

**Comparison between the scavenging efficiency of the
Silhouette and Porter Brown breathing systems used in
Inhalation Sedation for children.**

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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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Dedication

To my Parents, Sharifah and Zaabi

To my Siblings

To my lovely nieces and nephews

To my wonderful family and best friends

Without whom none of my success and achievements would be possible.

A special dedication to my beloved grandmother 'Haya Alzaid', may your soul rest in peace.

Abstract

Title: Comparison between the scavenging efficiency of the Silhouette and Porter Brown breathing systems used in Inhalation Sedation for children.

Background: Dental anxiety is a widespread problem in children. Children with dental anxiety frequently require referral to specialist paediatric dentists for treatment. Inhalation-sedation (IHS) using nitrous oxide/oxygen ($\text{N}_2\text{O}/\text{O}_2$) mixture is a pharmacological behaviour management technique that is widely used to manage dental anxiety in children. There have been some reports of occupational chronic exposure to N_2O being linked to serious health problems. Therefore, an effective scavenging system is necessary to reduce nitrous oxide levels in the surrounding environment, in order to reduce N_2O exposure of dental team professionals. There are a number of different inhalation sedation breathing systems such as the Porter Brown and the Silhouette systems. A previous assessment of the ability of different scavenging systems demonstrated that not all systems are equally effective. Few studies have compared the Porter Brown to other Systems with paediatric patients, but there were no previous studies in the literature showing the effectiveness of the Silhouette system or comparing it to other breathing systems.

Aims: This study aimed to investigate the scavenging efficiency and acceptability of the Silhouette breathing system compared to the Porter Brown breathing system, used in inhalation sedation for children. It also aimed to investigate if there was any difference in providing the sedation between the two systems.

Method: Children aged 7-15 years of age who were seen at Leeds Dental Institute for dental treatment under inhalation sedation were invited to this study. This study was designed as a randomised non-blinded controlled clinical trial. Children were introduced to both Porter Brown and Silhouette nose pieces in the assessment visit. Recruited children were allocated randomly to one of the two breathing system groups for their dental treatment. The scavenging efficiency of the breathing systems were assessed by measuring the N_2O levels in the ambient air using diffusion tubes. The participants' acceptability was assessed through a feedback questionnaire at the end of their treatment session.

Results: A total of 54 children were recruited, 27 participants in each group. An independent-sample t-test showed a statistically significant difference between the two breathing systems based on the N₂O exposure levels in the dentist zone ($p=0.045$).

There was a statistically significant difference in head movement in the Silhouette group compared with the Porter Brown. The participants in the Silhouette group found it easier to move their heads to the side. However, mask removal was reported to be more comfortable for the participants in the Porter Brown group. The results showed no statistically significant association between participant age and the comfort of wearing the mask. There were also no statistically significant differences between participant cooperation levels in either group. A statistically significant difference was observed in the anxiety levels before and after the treatment session in female participants. However, this difference was not statistically significant in male participants.

Conclusion: Both systems had active scavenging, with N₂O exposure levels being less than 100ppm over an 8-hour time period. Both breathing systems were accepted almost similarly.

Table of Contents

Chapter 1 Literature review	1
1.1 Dental anxiety	1
1.1.1 Aetiology of dental anxiety	2
1.1.2 Dental anxiety effect	2
1.1.3 Dental anxiety in the UK	3
1.1.4 Measures of dental anxiety	3
1.1.5 Behaviour rating scores	4
1.1.6 Anxiety self-reporting scales	6
1.2 Behaviour management techniques.....	9
1.2.1 Non-pharmacological behaviour management techniques...	10
1.2.2 Pharmacological management techniques	14
1.3 Nitrous Oxide/Oxygen inhalation sedation	18
1.3.1 Chronic Exposure to N ₂ O.....	21
1.3.2 Nitrous oxide environmental impact.....	22
1.3.3 Nitrous oxide monitoring methods – diffusion tubes	23
1.3.4 Inhalation sedation equipment.....	25
1.4 Rationale for this study.....	30
1.5 Aims and Objectives	35
1.6 Null hypotheses:.....	35
1.7 Outcome measures	36
1.7.1 Primary outcome.....	36
1.7.2 Secondary outcomes:	36
Chapter 2 Material and Methods	37
2.1 Ethical approvals and registrations	37
2.1.1 Sponsorship approval	37
2.1.2 Ethics and Clinical Services Unit approvals.....	37
2.1.3 NHS Research and Development (R&D) approval.....	37
2.1.4 Clinical trial registration on a publicly accessible database ..	38
2.2 Study settings and design	38
2.3 Eligibility criteria	39
2.3.1 Inclusion criteria	39
2.3.2 Exclusion criteria.....	39
2.3.3 Rationale behind the age range.....	39
2.4 Recruitment strategies	40

2.4.1	Assessment day (first visit)	40
2.4.2	First dental treatment day (2 nd visit).....	40
2.5	Sample size calculation.....	41
2.6	Methods of data collection	42
2.6.1	Demographic data	42
2.6.2	Medical status.....	42
2.6.3	Dental examination and diagnosis.....	42
2.6.4	Dental treatment	43
2.6.5	Participant feedback questionnaire (Appendix M)	43
2.6.6	Dentist and dental nurse feedback	43
2.6.7	Cooperation level.....	43
2.6.8	Anxiety level.....	43
2.7	Mask and circuit cost.....	43
2.8	Data analysis.....	44
Chapter 3	Results	45
3.1	Recruitment.....	45
3.2	Demographics	45
3.2.1	Age	45
3.2.2	Gender	46
3.3	The scavenging efficiency of breathing systems.....	46
3.3.1	Comparison between the two breathing systems sessions ..	46
3.3.2	The UK Health and Safety Executive recommendation.....	47
3.4	Breathing system feedback:.....	49
3.4.1	Participant feedback	49
3.4.2	Dentist feedback	60
3.4.3	Monitoring data sheet and dental nurse feedback.....	66
3.5	Level of participants' cooperation.....	67
3.5.1	Comparison between the cooperation level and mask	67
3.5.2	Comparison between the cooperation level base on gender	68
3.6	Dental anxiety levels	69
3.6.1	Participants anxiety levels before and after treatment.....	69
3.6.2	Anxiety levels before and after treatment based on gender .	70
3.6.3	Participant dental anxiety levels and age correlation.....	72
3.7	Treatment.....	72
3.7.1	Treatment and scavenging efficiency	74
3.7.2	Effect of treatment type on the participant cooperation level	75

3.7.3	Effect of treatments' type on child's dental anxiety	75
3.8	Mask and circuit costs	78
Chapter 4 Discussion		81
4.1	Introduction	81
4.2	Title, abstract, aims and objectives	81
4.3	Methodology and study design	81
4.3.1	Choice of the scales measures.....	83
4.3.2	Measurement of nitrous oxide levels using diffusion tubes ..	84
4.3.3	Sample size calculation	84
4.3.4	Missing data.....	85
4.3.5	Participants' feedback questionnaire	85
4.4	Discussion of results	86
4.4.1	Nitrous oxide levels and scavenging efficiency	87
4.4.2	Nitrous oxide levels and type of dental treatment.....	91
4.4.3	Nitrous oxide levels and child's behaviour.....	92
4.4.4	Nitrous oxide levels and child's anxiety	94
4.4.5	Dentist feedback	95
4.4.6	Monitoring sheet and dental nurse feedback.....	98
4.4.7	Patient feedback	99
4.4.8	Cost	101
4.5	Research achievement	104
4.6	Effect of the pandemic (covid-19) on this research.....	104
4.7	Evaluation the risk of bias	104
4.8	Limitations	108
4.9	Future recommendations	109
4.10	Conclusion	110
Chapter 5 Ethical consideration		112
5.1	Risks and benefits	112
5.1.1	Occupational risks	112
5.1.2	Patient risk	112
5.1.3	Benefits	113
5.2	Informed consent/ assent.....	113
5.3	Reimbursement/ Incentives.....	113
5.4	Confidentiality, anonymity and illegal activity	113
5.5	Data protection.....	114
5.6	Conflicts of interest.....	114

5.7	Withdrawal from the study.....	114
5.8	Declaration of the end of the study (Appendix S).....	115
5.9	Results dissemination	115
References		CXVI
Appendices		CXXVIII
Appendix A	Sponsorship approval.....	CXXVIII
Appendix B	Research Ethics Committee approval letter	CXXX
Appendix C	Clinical Service Unit approval	CXXXVII
Appendix D	NHS Research and Development approval	CXLVI
Appendix E	Research passport	CXLVIII
Appendix F	Disclosure and Barring Service checks	CLIV
Appendix G	Parents information sheet.....	CLV
Appendix H	Participant information sheet (7-10 years old)	CLVIII
Appendix I	Participant information sheet (11-15 years old).....	CLIX
Appendix J	Research poster.....	CLX
Appendix K	Parent consent form	CLXI
Appendix L	Child assent form.....	CLXII
Appendix M	Child feedback questionnaire	CLXIII
Appendix N	Monitoring and data collection sheet.....	CLXVII
Appendix O	Lead researcher feedback questions.....	CLXIX
Appendix P	Anxiety FIS assessment.....	CLXXI
Appendix Q	Dental School Research Day prize certificate.....	CLXXII
Appendix R	End of the study declaration notice form.....	CLXXIII
Appendix S	Declaration of the end of the study.....	CLXXV
Appendix T	Results dissemination letter.....	CLXXVI

List of tables

Table 1 Frankl behaviour rating scale.....	4
Table 2 Houpt behaviour rating score.....	6
Table 3 Stages of sedation	14
Table 4 Sedation levels (planes) of Nitrous oxide/Oxygen inhalation.....	19
Table 5 Indications and contraindications of N ₂ O Inhalation Sedation	20
Table 6 ASA physical statues classification system	42
Table 7 Comparison between Porter Brown and Silhouette sessions	47
Table 8 Participant feedback – (t-test).....	49
Table 9 Participant feedback - (Chi-square)	50
Table 10 Participant feedback based on gender (t-test).....	51
Table 11 Age correlation to Porter Brown and Silhouette systems acceptance	54
Table 12 The “like” feedback discription.....	56
Table 13 The “dislike” feedback discription	58
Table 14 Dentist feedback, (Chi-square).....	61
Table 15 Cooperation levels based on masks.....	67
Table 16 Cooperation levels based on mask and gender	68
Table 17 Anxiety levels in Porter Brown and Silhouette groups	69
Table 18 Anxiety levels in Porter Brown and Silhouette groups based on gender	71
Table 19 Age correlation to dental anxiety levels	72
Table 20 Overall treatments	73
Table 21 Treatments based on mask type	73
Table 22 Rubber dam Isolation.....	74
Table 23 Cooperation Levels based on treatment.....	76
Table 24 Anxiety levels based on treatment.....	77
Table 25 Costs breakdown of one kit of each breathing system	79
Table 26 Costs breakdown of the disposable parts.....	80
Table 27 Total costs of each breathing system	80
Table 28 Evaluation the risk of bias.....	105

List of figures

Figure 1 Diffusion tube.....	24
Figure 2 Clearview	27
Figure 3 Axxess.....	27
Figure 4 Matrix.....	27
Figure 5 Porter Brown mask	28
Figure 6 Porter Brown circuit	28
Figure 7 The Silhouette mask.....	29
Figure 8 Silhouette breathing circuit	29
Figure 9 Adhesive strip	29
Figure 10 Nasal Cannula	29
Figure 11 Porter Brown mask	34
Figure 12 The Silhouette mask.....	34
Figure 13 Participant age distribution	45
Figure 14 Nitrous oxide levels at the dentist's zone	48
Figure 15 Nitrous oxide levels at the dental nurse zone.....	48
Figure 16 Participant feedback (How did the mask feel on your nose) based on gender	51
Figure 17 Participant feedback (I like the mask) based on gender.....	52
Figure 18 Participant feedback (It was easy to breathe through the mask) based on gender.....	52
Figure 19 Participant feedback (It was comfortable when removing the mask) based on gender.....	52
Figure 20 Participant feedback (It was easy to move my head to the sides) based on gender.....	53
Figure 21 Dentist feedback (mask placement and removal, treatment accessibility)	63
Figure 22 Dentist feedback (Participants manoeuvrability, head movement, airflow monitoring)	64
Figure 23 Dentist feedback (nasal hood seal)	65
Figure 24 Dentist feedback (patient accepting the mask).....	65
Figure 25 Cooperation levels based on mask and gender	68
Figure 26 Anxiety level of Porter Brown and Silhouette groups based on gender	70
Figure 27 Exposure time of Porter Brown and Silhouette sessions.....	75

Abbreviation

ADA	American Dental Association
ASA	American Society of Anaesthesiologist
CDAS	Corah's Dental Anxiety Survey
CFSS	Children's Fear Survey Schedule
CFSS-DS	Dental Subscale of The Children's Fear Survey Schedule
CNS	Central Nervous System
EAI	Emergency Air Intake
FIS	Facial Image Scale
GA	General Anaesthesia
GCMS	Gas Chromatography-Mass Spectrometry
HSE	Health and Safety Executive
IHS	Inhalation Sedation
IV	Intravenous
LDI	Leeds Dental Institute
MCDAS	Modified Child Dental Anxiety Scale
MDAS	Modified Dental Anxiety Survey
MIH	Molar Incisor Hypomineralisation
N₂O/O₂	Nitrous Oxide/Oxygen
NIOSH	National Institute for Occupational Safety and Health
NRV	Non-Rebreathing Valve

PICO	P atient P roblem, I ntervention, C omparison or Control, And O utcome
ppm	Part Per Million
PSI	Palmar Sweat Index
RCTs	Randomised Controlled Trials
SFP	Smiley Faces Program
SFP-R	Smiley Faces Program - Revised
SU	Sedation Unit
TSD	Tell-Show-Do
VPS	Venham Picture Scale

Chapter 1 Literature review

1.1 Dental anxiety

Dental anxiety is a significant problem in children and is often the main reason for referral to paediatric dentists for dental care. Usually anxious or fearful children will try to avoid dental treatment. This may affect their ongoing oral health and lead to other psychological problems such as a social stigma of feeling of shame or inferiority (Berge et al.,2008).

Dental fear and dental phobia terms are frequently used interchangeably in literature, and hence it's difficult to distinguish them from dental anxiety.

However, they indicate different types of dental anxiety (Armfield ,2010; Porritt et al.,2012). "Dental fear represents a normal emotional reaction to a specific threatening external dental stimulus." (Porritt et al.,2012). Fear can range from feelings of undefined distress or restlessness to the extreme that reach up to panic (Armfield ,2010).

However, "Dental anxiety represents a general state in which the individual experiences a level of apprehension and is prepared for something negative to happen", while "Dental phobia is a severe type of dental anxiety, which may result in avoidance or endurance of the dental experience with significant discomfort" (Porritt et al.,2012). Moreover, phobia is a clinical diagnosis, and it can be distinguished when the avoidance of the feared stimulus affects the person's normal routine and interferes with his/her academic performance, social activities and relationships, and other situations like going to the dentist (Armfield, 2010).

Dental fear still exists in our population and it is well known that dental anxiety in children as well as adults is relatively high, although the exact percentage of those with dental anxiety is unknown. The levels of dental anxiety have not decreased remarkably in the past few decades. Armfield (2010) showed a great association between perceptions of going to the dentist and dental fear (Armfield,2010; Crego et al.,2014).

Children with dental anxiety mostly fear pain from needles and dental drills; other children are generally anxious in dental settings or about treatment.

However, some children show anxiety behaviours that are not related to dental anxiety.

1.1.1 Aetiology of dental anxiety

Dental anxiety in children is challenging to parents, dentists, and healthcare systems. A study investigated the influence of mothers on their children who are in the dental situation and it confirmed that there is a significant relationship between dental anxiety in children and parents (Themessl-Huber et al.,2010). Additionally, previous negative dental experiences play a major role in the development of dental anxiety and is associated with increased perception of pain and negative thoughts with regards to dental treatment. A study carried out in UK showed that there is a significant link between previous distressing dental experiences and the development of dental anxiety. Distressing dental experiences can result from pain due to invasive dental treatments e.g., injection and root canal, intimidating dentist behaviour and emotional distress that might be caused by upsetting stories about dental treatment told by others who are regarded as important, such as parents, close family members or friends (Humphris and King, 2011). Other factors that are known to cause dental anxiety in children are genetic susceptibility, personality tendency, and parents' influence on the child during the treatment session. The child patient expectation that a negative event could happen during dental treatment and the perception of unpleasant dental event is associated with higher level of dental fear and anxiety. These children appear to have greater incidence of missing and untreated teeth due to caries, which leads them to negatively assess their oral health (Carrillo-Díaz et al.,2013).

1.1.2 Dental anxiety effect

Dental anxiety is usually linked to demographic variables, such as gender, education level, and previous dental treatment experiences. Increased levels of anxiety can lead to avoidance of necessary dental care and act as a major barrier to delivery of oral health services, which in turn adversely affects oral health status and quality of life (Milgrom et al.,2010; Crego et al.,2014). This is confirmed by research that documented the presence of "vicious cycle dynamics" whereby dental anxiety is linked to lower frequency and irregular

dental visits, resulting in a poor oral health status and the consequent reinforcement of dental treatment related anxiety (Crego et al.,2014).

1.1.3 Dental anxiety in the UK

It was reported in the 2003 UK survey that 75% of children in the UK do not have anxiety and only less than 4% experience phobia that is severe enough to affect their dental attendance. Additionally, young children in the study who were extra anxious were prone to have more active caries than those who were not anxious. Children undergoing extractions; whether under general or local anaesthesia, showed to have increased dental fear. Furthermore, dental anxiety was increased in children between 12 and 15 years of age who are having restorative treatment, however, not in the younger age group (Nuttall et al.,2008).

In 2013, the Children's Dental Health survey collected direct information from children aged 12 and 15 for the first time, which was about their attitudes and perceptions towards their dental health. Fourteen percent of the 12-year-olds and ten percent of the fifteen-year-olds were in the extreme anxiety group, and anxiety was more common among girls than boys. Although some children with extreme anxiety still reported visiting the dentists for check-ups, the majority were visiting the dentist only when a problem happens to their oral health or otherwise, they never been to the dentist before (Health and Social Care Information Centre, 2015).

1.1.4 Measures of dental anxiety

Dental anxiety can be assessed by using various approaches, such as questionnaires and rating scales, which are the more common methods (Welbury et al.,2018). Behavioural assessments can also be used to evaluate anxiety levels. In addition, anxiety levels can be assessed through the use of psychometric scales by means of questionnaires. Furthermore, indirect measures such as measuring heart rate and palmar sweat index (PSI) have also been implemented to measure anxiety levels in children (Klingberg et al.,1995). The measuring tools should be quick, relevant for children and their dental experience, and simple to analyse and score (Buchanan, 2005). The tool should also be valid in its measure of anxiety, which may be problematic for indirect measures involving physiological measures (Buchanan and Niven,

2002). There is not yet a standardised method to evaluate dental anxiety and most methods involving questionnaires do not show constant reproducibility and reliability (Welbury et al., 2018).

1.1.5 Behaviour rating scores

The use of patient-administered questionnaires may not be suitable for children, especially young children, as their understanding and vocabulary may not be well developed. In these cases, behavioural scales may be used. The knowledge of these rating scores is valuable as it can assist in guiding the management techniques. In addition, these rating scores can be used in diverse research projects (Welbury et al., 2018).

1.1.5.1 Frankl behaviour rating scale

In this rating system the observed behaviour is divided into four categories, ranging from definitely positive to definitely negative. It is summarised in Table 1 (Frankl et al., 1962).

Table 1 Frankl behaviour rating scale

Rank	Symbol	Description
Definitely negative	--	• Refusal of treatment • Crying forcefully • Fearful • Any other overt evidence of extreme negativism
Negative	-	• Reluctant to accept treatment • Uncooperativeness • Some evidence of negative attitude but not pronounced
Positive	+	• Acceptance of treatment • Cautious behavior at times with reservation • Willingness to comply and cooperatively follows dentist's directions
Definitely positive	++	• Good rapport with the dentist • Interest in the dental procedures • Laughter and enjoyment

Frankl behaviour rating score is the most commonly used scale in both research and clinical settings since it's short and easy to use. However, it does not provide enough clinical information regarding the uncooperative behaviour of the child. For example, if the child is judged as "negative" this could be interpreted as that the child was uncooperative throughout the procedure while this was recorded because the child was tearful during providing local anaesthesia. Therefore, recording "-", tearful with LA" would be a better description of the clinical situation (Dean et al., 2010).

1.1.5.2 Houtp rating score

The Houtp scale was first proposed in 1985 (Larissa et al., 2016). Houtp rating score is used to assess the behaviour of children during their dental treatment visits (Lourenço-Matharu et al., 2012). The advantage of the Houtp scale is that it categorises the severity of behavioural expressions like sleep, movement, and crying, which helps in detecting the specific changes in the child's behaviour. Moreover, it has the possibility to identify the magnitude of child's movement or crying during dental procedures and also it can be applied in dental sedation. However, the disadvantage is that it requires highly trained and skilled examiner to appropriately categorise the child's behaviour in the treatment session (Larissa et al., 2016). The Houtp scale is still preferred among dentists in assessing behaviours related to specific dental procedures and it is widely used in paediatric dentistry as it is a reasonable choice for busy professionals. Houtp rating score is described in the following Table 2 (Larissa et al., 2016).

Table 2 Houpt behaviour rating score

Behaviour	Scoring
Sleep	1. Fully awake, alert. 2. Drowsy, disoriented. 3. Asleep.
Movement	1. Violent, interrupting treatment. 2. Continuous making treatment difficult. 3. Controllable, not interfering with treatment. 4. No movement.
Crying	1. Hysterical demanding attention. 2. Continuous persistent, making treatment difficult. 3. Intermitted, mild, not interfering with treatment. 4. No crying.
Overall behaviour	1. Aborted, no treatment rendered. 2. Poor, treatment interrupted; only partial treatment was completed. 3. Fair, treatment interrupted but eventually completed. 4. Good, difficult but all treatment was performed. 5. Very good, some limited crying or movement. 6. Excellent, no crying or movement.

1.1.6 Anxiety self-reporting scales

1.1.6.1 Corah's Dental Anxiety Survey (CDAS)

CDAS is a survey containing four questions, developed in 1969. It assesses patients' responses to four dental treatment settings: before attending the dental surgery, waiting in the dental operatory, sitting in the dental chair and undergoing dental treatment. Each question has five pre-structured answers evaluated on a scale from one to five; one indicates no anxiety whereas five indicates the maximum level of anxiety. Therefore, CDAS scores can range from 4 (no anxiety) to 20 (extreme high anxiety). CDAS is commonly used in research for assessing dental anxiety in adults across the world. It has a high level of reliability and predictive value. It has been criticised for exhibiting a

range of scores which are too narrow to be used in clinical studies. However, it is efficient in clinical settings because it is short and quick, as it can be completed in less than five minutes (Jimeno et al., 2011).

1.1.6.2 Modified Dental Anxiety Survey (MDAS)

MDAS was developed by Professor Gerry Humphris in 1995. It consists of 5 questions, each with a 5-category rating scale, ranging from 'not anxious' to 'extremely anxious'. The total score is the sum of all five items, which ranges from 5 to 25. Nineteen and above is the cut-off value that indicates a high level of anxiety. The MDAS used CDAS as its base. CDAS was modified by adding an extra item about the respondent's anxiety to a local anaesthetic injection, which is a very common fear among children and a major cause of anxiety for many individuals. The answer options were rephrased and simplified to reflect anxiety in a clearer order. The Modified Dental Anxiety Scale became the most frequently used dental anxiety questionnaire in the United Kingdom (Humphris et al., 1995).

1.1.6.3 Venham Picture Scale (VPS)

VPS was developed in 1977 and it involves eight pairs of pictures (Sonnenberg and Venham, 1977). Each pair consists of 2 poses of a child, one is in a non-fearful pose and the other is in a fearful pose. The child is asked to choose the picture, which more accurately reflects their feeling at that moment, the minimum score is zero and the maximum score is eight (Venham and Gaulin-Kremer, 1979). VPS has presented many advantages in research; it is simple, quick, and suitable for children 2-8 years old (Foster and Park, 2012). However, VPS has some limitations (Buchanan and Niven, 2002). It has failed to distinguish between anxious and non-anxious children because no parameters were set to specify high levels of anxiety. In addition, the figures on the card are all male, which maybe a problem when the young patient is a girl. Moreover, for teenagers some figures are unclear in what they are representing (Aartman et al., 1998).

1.1.6.4 Facial Image Scale (FIS)

FIS is a valid, easy and quick scale to measure the dental anxiety for young children. Children are asked to choose from a row of five faces, ranging from very unhappy to very happy, choosing the one that represents their feelings at

that moment. The scale is scored from 1 to 5, where 1 represents the most positive and 5 represents the most negative. The Facial Image Scale has shown good validity in research (Buchanan and Niven, 2002). It is quick and easy to use in clinical situations, suitable for young children, and gives immediate feedback for the dentist. It helps in appropriate treatment and management planning for every anxious child as well as providing interesting results regarding prevalence of child dental anxiety (Wong and Baker, 1988; Buchanan and Niven, 2002).

1.1.6.5 Smiley Faces Program (SFP)

SFP is a computerized scale developed to assess dental anxiety in children using faces response. It includes four questions relevant to a child's experience in the dental practice environment (having dental treatment the following day, sitting in the waiting room, having injection and a tooth drilled), where the child will select from a range of seven facial expressions representing how they feel. The computer graphics help the child to engage with the dental anxiety scale and it identifies children who are anxious about a particular procedure. Access to a computer or tablet device is required. SFP scale is short and fast to complete, and all the items included are relevant to most children's dental experiences. However, it's complicated for children younger than 6 years and children with learning difficulties. Generally, the SFP scale has the advantage of facilitating data collection, standardising assessment, and has demonstrated good reliability (Buchanan, 2005). The SFP was revised (SFP-R) by Buchanan to add a fifth item about dental extraction. In addition, the graphics and instructions were updated in the revised version (Buchanan, 2010).

1.1.6.6 Modified Child Dental Anxiety Scale (MCDAS)

Humphris and colleagues (1998) developed MCDAS based on the concept of CDAS. It involves eight questions to measure dental anxiety regarding certain dental procedures. A five-point likert scale is used, with answer options designed in ascending order of dental anxiety level. It is usually used in children aged from 8 to 15-year-olds. For younger children a faces version of MCDAS (MCDAS_f) was developed to assess dental anxiety (Howard and Freeman, 2007). The MCDAS is short and fast to complete, thus it is beneficial in planning interventions that aim to reduce dental anxiety (Jimeno et al., 2011).

1.1.6.7 Children's Fear Survey Schedule (CFSS)

CFSS consists of 80 items on a five-point likert-scale. The length of this scale has triggered the development of a shorter version called the Dental Subscale of the Children's Fear Survey Schedule (CFSS-DS). It includes 15 items, and every item has a score of maximum 5 points, ranging from "not afraid at all" (1) to "very much afraid" (5). A score of 38 points or more indicates clinical dental fear (Howard and Freeman, 2007).

1.2 Behaviour management techniques

Anxiety control and management includes using many different techniques, both pharmacological and non-pharmacological. For children who are cooperative or potentially cooperative, non-pharmacological methods of behaviour management can be suitable for anxiety control. On the other hand, pre-cooperative and uncooperative children may require conscious sedation or general anaesthesia (GA) (Welbury et al., 2018). In addition, when sedation is to be considered, it should be used as an adjunct to behaviour management techniques. The decision to choose the method of anxiety control should be made on a patient and treatment specific basis (SDCEP, 2017). Factors that should be considered are patient's age, treatment complexity, patient's anxiety level, response to previous sedation or expected response to sedation and medical status, as per the ASA classification (American Society of Anaesthesiologists, 2021).

All pharmacological and non-pharmacological methods should be considered when planning the treatment for each case (SDCEP, 2017; Welbury et al., 2018). It is recommended that dental treatments that require general anaesthesia must only be carried out in hospital settings, and only when all other alternatives, such as sedation, have been exhausted (Davies et al., 2008).

1.2.1 Non-pharmacological behaviour management techniques

1.2.1.1 Non-verbal communication

Nonverbal communication defined as “the act of conveying information without the use of words”. It occurs through facial expressions, gestures, body language, tone of voice, and other physical indications of mood, attitude, approbation, and so forth, some of which may require knowledge of the culture or subculture to understand” (American Psychological Association,2020). During dental visits non-verbal communication occurs constantly and may emphasise or oppose verbal signals. Having a child-friendly environment and happy smiling dental healthcare workers could be included in the context of such communication (Wright et al., 1987). Gentle pats on the shoulder have been found to minimise distress (Weinstein et al., 1982; Chadwick, 2002).

1.2.1.2 Voice control

Voice control is a type of nonverbal communication; this technique involves using a controlled voice tone, volume, or pace to influence and guide the patients’ behaviour. Young children often show better response to the tone of voice rather than the actual words (Wright et al., 1987). These techniques aim to improve attention and compliance, as well as to create authority. For instance, a sudden change from soft to firm voice tone would gain the attention of a child who is not complying. In this case what the dentist says is not as influential as the way it is said, because the aim is to create a direct influence on patients’ behaviour rather than their understanding (Feigal, 2001). Voice control showed a decrease in disruptive behaviours without generating long-term negative effects (Greenbaum et al.,1990). The technique is useful for inattentive but communicative children (Murphy et al.,1984; McKnight-Hanes et al.,1993; Roberts,1995). It is not suitable for very young children or for those with intellectual or emotional problems and it may not be acceptable to all parents or clinicians (Chadwick, 2002).

1.2.1.3 Tell-show-do (TSD)

This technique is mostly used to familiarise children with a procedure that is unknown to them (McKnight-Hanes et al.,1993). It is a simple approach that aims to introduce a new experience using the concept of learning by doing, while reducing the anxiety and the fear of the unknown. First, the “tell” phase

involves description of the procedure that is about to be performed with an age-appropriate explanation, using “‘childrenese’ language”. Next, the “show” phase involves physically demonstrating the procedure to the child (Fayle and Tahmassebi, 2003). For example, representing the practice of polishing with a slow handpiece on a finger. Then the “do” phase where the procedure is carried out and initiated with a minimum delay. Moreover, it is essential to use ‘childrenese’ language for example, using the word “hoover” to describe the suction (Fayle and Crawford, 1997). Many dentists use a personal version of this language and the whole dental team can adopt the same approach. However, emotive or negative words like “pain” or “blood” should be avoided. TSD technique has been shown to be an effective way of reducing anticipatory anxiety in new child patients (Carson and Freeman, 1998).

1.2.1.4 Enhancing control

In this technique, the patient is given a degree of control over their dentists' behaviour through the use of a stop signal. The use of these signals has been shown to reduce pain during dental treatments (Wardle, 1982). The stop signal is typically raising a hand; and it should be practiced. The dentist needs to quickly respond to it when the child uses it (Thrash et al., 1982; Feigal, 2001; Fayle and Tahmassebi, 2003). It is very useful technique for all patients who can communicate (Chadwick, 2002). Allen and co-workers stated that enhancing control as a behaviour management technique helped to decrease the disruptive behaviour in children aged 3-7 years. They also acknowledged that this strategy did not require extra time to bring the disruptive behaviour under control compared with other behaviour management techniques (Allen et al., 1992).

1.2.1.5 Behaviour shaping and positive reinforcement

Behaviour shaping consists of a well-defined series of steps towards an ideal behaviour (Wright, 1975). In other words, it is a technique that engages the development of an appropriate behaviour by reinforcing sequential approximations to the desired behaviour until it is accomplished (Fayle and Tahmassebi, 2003). This is best achieved by selective reinforcement. Reinforcement is the strengthening of a pattern of behaviour, increasing the probability of that behaviour being displayed again in the future (Sawtell et al., 1974). Anything that the children find to be pleasing or rewarding can act as a

positive reinforcement; stickers for example can be used at the end of a successful appointment. However, the most powerful reinforcements are social stimuli, such as, facial expressions, positive voice modulation, or verbal praise. A child-centred, empathic response giving particular praise, for example, “I like the way you keep your mouth open” has shown to be more effective than a general comment such as “Good boy” (Weinstein and Nathan, 1988). Many dental procedures require fairly complex behaviours and actions from the patients, which need to be explained and learned through small clear steps especially for children. Therefore, it is particularly important to use age specific language (Wright et al., 1987).

1.2.1.6 Modelling

Modelling is a technique that is based on the psychological principle that people normally learn through watching and observing the behaviour of others and imitating them. Therefore, by using a model, either live or by video to show the appropriate behaviour in the dental environment can be very effective in behavioural management (Ghose et al., 1969; Johnson and Machen, 1973; Machen and Johnson, 1974; Stokes and Kennedy, 1980). For example, decreasing anxiety by showing a positive outcome to a procedure that the child requires, then illustrating the rewards for performing it appropriately. To accomplish the best outcomes, models should be the same age as the target child, must exhibit appropriate behaviour and be praised (Fayle and Tahmassebi, 2003). Where an appropriate model is available, this technique could be very beneficial (Chadwick, 2002).

1.2.1.7 Distraction

Distraction method is a technique that aims to shift the patient’s attention from the dental setting (i.e., potentially unpleasant experience) to a completely different setting (Fayle and Tahmassebi, 2003). This technique is useful for all patients who can communicate verbally (Chadwick, 2002). Short-term distractors such as diverting the attention by pulling the lip while the local anaesthetic is given or asking the patients to raise their legs to stop them from gagging during radiography can be beneficial. Some studies have supported the use of audiotapes as effective means of distraction (Ingersoll et al., 1984). Other study showed that talking during the application of the topical paste or

administering local anaesthetic is considered a form of distraction (Wright et al., 1987).

1.2.1.8 Systematic desensitisation

Systemic desensitization is a technique that helps persons with explicit fears and specific anxieties to overcome those fears by repeated exposures to that stimulus or fear. A hierarchy of fear-producing stimuli is formed, and the patient is exposed to these stimuli progressively, starting with the stimulus posing the lowest threat (Fayle and Tahmassebi, 2003). In the dental situation, fear is usually related to a specific procedure like the use of local anaesthesia. First, the patient is taught to relax, and then the patient will be exposed to each of the anxiety-provoking stimuli in a hierarchy. He/she only progresses to the next step when they are capable. Several relaxation sessions with a psychologist or dentist who has received training may be required for true phobias (Wright et al., 1987). This technique is convenient for children who can clearly identify their fears and who can verbally communicate (Chadwick, 2002).

1.2.1.9 Negative reinforcement

Negative reinforcement is a method where an unpleasant or undesirable stimulus is applied to a behaviour being exhibited and is only removed or stopped after the desired behaviour is presented, therefore reinforcing the favoured behaviour (Fayle and Tahmassebi, 2003). This should not be confused with punishment, which is the application of an unpleasant stimulus to inappropriate behaviour.

1.2.2 Pharmacological management techniques

Using conscious sedation for children during treatment has several objectives; it assists in reducing fear and anxiety, it enhances pain control, and it reduces the movement of the child during treatment (Roberts,1990; NICE,2010). Sedation also prevents dental fear from developing when it is used on children “prophylactically” in some situations that may be potentially traumatic. Furthermore, it helps the dentist in facilitating the completion of the treatment, and in reducing stress and unpleasant emotions experienced by the dentist (Hallonsten et al.,2013; Welbury et al., 2018). The American Society of Anaesthesiologists b (2021) divided sedation into a continuum of 4 stages. These stages are described in Table 3.

Table 3 Stages of sedation

Stage of sedation	Definition
Minimal sedation – Anxiolysis	• Drug induced state. • Patient responds to verbal command. • Cognitive function and physical coordination may be impaired. • Airway reflexes and ventilatory and cardiovascular function maintained and unaffected.
Moderate sedation – Conscious sedation	• Drug induced depression of consciousness. • Patient responds purposefully to verbal commands and/or light tactile stimuli. • Respiration, airway and cardiovascular functions maintained, and no intervention required.
Deep sedation	• Drug induced depression of consciousness. • Patient not easily aroused, but can respond purposefully. • Airway and breathing may be impaired, but cardiovascular functions usually maintained.
General anaesthesia	• Drug induced loss of consciousness. • Patient cannot be aroused. • Airway and breathing needs to be maintained with positive pressure ventilation. • Cardiovascular function may be impaired.

1.2.2.1 General anaesthesia

Some patients lack the ability to cooperate during dental treatment for example, patients suffering from severe mental illness and/or physical impairment.

Therefore, treatment under general anaesthesia might be the only solution.

Moreover, some surgical procedures can last for extended period of time and could be exhausting so that no other methods of pain and anxiety control can be considered other than GA (Koch and Poulsen, 2009; Welbury et al., 2018).

In general, the clinician must ensure that the benefits of treatment outweigh the risks when making a decision to treat a child under general anaesthesia.

Furthermore, economic factors and accessibility to anaesthetic facilities should be taken into consideration (Cameron and Widmer, 2008).

When GA is performed in hospital settings, the prevalence of serious complications associated with dental treatment is decreased. It is safer than giving deep sedation to patients in non-hospital dental settings. However, the use of the GA for provision of dental treatment should be restricted since anaesthesia itself can exert physical and mental stress compared with the other treatment options (Blain and Hill, 1998; Cameron and Widmer, 2008; Welbury et al., 2018). GA should be the last resort to treat a child and used only when all efforts in the conventional manner have failed (Cameron and Widmer, 2008; Koch and Poulsen, 2009). In addition, appropriate consent as well as a thorough pre-anaesthetic assessment must be obtained prior to the procedure (Cameron and Widmer, 2008).

1.2.2.2 Conscious Sedation

Conscious sedation is defined as a technique involving the use of drug or multiple drugs to induce a state of Central Nervous system (CNS) depression in which dental treatment can then be carried out. Furthermore, the drugs used should have enough safety margin to avoid the loss of consciousness. It is important that verbal communication is maintained; however, in the case of special needs where verbal communication may be inadequate, the usual method of communication for the patient should be maintained (IACSD, 2015; SDCEP, 2017). The primary route of administration routinely used for sedation in children is inhalation, then followed by intravenous (IV), which should only be used in cases when inhalation sedation is not successful (Wilson, 2013). Other routes of administration include oral, transmucosal, and intramuscular. The

indications for those methods include difficulty with cannulation due to phobias, learning difficulties, or other disabilities, and anxiety levels too high for Nitrous oxide/ Oxygen inhalation. However, difficulty due to anatomical variations is a contraindication to oral and transmucosal sedation (SDCEP, 2017).

Indications and contraindications of conscious sedation

Conscious sedation can be used in cases of dental anxiety and phobia and is indicated when dental treatment is expected to be prolonged or traumatic. The treatment needed and the complexity of the treatment should be considered when discussing the need for conscious sedation. Certain medical conditions may impair the child's ability to cooperate or may possibly be exacerbated with the added stress of dental treatment; in these cases, conscious sedation is indicated. Furthermore, conscious sedation is indicated for children with special needs (SDCEP, 2017). Contraindications for the use of conscious sedation include children below the age of one, and expectant mothers in their first trimester (Hosey, 2002; Hallonsten et al., 2013).

1.2.2.2.1 Intravenous sedation

Intravenous (IV) sedation is suggested in some cases and should not be used for pre-cooperative children. Currently, the policy in the UK is that IV sedation should merely be used for children aged 16 and above. The recommended method is using a titrated dose of a single drug; often Midazolam, which is used for adolescents who are emotionally and psychologically stable (SIGN, 2004; Hosey, 2002). However, fixed and bolus doses are not acceptable routes of administration as they are not titratable. Nonetheless, continuous infusion of drugs, either as a single dose or in combination may be justified in some cases. The facilities available, the experience and training levels of the practitioner and the sedation team must be considered (IACSD, 2015).

1.2.2.2.2 Oral sedation

Intra-oral sedation is one of the most convenient and effective methods of sedation; it doesn't require injections or major patient cooperativity when compared to inhalation sedation (Girdler et al., 2009; Malamed, 2017). Oral sedation is satisfactory and acceptable technique for pain and anxiety management; however, the operator should be trained in airway management and should also be able to rescue the patient from a deeper level of sedation. In

addition, administration of the sedative agent should be done in clinic where a suitable member of staff can monitor the patient to ensure that the correct dose is given (Malamed, 2017).

Oral Sedative Agents

Several agents have been used as oral sedatives; and it is suggested that a complete medical history, patients' age, weight, and list of medications should be considered prior to sedation. Furthermore, the degree of anxiety and the level of sedation required for the patient should also be completed. Although titration may not be possible during the appointment, 'titration by the appointment' can be done; the efficacy of sedation at the first appointment is assessed, following which the dose for the next appointment can be adjusted as needed (Malamed, 2017).

1.2.2.2.3 Inhalation Sedation

Inhalation sedation is a type of conscious sedation that is administered via inhalation mask to produce a state of depression of the CNS, relaxing the patient and enabling treatment to be carried out (British Association of Oral Surgeons, 2011). There are several sedative agents that have been used for the employment of inhalation sedation such as Nitrous oxide and sevoflurane (Hosey, 2002; Soldani et al., 2010).

Nitrous oxide is an odourless and colourless gas that has a relatively quick onset (within 1 minute) and recovery, once stopped, due to its low solubility (Paterson and Tahmassebi, 2003; Krauss and Green, 2006). It is mild sedative agent that creates euphoria and depresses the CNS and consequently, memory, attention and intelligence are decreased (Girdler and Hill, 1998; Paterson and Tahmassebi, 2003).

Sevoflurane is a volatile and sweet-smelling gas, which is used in general anaesthesia, but has also been used as a form of conscious sedation with concentrations ranging from 0.1%-0.3%. It can be combined with 40% nitrous oxide, the remainder being oxygen. The concentration used may differ from patient to patient (Girdler et al., 2009; Soldani et al., 2010). Using concentrations of 0.1-0.3% sevoflurane with 40% nitrous oxide, can be more effective than nitrous oxide sedation alone. However, more training and additional cost are required. Lahoud and Averley (2002) concluded that when nitrous oxide alone fails, sevoflurane can be added, to reduce the need of GA.

There are other inhalation sedation agents such as isoflurane and halothane have been described, however, their use must be controlled until further research develops (Girdler and Hill, 1998).

1.3 Nitrous Oxide/Oxygen inhalation sedation

Inhalation sedation with nitrous oxide/oxygen is the only standard technique for children and it is a safe and effective technique, hence it is widely accepted and is considered the first choice for anxious children undergoing dental treatments especially for those who might need multiple treatment visits. However, the benefits of the technique rely on appropriate titration of nitrous oxide to the individual patient's response (British Association of Oral Surgeons, 2011; IACSD 2015; SDCEP 2017). Moreover, it is well known that practicing a short trial of nitrous oxide/oxygen at the assessment appointment for children can help to prepare them psychologically (SDCEP, 2017).

The concentration of nitrous oxide used varies from 30-70% mixed with the remaining percentage of oxygen, and depending on the amount used, different levels of sedation can be reached (Roberts, 1990; Krauss and Green, 2006). The levels (planes) of sedation for Nitrous Oxide/Oxygen mixture are described in table 4. In the United Kingdom, the recommended method of sedation for children is inhalation sedation using nitrous oxide/oxygen mixture where 83-96% of children successfully complete their treatments (Soldani et al., 2010).

There are three components in the use of inhalation sedation that are essential to increase success; administering low to moderate concentration of nitrous oxide that is titrated to individuals, comforting and semi-hypnotic cues, and using proper equipment with fail safes and regular maintenance, including the use of scavenging systems (Roberts, 1990; Krauss and Green, 2006). Furthermore, it is essential to use clinical and instrumental monitoring appropriate to the patient's medical status and the clinical situation pre-operatively, at suitable intervals during the procedure and post-operatively, which include pulse oximetry, blood pressure monitoring. And the entire clinical team need to be efficient in monitoring the condition of the patient (IACSD, 2015). After completing the treatment with nitrous oxide/oxygen inhalation sedation, it is essential for the patient to receive 100% oxygen for 3-5 minutes, followed by a period of ambient air to ensure complete elimination of nitrous oxide (Roberts 1990; Paterson and Tahmassebi, 2006).

Table 4 Sedation levels (planes) of Nitrous oxide/Oxygen inhalation

level (plane)	N₂O Concentration	Sedation signs and symptoms	Possible Side effect
Moderate sedation and analgesia	5-25%	Patient feels tingling in toes, fingers, oral cavity, hand and chest Patient is relaxed, with an increase in pain threshold and a decrease in anxiety and fear. Patient still responsive	No side effects but may have impaired hearing, vision, touch and proprioception
Dissociative sedation and analgesia (psychosedation)	20-55%	Patient may feel a sense of euphoria and detachment from the environment. Feeling worm, buzzing in ear, drowsiness and light headedness may be common Delayed responsiveness	Nausea and vomiting (rare)
Total Analgesia	50-70%	Patients more likely to dream Loss of ability to maintain mouth open and to respond to commands	Loss of consciousness possible

Nitrous Oxide (N₂O) Inhalation Sedation Indications and Contraindications are explained in table 5 (Altimimi, 2016).

Table 5 Indications and contraindications of N₂O Inhalation Sedation

Indication	Contra-indication
Mild to moderate fear and anxiety related to dental treatment	Claustrophobia: anxiety level may be increased when attempting to place the mask Mouth breathers
Acute dental problems where profound local anaesthesia cannot be achieved (acute pulpitis) and treatment of hypersensitive teeth	Myasthenia gravis and multiple sclerosis; muscle activity depressed, and using sedation may further depress muscle activity
Cardiovascular disease (angina, ischemic heart disease); high oxygen concentration reduces risk of ischemic attack	Children with behaviour problems; pre-cooperative and non-cooperative children may not breath through their nose and excessive crying will limited inhaled nitrous oxide
Respiratory disease (asthma); anxiety is reduced, and non-irritating vapour is used hence reducing risk of asthmatic attack	Chronic obstructive pulmonary disease: increase concentrations of oxygen may lead to apnoea as low concentrations of oxygen is the stimulus for breathing
Dental treatment will be traumatic to the patient	Psychological disorders (compulsive personality and personality disorders); patients may resist the effects of sedation
Pregnancy: only after 1 st trimester if needed	Pregnancy: best avoided during 1 st trimester and may need to delay treatment in 3 rd trimester.
Cerebrovascular disease as the risk of a hypoxic episode is low Epilepsy: anxiety and hypoxia reduced, both triggers for seizures	Upper respiratory tract infection and acute respiratory problems; inability to breathe through the nose and chance of possible cross contamination
Hepatic and renal disease; no biotransformation in the body	Diseases of closed spaces (bladder, ear infection, pneumothorax)
Medically compromised patient where risks involved with GA is too great	Inability to communicate Learning difficulties
Cerebral palsy; can control movements	Patients with head injury; intracranial pressure is increased with nitrous oxide
Sickle cell disease: high oxygen concentration reduces risk of sickle crisis	Hypovolemia: loss of consciousness may occur faster

1.3.1 Chronic Exposure to N₂O

Chronic occupational exposure to nitrous oxide has been linked to some safety and health risks for dental professionals (Freilich et al., 2007). Dentists and auxiliary staff members who are chronically exposed to nitrous oxide could suffer from adverse effects such as haematological disorders, pernicious anaemia and reproductive disorder, infertility and spontaneous abortion (Paterson and Tahmassebi, 2003). Moreover, renal and hepatic diseases, neurological disorders, and bone marrow suppression were also reported to be associated with chronic exposure to N₂O, though these effects involved significant daily exposure over long periods of time (Henry et al., 1992). The published literature showed weak to moderate association as most of the studies were carried out before the scavenging systems were required. At least one study has found that when using an appropriate scavenging system, there is no increased risk of spontaneous abortion when compared to the unexposed group (Rowland et al., 1995).

Appropriate use of scavenging systems and a proper ventilation reduces the nitrous oxide levels in the clinical environment dramatically which in turn reduces the healthcare workers exposure to nitrous oxide. Studies found that when the number of room air changes and percentage of fresh air increased will hugely decrease the room air concentration of nitrous oxide in the clinical environment. It is suggested that a minimum of 12 air changes per hour for dental operatories using nitrous oxide is required with negative pressure (Hansen et al., 2019).

Therefore, the UK Health and Safety Executive (HSE) specifies a maximum level of 100 part per million (ppm) nitrous oxide time-weighted over 8 hours (Health Safety and Executive, 2011). To achieve the maximum recommended level and to keep N₂O exposure to a minimum for the operator and staff, active scavenging must be employed (Craig and Boyle, 2016). All sedation and scavenging systems should be regularly maintained. It is recommended that this must be carried out once a year to provide best working practice and it is already established practice in the UK (Pickles, 2016).

The USA National Institute for Occupational Safety and Health (NIOSH) has reported investigations on the minimum N₂O levels that could interfere with the optimum performance of perception, cognitive and motor skills. These minimum

levels can be avoided in the dental environment by using an active scavenging device. NIOSH guidelines for N₂O exposures state that “occupational exposure to nitrous oxide, when used as the sole anaesthetic agent, shall be controlled so that no worker is exposed to time-weighted average concentrations greater than 25 ppm during anaesthetic administration” (NIOSH, 2014).

Previous studies have also shown an association between the cooperation levels and nitrous oxide levels in the ambient air (Badger and Robertson, 1982; Henry et al., 1992), however the design of the current study was not aimed to evaluate the relationship between the cooperation levels and the nitrous oxide levels in the ambient air.

1.3.2 Nitrous oxide environmental impact

In recent years, the contribution to global warming and climate change gas explained. More than 300 million major operations are taking place in hospitals all over the world each year. Many of which are relaying on anaesthetic gases to make patients unconscious. However, some of these gases are greenhouse gases, which are more potent than carbon dioxide in contributing to global warming, especially nitrous oxide (Cole-Adams, 2017).

The NHS accounts for 5.4% of the UK’s national greenhouse gas emissions and most of the anaesthetic gases are exhaled in the atmosphere (Hu et al., 2021).

Nitrous oxide is found in nature and accounts for around 59% of the heating effect of greenhouse gases in the atmosphere (Yee et al., 2019). Its long atmospheric lifespan of about 150 years that makes it the most effective global warming substance (Gadani and Vyas, 2011). The nitrous oxide is minimally metabolized in the human body, so it maintains its pharmacological effect when exhaled by the patient to the operating room, which will increase the healthcare worker exposure to nitrous oxide if the room is poorly ventilated (Yasny and White, 2012).

Furthermore, the scavenged anaesthetic gases are usually vented out of the building into the environment as Waste Anaesthetic Gases (WAGs). These gases will remain in the atmosphere for very long time leading to a great environmental impact and global warming (Gadani and Vyas, 2011).

Currently, nitrous oxide emissions from all different kinds of environmental sources are the most important ozone-depleting agent and expected to remain the largest in the 21st century (Yasny and White, 2012). The most practical control of the WAGs in operating rooms is gas scavenging. Particularly if combined with other control measures such as dilution ventilation. If anaesthetic gases are present in the room with increased concentrations, then airflow should be increased in the room to create air mixing and further dilution of the anaesthetic gases (Yasny and White, 2012).

During the past years the control of environmental contamination of anaesthetic gases is being improved by using advanced designs of scavenging systems, installing better ventilation systems, increasing the attention to equipment maintenance and leak detection, as well as careful anaesthetic practice. But still the environmental impact of WAGs remains a global concern (Yasny and White, 2012). The development of new technologies that aim to trap, recycle and reuse the anaesthetic gases rather than releasing them into the atmosphere can reduce the environmental impact of these greenhouse gases (Lahvic and Liu, 2020).

Implementing preventive practices such as reducing gas flow of anaesthetic gases, judicious checking of all connections of anaesthesia circuit and using properly fitting face masks can help in minimizing environmental pollution (Yasny and White, 2012).

In conclusion, optimizing practices, education, awareness, strategies development and implementation are very important aspects in the future of anaesthetic care practice and atmosphere (Yasny and White, 2012; Lahvic and Liu, 2020).

1.3.3 Nitrous oxide monitoring methods – diffusion tubes

There are several conditions in which nitrous oxide levels could be increased in the dental setting, which include: inadequate scavenging, lack of ventilation in the operating room, leakage from the equipment parts or from a poorly fitting mask, and exhaled gas from patients during talking or mouth breathing.

Monitoring exposure levels can be carried out in two ways: either by using a diffusion pen, which records the levels of N₂O in the ambient air surrounding the

operator or by using gas analyser, which records the levels of N₂O in the background and breathing zones in the operating room (Wilson, 2016).

Additionally, a wide range of methods and instruments can be used for sampling and analyses of anaesthetic gases in the operating surgery. These can be either active or passive sampling methods. Active samplers such as the Miran portable analyser that require the use of air sampling pump to actively collect the gases from the air to the device. Passive samplers collect air by diffusion and do not need active air movement. Nitrous oxide is one of the anaesthetic gases that is collected by diffusion passive samplers (diffusion tubes) (Reeve, 1855). Diffusion tubes (samplers) principle is that contaminant molecules diffuse from a higher concentration area in the workplace environment to a lower concentration (zero) in the collection device (tube). There are two types of passive samplers that work on the principle of diffusion, the samplers that require laboratory analysis and the direct reading sampler devices. The direct reading samplers are typically based on colorimetric techniques, while a solid sorbent material is used to collect the contaminant for the samplers that need laboratory analysis. These methods can be as reliable as active sampling methods (Salter and Ltd, 2005).

The diffusion (passive) tubes are stainless steel tubes that are 9 cm long and 0.5 cm wide (Gradko Environmental Laboratory a, n. d) with a 6-week shelf life (figure 1). Tubes must be exposed and returned to the laboratory for analysis within that time (Gradko Environmental Laboratory b, n.d).



Figure 1 Diffusion tube

(RA Medical Services Ltd a, 2014, p.1)

The air sample is removed from the diffusion tube by thermal desorption. This process works by removing the contaminant from the tube and exposing it to a high temperature. Heating the diffusion tube will allow the nitrous oxide sample to be extracted from the tube, which is then transferred to a Gas Chromatography-mass Spectrometry (GCMS) for analysis. The concentration of the gas in the tube will be determined first, and then the averaged concentration of the contaminant in the air during the monitoring period will be calculated. The sampling uptake rate and the exposure time will be used in the calculation. Each contaminant has a specific uptake rate and the nitrous oxide uptake rate is 1.25 ppm (Gradko Environmental Laboratory a, n.d).

There are a number of factors that could affect the performance of passive samples and hence affect the analyte uptake. They include temperature, humidity, air and water movement (Zabiegała et al., 2010). Obstructing the tubes by the wearers or using the tube the wrong way round or horizontally instead of vertically are other factors that could affect the sampling device. Furthermore, some other factors could arise from manufacture or during transport and storage, as some methods require storage and transportation under very low temperature, others require rapid analysis. Therefore, it is crucial to consider an effective storage and transport method to the laboratory to maintain the sample from distortion (Melanie, 2003).

Despite the pitfalls, the diffusive tubes are simple, cheap and reliable tools that are widely used for personal monitoring. The main benefit is that the diffusion tubes do not require a pump or flow rate measurement and they are less obtrusive to the wearer, especially in locations such as theatres where a larger device may be intolerable (Analytical Methods Committee, 2020).

1.3.4 Inhalation sedation equipment

All nitrous oxide delivery systems should have a scavenging system, a flow meter, a vacuum pump, and various mask sizes to ensure good fit of the mask on every patient (American Dental Association, 2019). Scavenging systems prevent unwanted nitrous oxide levels in the dental operating environment, therefore an effective scavenging system should be installed with every inhalation sedation unit to effectively collect, remove, and dispose waste gases (Freilich et al., 2007). The literature has also reported that rubber dam use,

decreasing patient talking, avoiding mouth breathing and encouraging patient cooperation are variables which affect the level of waste gas in the operating environment (Christensen et al., 1985).

Operating environments should have effective ventilation and/or airflow as well as active scavenging equipment that removes the waste gases to the outside environment. In general, scavenging systems use a vacuum or suction connected directly to the equipment of inhalation sedation, which is part of the breathing mask system. Additional scavenging may be carried out by placing a tube near the patient and operator to aid collecting the gas waste in the operating room or dental clinic (Freilich et al., 2007).

1.3.4.1 Inhalation sedation breathing systems

Two American companies: Porter Instruments and Accutron manufacture the most common inhalation sedation breathing systems.

The Accutron is one of the breathing systems that is widely used in the USA. The latest Accutron mask systems available in the market are the “Clear view” (Figure 2) and “Axess” (Figure 3). The Clearview mask came on the market in 2012. It is a disposable double mask system (clear outer mask, coloured inner mask). The inner mask comes with different colours and scents. The double mask feature gives a better anatomical fitting on the patient’s nose and thereby a better scavenging efficiency. In 2017, the Axess low profile mask was launched to the market. This system is similar in design to the Silhouette mask from the Porter Instruments Company, but it is autoclavable. Three mask sizes are available in the Axess breathing system (RA Medical Service Ltd, 2017). The vacuum control assembly circuit of the Accutron breathing systems meet the proposed scavenging flow rate recommendations of NIOSH and the American Dental Association (Accutron inc., n.d).

The Porter Instruments company has three different breathing systems. The Matrix (figure 4), the Porter Brown and the Silhouette breathing systems. The Matrix breathing system is autoclavable and light weight. It has the fewest number of components compared to other autoclavable systems and it has three mask sizes (Porter Instrument a, n.d.).



Figure 2 Clearview



Figure 3 Axess



Figure 4 Matrix

(Matrix by Midmark, 2006, p.1; RA Medical Services Ltd b, 2021, p.12,14)

Porter Brown System

The Porter Brown scavenger (Figure 5 and 6) is a double mask system that is characterized by a mask-within-a-mask scavenging system. The system includes easy to remove inner masks which vent into the outer mask. This helps in cleaning and sterilisation. The silicon tubing and the mask are highly durable and can be sterilised using either steam or chemical vapor autoclaves. The soft inner part of the mask system provides a comfortable fit and an excellent seal around the patient's nose. The Porter Scavenging System also provides single-use personal mask liners (usually flavoured). Masks are available in paediatric and adult sizes. The Porter Brown system is comfortable and lessens any resistance between the vacuum source and the patient and allows the patient to receive the appropriate amount of nitrous oxide and oxygen without any effort in respiration. The Porter Brown system provides a Non-Rebreathing Valve (NRV) and Emergency Air Intake (EAI) located on the reservoir bag to increase patient safety by making the breathing bag visible to the operator, so the patient's respiration rate and volume can be monitored (Porter Instrument Division b, n, d).

Studies have suggested that it is one of the most efficient systems for scavenging waste nitrous oxide. A pilot study undertaken in Canada showed that the Porter Brown system was more effective in reducing nitrous oxide exposure during inhalation sedation compared with the Matrix Medical Single Mask System (Freilich et al., 2007).

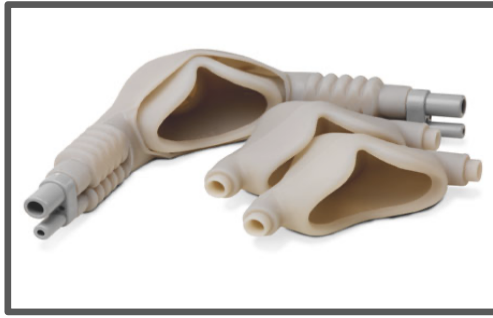


Figure 5 Porter Brown mask

(Porter instrument, 2021)

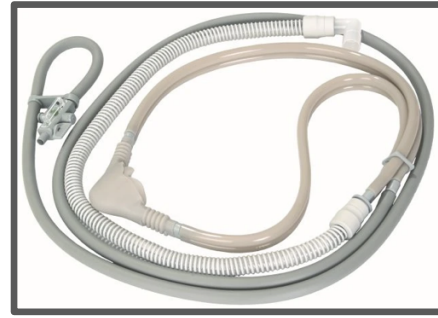


Figure 6 Porter Brown circuit

(RA Medical Services Ltd b, 2021, p.6)

Silhouette Nasal Mask System

The Silhouette System (Figure 7 and 8) came on the market in 2015. It is a new breathing system that was designed by a dentist named Robert Guyette to allow better access to the patient's oral cavity during dental procedures (Porter Instrument, 2015). The Silhouette low profile nasal mask provides a mask and breathing circuit allowing dentists to easily visualise and access all areas of the patient's mouth. The Silhouette is a lightweight single-use nasal mask with an adhesive strip across the bridge of the nose (Figure 9) to secure the mask in place and create a good seal around the patient's nose. This helps the built-in scavenging system to remove excess and exhaled nitrous oxide that could aid in lowering N₂O loss to the environment hence reducing N₂O exposure. It delivers the appropriate amounts of oxygen and nitrous oxide to the patient with normal respiratory effort (Porter Instrument, 2015; Porter Instrument Division a, n.d.).

The Silhouette mask is placed first on the patient's nose with nasal cannula (Figure 10) fully into the right nostril, then the comfort tubing is placed around the patient's ears. The sliding ring is attached to the circuit to secure it under the patient's chin. Dentists can easily work and treat the patient because of its compact size and transparency. Patients can turn their heads comfortably from side to side without any restriction. It is available in four different sizes to establish an appropriate mask size for the patient (Porter Instrument, 2015; Porter Instrument Division a, n.d.).

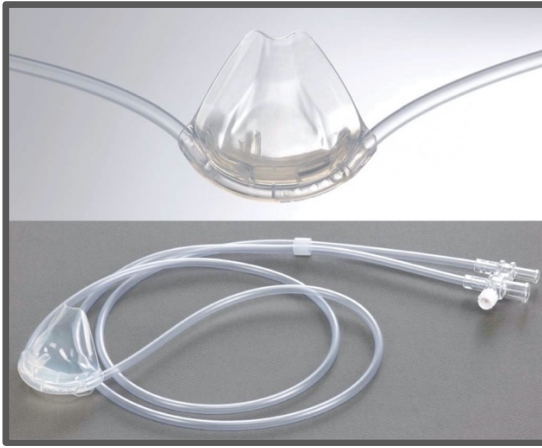


Figure 7 The Silhouette mask

Figure 8 Silhouette breathing circuit

(Porter Matrix, n.d, p 42,43)



Figure 9 Adhesive strip

Figure 10 Nasal Cannula

(Porter instrument b, n.d, p3)

1.4 Rationale for this study

A previous assessment of the ability of different scavenging systems demonstrates that not all breathing systems are equally effective. Christensen et al.(1985) examined the effectiveness of the Porter Brown and Fraser Harlake breathing systems in the adult population, every participant had 8 dental appointments (total of 80 appointments all together). Nitrous oxide levels in the dentist's breathing zone were measured during 80 standardized 15 minutes dental appointments using nitrous oxide-oxygen inhalation sedation. Ten healthy participants aged between 20 to 30 years old were assigned randomly to one of the two groups. Two investigator carried out the dental treatment and three variables were assessed (scavenging mask, talking, rubber dam) for their effects on the nitrous oxide levels in the ambient air. All treatment was done in a single dental suite. Air samples were collected continuously from the breathing zone by 3 sampling catheters during the 15 mins appointment and were analysed by the infrared spectrophotometry. Results showed a significant difference in the effectiveness of the 2 scavenging systems and found that the Porter Brown breathing system was more effective in reducing nitrous oxide levels in the dental environment. Neither the rubber dam nor the patient's talking significantly affected levels of scavenged nitrous oxide (Christensen et al.,1985). Other studies have compared different scavenging masks in adults. Few studies have compared the Porter Brown system to other scavenging systems for dental treatment with paediatric patients.

Henry et al.(1992) compared scavenged (Porter Brown breathing system) and non-scavenged breathing systems in a prospective study. Thirty-six children aged between 44-93 months were randomly allocated into two groups (18 child in each group). Participants received nitrous oxide-oxygen under standardized conditions during routine dental procedures, a determination of what factors influenced the selected dental procedures and patient behaviours on ambient nitrous oxide levels in the dentist's breathing zone was observed. An infrared spectrophotometer analyser used to determine the ambient N₂O levels continuously throughout the procedure and the time-weighted average (TWA). A video camera was used to synchronize the coded dental procedures and patient behaviours to the TWA ambient N₂O levels recorded. The results showed that the scavenging significantly reduced ambient N₂O levels in the

dentist's breathing zone but not to the level recommended by NIOSH. The administration of local anaesthesia consistently created a significant increase in the ambient N₂O levels. Patient behaviours of talking, crying, and movement also resulted in significant increases in the ambient N₂O levels. Patient talking, crying and/or breath-holding during local anaesthetic administration resulted in a three-fold increase in ambient N₂O levels compared to levels observed for cooperative children receiving local anaesthesia (Henry et al.,1992).

Furthermore, Chrysikopoulou et al.(2006) compared the effectiveness of 2 nasal hoods (Porter Brown and Accutron) in reducing waste nitrous oxide gas during conscious sedation for routine paediatric dental treatment. Thirty children, aged between 3 to 8 years were selected and randomly allocated into two groups (15 child in each group). In the first group, children started with the Porter Brown mask, which was then switched to the Accutron mask. In the second group, children used the reverse order of masks (cross over design). Four measurements of ambient nitrous oxide were recorded with a Miran Portable Ambient Air Analyzer 5 minutes after administration of nitrous oxide; placement of the rubber dam; change of the nasal hood; and reduction of the vacuum. Samples were taken 8 inches above the nose of the patient and in the room 5 feet away from the patient. Nitrous oxide levels were significantly lower with the Porter Brown system compared with the Accutron system. When the suction was reduced, there was an increase in nitrous oxide levels with the Porter Brown nasal hood, whereas the levels with the Accutron nasal hood remained high (Chrysikopoulou et al.,2006).

Gilchrist and collages (2007) evaluate the 8-h time-weighted average (8-h TWA) exposure to nitrous oxide of dentists working in a paediatric dental unit, and to relate this to various operator, patient and environmental factors. This prospective, open label study monitored nitrous oxide levels using either a personal dosimeter or an electronic sensor worn by the operator. Information was recorded by three dental operators administering nitrous oxide/oxygen for inhalational sedation. Thirty-four paediatric dental patients with age range from 6 to 15 years old were treated over a total of 17 treatment sessions. Active scavenging was used for all children; 23 were treated using the Porter Brown scavenging system and 11 with the Accutron system. Exposure to nitrous oxide expressed as an 8-h TWA ranged from 16 to 374 ppm, with a mean of 151 ppm.

The recommended 8-h TWA of 100 ppm was achieved in only 38% of cases. Ambient nitrous oxide levels apparently increased with restorative treatment, poorer behaviour, when the extractor fan was switched off, with patients over 10 years of age and an increased number of sequential patients. They found that Accutron was associated with higher levels of nitrous oxide in the ambient air, although the study was not designed to verify that (Gilchrist et al.,2007).

Certosimo et al.(2002) compared three nitrous oxide scavenging systems in adult population: The Porter Brown, the Accutron and the Matrix breathing systems. This study consisted of 12 healthy adult volunteers aged between 22 to 44, 7 males and 5 females, who were randomly selected from a population of dental school. The subjects participated in four clinical sessions at one-week intervals. During these sessions, each subject was exposed to either one of the three N₂O scavenger units or to a control that used no scavenger unit. The order of exposure to each of the variables was determined by a randomized computer-generated schedule established by an investigator not associated with the clinical portion of the study. A pilot study was performed to minimize variation between subjects, calibrate the instruments and the procedures, and expedite reproducibility. The study was carried out in the same ventilated operatory with an air flow rate that produced six air exchanges per hour. The N₂O delivery system was checked for proper connections and protection against gas leakage directly before each investigational session, in agreement with the recommendation protocol of the ADA. Prior to each session, room air was evaluated using an infrared spectrophotometer device to determine the baseline value of N₂O in the operatory. A portable infrared spectrophotometer sensor (Miran) was calibrated professionally prior to the study. The instruments sensor was placed opposite the dentist at height of 18 inches above the patient's nose. They found that Nitrous oxide levels were significantly lower when using the Porter Brown breathing system than either the Accutron or Matrix breathing systems. And that the application of the rubber dam isolation did not significantly affect the levels of ambient nitrous oxide even though it was reported that the levels decreased (Certosimo et al.,2002).

Freilich et al (2007) carried out a pilot study in the outpatient dental clinic at the Hospital for Sick Children to determine whether airborne nitrous oxide (N₂O) gas concentrations were within established regulatory limits. The effectiveness

of 2 scavenger mask systems, the Matrix Medical single-mask system and the Porter Brown double-mask system, for reducing airborne contamination in a clinical environment during the treatment of paediatric dental patients was compared. Nitrous oxide and oxygen mixture was administered for a variety of dental procedures. All 17 patients who participated in the study were cooperative throughout the time that N_2O/O_2 sedation was administered. Administration of N_2O and completion of the dental procedures were done by staff oral and maxillofacial surgeons, staff paediatric dentists, and residents or fellows. A Miran Sapphire direct air-sampling instrument (Thermo Electron Corporation, Waltham, Mass.) was used to measure N_2O levels of the ambient air in the treatment room. The sampling port was located 1.0 to 1.5 metres away from the patient, as close as practicable to the breathing zone of the dentist and auxiliary staff. Measurements of real-time N_2O concentration were recorded on the instrument and subsequently downloaded to a computer for analysis.

The same operatory was used to test both systems, and exactly the same air exchange conditions were present during the testing of both scavenging systems. Only one treatment involving N_2O/O_2 sedation of a patient was done in the study operatory during each 8-hour day. Measured concentrations of N_2O averaged over the procedure were used to calculate the time-weighted average exposure value (TWAEV), which is defined as the average of the airborne concentrations of a chemical agent determined from air samples to which a worker is exposed in a work day or work week (Freilich et al., 2007). Concentrations of N_2O would have exceeded the daily exposure limit if more than 1 procedure had been done on any given day with the single mask scavenging system. The results indicated that the Porter Brown breathing system was more effective in minimising the nitrous oxide levels in the ambient air (Freilich et al., 2007).

To date, the Silhouette system has not been used in inhalation sedation in the Leeds Dental Institute. At the inception of this study, there was no previous studies in the literature showing the effectiveness of the Silhouette system or comparing it to other systems.



Figure 11 Porter Brown mask



Figure 12 The Silhouette mask

1.5 Aims and Objectives

This study aimed to investigate the scavenging efficiency and the acceptability of the Silhouette breathing system compared with the Porter Brown breathing system used in inhalation sedation for children. It also aimed to investigate if there was any difference in providing the sedation between the two systems.

1.6 Null hypotheses:

- There are no differences in the scavenging efficiency of the Silhouette system compared with the Porter Brown system.
- There are no differences in providing sedation between the Silhouette system and the Porter Brown system for the operator.
- There are no differences in patient acceptability between the Silhouette system and the Porter Brown system.

1.7 Outcome measures

1.7.1 Primary outcome

- The scavenging efficiency of the two breathing systems was measured by calculating nitrous oxide levels in the ambient air using diffusion tubes. The result was reported by parts per millions (ppm) over 8 hours weighted period.

1.7.2 Secondary outcomes:

- Comfort of wearing the masks.

Feedback questionnaire was obtained from the participants after the treatment session.

- Level of cooperation.

The level of cooperation was measured at the end of the treatment session using the Houpt scale.

- Dental anxiety level.

The dental anxiety level was assessed twice; before and after the treatment session using the Facial Image Scale (FIS).

- The breathing system and circuit costs.

Chapter 2 Material and Methods

The present study was carried in the Sedation Unit at the Leeds Dental Institute.

2.1 Ethical approvals and registrations

2.1.1 Sponsorship approval

The sponsorship approval was granted (Appendix A) by the Faculty Research Manager, Head of Research Support for the Faculty Medicine and Health.

2.1.2 Ethics and Clinical Services Unit approvals

The Research and Ethics Committee form (REC), along with all relevant research documents were authorised and submitted through the Integrated Research Application System (IRAS ID: 233026). The Application was reviewed and approved by the Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (REC reference: 18/YH/0489) (Appendix B).

Following approval from NHS Research Ethics Committees (REC), the Leeds Dental Institute Clinical Service Unit (CSU) approval was granted (Appendix C).

2.1.3 NHS Research and Development (R&D) approval

NHS permission for research has been granted for this project at the Leeds Teaching Hospital Trust (LTHT)(Appendix D). R&D approval has been obtained following the authorisation of:

- a. Research passport (Appendix E)
- b. Disclosure and Barring Service (DBS) checks (Appendix F)
- c. Occupational health clearance.

2.1.4 Clinical trial registration on a publicly accessible database

The study protocol was submitted for publication on the following data accessible website and the protocol was made accessible to the public.

Unique Protocol ID: 2233026

Clinical Trials.gov Identifier: NCT04734509

Details can be found on the following link:

<https://clinicaltrials.gov>

2.2 Study settings and design

This study has been carried out in the Sedation Unit, Leeds Dental Institute.

This is a single centre randomised non-blinded controlled clinical trial. A total of fifty-four participants, aged between 7 to 15 years were recruited from the Sedation Unit (SU) waiting list at Leeds Dental Institute during the assessment appointment (1st visit). Eligible participants (n=54) were randomly assigned to one of two different inhalation sedation breathing systems: The Porter Brown system or the Silhouette system on the day of the treatment session (2nd visit). Therefore, each block randomised group had 27 subjects (n=27).

The randomisation was carried out prior to the start of each treatment session. It was achieved by preparing concealed envelopes containing a card with either the Porter Brown or the Silhouette breathing system. Neither of the participants nor the dental team were aware of which breathing system will be used until the day of the treatment. On the day of treatment, the dental nurse picked an envelope showing which breathing system will be used for the entire treatment session for all of the participants, hence the dental team were aware of which breathing system was used for all the participants in that treatment session. However, the participants were informed which mask their dental treatment will be carried out with when they arrived for their treatment session. This randomisation strategy was undertaken to ensure a balanced allocation of participants to each group during the study.

Each treatment session had three to five participants who were treated using one type of breathing system until a total of 54 participants were reached. A feedback questionnaire was given to all participants at the end of their treatment visit to assess the acceptability of the breathing systems.

The scavenging system efficiency of each breathing system was measured by calculating nitrous oxide levels in the ambient air using diffusion tubes in the treatment sessions. The tubes were attached to the clinician and nurses' uniforms and worn for the entire length of each treatment session. Using one type of breathing system for all participants in each treatment session allowed the calculation of the total leakage percentage from each system over a defined number of hours.

2.3 Eligibility criteria

2.3.1 Inclusion criteria

- Patients attending the sedation unit for dental treatment under inhalation sedation.
- Children aged 7 to 15 years.
- ASA Class I or II.
- Patients who were able to breathe through their nose with no upper respiratory tract problems including large adenoids/tonsils.
- Patients who were able to follow and comply with instructions.
- Patients who were having inhalation sedation for the first time.

2.3.2 Exclusion criteria

- Patients who were not able to communicate directly with the health care personnel carrying out the treatment.
- Uncooperative patients who refused treatment in the dental chair.
- Patients who were not able to breathe through their noses (mouth breathers).
- Patients who refused to wear the mask.
- ASA III and IV.

2.3.3 Rationale behind the age range

Participants aged from seven to fifteen years were included in this study, as the questionnaire has been validated for this age group. Although, the questionnaire was valid for children out of this range, the sample was narrowed to overcome the variation in the consent process as sixteen-year-old patients can consent for themselves. Additionally, the majority of the children seen for

dental treatment under inhalation sedation at Leeds Dental Institute are within this age group.

2.4 Recruitment strategies

Prior to the start of the study a meeting was convened with the lead sedation nurse and the lead researcher (HA) to explain the study and to introduce the new Silhouette breathing system. The potential participants were identified by the lead researcher who was part of the clinical care team. Participant Information Sheets (Appendix G,H,I) and a poster (Appendix J) about the study were enclosed along with the assessment appointment and were posted at least two weeks before the first visit.

2.4.1 Assessment day (first visit)

On the assessment day (first visit), routine dental examination, dental treatment plan confirmation and routine inhalation sedation consent was signed. Information Sheets (Appendix G,H,I) and the research procedures were explained in detail to parents and children in simple language and questions were answered. Both masks were shown and introduced to children and parents on the assessment day. When children agreed to participate, an appointment for the second visit was booked for commencement of dental treatment under inhalation sedation with the lead researcher (HA). Patients who did not meet the eligibility criteria or refused to participate in the study were booked for a routine appointment to continue the dental treatment under inhalation sedation in a different session with a different dentist.

2.4.2 First dental treatment day (2nd visit)

On the day of the first dental treatment under inhalation sedation (2nd visit), each participant was examined for eligibility before starting the treatment session. If the participant was not feeling well or had a blocked nose due to a common cold, the appointment was rescheduled. Informed consent (Appendix K) and assent (Appendix L) forms were explained and signed prior treatment commencement by those who met the eligibility criteria and agreed to participate.

Prior to starting the treatment, the lead researcher (HA) and the lead sedation nurse attached the diffusion tubes to their uniforms. They set-up and assembled

the breathing system parts and chose the correct size of mask for each participant. Based on the session randomisation, participants were treated under Inhalation Sedation using either Porter Brown or Silhouette breathing systems. The participants were monitored by the lead sedation dental nurse during the treatment session and information such as gas volumes, flow rate, patient breathing rate, heart rate, oxygen saturation and level of sedation were collected and recorded in the data monitoring sheet.

The participants were asked to complete a feedback questionnaire related to the mask used in their treatment session at the end of their visit (2nd visit). If participants needed further treatment, routine dental appointments under inhalation sedation (routinely using the Porter Brown system) were booked in another routine treatment session. Feedback regarding the ease of the breathing systems was collected from both the lead researcher (HA) and the lead sedation nurse following each participant as well. Demographic data such as age and gender, the treatment carried out, the monitoring data, behaviour and anxiety scores were also collected from each participant's dental records. At the end of each treatment session, the diffusion tubes were sealed by the lead researcher (HA) and sent to Gradko Environmental Laboratory for analysis. The results were reported in parts per million (ppm) over an 8-hour weighted period.

2.5 Sample size calculation

Statistical advice was sought, and sample size calculation was performed based on values from a similar study (Henry et al., 1992). The number of participants was (n=18) and the mean of the nitrous oxide levels in the ambient air for the Porter Brown breathing system was 36.6 ppm. The mean for our study for the same system was calculated as 40.2 ppm, this was considered statically significance. The standard deviation (sigma) was 4.7, according to these findings the sample size was calculated using an online sample size calculator: <https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html>. The suggestion was 27 participants (n=27) for each arm, this was expected to be sufficient to detect important differences between the two groups. We aimed to recruit three to six participants in every session to reach a total of 54 participants.

2.6 Methods of data collection

The potential participants were identified from the waiting list at the Sedation Unit. Potential participants were triaged based on new referrals, age and medical history from the electronic clinical records available. Data were collected from clinical records and monitoring sheets after gaining consent from the parents and children. These are included below.

2.6.1 Demographic data

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

2.6.2 Medical status

Based on the ASA classification (American Society of Anaesthesiologists, 2021) the medical status was recorded. Only ASA I and ASA II children were included in this study (Table 6).

Table 6 ASA physical statuses classification system

ASA	Definition
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

2.6.3 Dental examination and diagnosis

Clinical examination was carried out on the day of recruitment by the lead researcher (HA); this included extra-oral and intra-oral clinical examination, and radiographic examination. Dental diagnoses including caries, trauma, tooth surface loss, Molar Incisor Hypomineralisation (MIH), periodontal problems or soft tissue problems were identified and recorded.

2.6.4 Dental treatment

The dental treatment received under inhalation sedation for each participant was recorded on the data collection sheet; this includes administering of local anaesthesia, the use of rubber dam, restorations, fissure sealants, scaling, pulp therapy and extractions of either primary or permanent teeth.

2.6.5 Participant feedback questionnaire (Appendix M)

Participants were asked to fill a questionnaire in the recovery room after their first dental treatment under inhalation sedation. The questionnaire included eight questions, six were close-ended questions (rating scales format) and two were open-ended questions. Participants who were facing difficulty in reading or understanding the questions, were able to ask parents and the lead researcher to help them.

2.6.6 Dentist and dental nurse feedback

In each treatment session, both the lead researcher (HA) and the lead sedation dental nurse answered questions regarding the ease of setting up and using the breathing systems, and the ease of monitoring. The feedback and comments were collected for each participant. The dentist answered the questions through a questionnaire (Appendix O); however, the dental nurse feedback was collected in the monitoring sheet (Appendix N).

2.6.7 Cooperation level

At the end of the treatment session all participants were assessed for their cooperation level by the lead researcher (HA) using the Houpt Scale which was recorded in the data collection sheet (Appendix N).

2.6.8 Anxiety level

Dental anxiety level was assessed for each participant using the Facial Image Scale (FIS). This was recorded in the data collection sheet (Appendix N) by the lead researcher twice, before and after the dental treatment session.

2.7 Mask and circuit cost

The mask and circuit costs of the Porter Brown and Silhouette systems were calculated and compared. This included the cost of sterilisation.

2.8 Data analysis

The data was inserted into an electronic database and analysed using both IBM SPSS Statistics and Microsoft Excel. Summary statistics were calculated to include frequencies, means and standard deviations. Data was inspected for normality using Shapiro-Wilk test and was found to be normally distributed. Independent samples t-tests, Chi-square, Correlation test, Paired t-test, and Regression tests were used to analyse the data. P-values equal to or less than 0.05 were considered statistically significant.

Chapter 3 Results

3.1 Recruitment

A consecutive sample of participants was recruited from the Sedation Unit, Leeds Dental Institute. Seventy-six participants met the inclusion criteria and were invited to join this study. A total of 54 participants were recruited. Twenty-two potential participants refused to participate during the recruitment process. All eligible participants were randomly allocated for treatment under inhalation sedation to two groups, 27 participants in each group (Porter Brown breathing system group or Silhouette breathing system group).

3.2 Demographics

3.2.1 Age

This study recruited 54 child participants, aged from 7 to 15 years with a mean age of 9.63 years (S.D. =2.37). The figure below shows the participant age distribution.

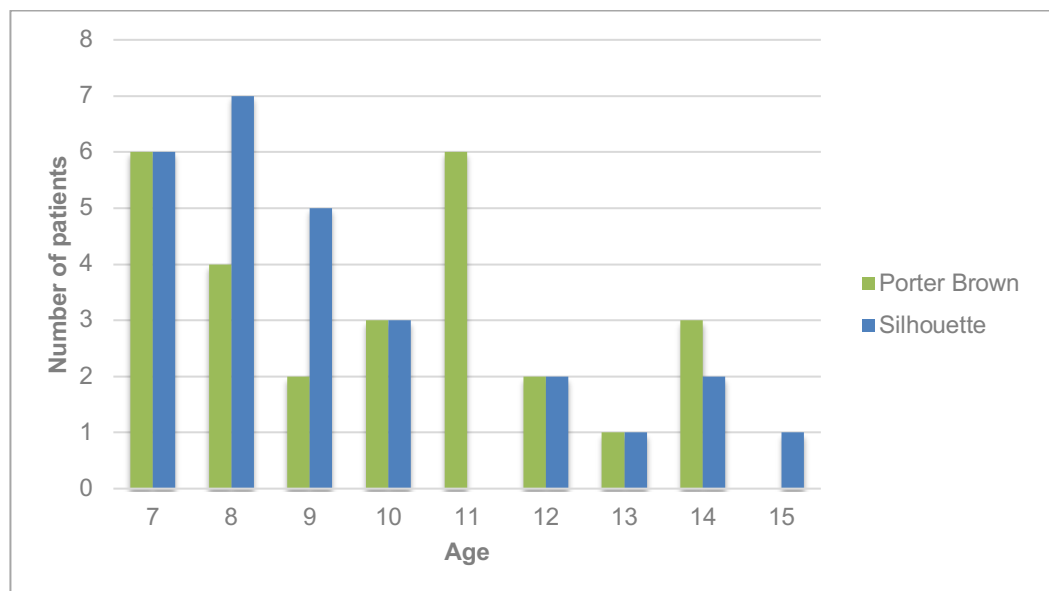


Figure 13 Participant age distribution

3.2.2 Gender

A total of 32 (59.3%) were females and 22 (40.7%) were males. Each group in the study had 11 males (20.35%) and 16 females (29.65%).

3.3 The scavenging efficiency of breathing systems

The scavenging efficiency of the two breathing systems was measured by calculating nitrous oxide levels in the ambient air using diffusion tubes.

3.3.1 Comparison between the two breathing systems sessions

An independent-samples t-test was run to determine if there were differences in the scavenging efficiency of Porter Brown and Silhouette breathing systems. This comparison was done based on the exposure time, number of participants per session, and the diffusion tubes that measured the nitrous oxide levels in the ambient air. The results showed a statistically significant difference between the breathing systems based on the dentist diffusion tubes ($p=0.045$). The data revealed that Porter Brown sessions (mean =2.56 ppm, S.D. = 2.01) had lower nitrous oxide levels in the ambient air than the Silhouette sessions (mean =22.60 ppm, S.D. ± 25.30). Interestingly, there was no statistically significant differences observed between Porter Brown and Silhouette sessions based on the dental nurse diffusion tubes. Moreover, there was no statistically significant difference between the exposure time and the number of participants in either group (Table 7).

3.3.2 The UK Health and Safety Executive recommendation

According to the UK Health and Safety Executive (HSE) guidelines, the results show that both breathing systems have an active scavenging system, where nitrous oxide exposure levels for both clinicians were less than 100ppm nitrous oxide time-weighted over 8 hours.

Table 7 Comparison between Porter Brown and Silhouette sessions

(based on diffusion tubes (nitrous oxide levels in the ambient air), number of participants and exposure time)

	Porter Brown session <i>N</i>=7 <i>mean (SD)</i>	Silhouette sessions <i>N</i>=9 <i>mean (SD)</i>	p-value
Exposure time\mins	318 (163)	195 (128)	0.129
Number of participants	3.86 (1.35)	3.00 (1.12)	0.200
Dentist diffusion tube(8hrTWAppm)	2.56 (2.01)	22.6 (25.3)	0.045
Nurse diffusion tube(8hrTWAppm)	2.24 (1.25)	10.2 (15.9)	0.175

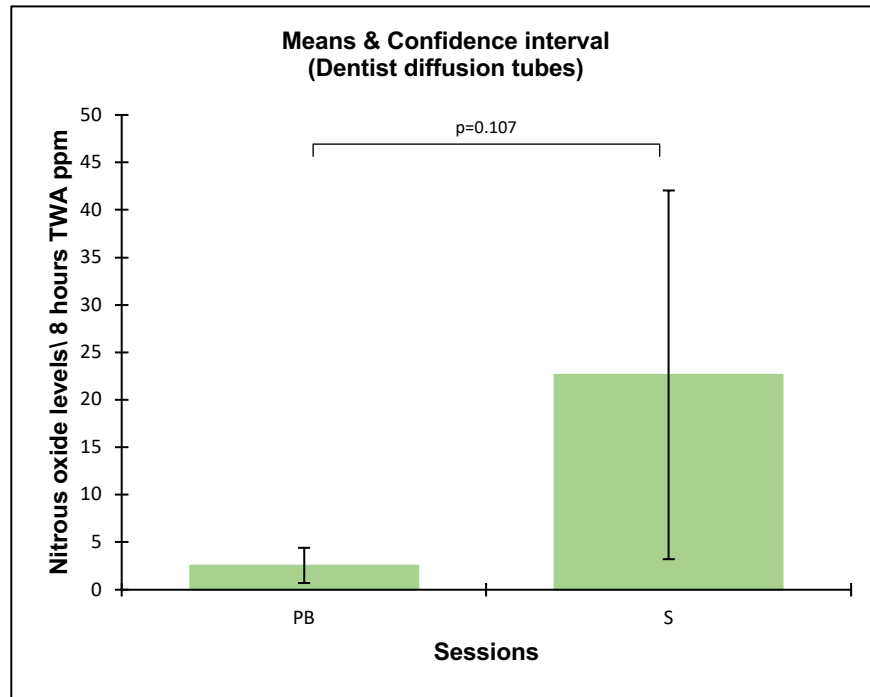


Figure 14 Nitrous oxide levels at the dentist's zone

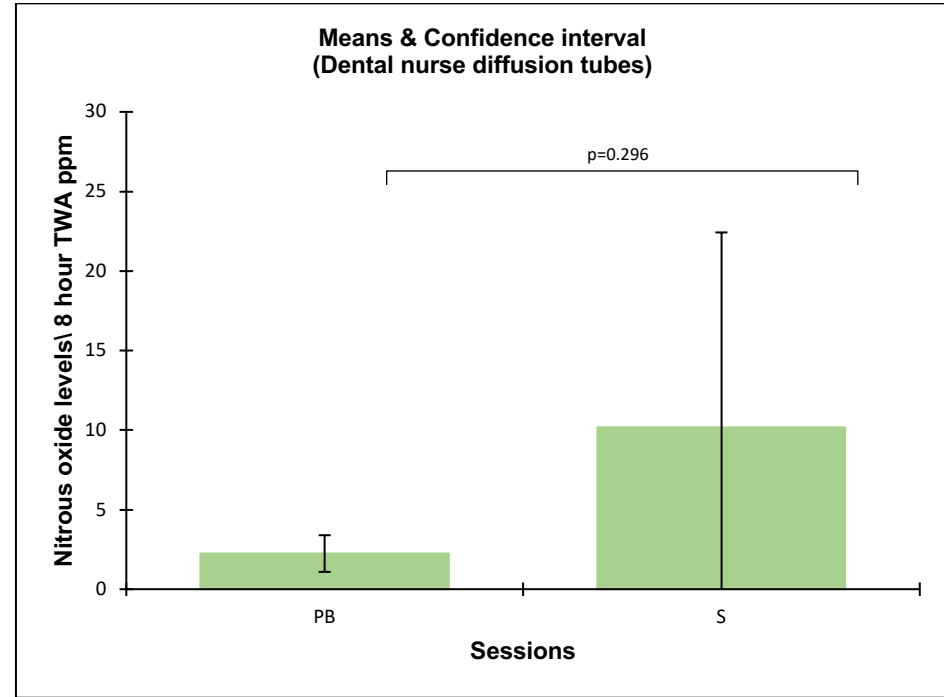


Figure 15 Nitrous oxide levels at the dental nurse zone

3.4 Breathing system feedback:

3.4.1 Participant feedback

3.4.1.1 Comfort of wearing the mask

Feedback about the comfort of wearing the mask was obtained from the participants after the treatment sessions through a questionnaire, which was developed and piloted prior the start of the study (Appendix M).

It was observed that the participants in the Silhouette group found it easier to move their head to the side than the participants in the Porter Brown group (Table 9). Mask removal was reported to be more comfortable for the participants in the Porter Brown group (mean = 4.48, S.D. = 0.70) when compared with participants in the other group (mean = 3.89, S.D. = 1.09). (Table 8). It was also observed that there was no difference in mask acceptance between males and females (Table 10).

Table 8 Participant feedback – (t-test)

	Porter Brown <i>N=27</i> <i>mean (SD)</i>	Silhouette <i>N=27</i> <i>mean (SD)</i>	OR	p.ratio	p-value
How did the mask feel on your nose	3.85 (1.17)	3.56 (1.34)	0.82 [0.53;1.28]	0.384	0.390
I like the mask	3.81 (1.36)	3.96 (1.16)	1.10 [0.71;1.70]	0.662	0.668
It was easy to breathe through the mask	4.30 (0.91)	3.81 (1.14)	0.62 [0.35;1.10]	0.103	0.094
It was comfortable when removing the mask	4.48 (0.70)	3.89 (1.09)	0.48 [0.25;0.92]	0.028	0.022
It was easy to move my head to the sides	3.67 (1.27)	4.19 (0.79)	1.61 [0.94;2.76]	0.082	0.078

Table 9 Participant feedback - (Chi-square)

	Porter Brown N=27 n(%)	Silhouette N=27 n(%)	p-value
1. How did the mask feel on your nose:			0.311
Very uncomfortable	1 (3.70%)	4 (14.8%)	
Uncomfortable	4 (14.8%)	1 (3.70%)	
not sure	2 (7.41%)	5 (18.5%)	
Comfortable	11 (40.7%)	10 (37.0%)	
Very comfortable	9 (33.3%)	7 (25.9%)	
2. I like the mask:			0.923
Strongly disagree	3 (11.1%)	2 (7.41%)	
Disagree	2 (7.41%)	1 (3.70%)	
Undecided	3 (11.1%)	3 (11.1%)	
Agree	8 (29.6%)	11 (40.7%)	
Strongly agree	11 (40.7%)	10 (37.0%)	
3. It was easy to breathe through the mask:			0.238
Strongly disagree	0 (0.00%)	2 (7.41%)	
Disagree	2 (7.41%)	2 (7.41%)	
Undecided	2 (7.41%)	2 (7.41%)	
Agree	9 (33.3%)	14 (51.9%)	
Strongly agree	14 (51.9%)	7 (25.9%)	
4. It was comfortable when removing the mask:			0.133
Disagree	0 (0.00%)	4 (14.8%)	
Undecided	3 (11.1%)	5 (18.5%)	
Agree	8 (29.6%)	8 (29.6%)	
Strongly agree	16 (59.3%)	10 (37.0%)	
5.It was easy to move my head to the sides:			0.003
Strongly disagree	1 (3.70%)	0 (0.00%)	
Disagree	4 (14.8%)	1 (3.70%)	
Undecided	9 (33.3%)	3 (11.1%)	
Agree	2 (7.41%)	13 (48.1%)	
Strongly agree	11 (40.7%)	10 (37.0%)	

Table 10 Participant feedback based on gender (t-test)

	Males			Females		
	Porter Brown	Silhouette	p-value	Porter Brown	Silhouette	p-value
	N=11	N=11		N=16	N=16	
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
How did the mask feel on your nose	3.45 (1.44)	3.82 (1.40)	0.555	4.12 (0.89)	3.38 (1.31)	0.069
I like the mask	3.18 (1.66)	4.00 (1.34)	0.219	4.25 (0.93)	3.94 (1.06)	0.383
It was easy to breathe through the mask	4.09 (1.04)	3.64 (0.92)	0.293	4.44 (0.81)	3.94 (1.29)	0.201
It was comfortable when removing the mask	4.55 (0.69)	3.82 (1.08)	0.077	4.44 (0.73)	3.94 (1.12)	0.147
It was easy to move my head to the sides	3.45 (1.29)	4.18 (0.98)	0.154	3.81 (1.28)	4.19 (0.66)	0.307

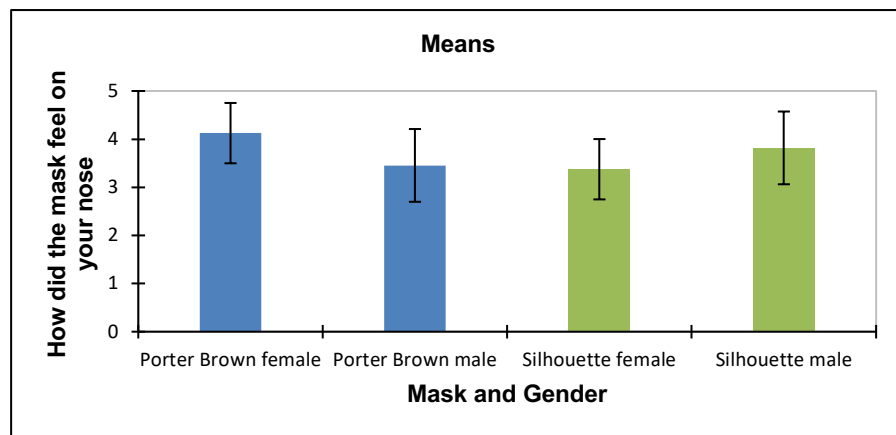


Figure 16 Participant feedback (How did the mask feel on your nose) based on gender

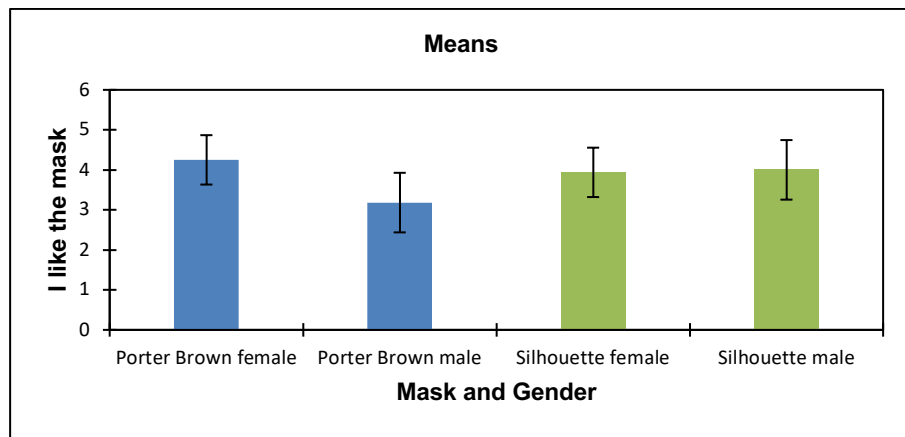


Figure 17 Participant feedback (I like the mask) based on gender

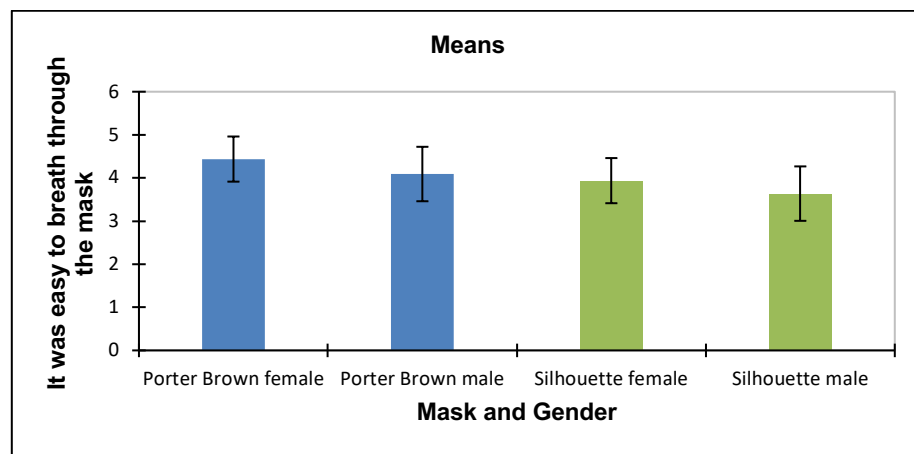


Figure 18 Participant feedback (It was easy to breathe through the mask) based on gender

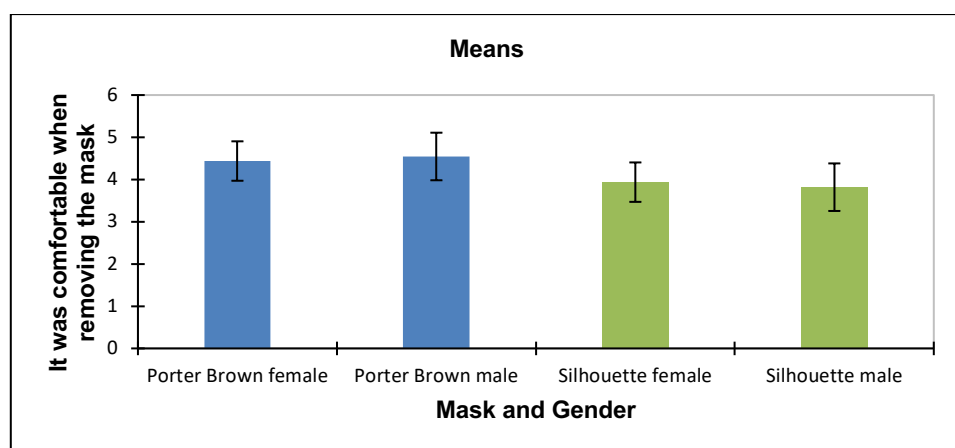
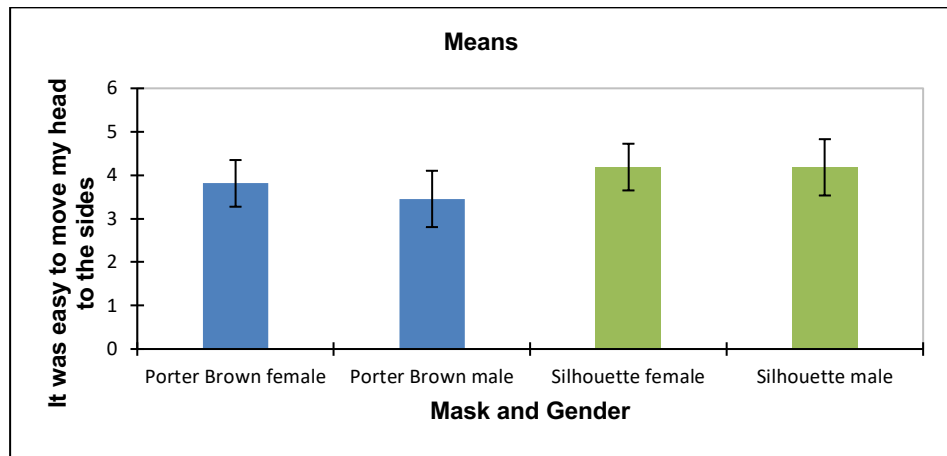


Figure 19 Participant feedback (It was comfortable when removing the mask) based on gender



**Figure 20 Participant feedback (It was easy to move my head to the sides)
based on gender**

3.4.1.2 Comfort of wearing the mask in relation to age

Table 11 shows the association between the mask comfort in relation to age. The results showed no statistically significant association between participant age and the comfort of wearing the mask.

Table 11 Age correlation to Porter Brown and Silhouette systems acceptance

		Age	How did the mask feel on your nose	Correlation			
				I like the mask	It was easy to breathe through the mask	It was comfortable when removing the mask	It was easy to move my head to the sides
Porter Brown Age	Pearson Correlation	1	0.289	0.295	0.088	0.010	0.142
	Sig. (2-tailed)		0.143	0.135	0.662	0.959	0.480
	N	27	27	27	27	27	27
Silhouette Age	Pearson Correlation	1	0.364	0.240	0.291	0.237	0.084
	Sig. (2-tailed)		0.062	0.229	0.140	0.233	0.676
	N	27	27	27	27	27	27

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

3.4.1.3 Children's descriptions of the masks:

In the last part of the questionnaire, the children were asked to write what they liked and disliked about the mask in their own words.

Feeling relaxed and comfortable, painless and sleepy, nice and easy to breathe were the main positive terms mentioned. Dislikes comments varied between 'hurt', 'weird', 'strange' and 'difficult to breathe'. Table 12 and 13 demonstrates the description of the children's positive and negative thoughts on both masks.

Table 12 The “like” feedback discription

	Porter brown	Silhouette
Relax Comfortable	<i>“ At first, I was very very anxious, but actually the mask really really helped me not to feel anything. Also, my dentist was GREAT!”</i> <i>“ It was very light on my nose; I didn’t really know it was there. The mask really relaxed me, and I didn’t have much pain”</i> <i>“ It was very comfortable and relaxing, it made things seen less scary”</i> <i>“ It was very comfortable when it was sat on my nose, I didn’t feel any pain”</i>	<i>“ It was comfortable, and it made me chill”</i> <i>“ Tickled me and comfortable”</i> <i>“ The size was good, it was comfortable”</i> <i>“ It fit lovely over my nose with no discomfort”</i>
Painless Sleepy	<i>“ Feels sleepy, less painful”</i> <i>“ It made me feel lightheaded”</i>	<i>“It helped me get numb”</i> <i>“ Because it makes me sleep”</i> <i>“ Made me feel dizzy and I liked that feeling”</i> <i>“ Relaxed and made me feel sleepy”</i> <i>“ It made me feel tingly and I didn’t feel the pain”</i>

Nice Easy breath	<i>“ It was helpful to use”</i> <i>“ The mask was fine”</i> <i>“ It didn’t go up my nose”</i> <i>“ It was cool”</i> <i>“ I liked the mask because I could breathe easily, and it was comfortable”</i>	<i>“ I like breathe through the mask”</i> <i>“ It was easy to breathe through”</i>
Nothing	<i>“ There is nothing bad about the mask”</i> <i>“ I liked the mask ; I didn’t dislike anything”</i>	

Table 13 The “dislike” feedback discription

	Porter brown	Silhouette
Hurt my nose	<i>“ The sides of the mask hurt but not that much”</i> <i>“ It hurt my nose”</i> <i>“ It hurt and it felt big over my face”</i> <i>“ It felt very heavy”</i>	<i>“ It hurt my nose a lot”</i> <i>“ I didn’t like the way the air pushed up my nose”</i> <i>“Because it went up my nose, I was very nervous”</i> <i>“ It hurt my nose”</i> <i>“ I didn’t like it up my nose”</i> <i>“ The mask felt uncomfortable when the air pushed up my nose”</i>
Dizzy Fainting Nervous	<i>“ It made me feel dizzy and nauseated”</i> <i>“ I felt fainty”</i>	<i>“ At first I was panicking and didn’t like the feeling”</i> <i>“ At first I felt scared but now I feel alright”</i>
Weird Strange	<i>“ It felt weird”</i> <i>“ Because it was tingling”</i> <i>“ Because I didn’t know what to expect at the beginning”</i>	<i>“ It was strange at first ”</i> <i>“ It looked weird ”</i> <i>“ It feels weird at the end of the visit ”</i> <i>“ Feeling weird putting it on and off ”</i> <i>“ I think it felt weird, I didn’t dislike it though”</i> <i>“ I was cold ”</i> <i>“ It felt weird at first but afterwards it was good ”</i>

Breathing	<i>“ Sometimes I forgot to breathe through my nose”</i> <i>“ You had to keep your lips closed”</i> <i>“ Couldn’t breathe properly”</i>	<i>“ It comes unstuck sometime ”</i> <i>“ Didn’t like the sticky thing at it ”</i>
Tightness Moving	<i>“ Didn’t like that I couldn’t really move”</i> <i>“ It was tight when taking it off. There was also air coming through to my eyes”</i> <i>“ Left marks on my face”</i>	

3.4.2 Dentist feedback

The treatment was undertaken by one operator (HA). HA answered a simple questionnaire (Appendix O) to give a feedback about the breathing system after the treatment of each participant. Table 14 showing the dentist feedback on both breathing systems. The data demonstrate that the Porter Brown mask (88.9%) was slightly easier in placement than the Silhouette mask (65.4%). All participants in the Silhouette group were graded as having easy manoeuvrability, while only 40.7% of the participants in the Porter Brown group were graded as having easy manoeuvrability. Both breathing systems have easy treatment site accessibility, but the Silhouette system was slightly easier (96.2%). The Porter Brown breathing system (70%) was easier with the airflow monitoring than the Silhouette system (23%). Interestingly, all participants in the Silhouette group were able to move their head easily, while all participants in the Porter Brown group were unable to move their head. The nasal hood seal of the Porter Brown was scored as “good” with most of the participants (96.3%), while in the Silhouette group it was scored as “good” only with 50% of them. Removing the masks from on the participants was scored as easy in both groups. The data showed that both breathing systems were accepted almost similarly between the participants.

Table 14 Dentist feedback, (Chi-square)

	Porter Brown	Silhouette
	N=27 n(%)	N=27 n(%)
1. Mask Placement		
Very Difficult	1 (3.70%)	0 (0.0%)
Difficult	2 (7.40%)	2 (7.7%)
Neutral	0 (0.0%)	7 (26.9%)
Easy	10 (37.10%)	8 (30.8%)
Very easy	14 (51.80%)	9 (34.6%)
2. Patients manoeuvrability		
Very Difficult	0 (0.0%)	0 (0.0%)
Difficult	0 (0.0%)	0 (0.0%)
Neutral	16 (59.3%)	0 (0.0%)
Easy	8 (29.6%)	20 (76.9%)
Very easy	3 (11.1%)	6 (23.1%)
3. Treatment site Accessibility		
Very Difficult	0 (0.0%)	0 (0.0%)
Difficult	0 (0.0%)	0 (0.0%)
Neutral	9 (33.3%)	1 (3.8%)
Easy	14 (51.9%)	6 (23.1%)
Very easy	4 (14.8%)	19 (73.1%)
4. Airflow monitoring		
Very Difficult	0 (0.0%)	2 (7.70%)
Difficult	0 (0.0%)	1 (3.80%)
Neutral	0 (0.0%)	17(65.40%)
Easy	17 (63.0%)	6 (23.0%)
Very easy	10 (37.0%)	0 (0.0%)

5. Removing the mask

Very Difficult	0 (0.0%)	0 (0.0%)
Difficult	0 (0.0%)	0 (0.0%)
Neutral	0 (0.0%)	2 (8.0%)
Easy	1 (3.8%)	12 (48.0%)
Very easy	25 (96.2%)	11 (44.0%)

6. Head movement

Very Difficult	1 (3.7%)	0 (0.0%)
Difficult	26 (96.3%)	0 (0.0%)
Neutral	0 (0.0%)	0 (0.0%)
Easy	0 (0.0%)	16 (61.5%)
Very easy	0 (0.0%)	10 (38.5%)

7. Patients accepting the mask

Strongly Disagree	1 (3.7%)	2 (7.4%)
Disagree	2 (7.4%)	1 (3.7%)
Undecided	3 (11.1%)	2 (7.4%)
Agree	9 (33.3%)	9 (33.3%)
Strongly Agree	12 (44.4%)	13 (48.1%)

8. Nasal hood seal

Very bad	0 (0.0%)	0 (0.0%)
Bad	0 (0.0%)	2 (7.7%)
Neutral	1 (3.7%)	11 (42.3%)
Good	15 (55.6%)	10 (38.5%)
Very Good	11 (40.7%)	3 (11.5%)

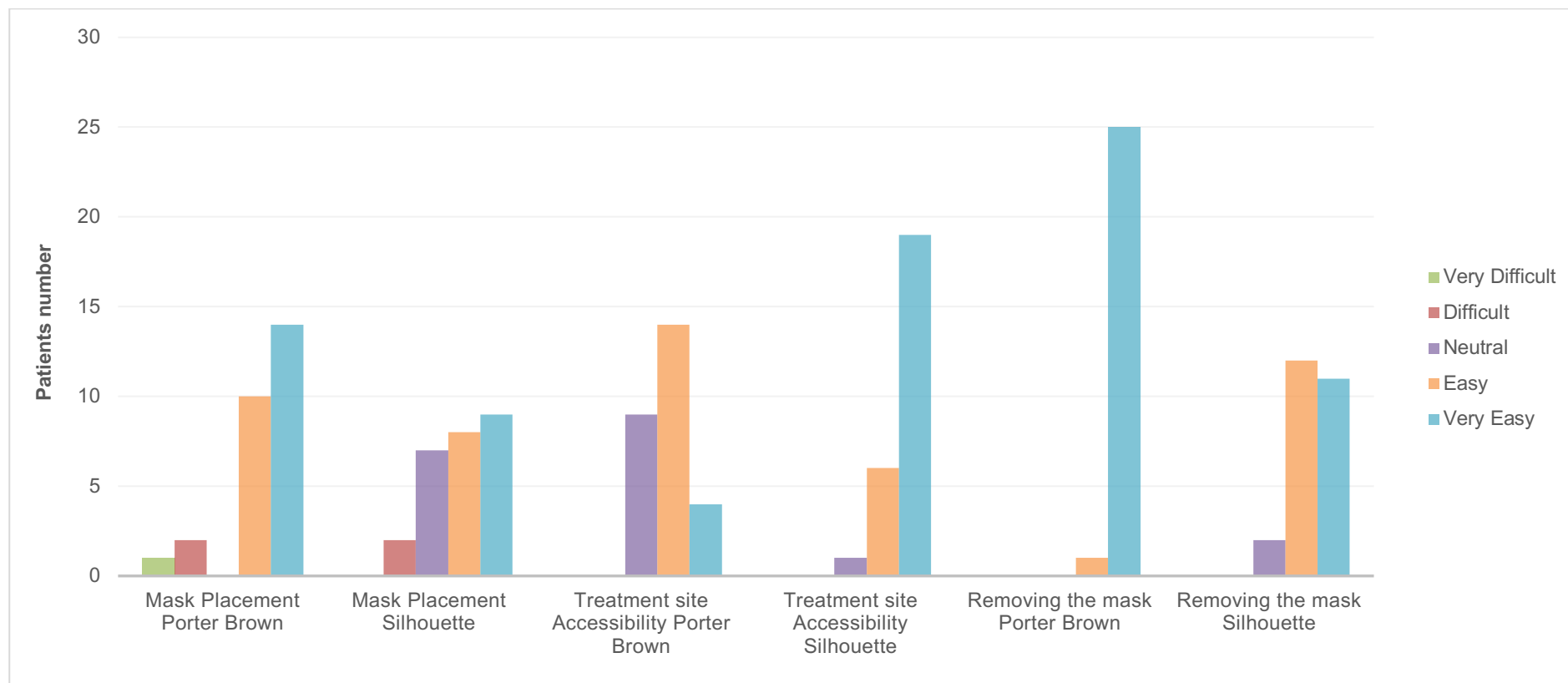


Figure 21 Dentist feedback (mask placement and removal, treatment accessibility)

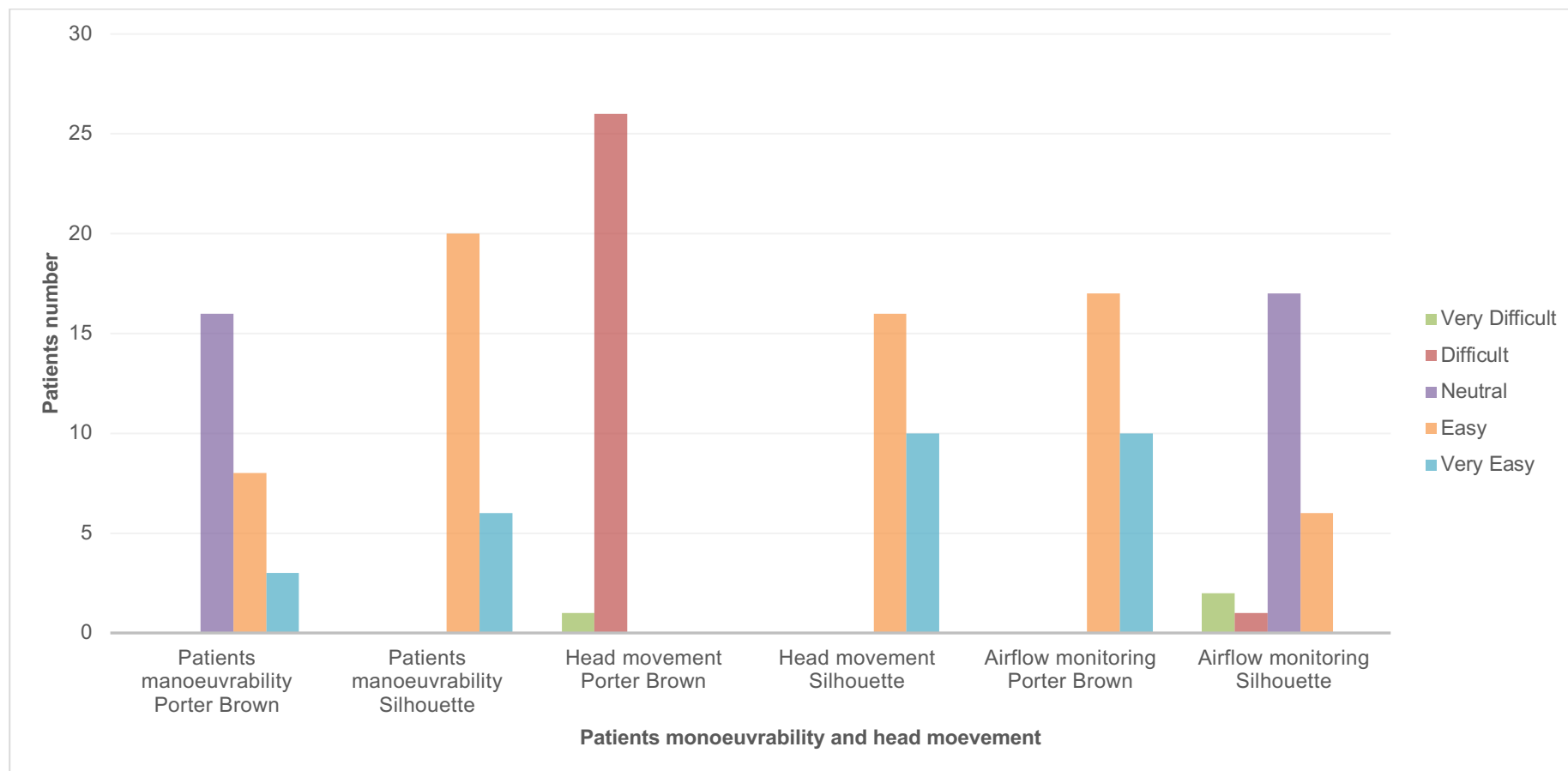


Figure 22 Dentist feedback (Participants manoeuvrability, head movement, airflow monitoring)

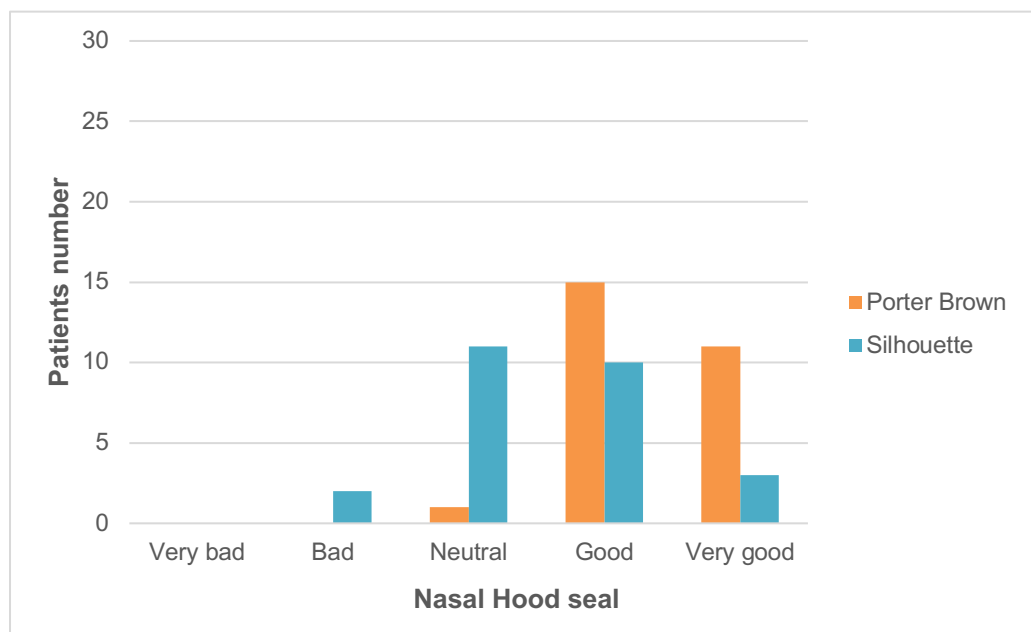


Figure 24 Dentist feedback (nasal hood seal)

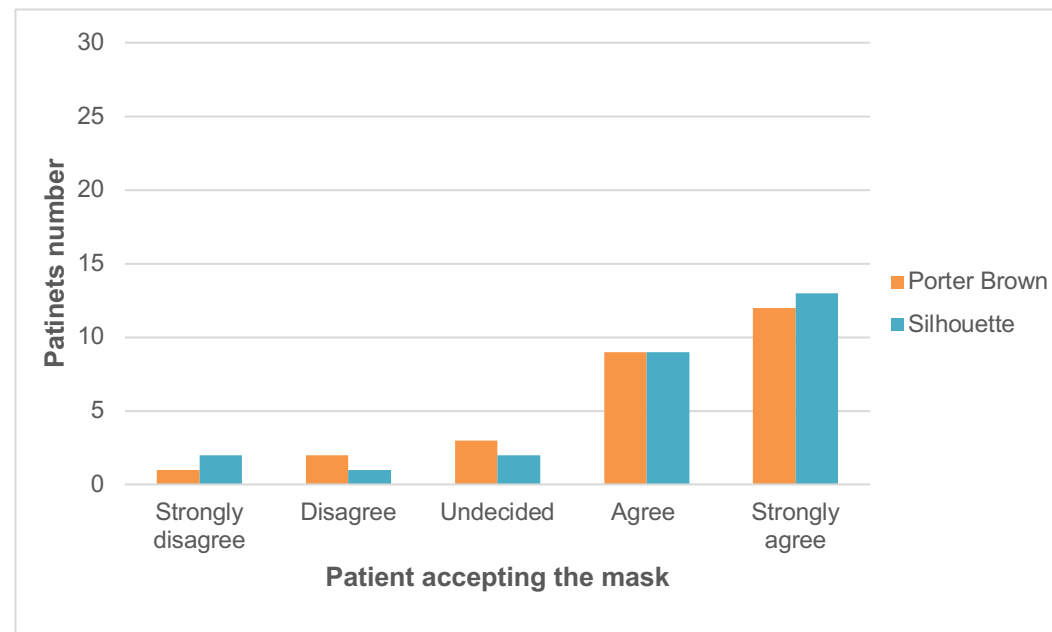


Figure 23 Dentist feedback (patient accepting the mask)

3.4.3 Monitoring data sheet and dental nurse feedback

In this study almost two thirds of sessions were assessed and monitored by the same sedation dental nurse. The remaining 30% of sessions were assessed by different dental nurses. Monitoring data and dental nurse feedback were collected and recorded in the monitoring data sheet (Appendix N) and it included the following:

3.4.3.1 Assembling, disassembling and set up time

Overall, there was no difference in the setting up time between the two systems; it took around 3 to 5 minutes to set up the circuit in place and to do the safety checks for both breathing systems. There was no difference in the difficulty of setting up or removing the circuits in either breathing systems.

3.4.3.2 Monitoring respiratory rate

Monitoring the respiratory rate with the Porter Brown breathing system was easier than the Silhouette breathing system due to the being able to monitor the reservoir bag. In Porter Brown breathing system the monitoring was done by observing both the participant's chest and the reservoir bag. While with the Silhouette breathing system, it was done by monitoring the participant's chest only, which is more challenging with the absence of the reservoir bag.

3.4.3.3 Time recorded for participants to be sedated before treatment started

It was observed that some participants needed more time to be sedated with the Silhouette breathing system than with the Porter Brown system before dental treatment commenced. For the Silhouette system, some participants took up to 13 mins, while for the Porter Brown, most participants took between 5 to 6 mins before treatment started. The mean time for patients to be sedated was around 7 mins in both breathing systems. The mean time for Porter Brown was 7.48 mins (SD = 2.966) while for Silhouette it was 7.65 mins (SD = 2.741).

3.4.3.4 Oxygen\ Nitrous Oxide ratio

There was no difference observed between the two breathing systems in the oxygen and nitrous oxide sedation ratios used. Regardless of the breathing

system, the ratio varied between participants depending on the treatment type. Most participants received 70% O₂ with 30% N₂O, when treatment became more complex the nitrous oxide percentage increased. Some participants were sedated appropriately with a lower percentage of nitrous oxide.

3.5 Level of participants' cooperation

Treatment was provided by one dentist (lead researcher HA) for all participants. The level of participants' cooperation was assessed and recorded at the end of each treatment session using the Houpt scale.

3.5.1 Comparison between the cooperation level and mask

A t-test analysis was carried out to determine the difference between participants' cooperation levels in the Porter Brown and Silhouette groups. The results showed no statistically significant differences between participant' cooperation levels in the two groups (Table 15). The participants cooperation levels were not affected by the type of mask used in the treatment sessions.

Table 15 Cooperation levels based on masks

	Porter Brown <i>N=27</i> <i>Mean (SD)</i>	Silhouette <i>N=27</i> <i>Mean (SD)</i>	p-value
Houpt Scale	5.22 (1.60)	5.15 (1.56)	0.864

3.5.2 Comparison between the cooperation level base on gender

Further analysis was carried out to assess the difference between participants' cooperation levels in Porter Brown and Silhouette groups based on gender. The results showed no statistically significant differences between participants' cooperation levels in the two groups with the gender category (Table 16). The participants' cooperation levels were not affected by the gender or type of mask used in the treatment sessions.

Table 16 Cooperation levels based on mask and gender

	Males			Females		
	Porter Brown	Silhouette	p-value	Porter Brown	Silhouette	p-value
	<i>N=11</i>	<i>N=11</i>		<i>N=16</i>	<i>N=16</i>	
	<i>Mean (SD)</i>	<i>Mean (SD)</i>		<i>Mean (SD)</i>	<i>Mean (SD)</i>	
Houpt Scale	4.73 (2.00)	5.73 (0.65)	0.141	5.56 (1.21)	4.75 (1.88)	0.158

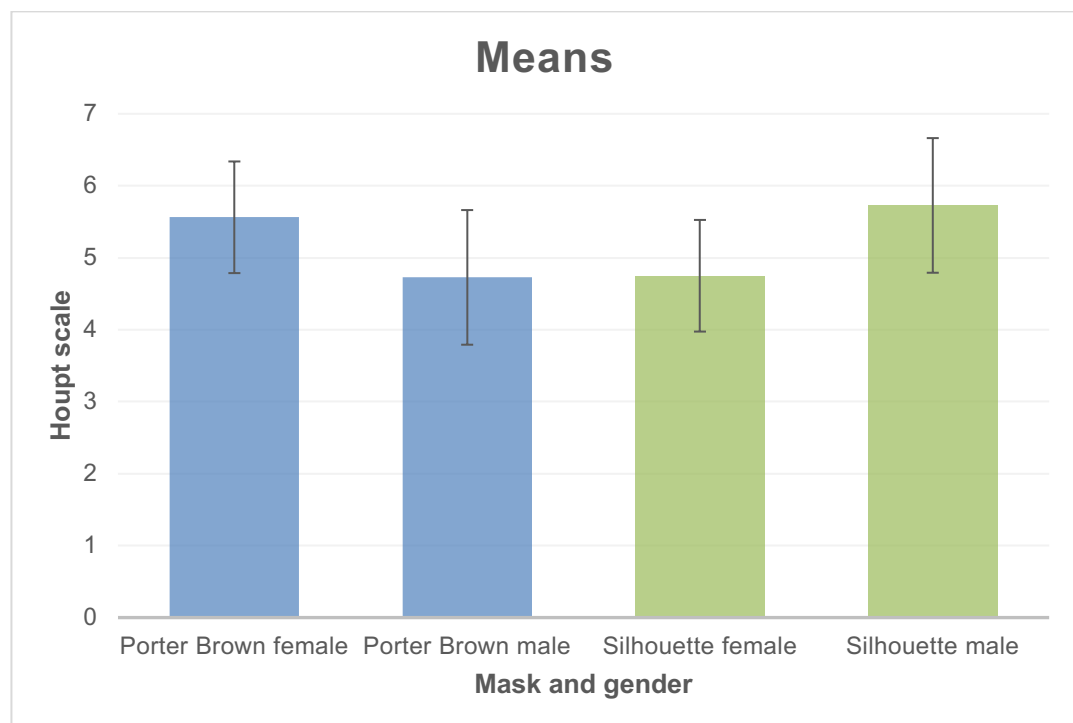


Figure 25 Cooperation levels based on mask and gender

3.6 Dental anxiety levels

The dental anxiety levels were assessed and recorded before and after the dental treatment by the lead researcher (HA). Dental anxiety was measured by using the Facial Image Scale (FIS).

3.6.1 Participants anxiety levels before and after treatment

A paired t-test was used to determine whether there was a difference between the participant dental anxiety level before and after the treatment in each group, and if there was a difference in the anxiety level between the two groups. The results showed a statistically significant differences between the participants' anxiety levels before and after the treatment regardless of the type of mask used. It was observed that participants' had higher anxiety levels before treatment when compared to after treatment, Porter Brown (mean difference =0.93, C.I. = [0.33, 1.53], $p=0.004$), Silhouette (mean difference =0.85, C.I. = [0.35, 1.35], $p=0.002$). Moreover, the participants' in the Porter Brown group felt more anxious before and after the treatment when compared to participants' in the Silhouette group.

Table 17 Anxiety levels in Porter Brown and Silhouette groups

		Mean	N	Std. Deviation	Std. Error Mean	P-value (paired t-test)	Mean difference	95% Confidence Interval of the Difference	
Porter Brown mask	FIS: Before	2.74	27	1.023	0.197	0.004	0.926	Lower	Upper
	FIS: After	1.81	27	1.039	0.200			0.326	1.526
Silhouette mask	FIS: Before	2.41	27	1.217	0.234	0.002	0.852	Lower	Upper
	FIS: After	1.56	27	0.974	0.187			0.353	1.351

3.6.2 Anxiety levels before and after treatment based on gender

A statistically significant difference was observed in the anxiety levels before and after the treatment in female participants in both Porter Brown group (mean difference =1.19, C.I. = [0.48, 1.90], $p=0.003$) and Silhouette groups (mean difference =0.88, C.I. = [0.20, 1.55], $p=0.014$). However, differences were not statistically significant for male participants.

It was observed that females had higher anxiety levels before and after treatment than males. Females were scored as more anxious before treatment than after treatment. Furthermore, female participants' in the Silhouette group had lower anxiety levels than females in the Porter Brown group.

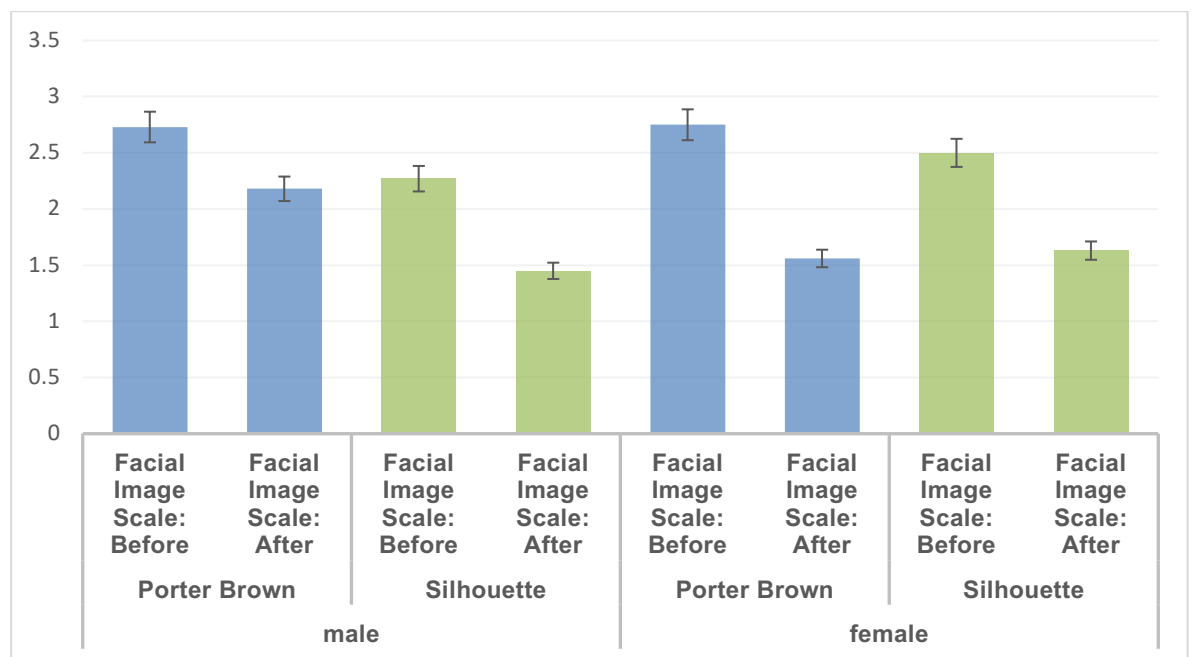


Figure 26 Anxiety level of Porter Brown and Silhouette groups based on gender

Table 18 Anxiety levels in Porter Brown and Silhouette groups based on gender

			Paired Differences							
Gender			Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2- tailed)
						Lower	Upper			
Male	Porter Brown	Facial Image Scale: Before - Facial Image Scale: After	0.545	1.753	0.529	-0.632	1.723	1.032	10	0.326
	Silhouette	Facial Image Scale: Before - Facial Image Scale: After	0.818	1.328	0.400	-0.074	1.710	2.043	10	0.068
Female	Porter Brown	Facial Image Scale: Before - Facial Image Scale: After	1.188	1.328	0.332	0.480	1.895	3.578	15	0.003
	Silhouette	Facial Image Scale: Before - Facial Image Scale: After	0.875	1.258	0.315	0.204	1.546	2.782	15	0.014

3.6.3 Participant dental anxiety levels and age correlation

Pearson correlation analysis was carried out to measure the association between participants' age and the dental anxiety levels in the two groups. No significant association was observed between participants' age and the anxiety levels before or after treatment in either group.

Table 19 Age correlation to dental anxiety levels

Mask		Age	Facial Image Scale: Before	Facial Image Scale: After
Porter Brown		Pearson Correlation	1	0.164
	Age	Sig. (2-tailed)	0.413	0.362
		N	27	27
Silhouette		Pearson Correlation	1	0.052
	Age	Sig. (2-tailed)	0.798	0.593
		N	27	27

3.7 Treatment

Local anaesthesia (74%) and fissure sealants (59%) were the most common type of procedure participants received, regardless of the mask type. Almost all procedures were provided equally in the two groups, except for restorations and extractions of permanent teeth. Participants received more restorations in the Porter Brown group, while they received more extractions and fissure sealants in the Silhouette group. In each group, three procedures were interrupted, and treatment was stopped. It was observed that treatments were interrupted either after administering local anaesthesia or when the participants didn't like the sedation feeling. There were no associations observed between the type of treatment received and the type of the mask used (Table 21).

Table 20 Overall treatments

	[ALL] N=54 n(%)
Treatment	
Local anaesthesia	40 (74.1%)
Filling permanent teeth	13 (24.1%)
Fissure sealant	32 (59.3%)
Filling primary tooth/ SSC primary	7 (13.0%)
Extraction primary tooth	14 (25.9%)
Extraction permanent tooth	9 (16.7%)
Treatment interrupted/ no treatment done	6 (11.1%)
Scaling / polishing / prophylaxis	8 (14.8%)

Table 21 Treatments based on mask type

	Porter Brown N=27 n(%)	Silhouette N=27 n(%)	p-value
Treatment:			
Local anaesthesia	22 (81.5%)	18 (66.7%)	0.352
Filling permanent teeth	9 (33.3%)	4 (14.8%)	0.203
Fissure sealant	15 (55.6%)	17 (63.0%)	0.782
Filling primary tooth/ SSC primary	4 (14.8%)	3 (11.1%)	1.000
Extraction primary tooth	7 (25.9%)	7 (25.9%)	1.000
Extraction permanent tooth	3 (11.1%)	6 (22.2%)	0.467
Treatment interrupted/ no treatment done	3 (11.1%)	3 (11.1%)	1.000
Scaling / polishing / prophylaxis	5 (18.5%)	3 (11.1%)	0.704

3.7.1 Treatment and scavenging efficiency

It was difficult to statistically determine if the scavenging efficiency was affected by the type of treatment. That is because the exposure time was measured per session rather than per individual participant. The total duration of treatment in the Porter Brown sessions was around 1.6 times more than the duration of treatment in the Silhouette sessions.

In the Porter Brown sessions, most of the procedures received were restorations of either permanent or primary teeth under rubber dam isolation. Whereas in the Silhouette sessions, most of the procedures provided were extractions and fissure sealants without the use of rubber dam isolation. Table 22 shows the use of rubber dam isolation with participants in both groups. Rubber dam isolation was used for 40% of the participants in Porter Brown group, while it was used only in 22.2% of the participants in the Silhouette group.

Table 22 Rubber dam Isolation

	Porter Brown <i>N=27 n(%)</i>	Silhouette <i>N=27 n(%)</i>	p-value
Rubber dam isolation	11(40.7%)	6(22.2%)	0.862

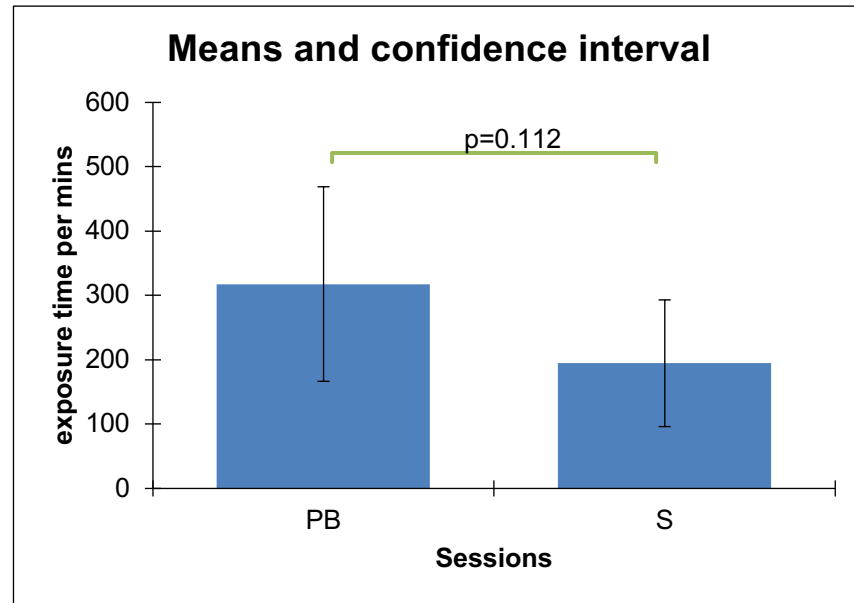


Figure 27 Exposure time of Porter Brown and Silhouette sessions

3.7.2 Effect of treatments type on the participant's cooperation level

Table 23 shows the results of a regression analysis that was performed to determine the effect of the treatment type that participants received in each group with regard to participant cooperation levels.

An insignificant effect was observed between the type of mask, participants' age and gender on the cooperation levels of the participants, i.e., participants cooperation levels were not affected by the participants' age, the gender or the mask type. However, a significant effect was observed to the patient's cooperation level when the treatment was interrupted or when no treatment provided. It was observed that as the value of treatment type: "treatment interrupted/ no treatment done" increases by one unit, the cooperation level of the participants will decrease by 0.69 units. The effect of the rest of the procedures on the cooperation level was not statistically significant.

3.7.3 Effect of treatments' type on child's dental anxiety

Regression analysis was performed to check the effect of the breathing system type, participants' age, gender and the type of treatment that the participants received on the participants' anxiety level (Table 24). No significant effect was observed between the variables, i.e., Participants anxiety level was not affected by the treatment type, the participants' age, gender or the type of mask used.

Table 23 Cooperation Levels based on treatment

Model	Unstandardized		Standardized	t	Sig.	95.0% Confidence	
	Coefficients		Coefficients			Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	4.22	1.085		3.891	0.000	2.032	6.410
Mask	0.062	0.294	0.020	0.211	0.834	-0.531	0.655
Gender	0.041	0.292	0.013	0.140	0.890	-0.548	0.629
Age	0.060	0.071	0.090	0.841	0.405	-0.084	0.203
Treatment							
1 Local anaesthesia	0.554	0.563	0.156	0.985	0.330	-0.581	1.689
Filling permanent teeth	-0.086	0.522	-0.024	-0.165	0.869	-1.141	0.968
Fissure sealant	0.165	0.356	0.052	0.464	0.645	-0.554	0.884
Filling primary tooth/ SSC primary	0.105	0.516	0.023	0.203	0.840	-0.937	1.146
Extraction primary tooth	0.404	0.530	0.114	0.761	0.451	-0.666	1.473
Extraction permanent tooth	-0.229	0.694	-0.055	-0.329	0.744	-1.629	1.172
Treatment interrupted/ no treatment done	-3.425	0.602	-0.693	-5.693	0.000	-4.639	-2.211
Scaling / polishing / prophylaxis	0.299	0.457	0.068	0.654	0.517	-0.623	1.221

Table 24 Anxiety levels based on treatment

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	-1.088	1.511		-0.720	0.476	-4.138	1.962
Mask	-0.012	0.409	-0.004	-0.029	0.977	-0.838	0.814
Gender	-0.134	0.406	-0.048	-0.329	0.744	-0.954	0.686
Age	0.020	0.099	0.033	0.197	0.845	-0.180	0.219
Treatment							
1 Local anaesthesia	-0.006	0.784	-0.002	-0.007	0.994	-1.587	1.576
Filling permanent teeth	-0.763	0.728	-0.238	-1.048	0.301	-2.232	0.706
Fissure sealant	0.473	0.496	0.170	0.953	0.346	-0.528	1.475
Filling primary tooth/ SSC primary	-0.168	0.719	-0.041	-0.233	0.817	-1.619	1.284
Extraction primary tooth	0.038	0.738	0.012	0.051	0.960	-1.453	1.528
Extraction permanent tooth	-0.438	0.967	-0.119	-0.453	0.653	-2.390	1.513
Treatment interrupted/ no treatment done	1.423	0.838	0.326	1.698	0.097	-0.269	3.115
Scaling / polishing / prophylaxis	0.518	0.637	0.134	0.814	0.420	-0.767	1.803

3.8 Mask and circuit costs

The costs for both systems were calculated and compared according to the prices in the manufacturers' catalogues at the time that this study was carried out. These are approximate costs.

Table (25) showing the break down price of one kit for each breathing system. The Porter Brown breathing system is a sterilisable system, while most of the Silhouette breathing system parts are disposable. The coaxial tubing in the Porter Brown is disposable and needs replacing with every participant. The mask sizer and vacuum tubing in the Silhouette system can be sterilised. The results showed that the total cost per one kit including sterilisation for the Porter Brown breathing system was £452.4, while it costs £151.73 for the Silhouette system. Table (26) showing the breakdown price of the disposable parts of both breathing systems, while table (27) is showing the total cost of one of each of the breathing system for this study as well as displaying the cost of the breathing systems for 100 patients, and the average yearly cost for the patients at the Sedation Unit in Leeds Dental Institute (LDI) over one year period.

The Sedation Unit in LDI receive an average 770 patients yearly. In order to compare between the costs of the two systems, a calculation needs to be carried out for 100 patient and over a year to evaluate which breathing system is cost effective over the other.

The total cost of the Porter Brown breathing system for the 27 participants was £2420.60, while it costed £1256.51 in the Silhouette group. The costs calculation of the current study is showing that the Porter Brown breathing system costs nearly double the price of the Silhouette breathing system. However, when the calculations are carried out over a year for an average of 770 patients, it can be seen from Table 21 that the Silhouette breathing system costs more than double the Porter Brown system.

Table 25 Costs breakdown of one kit of each breathing system

Porter Brown kit		Silhouette kit	
Description	Price	Description	Price
Porter Liner adult size	£14	Flowmeter connector kit Including: (4 sterilisable colour-coded sized masks, a sterilisable 2 meter fresh gas/vacuum tubing and one disposable set of the Silhouette adapter kit). The Silhouette adapter kit includes: (the cannula adapter, breathing bag cap and clip)	£44
Porter liner paediatric size	£14		
Y hose connector	£26		
Vacuum hose connector	£26		
Mask tubing connector set	£26		
Porter outer hood adult size	£122		
Porter outer hood paediatric size	£122		
Disposable Coaxial tubing *	£3		
Total cost of the parts	£353	1 Silhouette mask	£8.33
Metal basket base	£47.80	Metal basket base	£47.80
Metal basket lid	£47.30	Metal basket lid	£47.30
Sterilisation cost for one kit	£4.30	Sterilisation cost	£4.30
Total cost per one kit including sterilisation	£452.40	Total cost per one kit including the mask and the sterilisation	£151.73

* The coaxial tubing is a disposable part in the Porter Brown breathing system and it's usually sold per pack

Table 26 Costs breakdown of the disposable parts

Disposable parts	
Description	Price
1 Silhouette mask	£8.33
1 Silhouette adapter kit	£10
12 Silhouette masks *	£100
1 Porter Brown disposable Coaxial tubing	£3
50 Porter Brown disposable Coaxial tubing (1 pack)	£150

* The Silhouette masks are sold per pack (either contains 12 or 24 masks)

Table 27 Total costs of each breathing system

Description	Price	
	Porter Brown	Silhouette
Cost of one kit + sterilisation	£ 452.40*	£151.73**
Cost of the 27 kits + sterilisation (current study)	£ 2420.60*	£1256.51**
Cost of 100 kits + sterilisation	£ 2953.50*	£ 2908.50**
Cost for a year + sterilisation (average 770 patients yearly)	£ 7844.50*	£18183.75**

* the price of the disposable coaxial tubing was added to the total cost

** The price of the disposable Silhouette masks and the disposable adapter kits were added to the total cost

Chapter 4 Discussion

4.1 Introduction

This chapter will discuss different elements of the study, which are the reasons behind performing specific designs and statistical tests. Strengths and limitations as well as improvements that could be achieved are discussed. Recommendations for future research are made.

4.2 Title, abstract, aims and objectives

The PICO format (**P**atient **P**roblem, **I**ntervention, **C**omparison or **C**ontrol, and **O**utcome) was used to formulate the title of this study and to summarise the aim, the population, the control group, the intervention, and both primary and secondary outcomes and measures. A randomised controlled trial is the type of the study, which has been identified in the title. A structured summary of the trial design, methods, results, and conclusions were recognised in the abstract. The aim of the study was specific. Objectives and hypotheses were clear. The study assumed null hypotheses, which are: there are no differences between the scavenging efficiency of the two breathing systems; there is no difference in participants' acceptability between the two systems; and there is no difference in providing the sedation between the two systems.

4.3 Methodology and study design

It is crucial to consider the choice of measures in the planning process of a study. In this research, a randomised non-blinded controlled clinical trial design was conducted. Randomised Controlled Trials (RCTs) are considered a standard approach in providing the highest level of evidence and reducing the risk of bias. Moreover, randomising participants will ensure balanced allocation between groups allowing attribution of any differences in the outcomes to the study intervention. In addition, with RCTs a greater sample size collection will be possible (Bondemark and Ruf, 2015; Hariton and Locascio, 2018).

According to Kang (2013), the possibilities of participants dropping out of the study would be reduced when the numbers of study visits are limited. Subsequently, the amount of missing data in the clinical research will be

minimised. In this study, the chance of the dropout rate was reduced because each participant was seen only once after recruitment.

Many procedures have been proposed for the random assignment of participants to treatment groups in clinical trials. Randomisation techniques, such as simple randomization, block randomization, and stratified randomization could be used. The key advantage of randomization is that minimise the allocation and selection bias. It also ensures against the accidental bias in the experiment and produces comparable groups in all the respect except the intervention each group received. Each method has its advantages and disadvantages. It is very important that the researcher selects a method that will produce valid results for the proposed study (Suresh, 2011).

Simple randomization is based on a single sequence of random assignments. This technique maintains complete randomness of the assignment of a subject to a particular group. Flipping a coin is the most common and basic method of simple randomization. This approach of randomization is simple and easy to perform a clinical research. In large clinical research, the advantage of using simple randomization is to generate similar numbers of subjects among groups. However, in relatively small sample size clinical research, simple randomization could be problematic resulting in an unequal number of participants among groups (Suresh, 2011).

The block randomization is a method designed to randomly assign subjects within blocks resulting in equal sample sizes across groups over time. Blocks are best to be used in small increments, which keeps a similar number of subjects in each group at all times. The size of the block is determined by the researcher and should be a multiple of the number of the treatment groups. For example, if there are two treatment groups, block size should be either 4, 6, or 8). Once the size of the block is determined, all possible balanced combinations of assignment within the block (i.e. equal number for all groups within the block) must be calculated. Blocks are then randomly chosen to determine the patients' assignment into the groups. The main limitation of block randomisation is that the allocation of participant's may be predictable resulting in selection bias (Suresh, 2011).

The stratified randomization is a simple and useful method that designed to address the need to control and balance the influence of covariates. This

method is used to ensure balance among groups in terms of subjects' baseline characteristics (covariates). The research must identify specific covariates that influence the study's dependent variable. Stratified randomization is based on generating a separate block for each combination of covariates, followed by random subjects' assignment of the appropriate block of covariates. Once all subjects have been identified and assigned into blocks, simple random sampling is performed within each block to assign subjects to one of the groups (Suresh, 2011).

The disadvantage of stratified randomization is that becomes complicated to implement if many covariates must be controlled. Stratified randomization has another advantage as it works only when all subjects have been identified before group assignment. However, this method is rarely applicable because clinical research subjects are often enrolled one at a time on a continuous basis. When baseline characteristics of all subjects are not available before assignment, using stratified randomization is difficult (Suresh, 2011).

The randomization plan for treatment assignment to patient can be generated by the researcher using online software. This online software is very simple and easy to implement. Up to 10 treatments can be allocated to patients and the replication of treatment can also be performed up to 9 times. The main limitations of this software are that once the randomization plan is generated, same randomization plan cannot be generated as this uses the seed point of local computer clock and is not displayed for further use. Other limitation is that maximum of only 10 treatments can be assigned to patients (Suresh, 2011).

In this research a block randomisation was used to ensure a balance in the sample size across groups over time. Selection bias in this study is reduced by keeping the investigator blinded to the participant's allocation till the day of treatment.

4.3.1 Choice of the scales measures

Both the FIS and the Houpt scale are routinely used in the sedation unit at Leeds dental institute for all patients and they are recorded routinely in the patients dental records. The Facial Image Scale has shown good validity in measuring dental anxiety for research purposes (Buchanan and Niven, 2002). In the current study the Facial Image Scale was used because it is simple and

easy especially in clinical situations, less time consuming, and more suitable for younger children who lack the cognitive ability to understand and complete other anxiety questionnaires, it gives immediate indication of anxiety and provide interesting results regarding prevalence of dental anxiety in children (Wong and Baker, 1988; Buchanan and Niven, 2002). On the other hand, the Houpt scale has advantage which is that it categorises the severity of behavioural expressions like sleep, movement, and crying, this helps in detecting the specific changes in the child's behaviour. It has the possibility to identify the magnitude of child's movement or crying during dental procedures and also it can be applied in dental sedation. Houpt scale still preferred among dentists in assessing behaviours related to specific dental procedures and it is widely used in paediatric dentistry as it is a reasonable choice for busy professionals (Larissa et al., 2016). For these reasons, both the FIS and the Houpt scale have been used in this study.

4.3.2 Measurement of nitrous oxide levels using diffusion tubes

There is no standard method to measure the nitrous oxide levels in dental settings. Gilchrist and colleagues (2007) used two methods in their study, either an electronic monitor or a personal dosimeter. Hansen et al.(2019) compared two nitrous oxide measurement devices (the direct reading and the passive sampling) for dental employees in dental clinics. They found that there was no significant difference between similar exposure group concentrations using either of the sampling methods.

In this present study, the choice for diffusion tubes was determined according to simplicity, availability, reliability and cost-effectiveness. Diffusion tubes (passive method) are becoming increasingly popular as an alternative to active methods. They are simple and lightweight; they don't need a pump or power to be used. Diffusion tubes are widely used for personal monitoring and are less obtrusive to the wearer (Zabiegała et al.,2010; Analytical Methods Committee, 2020). For these reasons, diffusion tubes were chosen as the method to measure the nitrous oxide levels in the ambient air in this study.

4.3.3 Sample size calculation

At the time this study was designed, there were few published articles describing similar studies. Advice was sought from a qualified statistician at the

University of Leeds and the sample size was agreed to be determined based on Henry et al's.(1992) study. In their study, 18 participants were recruited to the Porter Brown system and the mean nitrous oxide level in the ambient air was 36.6 ppm. It was estimated that the mean of nitrous oxide levels in the ambient air for this study would be 40.2 ppm, which is 10% more than the mean in Henry's study to be considered clinically significant, with an estimated standard deviation of 4.7 and with a significance level (alpha) of 0.05. Taking these findings into account, it was suggested to recruit a total of 54 participants (27 in each group) to ensure an appropriate and statistically valid sample size that would successfully answer the research hypotheses.

4.3.4 Missing data

There are numerous ways to analyse missing values during statistical analysis. One way is by dropping or ignoring the data from being analysed. This means there will be a reduction in the overall sample size. According to Kang (2013), this can be applied when the missing values are less than 5%. This approach was used for the analysis of the Porter Brown breathing system sessions, where two of the sessions were excluded from the analysis because the diffusion tubes were not available due to late delivery of the shipment. Participants who were scheduled to have their treatment sessions at that time were contacted by phone to reschedule their appointments. Most participants accepted postponing their treatment session for the next available appointment. However, two participants attended their scheduled treatment session (one participant in each session). Therefore, the treatment was completed, and data was collected for these participants. However, the nitrous oxide exposure levels were not collected in those two sessions.

4.3.5 Participants' feedback questionnaire

Designing the questionnaire was one of the essential steps in the methodology process of this research. A questionnaire containing simple and easy questions for the children between 7 to 15 years old was designed by the chief investigator (HA). Prior to the start of the current study, the questionnaire was piloted to evaluate its ease of understanding for children of this age group, and also to ensure if further clarification was required. The questionnaire was piloted in the Sedation Unit at Leeds Dental Institute, where ten children who were

coming for their routine dental visits were asked to complete the questionnaire and to provide comments. Feedback and comments were collected, and the majority of the children found it clear and easy to read and understand. The questionnaire took around 5-10 minutes to complete. Minor amendments were made following this pilot test, this included simplifying some questions and adding smiley face Likert scale to make it clearer and more understandable. On the day of treatment in this study, participants were asked to answer the questionnaire after their full recovery. The investigator handed each participant a questionnaire sheet and a pen. They were reassured that information would be anonymous to encourage them to complete all the questions. All questionnaires were completed within 5 to 10 minutes and the completion rate was 100% with no missing responses. Feedback was collected even when a treatment was interrupted or not completed successfully.

4.4 Discussion of results

This study aimed to investigate the acceptability and the scavenging efficiency of the Silhouette breathing system and compare it with the Porter Brown breathing system used in inhalation sedation for children. It also aimed to investigate if there was any difference in providing the sedation between the two systems. The primary outcome of this study was to examine the scavenging efficiency between the two breathing systems. This was measured by the nitrous oxide levels in the ambient air using diffusion tubes. It was assumed that there are no differences in participants' acceptance between the two systems and there was no difference in how the operator provided the sedation. In this study the cooperation level, the anxiety level and the cost were also compared and analysed as a secondary outcomes.

The results of this study indicated that the scavenging efficiency of Porter Brown system was superior to the Silhouette system. The data also suggested that the participants accepted both breathing systems almost equally, and there was no difference in how the operator was providing the sedation in both systems, where most of the treatments were completed successfully. Furthermore, the analyses confirmed that neither the cooperation level nor the anxiety levels were affected by the type of mask, age or gender. However, the participants' anxiety levels were higher before commencing the treatment than after, regardless of the type of breathing system used.

4.4.1 Nitrous oxide levels and scavenging efficiency

In this research, a total of 15 dental treatment sessions (one – five participants) using inhalation sedation were measured for nitrous oxide exposure to assess the scavenging efficiency of the Silhouette and Porter Brown breathing systems. According to the UK Health and Safety Executive (HSE) guidelines (Health Safety and Executive, 2011), nitrous oxide exposure levels should not exceed 100 ppm time-weighted average over 8 hours. While the USA National Institute for Occupational Safety and Health (NIOSH) recommended a 25-ppm time-weighted average during the anaesthetic period as the exposure limit for nitrous oxide (NIOSH, 2014). In this study, none of the sessions exceeded the UK HSE limits. However, two of the Silhouette breathing system sessions exceeded the NIOSH guideline exposure limits, while the Porter Brown sessions remained within the guideline.

The results of this current study suggest that both scavenging systems were active, but the results indicate the Porter Brown system was more efficient than the Silhouette system. There was a statistically significant difference between the two systems based on the amount of nitrous oxide in the ambient air within the dentist's breathing zone. This means that the dentist was exposed to higher levels of nitrous oxide during the dental treatment with Silhouette breathing system than with the Porter Brown system. Interestingly, although the nitrous oxide levels in the dental nurse breathing zone were higher with the Silhouette system, the difference was not statistically significant.

The majority of previous studies have found that the Porter Brown breathing system was more efficient in comparison with other breathing systems. Gilchrist and colleagues (2007) evaluated the exposure to nitrous oxide of dentists working in a paediatric dental unit and compared the Porter Brown system with the Accutron system. It was found that the Porter Brown system appeared to be associated with lower levels of nitrous oxide in the ambient air when compared with the Accutron breathing system. However, their study was not designed to test one scavenging system against the other, therefore it was difficult to verify that. Chrysikopoulou and colleagues (2006) compared the effectiveness of Porter Brown and Accutron systems in reducing waste nitrous oxide during routine paediatric dental treatment. They found that nitrous oxide levels were

significantly lower with the Porter Brown system compared with the Accutron system. In addition, a study by Marshall et al.(2007) investigated the effectiveness of two scavenger mask systems, the Matrix Medical single-mask system and Porter Brown mask system in the reduction of nitrous oxide exposure during dental treatment in paediatric patients. They found that the Porter Brown scavenging system was more effective than the Matrix system. Furthermore, Certosimo et al.(2002) evaluated the efficacy of three nitrous oxide scavenging units during dental treatment: The Porter Brown, the Accutron and the Matrix systems. The finding of their study was that nitrous oxide levels were significantly lower when using the Porter Brown system compared to the Matrix or Accutron systems.

Despite the different methods that have been used to evaluate and compare different scavenging systems, the current study is in good agreement with the previous findings about the superiority of the Porter Brown scavenging system over other systems.

The results of the present study also showed that the amount of nitrous oxide exposure for the dentist and dental nurse were different within the same system. It was noticed that the dentist had almost double the exposure amount than the dental nurse in the Silhouette system. When using the Porter Brown breathing system, both the dentist and dental nurse were exposed to similar levels of nitrous oxide. Comparing this with the available literature, there were two points of view that support the results of the current study. During the investigation of nitrous oxide exposures between dentists and their dental assistants by Dunning et al.(1996,1997), the dentists' nitrous oxide exposure was significantly greater than that of their dental assistants. Hansen et al.(2019) investigated the nitrous oxide exposure among dental employees during dental procedures, using both passive and active sampling methods. They found that the dentist showed higher exposure levels when compared with the dental assistants. These findings were similar to the findings for the Silhouette breathing system in our study.

In another environment, Westberg et al.(2008) compared the nitrous oxide exposure among midwives and their assistants in delivery suites in six Swedish hospitals using three types of face masks. They found that there was no statistically significant difference between the nitrous oxide exposure of the

midwives and their assistants. This result was similar to our study when using the Porter Brown system for the patients during dental treatment.

Although the dentist's nitrous oxide exposure levels were expected to be higher due to the closer proximity to the patient, it was found that the dental nurse was exposed to a higher level of nitrous oxide in two sessions: one in Porter Brown and one in Silhouette. When reviewing these sessions, it was found that one of the participants in the Porter Brown session was very anxious, he interrupted the treatment and removed the mask. While in the Silhouette session, it was found that all participants in this session had extractions, and one of them was anxious, crying and struggling to breath properly during the treatment. This resulting in the dental nurse becoming much closer to the participants to help the dentist in controlling the situation and to coach the participants to continue breathing until the treatment completed and full recovery achieved. These are the possible explanation as to why the dental nurse was exposed to more nitrous oxide in these sessions.

The scavenging efficiency is not the only variable that can affect nitrous oxide levels in the ambient air. There are many considerations that can affect and increase nitrous oxide levels in the dental team breathing zones. These include: the position of the dental team members and the distance to from the nitrous oxide source, the efficiency of mask fit, the patient's respiratory rate, the amount of mouth breathing by the patient, the room size and ventilation efficiency, the type of treatment and the use of rubber dam isolation. Patient cooperation and anxiety are other factors that can also contribute to nitrous oxide levels in the ambient air (Hansen et al., 2019).

Some of these variables may continue to expose the dental practitioner to relatively high levels of nitrous oxide even after the dental procedure is completed. The nitrous oxide left over from the previous procedure or treatment (one patient after the other) can accumulate and add to the background levels if back-to-back procedures under IHS have been carried out and if the room is not ventilated properly between patients. Furthermore, errors and bias may occur during sample collection and this depends on the accuracy and reliability of the method used to collect the nitrous oxide sample from the ambient air (Hansen et al., 2019).

As mentioned previously, passive diffusion tubes were used in this study to measure the nitrous oxide levels in the ambient air to assess the scavenging efficiency of the Silhouette and Porter Brown breathing systems. According to the manufacturer, the shelf life of the diffusion tubes is around 6 weeks, and they have to be exposed and returned to the laboratory within this period for analysis. Tubes should be stored and prepared in a dark place away from any heat source. The sampling time should be recorded to ensure that time is sufficient and enough nitrous oxide is collected for the laboratory detection and analysis (Gradko Environmental Laboratory b, n.d).

According to the diffusion tubes laboratory analysis for this present study, it was reported that the nitrous oxide levels were below the reporting limit in five sessions. This means that the amount of nitrous oxide was below the instrument's sensitivity. The reporting limit is the smallest reported concentration of the gas that can be reported by the laboratory, which is 1.25 ppm for the nitrous oxide. In these sessions the nitrous oxide levels were below 1.25ppm (LCS Laboratory Inc, n.d; Marks International Ltd, 2015). Three of them were reported below the limit with both diffusion tubes (the dentist and the dental nurse), while in the other two sessions it was only reported with the dental nurse diffusion tube.

There are some factors that may affect the integrity of the collected samples. Possible reasons reported in the literature that may cause tube obstruction and analysis errors could be temperature, humidity, air flow and movement (Zabiegała et al.,2010). Furthermore, using the tube the wrong way around with nitrous oxide entering the wrong path or using the tubes horizontally instead of vertically, will interfere with the gas entering the tube. Blocking the sampling device by the clinician during routine dental activity, manufacturer's equipment failure, tube storage and transport are other factors that have been reported in the literature to cause poor readings (Melanie,2003; Zabiegała et al., 2010).

In this study, standards were set in all sessions to try to control these factors as much as possible to avoid any possible errors from occurring in the sampling method. All treatment sessions were carried out with the same team, in the same room size and ventilation quality, and all the manufacturer instructions were followed promptly. If any of the previous factors occurred accidentally in some of the sessions, this was not assessed in this research. However, future

studies should consider the previous factors during nitrous oxide sample collection.

4.4.2 Nitrous oxide levels and type of dental treatment

The type of treatment undertaken, and the degree of cooperation and anxiety of the patient may contribute to elevated nitrous oxide levels in the ambient air. In this section, the relationship between these factors and their possible effect on nitrous oxide levels will be discussed. The data obtained from this study demonstrated that local anaesthesia and fissure sealants were the most common procedures received in both groups. In the Porter Brown group, the majority received either permanent or primary teeth restorations. In the Silhouette group most treatments were extractions and fissure sealants. Restorations were carried out under ideal isolation condition using rubber dam. This was used in 40 percent of the cases in the Porter Brown group. It was used in just over 20 percent of the cases in the Silhouette group. Moreover, the average duration of the Porter Brown sessions was longer than the Silhouette; the most likely reason being the types of treatment provided in these sessions. It was expected that there would be a direct proportional relationship between the treatment duration and nitrous oxide levels in the ambient air, as this was suggested by most previous studies. However, the data in this study showed that although the average duration of the Porter Brown sessions was longer, nitrous oxide levels in the ambient air were lower when compared with the sessions using the Silhouette breathing system.

The analysis also confirmed that three procedures were interrupted in each mask group, and treatment was not completed successfully when this happened. It was noted that the interruption was either following the administration of local anaesthetic or when the participant did not like the sedation feeling; regardless of the type of mask used. This implies that there was no association between the treatment success and the type of mask used.

It was difficult to statistically test if the nitrous oxide levels were affected by one type of treatment over the other, because the exposure levels were measured per session rather than per patient. As stated earlier, nitrous oxide may accumulate with back-to-back patients being treated. This also made it difficult to determine which procedure had more effect on the exposure levels. Despite

the difficulty, the results of the current study gave an indication that nitrous oxide levels were affected by a set of factors including the exposure time, the treatment type, and the use of rubber dam isolation.

The results of the present study do not fit well with the results of Gilchrist et al.(2007). In their study they suggested that the higher nitrous oxide exposure levels were associated with restorative treatment. They described restorative treatment being responsible for increasing the exposure levels because the children keep their mouths open for a longer time. In addition, they argued that rubber dam doesn't limit the exposure despite the fact that it was only used in a few sessions. In contrast to their findings, other studies have shown a reduction in the nitrous oxide levels in the ambient air when rubber dam was used (Almquist and Young, 1983), while others have found there is no difference in the nitrous oxide levels when using the rubber dam (Christensen et al.,1985; Henry et al.,1992). The current study suggests that the use of rubber dam reduces the nitrous oxide levels in the ambient air.

4.4.3 Nitrous oxide levels and child's behaviour

The Houpt rating score is one of the tools that has been used to evaluate children's behaviour during dental visits (Lourenço-Matharu et al.,2012). In this study the operator (HA) used this scale to assess the participant's behaviour. The finding of this study demonstrated that there was no difference between participants' cooperation levels in the Porter Brown group as compared with the Silhouette group. It was also demonstrated that the participant's cooperation was not affected by the type of mask used in their treatment session. The results also suggested that there was no association between the participants' cooperation and their age or gender in either group. This means that the mask type, the participant's age or gender were not contributing factors in the cooperation levels. These findings were not statistically significant. The data from this present study suggests that the cooperation levels were not affected by the treatment types. This finding was also not significant. However, a statistically significant association was observed between the cooperation level when the treatment was interrupted and when treatment was not provided. This means that when a participant interrupted the treatment, the cooperation level was poor.

The majority of the participants showed positive behaviour and their dental treatment was completed successfully. The operator used non-pharmacological behaviour management techniques such as: tell-show-do and positive reinforcement in addition to the pharmacological behaviour management of the nitrous oxide sedation, to enhance their behaviour and reduce their anxiety. These techniques were very helpful to make them feel more relaxed subsequently cooperate during treatment.

Vanhee et al.(2020) looked at child behaviour during dental care under nitrous oxide sedation using two different gas distribution systems. The results of their study showed that there was no significant difference in the child's behaviour under inhalation sedation with either of the two gas administration systems. A significant difference in the behaviour was observed following giving local anaesthetic. Their finding is in contrast with the current study. In this study, treatment was interrupted mainly following administration of local anaesthetic, and it was observed that the cooperation level was poor when the treatment was interrupted. Another double blinded cross over design study, Primosch et al.(1999) investigated the effect of administering nitrous oxide inhalation sedation (alternating between 40% N₂O and 60% O₂ or 100% O₂) on behaviour during two sequential restorative appointments in children. The results of their study showed that there were no statistically significant differences in the behaviour between the two groups and there was no difference between the two groups in gender or age. These findings support the results of the present study, as there was no association between gender and age with the cooperation levels.

Previous studies have shown an association between the cooperation levels and nitrous oxide levels in the ambient air (Badger and Robertson,1982; Henry et al.,1992). Although it has been suggested in the literature that nitrous oxide levels in the ambient air increased with poor cooperation, the design of the current study was not aimed to evaluate the relationship between the cooperation levels and the nitrous oxide levels in the ambient air. In addition, the nitrous oxide levels in this study were measured for an overall session rather than for each participant.

4.4.4 Nitrous oxide levels and child's anxiety

The facial image scale (FIS) is a validated anxiety scale that evaluates the anxiety of children from 3 to 18 years-of-age (Buchanan and Niven, 2002). The FIS was used before and after treatment to assess the anxiety levels of the participants enrolled in the present study. Statistical analysis revealed that there was no association between anxiety levels and the type of the breathing system that was used during the dental treatment. However, there was a difference between the anxiety levels before and after the treatment in both groups, as the participants were more anxious before treatment than after treatment. This finding was statistically significant. When comparing the anxiety levels of both genders, female anxiety levels before the treatment were found to be significantly different than after their treatment in both groups. They were scored as more anxious before treatment than after treatment. This difference was not significant in male participants. Participants who were in the Porter Brown mask group were more anxious than participants in the Silhouette mask group before and after treatment. However, these findings were not statistically significant. The outcomes of this study suggest that the participants' anxiety levels were not affected directly by the type of treatment undertaken, age, gender or the type of breathing system that was used in their treatment session. These findings are similar to Kilinc et al's.(2016) study, who used facial image scales to assess paediatric anxiety. When the results of the present study were compared to the literature, Buchanan and Niven (2002) found that there were no significant differences in terms of gender regarding the scores that measure dental anxiety levels with FIS or the Venham picture test (VPT). At least one other study found that female adolescents experienced more dental anxiety levels than their male counterparts (Brukiene et al.,2006).

Kilinc et al.(2016) found that no statistically significant differences were observed in the pulse rates, FIS scores, VPT scores, or Frankl behaviour rating scores in terms of gender. Many other studies have found a strong relationship between age and dental anxiety levels (Buchanan and Niven, 2002; Kilinc et al.,2016). These studies reported that younger children were more anxious than older children (Yamada et al.,2002; Shinohara et al.,2005). However, these findings are in contrast to the present study.

Alexopoulos et al.(2007) compared between dental anxiety levels in children undergoing two separate sedation cohorts: either nitrous oxide inhalation sedation or propofol intravenous sedation using different anxiety scales. They found that the two cohorts were nearly similar in respect to Modified Child Dental Anxiety Scale (MCDAS) and Children's Fear Survey- Dental Subscale(CFSS-DS) anxiety scales pre-operatively. And there was a significant anxiety reduction within the same group post-operatively when it was measured by the MCDAS, CFSS-DS and the Visual Analogue Scales (VAS). There were also significant reductions in self-reported dental anxiety post-operatively with propofol. These findings were consistent with the current findings.

4.4.5 Dentist feedback

The operator's feedback was recorded through a questionnaire (Appendix O), which was completed after each participant's appointment. The questions assessed the ease of the mask placement and removal, treatment site accessibility, participant's manoeuvrability and head movements, nasal hood seal, airflow monitoring, participant's mask acceptance from the dentist's point of view, and the success of the overall treatment.

The findings of the feedback indicated that placing and removing the masks was not difficult; the main challenge was introducing the masks to an anxious participant for the first time. In the first few sessions with the Silhouette system, it was more challenging introducing and placing the mask on the participants. Around one third of the participants in the Silhouette group faced difficulty with mask placement and removal. They were graded between difficult and neutral. Most participants (especially younger children) had difficulties because they did not like the way the air pushed up the right nostril from the nasal cannula. It was challenging to keep the participants calm and to keep the mask seated while they become sedated. The operator realised that when the airflow was lower with the Silhouette system, the feeling of discomfort reduced, and participants were calmer wearing the mask. Therefore, in the subsequent Silhouette sessions the airflow was reduced at the beginning of the treatment session for each participant to around 3 to 4 L/min, and then the airflow was gradually increased to allow the participant to get adequate amounts of nitrous oxide and oxygen. This technique helped the participants to accept wearing the Silhouette

mask and made its placement easier and more comfortable. In the Porter Brown system, the airflow started at a higher level than with the Silhouette.

In general, placing the Porter Brown mask on patients was slightly easier than the Silhouette mask. The majority were graded easy for mask placement. Three of the participants who had Porter Brown masks had difficulties not only in placing the mask, but also during the entire treatment session, this was likely due to their lack of cooperation and higher anxiety. These participants were scored either 3 or 4 in the FIS anxiety scale pre-operatively and were scored between 2 to 5 in the Houpt cooperation scale.

Moreover, removing the masks from on the participants was not difficult, however some participants commented on the sticky strip on their nasal bridge for the Silhouette mask. This was uncomfortable for some when the mask was being removed. For the Porter Brown mask, participants commented on the marks left on their face following mask removal, which usually disappeared after a few minutes. Three participants were not scored completely in this section because they interrupted the treatment by removing their masks and the treatment was not completed successfully. The anxiety score for these participants pre-operatively was either 1 or 2 in the FIS. Two participants were wearing Silhouette masks and one participant was wearing a Porter Brown mask.

In general, the treatment site was acceptably accessible with both breathing systems and it was not difficult to deliver the dental treatment for participants using either of them. However, it was observed that the Silhouette mask weighed less than the Porter Brown mask, which made it easier to access the anterior area. The Silhouette mask was scored as easy treatment site accessibility in 96.2% of the participants, while in Porter Brown only 66.7% of the participants were scored as having easy and accessible sites for treatment. The rest of the participants were graded as having neutral treatment site accessibility.

When comparing the ease of participant movement during the dental treatment with Porter Brown or Silhouette systems, the Silhouette showed better manoeuvrability and head movement. The Porter Brown system is a heavier system than the Silhouette, when it is placed on the participant, and is often secured behind the head rest making head movement quite difficult. The

Silhouette system is lighter and is secured under the participant's chin after passing the tubes behind the ears; this makes it easier to move the head and body. All participants wearing the Silhouette breathing system were scored as having easy manoeuvrability and head movement. However, participants wearing Porter Brown masks faced difficulty in head movement and only 40% of them scored as having easy manoeuvrability.

Overall, the results of this study suggest that the Porter Brown mask had a better nasal hood seal than the Silhouette mask. The majority (96.3%) of the participants in the Porter Brown mask group had a good nasal seal. In the Silhouette group, only half of the participants had a good seal. Two of the participants scored as having a bad seal and 11 were scored as having neutral nasal seal when wearing the Silhouette mask. Although the Silhouette mask has a sticky pad to allow the mask to be sealed on the nasal bridge, it detached during the dental treatment sessions in almost all the participants, and finger pressure was required to reattach the pad on the participants' noses. This could be one of the possibilities that contributed to the greater nitrous oxide levels during the sessions.

Gilchrist and colleagues (2007) assessed the mask fitting when they compared between the Porter Brown and the Accutron systems, and rated it as poor, adequate or good. This was similar to the current study when assessing the nasal hood seal of both masks. However, the operator in the present study assessed the entire breathing system and compared between them. The only similar criteria between the current study and Gilchrist et al's (2007) study was the mask fitting. In their study, the majority of patients were rated as having good mask fitting irrespective of the type. In the current study, the operator rated 96.3% of the participants as having good nasal seal in the Porter Brown group, while only 50% of the participants were rated as having a good seal in the Silhouette group.

Airflow monitoring with the Silhouette breathing system was challenging due to the absence of a reservoir bag. This made it more difficult to decide if the flow rate was appropriate for the participants because it was monitored only by the flowmeter device. The monitoring in the Porter Brown breathing system was easier with the presence of the reservoir bag as the monitoring was carried out by the gas flowmeter and observing the reservoir bag.

The results suggest that almost all participants accepted both masks similarly and their treatments were completed successfully. In each group, approximately 10% didn't tolerate or accept the mask, and treatments were interrupted. Some participants accepted the mask at the start of the session, but their treatment was then interrupted, either after administering local anaesthetic or later on. Participant anxiety, the sedation feeling, or the type of treatment itself were most likely the causes for treatment interruption. The tell-show-do technique helped anxious participants to accept wearing the mask and to complete their treatment successfully.

4.4.6 Monitoring sheet and dental nurse feedback

In this study almost two thirds of the sessions were assessed and monitored by the same sedation dental nurse. The remaining 30% of the sessions were assessed by different dental nurses. Dental nurse feedback was recorded and documented in a monitoring data sheet (Appendix N). This included questions on the ease of assembling and disassembling the circuit, the setup time, and the vital signs monitoring (respiratory rate and heart rate). The time that was needed for the participants to be sedated and the oxygen and nitrous oxide ratio was also recorded in the monitoring sheet.

The results suggested that there was no difference in the difficulty of setting up or removing the circuit in either breathing systems. Results also suggested that there was no difference in the setting up time between the two systems, and it took around 3 to 5 minutes to set up the circuit and carry out the safety checks for both breathing systems. However, it was noted that in the beginning of each Silhouette session, an extra few minute was needed to disassemble the previous circuit attached to the machine requiring removing the reservoir bag attached to the flowmeter, which is used with the routine Porter Brown breathing system. Though, if the flowmeter machine was already sat-up for the Silhouette breathing system as a routine system, there would not be an extra time required to disassemble the precious circuit attached.

It was also noted that the Silhouette tubes were heavier compared to the Porter Brown tubes, despite the fact that the Silhouette mask was lighter weight. The tubes in the Silhouette system tipped the vacuum control block and detached it with some participants, even though it was clipped to the participants' clothes.

In general, monitoring the respiratory rates of cooperative participants who accepted dental treatment was not very difficult for dental nurses, regardless of the type of the mask used. However, the monitoring was easier with the Porter Brown breathing system due to being able to monitor the reservoir bag. Most dental nurses and dentists monitor the breathing by observing both the patient's chest movements and the reservoir bag for the Porter Brown breathing system. For the Silhouette breathing system, the monitoring was more challenging due to the absence of the reservoir bag. Therefore, the nurses relied mainly on patients' chest movements and this was difficult with uncooperative anxious participants due to their body movements. Nurses also faced difficulty monitoring the breathing volumes and deciding if enough gases were being supplied with the absence of the reservoir bag in the Silhouette system. It was also observed that some participants needed more time to be sedated with the Silhouette breathing system before dental treatment commenced. For the Silhouette system, some participants took up to 13 mins to be sedated before treatment could commence, while in the Porter Brown group, it took from five to six mins. The average time for patients to be sedated was around seven mins for both breathing systems.

There were no differences observed between the two breathing systems in the oxygen and nitrous oxide ratios used. Regardless of the breathing system, the ratio varied between participants depending on the treatment type. Most participants received 70% O₂ with 30% N₂O. When treatment became more complex the nitrous oxide percentage increased. Some participants were sedated appropriately with a lower percentage of nitrous oxide.

4.4.7 Patient feedback

Prior to discharge and following their recovery from sedation, the participants were provided with a questionnaire (Appendix M) to give their feedback about the breathing system that was used in their treatment session. The feedback was designed to assess the comfort and the acceptability of the breathing systems. The finding illustrated that the participants in the Silhouette group were able to move their heads to the side more easily than participants in the Porter Brown group; this finding was statistically significant. The likely reason is that the Silhouette mask is lighter in weight and is secured below the chin rather than secured around the dental chair as is the case with the Porter Brown

breathing system. This can make movement difficult. The present study also found that removing the Porter Brown mask from participants was more comfortable when compared with the Silhouette mask; this finding was also statistically significant. The explanation for this finding is most likely due to the presence of the sticky strip around the nasal bridge and the nasal cannula where both can lead to some discomfort for the participant.

The results of the current study highlighted that both males and females accepted the systems and there was no difference between the two systems in terms of acceptability and comfort. There was no association between participant age and their feedback on the breathing systems. However, it was noted that older participants were more likely to accept the Silhouette mask than the younger ones. Most younger participants commented in the open question section that they did not like the way the air was pushing into their right nostril. However, this finding was not statistically significant.

In the last part of the questionnaire, participants were asked to write in their own words what they liked and disliked about the mask. Children may describe things in different terms to adults, due to different vocabulary, concepts, and perceptions.

This section of the questionnaire was thematically analysed by describing and interpreting the participants' views into themes. The research investigator looked at the participants' feedback on the like and dislike section, then the responses were divided into 4 or 5 themes, then the data were collected and analysed according to that. These themes are described in table (12 and 13) in the results section.

According to (Smith and Firth, 2011), there have been three main types of qualitative data analysis:

- Socio-linguistic methods that explore the use and meaning of language; for example discourse and conversation analysis.
- Methods typified by grounded theory, that focus on developing theory.
- Methods that describe and interpret participants' views such as content and thematic analysis.

The framework approach, which is developed from thematic analysis is being more popular nowadays in analyzing qualitative data as it manages the qualitative data and undertakes data analysis simultaneously. It is a matrix based analytic method for synthesizing data and organizing it. Moreover, it facilitates data management such that all stages involved in the 'analytical hierarchy' can be systematically conducted (Ritchie and Lewis, 2003). The analysis is made in a way that it can be viewed and assessed by people rather than the primary analyst (Pope et al., 2000).

The majority of the responses mainly described thoughts about the sedation and it's feeling rather than about the mask itself. Most positive comments regardless of the mask type, were about feeling relaxed and comfortable, painless and sleepy or nice and easy to breathe. The negative comments included nose hurting, dizzy, fainting, nervous, weird, strange and unable to move.

Some participants commented on the mask itself. Participants in the Porter Brown mask group commented about the mask size, the weight, movement, tightness and the marks that were left on their faces following its removal. Participants who had the Silhouette mask, commented on the discomfort when the air was pushing into their noses. Others commented on the sticky part and the way it got detached, which was uncomfortable. On balance, in this study, the majority of the participants accepted both masks and there was no difference between the two groups with gender or age.

4.4.8 Cost

This research was conducted at the Leeds Dental Institute. The Porter Brown breathing system is the breathing system routinely used in the Sedation Unit. The Silhouette breathing system was purchased for the purposes of this study. The costs for both systems were calculated and compared according to the prices in the manufacturers' catalogues at the time this study was carried out. Calculating the cost of medical devices can be challenging. To measure the cost-effectiveness of a medical device, two parameters are needed: the cost and the effect (economic evaluation) (Goodacre and McCabe, 2002). It is important to take into account all the benefits of a medical device when calculating the cost-effectiveness to ensure the value of the device is not

underestimated. The effectiveness of a medical device can be assessed through many variables such as: success rate, complication rate, procedure duration and diagnostic performance. Some medical devices require a person for the operation, and it depends on the operator's skill and experience. This is called "device-operator interaction"; the more the experienced and skilled the device operator is, the greater the benefits (Kingkaew and Teerawattananon, 2014).

In this study, a maximum of five participants were treated in every session. Therefore, the calculations were made initially for five kits of each breathing system. Then in the subsequent sessions, the cost of the disposable parts was added to the total cost of the five kits along with the sterilisation fees for the reusable parts every time these kits were used. The cost of the sterilisation baskets and lid covers were included with the initial calculations.

In the Silhouette breathing system, each kit (flowmeter connector kit) that was bought included four sterilisable colour-coded sizer masks, sterilisable two-meter fresh gas/vacuum tubing and one disposable set of the Silhouette adapter kit. The adapter kit included the cannula adapter, breathing bag cap and a clip which is used to attach the mask to the patient's clothes. In this kit, only the mask sizer and vacuum tubing can be sterilised, therefore extra adapter kits were bought for the additional participants.

The results of the current study showed that the sterilisation and circuit costs for the Porter Brown breathing system for 27 participants were almost double the costs of the Silhouette system for the other 27 participants. Interestingly, although the Porter Brown system was more expensive initially, the costs of the Silhouette breathing system massively increased when the calculation of the cost was projected for supply required for one year use at the Leeds Dental institute. The cost was found to be more than double that of the Porter Brown system.

The reason for the difference in the costs between the two systems is that the Silhouette breathing system is a single-use system and the disposable parts need to be replaced for every patient. This means that the cost of the Silhouette system has a direct proportional relationship with the number of patients, where the cost will increase as the number of patients increases. On the other hand, the cost calculated for the Porter Brown system is mainly for sterilisation,

because it can be reused many times over an average of two years before replacing the reusable parts. The predicted lifetime of the Porter Brown system parts is approximately 12 to 18 months with normal use. However, the lifetime may change depending on the sterilisation temperatures and the frequency of use (RA Medical Services Ltd, 2020).

According to the findings in this study, it is suggested that the Porter Brown breathing system is more cost effective compared with the Silhouette system. This conclusion was made not only because the Porter Brown system costs less, but also because its' scavenging efficiency was superior to the Silhouette system.

Environmental cost

The use of disposable medical devices or part of the medical devices such as masks are being very common (popular) now in the market, which are taking place of the traditional reusable masks due to the infection control concerns (Sanchez et al.,2020).

The single-use disposable products are creating environmental impact especially that health care related pollution is increasing and becoming a great concern. In fact, both disposable and reusable devices have an impact on the environmental pollution. Reusable devices need water, energy, chemicals and workers to do the process of cleaning. On the other hand, disposable devices such as Silhouette mask require additional materials for manufacturing, transportation and waste disposal. It is not clear, yet which type has more advantage on the environment (Sanchez et al.,2020).

The evaluation and comparison of resource use, environmental impact and public health impact together with institutional costs and the life cycle of each device can help in identifying the advantages and disadvantages of disposable and reusable devices, which in turn will help in calculating the environmental cost (Sanchez et al.,2020).

Having mentioned that, the environmental cost for the current study was not calculated, and its recommended for future studies to look at the environmental cost of both breathing systems.

4.5 Research achievement

The initial results of this study were presented in the Leeds Dental School research day in July 2019, and the prize for the best verbal research presentation was won (Appendix Q).

4.6 Effect of the pandemic (covid-19) on this research

Recruitment and data collection processes were completed in August 2019, so this stage of the project was not impacted by the Covid-19 pandemic. Statistical analyses and the write up processes were affected during this period as all supervisory meetings took place online. Most international students were very concerned and anxious during this period, worried about their families and their relatives, with the fear from the unknown. I was in Leeds and went through the first U.K national lockdown before we were evacuated by the Kuwait government on the 28th of April 2020. During this lockdown, it was difficult to maintain progress as waiting for evacuation was exhaustingly stressful and unpredictable as the date of travel was sudden and unknown. When I went back home; I stayed under governmental enforced quarantine away from my family for 28 days, from 28th April to 26 May 2020. Working and focusing during this period of time was very difficult and challenging. There was a sedentary phase between March 2020 to July 2020, where productivity was very slow and not as I wished for. The original submission date was 31 August 2020. However, progress was affected with the pandemic, and a 6 months extension was granted. I continued writing this thesis in Leeds between September 2020 and February 2021, when the second and third waves and lockdowns occurred. When I came back to Leeds, I was under U.K. governmental-required quarantine for two weeks, from 6th of September to 20th of September 2020. It was challenging again to focus and concentrate, especially because I was worried about my visa and I had to apply for the exceptional assurance for extension. Despite these difficulties and stressful moments during this year, this research and writing have been completed successfully.

4.7 Evaluation the risk of bias

The following tables assessing and evaluating the risk of bias within the study according to the Cochrane criteria.

Table 28 Evaluation the risk of bias

Domain	Assessment of the current study	Support for judgment
Selection bias Random sequence generation	Low	- Eligible participants (n=54) were randomly assigned to two different groups of inhalation sedation breathing systems. - Block randomisation was carried out prior to the start of each treatment session to ensure balanced allocation of participants in each group.
Selection bias Allocation concealment	Low	- “It was achieved by preparing concealed envelopes containing a card with either the Porter Brown or the Silhouette breathing system. Neither of the participants nor the dental team were aware of which breathing system will be used until the day of the treatment ”.
Performance bias Blinding (participants and personnel)	High	- This is a single centre randomised non-blinded controlled clinical trial. - Neither of the participants nor the dental team were aware of which breathing system will be used until the day of the treatment. On the day of treatment, the dental nurse picked an envelope showing which breathing system will be used

		for the entire treatment session for all of the participants, hence the dental team were aware of which breathing system was used for all the participants in that treatment session. However, the participants were informed which mask their dental treatment will be carried out with when they arrived for their treatment session.
Detection bias Blinding (outcome assessment)	High	No measures were taken to blind outcome assessors from knowledge of which intervention a participant received.
Attrition bias Incomplete outcome data	Low	- “dropping or ignoring the data from being analysed. This means there will be a reduction in the overall sample size. This approach was used for the analysis of the missing Porter Brown breathing system sessions, where two of the sessions were excluded from the analysis because the diffusion tubes were not available due to late delivery of the shipment. According to Kang (2013), this can be applied when the missing values are less than 5%”.

		“In this study, the chance of the dropout rate was reduced because each participant was seen only once after recruitment”.
Reporting bias Selective reporting	Low	- All outcomes were reported.
Other Bias Recall Bias	Low	- Participants were asked to answer the questionnaire soon after the end of the treatment session after their full recovery (10 mins).

4.8 Limitations

There were number of limitations associated with the current study. The ethical approval process was one of the faced in this research. The process to grant all ethical approvals took several months, and subsequently delayed the recruitment phase.

In this study the children were recruited from the Sedation Unit on the assessment appointment. Usually, when a patient attends the assessment appointment for treatment planning and consent signing, he or she will have the chance to try the inhalation sedation (IHS) with the Porter Brown breathing system. However, according to the current study design this was not done. Hence some parents were unhappy to have an additional visit only for treatment planning and to sign consents prior to the treatment session. Recruiting participants on the day of consultation could have overcome this and would have reduced the numbers of dental appointments. However, this option was difficult for the current study, because children have to be referred to the sedation unit and be on a waiting list prior to treatment under inhalation sedation. Children have to be seen for treatment in the order they were placed in the waiting list. Due to the limited time available for this research to be conducted, the participants were recruited from the sedation waiting list rather than from the consultation appointment.

One of the limitations of this study was that the types of treatment carried out were not controlled i.e., participants were treated as per their treatment plan. Therefore, it was not possible to test the relationship between each treatment type and the nitrous oxide levels in the ambient air. In addition, the nitrous oxide levels were measured per session rather than per participant due to a limited budget and restricted time available.

This design could have been improved by treating one participant in each session, and then the nitrous oxide levels would have been monitored for every participant individually. Moreover, creating treatment criteria for the treatment sessions; for example, including only permanent tooth extraction or fillings would have facilitated the comparison between treatment types and its effects on nitrous oxide levels.

One of the barriers of this research is that diffusion tubes must be pre-ordered by the Student Services Team who are responsible for all research orders. Although the diffusion tube orders were undertaken in advance, there were some errors and delays with some of them. This affected the study by delaying the participants' appointments where rescheduling had to be done.

Another drawback of this research was that a postgraduate student was undertaking the treatment, with a clinical supervisor supervising to check the patient before and after the treatment. This interruption could have contributed to increased nitrous oxide levels, where contamination could have occurred from the adjacent treatment bays when the surgery door was opened.

One of the limitations in this study is that most of the participants responses were mainly describing their thoughts about the sedation and it's feeling rather than about the mask itself. The reason behind it could be that the questions were open ended and not specific to the mask itself. In addition to that, the children may describe and understand things in different terms to adults, due to different vocabulary, concepts, and perceptions. This could be overcome by improving the questionnaire and eliminating the open-ended questions to be more specific to the mask type and shape.

4.9 Future recommendations

Further research is needed with a larger sample size, narrower age range of the participants, and improved feedback questionnaire. This could be achieved by eliminating the open-ended questions for better analysis and to be more specific to the mask type and shape especially with the Silhouette mask.

Moreover, future research is needed to study the Silhouette breathing system for adolescents, to evaluate the system for older participants and to get more specific feedback from them.

4.10 Conclusion

From this study, it can be concluded that:

1. The Porter Brown scavenging system was superior to the Silhouette scavenging system based on the nitrous oxide levels measured in the ambient air.
2. The participants accepted both breathing systems almost similarly.
3. There was no difference in providing the sedation by the operator for either system.
4. There was no difference between participants' cooperation levels in both groups.
5. Neither the mask type nor the participants' age and gender were contributing factors on the cooperation levels.
6. There was no association between the anxiety levels and the type of the breathing system that was used during the dental treatment.
7. Participants' anxiety levels were not affected directly by the treatment type, or the patients' age and gender.
8. Monitoring the respiratory rates (RR) using the Porter Brown (PB) breathing system was easier than the Silhouette breathing system, since the PB breathing system has a reservoir bag that can be observed.
9. The nitrous oxide levels in the ambient air were affected by a group of factors: the scavenging efficiency, the quality of the mask fitting, type of treatment, use of rubber dam isolation, participant cooperation and anxiety levels.
10. The economic evaluation of the breathing systems suggests that the Porter Brown breathing system is more cost effective than the Silhouette system.

Rejected hypothesis

- There are no differences in the scavenging efficiency of the Silhouette breathing system compared with the Porter Brown breathing system.

Accepted hypothesis

- There are no differences in patient acceptability between the Silhouette and the Porter Brown breathing systems.
- There are no differences in providing the sedation between the Silhouette and the Porter Brown breathing systems for the operator.

Chapter 5 Ethical consideration

5.1 Risks and benefits

5.1.1 Occupational risks

Chronic occupational nitrous oxide exposure has been linked to some safety and health concerns for dental professionals. The UK Health and Safety Executive (HSE) specifies a maximum exposure level of 100ppm nitrous oxide time-weighted over 8 hours (Health Safety and Executive, 2011). This can be achieved by keeping N₂O exposure to the minimum for operator and staff by using an active scavenging system. In the sedation unit, safety procedures and scavenging equipment are used to reduce the risk of chronic exposure of nitrous oxide to staff.

5.1.2 Patient risk

The more common risks for routine sedation treatment are nausea and vomiting in 10% of patients. However, all the staff and researchers are trained to deal with any side effects that may have arisen from the sedation. This research was conducted in the Leeds Dental Institute, Sedation Unit where the clinic is equipped with a crash trolley to deal with medical emergencies. The Leeds Dental Institute also has access to Leeds General Infirmary. Furthermore, the chief investigator and the research assistants are appropriately trained in managing medical emergencies when needed.

With research that includes human participants, every participant is always treated as being potentially infectious for blood-borne pathogens and the risk of undeclared infectious diseases remain a possibility. In this study, only ASA I and II participants were included, which means that we did not include participants who had potential infectious diseases such as hepatitis B.

Cross-infection control measures were applied including wiping dental chairs and units after each participant, single-use isolation barriers used on light and dental unit handles. Clinical and participant-contaminated waste were disposed in the appropriate bins per the local safety protocols of the Leeds Dental Institute clinics.

5.1.3 Benefits

There were direct benefits to each participant in that they received a stage of their clinical treatment. We were hoping to understand more about the efficiency of the breathing systems used in inhalation sedation, which would help us to improve the way that our treatment is provided for children in the Sedation Unit.

5.2 Informed consent/ assent

The lead researcher who has been supervised and trained in obtaining consent, took informed consent/ assent from children aged from 7 to 15 years-of-age and their parents/guardians. The lead researcher has comprehensive knowledge about the study and was able to adequately inform participants and their parents/ guardians of all aspects of the study. Information materials including the routine department leaflets and brochures that are given to all patients prior to sedation were also given to the participants. Participants were able to ask more detailed questions and information about their treatment and the study. Children were asked to sign an assent form (Appendix L) in addition to the consent form signed by their parents/guardians (Appendix K). Copies of the signed consent\assent forms were given at the end of the treatment sessions.

5.3 Reimbursement/ Incentives

For this research, each participant was given an electronic toothbrush at the end of the treatment session as a modest present for their time and any inconvenience associated with the study. This was not likely to have affected their informed judgment to participate.

5.4 Confidentiality, anonymity and illegal activity

This research involved the collection of confidential and sensitive clinical data from participants. Every precaution was taken to ensure confidentiality and anonymity in recording the data. All research data information and documents, including all records of the identities and treatments of participants that were maintained in connection with the study have been regarded as confidential. The anonymity of participating participants has been maintained and their ID numbers have been concealed in the study documents.

The lead researcher (HA) has safely maintained all documents that identify the study participants(e.g., signed consent forms). To ensure confidentiality,

research electronic data/ documents were stored on a password-protected folder on the University of Leeds main server. Consent forms and any hard copies are stored in a locked filing cabinet in the School of Dentistry with access only by the lead researcher and the lead supervisor. The research data will be kept for at least two years after submission of the thesis or three years after the end of the study whichever is the longer.

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

5.5 Data protection

Collection of personal data has followed the eight principals of the Data Protection Act 2018. Any hard copies were stored in a locked filing cabinet in the School of Dentistry with access only by the lead researcher and the lead supervisor and were never taken off the premises at any time. Electronic data were stored in a password- protected folder on the secure University of Leeds server to ensure data were protected and that the data was backed-up appropriately.

5.6 Conflicts of interest

There was no potential for conflicts of interest in this research. This project was part of the Professional Doctorate Degree in Paediatric Dentistry. The lead researcher is Ms. Haya AL Zaabi under the supervision of Dr J.Tahmassebi (main supervisor), Professor B. Drummond and Dr K. Kenny (co-supervisors)

5.7 Withdrawal from the study

The study participants and their parents were been assured that their participation was completely voluntary and that withdrawal from the study at any point would not jeopardize current or future treatment. They were also assured that their routine dental visits would be carried out as normal even if they did not consent to take part in the study. All data information about withdrawn participants were analysed and reported in the study.

5.8 Declaration of the end of the study (Appendix S)

A notice of declaration of the end of the study (Appendix R) was sent to all the bodies who provided ethical approval to carry out this research project and an acknowledgment was received (Appendix S). The notice was sent after the end of the study when of 54 recruited participants completed their involvement.

5.9 Results dissemination

Results were disseminated by post to all participants who wanted to receive a summary of the results (Appendix T).

References

- Aartman, I.H., van Everdingen, T., Hoogstraten, J. and Schuurs, A.H., 1998. Self-report measurements of dental anxiety and fear in children: a critical assessment. *ASDC Journal of Dentistry for Children*, 65(4), pp.252-258.
- Accutron inc., n.d. Personal Inhaler and Nasal Hoods Brochures. Available at: <https://media.dentalcompare.com/m/25/Downloads/Personal%20Inhaler%20Plus%20Nasal%20Hoods%20Brochures.pdf> [Accessed 4th of February 2021].
- Alexopoulos, E., Hope, A., Clark, S.L., McHugh, S. and Hosey, M.T., 2007. A report on dental anxiety levels in children undergoing nitrous oxide inhalation sedation and propofol target controlled infusion intravenous sedation. *European Archives of Paediatric Dentistry*, 8(2), pp.81-86.
- Allen, K.D., Loiben, T., Allen, S.J. and Stanley, R.T., 1992. Dentist-implemented contingent escape for management of disruptive child behavior. *Journal of Applied Behavior Analysis*, 25(3), pp.629-636.
- Almquist, T.C. and Young, J.M., 1983. Clinical-evaluation of nitrous-oxide oxygen conscious sedation delivery systems. *Journal of Dental Research*, 62, p.173.
- Altimim, A., 2016. Quality of Life and Treatment Outcome Under Inhalation Sedation. D.Paed.Dent thesis, *University of Leeds*.
- American Dental Association, 2019. Nitrous oxide. Available at: <https://www.ada.org/en/member-center/oral-health-topics/nitrous-oxide> [Accessed March 2018].
- American Psychological Association, 2020. APA Dictionary of Psychology, Non-Verbal Communication Available at: <https://dictionary.apa.org/nonverbal-communication> [Accessed February 2021].
- American Society of Anesthesiologist a, 2021. ASA Physical Status Classification Available at: <https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system> [Accessed February 2021].
- American Society of Anaesthesiologist b, 2021. Continuum of depth of sedation: Definition of general anaesthesia and levels of sedation/analgesia. Available at: <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia> [Accessed 18th of January 2021].

- Analytical Methods Committee, 2020. Thermal desorption part 1: introduction and instrumentation. *Analytical Methods*, 12(26), pp.3425-3428.
- Armfield, J.M., 2010. How do we measure dental fear and what are we measuring anyway? *Oral health & preventive dentistry*, 8(2), pp.107-155.
- Armfield, J.M., 2010. Towards a better understanding of dental anxiety and fear: cognitions vs. experiences. *European Journal of Oral Sciences*, 118(3), pp.259-264.
- Badger, G. and Robertson, C.W., 1982. Nitrous oxide waste gas in the pedodontic operator. *Journal of the American Dental Association* (1939), 104(4), pp.480-481.
- Blain, K.M. and Hill, F.J., 1998. The use of inhalation sedation and local anaesthesia as an alternative to general anaesthesia for dental extractions in children. *British dental journal*, 184(12), pp.608-611.
- Bondemark, L. and Ruf, S., 2015. Randomized controlled trial: the gold standard or an unobtainable fallacy? *European Journal of Orthodontics*, 37(5), pp.457-461.
- British Association of Oral Surgeons, 2011. Conscious Sedation. Available at: https://www.baos.org.uk/resources/BDAGuidanceconscious_sedation_-_nov_11.pdf . [Accessed April 2018].
- Brukiene, V., Aleksejuniene, J. and Balciuniene, I., 2006. Is dental treatment experience related to dental anxiety? A cross-sectional study in Lithuanian adolescents. *Stomatologija*, 8(4), pp.108-115.
- Buchanan, H. and Niven, N., 2002. Validation of a Facial Image Scale to assess child dental anxiety. *International journal of paediatric dentistry*, 12(1), pp.47-52.
- Buchanan, H., 2005. Development of a computerised dental anxiety scale for children: validation and reliability. *British Dental Journal*, 199(6), pp.359-362.
- Buchanan, H., 2010. Assessing dental anxiety in children: The Revised Smiley Faces Program. *Child: care, health and development*, 36(4), pp.534-538.
- Cameron, A.C. and Widmer, R.P., 2008. Handbook of pediatric dentistry. *Elsevier Health Sciences*.
- Carrillo-Díaz, M., Crego, A., Armfield, J. and Romero, M., 2013. The moderating role of dental expectancies on the relationship between cognitive vulnerability and dental fear in children and adolescents. *Community dentistry and oral epidemiology*, 41(3), pp.269-278.

- Carson, P. and Freeman, R., 1998. Tell-show-do: reducing anticipatory anxiety in emergency paediatric dental patients. *International Journal of Health Promotion and Education*, 36(3), pp.87-90.
- Certosimo, F., Walton, M., Hartzell, D. and Farris, J., 2002. Clinical evaluation of the efficacy of three nitrous oxide scavenging units during dental treatment. *General dentistry*, 50(5), pp.430-437.
- Chadwick, B. 2002. Non-pharmacological behaviour management. *Annals of The Royal College of Surgeons of England, Faculty of Dental Surgery*.
- Christensen, J.R., Vann jr, W.F. and Linville, D.R. 1985. Measurement of scavenged nitrous oxide in dental operatory. *American Academy of Paediatric Dentistry*, 7(3), pp. 192-197.
- Chrysikopoulou, A., Matheson, P., Milles, M., Shey, Z. and Houpt, M., 2006. Effectiveness of two nitrous oxide scavenging nasal hoods during routine paediatric dental treatment. *Pediatric dentistry*, 28(3), pp.242-247.
- Cole-Adams, K. 2017. Surgeons Go Green: Recycling general anaesthetic. [Online]. Available at: <https://pursuit.unimelb.edu.au/articles/surgeons-go-green-recycling-general-anaesthetic> [Accessed June 2021].
- Craig, D. and Boyle, C., 2016. Guide to Inhalation Sedation. *RA: Medical Services Ltd UK*.
- Crego, A., Carrillo, M., Armfield, J.M. and Romero, M., 2014. From public mental health to community oral health: the impact of dental anxiety and fear on dental status. *Frontiers in public health*, 2, p.16.
- Davies, C., Harrison, M. and Roberts, G., 2008. Guideline for the use of general anaesthesia (GA) in Paediatric Dentistry. The Royal College of Surgeons of England 2008.
- Dean, J. A., Avery, D. R. and McDonald, R. E., 2010. McDonald and Avery dentistry for the child and adolescent. *Elsevier Health Sciences*.
- Dunning, D.G., McFarland, K. and Safarik, M., 1996. Nitrous-oxide use. I. Risk of potential exposure and compliance among Nebraska dentists and dental assistants. *General dentistry*, 44(6), pp.520-523.
- Dunning, D.G., McFarland, K. and Safarik, M., 1997. Nitrous-oxide use. II. Risks, compliance, and exposure levels among Nebraska dentists and dental assistants. *General dentistry*, 45(1), pp.82-86.

- Fayle, S. and Crawford, P.J.M., 1997. Making dental treatment acceptable to children. *Dent Profile*, 41, pp.178-182.
- Fayle, S.A. and Tahmassebi, J.F., 2003. Paediatric Dentistry in the new millennium: 2. Behaviour management—Helping children to accept dentistry. *Dental update*, 30(6), pp.294-298.
- Feigal, R.J., 2001. Guiding and managing the child dental patient: a fresh look at old pedagogy. *Journal of dental education*, 65(12), pp.1369-1377.
- Foster, R.L. and Park, J.H., 2012. An integrative review of literature examining psychometric properties of instruments measuring anxiety or fear in hospitalized children. *Pain Management Nursing*, 13(2), pp.94-106.
- Frankl, S., Shiere, F. and Fogels, H., 1962. Should the parent remain with the child in the dental operator? *J. Dent. Child.*, 29, pp.150-163.
- Freilich, M.M., Alexander, L., Sándor, G.K.B and Judd, P., 2007. Effectiveness of 2 scavenger mask systems for reducing exposure to nitrous oxide in a hospital-based paediatric dental clinic: a pilot study. *Journal of the Canadian Dental Association*, 73(7), pp.515-615d.
- Gadani, H. and Vyas, A., 2011. Anesthetic gases and global warming: Potentials, prevention and future of anaesthesia. *Anesthesia, essays and researches*, 5(1), pp.5-10.
- Ghose, L.J., Giddon, D.B., Shiere, F.R. and Fogels, H.R., 1969. Evaluation of sibling support. *ASDC journal of dentistry for children*, 36(1), p.35.
- Gilchrist, F., Whitters, C.J., Cairns, A.M., Simpson, M. and Hosey, M.T., 2007. Exposure to nitrous oxide in a paediatric dental unit. *International journal of paediatric dentistry*, 17(2), pp.116-122.
- Girdler, N. M., Hill C. M., Wilson, K. E. 2009. Clinical Sedation in Dentistry. *Chichester: Wiley-Blackwell*.
- Girdler, N. and HILL, C. 1998. Sedation in dentistry, Wright.
- Goodacre, S. and McCabe, C., 2002. An introduction to economic evaluation. *Emergency medicine journal: EMJ*, 19(3), pp.198-201.
- Gradko environmental a, n.d. How do sorbent tubes work for VOC monitoring? Available at: [how-do-sorbent-tubes-work.pdf](#) [Accessed November 2020].
- Gradko environmental b, n.d. Personal Monitor Instructions – Anaesthetic gases: Application Note 001. Available at;

<https://www.gradko.com/assets/downloads/Personal%20Monitoring%20-%20N2O%20Instructions.pdf> [Accessed November 2020].

Greenbaum, P.E., Turner, C., Cook, E.W. and Melamed, B.G., 1990. Dentists' voice control: Effects on children's disruptive and affective behavior. *Health Psychology*, 9(5), pp.546-558.

Hallonsten, A.L., Jensen, B., Raadal, M., Veerkamp, J., Hosey, M.T. and Poulsen, S., 2013. EAPD guidelines on sedation in paediatric dentistry. *European Academy of Paediatric Dentistry*. Available at: https://www.eapd.eu/uploads/5CF03741_file.pdf [Accessed November 2020].

Hansen, J., Schaal, N., Juarez, T. and Woodlee, C., 2019. Nitrous Oxide Exposure Among Dental Personnel and Comparison of Active and Passive Sampling Techniques. *Annals of work exposures and health*, 63(3), pp.337-348.

Hariton, E. and Locascio, J.J., 2018. Randomised controlled trials—the gold standard for effectiveness research. *BJOG: an international journal of obstetrics and gynaecology*, 125(13), p.1716.

Health and Social Care Information Center, 2015. Children's Dental Health Survey 2013; Report 1: Attitude, Behaviors and Children's Dental Health. Available at: <https://files.digital.nhs.uk/publicationimport/pub17xxx/pub17137/cdhs2013-report1-attitudes-and-behaviours.pdf> [Accessed February 2021].

Health Safety and Executive. 2011. Workplace Exposure Limits. www.hsebooks.co.uk. Available at: www.hse.gov.uk/pUbns/priced/eh40.pdf. [Accessed December 2017].

Henry, R.J., Primosch, R.E. and Courts, F.J., 1992. The Effects of Various Dental Procedures and Patient Behaviors Upon Nitrous Oxide Scavenger Effectiveness. *Paediatric Dentistry*, 14(1), pp.19-25.

Hosey, M. 2002. Managing anxious children: the use of conscious sedation in paediatric dentistry. *International Journal of Paediatric Dentistry*, 12(5), pp.359-372.

Howard, K.E. and Freeman, R., 2007. Reliability and validity of a faces version of the Modified Child Dental Anxiety Scale. *International Journal of Paediatric Dentistry*, 17(4), pp.281-288.

Humphris, G. and King, K., 2011. The prevalence of dental anxiety across previous distressing experiences. *Journal of anxiety disorders*, 25(2), pp.232-236.

- Humphris, G., Morrison, T. and Lindsay, S.J.E., 1995. The Modified Dental Anxiety Scale: UK norms and evidence for validity. *Community Dental Health*, 12(3), pp.143-150.
- Humphris, G.M., Wong, H.M. and Lee, G.T.R., 1998. Preliminary validation and reliability of the modified child dental anxiety scale. *Psychological reports*, 83(3_suppl), pp.1179-1186.
- Hu, X., Pierce, J.T., Taylor, T. and Morrissey, K., 2021. The carbon footprint of general anaesthetics: A case study in the UK. *Resources, Conservation and Recycling*, 167(2021), p.105411.
- Ingersoll, B.D., Nash, D.A. and Gamber, C., 1984. The use of contingent audiotaped material with paediatric dental patients. *Journal of the American Dental Association*, 109(5), pp.717-719.
- Intercollegiate Advisory Committee for Sedation in Dentistry, 2015. Standards for Conscious Sedation in the Provision of Dental Care. Available at: <https://www.rcseng.ac.uk/-/media/files/rcs/fds/publications/standards-for-conscious-sedation-and-accreditation/dental-sedation-report-v11-2020.pdf> [Accessed January 2021].
- Jimeno, F.G., Bielsa, S.Y., Fernández, C.C., Rodríguez, A.L. and Bellido, M.M., 2011. Objective and subjective measures for assessing anxiety in paediatric dental patients. *European Journal of Paediatric Dentistry*, 12(4), pp.239-244.
- Johnson, R. and Machen, J.B., 1973. Behavior modification techniques and maternal anxiety. *ASDC journal of dentistry for children*, 40(4), pp.272-276.
- Kang, H., 2013. The prevention and handling of the missing data. *Korean journal of anesthesiology*, 64(5), pp.402-406.
- Kilinc, G., Akay, A., Eden, E., Sevinc, N. and Ellidokuz, H., 2016. Evaluation of children's dental anxiety levels at a kindergarten and at a dental clinic. *Brazilian oral research*, 30(1).
- Kingkaew P and Teerawattananon, Y., 2014. The economic evaluation of medical devices: challenges. *J Med Assoc Thai*, 97(5), pp. S102-S107.
- Klingberg, G., Löfqvist, L.V. and Hwang, C.P., 1995. Validity of the children's dental fear picture test (CDFP). *European journal of oral sciences*, 103(1), pp.55-60.
- Koch, G. and Poulsen, S., 2009. Pediatric dentistry: a clinical approach. *Wiley-Blackwell*.

Krauss, B. and Green, S.M., 2006. Procedural sedation and analgesia in children. *The Lancet*, 367(9512), pp.766-780.

Lahoud, G.Y. and Averley, P.A., 2002. Comparison of sevoflurane and nitrous oxide mixture with nitrous oxide alone for inhalation conscious sedation in children having dental treatment: a randomised controlled trial. *Anaesthesia*, 57(5), pp.446-450.

Lahvic, N. and Liu, M., 2020. Waste gas scavenging system. [Online]. Available at: <https://www.statpearls.com/ArticleLibrary/viewarticle/31305> [Accessed June 2021].

LCS Laboratory Inc, n.d. What is "Reporting Limit" on a Laboratory Report? Available at [What is "Reporting Limit" on a Laboratory Report? – LCS Laboratory Inc.](#) [Accessed January 2021].

Lourenço-Matharu, L., Ashley, P.F. and Furness, S., 2012. Sedation of children undergoing dental treatment. *Cochrane Database of Systematic Reviews*, (3).

Machen, J.B. and Johnson, R., 1974. Desensitization, model learning, and the dental behavior of children. *Journal of Dental Research*, 53(1), pp.83-87.

Malamed, S.F., 2017. *Sedation: a guide to patient management*. 6th ed. Missouri: Mosby Elsevier.

MARKES international Ltd, 2015. Application Note 1: Uptake rates for tube-type axial diffusive samplers. Available at: <https://www.selectscience.net/application-articles/uptake-rates-for-tube-type-axial-diffusive-samplers/?artid=38041> [Accessed December 2020].

Matrx by Midmark, 2006. The Matrx Scavenger. Figure 4 available at: <https://swmdinc.com/equipment/Analgesia/matrx/Scavenger.pdf> [Accessed February 2021].

McKnight-Hanes, C., Myers, D.R., Dushku, J.C. and Davis, H.C., 1993. The use of behavior management techniques by dentists across practitioner type, age, and geographic region. *Pediatric dentistry*, 15, pp.267-267.

Melanie, B., 2003. Where will it all go wrong? Taking valid workplace air samples 6 common pitfall areas and how to avoid them. Available at: [SKC Article \(P47&48\) \(skcltd.com\)](#) [Accessed November 2020].

Milgrom, P., Newton, J.T., Boyle, C., Heaton, L.J. and Donaldson, N., 2010. The effects of dental anxiety and irregular attendance on referral for dental treatment

under sedation within the National Health Service in London. *Community dentistry and oral epidemiology*, 38(5), pp.453-459.

Murphy, M. G., Fields JR, H. W. and Machen, J. B. 1984. Parental acceptance of pediatric dentistry behavior management techniques. *Pediatric Dentistry*, 6(4), 193-198.

National Institute for Health and Clinical Excellence (NICE), 2010. Sedation in children and young people: sedation for diagnostic and therapeutic procedures in children and young people. Available at:

<https://www.nice.org.uk/guidance/cg112/evidence/full-guideline-136287325>

[Accessed November 2018].

National Institute for Occupational Safety and Health, 2014. Controlling Exposures to Nitrous Oxide During Anesthetic Administration. Available at:

<https://www.cdc.gov/niosh/docs/94-100/>. [Accessed April 2018].

Nuttall NM, Gilbert A, Morris J. Children's dental anxiety in the United Kingdom in 2003. *Journal of dentistry*. 2008 Nov 1;36(11):857-60.

Parker Hannifin Corporation, Porter Instrument Division a, n.d. User Instructions for Assembly Installation and Cleaning - PORTER Scavenger System with the Silhouette Disposable Breathing Circuit. Catalog no. FM-1313. USA. Available at: <https://ramedical.com/wp-content/uploads/2017/11/Silhouette-User-Instructions-FM-1313-1-15.pdf> [Accessed November 2017].

Parker Hannifin Corporation, Porter Instrument Division b, n, d. User Instructions for Assembly Installation and Cleaning - PORTER Scavenger Rubber Goods System. Catalog no. FM-809. USA. Available at: <https://porterinstrument.com/pdf/datasheets/Porter-Scavenger-Rubber-Goods-System-Users-Manual-FM-809.pdf> [Accessed December 2017].

Paterson, S.A. and Tahmassebi, J, 2003. Paediatric dentistry in the new millennium: 3. Use of inhalation sedation in paediatric dentistry. *Dental update*, 30(7), pp.350-358.

Pickles, J. 2016. Guide to Scavenging of Nitrous Oxide. *RA: Medical Services Ltd. UK*. Available at: <https://ramedical.com/wp-content/uploads/2016/08/DN-Guide-to-Scavenging-1.pdf> [Accessed December 2017].

Porritt, J., Marshman, Z. and Rodd, H.D., 2012. Understanding children's dental anxiety and psychological approaches to its reduction. *International journal of paediatric dentistry*, 22(6), pp.397-405.

Porter Instrument. 2015. Silhouette Nitrous Mask: Nasal Hood Style for Nitrous Oxide Sedation Porter Instrument. Available at:

<http://www.porterinstrument.com/silhouette>. [Accessed April 2018].

Porter instrument, 2021. Porter Double Mask Autoclavable Nasal Hood Kit with Liners. Figure 5 available at: <https://www.porterinstrument.com/dental/porter-double-mask-autoclavable-hood-kit-w-liners> [Accessed January 2021]

Porter Instrument a, n.d. Matrx Scavenger Breathing Circuit Inhalation sedation delivery system manual. Available at: [Matrx-Scavenger-Instruction-Manual-10489600.pdf \(porterinstrument.com\)](https://www.porterinstrument.com/files/10489600.pdf) [Accessed January 2021].

Porter instrument b, n.d. Porter Silhouette Low Profile Nasal mask. Figure 7&8 available at: <https://porterinstrument.com/pdf/datasheets/Porter-Silhouette-Nasal-Mask-Brochure-FM-1320.pdf> [Accessed February 2021].

Porter Matrx, n.d. Silhouette Low Profile Nasal Mask. Figure 6 available at: [Porter-Matrx-Breathing-Circuit-Parts-FM-1360.pdf \(porterinstrument.com\)](https://porterinstrument.com/files/Porter-Matrx-Breathing-Circuit-Parts-FM-1360.pdf) [Accessed February 2021]

Primosch, R.E., Buzzi, I.M. and Jerrell, G., 1999. Effect of nitrous oxide-oxygen inhalation with scavenging on behavioural and physiological parameters during routine paediatric dental treatment. *Pediatric Dentistry*, 21(7), pp.417-20.

RA Medical Services Ltd, 2014. Guide to Inhalation sedation safety. Figure 1 available at: <https://ramedical.com/wp-content/uploads/2016/09/GUIDE-TO-Inhalation-Sedation-Safety.pdf> [Accessed December 2017].

RA Medical Service Ltd, 2017. Explanatory Overview of Dental Nitrous Oxide Scavenger Breathing Systems. Available at: [Explanatory Overview of Dental Nitrous Oxide Scavenger Breathing Systems - RA Medical Services Ltd](https://www.ramedical.com/wp-content/uploads/2017/01/Explanatory-Overview-of-Dental-Nitrous-Oxide-Scavenger-Breathing-Systems-RA-Medical-Services-Ltd.pdf) [Accessed January 2021].

RA Medical Service Ltd, 2020. Covid 19 Infection control Guide. Available at: [Covid 19 Infection control Guide - RA Medical Services Ltd](https://www.ramedical.com/wp-content/uploads/2020/03/Covid-19-Infection-control-Guide-RA-Medical-Services-Ltd.pdf) [Accessed December 2020].

RA Medical Services Ltd, 2021. The Inhalation Sedation Specialists. Figure 2,3,5 available at: <https://ramedical.com/wp-content/uploads/2021/02/RA-Medical-Catalogue-2-2021-rev-B1-WEB-1.pdf> [Accessed February 2021].

Reeve, 1855. Sampling Solutions for Health Care. Available at: [Sampling Solutions for Health Care \(skcltd.com\)](https://www.skcltd.com/solutions-for-health-care) [Accessed November 2020].

- Roberts, G.J., 1990. Inhalation sedation (relative analgesia) with oxygen/nitrous oxide gas mixtures: 1. Principles. *Dental update*, 17(4), pp.139-142.
- Roberts, J.F., 1995. How important are techniques? The empathic approach to working with children. *ASDC journal of dentistry for children*, 62(1), pp.38-43.
- Rowland, A.S., Baird, D.D., Shore, D.L., Weinberg, C.R., Savitz, D.A. and Wilcox, A.J., 1995. Nitrous oxide and spontaneous abortion in female dental assistants. *American Journal of Epidemiology*, 141(6), pp.531-538.
- Salter and Ltd, 2005. Active versus Passive Air Sampling. Available at: file:///C:/Users/M&H/Downloads/072_073_iet_sept_05.pdf [Accessed November 2020].
- Sanchez, S.A., Eckelman, M.J. and Sherman, J.D., 2020. Environmental and economic comparison of reusable and disposable blood pressure cuffs in multiple clinical settings. *Resources, Conservation and Recycling*, 155(2020), p.104643.
- Sawtell, R., Simon jr, J. and Simeonsson, R. 1974. The effects of five preparatory methods upon child behavior during the first dental visit. *ASDC Journal of Dentistry for Children*, 41(5), pp.367-375.
- Scottish Dental Clinical Effectiveness Programme. (SDCEP). 2017. Conscious Sedation in Dentistry Dental Clinical Guidance, 3rd edition. Dundee: Scottish Dental Clinical Effectiveness Programme.
- Scottish Intercollegiate Guidelines Network (SIGN). 2004. Safe Sedation of Children Undergoing Diagnostic and Therapeutic Procedures A national clinical guideline [58]. Scotland: Scottish Intercollegiate Guidelines Network.
- Shinohara, S., Nomura, Y., Shingyouchi, K., Takase, A., Ide, M., Moriyasu, K., Idaira, Y., Takahashi, T., Yamada, Y., Aoyagi, Y. and Asada, Y., 2005. Structural relationship of child behavior and its evaluation during dental treatment. *Journal of oral science*, 47(2), pp.91-96.
- Suresh, K.P., 2011. An overview of randomization techniques: an unbiased assessment of outcome in clinical research. *Journal of human reproductive sciences*, 4(1), pp.8-11.
- Soldani, F., Manton, S., Stirrups, D.R., Cumming, C. and Foley, J., 2010. A comparison of inhalation sedation agents in the management of children

receiving dental treatment: a randomized, controlled, cross-over pilot trial.

International Journal of Paediatric Dentistry, 20(1), pp.65-75.

Sonnenberg, E. and Venham, L., 1977. Human figure drawings as a measure of the child's response to dental visits. *ASDC journal of dentistry for children*, 44(6), pp.438-442.

Stokes, T.F. and Kennedy, S.H., 1980. Reducing child uncooperative behavior during dental treatment through modelling and reinforcement. *Journal of Applied Behavior Analysis*, 13(1), pp.41-49.

THEMESSL-HUBER, M., Freeman, R., Humphris, G., Macgillivray, S. and Terzi, N., 2010. Empirical evidence of the relationship between parental and child dental fear: a structured review and meta-analysis. *International journal of paediatric dentistry*, 20(2), pp.83-101.

Thrash, W.J., Marr, J.N. and Box, T.G., 1982. Effects of continuous patient information in the dental environment. *Journal of dental research*, 61(9), pp.1063-1065.

Vanhee, T., Lachiri, F., Van Den Steen, E., Bottenberg, P. and Abbee, A.V., 2020. Child behaviour during dental care under nitrous oxide sedation: a cohort study using two different gas distribution systems. *European Archives of Paediatric Dentistry*, pp.1-7.

Venham, L.L. and Gaulin-Kremer, E., 1979. A self-report measure of situational anxiety for young children. *Pediatric Dentistry*, 1(2), pp.91-96.

Wardle, J., 1982. Fear of dentistry. *British Journal of Medical Psychology*, 55(2), pp.119-126.

Weinstein, P. and Nathan, J.E., 1988. The challenge of fearful and phobic children. *Dental Clinics of North America*, 32(4), pp.667-692.

Weinstein, P., Getz, T., Ratener, P. and Domoto, P., 1982. The effect of dentists' behaviors on fear-related behaviors in children. *Journal of the American Dental Association*, 104(1), PP.32-38.

Welbury, R., Duggal, M., and Hosey, M., 2018. *Paediatric Dentistry*. 5thed. Oxford University Press.

Westberg, H., Egelrud, L., Ohlson, C.G., Hygerth, M. and Lundholm, C., 2008. Exposure to nitrous oxide in delivery suites at six Swedish hospitals. *International archives of occupational and environmental health*, 81(7), pp.829-836.

Wilson, K., 2016. Guide to Inhalation Sedation Safety. *RA: Medical Services Ltd. UK.*

Wilson, K.E., 2013. Overview of paediatric dental sedation: 1. current UK guidelines. *Dental update*, 40(9), pp.728-730.

Wong, D.L. and Baker, C.M., 1988. Pain in Children: Comparison of Assessment Scales. *Pediatric Nursing*. 14(1), pp. 9-17.

Wright, G. Z., 1975. Behavior management in dentistry for children. *Saunders*.

Wright, G. Z., Starkey, P. E., Gardner, D. E. And Curzon, M. E., 1987. Child management in dentistry. *Wright*.

Yamada, M.K.M., Tanabe, Y., Sano, T. and Noda, T., 2002. Cooperation during dental treatment: The Children's Fear Survey Schedule in Japanese children. *International journal of paediatric dentistry*, 12(6), pp.404-409.

Yasny, J.S. and White, J., 2012. Environmental implications of anaesthetic gases. *Anesthesia progress*, 59(4), pp.154-158.

Yee, R., Wong, D., Chay, P.L., Wong, V.Y.Y., Chng, C.K. and Hosey, M.T., 2019. Nitrous oxide inhalation sedation in dentistry: An overview of its applications and safety profile. *Singapore dental journal*, 39(01), pp.11-19.

Zabiegała, B., Kot-Wasik, A., Urbanowicz, M. and Namieśnik, J., 2010. Passive sampling as a tool for obtaining reliable analytical information in environmental quality monitoring. *Analytical and bioanalytical chemistry*, 396(1), pp.273-296.

Appendices

Appendix A Sponsorship approval



Trueman House
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17 September 2018

To Whom it May Concern

Dear Sirs,

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

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

EMPLOYERS LIABILITY

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

INSURER	:	Zurich Municipal
POLICY NUMBER	:	NHE-03CA02-0016
PERIOD OF INSURANCE	:	29 th September 2018 – 28 th September 2019
LIMIT OF INDEMNITY	:	£40,000,000 each occurrence including costs and expenses

PUBLIC/PRODUCTS LIABILITY

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

INSURER	:	Zurich Municipal
POLICY NUMBER	:	NHE-03CA02-0016
PERIOD OF INSURANCE	:	29 th September 2018 – 28 th September 2019
LIMIT OF INDEMNITY	:	£40,000,000 each occurrence (and in the aggregate in respect of Products)

PROFESSIONAL INDEMNITY

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

INSURER	:	Royal & Sun Alliance
POLICY NUMBER	:	RKK665002
PERIOD OF INSURANCE	:	29 th September 2018 – 28 th September 2019
LIMIT OF INDEMNITY	:	£10,000,000 each occurrence and in the aggregate

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

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

/Continued.....

- 2 -

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

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

Yours faithfully,


Rhydian Thomas
Director

Direct Dial: 0113 393 6826
Email: rhydian.thomas@hibl.co.uk

Appendix B Research Ethics Committee approval letter



Miss Haya Alzaabi
Flat 6 , 65 Saint Paul's street
Leeds
LS12TE

18 January 2019

Dear Miss Alzaabi



Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	Comparison of the Silhouette and Porter Brown Systems Used in Inhalation Sedation
IRAS project ID:	233026
Protocol number:	N/A
REC reference:	18/YH/0489
Sponsor	University of Leeds

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?

You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the “*summary of assessment*” section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a ‘green light’ email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important 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 of the research management function for each organisation can be accessed [here](#).

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

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.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Tel: 01133437587

Email: governance-ethics@Leeds.ac.uk

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **233026**. Please quote this on all correspondence.

Yours sincerely

Helen Penistone
Assessor

IRAS project ID	233026
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Email: hra.approval@nhs.net

Copy to: *Faculty NHS Research Ethics Officer, University of Leeds (sponsor contact)*
Ms Doly Coutinho, Research & Innovation Department (lead NHS R&D contact)

IRAS project ID	233026
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List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [poster]	V3	09 January 2019
Covering letter on headed paper [covering letter]	V1	14 January 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Leeds]		17 September 2018
HRA Schedule of Events	1	17 January 2019
HRA Statement of Activities	1	18 January 2019
IRAS Application Form [IRAS_Form_20112018]		20 November 2018
Non-validated questionnaire [lead researcher questionnaire]	V4	09 January 2019
Other [FIS]	V2	09 January 2019
Other [monitoring sheet]	V6	09 January 2019
Other [Data collection sheet]	V3	09 January 2019
Participant consent form [parent consent form]	V5	09 January 2019
Participant consent form [child assent form]	V5	09 January 2019
Participant information sheet (PIS) [information sheet 7to10]	V5	09 January 2019
Participant information sheet (PIS) [child information sheet 11 to 16]	V7	09 January 2019
Participant information sheet (PIS) [parent information sheet]	V8	18 January 2019
Research protocol or project proposal [Protocol]	V12	07 November 2018
Summary CV for Chief Investigator (CI) [CV]	V1	07 November 2018
Summary CV for supervisor (student research) [CV]		07 November 2018
Summary CV for supervisor (student research) [CV]		07 November 2018
Summary CV for supervisor (student research) [CV]		07 November 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [study schema]	V3	07 November 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [timeline]	2	07 November 2018
Validated questionnaire [child feedback questionnaire]	V3	09 January 2019

Summary of assessment

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

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Non-substantial amendments were made to the Parent Information Sheet following the REC favourable opinion.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	No external funding has been sought to support the study. No funding will be available to site.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments

Section	Assessment Criteria	Compliant with Standards	Comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

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

This is a single site study. The site will host all site activities.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

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

A principal investigator has been identified at site.

No training will be provided to local staff at site.

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

HR Good Practice Resource Pack Expectations

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

Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires), would be expected to obtain an honorary research contract from the NHS organisation. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

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

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

Appendix C Clinical Service Unit approval

The Leeds Teaching Hospitals 
NHS Trust

LTHT Research Study Capacity and Capability Assessment Form

A new **LTHT wide process** for the assessment of capacity and capability (formerly known as CSU approval) of research studies conducted at LTHT will be introduced from the 18th September 2017.

From this date onwards, if you wish to conduct a research study at LTHT involving LTHT patients please complete the attached form and submit to your CSU for review and approval. A completed and fully signed copy of this form must be submitted to LTHT R&I as evidence of CSU confirmation that there is capacity and capability within the CSU to deliver the study safely and effectively, meeting all governance requirements and performance targets. Supplementary CSU specific feasibility paperwork may still be used locally to aid decision making but only this form will be accepted by LTHT R&I as part of the organisational confirmation of capacity and capability process.

- **Part A** - must be completed for all research studies
- **Part B** - should be completed where applicants require use of **LTHT Clinical Research Facility** (LCRF) facilities and resources

PART A (to be completed by all research teams)

Section 1: Study Details

Study Acronym: Comparison of the Silhouette and Porter Brown Systems

Full Study Title: Comparison of the Silhouette and Porter Brown breathing Systems Used in Inhalation Sedation

Reference Numbers:

R&I	IRAS Number	NIHR Portfolio (if applicable)
18/EE/0397	233026	Click here to enter text.

Chief/Principal Investigator Details:

Name: Haya Alzaabi
Email: dnhza@leeds.ac.uk
Telephone: 07749098178

Has the Chief/Principal Investigator acted in this capacity for a previous study?

If no, please give details of any

CI/PI training undertaken:

All new CIs/PIs at LTHT must have completed CRN PI training before their study can be approved. In-house training sessions will be made available to support compliance.

Study Lead Nurse/ Research Fellow Details:

Name	Job title	Email
Nil	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

Predicted Start date: Feb 2019

Duration: 7 months

No. of participants to be recruited at this centre: 54

How will participants be recruited?: From Sedation unit,
Paediatric Department,
Leeds Dental Institute

How many patients at LTHT would have been eligible in the last 12 months?: Not sure, but is quiet
enough maybe around
60 or more

Section 2: Study Overview**Chief Investigator Details:**

Name: Haya Alzaabi
Lead Centre Location: Leeds Dental Institute

Patient and Public Involvement: If PPI involvement has taken place locally, please describe.

Study summary: Please provide a (plain English) summary of your study.

This is a randomised non-blinded controlled clinical trial, which involves the measurement of efficiency and acceptability of the Silhouette Mask system and compares it with the Porter Brown Mask system used for Inhalation Sedation in children having dental treatment at the Leeds Dental Institute.

All eligible participants will be introduced to both masks (Porter Brown and Silhouette) in the assessment session prior to their first treatment session. Then participants will be randomly allocated to undergo treatment under nitrous oxide-oxygen inhalation sedation using either the Porter Brown or the Silhouette System. The efficiency and acceptability will be measured by a

Are there any elements of the study schedule that constitute Standard of Care?

No

If yes, please give details:

[Click here to enter text \(250 words maximum\).](#)

Total planned recruitment nationally/internationally:

54

Tick all NIHR reporting groups applicable to the study:

Biomedical Research Centre (BRC) ☐

Clinical Research Facility (CRF) ☐

MedTech and In Vitro Diagnostic Cooperative (MIC) ☐

NIHR Portfolio Performance Initiation & Delivery (PID) ☐

None of the above

Are there specific competencies or training requirements for the study team?:

No

If yes, please specify: [Click here to enter text.](#)

Section 3: Study Type

Please select the most appropriate study type from the following drop downs. All questions are mandatory:

A. Is the study interventional or non-interventional?

Interventional

Interventional studies ONLY:

B1. What phase is your study?

Other - Please define below

Version 1.0, 07/11/2017, LTHT Research & Innovation

If Other selected, please define:

Treatment- data
collection

Non-interventional studies ONLY:

B2. What type is your study?

Choose a category.

If Other selected, please define:

Click here to enter text.

All studies:

C. Please select the primary intervention/area:

Device

If Other selected, please define:

D. Is this study classified as Experimental Medicine?

No

E. Is this study randomised?

Yes

F. Is this study classified as First in Human?

No

G. Is this study a Clinical Trial of an Investigational Medicinal Product (CTIMP), requiring a Clinical Trials Authorisation (CTA) from the MHRA?

No

H. Is this study an Advanced Therapy Investigational Medicinal Product (ATIMP)?

No

I. Is your study classified as early phase (Pilot/Feasibility, Phase 0, I or II)?

No

J. Is your study classified as late phase (Phase 3 or 4) and has a translational aspect?

No

Section 4: Study Support

Please select the relevant support departments you have already contacted and provide contact information:

Radiology ☐

Name of contact:

Click here to enter name.

Email:

Click here to enter email.

Pharmacy ☐

Name of contact:

Click here to enter name.

Email:

Click here to enter email.

Pathology ☐

Name of contact:

Click here to enter name.

Version 1.0, 07/11/2017, LTH Research & Innovation

Email: Other ☐

Please specify department:
Name of contact:
Email:

CTIMP studies: Is there an exit strategy in place for the end of the study?

Section 5: Funding Details

Main Funding Organisation

Are you in receipt of funding to support this study?

Name of main funding organisation:

Select the category of the main study type:
If selected DH/NIHR, or Other, please define:

Have you selected "Use of the CRF" in the set-up costs section of the commercial study costing template?

Have you applied for NIHR portfolio adoption?:
If yes, date applied:
Number (if known/assigned):

Are any research fellowships, Masters or PhD students attached to or supported by the study?

NOTE: If yes, University of Leeds honorary contracts and GCP training are required prior to commencement of the study.

Grant Administering Organisation (if applicable, please state for academic studies)

Which body will provide the research grant?

Which organisation will administer the research grant?

Sponsor

Which organisation will be acting as the research governance sponsor?

Has research governance sponsorship been confirmed?

Account Holder

The account for the study will be held at:
 If Other, please give details:

CSU Signature

CI/PI Name (print): Haya Alzaabi	Date: 26/01/2019
CI/PI Signature: <i>Haya alzaabi</i>	
Outcome of review: Agreed ☒ Provisional ☐ Rejected ☐	
Details if Provisional or Rejected:	
Name of CSU Approved Signatory (print) Dr J C STEELE CLINICAL DIRECTOR, LEEDS DENTAL INSTITUTE	Date: 07/02/2019
CSU Signature: 	

If your study is early phase or late phase with a translational aspect (see Section 3, Questions I and J), it may qualify to be supported by the Leeds Clinical Research Facility. If so, please complete PART B:

PART B (to be completed if LCRF support is to be requested)

Section 6: Site Specific Information

Please tick which site facilities you wish to use:

Bexley (SJUH) ☐	Jubilee (LGI) ☐	Chapel Allerton ☐
Dental (DenTRU) ☒	Clarendon Wing (Paeds) ☐	

Please tick which LCRF services/ facilities you would like to use:

ECG ☐	Inpatient monitoring ☐	Blood testing/ sampling ☐
Patient monitoring ☐	Cardiac ultrasound ☐	Cardiac monitoring ☐
Drug infusion ☐	ETT/ CPEX ☐	
Other (please specify) ☒		
Sedation unit		

Intensity of study (Please see Appendix A for instructions on how to assess):

Risk of study (Please see Appendix B for instructions on how to assess):

Please outline any other issues that may impact on capacity and capability:

[Click here to enter text.](#)

Describe any safety aspects that LCRF staff need to be aware of (e.g. adverse drug reactions, risk to patients from procedures, etc.)

The risk for any routine sedation treatment is increase risk of nausea and vomiting (10% of the patients). All the staff and researchers are trained to deal with any side effects that may arise from sedation.

Publication Guidelines & Acknowledgement

Work undertaken in the LCRF should be acknowledged in all publications and press releases. This includes work that is funded through any charity or grant funding source and not merely that directly funded by NIHR.

If any person or organisation involved in the study wants to publish a press release regarding work to be published, the NIHR Clinical Commissioning Facility (CCF) must be sent a copy of the manuscript 28 days before publication (see LCRF Hub Team for guidance).

Please tick here to acknowledge you have read and agreed to these guidelines: ☒

Section 7: Approvals and Signatures

You must submit this form to the email address below, after which the LCRF Senior Hub Team will discuss with the research study team and, subject to agreement, give approval for LCRF support.

LCRF Contact Details

Email: leedsth-tr.CRF@nhs.net

Telephone: 0113 20 60474

Address: Leeds Clinical Research Facility, First Floor, Research & Innovation Centre, St. James's University Hospital, Beckett Street, Leeds, West Yorkshire, LS9 7TF

CI/PI Name (print):	Date:
CI/PI Signature:	
Outcome of review: Agreed ☐ Provisional ☐ Rejected ☐	
Details if Provisional or Rejected: Click here to enter text.	
Name of CRF Approved Signatory (print):	Date:
Review Signature:	

Appendix A: Assessing the Intensity of Your Study

Please read the handbook carefully and complete the spreadsheet. This spreadsheet may take an hour or more for complex studies.

Please submit the completed Intensity Spread Sheet with your completed Capacity & Capability Assessment and Application Form.

Handbook for completing the Intensity Tool Spread Sheet	 CRF Intensity Tool v12_01Apr14_Handb
Intensity Tool Spread Sheet	 CRF Intensity Tool v12_01Apr14.xlsx

Appendix B: Assessing the Risk of Your Study

Please read the instructions and use the tool to assess the risk of your study.

Instructions for Assessing Risk	 Risk Tool Guidance for CRFs.docx
Risk Assessment Tool	 UKCRF Risk assessment tool.doc

Appendix D NHS Research and Development approval



Date: 17th July 2019
Our Ref: DT19/121465

Private and Confidential

Dr Haya Alzaabi
Flat 6
65 St Paul's Street
Leeds
LS1 2TE

LTHT Resourcing Service
Trust Headquarters
St James's University Hospital
Beckett Street
Leeds
LS9 7TF

Direct Line (0113) 2065980
www.leedsth.nhs.uk

Dear Dr Alzaabi

Letter of Access for Research - Project Title: Comparison of the Silhouette and Porter Brown breathing systems used in Inhalation Sedation

This letter confirms your right of access to conduct research through The Leeds Teaching Hospitals NHS Trust for the purpose and on the terms and conditions set out below. This right of access commences on **16th July 2019** and ends on **15th July 2022** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at The Leeds Teaching Hospitals NHS Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to The Leeds Teaching Hospitals NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through The Leeds Teaching Hospitals NHS Trust, you will remain accountable to your employer **University of Leeds** but you are required to follow the reasonable instructions of **John Steele** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

You must act in accordance with The Leeds Teaching Hospitals NHS Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

Chair Dr Linda Pollard CBE DL Chief Executive Julian Hartley

The Leeds Teaching Hospitals NHS Trust incorporating: Chapel Allerton Hospital, Leeds Cancer Centre, Leeds Children's Hospital, Leeds Dental Institute, Leeds General Infirmary, Seacroft Hospital, St James's University Hospital, Wharfedale Hospital.

You are required to co-operate with The Leeds Teaching Hospitals NHS Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on The Leeds Teaching Hospitals NHS Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Where required by law, your HEI employer will initiate your Independent Safeguarding Authority (ISA) registration, and thereafter, will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity. You MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

The Leeds Teaching Hospitals NHS Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Mandy Walker
Head of Resourcing

cc: R&D office at Leeds Teaching Hospitals NHS Trust
HR department of the substantive employer (and provider of honorary clinical contract, where applicable)

Chair Dr Linda Pollard CBE DL Chief Executive Julian Hartley

The Leeds Teaching Hospitals NHS Trust incorporating: Chapel Allerton Hospital, Leeds Cancer Centre, Leeds Children's Hospital, Leeds Dental Institute, Leeds General Infirmary, Seacroft Hospital, St James's University Hospital, Wharfedale Hospital.

Appendix E Research passport

Research Passport Application Form – Version 3 01/09/2012

Please refer to the guidance notes before completing the form.

Section 1 - Details of Researcher To be completed by Researcher			
1.	Surname: Alzaabi		Prof ☐ Dr ☒ Mr ☐ Mrs ☐
	Forename(s): Haya		Miss ☐ Ms ☐ Other ☐
	Home Address: Flat 6, 65 St Paul's Street, LS12TE, Leeds, UK		
	Work Tel: Mobile: 07749098178 Email: dnhza@leeds.ac.uk		
2.	Date of birth: 24/09/1987	Gender: Male ☐ Female ☒	
	Ethnicity: Arab	National Insurance number: N/A	
3.	Professional registration details, if applicable (Doctors undertaking any form of medical practice should confirm they have a licence to practise). N/A ☒		
4.	Employer:		or place of study: University Of Leeds
	Work Address/Place of Study: Department of Paediatric Dentistry, University of Leeds, School of Dentistry -Clarendon Way Leeds, UK LS2 9LU		
	Post or status held: Post Graduate student 3rd year		
Section 2 - Details of Research To be completed by Researcher			
5.	What type of Research Passport do you need? Project-specific ☒ Multi-project ☐		
	If you will be conducting one project only please complete the details below. If you anticipate that you will be undertaking more than one project at any one time, please give details in the Appendix.		
	Project Title: Comparison of the Silhouette and Porter Brown breathing Systems Used in Inhalation Sedation		
	Project Start Date: Feb 2019 End Date:		
	Proposed start and end-date of 3-year Research Passport: 07/19/121465		
	Start Date: Feb 2019 End Date: August 2019		
	NHS organisation(s):	Dept(s):	Proposed research activities:
	Leeds Dental Hospital LTHT	Paediatric Dentistry-Sedation Unit	feedback questionnaire after treatment under Sedation
			Manager in NHS organisation: Dr John Steele
Section 3 – Declaration by Researcher To be completed by Researcher			
6.	Have you ever been refused an honorary research contract?		Yes ☐ No ☒
	Have you ever had an honorary research contract revoked?		Yes ☐ No ☒
	If yes to either question, please give details:		
I consent to the information provided as part of this Research Passport and attached documents being used, recorded and stored by authorised staff of the NHS organisations where I will be conducting research.			
Signed: Haya Alzaabi		Date: 6/02/2019	
When Sections 1-3 have been completed, the researcher should forward the form to the appropriate person to complete Section 4.			

Section 4 - Suitability of Researcher																	
<i>To be completed by researcher's substantive employer, e.g. line manager, or academic supervisor</i>																	
7.a	Will this person's research activity mean that they may be undertaking regulated activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012)? (please use the Research Passport algorithm to make this judgement)																
	Yes ☒ No ☐																
7.b	I am satisfied that the above named individual is suitably trained and experienced to undertake the duties associated with the research activities outlined in this Research Passport form.																
	Signed: <u>J. Tahmassebi</u> Date: <u>20/2/2019</u>																
	Name: <u>Jinious Tahmassebi</u> Job Title: <u>Associate Professor</u>																
	Department and Organisation:																
	Address: <u>Department of Paediatric dentistry- Worsley Building - School of Dentistry</u>																
	Tel No: <u>0113 343 3955</u> Email: <u>J.Tahmassebi@leeds.ac.uk</u>																
	Managerial responsibility for the applicant: <u>Academic Supervisor</u>																
When Section 4 has been completed, the researcher should forward the form to the appropriate person to complete Section 5.																	
Section 5 - Pre-engagement checks <i>To be completed by the HR department of the researcher's substantive employer or registry at place of study</i>																	
8.	Does the above named individual's research involve Regulated Activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012)?																
	☒ Yes ☐ No																
	If yes to the above, has the above named individual been checked against ISA barred lists for adults and/or children, as appropriate and have you received confirmation via the criminal record disclosure that the person is not barred from working with adults and/or children? (NB individuals who are barred from working with adults or children must not undertake a regulated activity in the NHS with the vulnerable group from which they are barred, and you must not submit a Research Passport form in such cases).																
	Checked against: ISA Adults List? Yes ☐ No ☐ N/A ☒ ISA Children's List? Yes ☒ No ☐ N/A ☐																
	Can you confirm that a clear criminal record disclosure has been obtained for the above-named individual, with no subsequent reports from the individual of changes to this record? NB for Regulated Activity this must be an enhanced level criminal record check. For non-regulated activity, ensure the criminal record check is at the mandated level.																
	Yes ☒ No ☐ N/A ☐																
	If yes, please provide details of the clear disclosure:																
	Date of disclosure: <u>25/4/2019</u> Type of disclosure: <u>ENHANCED</u>																
	Disclosure No.: <u>001655853922</u> Organisation that requested disclosure: <u>UNIVERSITY OF LEEDS</u>																
9.	Have the pre-engagement checks described below been carried out with regard to the above-named individual and is confirmation of the necessary checks, including any required satisfactory documentary evidence, available in the employing organisation's/place of study's records?																
	<table border="0"> <tr> <td colspan="2">■ Employment/student screening:</td> </tr> <tr> <td>○ ID with photograph</td> <td>Yes ☒ No ☐</td> </tr> <tr> <td>○ two references</td> <td>Yes ☒ No ☐</td> </tr> <tr> <td>○ verification of permission to work/study in the UK</td> <td>Yes ☒ No ☐</td> </tr> <tr> <td>○ exploration of any gaps in employment</td> <td>Yes ☒ No ☐</td> </tr> <tr> <td>■ Evidence of current professional registration</td> <td>Yes ☒ No ☐ N/A ☐</td> </tr> <tr> <td>■ Evidence of qualifications</td> <td>Yes ☒ No ☐</td> </tr> <tr> <td>■ Occupational health screening / clearance</td> <td>Yes ☒ No ☐</td> </tr> </table>	■ Employment/student screening:		○ ID with photograph	Yes ☒ No ☐	○ two references	Yes ☒ No ☐	○ verification of permission to work/study in the UK	Yes ☒ No ☐	○ exploration of any gaps in employment	Yes ☒ No ☐	■ Evidence of current professional registration	Yes ☒ No ☐ N/A ☐	■ Evidence of qualifications	Yes ☒ No ☐	■ Occupational health screening / clearance	Yes ☒ No ☐
■ Employment/student screening:																	
○ ID with photograph	Yes ☒ No ☐																
○ two references	Yes ☒ No ☐																
○ verification of permission to work/study in the UK	Yes ☒ No ☐																
○ exploration of any gaps in employment	Yes ☒ No ☐																
■ Evidence of current professional registration	Yes ☒ No ☐ N/A ☐																
■ Evidence of qualifications	Yes ☒ No ☐																
■ Occupational health screening / clearance	Yes ☒ No ☐																
	Is the named individual on a fixed term contract or is the contract end imminent? Yes ☐ No ☒																
	Please indicate current contract end-date Date:																
	Signed: <u>V. B. CROUCH</u> Date: <u>12th JULY 2019</u>																
	Name: <u>V. B. CROUCH</u> Job Title: <u>STUDENT EDUCATION SERVICE OFFICER</u>																
	Organisation: <u>UNIVERSITY OF LEEDS</u> Department: <u>FACULTY GRAD SCHOOL, RMH</u>																
	Address: <u>RM 9.29, WORSLEY BUILDING CLARENDON WAY, LEEDS</u>																
	Tel No: <u>0113 343 7497</u> Email: <u>V.B.CROUCH@LEEDS.AC.UK</u>																
Please return the form to the researcher.																	

Section 6 - Instructions to applicants	
<i>To be completed by Researcher</i>	
<i>Please indicate which of the following documents are attached to this Research Passport:</i>	
Current curriculum vitae, including details of qualifications, training and professional registration (please use the template C.V. at http://www.rdforum.nhs.uk/docs/template_cv.doc)	Yes ☐ No ☒
Researcher's copy of criminal record disclosure. NB where research involves regulated activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012), the disclosure must include confirmation of a check against the appropriate ISA barred list(s).	Yes ☐ No ☒ N/A ☐
Evidence of occupational health screening / clearance	Yes ☐ No ☒ N/A ☐
Appendix – List of projects and amendments	Appendix numbers: N/A ☒

Please send the completed form and original documents to the Lead R&D office. The completed form and original documents will be returned to you. This package of documents will be used to validate your completed Research Passport form. You may then, and where relevant, provide the Research Passport to other NHS organisations.

You must inform all NHS organisations that have received this Research Passport of any changes to the information supplied above. Failure to do so may result in withdrawal of your honorary research contract or letter of access. As part of the quality control procedures for the Research Passport, random checks on the accuracy of the information held on this Research Passport may be made.

Section 7			
This section should be completed by HR in the Lead NHS organisation, only if additional checks are undertaken			
The following additional checks have been completed:			
Having confirmed that the necessary additional pre-engagement checks have been completed, I am satisfied that the above named researcher is suitable to carry out the duties associated with their research activity outlined in this Research Passport.			
Signed:		Date:	
Name:		Job Title:	
Organisation:		Department:	
Email:			
Section 8 - For Office Use Only			
This section should be completed by the NHS R&D office that received the initial application. The NHS R&D office must countersign and date retained photocopies of the documents. The grey section must be completed before the form is returned to the applicant.			
CV reviewed?	Yes ☒ No ☐	Training?	Yes ☐ No ☒
Evidence of qualifications?	Yes ☐ No ☒	Appendix pages reviewed?	Numbers:
Professional registration details reviewed?	Yes ☐ No ☐ N/A ☒	Occupational health clearance reviewed?	Yes ☒ No ☐ N/A ☐
Criminal record disclosure reviewed?	Yes ☒ No ☐ N/A ☐	Date of disclosure: 25/04/2019 Disclosure No: 001655853922	
For regulated activity as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012), did the criminal record disclosure confirm a satisfactory check against the appropriate ISA barred list(s)			Yes ☐ No ☐ N/A ☒
Enter Electronic Staff Record Number (if issued):			
Confirmation of valid Research Passport:			
Project specific ☒ Three-year ☐ Other End date ☐ Date:			
Signed:	<i>Mohammed Khan</i>		Date:
Name:	Mohammed Khan		
NHS Organisation Name and contact details			
Leeds Teaching Hospital (NHS Trust) Research & Innovation Centre St James University Hospital, Leeds			
Date Honorary Research Contract/letter of access issued (delete as appropriate)			

If required, this section should be added to the Research Passport Form and completed by each NHS R&D office receiving the valid Research Passport. The original Research Passport form and documents should be returned to the applicant.

Has the Research Passport been validated by a Lead NHS organisation and is this validation acceptable to this NHS organisation? Yes ☐ No ☐

CV reviewed?	Yes ☐ No ☐	Training?	Yes ☐ No ☐
Evidence of qualifications?	Yes ☐ No ☐	Appendix pages reviewed?	Numbers:
Professional Registration details reviewed?	Yes ☐ No ☐ N/A ☐	Occupational health clearance reviewed?	Yes ☐ No ☐ N/A ☐
Criminal record disclosure reviewed?	Yes ☐ No ☐ N/A ☐	Date of disclosure:	
		Disclosure No:	

For regulated activity as defined in the Safeguarding Vulnerable Groups Act 2006, as amended by the Protection of Freedoms Act 2012, did the criminal record disclosure confirm a satisfactory check against the appropriate ISA barred list(s)

Yes ☐ No ☐ N/A ☐

Checked Electronic Staff Record: Yes ☐ No ☐ N/A ☐

Signed:

Date:

Name:

NHS organisation name and contact details:

Date honorary research contract/letter of access issued (delete as appropriate)

Passport Appendix. List of projects and amendments

 Appendix Number:

If you are applying for a three-year Research Passport, please use this section to enter details of projects and activities that will be covered by this Research Passport. Once you have a validated Research Passport, you may add details of subsequent projects during the three years that this Research Passport is valid.

If you are applying for a project-specific Research Passport, but need to add further sites to the project, please enter the details below.

Whenever you add further details, the full Research Passport and accompanying documents must be submitted to the relevant NHS organisations.

Title:		Start Date:	End Date:
NHS organisation(s):	Dept(s):	Proposed research activities:	Manager in NHS organisation:

Amendments to the Research Passport

Please state what these are, e.g. they might be a change in name or employment details, or a change in research activities.

Please check with the NHS organisation where you are undertaking your research if you are unsure whether you will need to submit new evidence of pre-engagement checks on a new Research Passport form, which will need to be validated by the NHS organisation(s) hosting your research.

Date	Old Details	New Details	Office use only NHS R&D contact details and signature

To add more projects please copy this page or download further blank pages. Each appendix page should be numbered.

For office use only:

A photocopy of the appendix should be retained whenever any amendments or additions to the appendix are made.

Appendix F Disclosure and Barring Service checks

12 July 2019

Uni of Leeds - Faculty of Medicine and Health

1 Wilford Business Park
Ruddington Lane
Nottingham
NG11 7EP**telephone:**
0845 251 5000
facsimile:
0115 982 1307
email:
onlinedisclosures@gbgplc.com
website:
<https://gbg.onlinedisclosures.co.uk>

This is not a certificate issued by the DBS.

Please find below the result of the recent DBS Disclosure application you requested us to process on your behalf.

Name of employer:	Uni of Leeds - Faculty of Medicine and Health
Position applied for:	Clinical Researcher - Child
Applicant Name:	Haya Alzaabi
Date of Birth:	24/09/87
Gender:	Female
Postcode	LS1 2TE
Disclosure number:	001655853922
Date of Issue:	25/04/2019
Disclosure Type:	ENHANCED
Police National Computer	None Recorded
DBS Children's Barred List	None Recorded
DBS Vulnerable Adults' Barred List	Not Requested

If you have any further queries, please do not hesitate to call the GBG OnlineDisclosures helpline.

Yours sincerely

A handwritten signature in black ink, appearing to be 'JGA' followed by a horizontal line.

OnlineDisclosures Team
GBG

Appendix G Parents information sheet

The Leeds Teaching Hospitals 
NHS Trust

School of Dentistry



UNIVERSITY OF LEEDS

V:8 18/01/2019

IRAS Project ID:233026

Parent information sheet

Research Title:

Comparison of the Silhouette and Porter Brown Systems Used in Inhalation Sedation in Dentistry for Children.

Introduction

My name is Haya Alzaabi and I am a Post graduate student in the School of Dentistry at the University of Leeds. I would like to invite you and your child to take part in a research project. Before you decide whether to take part, you need to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to discuss or ask questions. Taking part in the study will add approximately 10 to 15 minutes to your appointment to allow your child to answer some questions about what they thought about the mask used in their treatment session.

Study purpose

The purpose of this study is investigating the efficiency and acceptability of two routinely used masks in inhalation sedation for children receiving dental treatment and will compare between these two breathing systems.

Some questions you may ask

1. Why have I been invited to take part in this study?

Your child has been invited to take part in this study because he/she is having dental treatment under inhalation sedation at Leeds Dental Institute.

2. Who is eligible to participate?

We are inviting healthy children aged from 7 to 16 years attending the Inhalation Sedation Unit for comprehensive dental care. They should not have had Inhalation Sedation treatment before and should be able to breathe through their nose normally and follow our instructions. We cannot include children who are not able to communicate directly with the dentist who is carrying out the treatment or who can't breathe through their nose.

3. Do we have to take part?

No, your child does not have to participate and this will not affect the treatment that your child is receiving. You can withdraw at any time without giving a reason, but if you decide to withdraw part way through, the data collected to that point may still be used. If you and your child decide to take part, a signed consent form and an assent form is needed. If you wish to receive a summary of the results, we can send it to you by post or email.

4. What will happen and what do we have to do?

We would like to ask your child some questions after the routine dental treatment session and get his/her feedback about the mask that has been used during the session. The

questions will be asked through a simple questionnaire that will add about 10 to 15 minutes to the routine dental appointment.

The Porter Brown system (grey mask) is routinely used for patients having dental treatment under inhalation sedation at Leeds Dental Institute, however if your child enrolled in this study he/she will be randomly allocated to either the Porter Brown system or the Silhouette system (transparent/clear mask).

The randomisation process will be by opening a sealed envelope on the day of the treatment session to know which nose piece will be used.

Each participant will receive an electric toothbrush as a modest present to their participation time after their treatment session.

5. What are the possible benefits of taking part?

We hope to understand more about the efficiency of the masks used in inhalation sedation, which will help us to improve how we provide treatment for children in the Sedation Unit.

6. What are the possible risks or disadvantages of taking part?

The possible risks or side effects are the same risks of having treatment under inhalation sedation, which are very remote. There is a small possibility of getting nauseous or having a headache. Rarely, inhalation sedation may cause your child to vomit.

7. What will happen to the results of the research?

The information will be stored safely and securely in accordance with the Data Protection Act 2018. All the data collected will be kept confidential and anonymised so that those reading reports from the research will not know who has contributed to it. All research data are intended to be used for the Professional Doctorate research project by Haya Alzaabi and will be published in her thesis.

The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from your child and their medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about your child for 2 years after the study has finished until 2021.

The University has in force a Public and Products Liability policy which provides cover for claims for "negligent harm" and the activities of this study are included within that coverage subject to the terms, conditions and exceptions of the policy.

Your rights to access, change or move your child's information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about your child that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Leeds teaching Hospital NHS Trust will use your child's name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from The University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Leeds teaching Hospital NHS Trust will pass these details to University of Leeds along with the information collected from

your child and their medical records. The only people in University of Leeds who will have access to information that identifies you will be people who need to contact you to the research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. University of Leeds/LTHT will keep identifiable information about your child from this study for 2 years after the study has finished until 2021. You can find out more about how we use your information by contacting the University of Leeds Data Protection Officer on DOP@leeds.ac.uk

8. What if I need to complain?

The normal complaints process will apply. You can have more information on the NHS patient advice. You can also contact the Patient Advice and Liaison Service (PALS) office in Leeds.

PALS contact details:

Telephone: 0800 0525270

Email: pals@leedspct.nhs.uk

Office address:

Patient Advice and Liaison Service

NHS Leeds
1st Floor rear
North West House
West Park Ring Road
Leeds
West Yorkshire

9. Who is organising and funding this research?

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

10. Who reviewed this study?

This study has been reviewed by University of Leeds.

This study has been granted ethical approval by an NHS Research Ethics Committee.

Contact details of researchers:

- **Dr. Jinous Tahmassebi**
Associate Professor in Paediatric Dentistry
School of Dentistry -University of Leeds
Level 6 – Worsley Building - Clarendon Way - Leeds - LS2 9LU
Email: J.Tahmassebi@Leeds.ac.uk
Telephone: 01133433955
- **Ms Haya Alzaabi**
Postgraduate in Paediatric Dentistry
School of Dentistry -University of Leeds
Level 6 – Worsley Building - Clarendon Way -Leeds - LS2 9LU
Email: dnhza@leeds.ac.uk

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

Appendix H Participant information sheet (7-10 years old)

The Leeds Teaching Hospitals 
NHS Trust
 School of Dentistry


 UNIVERSITY OF LEEDS
 V:5 09/01/2019
 IRAS Project ID: 233026

Child participant information sheet (7-10 years)

How Children Feel About the Mask Used for Breathing the Magical Gas in Our Hospital

Who am I?

My name is Haya Alzaabi.
 I am a children dentist.
 I study at the Dental School at University of Leeds.



I am doing research and would like you to help me

Research is when people explore and look for information. I am looking for information about the mask that you will wear on your nose when breathing the magical gas.
 This will help us understand how you feel about the mask.

Can you help me?

If you would like to help, I will ask you to answer some questions about the mask after trying it.
 Your mum or dad or guardian can help you answer the questions.



What will happen?

I will meet you again when you visit us in the clinic.
 I will explain everything to you when you arrive.
 I will ask you to tick some boxes on a question sheet.

Will anyone know any information about you?

Your dentist and the research team will know your information but we will not share it with anyone else.

What if you don't want to join us?

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

What if you have questions?

Your mum or dad or guardian have a sheet with more information.
 If you have any other questions, you can send me an email.
 (dnhza@leeds.ac.uk)



Appendix I Participant information sheet (11-15 years old)

Child participant information sheet (11-15 years)

How Young People Feel About the Masks Used for Breathing the Magical Gas in Our Clinic?

Who am I?

My name is Haya Alzaabi and I am a dentist who treats children at Leeds Dental Institute.

What am I going to do?

We have two different masks that are used in breathing the magical gas when doing the dental treatment. I am going to explore which of these two masks is better.

One mask is **grey** in colour and the other mask is **clear**.

What will happen?

1. I will meet you next time you visit us at the dental clinic.
2. I will explain everything to you when you arrive.
3. If you are happy to take part your parents will be asked to sign a consent form and you will sign an assent form.
4. You are going to have your treatment session using either the **grey** mask or the **clear** mask.
5. After the treatment session, I will ask you to tick some boxes on a question sheet (Questionnaire) to see what you think about the mask.

Will anyone know any information about you?

No, all your information will be stored safely and securely and the information will be confidential and anonymous so that the reader will not know you.

What if you don't want to take part?

If you don't like to join, it's up to you and your choice will not affect your treatment that you receive.

What if you have questions?

Your parents or guardian have a detailed information sheet, however if you have any other question you can send me an e-mail or ask your parents to send me email on your behalf. (dnhza@leeds.ac.uk)

Appendix J Research poster

The Leeds Teaching Hospitals **NHS**
NHS Trust

School of Dentistry



UNIVERSITY OF LEEDS

V: 3 09/01/2019
IRAS Project ID: 233026

How children feel about
the masks used for
breathing the magical gas
in our clinic?



1

2

Can you help me with my project?

Appendix K Parent consent form

The Leeds Teaching Hospitals 
NHS Trust



UNIVERSITY OF LEEDS

School of Dentistry

V:5 09/01/2019

IRAS Project ID: 233026

Participant code:

Participant Consent Form for Parents/Guardians

Haya Alzaabi conducts this research as her professional doctorate project, under supervision of
Dr J.Tahmassebi , Dr B.Drummond, Dr.K.Kenny

Title of Research:

Comparison of the Silhouette and Porter Brown Systems Used in Inhalation Sedation in Dentistry for
Children.

1. I confirm that I have read and understand the information sheet explaining the above research project and I have had the opportunity to ask questions about the project. ☐
2. I understand that my child's participation is voluntary and that we are free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should we not wish to answer any particular question or questions, we are free to decline. ☐
3. I understand that my child's name will not be linked with the research materials, and we will not be identified or identifiable in the report or reports that result from the research. ☐
4. I agree for the data collected from our participation can be used in the future for educating dentists and the dental team. ☐
5. I and my child agree to take part in the above research project. ☐
6. I would like to receive a simple summary of the results by post ☐

Participant's guardian:

Date:

Signature:

lead researcher:

Date:

Signature:

Relation to the patient:

Participant's name:

participants copy given

☐

Appendix L Child assent form

The Leeds Teaching Hospitals 
NHS Trust



UNIVERSITY OF LEEDS

School of Dentistry

V: 5 09/01/2019

IRAS Project ID: 233026

Participant code:

Child Assent

Haya, Dr Bernadette, Dr Kate and Dr Jinous are a research team of this project.

Project Name:

How Children Feel About the Mask Used for Breathing the Magic Gas in Our Hospital

- I have read (have read to me) and understand the information sheet of this study and have had time to ask questions. ☐
- I understand that I can take part if I want and its alright if I don't and I can stop at any time, without any problem. ☐
- I understand that all my information will be kept safe. ☐
- I understand that even if I don't take part in this study, still I can receive my dental treatment. ☐
- I understand that Haya will ask me few questions about the mask after finishing my treatment. ☐
- I understand that I will answer the questions by ticking boxes on a question sheet which will take about 10 to 15 mins. ☐
- I agree to take part in this study. ☐

Participant's name:

Date:

Signature:

lead researcher:

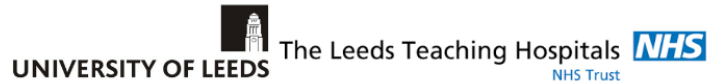
Date:

Signature:

participants copy given ☐

Appendix M Child feedback questionnaire

School of Dentistry

V:3 09/01/2019
IRAS Project ID: 233026**PATIENT QUESTIONNAIRE(AGES 7-15)**

We would like to know what do you think about the mask used today at the dentist.

This can help us find out which mask is the best.

Please answer the following questions.

Your mum, dad, or guardian can help you answer.

➤ I am (please circle):  Male  Female

➤ I am _____ years old

How did the mask feel on your nose?☐ Very comfortable☐ Uncomfortable☐ Comfortable☐ Very uncomfortable☐ Not sure**Please turn over**

**Please put a tick
✓ for each
question**



Strongly
Agree



Agree



Undecided



Disagree



Strongly
Disagree

1. I liked the mask

☐
☐
☐
☐
☐

**2. It was easy to breathe
through the mask**

☐
☐
☐
☐
☐

**3. It was comfortable
when removing the
mask**

☐
☐
☐
☐
☐

**4. It was easy to move
my head to the sides**

☐
☐
☐
☐
☐

5. Did you feel any air leaking around your lips or nose?

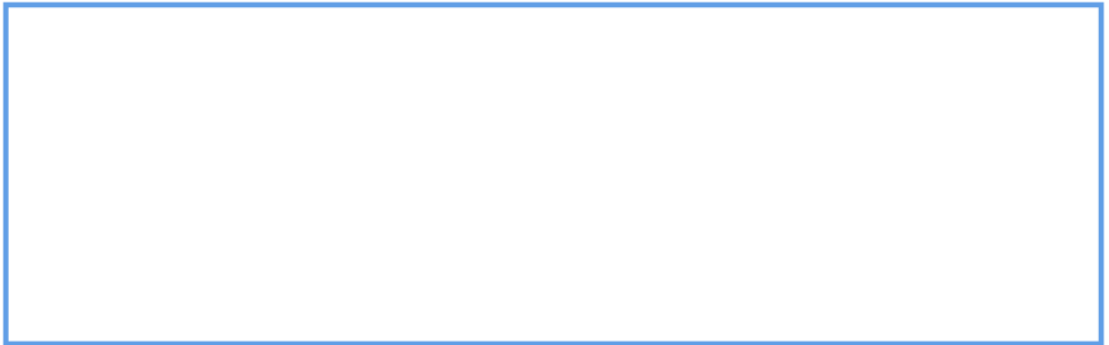
Yes

No

6. I liked the mask because:



7. I didn't like the mask because:



Thank you for your
feedback

Appendix N Monitoring and data collection sheet

The Leeds Teaching Hospitals 
 School of Dentistry


 UNIVERSITY OF LEEDS
 V: 6 09/01/2019
 IRAS Project ID: 233026

Data collection sheet for patients

Participant number:
 Patient Age:
 Date:
 type of the mask: Porter brown / Silhouette
 time spent to setup the circuit:

Stage	Time	HR bpm	SpO ₂	Resp/rate min	Colour	%N ₂ O	%O ₂	Flow rate L/min
100% O ₂ given for 5 to 10 mins at end of procedure (tick)								

- Any equipment issue before sedation and treatment
- Monitoring the respiratory rate by the Breathing bag/ patient chest or both
- Airflow monitoring by Breathing bag/ black ball level on machine or both
- Any patient issues during sedation or treatment
- Any equipment issues after sedation and treatment
- Other comments

Houpt global rating scale		Anxiety level before	
		Anxiety level after	

Treatment records:

Tooth	Treatment

Appendix O Lead researcher feedback questions



09/01/2019

V: 4

School of Dentistry

IRAS Project ID: 233026

Lead researcher feedback questions

1. Breathing system used in this treatment session is
 - a. Porter Brown system
 - b. Silhouette system
2. How easy was it to place the mask on the patient's nose?
 - a. Very difficult
 - b. Difficult
 - c. Neutral
 - d. Easy
 - e. Very easy
3. How easy was the patient manoeuvrability?
 - a. Very difficult
 - b. Difficult
 - c. Neutral
 - d. Easy
 - e. Very easy
4. How easy was the accessibility to the treatment site?
 - a. Very difficult
 - b. Difficult
 - c. Neutral
 - d. Easy
 - e. Very easy
5. How easy was it to monitor the airflow?
 - a. Very difficult
 - b. Difficult
 - c. Neutral
 - d. Easy
 - e. Very easy

6. How easy removing the mask?
 - a. Very difficult
 - b. Difficult
 - c. Neutral
 - d. Easy
 - e. Very easy

7. How easy was the head movement?
 - a. Very difficult
 - b. Difficult
 - c. Neutral
 - d. Easy
 - e. Very easy

8. I think the child accepted the mask?
 - a. Strongly disagree
 - b. Disagree
 - c. Undecided
 - d. Agree
 - e. Strongly agree

9. How good was the seal of the Nasal Hood piece?
 - a. Very bad
 - b. Bad
 - c. Neutral
 - d. Good
 - e. Very good

10. Other comments/ like or dislike?

Appendix P Anxiety FIS assessment

The Leeds Teaching Hospitals 
NHS Trust
School of Dentistry


UNIVERSITY OF LEEDS
IRAS Project ID:233026
V:2 09/01/2019



1



2



3



4



5

Appendix Q Dental School Research Day prize certificate

School of Dentistry
FACULTY OF MEDICINE AND HEALTH



RESEARCH DAY
11 July 2019

Haya Alzaabi

Has been awarded the prize for
Verbal Presentation

Dr Xuebin Yang
Director of Postgraduate Research Studies

Dr Thuy Do
Deputy Director of Postgraduate Research Studies

Appendix R End of the study declaration notice form



Health Research Authority

DECLARATION OF THE END OF A STUDY

(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript by the Chief Investigator and submitted to the Research Ethics Committee (REC) that gave a favourable opinion of the research within 90 days of the conclusion of the study or within 15 days of early termination.

For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	Miss Haya Alzaabi
Address:	Flat 6, 65 Saint Paul's street, Leeds, LS12TE
Telephone:	07749098178
Email:	dnhza@leeds.ac.uk
Fax:	-

2. Details of study

Full title of study:	Comparison of the Silhouette and Porter Brown systems used in inhalation Sedation
Research sponsor:	University of Leeds
Name of REC:	Yorkshire & The Humber – Bradford Leeds Research Ethics Committee
REC reference number:	18/YH/0489

3. Study duration

Date study commenced:	28\02\2019
Date study ended:	15\08\2019
Did this study terminate prematurely?	No <i>If yes, please complete sections 4, 5, 6, & 7. If no, please go direct to section 8.</i>

4. Recruitment

Number of participants recruited	
Proposed number of participants to be recruited at the start of the study	

If different, please state the reason or this	
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5. Circumstances of early termination

What is the justification for this early termination?	
---	--

6. Temporary halt

Is this a temporary halt to the study?	Yes / No
If yes, what is the justification for temporarily halting the study? When do you expect the study to re-start?	<i>e.g. Safety, difficulties recruiting participants, trial has not commenced, other reasons.</i>

7. Potential implications for research participants

Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them.	
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8. Final report on the research

Is a summary of the final report on the research enclosed with this form?	No <i>If no, please forward within 12 months of the end of the study.</i>
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9. Declaration

Signature of Chief Investigator:	
Print name:	Haya Alzaabi
Date of submission:	04/12/2020

Appendix S Declaration of the end of the study

IRAS PROJECT ID 233026, REC Reference 18/YH/0489 : Acknowledgement of end of study

bradfordleeds.rec@hra.nhs.uk <noreply@harp.org.uk>

Mon 12/7/2020 10:12 AM

To: Haya Alzaabi <dnhza@leeds.ac.uk>

Cc: Medicine and Health Research Governance <governance-ethics@leeds.ac.uk>

Dear Miss Alzaabi,

Study title:	Comparison of the Silhouette and Porter Brown Systems Used in Inhalation Sedation
REC reference:	18/YH/0489
Protocol number:	N/A
EudraCT number:	
IRAS project ID:	233026

Thank you for sending the declaration of end of study form, notifying the Research Ethics Committee that the above study concluded on 15 August 2019. I will arrange for the Committee to be notified.

A summary of the final research report should be provided to the Committee within 12 months of the conclusion of the study. This should report on whether the study achieved its objectives, summarise the main findings, and confirm arrangements for publication or dissemination of the research including any feedback to participants.

18/YH/0489 Please quote this number on all correspondence

Yours sincerely

Kavita Prajapati

NHSBT Newcastle Blood Donor Centre | Holland Drive | HRA Newcastle | NE2 4NQ

E. bradfordleeds.rec@hra.nhs.uk

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Appendix T Results dissemination letter



UNIVERSITY OF LEEDS

10 December 2020

Department of Paediatric Dentistry
School of Dentistry
Clarendon Way, Leeds, LS2 9LU, UK

To families and children who participated in my project about the masks we used when you had sedation,

I would like to thank you for taking part in this project. I have greatly valued your contribution and your willingness to share your thoughts about your experience which was very important to us to improve our dental care for children.

Our research has been completed and we could not have done it without you. The results have come out, and I would like to share a summary of the results with you.

Project title: “Comparison of the Silhouette and Porter Brown masks used in inhalation sedation in dentistry for children”

The aim of this study was to examine the masks and to see which one was better and more preferable for children who need dental treatment using inhalation sedation (the magical gas).

Summary:

1. Fifty-four boys and girls (including you!) have joined our project. They were between 7 and 15 years old.
2. Children found it easier to move their heads with the Silhouette mask (**Clear**) than the Porter Brown mask (**Grey**).
3. The mask preference was not related to the age.
4. Whether the grey mask or clear mask was used did not affect how worried the child felt about the dental treatment.
5. The dentist was exposed to the gas more with the Silhouette system (**Clear**), while there was no difference for the dental nurse when either mask was used.
6. The results showed that both breathing systems were efficient and acceptable, and both systems can be used successfully for dental treatment under inhalation sedation for children.



We plan to publish the results from this study in the dental literature. If you have any questions or concerns, please contact me.

Again, thank you for your time and efforts that made this research possible.

With warm regards,
Ms Haya Alzaabi
Postgraduate in Paediatric Dentistry
Email: dnhza@leeds.ac.uk

Professor Bernadette Drummond
Professor HoD Paediatric Dentistry
Email: b.k.drummond@leeds.ac.uk

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