with other medical disorders, this methodology is infrequently reported in child dental literature. Interviewing children with dental caries is not a novel approach in this field. Gilchrist and colleagues were one group of researchers who interviewed children with dental caries aged 5-16 years (Gilchrist, 2015). However, the aim of this research was the development of a child-

centred caries-specific measure of OHRQoL, the CARIES-QC measure. Therefore, children were interviewed prior to receiving dental treatment. A recent study which employed interviews and video diaries to explore children's own descriptions of the physical and psychological aspects of their dental GA obtained a wealth of information with regards to the impact of such treatment on children (Rodd et al., 2014). However, this study focused on the short-term impacts, as children were interviewed 2-weeks after their procedure. Although some of the post-operative impacts reported by children were closely related to those reported by parents/carers, such as nausea, bleeding, tiredness and pain, this enquiry identified additional physical and psychological impacts throughout the care pathway. This shows that children's accounts are invaluable in filling the gaps in children related research. To date no study has explored the effect of dental extractions under GA on future treatment preference.

#### **2.4.1 Limitations of quantitative measures**

Qualitative methods have long been used to inform more quantitative research approaches, notably assisting with research design and the development of outcome measures. They have been used in preliminary work for surveys to develop and test questionnaires—for example, the development of quantitative measures of patients' views should begin with an exploration of the views of samples of patients using qualitative methods (Pope et al., 2002). Although previous research showed noticeable improvements in child OHRQoL following comprehensive dental treatment under GA (Knapp et al., 2017a), this was mainly reached using quantitative methods. It is not just to compare quantitative methods with qualitative methods as both approaches differ in terms of what new knowledge they can offer. It is vital that a researcher understands what each method is designed to explore. Quality of life measures, such as the CARIES-QC and COHQoL, are forms of quantitative measures. They are designed to provide quantified answers through the completion of questionnaires. Conversely, qualitative approaches are commonly used to explore, interpret, or obtain a 'deeper

understanding' of certain aspects of human beliefs, attitudes or behaviour, such as people's personal experiences and perspectives.

## **2.4.2 Qualitative data collection methods**

The use of qualitative methods in qualitative research involves the systematic collection, organisation, and analysis of textual material derived from talk or observation (Pope et al., 2002). Interviews and focus groups are the main qualitative research methods employed. Interviews aim to explore the views, experiences and beliefs of the individuals of interest. There are two main types of interviews: unstructured in-depth interviews and semi-structured interviews. Unstructured interviews are reserved for research topics where virtually nothing is known about the subject area. Their lack of predetermined interview questions provides minimal guidance on what to talk about (Gill et al., 2008a), and questions are based on what the interviewee responds (Britten, 1995). Conversely, semi-structured interviews consist of several key questions that help to define the areas to be explored, but also allows the interviewer and interviewee to diverge in order to pursue an idea or response in more detail. A focus group can be defined as a group discussion on a given topic organised for research purposes. This discussion is guided, monitored and recorded by a researcher (sometimes called a moderator or facilitator). Focus groups are used for the generation of information on collective views and the meanings that lie behind those views (Stewart et al., 2008).

### **2.4.2.1 Selection of data collection method**

Selecting a data collection method in qualitative research depends on three key factors: the nature of data sought, the subject area, and the nature of the study group (Ritchie and Lewis, 2003).

#### **2.4.2.1.1 The nature of the data sought**

Interviews are used to collect data where it is important to set the perspectives heard within the context of personal experience. Focus groups can be particularly useful where the interaction between participants, will itself illuminate the research issue.

#### **2.4.2.1.2 The subject area**

Where personal experience or matters sensitive in nature are explored, interviews are preferred as they allow personal focus on the interviewee and provides opportunity for clarification and detailed understanding. This method provides privacy and allows participants to talk freely even about sensitive matters. On the other hand, focus groups are useful in generation of information on collective views and the meanings that lie behind those views (Stewart et al., 2008). Participants are inspired from their involvement in discussion and hearing from others. Although this may result in bias as people are less willing to share thoughts and ideas which are less socially acceptable.

#### **2.4.2.1.3 Nature of the study group**

Interviews provide accessibility for participants who are likely to be less willing or able to travel, because interviews generally take place at a location of the participant's choosing. Interviews allow participants to talk in privacy and freely. This is of particular importance where sensitive matters are researched or where the presence of another participant may inhibit contribution to the interview. Focus groups may be resorted to where the participants share a similar background or relationship to the research topic (Ritchie and Lewis, 2003).

### **2.4.3 Qualitative interviews**

Interviews are, therefore, most appropriate where little is already known about the study phenomenon or where detailed insights are required from individual participants.

They are also particularly appropriate for exploring sensitive topics, where participants may not want to talk about such issues in a group environment (Gill et al., 2008a). The flexibility of this process, particularly when compared with structured interviews, allows for the discovery or elaboration of information that is important to participants but may not previously have been thought of as pertinent by the research team (Gill et al., 2008a). All interviews should be tape-recorded and transcribed verbatim afterwards, as this protects against bias and provides a permanent record of what was and was not said (Gill et al., 2008a). Another advantage of audiotaping is the opportunity the tapes offer for subsequent analysis by independent observers (Mays and Pope, 1995a).

#### **2.4.3.1 Key features of qualitative interview**

The first key feature of the qualitative interview is that it is intended to combine structure with flexibility, interviews will generally be based on some form of topic guide setting out the key issues to be covered during the interview. A second key feature is that the interview is interactive in nature between the researcher and interviewee. Thirdly, the researcher uses a range of probes and other techniques to achieve depth of answer in terms of explanation and exploration. An initial response is often at a fairly 'surface' level: the interviewer will use follow-up questions to obtain a deeper and fuller understanding of the participant's meaning (Arthur and Nazroo, 2003).

#### **2.4.3.2 Topic guides**

Topic guides are documents that identify the key issues and subtopics to be explored (Arthur and Nazroo, 2003). A well-designed topic guide will provide flexible direction to the interview process. It can also enhance the consistency of data collection, particularly if there are a number of researchers involved in the interview process. Ritchie and co-authors emphasise the importance of including the topic guide used in the study report as an important element of documenting the research approach and making it transparent (Ritchie and Lewis, 2003). A well designed topic guide will

provide flexible direction to fieldwork process and essential documentation of a central aspect of the research. The use of topic guides in qualitative research is strongly recommended and careful investment in their design is needed (Arthur and Nazroo, 2003).

#### **2.4.4 Interviewing children**

Whilst children related research in dentistry is extremely common, the majority of this research has been quantitative in nature. Qualitative research methods, such as interviews, have not been conducted widely with respect to studies involving children in dentistry. The problem of not involving children in research that is interested in them is that their own views and beliefs about issues that are of importance to dentistry are not properly recognised. However, the United Nations' 'Convention on the rights of the child' (1989) recommends that, wherever possible, children should be involved and consulted about all activities that affect their lives – including research (Fraser et al., 2004).

Many concerns arise when conducting research with children and these relate to ethical issues, such as consent, confidentiality, and vulnerability. There are also concerns about whether children possess the appropriate cognitive, linguistic and social skills to provide adult interviewers with reliable and valid interview data. Children have traditionally been excluded from personally participating in research as they have been considered to be too immature (Mayall, 2011). Obviously, there are areas where a parent is better able to provide information about their child than the child is, for example in studies that require a detailed knowledge of early childhood illnesses or dental treatment (Gill et al., 2008a). Research has shown that conducting qualitative interviews with children can yield rich, deep, trustworthy accounts and lead to revelations of knowledge not commonly known by adults (Gill et al., 2008a). In fact, with the appropriate support from experienced researchers, interviews can yield

detailed, reliable and trustworthy accounts from children as young as six years of age (Gill et al., 2008a).

The semi-structured interview format is, arguably, the most suitable for children, as it provides them with some guidance on what to talk about. Children, particularly younger children, generally find such guidance helpful in an interview situation (Gill et al., 2008a). Children often require far more guidance and support during interviews than adults do (Docherty and Sandelowski, 1999). This may simply involve clarifying or rephrasing questions if a child does not understand what they have been asked. The child's developmental requirements and language levels dictate the level of modification required in conducting an interview.

However, it is also important not to influence children's responses in any way and, as with adults, the use of 'leading' or 'loaded' questions must therefore be avoided (Gill et al., 2008a). It is important that the interviewers avoid the display of feelings, such as surprise or horror, at what the child is reporting (Docherty and Sandelowski, 1999).

Interviewers should also be aware that children may respond to questions regardless of whether they actually know the answer or have an opinion on the topic. To avoid guessing, which can affect data quality, children should therefore be told that if they are unsure about a question it is okay for them to say 'I don't know' or to ask for further clarification (Gill et al., 2008a).

#### **2.4.5 Rigour, reliability and validity in qualitative research**

Various strategies are available within qualitative research to protect against bias and enhance the reliability of findings. Quantitative and qualitative approaches are fundamentally different in their ability to ensure the validity and reliability of their findings (Mays and Pope, 1995b). As in quantitative research, the basic strategy to

ensure rigour in qualitative research is systematic research design, data collection, interpretation, and communication. Beyond this, qualitative researchers should provide detailed and transparent accounts of the study method and data in any reports or publications, that would allow another trained researcher to follow to the given conclusions, and the production of a plausible and coherent explanation of the phenomenon studied (Stewart et al., 2008).

Reliability is generally understood to concern the replicability of research findings and whether or not they would be repeated if another study, using the same or similar methods, was undertaken (Ritchie and Lewis, 2003). The reliability of the analysis of qualitative data can be enhanced by organising an independent assessment of transcripts by additional skilled qualitative researchers and then, comparing agreement between the raters (Mays and Pope, 1995b). Reliability, which is a particular strength of quantitative research, cannot always be judged so easily within a qualitative study. The settings and groups studied within qualitative research may be unique to the particular context or time period, and it is unlikely that a study can be replicated in the way that a controlled experiment can. Sometimes it is possible to involve other skilled qualitative researchers in the analytical process to code the data independently or to discuss emerging themes and categories to try to reach consensus about the interpretation of the data (Pope et al., 2002). However, as Burnard and colleagues explain, this approach is not without its issues. It is possible that each researcher may interpret the data differently. If both perspectives are grounded in and supported by the data, is one interpretation necessarily stronger or more valid than the other? (Burnard et al., 2008).

Validity is traditionally understood to refer to the correctness or precision of a research reading. In qualitative research it concerns the extent to which the phenomena under study is being accurately reflected, as perceived by the study population (Ritchie and Lewis, 2003). When it comes to judging the quality of qualitative research, qualitative

methods are often seen as scoring highly in terms of internal validity. By documenting how people really behave in “natural” everyday situations and examining in detail what people mean when they describe their experiences, feelings, attitudes and behaviour, these methods are seen as providing an accurate representation of the phenomena studied (Mays and Pope, 1995b).

The process of analysis should be systematic and rigorous and it is important that a detailed explanation of how data was collected and analysed is provided to allow readers to judge the evidence and interpretations presented. This clear description is also essential for judging the transferability of findings to other settings or groups (Pope et al., 2002).

#### **2.4.6 Sampling**

When conducting interviews, how qualitative researchers choose their participants, and how many are sampled, is an important consideration. Qualitative research uses non-probability samples for selecting the population for study. Non-probability sampling is the term given to a range of sampling strategies used in qualitative research. The intention is not to produce a sample which is statistically representative, and the probability of units being selected is not known. In a non-probability sample, units are deliberately selected to reflect particular features of, or groups within the sampled population. The most robust approaches to which are purposive sampling and theoretical sampling. Purposive sampling involves choosing potential participants because they have particular features or characteristics which will enable detailed exploration and understanding of the central themes and puzzles which the researcher wishes to study (Ritchie and Lewis, 2003). Whilst in theoretical sampling, a particular kind of purposive sampling, participants are selected on the basis of their potential contribution to theory development. Purposive sampling is widely used in qualitative research as a means of recruiting participants who share experience of a certain

phenomenon (Bradbury-Jones et al., 2013); in the case of this study, participants are children with dental caries who underwent dental extractions under GA.

#### **2.4.6.1 Determination of sample size**

Sampling in qualitative research is not designed to be representative of a wider population, but purposive to capture diversity around a phenomenon (Polit and Beck, 2010). Qualitative samples are usually small in size. There are three main reasons for this:

1. If the data are properly analysed, there will come a point where very little new evidence is obtained from each additional fieldwork unit or participant. This is because phenomena need only to appear once to be part of the analytical map.
2. Statements about incidence or prevalence are not the concern of qualitative research.
3. The type of information that qualitative studies yield is rich in detail (Ritchie and Lewis, 2003).

An appropriate sample size for a qualitative study is one that adequately answers the research question. For simple questions or very detailed studies, this might be in single figures; for complex questions large samples and a variety of sampling techniques might be necessary. In practice, the number of required subjects usually becomes obvious as the study progresses, as new categories, themes or explanations stop emerging from the data (data saturation) (Marshall, 1996).

#### **2.4.7 Qualitative data analysis**

Interview transcripts, field notes and observations provide a descriptive account of the study, but they do not provide explanations (Pope et al., 2000). It is the researcher who has to make sense of the data that have been collected by exploring and interpreting

them. In much qualitative research the analytical process begins during data collection as the data already gathered are analysed and shape the ongoing data collection. In most qualitative analyses the data are preserved in their textual form and “indexed” to generate or develop analytical categories and theoretical explanations (Pope et al., 2000).

Qualitative research uses analytical categories to describe and explain social phenomena. These categories may be derived inductively—that is, obtained gradually from the data, or used deductively, either at the beginning or part way through the analysis as a way of approaching the data. Deductive analysis is less common in qualitative research but is increasingly being used, for example in the “framework approach”. In this approach predetermined framework and theories are used to analyse the data. This approach is useful in studies where researchers are already aware of probable participant responses (Burnard et al., 2008). Whilst inductive analysis relies on the identification of analytical categories and development of hypotheses from the analysis of the data, this approach, though laborious, is particularly useful where little or nothing is known about the topic.

#### **2.4.7.1 Framework analysis**

There are a number of approaches to qualitative data analysis. Smith and Firth summarised the main methods for undertaking qualitative data analysis which can be divided into three categories (Smith and Firth, 2011):

- Sociolinguistic methods, such as discourse and conversation analysis, that explore the use and meaning of language.
- Grounded theory, that focus on developing theory derived from data through a set of procedures and interconnected stages.
- Content and thematic analysis, that describe and interpret participants views.

The framework method sits within a broad family of analysis methods often termed thematic analysis or qualitative content analysis. These approaches identify commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions clustered around themes. The framework method was developed by researchers, Jane Ritchie and Liz Spencer, from the Qualitative Research Unit at the National Centre for Social Research in the United Kingdom in the late 1980s for use in large-scale policy research (Gale et al., 2013).

The framework approach enables the researcher to explore data in depth while simultaneously maintaining an effective and transparent audit trail, which enhances the rigour of the analytical processes and the credibility of the findings (Ritchie and Lewis, 2003).

#### **2.4.7.2 Computer software for data analysis**

There are several computer-assisted qualitative data analysis software (CAQDAS) packages available that can be used to manage and help in the analysis of qualitative data. Common programmes include ATLAS.ti and NVivo. It should be noted, however, that such programs do not ‘analyse’ the data – that is the task of the researcher – they simply manage the data and make handling of them easier (Burnard et al., 2008).

Such software can allow basic “code and retrieval” of data, and more sophisticated analysis using algorithms to identify co-occurring codes in a range of logically overlapping or nesting possibilities, annotation of the text, or the creation and amalgamation of codes (Pope et al., 2000).

## **2.5 Aims and Objectives**

### **2.5.1 Phase I Changes in OHRQoL following dental extractions under general anaesthesia**

#### **2.5.1.1 Rationale**

Most studies have explored the changes in OHRQoL in children who received dental treatment under GA using proxy reports (Knapp et al., 2017a). A systematic review of parent and child reports of health-related quality of life (HRQoL) revealed greater agreement between proxy and child ratings in some subscales (e.g., physical HRQoL) than other, less observable, subscales (e.g., emotional or social HRQoL) (Eiser and Morse, 2001). To date only one study used CARIES-QC, a child self-report measure, to assess changes in OHRQoL following dental extractions under GA, this was carried out to evaluate the CARIES-QC measure in terms of its reliability, validity and responsiveness (Gilchrist, 2015). This highlighted the need for child self-reported measures to be used in future OHRQoL research to further explore child reports on changes in OHRQoL following dental extractions under GA. In addition it has been recommended by a recent systematic review that future work should explore whether the actual number of dental extractions impacts on OHRQoL (Knapp et al., 2017a).

#### **2.5.1.2 Aim**

In the quantitative phase of this study we aimed to measure changes in OHRQoL using a child self-report measure before dental treatment under a general anaesthetic and after one and three months.

The child self-report measure that was used in this study is the CARIES-QC (Caries Impacts and Experiences Questionnaire for Children) (Gilchrist, 2015).

### **2.5.1.3 Null hypotheses**

There is no statistically significant association between OHRQoL and dental extractions under a general anaesthetic.

There is no statistically significant difference between changes in OHRQoL and number of teeth extracted.

### **2.5.1.4 Outcome measures**

- Compare changes in OHRQoL before, one month and three months after dental extractions under GA using a child self-report measure and understand what changes are experienced by children undergoing dental extractions under GA.
- Compare OHRQoL between different socioeconomic groups.
- Assess if severity of dental decay has an effect on OHRQoL by measuring DMFT/dmft values.
- Assess if number of extractions has effect on changes in OHRQoL.

## **2.5.2 Phase 2 Children's experience following dental extractions under general anaesthesia**

### **2.5.2.1 Aim**

The aim of the second phase of this study was to elicit children's experiences of dental caries and dental extractions under a general anaesthetic.

## Chapter 3 Material and Methods

The present study was carried out in two phases:

Phase 1 included the quantitative part of the study to assess changes in OHRQoL following dental extractions under GA. Baseline questionnaires were given on the day of the GA. Clinical data was recorded and participants were followed-up after one-month and three-months.

Phase 2 included the qualitative part of the study to explore children's experience following dental extractions under GA. Face to face interviews were carried out after the GA to explore children's views and perspectives.

This chapter discusses the process of ethical approval, data acquisition and analyses for both phases.

### 3.1 Ethical approval

Prior to commencing the study, ethical approval was sought from Yorkshire & The Humber - Leeds West Research Ethics Committee (REC reference: 17/YH/0079). Health Research Authority approval has been granted for this study, IRAS project ID 212599 (Appendix I).

## **3.2 Phase I: Changes in OHRQoL following dental extractions under general anaesthesia**

### **3.2.1 Study setting**

This is a single centre study that has been carried out at the One Day Unit, Leeds Dental Institute.

### **3.2.2 Study design**

This part of the study was a quantitative prospective longitudinal study assessing the changes in OHRQoL following dental extractions under GA, using a validated caries specific questionnaire.

The sample consisted of children having dental extractions under GA at the Leeds Dental Institute from June 2017 to October 2017. All patients were referred to the One Day Unit for dental extractions under GA following consultation with a specialist or consultant in paediatric dentistry at the Children's Department at the Leeds Dental Institute.

All patients who met the inclusion criteria (see Section 3.2.3) were informed about the nature of the study through delivery of participant information sheets by post at least one week before their scheduled appointment. Separate information sheets were developed for the parents or legal guardians and the children (Appendix II and Appendix III).

On the day of the GA the child and parent or legal guardian were approached by the investigator and asked whether they wished to participate. Prior to recruitment they were given the opportunity to ask further questions and were reassured that their decision in participation would not affect the quality of their treatment. Once the participant showed interest to take part in the study written consent was obtained. The

parent or legal guardian was asked to sign a consent form (Appendix VI) following which, the child was asked to sign an assent form (Appendix VIII).

The questionnaire used in this study was the CARIES-QC (Caries Impacts and Experiences Questionnaire for Children) adapted from (Gilchrist, 2015).

The study involved completion of baseline and follow-up questionnaires by the child. The baseline questionnaire (Appendix IX) was completed on the same day the child attended the clinic for dental extractions under GA. The follow-up questionnaires (Appendix X) were posted by mail after one month and three months. The questionnaires were sent by post along with a pre-paid envelope with a return address printed. Where the questionnaire was not returned within two weeks, a follow-up telephone call was made and a second questionnaire was sent.

Each questionnaire was expected to take on average 2-5 minutes to complete depending on the child's reading ability and comprehension level. Parents were advised that they could assist their child in reading the questions if required, however, it was the child's response which was to be reported.

### **3.2.3 Sample and Recruitment**

Children referred to the Leeds Dental Institute undergo a clinical examination which in some instances is supplemented by a radiographic examination. The child is placed on the One Day Unit waiting list when the treatment plan involves dental extractions under GA.

A consecutive sample of children on the waiting list for dental extractions under GA in the One Day Unit were recruited to the study. Potential participants on the One Day Unit waiting list were identified and informed about the study through posting participant information sheets. Following this, on the day of the procedure the

investigator approached potential participants and their parents and provided more detailed information about the study both verbally and through the distribution of age-appropriate information sheets detailing the project and containing contact details and what to do if they had any concerns. The study participants were recruited from June 2017 to October 2017.

### **3.2.3.1 Inclusion criteria**

- Children aged five to eight years at recruitment
- Children with caries in the primary or mixed dentition
- Planned to receive dental extractions under GA
- Children with medical status ASA I, II
- Able to understand English

### **3.2.3.2 Exclusion criteria**

- Children younger than five years and nine years and older.
- Children who were not able to understand English or if their parents do require an interpreter.
- Children with medical status ASA III or greater.
- Treated only for a condition other than dental caries.
- Children with learning difficulties who would be unable to participate even with support.

### **3.2.4 Size of sample**

Sixteen children were required to achieve 90% power to detect a difference of 3.5 between the baseline mean CARIES-QC score of 9.5 and the follow-up mean CARIES-QC score of 6.0 with an estimated standard deviation of 4.0 and with a significance level (alpha) of 0.05 using a two-sided paired t-test.

At least thirty two participants were required to be recruited in the study to account for 50% loss of follow-up. The data of baseline and follow-up mean CARIES-QC score used in sample size calculation was adapted from a previous study (Gilchrist, 2015).

### **3.2.5 Rationale behind development of inclusion and exclusion criteria**

Participants younger than five years old were excluded from the study, as the questionnaire has been validated for children aged five to sixteen years. Although, the questionnaire is valid for children aged five to sixteen years, the sample has been limited to children aged five to eight, to ensure that each age group has similar numbers of participants. The majority of children seen for dental extractions under GA are within this range.

The CARIES-QC is validated for English speakers only and did not go through cross-cultural validation. Therefore, non-English speakers have been excluded from the study, as the translation of the questionnaire would affect the validity of the instrument used. Patients with an ASA III or greater were also not included to eliminate the possibility of confounding factors as this could potentially affect the interpretation of the results obtained.

### **3.2.6 Methods of data collection**

Potential participants were identified from the waiting list at the One Day Unit who were waiting to have dental extractions under GA. Participants were filtered based on age and medical history from the clinical records available.

Further data from clinical records was only obtained and collected following consent from the parent and child. This included collecting data in the following domains:

### **3.2.6.1 Demographic data:**

#### **3.2.6.1.1 Gender and age at date of recruitment**

Gender and age were recorded for each participant. Age at the time of recruitment was recorded in years and months.

#### **3.2.6.1.2 Socioeconomic status**

Socioeconomic status was determined using the English Index of Multiple Deprivation score/rank (2015) and was calculated using GeoConvert applied to the participants postcodes (The UK Data Service). Scores were assigned based on postcodes. Scores are categorised into ten deciles. For statistical purposes scores were recorded in quintiles and were categorised into five different groups: most deprived (1) , more deprived (2), average (3), less deprived (4), least deprived (5).

### **3.2.6.2 Clinical records**

The following data was obtained from clinical records.

#### **3.2.6.2.1 Dental diagnosis and DMFT/dmft scores**

A clinical examination was carried out on the day of the dental treatment under GA by a specialist or consultant in paediatric dentistry. This included records of extra-oral and intra-oral clinical findings. DMFT/dmft scores were recorded from data obtained from clinical and radiographic records (where available). Dental diagnoses other than dental caries was also recorded. This included trauma, severe tooth surface loss, and molar incisor hypomineralisation.

### 3.2.6.2.2 Dental treatment received

The total number of teeth extracted was recorded. This was then subdivided into the number of primary teeth and number of permanent teeth extracted, as well as recording the number of anterior teeth extracted. In some instances where non-carious teeth were extracted for orthodontic reasons or for balancing this was documented.

### 3.2.6.3 Medical status

The medical status was based on the ASA classification (American Society of Anaesthesiologists, 2014). Only children classified by the anaesthetist as ASA I and ASA II were included in this study. In fact, children of ASA III and greater are not admitted to the One Day Unit (Table 3).

**Table 3 ASA Physical Status Classification System**

<b>ASA</b>	<b>Definition</b>
ASA I	A normal healthy patient
ASA II	A patient with mild systemic disease
ASA III	A patient with severe systemic disease
ASA IV	A patient with severe systemic disease that is a constant threat to life
ASA V	A moribund patient who is not expected to survive without the operation
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes

#### **3.2.6.4 Waiting time**

The time taken from placement on the waiting list to the time the participants received their dental extractions under GA was recorded to inform about the nature of the service.

#### **3.2.7 Questionnaire**

Participants were asked to fill the initial questionnaire prior to their dental treatment. The initial questionnaire included 12 questions and 1 global question with a 3-response format. If a child found it difficult to read the questions, either the parent or investigator read out the form, ensuring that the child answered the question on their own.

#### **3.2.8 Data analysis**

The data was entered into an electronic database and analysed using IBM SPSS Statistics (version 23). Summary statistics were calculated to include frequencies, means and standard deviations, where appropriate. Comparison of baseline scores between different age groups and socioeconomic status was carried out with the use of Kruskal-Wallis H test after checking the assumptions of the tests had been met. Correlation tests were carried out to assess relation between baseline and follow-up scores with DMFT/dmft and total number of teeth extracted. Effect size was calculated by dividing mean change in scores by the standard deviation of pre-treatment scores. P-values equal to or less than 0.05 were considered statistically significant.

### **3.3 Phase 2: Children's experience following dental extractions under general anaesthesia**

#### **3.3.1 Study design**

This qualitative part of the study involved carrying out interviews with children who underwent dental extractions under GA. The literature review informed the topic guide (Appendix XII) and therefore acted as a guide to subjects that could be explored in the interviews. The interview started by asking the child "How do your teeth feel now?" aiming to direct the child to the main theme of the interview. The topic guide was divided into three main time frames: before having their dental treatment (dental extractions under GA), the hospital visit itself, after receiving their dental treatment. The key topics explored included:

- Effect of dental decay before treatment
- Attending the dental hospital for treatment
- How do they feel about their teeth now that they have received their treatment
- Thoughts about having similar treatment in the future

Each key theme was further divided into subtopics to further allow in-depth data collection.

#### **3.3.2 Study sample**

The investigator reviewed the patients list in a retrospective manner and invited participants who met the inclusion criteria. Children aged five to eight years who received dental extractions under GA were recruited from Leeds Dental Institute, One Day Unit using purposive sampling. Children aged 9 and above were not included as the majority of patients admitted to the One Day Unit undergo extraction of permanent

teeth affected by molar incisor hypomineralisation. To be included in the study the participant must have undergone dental extractions of carious teeth under a GA. Participants were recruited to the study until it was felt that no new themes were emerging.

### **3.3.2.1 Inclusion and exclusion criteria**

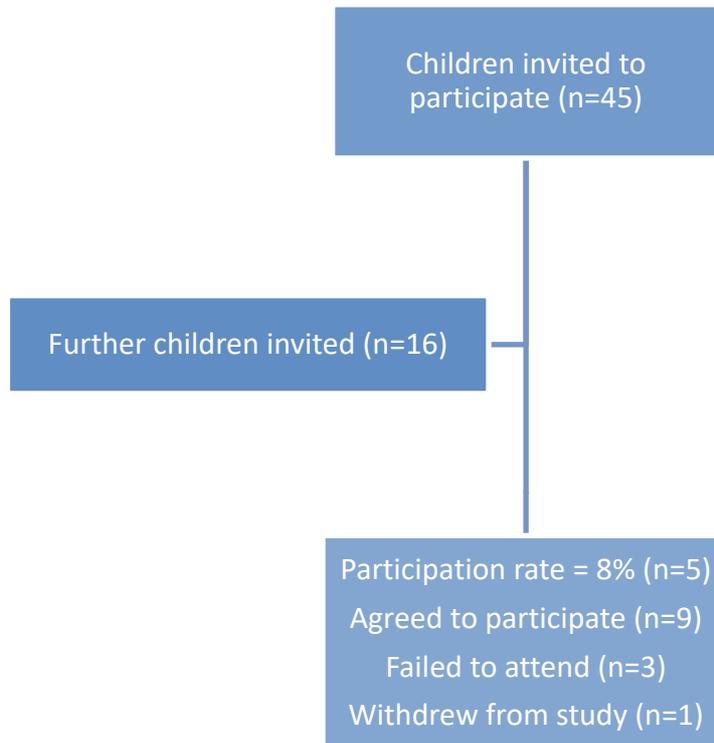
Inclusion and exclusion criteria from the first phase of the study were applied to this part of the study (see Section 3.2.3).

### **3.3.3 Recruitment**

Potential participants who met the inclusion criteria were identified from the One Day Unit patients list by the investigator. Participants were recruited in a retrospective manner. A purposive sampling method was employed to ensure that a representative sample was included. Parent and child participant information sheets were sent by post (Appendix IV and Appendix V). Forty-five families were initially invited to participate in the study. Seven agreed to participate, of which three failed to attend the interview and one family withdrew from participation. A further sixteen participants were invited, of which two agreed to participate. If the child and parent agreed to participate, the interview was arranged at a time suitable for the child and accompanying parent. A letter with details of the time and venue of the interview was sent by the post to confirm the appointment.

Prior to conducting the interview, the investigator read and explained the participant information sheet to the child to ensure that the child understood the purpose of the study. The child and parent were reassured that participation was voluntary. To address the ethical issues, all children were informed that they could stop taking part at any time and an explanation was given about why the interviews were being recorded. Informed written consent (Appendix VII) and assent forms (Appendix VIII) were

obtained from the parent and child, respectively. A copy of the forms was handed to the parents and another was logged in the participant's clinical records. The final copy was kept by the investigator with the other research documents. To protect participant's anonymity, they were each assigned a code from C1-C5.



**Figure 1 Recruitment details for interviews**

### **3.3.4 Data collection**

The semi-structured interviews were conducted by the investigator during July and August 2018. All interviews were carried out face-to-face in a non-clinical area at the School of Dentistry, University of Leeds. In all instances the child was accompanied by a parent for the duration of the interview. All interviews were audio-taped and sound recordings were transcribed verbatim. The topic guide was referred to in all sessions and participants were interviewed about their experience with their current oral health, previous oral health (prior to receiving the dental extractions under GA) and their experience on the day of the general anaesthetic. Following the interview, the children

were thanked and given a £20 gift voucher and a gift bag.

Data on patient demographics, DMFT/dmft, and numbers and type of teeth extracted were recorded.

### **3.3.5 Data analysis**

The framework approach described by Ritchie and Lewis (2003) was employed in the thematic analysis of the interviews transcripts. Gale and colleagues described this further in a recent paper, and their approach was followed to guide the investigator through each stage (Gale et al., 2013). The following stages summarise the process of analysis:

#### **Stage 1: Transcription**

The process of transcription is a good opportunity to become immersed in the data and is to be strongly encouraged for new researchers (Gale et al., 2013). All transcripts were checked for errors by re-listening to the audio-recordings and reading the transcripts simultaneously.

#### **Stage 2: Familiarisation with the interview**

The investigator thoroughly read and re-read each transcript and listened back to the audio-recorded interviews to become familiar with the available data.

#### **Stage 3: Coding**

After familiarisation, the investigator carefully read the transcript line by line, applying a paraphrase or label (a 'code') that describes what has been interpreted in the passage as important. The process initially involved using electronic versions of the transcripts with key phrases highlighted and comments written in the margins to record preliminary

thoughts. Key phrases were summarised using participants' own words ('in-vivo' codes). In-vivo codes are advocated in the framework approach as a means of staying 'true' to the data (Ritchie and Lewis, 2003). An attempt to summarise what the children were describing was made by developing codes and categories as the investigator reviewed each line of each transcript.

Initial thoughts began to develop into more formal ideas from which a coding matrix was generated. The coding matrix enabled changes to be tracked and progress to be recorded. Table 4 gives an example of the coding matrix, highlighting the processes involved in identifying codes and categories.

**Table 4 Example of coding matrix created during data analysis to identify codes and categories**

In-vivo code	Preliminary thoughts	Initial categories
<i>"I was nervous, not scared, just nervous"</i>	Not afraid from undergoing operation, however, nervous about it	Emotion before operation
<i>"I was dizzy, proper dizzy"</i>	Child felt dizzy when recovering from anaesthesia	Dizziness

#### **Stage 4: Developing a working analytical framework**

Codes which were conceptually related were grouped together into categories. This formed the initial analytical framework. Codes could have been grouped into either: physical impacts, psychological impact, treatment preference or by organising the codes into a chronological manner in line with the journey from experience pre-

operatively up to experience post-operatively. After a meeting with the supervising qualitative researcher an agreement was reached to order the categories chronologically and include physical and psychological impacts as subthemes. The final framework consisted of several codes which were clustered into four main categories each with a brief explanatory description of their meaning and examples of what ideas or elements might be summarised under that code. Table 5 shows an example of a category from the final analytical framework with a description of the codes.

**Table 5 Example of a category from the final analytical framework with constituent codes, and descriptions of codes**

	<b>Peri-operative: On the day of the GA</b>	
	<b>Code</b>	<b>Description</b>
<b><i>Physical impacts:</i></b> Physical impact of oral disease and/or treatment. Oral disease and treatment have a physical impact on affected people. These can vary from being positive to negative feelings.	<b>Onset of anaesthesia</b>	First experience Unknown/new feeling Quick
	<b>Recovering from anaesthesia</b>	Feeling weird Dizziness Feeling tired upon recovering from anaesthesia Bleeding
	<b>Pain</b>	Pain from insertion of cannula Pain from dental extractions
	<b>Taste</b>	Taste from medication
<b><i>Psychological impacts:</i></b> Effect of oral disease and treatment on a person's emotion and feelings.	<b>Emotion</b>	Feelings before having treatment

The full analytical framework is included as Appendix XI.

### Stage 5: Applying the analytical framework

The initial analytical framework was applied by indexing the transcripts using the existing categories and codes. This was done by highlighting each meaningful passage of text and selecting and attaching an appropriate code from the final analytical framework. Below is an extract from one of the transcripts where parts of the text that were relevant for the theme “post-operative physical impacts” in which the interviewee discussed how upon mastication she feels uncomfortable, particularly when consuming hard food such as apples. From the analytical framework the code “Discomfort” was selected.

<p>HA: How about when you eat? How do they feel?</p> <p>C4: <u>When my food goes in the holes where the teeth were taken out, that's hurting a bit.</u></p> <p>HA: So is it where there are spaces between your teeth, is that where it hurts a bit?</p> <p>C4: Ahem.</p> <p>HA: So is there any kind of food that you cannot eat at all because of your teeth?</p> <p>C4: mmmm, sometimes when I eat apples it starts hurting</p>	<p><b>DISCOMFORT</b></p>
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**Stage 6: Charting data into the framework matrix**

Charting involves summarising the data by category from each transcript. A spreadsheet was used to generate a matrix and the data were 'charted' into the matrix for each theme using Microsoft Excel. As illustrated in the next page (Table 6), the matrix is comprised of one row per participant and one column per code. A separate sheet was used for each category. Data was abstracted from transcripts for each participant and code, summarised using verbatim words and inserted into the corresponding cell in the matrix.

Table 6 Example of charting data into the framework matrix

Peri-operative: On the day of the GA						
Participant/ Category	Onset of anaesthesia	Recovering from anaesthesia	Pain	Function	Taste	Emotion
<b>C3</b>		I was dizzy, proper dizzy I skipped some days of school		I can only eat soft things afterwards	C3: Fine, but the sleepy juice was not alright HA: Not alright? How did it feel like? C3: It felt disgusting, I had to drink it	I was nervous, not scared, just nervous
<b>C4</b>	C4: It was a little bit different HA: How was it different? C4: Because I normally stay up for a bit, it was a bit different because I didn't have a blanket on me. I had a cream on my hand	Because when I woke, it, my brain goes weird since I woke up	It kind of hurt when I first started brushing my teeth			

**Stage 7: Interpreting the data**

Themes were generated from the data set by reviewing the matrix and making connections within and between participant and categories. This process was influenced both by the original research objectives and by concepts generated inductively from the data. During the interpretation stage, the investigator tried to go beyond descriptions of individual cases towards developing themes which offered possible explanations for what was happening within the data.

The final stage involved making sense of the concepts and themes in terms of participants' experiences. This was achieved by exploring the relationship between the core concepts and the established literature.

### **3.4 Ethical considerations**

#### **3.4.1 Consent/assent**

Children who were on the waiting list for dental treatment under GA at the Leeds Dental Institute were invited to participate in the study by posting two separate participant information sheets, one for the parent/guardian and one for the potential participant child.

On the day of the appointment where the child and guardian showed willingness to participate in the study, consent and assent forms were given. The investigator read the participant information sheet to the child to ensure that the child understood the purpose of the study and also to ensure that participation was voluntary.

Parents/guardians and children were reassured that their choice to participate would not affect the quality of the child's dental treatment. Written consent was obtained from both the parent and child prior to inclusion in the study. Separate signed consent forms from the parent and signed assent form from the child were obtained.

#### **3.4.2 Confidentiality/data protection issues**

As this research involved the collection of confidential and plausibly sensitive clinical and researched based data from the participant, precautions were taken to ensure confidentiality and anonymity. All research data was anonymised so that participants could not be identified, except by the investigator. Research data was kept secure in a password protected computer file on the University of Leeds main server. Any hand written records or charts were uploaded to the same password protected file immediately and the original hand written documents then destroyed. Data will be kept for at least two years after submission of the thesis for publication or three years after the end of the study whichever is longer.

Parents/legal guardians were informed that any results from the study may be disseminated through the National Research Ethics Service, thesis publication, peer reviewed journals and/or conference proceedings; anonymity will be maintained at all times.

### **3.4.3 Withdrawal from the study**

All information sheets, consent and assent forms were written in such a way to ensure that the parents/legal guardian were aware of their right to withdraw their child from the study at any time without interfering with the treatment of their child. Any collected data until the time of withdrawal that was taken with the consent was kept and used in the research. After withdrawal from the research, no further data from the participant would be acquired.

## Chapter 4 Results

### 4.1 Phase I: Changes in OHRQoL following dental extractions under general anaesthesia

#### 4.1.1 Recruitment

A consecutive sample of participants was recruited from the One Day Unit, Leeds Dental Institute. Forty-six participants met the inclusion criteria and were invited to participate in the study. A total of 35 participants were recruited in this part of the study. During the recruitment process 11 potential participants refused to participate, of which three refused due to the child being anxious on the day of their appointment and eight parents were not willing to involve their child in the study.

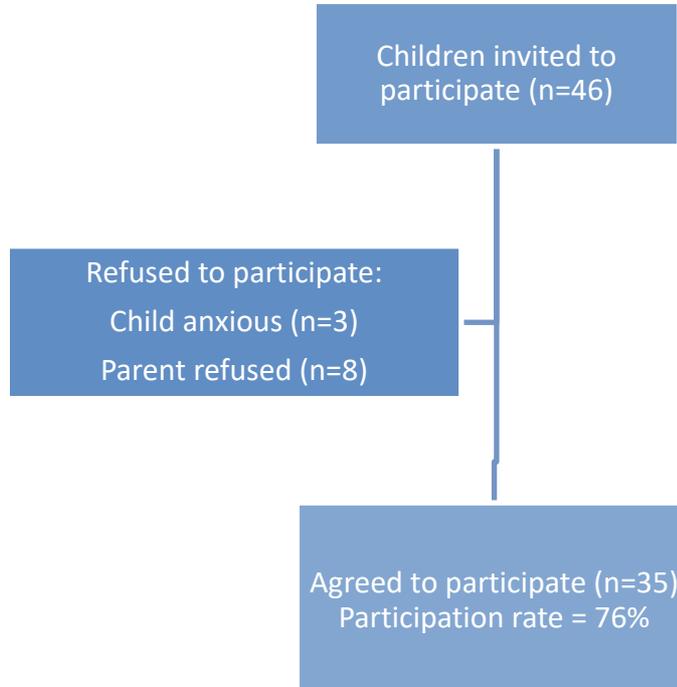
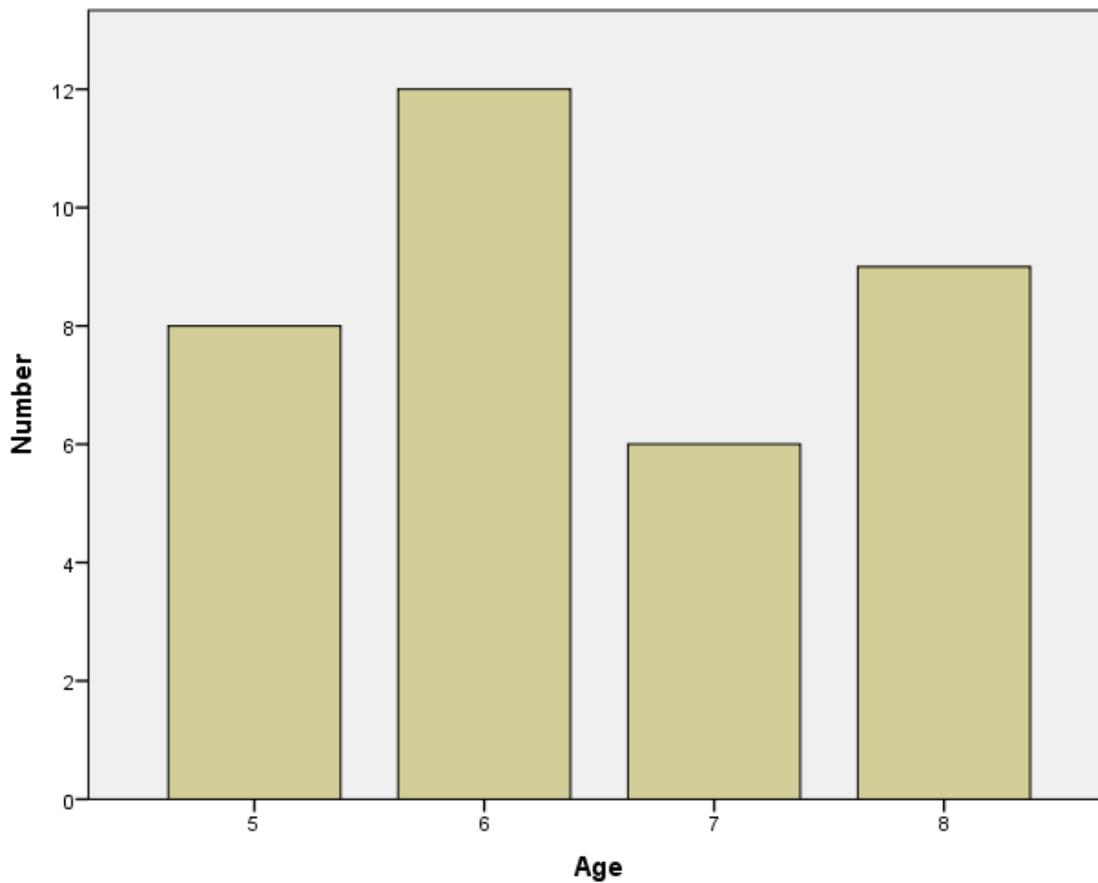


Figure 2 Recruitment details for questionnaire

## 4.1.2 Demographics

### 4.1.2.1 Age

This study recruited participants in the age range of 5 to 8 years. The mean age of the participants was 6.46 years (sd = 1.12 ; median = 6.00 ). Figure 3 shows the participants age distribution.



**Figure 3** Participants age distribution

### 4.1.2.2 Gender

Almost similar numbers of males and females were recruited, 51% (n=18) were female and 49% (n=17) were male.

### 4.1.2.3 Socioeconomic status

The recruited sample were of varying levels of deprivation with the majority (57.1%) being of the most deprived status (Table 7).

**Table 7 Deprivation quintiles of the participants**

<b>IMD</b>	<b>Percentage (number or participants)</b>
Most deprived	57.1% (20)
More deprived	14.3% (5)
Average	11.4% (4)
Less deprived	8.6% (3)
Least deprived	8.6% (3)

### 4.1.3 Waiting time

The time period from placing the children on the waiting list to the time the participants underwent their dental extractions under GA was recorded. The mean (range) waiting time was 8.8 (1-19) weeks.

#### 4.1.4 Caries experience and dental treatment received

The mean (sd) of DMFT/dmft was 7.66 (3.71) and median = 8.00 (range = 1-20) and the mean (sd) of total number of teeth extracted under GA was 7.94 (sd = 3.27) and median = 8.00 (range = 1-14). Table 8 shows details of the mean (range) number of teeth extracted based on type of teeth.

**Table 8 Caries experience and number of dental extractions received**

	Minimum	Maximum	Mean	Std. Deviation
DMFT/dmft	1	20	7.66	3.71
<b>Teeth extracted</b>				
Anterior primary	0	6	0.97	1.98
Posterior primary	0	8	5.80	2.70
Posterior permanent	0	4	0.60	1.29
Balancing or orthodontic reasons	1	2	1.80	0.45
Mobile teeth	1	3	1.57	0.79
Total teeth extracted	1	14	7.94	3.27

#### **4.1.5 CARIES-QC**

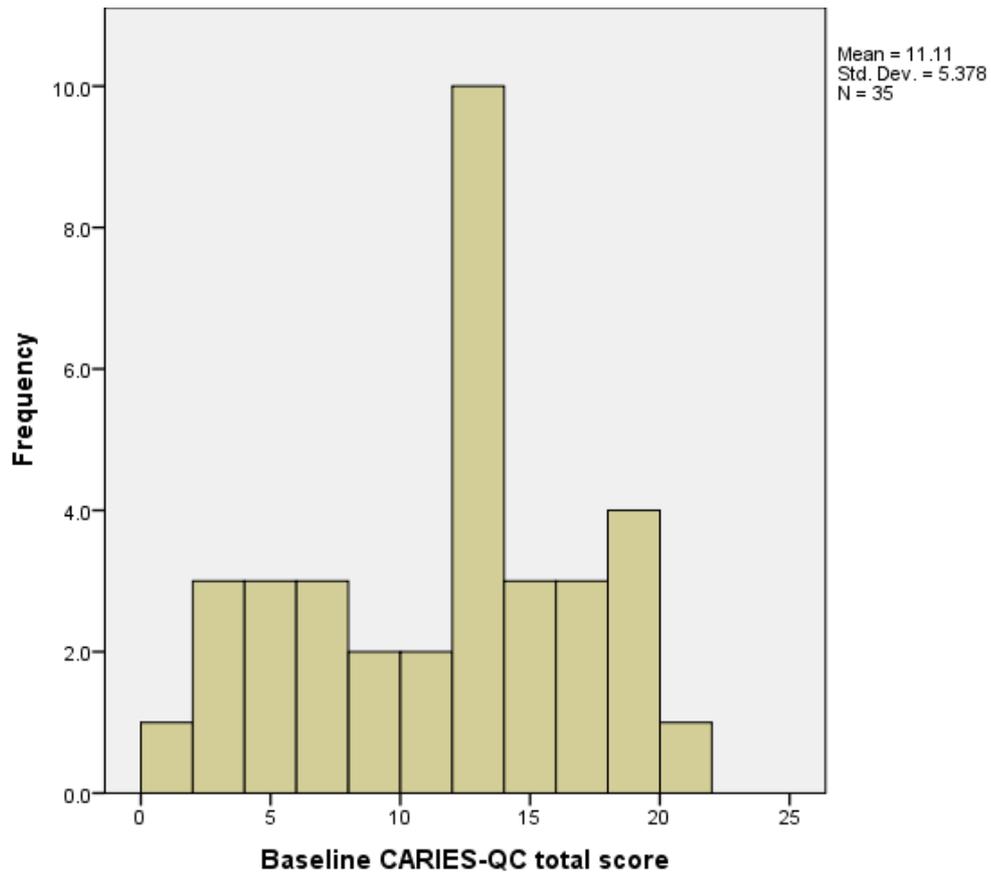
All 35 participants recruited in this study completed the initial questionnaire, which was distributed prior to their treatment. All questions were answered and most children were able to read the questions on their own. However, it was observed by the investigator that in the younger age group some help with reading the questions was required. In these instances the accompanying parent read the questions to the child. However, the children were observed by the investigator to ensure that they answer the questions independently.

#### **4.1.6 Baseline CARIES-QC scores**

At baseline, the mean (range) total raw score was 11.11 (1-20) and the mean (range) CARIES-QC interval score was 11.64 (2.63-17.76). The impact which was most commonly reported by participants at baseline was “getting food stuck” with almost all but one participant (n=34, 97.1%) reporting this impact. The least reported impact was “interfering with schoolwork” (n=13, 37.1%). The majority of the items were reported by more than 50% of participants. Interestingly 12 (34.3%) participants reported that their teeth “do not hurt”. However, the 12 participants who reported that their teeth “do not hurt” have reported other impacts related to their caries experience with CARIES-QC raw total scores ranging from 1-13 (mean = 5.75). This compared with scores of 5-20 (mean = 13.9) for those reporting “a bit” or “a lot” for pain for the question asking if their teeth hurt. At baseline 27 participants (77.1%) reported that their teeth were “a bit” or “a lot” of a problem with respect to the global question. Further details are displayed in Table 9.

**Table 9 Responses to CARIES-QC at baseline**

Item	Response frequency and (proportion)			
	Not at all	A bit	A lot	Total of positive responses ("A bit" or "a lot")
1. How much do your teeth hurt you?	12 (34.3%)	17 (48.6%)	6 (17.1%)	23 (65.7%)
2. Do your teeth make it hard to eat some foods?	11 (31.4%)	13 (37.1%)	11 (31.4%)	24 (68.6%)
3. Do you have to eat on one side of your mouth because of your teeth?	10 (28.6%)	10 (28.6%)	15 (42.9%)	25 (71.4%)
4. Do you get food stuck in your teeth?	1 (2.9%)	17 (48.6%)	17 (48.6%)	34 (97.1%)
5. How much do you get kept awake by your teeth?	18 (51.4%)	12 (34.3%)	5 (14.3%)	17 (48.6%)
6. How much do your teeth annoy you?	9 (25.7%)	11 (31.4%)	15 (42.9%)	26 (74.3%)
7. How much do your teeth hurt when you brush them?	19 (54.3%)	11 (31.4%)	5 (14.3%)	16 (45.7%)
8. Do you have to eat more carefully because of your teeth?	10 (28.6%)	14 (40%)	11 (31.4%)	25 (71.4%)
9. Do you have to eat more slowly because of your teeth?	17 (48.6%)	8 (22.9%)	10 (28.6%)	18 (51.4%)
10. Do you feel cross because of your teeth?	16 (45.7%)	7 (20%)	12 (34.3%)	19 (54.3%)
11. How much have you cried because of your teeth?	12 (34.3%)	9 (25.7%)	14 (40%)	23 (65.7%)
12. Do your teeth make it hard to do your schoolwork?	22 (62.9%)	8 (22.9%)	5 (14.3%)	13 (37.1%)
13. How much of a problem are your teeth for you?	8 (22.9%)	13 (37.1%)	14 (40%)	27 (77.1%)



**Figure 4 Baseline CARIES-QC total (raw) scores**

#### **4.1.6.1 Difference in baseline mean CARIES-QC score between subgroups**

In the analysis below the CARIES-QC interval score was used instead of the CARIES-QC raw total score (refer to 2.3.3 Scoring of CARIES-QC for details).

##### **4.1.6.1.1 Gender**

The data was normally distributed, as assessed by Shapiro-Wilk's test,  $p > 0.05$ . There were no outliers in the data, as assessed by inspection of a boxplot. An independent-samples t-test was run to determine if there were differences in baseline mean CARIES-QC scores between male and female participants. Male baseline mean CARIES-QC score was higher than female baseline mean CARIES-QC scores with a

mean difference of 0.4 (95% CI, -2.26 to 3.05). However, there was no statistically significant difference in baseline mean scores between males and females,  $p=0.76$ .

#### **4.1.6.1.2 Age**

The data was inspected for normality and was found to be not normally distributed. A Kruskal-Wallis H test was run to determine if there were differences in baseline CARIES-QC scores between different age groups. Distributions of baseline scores were not similar for all groups, as assessed by visual inspection of a boxplot.

Median baseline CARIES-QC scores were not statistically significantly different between age groups,  $p=0.39$ .

#### **4.1.6.1.3 Socioeconomic status**

The data was inspected for normality and was found to be not normally distributed. A Kruskal-Wallis H test was run to determine if there were differences in baseline CARIES-QC scores between different deprivation groups. Distributions of baseline CARIES-QC scores were not similar for all groups, as assessed by visual inspection of a boxplot. Median baseline CARIES-QC scores were statistically significantly different between groups,  $p<0.05$ .

Subsequently, pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. This post hoc analysis revealed statistically significant differences in median baseline scores between less deprived (5.84) and more deprived (14.84) groups,  $\chi^2(3) = 10.26$  ( $p=0.008$ ), but not between the other deprivation groups.

#### **4.1.6.1.4 DMFT/dmft**

A Spearman's rank-order correlation was run to assess the relationship between DMFT/dmft and baseline mean CARIES-QC scores. Preliminary analysis showed the relationship to be monotonic, as assessed by visual inspection of a scatterplot. An increase in DMFT/dmft was strongly associated with an increase baseline mean CARIES-QC score. There was a statistically significant, strong positive correlation between DMFT/dmft and baseline mean CARIES-QC scores,  $r = 0.686$ ,  $p < 0.0005$ .

#### **4.1.7 Follow-up CARIES-QC scores**

#### **4.1.8 Response rate**

At the one-month follow-up 17/35 of questionnaires were returned through the post giving a response rate of 49%. Response rate was lower at the three-month follow-up with 37% ( $n=13$ ) participants returning the follow-up questionnaire through the post. Only 2 participants returned both questionnaires. In total 28/35 (80%) participants returned at least one follow-up questionnaire and 7 participants did not return either of the questionnaires accounting for an overall 20% loss to follow-up.

#### **4.1.9 Impacts reported at follow-up**

Of the 28 participants who returned the follow-up questionnaire, 25 (89.2%) reported an improvement since baseline, 1 (3.6%) reported no change and 2 (7.1%) reported a deterioration in their oral condition. All items were reported at least once by the participants. It was observed at the one-month follow-up "getting food stuck" remained the most reported item (82.4%,  $n = 14$ ). However, only 1 participant reported that "teeth hurt" (5.9%,  $n = 1$ ). Items relating to mastication such as "hard to eat some foods" ( $n=13$ , 76.5%) were reported at a greater proportion than items related to pain as illustrated in Table 10. Similar findings were reported at the three-month follow-up as

described in Table 11. At the follow-up only 2 (5.7%) participants scored the lowest possible score (0).

**Table 10 Response to CARIES-QC at 1-month (n=17)**

Item	Response (frequency and proportion)			Total of positive responses ("A bit" or "a lot")
	Not at all	A bit	A lot	
1. How much do your teeth hurt you?	16 (94.1%)	1 (5.9%)	0	1 (5.9%)
2. Do your teeth make it hard to eat some foods?	4 (23.5%)	12 (70.6%)	1 (5.9%)	13 (76.5%)
3. Do you have to eat on one side of your mouth because of your teeth?	8 (47.1%)	5 (29.4%)	4 (23.5%)	9 (52.9%)
4. Do you get food stuck in your teeth?	3 (17.6%)	10 (58.8%)	4 (23.5%)	14 (82.4%)
5. How much do you get kept awake by your teeth?	16 (94.1%)	1 (5.9%)	0	1 (5.9%)
6. How much do your teeth annoy you?	13 (76.5%)	4 (23.5%)	0	4 (23.5%)
7. How much do your teeth hurt when you brush them?	11 (64.7%)	5 (29.4%)	1 (5.9%)	6 (35.3%)
8. Do you have to eat more carefully because of your teeth?	9 (52.9%)	7 (41.2%)	1 (5.9%)	8 (47.1%)
9. Do you have to eat more slowly because of your teeth?	10 (58.8%)	4 (23.5%)	3 (17.6%)	7 (41.2%)
10. Do you feel cross because of your teeth?	15 (88.2%)	1 (5.9%)	1 (5.9%)	2 (11.8%)
11. How much have you cried because of your teeth?	13 (76.5%)	3 (17.6%)	1 (5.9%)	4 (23.5%)
12. Do your teeth make it hard to do your schoolwork?	16 (94.1%)	1 (5.9%)	0	1 (5.9%)
13. How much of a problem are your teeth for you?	12 (70.6%)	4 (23.5%)	1 (5.9%)	5 (29.4%)
14. Since the last time you answered these questions, do you think your teeth are:	<b>Better</b>	<b>The same</b>	<b>Worse</b>	
	15 (88.2%)	0	2 (11.8%)	

**Table 11 Response to CARIES-QC at 3-months (n=13)****Response (frequency and proportion)**

<b>Item</b>	<b>Not at all</b>	<b>A bit</b>	<b>A lot</b>	<b>Total of positive responses ("A bit" or "a lot")</b>
1. How much do your teeth hurt you?	12 (92.3%)	1 (7.7%)	0	1 (7.7%)
2. Do your teeth make it hard to eat some foods?	8 (61.5%)	5 (38.5%)	0	5 (38.5%)
3. Do you have to eat on one side of your mouth because of your teeth?	7 (53.8%)	5 (38.5%)	1 (7.7%)	6 (46.2%)
4. Do you get food stuck in your teeth?	7 (53.8%)	4 (30.8%)	2 (15.4%)	6 (46.2%)
5. How much do you get kept awake by your teeth?	10 (76.9%)	3 (23.1%)	0	3 (23.1%)
6. How much do your teeth annoy you?	9 (69.2%)	3 (23.1%)	1 (7.7%)	4 (30.8%)
7. How much do your teeth hurt when you brush them?	10 (76.9%)	3 (23.1%)	0	3 (23.1%)
8. Do you have to eat more carefully because of your teeth?	8 (61.5%)	4 (30.8%)	1 (7.7%)	5 (38.5%)
9. Do you have to eat more slowly because of your teeth?	9 (69.2%)	3 (23.1%)	1 (7.7%)	4 (30.8%)
10. Do you feel cross because of your teeth?	11 (84.6%)	2 (15.4%)	0	2 (15.4%)
11. How much have you cried because of your teeth?	11 (84.6%)	1 (7.7%)	1 (7.7%)	2 (15.4%)
12. Do your teeth make it hard to do your schoolwork?	13 (100%)	0	0	0
13. How much of a problem are your teeth for you?	12 (92.3%)	0	1 (7.7%)	1 (7.7%)
14. Since the last time you answered these questions, do you think your teeth are:	<b>Better</b>	<b>The same</b>	<b>Worse</b>	
	12 (92.3%)	1 (7.7%)	0	

#### **4.1.9.1 Follow-up questionnaire at one month and three months**

Data from 28 participants was available at the follow-up. Their mean (sd) age was 6.5 years (1.17) and 57.1% were female whilst 42.9% were male. The mean (range) DMFT/dmft was 7.46 (2-14). The mean (range) of total number of teeth extracted under GA for the participants who responded at follow-up was 7.9 (2-14).

#### **4.1.10 Change between baseline and follow-up CARIES-QC scores**

##### **4.1.10.1 Change between baseline and one-month follow-up**

A paired-samples t-test was used to determine whether there was a statistically significant mean difference between baseline CARIES-QC score and follow-up CARIES-QC score at the one-month follow-up. Data are mean  $\pm$  standard deviation, unless otherwise stated. Two outliers were detected that were more than 1.5 box-lengths from the edge of the box in a boxplot. Inspection of their values did not reveal them to be extreme and they were kept in the analysis. The assumption of normality was not violated, as assessed by Shapiro-Wilk's test,  $p=0.780$ . Participants had higher baseline CARIES-QC scores ( $11.4 \pm 4.3$ ) as compared with one-month follow-up CARIES-QC scores ( $7.4 \pm 3.2$ ), a statistically significant decrease of 4 (95% CI, -6.5 to -1.5),  $p<0.005$ .

##### **4.1.10.2 Change between baseline and three-months follow-up**

A paired-samples t-test was used to determine whether there was a statistically significant mean difference between baseline CARIES-QC score and follow-up CARIES-QC score at the three-months follow-up. Data are mean  $\pm$  standard deviation, unless otherwise stated. The differences between mean baseline CARIES-QC score and mean follow-up CARIES-QC score at the three-months follow-up were normally distributed, as assessed by Shapiro-Wilk's test ( $p=0.62$ ), and by visual inspection of a

Normal Q-Q Plot. Participants had higher baseline CARIES-QC scores ( $11.3 \pm 3.5$ ) as opposed to three-months follow-up CARIES-QC scores ( $5.5 \pm 3.5$ ), a statistically significant decrease of 5.8 (95% CI, -8.6 to -3.0),  $p < 0.005$ .

#### 4.1.10.3 Difference between one-month and three-month follow-ups

An independent-samples t-test was run to determine if there were differences in mean CARIES-QC scores between the one-month and three-month follow-ups. One-month follow-up mean CARIES-QC score was higher than three-months follow-up mean CARIES-QC scores with a mean difference of 2.43 (95% CI, -0.15 to 5.0).

However, there was no statistically significant difference in mean interval scores between one-month and three-months follow-up interval scores,  $p = 0.64$ .

#### 4.1.11 Effect size

The effect size ( $d$ ) was calculated using the following formula:

$$d = \frac{M}{SD}$$

$M$  = mean difference between the two related groups

$SD$  = standard deviation of baseline scores

An effect of  $< 0.2$  indicated a small, but clinically meaningful magnitude of change,  $0.2 - 0.7$  a moderate change, and  $> 0.7$  a large change (Malden et al., 2008).

At the one-month follow-up effect size was 0.93 (mean=4, sd=4.3), whilst at the three-month follow-up effect size was 1.66 (mean=5.8, sd=3.5). At both time intervals the effect size was large.

#### 4.1.12 Overall comparison between baseline and follow-up

An overall comparison between mean CARIES-QC interval scores at baseline and follow-up was made showing a mean change score of 4.89. Further descriptive analysis was performed on participants who reported improvement, no change, or worsening with regards to the global question (Table 12). This was carried out by assessing the difference in scores between baseline and follow-up. Change scores were calculated by subtracting follow-up scores from baseline scores. Thus, a positive change score indicates an improvement in OHRQoL, and a negative change scores indicates a deterioration.

**Table 12 Mean CARIES-QC scores at baseline and follow-up**

Reported condition at follow-up	Mean (range) score at baseline	Mean (range) score at follow-up	Mean (range) change score
All follow-up participants (n=28)	11.64 (2.63 - 17.76)	6.75 (0 - 13.03)	4.89 (-3.21- 16.17)
Improved (n=25)	11.26 (2.63 - 17.76)	6.17 (0 – 10.64)	5.09 (-3.21 – 16.17)
Stayed the same (n=1)	14.22	13.03	1.19
Deteriorated (n=2)	14.31 (12.45 – 16.17)	10.81 (8.60-13.03)	3.50 (3.14 – 3.85)

The minimally important difference (MID) of the total scores was calculated using the mean change scores of those who had reported 'improvement' on the global transition rating. The MID is the smallest difference in score which the participant viewed as being beneficial. MID reference values were taken from Malden et al., 2008 who used

an anchor-based approach in which the global transition rating acted as the anchor or 'reference' point.

The mean difference in CARIES-QC score between baseline and follow-up for those who felt they had improved was 5.09 (range = -3.21 - 16.17), thus indicating a minimal important difference (MID) of 5.09 points.

Interestingly, as shown in Table 13, five of the participants who reported improvement in their OHRQoL in response to the global question, produced negative score changes (i.e. deterioration) when their CARIES-QC scores were examined. However, at baseline all participants scored lower than the sample's mean score.

**Table 13 CARIES-QC score of participants with higher scores at follow-up compared to baseline**

<b>Score at baseline</b>	<b>Score at follow-up</b>	<b>Score difference</b>
8.6	9.32	-0.72
8.6	9.32	-0.72
4.5	5.84	-1.34
8.6	10.00	-2.4
2.63	5.84	-3.21

In contrast, participants who reported their oral health condition deteriorated in response to the global question had lower scores at the follow-up when compared with their baseline scores as demonstrated in Table 14. However, at baseline both participants scored higher than the sample's mean score. One participant had 10 primary teeth extracted (6 posterior and 4 anterior teeth) and the other had a total of 14 teeth (all primary molars, first permanent molars and two primary anterior teeth) which is higher than the mean of the recruited sample. Whilst the one participant who reported no change in oral health status demonstrated a score change of +1.19, which was less than the MID for this sample.

**Table 14 CARIES-QC score of participants who reported worsened oral health**

<b>Score at baseline</b>	<b>Score at follow-up</b>	<b>Score difference</b>
12.45	8.6	+3.85
16.17	13.03	+3.14

#### **4.1.13 Total number of teeth extracted and follow-up CARIES-QC score**

##### **4.1.13.1 Follow-up score**

A Spearman's rank-order correlation was run to assess the relationship between total number of teeth extracted and follow-up CARIES QC score. Data from 28 participants was included in this analysis. Preliminary analysis showed the relationship to be monotonic, as assessed by visual inspection of a scatterplot. There was a statistically

significant moderate correlation between total number of teeth extracted and follow-up CARIES-QC score,  $r = 0.45$ ,  $p < 0.05$ .

#### **4.1.13.2 Difference between baseline and follow-up score**

A Spearman's rank-order correlation was run to assess the relationship between total number of teeth extracted and difference between CARIES QC score at baseline and follow-up. There was no statistically significant relationship between difference in CARIES-QC scores and total number of teeth extracted,  $r = -0.15$ ,  $p = 0.45$ .

#### **4.1.14 Summary of significant findings**

1. In this study, there was no difference in baseline CARIES-QC score between gender and different age groups, however, the mean ranks of baseline mean CARIES-QC scores were statistically significantly different between SES groups,  $p < 0.05$ .
2. There was a statistically significant, strong positive correlation between DMFT/dmft and baseline mean CARIES-QC scores,  $r = 0.686$ ,  $p < 0.0005$ .
3. The most reported item at follow-up was "getting food stuck", and the least reported item was "teeth hurt".
4. There was a statistically significant difference between baseline CARIES-QC and the one-month and three-months follow-up with a large effect size of 0.93 at one-month, and 1.66 at three-months.
5. There was a statistically significant moderate correlation between total number of teeth extracted and follow-up CARIES-QC score,  $r = 0.453$ ,  $p < 0.05$ .

However, there was no statistically significant difference between total number of teeth extracted and difference in CARIES-QC score between baseline and follow-up,  $r = -0.15$ ,  $p = 0.45$ .

## **4.2 Phase 2: Children's experience following dental extractions under general anaesthesia**

### **4.2.1 Study sample**

A total of five children agreed to participate and were enrolled to this study. The mean age of the participants was 7 years and 2 months. All children received application of a topical anaesthetic at the cannula insertion site on the dorsal surface of their hands. No children received intra-operative local anaesthetic to extraction sites. Oral paracetamol was administered pre-operatively to all children for pain relief. Oral sedation with midazolam was administered pre-operatively for one of the children. The GA procedure involved an intravenous induction which was, at times, supplemented with a gas induction. On average, participants underwent the removal of about 6 primary teeth (range = 2-13 teeth). No other dental treatment was performed. The details of the children are summarised in Table 15. Clinical records of the participants were not examined by the investigator prior to the interview, merely to reduce preconceptions of each child's oral health status. Only data related to the inclusion criteria was checked beforehand. The records were reviewed following completion of the interview.

**Table 15 Demographic details of participants who underwent dental extractions under GA**

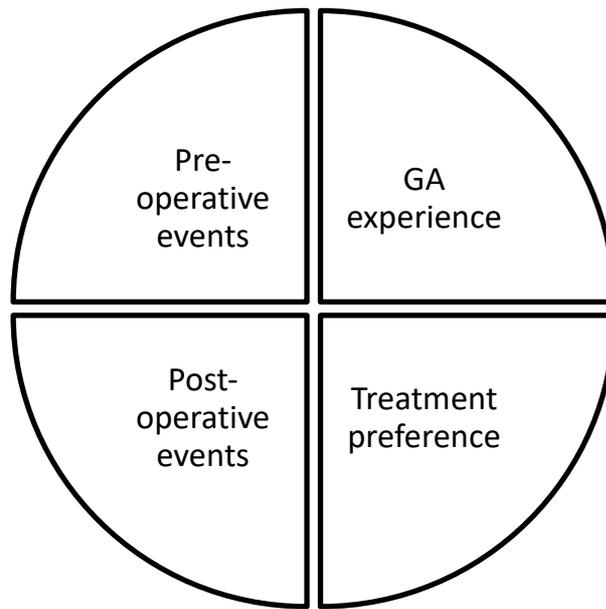
	<b>Gender</b>	<b>Age</b>	<b>Ethnicity</b>	<b>dmft</b>	<b>Total number of teeth extracted (mobile)</b>	<b>Time between GA and interview</b>
<b>C1</b>	Male	7 years 10 months	White other	6	8 (2)	11 weeks
<b>C2</b>	Female	7 years	White other	12	13 (2)	15 weeks
<b>C3</b>	Male	7 years 1 month	Pakistani	6	6 (2)	10 weeks
<b>C4</b>	Female	7 years 6 months	White British	4	4 (0)	13 weeks
<b>C5</b>	Female	6 years 8 months	Black African	10	2 (1)	10 weeks

### **4.2.2 Interviews**

Interviews with 5 children were held by the investigator. All participants were accompanied by one of their parents throughout the interview. The interview sessions varied in length from 6 minutes to 18 minutes, with a mean duration of 11 minutes 48 seconds. In 4 out of 5 interviews the parent was active in the discussion especially when questions which required recall were asked. The presence of parents aided the discussion of events with the children. The transcripts were initially analysed to gain a broad understanding of the areas covered. The children described narratives of the impact of having caries and the treatment they had received. One child did not always express herself in sentences, instead she provided “yes” or “no” answers.

### 4.2.3 Framework Analysis

The results of the analysis of the semi-structured interviews were informed by the chronology of the care pathway: pre-operative events, GA experience and post-operative events. A separate category involved their preference to the choice of treatment in the future, this was under the theme of: treatment preference.



**Figure 5 Main themes identified in the framework analysis**

### 4.2.3.1 Pre-operative events

Part of the interview included children talking about their experience with dental caries prior to having their extractions. The main topics mentioned were pain and function.

#### 4.2.3.1.1 Pain

Dental pain prior to having the dental extractions was recalled repeatedly by the interviewees; however, some children used different words to describe the pain. C1, who had extraction of 6 teeth due to caries, reported negatively when asked if he experienced any pain from his teeth before having them extracted. However, when prompted by his accompanying mum he described the pain as being a disaster.

*“HA: Before going to sleep did your teeth hurt?”*

*C1: No*

*Mum: They did, remember?*

*C1: Ohhhh, it was a disaster.”*

He also felt at the time when he had the dental pain episodes, he didn't know what to do to make himself better.

*“I went to school then a little bit later my teeth start hurting painly. And I don't know what to do.” (C1)*

Upon reporting dental pain prior to the extractions, one child showed that she was aware and realised that her symptoms were not a good sign and indicated a negative impact on her teeth.

*“It felt like that was not good for my teeth.” (C2)*

#### 4.2.3.1.2 Function

Dental cavities are considered problematic as they hinder proper tooth brushing. One child reported that food gets stuck between her teeth.

*“Because when I’m brushing there, there it’s not good for my teeth. The food get stuck inside in it.” (C2)*

#### 4.2.3.1.3 Emotion

Children were not happy with how their teeth made them feel as some felt emotional about their condition. C5 mentioned she cried from toothache.

*“HA: Did you used to wake up from your teeth, or were they okay at night?”*

*C5: I, a little bit cried.”*

#### 4.2.3.2 General anaesthetic experience

In this research interest in eliciting the children’s experience from the GA was a main element. The children had their interview at a range of 10-15 weeks after their GA procedure.

##### 4.2.3.2.1 Pain

All children received the general anaesthetic via the intravenous route. Unsurprisingly, some children recalled that the needle was painful.

*“Oh the stingy thing.” (C1)*

*“It was a bit painful with the needle in.” (C4)*

Pain was also experienced upon recovery from the general anaesthetic. C5 reported that she felt her teeth hurt as she woke up.

*“HA: How about when you woke up? How did that feel like?”*

*C5: It felt a little bit hurting.*

*HA: What was hurting?*

*C5: My teeth hurt.”*

Pain shortly after the procedure was reported on some accounts, such as upon toothbrushing.

*“It was painful for a while.” (C1)*

*“It kind of hurt when I first started brushing my teeth.” (C4)*

#### **4.2.3.2.2 Taste**

C3 was one of the children who was given oral midazolam as a premedication prior to his GA. He described the taste of the medicine being unpleasant.

*“C3: Fine, but the sleepy juice was not alright.*

*HA: Not alright? How did it feel like?”*

*C3: It felt disgusting, I had to drink it.”*

#### 4.2.3.2.3 Emotion

The thought of going to sleep at a hospital may bring about different emotions. Although, the induction of general anaesthetic was uneventful, some children felt nervous about it.

*“I was nervous, not scared, just nervous.” (C3)*

#### 4.2.3.2.4 Onset of anaesthesia

It is worth noting here that none of the participants had experienced a GA previously. Upon enquiring about their experience with the GA itself the children described the feeling as “weird” and going to sleep right away.

*“Weird, I closed my eyes straight away.” (C1)*

*“C4: It was a little bit different*

*HA: How was it different?*

*C4: Because I normally stay up for a bit.”*

#### 4.2.3.2.5 Recovering from anaesthesia

When asked about how they felt when they woke up some mainly recalled physical impacts, such as feeling dizzy, feeling weird, or bleeding from the extraction sites.

*“My head was turning around.” (C2)*

*“I was dizzy, proper dizzy.” (C3)*

*“... my brain goes weird since I woke up.” (C4)*

One child noted that he felt tired and can't move his legs.

*"I felt really tired and my legs can't move." (C1)*

C2, who had 13 primary teeth extracted mentioned bleeding.

*"..but the blood was going on me." (C2)*

#### **4.2.3.3 Post-operative events**

This study was interested in further understanding how children felt about the outcome of the treatment they received. Children were asked about how their teeth feel following their treatment.

##### **4.2.3.3.1 Comfort**

No children reported having pain from their teeth at the time of their interview. All responded positively when asked "How do your teeth feel now?"

*"Like it didn't hurt when we take out my teeth out." (C1)*

*"They feel alright" (C3)*

*"Good." (C5)*

##### **4.2.3.3.2 Function**

Children reported variably with regards to the effect of eating with missing teeth. Some felt eating is easier now that they are not feeling pain anymore.

*C1: It is easier now*

*HA: Why is it easier now?*

*C1: Because my teeth are not hurting very much*

Others reported that eating, especially hard food, is not without its difficulties.

*"I can't bite it." (C2)*

*"I just bite a chocolate but I couldn't bite." (C2)*

One child specified that it is uncomfortable when she bites on areas where there are no teeth.

*"When my food goes in the holes where the teeth were taken out, that's hurting a bit." (C4)*

*"...sometimes when I eat apples it starts hurting." (C4)*

#### **4.2.3.4 Treatment preference**

When children were asked about their choice of treatment if they required similar treatment in the future, all preferred to have a general anaesthetic rather than undergo dental treatment under a local anaesthetic. On a couple of accounts, the reason mentioned was to avoid feeling any pain.

*"Asleep. It's better." (C2)*

*"I'd rather do it while I'm asleep, because I don't want to feel any pain." (C3)*

*"I wouldn't like to be awake... I don't want to feel any pain." (C4)*

One child mentioned not being scared about having similar treatment in the future.

*"I wouldn't be scared." (C1)*

#### 4.2.3.5 Parents participation in interviews

Recalling pre-operative events which occurred weeks or months before may not be easily remembered with great detail. Significant impacts or recurrent episodes were reported in the interviews. Some children had difficulty recalling events from the past. In 4 out of 5 interviews parents contributed to the interview. On multiple occasions the accompanying parent prompted their child, while when some children felt they can't remember past events they asked their parent to help as demonstrated in the following quotations:

##### **Prompting by parents:**

The quotations below show examples where parents helped their children recall past events when they did not recall them happening.

*“HA: Before going to sleep did your teeth hurt?”*

*C1: No*

*Mum: They did, remember?*

*C1: Ohhhh, It was a disaster”*

*“HA: Did you take any medicine for your teeth?”*

*C1: No no, I didn't*

*Mum: The sweet one remember?*

*C1: Yes, I'm calling it lemon now.”*

*“HA: Did your teeth used to hurt before you had them taken out?”*

*C3: Ummmmm, I don't remember*

*Mum: Yes, you used to have pain from your teeth.”*

##### **Rechecking with parent:**

Here is a set of examples where the children referred to their parents when they were unsure.

*“C1: I eat the same food, it hasn’t changed. Has it changed mama?”*

*“C1: Before, it was fine I think, Was it? (asking mum) Ummm I don’t know.”*

*“HA: How much did they hurt you?”*

*C2: Daddy how much?”*

Parents were satisfied with their children’s experience and were quite relieved that their children coped well with the procedure and did not have a traumatic experience.

*“Of course, he was a little bit worried but because of how everything was organised he wasn’t that scared or as worried. So basically, that’s it. So definitely does not have bad memories or a traumatic experience or anything like that.” (C1’s mum)*

*“My daughter is a sensory child so out of everybody she would have probably found it more difficult than anybody else because she’s so sensory in that respect and she was fine with it and it was a good overall experience I think, you know much better than her being awake and having the operation. The fact that she coped alright with it shows it’s probably the best thing to do.” (C4’s mum)*

## Chapter 5 Discussion

### 5.1 Introduction

This study investigated changes in OHRQoL of five to eight year old children with dental caries following dental extractions under GA. This study was carried out over two phases. The first phase was a quantitative study assessing changes in OHRQoL following dental extractions under GA, using the CARIES-QC measure. This study is one of the few studies which has investigated changes in OHRQoL using a child-self report measure. The use of OHRQoL measures enables evaluation of the impact of dental treatment from a patient's perspective (Knapp et al., 2017a). The study design was a prospective longitudinal study and involved consecutive samples. OHRQoL was measured at baseline and then at one-month and three-months follow-up. A systematic review investigating change in children's OHRQoL following dental treatment under GA for the management of dental caries revealed all included studies relied on proxy reports of OHRQoL (Knapp et al., 2017a). Therefore there is a need for further studies employing validated, child self-report measures of OHRQoL.

The second phase of the study was a qualitative study exploring children's experience following dental extractions under GA. Qualitative interviews were carried out with children several weeks following their procedure. This is one of the few studies carried out in the UK, and the first to be carried out in Leeds.

This study is important and adds to the evidence of the relationship between dental extractions of carious teeth under GA and the improvement of the OHRQoL from children's perspectives.

## **5.2 Phase 1 : Changes in OHRQoL following dental extractions under general anaesthesia**

### **5.2.1 Discussion of methodology**

#### **5.2.1.1 Choice of measure**

Current literature on changes in OHRQoL in children following dental treatment under GA for the management of dental caries was primarily investigated with use of proxy reports of OHRQoL. The most commonly used instruments were the Early Childhood Oral Health Impact Scale (ECOHIS) (Pahel et al., 2007) and the Parental-Caregiver Perceptions Questionnaire (P-CPQ) (Jokovic et al., 2003). A recent systematic review highlighted the need for child self-report measures to be used in future OHRQoL research due to the evidence showing parents/caregivers generally have a low to moderate overall agreement with their child's ratings (Knapp et al., 2017a). In this study CARIES-QC, a caries-specific measure of OHRQoL, was used to measure OHRQoL before and after dental extractions under GA (Gilchrist, 2015). The measure has been validated for the studied population. Furthermore, CARIES-QC showed a high level of internal consistency (Cronbach's alpha = 0.9). Potential alternatives to the CARIES-QC were the COHIP (Broder et al., 2007) and CPQ (Jokovic et al., 2002; Jokovic et al., 2004), however, both measures have been validated for children aged 8-15 years and 8-14 years, respectively. To involve children younger than 8-years, use of a validated questionnaire for the younger age group was required.

#### **5.2.1.2 Sample selection**

Approximately 46,500 children and young people under 19 were admitted to hospital for a primary diagnosis of dental caries in 2013–14 in the UK. These numbers were highest in the five- to nine-year-old age group which made up more than 50% of total hospital admissions for people admitted to hospital with a primary diagnosis of dental

caries (Royal College of Surgeons, 2015). Based on the above findings our study sample included children aged five- to eight-years of age as this age-group would yield results which are most representative of this sample. It was not possible to include children younger than five years as the CARIES-QC questionnaire was not validated for this age group. Children nine years of age and older most commonly require extractions for teeth affected with MIH in addition to dental caries. Possible future work could assess changes in OHRQoL in children with MIH as a separate sample. Children unable to read English were excluded from this study as the measure was designed to be administered in English.

A consecutive sample was recruited in this study. According to Knapp et al., a consecutive sample, as opposed to a convenience sample, would be more representative of the whole population (Knapp et al., 2017a).

### **5.2.1.3 Questionnaire**

#### **5.2.1.3.1 Completion of the questionnaire**

On the day of the GA, children were only approached if they had completed all their pre-GA checks, to ensure minimal disruptions to the clinic. The investigator was present during the completion of the baseline questionnaires, mainly to observe completion of the questionnaire by children rather than their accompanying parents and ensure that all questions were answered. Although younger children required some help reading the questions, it was noticed that their input rather than their parents was recorded. The investigator handed each child the questionnaire and a pen to encourage self-completion. The presence of the investigator had a beneficial effect on completion rate with no responses missing at baseline. Similarly completion rate was 100% at both follow-ups. It is acknowledged since follow-up questionnaires were completed at home, there is a possibility questionnaires were not filled solely by

children. Instructions on questionnaire completion by children were given in written form through a letter attached to the questionnaire.

#### **5.2.1.3.2 Response rate**

Loss to follow-up is one of the challenges anticipated in studies of this nature. Reports have varied with respect to loss to follow-up in similar studies, ranging from 0% (Baghdadi, 2015) to 47.8% (Yawary et al., 2016). The wide range of loss to follow-up reports could potentially be attributed to the variation in data collection methods used. The aim of this study was to assess changes in OHRQoL over two periods, one-month and three-months post-operatively, to assess the pattern of change in OHRQoL over different time periods. Loss to follow-up was considered when determining sample size calculation, in this study; thirty five participants were recruited, to account for 50% loss to follow-up. As reported previously, data was available for seventeen participants (17/35) at the one-month follow-up and for thirteen participants (13/35) at the three-months follow-up. Unfortunately, data was only available for two participants over both periods, deeming it not possible to compare data across the two follow-up periods. It seems including two follow-up periods, eight weeks apart, created a burden attributing to the low response rate.

The follow-up questionnaires were sent through the post; the main drive for this decision is that the majority of patients are initially referred from primary care services, usually a general dental practice located closer to the participants residence, to tertiary care services, the Leeds Dental Institute. Following dental GA, participants are referred back to their referring dentist for continued preventive care. Arranging for a review appointment for follow-up may have potentially improved response rates. In a similar study, follow-up appointments were arranged at two-weeks and three-months post-operatively. If participants did not present for a review appointment, then the questionnaire was posted to their address with a prepaid return envelope.

Furthermore, if the questionnaire was not returned, then the investigator conducted a telephone interview to complete the questionnaire. The use of multiple data collection methods yielded a response rate of 76% and 59% at the two-week and three-month follow-ups, respectively (Yawary et al., 2016).

In another study which included data from 140 participants, a combination of data collection methods were used at the one-month follow-up. A review appointment was arranged for a dental check-up and completion of the follow-up questionnaire. Where the parents failed to attend the appointment, the questionnaire was mailed to the participants. Twenty three failed to attend the follow-up appointment, of which only five returned the questionnaire by post (Jankauskiene et al., 2014).

Children may be referred for management of dental caries under GA for several reasons such as, the advanced nature of the dental caries and the inability of the child to tolerate the complex treatment due to behavioural issues and or dental fear that may have accumulated over time (Park et al., 2018). In a study which explored the prevalence of postoperative morbidity in children undergoing tooth extraction under GA in relation to pre-operative dental anxiety and anaesthetic induction distress, found that non-respondent parents were significantly more dentally anxious than respondents (Hosey et al., 2006). Although dental anxiety was not measured in this study, it is plausible that parent or child dental anxiety contributed to loss to follow-up.

The low response rate is one of the major limitations in this study. It appears achieving a high response rate requires exhaustive measures. It is worthwhile for future research to investigate methods to improve participation, this is particularly important as it will allow the collection of follow-up data from a larger sample, potentially a more representative sample of the studied population.

#### **5.2.1.3.3 Recall bias**

Recall bias can be a methodological issue in research that involves interviews or questionnaires. The accuracy of the information reported by the participants could potentially be affected by recall bias. Ideally, a test-retest reliability of the questionnaires would be carried out on 10% of participants after two or three weeks. However, consideration with regards to the sporadic nature of symptoms from carious teeth could affect the result, as participants may have a different oral health status at the retest period. During development of the CARIES-QC measure a test-retest reliability was carried out on 30 participants with test intervals ranging from 3-127 days. The test-retest reliability (intraclass correlation coefficient = 0.68) was a little lower than the ideal of >0.7 (Gilchrist, 2015). Repeating the test-retest reliability would require a larger sample size and preferably a more consistent recall period.

#### **5.2.1.4 Follow-up period**

In this study, children were followed-up for a period up to three-months post-operatively. There still remains a need for long-term follow-up studies, so as to ascertain whether the change in OHRQoL was sustained over time (Park et al., 2018). However, the low response rate at the follow-up periods made it difficult to justify extending the follow-up periods, which may be considered as a limitation. Nevertheless, the follow-up period in this study was higher than in other similar studies (Thomson et al., 2014; de Souza et al., 2016).

### **5.2.2 Discussion of results**

The findings of the current study illustrated that OHRQoL in children with dental caries had significantly improved following dental extractions under GA at both follow-up periods. The lack of a control group precludes evaluating that all improvement resulted

from the treatment provided; however, withholding treatment from suitable controls would be unethical.

To date the measure has been used twice. It was first used as part of the validation process which proved CARIES-QC to have acceptable psychometric properties and appears to be acceptable to participants with dental caries, aged 5-16 years (Gilchrist, 2015). A total of 197 participants with dental caries were recruited at baseline, of which 42 completed the questionnaire at follow-up. Although some of the participants had dental extractions under GA, the effect of number of teeth extracted was not investigated. Knapp and colleagues only used the measure in the assessment of the caries impact before treatment under GA on the everyday lives of children and their families (Knapp et al., 2017b). The following sections discuss the results on changes in OHRQoL following dental extractions under GA using the CARIES-QC measure. It is appropriate to briefly consider the generalisability of the study findings, considering the low response rate.

### **5.2.2.1 Demographics**

Children from a lower socio-economic group are more likely to experience, and have greater severity of dental caries than those from higher socio-economic groups (Royal College of Surgeons, 2015). In fact, it was observed that 57.1% of the sample was from the most deprived group. This correlates well with the current study, as there was a statistically significant difference in baseline CARIES-QC score between different socio-economic groups,  $p < 0.05$ . However, in this study, there was no difference in baseline CARIES-QC score between gender and different age groups.

### **5.2.2.2 Caries experience**

The mean dmft of 5-year old children in Leeds has been reported in 2015 as 1.1 whilst the mean dmft of 5-year old children in Leeds who had caries experience was 3.5

(Public Health England, 2017). The recruited sample had a higher DMFT/dmft level with a mean of 7.66. It was not surprising that participants with higher caries levels reported higher baseline CARIES-QC scores and a statistically significant, strong positive correlation was found. A cross-sectional study, which was conducted on children aged 11-12 years, evaluated the impact of dental health on children's OHRQoL using CPQ 11-14; this study found children with a DMFT/dmft of 2–3 were 2.8 times more likely to have functional limitations than those with a DMFT/dmft of 0, while children with a DMFT/dmft of more than 4 were 4.4 times more likely to experience functional limitations (Alsumait et al., 2015).

### **5.2.2.3 OHRQoL**

Dental caries leads mainly to intermittent dental pain that is not permanently present. The findings showed that not all participants reported having pain at baseline. At baseline children who reported their teeth hurt had higher baseline scores than children reporting their teeth did not hurt. The mean difference of the total (raw) scores of children reporting teeth hurt as opposed to teeth not hurting at baseline was 8.15. Children with oral symptoms due to caries are more likely to have worse OHRQoL. At baseline oral symptoms were reported at a lower rate than functional limitations, this difference can be attributed to the fact oral symptoms are sporadic in nature. The present study also found, with respect to OHRQoL, children were most likely to report difficulties relating to functional limitation at both baseline and follow-up. Markedly, the activities that were reported as most affected included having food stuck in between the teeth and dental sockets and difficulty chewing food. However, this finding needs to be interpreted with caution, getting food stuck could have potentially been over-reported. This can be explained by the possibility children are referring to getting food stuck from consuming retentive food and not from getting food stuck to dental cavities. This has been inferred due to the relatively high number of reports with the question

enquiring about getting food stuck. One way to further analyse this, is by comparing the results to this question with a control group with no caries experience.

Interference with schoolwork was not reported highly at baseline and follow-up; in fact, it was the least reported item at baseline. Response to this question requires making a connection between oral health and schoolwork. It would have been more accurate to assess if children required medical attention to manage oral symptoms while at school, by possibly checking the school nurse records, or checking if the parents were contacted while the child was at school. An indirect way where oral health may affect schoolwork, is by not being able to sleep at night. As opposed to the findings of this study, some parents of school-age children suggested that their child's concentration and schoolwork had improved following dental treatment under general anaesthesia, with teachers commenting on an improvement in the classroom setting (Anderson et al., 2004). In children with dento-alveolar trauma, school functioning was the most affected area of children's OHRQoL. It is likely that the majority of children with dento-alveolar trauma would have needed to take time off school to attend their treatment appointment (Porritt et al., 2011).

Overall, there was a significant difference in children's OHRQoL before and after dental extractions. As anticipated, the effect size observed was large. The large reductions in scores were associated with effect sizes showing large clinically meaningful changes in the total CARIES-QC scores. OHRQoL improved following multiple extractions. However, participants with more teeth extracted had higher DMFT/dmft, hence poorer OHRQoL at baseline and follow-up when compared to participants with lower DMFT/dmft who had a lower number of teeth extracted. A study on children aged 11-12 years old found that children with more than four missing teeth were 45% more likely to experience emotional stress (Alsumait et al., 2015). There was a strong positive correlation between total number of teeth extracted and follow-up scores explaining the poorer OHRQoL at follow-up. However, when assessing if

number of teeth extracted had an effect on the magnitude of change in OHRQoL, no statistically significant association was found. This is the first study to investigate the effect of number of teeth extractions on changes in OHRQoL. Our findings relate to a qualitative study which explored parents' experience following their child's dental general anaesthesia. Amin et al. reported losing teeth was an issue for many children, resulting in negative functional psychological impacts (Amin et al., 2006).

The minimal important difference reported in this study (MID = 5.09) was relatively comparable to a similar study (MID = 4.46) (Gilchrist, 2015). The minimal important difference was exceeded by only 40% of children, despite the 'large' effect size calculated for the change in mean CARIES-QC score. This suggests that the magnitude of the change in score was great among the 40% who exceeded the minimal important difference.

Assessing whether different treatment approaches produce different change in scores was not investigated in this study. However, de Souza and colleagues attempted to make a comparison between two distinct but well-recognised approaches, dental extractions and comprehensive oral rehabilitation, in management of dental caries in young children under GA. Their findings showed the magnitude of change in OHRQoL between the two treatment groups was not statistically significant both at baseline and post-operatively (Mann-Whitney  $p = 0.176$  and  $p = 0.736$ , respectively) (de Souza et al., 2016). However, as with many previous studies, the findings represent data from proxy-reports. It would be interesting to repeat the study using a child self-report measure. Yet, the evidence is not conclusive on whether there is any difference in OHRQoL between an intervention conducted under GA and one conducted under local anaesthesia or inhalation sedation. There are several reasons why this is rather challenging to answer, but it shouldn't stop future researchers from posing it.

### 5.2.3 Limitations

A number of limitations must be acknowledged when considering the results of the present study. Recall bias was one of the limitations considered in this study. It is an issue relating to questionnaires requiring recall of previous events, it might be difficult to recall events of oral symptoms which are episodic in nature. Moreover, the children were approached on the day of the GA, although children's anxiety did not affect participation rate largely, it was felt parents were less likely to allow their child to participate. This could be overcome by recruiting participants on the day of the consultation appointment or by arranging an appointment to carry out prevention whilst they are on the waiting list, particularly all participants are at a high caries risk. This study did not compare changes in OHRQoL in patients who did not meet the inclusion criteria; only patients receiving dental extractions were included. The exclusion of children who did not speak English could have caused or contributed to sampling bias. Including non-English speaking would mandate using tested and translated versions of the questionnaire. Currently, only one translated version is available in Dutch. Another potential limitation of the study was that all of the participants included in this study were receiving their dental treatment from one dental hospital within the United Kingdom. Therefore generalisability of the results found within this study may not be applicable to children receiving dental treatment in other geographical areas. The response rate of this study is not optimal, although similar to previously reported studies exploring changes in OHRQoL with use of questionnaires. These limitations may impact both the validity and the reliability of the study.

#### **5.2.4 Recommendations for future research**

The results of the current study showed improvement in OHRQoL three months after dental extractions after three-months; however, no longer term data was collected. Future research is still required to evaluate if improvement in OHRQoL is sustained after six months or more. At present there is no standardised method to assess OHRQoL. Currently available methods use quantitative data to measure qualitative outcomes. This study included a second phase where interviews were used as a qualitative measure with some participants. However, no questionnaires were completed by participants included in the qualitative phase of the study. Future studies could combine both quantitative and qualitative measures on the same participants and assess if the qualitative data matched quantitative data. This study only investigated one treatment approach, dental extractions under GA. This highlights the need for future research to compare the impact of different treatment approaches, which will add to clinical evidence and provide justification for treatment options. Further research is needed to establish if treatment under GA helps to reduce child dental anxiety in relation to provision dental treatment, since a high proportion of children are referred to GA services for management of dental anxiety.

Finally, more research needs to be carried out to assess and evaluate the cost-effectiveness of GA treatment in relation to OHRQoL against other behaviour management techniques, such as sedation.

### 5.2.5 Conclusion

1. OHRQoL did improve following dental extractions under GA, with large effect sizes observed at one-month and three-months follow-up.
2. Higher DMFT/dmft is associated with poorer OHRQoL
3. Socioeconomic status was significantly associated with OHRQoL, while age and gender had no association with OHRQoL.
4. The number of teeth extracted was strongly correlated with OHRQoL. Children with higher numbers of teeth extracted had poorer OHRQoL at baseline and follow-up.
5. The total number of teeth extracted was not associated with difference in OHRQoL between baseline and follow-up.

Therefore we can reject the following null hypotheses:

- There is no statistically significant association between OHRQoL and dental extractions under a general anaesthetic.
- There is no statistically significant difference between changes in OHRQoL and number of teeth extracted.

## **5.3 Phase 2: Children's experience following dental extractions under general anaesthesia**

### **5.3.1 Research question**

The aim of the qualitative part of the study was to explore children's experiences following dental extractions under a general anaesthetic. More specific objectives included further understanding how children feel about their oral health after having dental extractions and investigate how their overall experience made them feel about receiving similar treatment in the future. Rodd and colleagues conducted a similar study with the use of video diaries and semi-structured interviews (Rodd et al., 2014). Insights into children's experiences of having teeth removed under GA were revealed, which included the effect of the cannula which in some cases caused greater discomfort than the extractions themselves. However, this study had a short follow-up period of two weeks. Thus any long-term physical and psychological impacts arising from multiple extractions under GA were elusive (Rodd et al., 2014). It was felt conducting interviews after a longer follow-up period would identify any persistent or new impacts, allowing a clearer understanding of impacts from dental extractions under GA, although a longer follow-up period could potentially increase the risk of recall bias. The following sections discuss the choice of methodology and the study's findings.

### **5.3.2 Choice of methodology**

#### **5.3.2.1 Qualitative interviews**

While quantitative methods provide some measure of impacts in QOL for children with dental caries managed by dental extractions, methodology using a qualitative approach yields personal narratives that inform us about individual experiences and perceptions. Qualitative approaches are commonly used to obtain a 'deeper understanding' of people's personal experiences and perspectives (Gill et al., 2008b). A qualitative

methodology was used in order to further understand children's experience with dental extractions under GA. As discussed previously, the most common qualitative research methods used in healthcare settings are interviews and focus groups (Stewart et al., 2008). Both methods have benefits such as flexibility in data collection and the opportunity they provide to access personal perspectives and beliefs. Although focus groups may have been useful to generate data, it is unlikely such depth on personal perspectives on children's experiences could have been obtained from a group discussion. Focus groups with children may potentially result in some interruptions, such as being interrupted by another participant while the discussion is ongoing. An uninterrupted interview is essential for children to develop their accounts properly (Borgers et al., 2000). Children may also find unnecessary interruptions distracting and confusing, which may ultimately result in the collection of incomplete or inaccurate data (Gill et al., 2008a). Another limitation of focus groups is that views of some children may have not been heard due to not feeling comfortable talking in front of others.

Qualitative interviews are a valuable tool in child related research as they are believed to provide a deeper understanding than would be obtained from purely quantitative methods such as questionnaires. Interviews can be used to explore the views, experiences, beliefs and motivations of individual participants (Gill et al., 2008b). In this study the semi-structured interviews worked well, in that each child had sufficient time to reflect on their GA experience whilst the investigator provided some guidance. The interviews were relatively short as the topic was rather specific. It has been suggested that children aged 4-7years have a relatively short attention span and easily lose interest. Therefore, it is recommended that tasks involving young children, such as interviews, should be kept short (Borgers et al., 2000).

### **5.3.2.2 Data collection**

During the formulation of the topic guide thought was given to the order in which each topic might usefully be approached in the interview. A relatively structured discussion guides both the interviewer and interviewee throughout the topic. This has shown to be particularly essential in guiding the children throughout their journey from the pre-operative experience up until their current oral health status. The opening topic revolved around how children feel about their teeth at the time of interview. The main purpose of this question was to orient the participants and help them understand the conversational style of data collection. Where the subject of the study is an event, it is often most useful to structure the interview chronologically as this seems to aid recall (Ritchie and Lewis, 2003). The interview then progressed by asking the children about their experience on the day of the GA. In most instances the question was “Do you remember the last time you came to the hospital? .... Can you tell me what happened on that day?”. Discussing processes broadly chronologically from beginning to end (albeit with some forward and backward referencing) will feel smoother and will often aid in-depth exploration (Ritchie and Lewis, 2003). The topic guide was developed to direct the children to think about how they feel about their teeth at the current time followed by how they felt in the past when they had their procedure and finally how they felt before having their teeth extracted. Talking about these events in that particular order helped participants reflect on the events as the thought of the most recent event triggered the recall of an earlier event and so forth.

### **5.3.2.3 Framework analysis**

The framework method is appropriate for thematic analysis of textual data, particularly interview transcripts, where it is important to be able to compare and contrast data by themes across many cases, while also situating each perspective in context by retaining the connection to other aspects of each individual's account. The framework method is most suitable for analysis of interview data, where it is desirable to generate

themes by making comparisons within and between cases. The framework approach was an invaluable tool for data analysis of qualitative data. This approach provided an effective route map for the journey and enabled a case and theme-based approach to data analysis. This approach enabled the researcher to track decisions, which ensured links between the original data and findings are maintained and transparent. This adds to the rigour of the research process and enhances the validity of the findings (Smith and Firth, 2011). Despite the small sample size of five participants, the interviews generated a wealth of data which was incorporated in the analysis. The framework approach creates a scaffold upon which data is organised allowing the researcher to analyse data obtained through continuously moving forward and backward between the data from the interview transcripts. Links of the data with initial categories resulted in the emergence of the final categories and the development of the final analytical framework that describes the children's experiences. This process reiterates the main principle of the framework approach - the interconnected stages are not linear, but a scaffold that guides the analysis (Ritchie and Lewis, 2003).

#### **5.3.2.4 Study Sample**

The participants were recruited using purposive sampling in a retrospective manner. Participants who had their operation in the last three months were invited. It was felt by the investigator if the GA experience had happened more than three months ago, it may have been difficult for children to remember details of past events, thus increasing the risk of recall bias. The study was carried out around July and August 2018, this period coincided with the schools summer holiday. This was to ensure children were not taking time away from school. Recruitment to this phase of the study proved challenging with a low participation rate (8%). Several reasons could have contributed to this: most patients are discharged back to their general dental practitioner and do not have scheduled follow-up appointments and since the interview was not carried at the participants homes, arrangement for transport was necessary. This could have potentially excluded participants with difficulty in transport arrangements. Arranging for

interviews to be carried out at home may have yielded a higher participation rate in this case. However, fieldwork safety implications for the researcher need to be considered. Parents act as gateway keepers and their willingness to allow their child to participate is essential prior to recruiting their children. It was observed in this study some parents refused to allow their child to participate and various reasons were given, such as some felt their child didn't want to talk about their experience, or being unable to take time off from work. Despite the challenges encountered during the recruitment process, children from different ethnicities were included in the sample. As all interviewed participants had a good GA experience, the findings of this study thus need to be interpreted with caution as there is a possibility families and children who had an unpleasant experience did not agree to participate.

#### **5.3.2.5 Involving children**

Historically, it has been suggested that children are not articulate enough to express their personal views and perspectives (Lloyd et al., 2006). This in turn has excluded children from many child-related research. Alternatively, proxy views and perspectives were sought in children's research. Such representations, however, provide more information about the experiences and subjectivity of the carers or proxies than about the children (Lloyd et al., 2006). Despite the shift to include children's perspectives in research and document principles related to good data collection with children, practical challenges inherent in conducting interviews with children remain. Working with children in research interviews requires taking certain measures to facilitate the data collection process. Building a strong rapport, developing an appropriate interview structure and selecting the setting for the interview must be considered carefully when interviewing children (Irwin and Johnson, 2005). The investigator was a postgraduate in paediatric dentistry and has experience working with children. This was advantageous in building rapport with the children. Each child was first met at the entrance of the dental hospital. It was felt passing by the place where the GA was carried out would aid

in recalling previous events. The interview was then held in a non-clinical room at the dental school which is located in a different floor from the hospital. The room was quiet and private to ensure the confidentiality of each child and to avoid any distractions during the interview. Prior to the interview, the children were engaged in an informal conversation, such as asking the children about their plans for the holidays, this mainly aimed to ease the children into the interview.

It was acknowledged that some children might find the verbal ability necessary to engage in a qualitative interview challenging, Wilson and Powell suggested that closed-ended questions can put less weight on the child's verbal ability (Wilson and Powell, 2001). The interviews were flexible depending on the child's engagement in the interview. Where it was felt the child was unable to deal with some of the open-ended questions, a series of direct questions were asked until the child began to engage in the interview. The benefit of closed-ended questions when used at the beginning of an interview is to assist in identifying openings for additional questions by forging a path to developing a better understanding of the child's experiences (Irwin and Johnson, 2005). One study carried out interviews with children in their homes to obtain accounts of their experiences of having a general anaesthetic in general dental practice (Bridgman et al., 1999). The interviews took the form of a qualitative enquiry where each interview started with an open-ended question: "tell us the story of what happened the day you went to the dentist to have your teeth out" (Bridgman et al., 1999).

The interviews were rather short in duration and it is plausible children were fatigued with the interview process. Wilson and Powell, whose expertise involves interviewing children for information on legal matters, advised that a "young child does not tend to say much at any one time" and is less likely to give a detailed account of events (Wilson and Powell, 2001). Strategies that would have possibly improved data collection process include: the use of multiple interviews, so that the needs of the child

can be respected, as some children might find a long interview more challenging than two or three shorter ones. However, with this in mind participation rate was rather low thus including an additional session might be burdensome on some potential participants. Another documented method is the 'draw, write and tell'. As the name suggests the child can draw and write ideas around the topic in mind and explain to the interviewer what the drawing suggests. The method has been identified as a child-centred method, which supports children's thought processes and enables individuals to communicate using a range of methods (Angell et al., 2015). Interestingly, a similar study used a rather different approach, in addition to the interviews, children, aged 7-13 years, were provided with a video camera to keep a video-diary of their journey (Rodd et al., 2014). This approach is interesting as children can provide their accounts at the comfort of their homes and at a time suitable for them, optimising children's participation and placing them at the centre of the research.

### **5.3.2.6 Ethical considerations**

Ethical issues in qualitative research are often more complex in studies involving children. Consideration of power imbalance, confidentiality and assent is required. The investigator ensured participants were informed about the voluntary nature of the study, their right to withdraw anytime and stop the interview at any time point. An age appropriate information sheet was posted prior to the interview. A verbal explanation was given on the day of the interview prior to obtaining consent and assent from parents and participants, respectively. Children who showed willingness to participate in the interview were asked to give their assent alongside their parents' consent. The interviewer is a postgraduate in paediatric dentistry and has experience in assessing children's body language. This was essential as it allowed the interviewer to observe the children throughout the interviews for any signs of unwillingness to continue, such as becoming restless or noticing a change in the tone of voice (Helseth and Slettebo, 2004). Researchers should be aware that, despite an explanation, some children may

want to stop an interview but may feel too intimidated to do so (Gill et al., 2008a). On one occasion a child's tone of voice has changed 10 minutes into the interview, the interviewer asked the child if she would like to continue or prefer to stop. The interview was stopped and the child was reassured and thanked for her participation. All children were accompanied by a parent throughout the interview.

### **5.3.3 Data analysis**

Data analysis was carried out by the investigator using the framework approach. Guidance from an associate professor in social sciences (JG), who has experience in qualitative research, was sought. Themes captured in the interviews were arranged in a chronological manner in relation to the children's journey, including pre-operative events, the GA itself, and post-operative events. It was interesting to capture the children's perspectives at each stage. Participants, who were around 6-7 years of age, were able to describe their experiences. However often their responses were short and were not elaborate. Children were able to recall the day of the GA with some detail and describe their current feelings about their oral health, however, it was rather challenging to remember how their teeth felt prior to the GA. Below is a discussion of each theme explored in this study.

#### **5.3.3.1 Pre-operative events**

As part of this study there was an interest to explore the impact of dental caries on children. Caries has several impacts which vary in nature on a case to case basis. Participants were able to recall experiencing pain, having food stuck between their teeth and feeling upset. Recalling past events proved to be challenging for the children as it was observed on several instances in the interviews. Some respondents were unable to recall previous experiences of dental pain without prompting by their accompanying parent. However, in some cases following guidance children were able to recall past events with great detail. This was demonstrated in one of the interviews

where one child mentioned having pain when he was on holiday, he described the event with great detail.

*“Well, when I was in Italy in the hotel with my family, my teeth start hurting. I don’t know how.” (C1)*

His mum’s response to his recall of the event was:

*“Even I forgot Italy when you had tooth pain there. You remember.” (C1’s mum)*

Therefore, recalling past events by parents solely may not always be the solution to extract a complete thorough account. In fact, children’s input has shown that their contribution is as valuable as that of adults.

It is vital to mention that the risk of recall bias is rather high especially when children have been asked to recall events which occurred over three months ago. The potential for recall bias could have been minimised by interviewing the children at different time frames to greater capture their experience prior to having any treatment. This approach would also allow researchers to investigate the children’s thoughts and feelings prior to undergoing a GA. This was revealed in a similar study which showed that children feel scared and worried before their admission, which may largely originate from not knowing exactly what is going to happen to them (Rodd et al., 2014).

Getting food stuck was another impact which was brought up quite frequently. The oral cavity is a highly sensitive area, and where a foreign object is stuck persistently this could be irritating. In fact in the quantitative part of this study “getting food stuck” was reported by 97% of participants, being the most reported impact at baseline.

### 5.3.3.2 GA experience

The children were interviewed at a range of 10-15 weeks following their procedure. All children had no previous experience of GA. It was interesting to explore their first GA experience. They described the onset of the anaesthetic to be quick when compared to sleeping. However, when probed about how the anaesthetic itself felt like, they were not able to verbalise their feeling and rather used the word “weird”. Therefore it wasn’t obvious how they exactly felt about the GA. In some situations, we might need to help children find words to express themselves. When we do this, we need to ensure that the words we offer fit the ideas of the child and not our preconceived ideas (Irwin and Johnson, 2005). A “shopping list” of terms could have been offered to select from when they were struggling describing the weird feeling from the anaesthetic itself, offering options such as “floating” or “tired”. It should be recognized that language is only one route to understanding a child’s perspective; others are observational data, drawing and play acting (Irwin and Johnson, 2005).

It seems that the main event remembered at the time of administering the GA was the cannulation. The children recalled they had a needle and they described it as “sharp” and “painful”. Upon recovery, children mainly recalled physical impacts. Dizziness was a main theme alongside bleeding and feeling tired. A study which observed demeanour of the children immediately after the surgical procedures reported 71% of participants were bleeding, and 30% were drowsy (Bridgman et al., 1999). The GA setting of that study differs from the current study. At the time, dental GA was performed in the dental chair. Following the Department of Health’s report *A Conscious Decision*, dental GA has been restricted to hospital settings (Department of Health, 2000).

Children also brought up the difficulty in brushing immediately post-operatively as a result of pain from the extraction sites. Narratives about the GA touched upon the emotions it brought. A few recollections of being nervous were mentioned. One

qualitative study which investigated child-reported impacts associated with a dental general anaesthetic has revealed that children certainly feel scared and worried before their admission, which may largely stem from not knowing exactly what is going to happen to them (Rodd et al., 2014).

### **5.3.3.3 Post-operative events**

It has been long well-established that dental extractions under GA improves OHRQoL (Knapp et al., 2017a; Park et al., 2018). On several accounts children were relieved their teeth did not hurt anymore and reported eating hard foods such as apples was comfortable. On the other hand, some children pointed out they had been experiencing difficulty with mastication. The impact on mastication following dental extractions was rather significant to some children. This was described as not being able to bite some food and requiring food to be chopped; one child mentioned biting on edentulous areas is “uncomfortable and hurts a bit”.

*“When my food goes in the holes where the teeth were taken out, that’s hurting a bit.” (C4)*

It would be interesting to use the qualitative approach to investigate whether children’s eating have changed following dental extractions by comparing their pre-operative and post-operative habits.

### **5.3.3.4 Treatment preference**

Most children who undergo GA for dental extractions are referred due to being dentally anxious. Although all efforts are made to ensure definitive treatment is provided to avoid a second GA, it is important children experience an un-eventful, non-traumatic GA. One of the main interesting findings was that all children preferred to have a GA if they required similar treatment in the future as opposed to being awake and having

dental treatment under LA. It is worth noting two of the children had previous dental treatment under LA, which included dental restorations and extractions. However, as they developed dental anxiety they were then referred to the GA service. Two parents were satisfied with the outcome and believe the mode of delivery of treatment suited their child. Given that these findings are based on a small sample size, the results from such analysis should therefore be treated with considerable caution. It is possible, children or parents of children who had an unpleasant experience refused to participate. Similarly, a study which enquired about the parent's willingness for their child to undergo a future GA, using a 5-point scale, ranging from 'definitely yes' to 'definitely no' found that over half of parents intimated that they were likely to opt to have GA again (Hosey et al., 2006). Cantekin et al. investigated the effect of dental rehabilitation under GA on dental fear using Children's Fear Survey Schedule (CFSS-DS) and found CFSS-DS anxiety scores after dental treatment were significantly higher ( $p < 0.001$ ) with a trend of higher CFSS-DS scores in children who received increasing numbers of extractions (Cantekin et al., 2014). On the other hand, Klaassen et al. used the same instrument to measure dental anxiety and reported no significant difference was found between pre-test and post-test anxiety scores following dental treatment under GA (Klaassen et al., 2009).

#### **5.3.3.5 Presence of parents**

As mentioned previously, parents were present in all interviews. An explanation was given prior to the interview with regards to the research primarily focusing on children's views. Some parents were passive throughout the interview, whilst the majority engaged in the conversation particularly when they felt their child had difficulty recalling events. It was observed on several occasions, children involved their parents in the interview especially when they required confirmation to their responses. When parents are present during interviews with young children, they might also contribute to the

interview in ways that could be seen as leading the child in a complementary way (Irwin and Johnson, 2005).

Initially, there was concern that parents contributions directed the children in leading ways. However, following the analysis it was realised that in fact parents were mainly objective and did not impose their views on their children in the interviews. Parents would insert cues in the conversation to prompt their child such as “Remember when ..”, “Weren’t you...?” The quotation below shows an example where a parent guided the child in the conversation.

*“HA: Before going to sleep did your teeth hurt?”*

*C1: No*

*Mum: They did, remember?*

*C1: Ohhhh, It was a disaster”*

Parent’s contributions in the children’s interviews appeared to complement the children’s interactions throughout the interview. Children are likely to be supported by a parent in many, but not all, of their interactions; therefore, it would seem reasonable that contributions to a child’s stories should be expected in an interview with a child when a parent is present (Irwin and Johnson, 2005).

### **5.3.4 Limitations**

There are several limitations with this study that need to be acknowledged. Firstly, this was a qualitative study that focused on perspectives of a purposively selected sample from a single centre. Given that the findings are based on children aged 6-7 years the results from such analyses should therefore be treated with utmost caution. The findings represent the views of children in this age group in particular. Like most other qualitative studies, transferability to other contexts requires careful consideration.

Although efforts were made to undertake good purposive sampling, it appears children with an unpleasant experience were not included. Additionally, further research is required to determine if the findings are consistent with children who received dental restorations in addition to dental extractions. Although the analysis was overseen by an experienced qualitative researcher, rigour and reliability could have been improved by arranging an independent assessment of transcripts to allow for comparison of results between different raters. This is particularly relevant here, as the investigator had no prior experience of undertaking qualitative research.

Qualitative interviews require considerable skill on the part of the interviewer in qualitative research, thus the level of the interviewer's skills is vital for a well conducted study. Additionally, all interviews were carried out by the same interviewer, and it would be interesting if different interviewers would have captured additional perspectives. Alternatively, the interviewer's interviewing technique could have been monitored through critically appraising audio recordings by more experienced qualitative researchers, such as noting if interviewer was being directive and leading or whether interviewees were given enough time to explain what they meant. Finally, it is worth noting, data was not collected contemporaneously, thus the risk of recall bias needed to be accounted for.

### **5.3.5 Conclusion**

Qualitative interviews have proved to be a good method of exploring individual views and perspectives with respect to children's experience with dental extractions under GA. In general, children were able to describe their overall experience with some probing and prompting. They were able to recall specific events which occurred on the day of the GA. Children reported they had a good GA experience and were not anxious about undergoing similar treatment in the future. From the data obtained it was not possible to describe or analyse the GA experience of children who had dental

restorations and extractions, nor is it possible to understand how older children felt. All children in the sample interviewed reported they would prefer to be asleep to have the treatment rather than be awake if they required similar treatment in the future. Parents contributions to the interviews were rather useful as they aided their children recall past events.

### **5.3.6 Recommendations for future research**

This research has proved that qualitative interviews are a good method of exploring individual views and perspectives. Compared to the first phase of the study, new insights were explored. Application of qualitative research remains relatively scarce in the field of dentistry. There are many avenues which remain unexplored. Several questions are yet to be answered, these include:

- how children feel about receiving dental restorations and extractions under GA as opposed to dental extractions only
- how older children feel about receiving similar treatment
- whether reports from self-completed questionnaires correlate with qualitative data obtained
- how children feel about receiving treatment under local anaesthesia, inhalation sedation as opposed to GA.

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## Appendix I Ethical approval letter



## Health Research Authority

Ms. Hessa AlBader  
 Professional Doctorate in Paediatric Dentistry  
 University of Leeds  
 Level 6, Worsley building  
 Clarendon Way  
 Leeds  
 LS2 9LU

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

15 May 2017

Dear Ms Albader,

**Letter of HRA Approval**

<b>Study title:</b>	<b>Changes in Oral Health Related Quality of Life in Children Following Dental Treatment under a General Anaesthetic Using a Child Self-Report Measure</b>
<b>IRAS project ID:</b>	<b>212599</b>
<b>REC reference:</b>	<b>17/YH/0079</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.

IRAS project ID	212599
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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](#), 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](#).

### 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	212599
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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 use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

**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 **212599**. Please quote this on all correspondence.

Yours sincerely,

Steph Blacklock  
Senior Assessor

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

Copy to: *NHS Research Ethics Officer*  
*Ms Anne Gowing, The Leeds Teaching Hospitals NHS Trust*

## Appendix II Parents participation information sheet: Questionnaire

IRAS Project ID: 212599  
REC Reference: 17/YH/0079



Version 2 – 04/04/2017

### Parent/Guardian Participant Information Sheet

#### Title of Study

#### **Effect of Dental Decay on Children Before and After Having Dental Treatment Under a General Anaesthetic**

Your child has been invited to take part in our research study. Before you decide whether you would like your child to participate or not, please allow some time to read the information below.

#### **What is the purpose of this study?**

Many children in the UK have dental decay and require treatment. Some children end up having their teeth fixed or removed under a general anaesthetic. Numerous studies have looked into the impact of dental decay and the effect of dental treatment on the child's quality of life. Previous studies asked the parents to complete a questionnaire on the effects of dental decay and dental treatment on their child.

This study aims to see how children feel about the effects of dental decay on them, before and after having their teeth treated under a general anaesthetic. In this study the child will be asked to complete a child-friendly questionnaire.

#### **Who is doing the study?**

The study will be carried out in the Children's Department at the Leeds Dental Institute by Ms. Hessa AlBader (a postgraduate in Paediatric Dentistry) under the supervision of Dr. Jinous Tahmassebi (Associate Professor in Paediatric Dentistry). This study will be contributing to a Postgraduate Research Degree.

#### **Who is being asked to participate?**

We will be inviting all children between the ages of 5-8 years who are scheduled to receive dental treatment under general anaesthesia at the Leeds Dental Institute.

#### **What will be involved if I allow my child to take part in this study?**

If you agree to allow your child to be part of our study, we will approach you on the day of your child's appointment and we will ask you to sign a consent form and ask your child to sign an assent form, if you are happy to take part. We will then provide your child with a questionnaire that usually takes 2-5 minutes to complete. We will also ask your child to fill a similar questionnaire at 1 and 3 months after your child have received the treatment. The subsequent questionnaires will either be posted or will be handed in to your child if they have any further appointments arranged at our clinic.

If the questionnaires were posted, you will receive a pre-paid envelope with a return address printed on.

This will not interfere with the type or quality of treatment your child will receive.

Another part of the study is to invite some children to an interview where they will be able to freely express themselves on their feelings of dental decay and having dental treatment under a general anaesthetic. More information will be provided on a separate sheet.

*If you and your child are willing to participate, please inform one of the researchers.*

#### **What are the advantages and disadvantages of taking part?**

Taking part in this study may not necessarily have any direct benefits for you or your child. However, the results of this study could provide us with a better understanding of how children are affected by dental decay and the subsequent effects after they receive their dental treatment. This could also help us inform patients what to expect following dental treatment in the future.

**Can I withdraw from the study at any time?**

Yes, you can withdraw at any time throughout the course of the study without giving any reason. Your child's treatment will not be affected in any way. If we have collected any data obtained from your child's dental records they will be discarded appropriately.

**Will the information obtained in the study be confidential?**

All data regarding your child will remain confidential. Clinical information regarding your child will be stored in your child's NHS records, which are only accessible by NHS clinicians. The data collected will be kept secure and confidential using non-identifiable information and using the university's password-protected computers. They will be stored in lockable secure locations. No personal identifiable data will be published. Data handling procedures will be carried out in accordance with the Data Protection Act 1998.

**What will happen to the results of the study?**

The results will be published in the form of a report and a journal article but neither your child's name nor any information that could identify them will appear. If you would like to know the results of the study, please let one of the research team know, and we would be happy to share them with you.

**Who has reviewed the study?**

Health Research Authority – Leeds West Research Ethics Committee

IRAS Project ID: 212599

REC Reference: 17/YH/0079

**If you would like more information or have any questions or concerns about this study or would like to request a summary of the results of the study, feel free to contact us on the telephone numbers and e-mail addresses below.**

Ms Hessa AlBader  
Postgraduate in Paediatric Dentistry  
School of Dentistry  
University of Leeds  
Level 6 - Worsley Building  
Clarendon Way  
Leeds LS2 9LU  
E-mail: [dnhtab@leeds.ac.uk](mailto:dnhtab@leeds.ac.uk)

Dr. Jinous Tahmassebi  
Associate Professor in Paediatric Dentistry  
School of Dentistry  
University of Leeds  
Level 6 - Worsley Building  
Clarendon Way  
Leeds LS2 9LU  
Tel: 01133433955  
Fax: 01133436140  
E-mail: [j.tahmassebi@leeds.ac.uk](mailto:j.tahmassebi@leeds.ac.uk)

***Thank you for taking the time to read this information sheet.***

## Appendix III Children's participant information sheet: Questionnaire



Child Participant Information Sheet (5-8years): Questionnaire

UNIVERSITY OF LEEDS

Version 2- 04/04/2017

IRAS Project ID: 212599

# How Children Feel About Teeth Decay



## Who am I?

My name is Hessa AlBader.  
I study at the dental school at the University of Leeds.



## I am doing a research and would like you to help me.

Research is when people explore and look for information.  
I am looking for information about how teeth decay affect you.  
This will help us understand how you feel.



## Can you help me?

If you would like to help, I will ask you to answer some questions  
about your teeth.  
Your mum or dad or guardian can help you answer the questions.



## What will happen?

I will meet you next time you visit us at the dental clinic at Leeds.  
I will explain everything to you.  
I will ask you to tick some boxes on a sheet.



## Will anyone know any information about you?

Your information will be a secret.



## What if you don't want to take part?

If you don't want to join it is up to you.  
No one will be cross.



## What if you have questions?

Your mum or dad or guardian have a paper with more information.  
If you have any other questions you can send me an e-mail.  
Your mum or dad or guardian can help you with that.



## Appendix IV Parents participant information sheet: Interview

IRAS Project ID: 212599  
REC Reference: 17/YH/0079



Version 2 – 04/04/2017

### Parent/Guardian Participant Information Sheet on Interview

#### Title of Study

#### **Effect of Dental Decay on Children Before and After Having Their Dental Treatment Under a General Anaesthetic**

Your child has been invited to take part in an interview in our research study. Before you decide whether you would like your child to participate or not, please allow some time to read the information below.

#### **What is the purpose of this study?**

Many children in the UK have dental decay and require treatment. Some children end up having their teeth fixed or removed under a general anaesthetic. Numerous studies have looked into the impact of dental decay and the effect of dental treatment on the child's quality of life. Previous studies asked the parents to fill out a questionnaire on the effects of dental decay and dental treatment on their child.

This study aims to see how children feel about the effects of dental decay on them, before and after having their teeth removed under a general anaesthetic.

#### **Who is doing the study?**

The study will be carried out in the Children's Department at the Leeds Dental Institute by Ms. Hessa AlBader (a postgraduate in Paediatric Dentistry) under the supervision of Dr. Jinous Tahmassebi (Associate Professor in Paediatric Dentistry). This study will be contributing to a Postgraduate Research Degree.

#### **Who is being asked to participate?**

We will be inviting all children between the ages of 5-8 years who are scheduled to receive dental treatment under general anaesthesia at the One Day Unit (our out-patient clinic).

#### **What will be involved if I allow my child to participate in an interview?**

If you agree to allow your child to take part in the interview we will arrange a suitable time for you and your child to attend the interview, which will be held at the Leeds Dental Institute.

We will ask you to sign a consent form and ask your child to sign an assent form.

No dental treatment will be carried out in this session, unless you have a separate appointment booked at the same clinic. The interview will be recorded using an audio recorder. You will be allowed to stay in the room with your child. The length of the interview depends on your child's input during the interview. However, we expect it to take an average of 30 minutes.

Your child can choose a different name, to make the recordings anonymous.

The questions asked in the interview will mainly focus on your child's feelings and experience from having dental decay treated under a general anaesthetic.

#### **What are the advantages and disadvantages of taking part?**

Taking part in this study may not necessarily have any direct benefits for you or your child. However, the results of this study could provide us with a better understanding of how children are affected by dental decay and the subsequent effects after they receive their dental treatment. This could also help us inform patients what to expect following dental treatment in the future.

#### **Can I withdraw from the study at any time?**

Yes, you can withdraw at any time throughout the course of the study without giving any reason.

Your child's treatment will not be affected in any way. If we have collected any data obtained from your child's dental records they will be discarded appropriately.

**Will the information obtained in the study be confidential?**

All data regarding your child will remain confidential. Clinical information regarding your child will be stored in your child's NHS records, which are only accessible by NHS clinicians. The data collected will be kept secure and confidential using non-identifiable information and using password-protected computers. They will be stored in lockable secure locations. Some quotes from the interview may be published, however, no personal identifiable data will be published, as all data will be anonymised. All audio recordings will be deleted once the research has been completed.

Data handling procedures will be carried out in accordance with the Data Protection Act 1998.

**What will happen to the results of the study?**

The results will be published in the form of a report and a journal article but neither your child's name nor any information that could identify them will appear. If you would like to know the results of the study, please let one of the research team know, and we would be happy to share them with you.

**Who has reviewed the study?**

Health Research Authority – Leeds West Research Ethics Committee

IRAS Project ID: 212599

REC Reference: 17/YH/0079

**If you would like more information or have any questions or concerns about this study or would like to request a summary of the results of the study, feel free to contact us on the telephone numbers and e-mail addresses below.**

**If you are interested in taking part feel free to e-mail us on the e-mail addresses below.**

Ms Hessa AlBader  
Postgraduate in Paediatric Dentistry  
School of Dentistry  
University of Leeds  
Level 6 - Worsley Building  
Clarendon Way  
Leeds LS2 9LU  
E-mail: [dnhtab@leeds.ac.uk](mailto:dnhtab@leeds.ac.uk)

Dr. Jinous Tahmassebi  
Associate Professor in Paediatric Dentistry  
School of Dentistry  
University of Leeds  
Level 6 - Worsley Building  
Clarendon Way  
Leeds LS2 9LU  
Tel: 01133433955  
Fax: 01133436140  
E-mail: [j.tahmassebi@leeds.ac.uk](mailto:j.tahmassebi@leeds.ac.uk)

***Thank you for taking the time to read this information sheet.***

## Appendix V Children's participation information sheet: Interview



Child Participant Information Sheet (5-8years): Interview



UNIVERSITY OF LEEDS

Version 2- 04/04/2017  
IRAS Project ID: 212599

# How Children Feel About Teeth Decay



## Who am I?

My name is Hessa AlBader.  
I study at the dental school at the University of Leeds.



## I am doing a research and would like you to help me.

Research is when people explore and look for information.  
I am looking for information about how teeth decay affect you.  
This will help us understand how you feel.



## Can you help me?

I would like to talk with you about your teeth.  
I will record what we say using a microphone. It is like recording your voice when you sing.



## What if you would like to take part?

I will meet you next time you visit us at the dental clinic at Leeds.  
I will explain everything to you.



## Will anyone know any information about you?

Your information will be a secret. You can choose a different name.



## What if you don't want to take part?

If you don't want to join it is up to you.  
No one will be cross.



## What if you have questions?

Your mum or dad or guardian have a paper with more information.  
If you have any other questions you can send me an e-mail.  
Your mum or dad or guardian can help you with that.



## Appendix VI Parent consent form: Questionnaire



UNIVERSITY OF LEEDS

Version 1 Date 08/01/2017

IRAS Project ID: 212599

Patient Identification Number for this study:

**PARENT CONSENT FORM - Questionnaire****Title of project:**

Changes in Oral Health Related Quality of Life in Children Following Dental Treatment under a General Anaesthetic Using a Child Self-Report Measure

**Name of researcher:** Hessa AlBader

Please initial box

1. I confirm I have read and understood the information sheet dated 08/01/17 - version 1 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time without giving any reason, without my child's medical care or legal rights being affected.
3. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from research team, from regulatory authorities or from the NHS Trust, where it is relevant to my child's taking part in this research. I give permission for these individuals to have access to my child's records.
4. I agree for my child to take part in the above study.

Name of parent/guardian

Signature

Date

Name of person taking consent

Signature

Date

When completed:

1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

## Appendix VII Parent consent form: Interview



UNIVERSITY OF LEEDS

Version 1 Date 08/01/2017

IRAS Project ID: 212599  
REC Reference: 17/YH/0079

Patient Identification Number for this study

**PARENT CONSENT FORM - Interview**

**Title of project:**

Changes in Oral Health Related Quality of Life in Children Following Dental Treatment under a General Anaesthetic Using a Child Self-Report Measure

**Name of researcher:** Hessa AlBader

Please  
initial box

1. I confirm I have read and understood the information sheet dated 04/04/17 - version 2 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my child's participation is voluntary and that I am free to withdraw at any time without giving any reason, without my child's medical care or legal rights being affected.
3. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from research team, from regulatory authorities or from the NHS Trust, where it is relevant to my child's taking part in this research. I give permission for these Individuals to have access to my child's records.
4. I understand that the interview will be recorded using an audio recording device.
5. I agree for my child to take part in the above study.

\_\_\_\_\_  
Name of parent/guardian

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person taking consent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

When completed:

1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

## Appendix VIII Child assent form



UNIVERSITY OF LEEDS

Version 1 Date 08/01/17

IRAS Project ID: 212599

Patient Identification Number for this study:

**ASSENT FORM (Age 5-8years)****Title of project:**

Changes in Oral Health Related Quality of Life in Children Following Dental Treatment under a General Anaesthetic Using a Child Self-Report Measure

**Name of researcher:** Hessa AlBader

Please circle Yes/No if you agree with what is written.

Please put a circle

- |   |          |
|---|----------|
| 1. Has someone read to you the information about the study?   | Yes / No |
| 2. Has somebody explained to you what the study is about?     | Yes / No |
| 3. Do you understand what this study is about?                | Yes / No |
| 4. Have you asked all the questions you want?                 | Yes / No |
| 5. Do you understand all the answers to your questions?       | Yes / No |
| 6. Do you understand it's OK to stop taking part at any time? | Yes / No |
| 7. Are you happy to take part?                                | Yes / No |

If you answered NO to any question or you do not want to take part then don't write your name below.

_____	_____	_____
Name of Child	Signature	Date

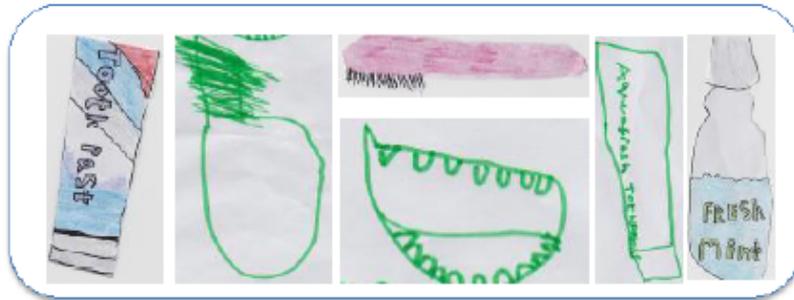
_____	_____	_____
Name of Person taking consent	Signature	Date

When completed:

1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

## Appendix IX CRIES-QC initial questionnaire

## Caries Impacts and Experiences Questionnaire for Children



These questions ask how you feel about your teeth. Read all the answers and see which one is most like you.

Please put a circle round the answer like this . Only make one circle for each question.

Here's one I have done to show you:

How happy do you feel about your teeth?

Not at all      A bit       A lot

I feel very happy about my teeth, so I have circled this one

Now please think about your teeth and answer the questions on the next pages.

Please **circle one answer** for each question.

**1. How much do your teeth hurt you?**

Not at all      A bit      A lot

**2. Do your teeth make it hard to eat some foods?**

Not at all      A bit      A lot

**3. Do you have to eat on one side of your mouth because of your teeth?**

Not at all      A bit      A lot

**4. Do you get food stuck in your teeth?**

Not at all      A bit      A lot

**5. How much do you get kept awake by your teeth?**

Not at all      A bit      A lot

**6. How much do your teeth annoy you?**

Not at all      A bit      A lot

Please go to the next page.

Please circle one answer for each question.

**7. How much do your teeth hurt when you brush them?**

Not at all

A bit

A lot

**8. Do you have to eat more carefully because of your teeth?**

Not at all

A bit

A lot

**9. Do you have to eat more slowly because of your teeth?**

Not at all

A bit

A lot

**10. Do you feel cross because of your teeth?**

Not at all

A bit

A lot

**11. How much have you cried because of your teeth?**

Not at all

A bit

A lot

Please go to the next page.

Please **circle one answer** for each question.

**12. Do your teeth make it hard to do your schoolwork?**

Not at all

A bit

A lot

**13. How much of a problem are your teeth for you?**

Not at all

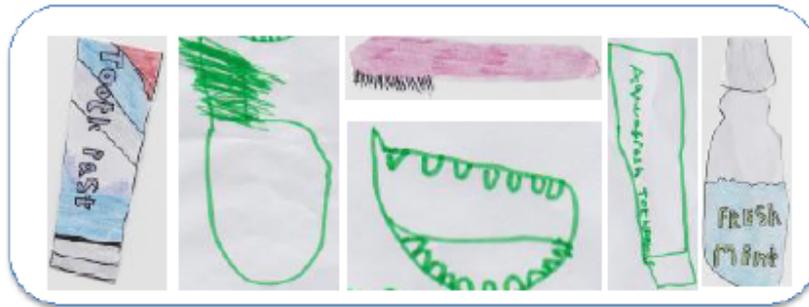
A bit

A lot

**Thank you for answering the questions!**

## Appendix X CRIES-QC follow-up questionnaire

## Caries Impacts and Experiences Questionnaire for Children



These questions ask how you feel about your teeth. Read all the answers and see which one is most like you.

Please put a circle round the answer like this . Only make one circle for each question.

**Here's one I have done to show you:**

**How happy do you feel about your teeth?**

Not at all      A bit       A lot

I feel very happy about my teeth, so I have circled this one

Now please think about your teeth and answer the questions on the next pages.

Please **circle one answer** for each question.

**1. How much do your teeth hurt you?**

Not at all      A bit      A lot

**2. Do your teeth make it hard to eat some foods?**

Not at all      A bit      A lot

**3. Do you have to eat on one side of your mouth because of your teeth?**

Not at all      A bit      A lot

**4. Do you get food stuck in your teeth?**

Not at all      A bit      A lot

**5. How much do you get kept awake by your teeth?**

Not at all      A bit      A lot

**6. How much do your teeth annoy you?**

Not at all      A bit      A lot

Please go to the next page.

Please **circle one answer** for each question.

**7. How much do your teeth hurt when you brush them?**

Not at all

A bit

A lot

**8. Do you have to eat more carefully because of your teeth?**

Not at all

A bit

A lot

**9. Do you have to eat more slowly because of your teeth?**

Not at all

A bit

A lot

**10. Do you feel cross because of your teeth?**

Not at all

A bit

A lot

**11. How much have you cried because of your teeth?**

Not at all

A bit

A lot

Please go to the next page.

Please **circle one answer** for each question.

12. Do your teeth make it hard to do your schoolwork?

Not at all

A bit

A lot

13. How much of a problem are your teeth for you?

Not at all

A bit

A lot

14. Since the last time you answered these questions, do you think your teeth are:

Better

The same

Worse

Thank you for answering the questions!

## Appendix XI Analytical framework

<b>Pre-operative events: Before having dental treatment under general anaesthesia.</b>		
	<b>Code</b>	<b>Description</b>
<b>PHYSICAL IMPACTS:</b> Effect of oral disease on affected people. These can vary from being positive to negative impacts.	Pain	Pain symptoms from carious teeth
	Function	Food gets stuck in dental cavities
<b>Psychological impacts:</b> Effect of oral disease on a person's emotion and feelings.	Emotion	Crying

	<b>Peri-operative: On the day of the GA</b>	
	<b>Code</b>	<b>Description</b>
<b>Physical impacts:</b> Physical impact of oral disease and/or treatment. Oral disease and treatment have a physical impact on affected people. These can vary from being positive to negative feelings.	Onset of anaesthesia	First experience Unknown/new feeling Quick
	Recovering from anaesthesia	Feeling weird Dizziness Feeling tired upon recovering from anaesthesia Bleeding
	Pain	Pain from insertion of cannula Pain from dental extractions
	Taste	Taste from medication
<b>Psychological impacts:</b> Effect of oral disease and treatment on a person's emotion and feelings.	Emotion	Feelings before having treatment

<b>Post-operative: After treatment</b>	
<b>Code</b>	<b>Description</b>
Pain and discomfort	Pain upon biting on edentulous areas Difficulty brushing post-operatively
Function/eating	Eating hard foods is difficult due to number of missing teeth (Difficulty eating) Comfort when eating as teeth are now pain free

<b>Treatment preference:</b> Choice of mode of treatment in the future is influenced by physical impacts of other treatment options.	
<b>Code</b>	<b>Description</b>
Decision making/Choice of treatment	Preference to undergo general anaesthesia or local anaesthesia <i>(Preference influenced by avoiding feeling pain from extractions while awake)</i>

## Appendix XII Interview Topic Guide

Version 1  
Date: 20/1/2017

### Interview Topic Guide

#### Effect of dental decay before treatment

- Did it hurt?
- Did it affect your eating? (avoiding certain foods?)
- Did it affect your sleep?
- Did it affect your attendance to school?
- Did you need to take medicine?

#### Attending the dental hospital for treatment

- What was it like?
- How did you feel before coming to the hospital?
- How was your experience with the general anaesthetic and waking up after?
- How would you describe the experience to a friend?
- Did it make you feel better?

#### How do they feel about their teeth now?

- Are you able to enjoy your food?
- Have you changed the type of food you eat?
- Has it affected your daily care of your teeth?

#### Anything else?

## References

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