AN EXPLORATORY QUALITATIVE STUDY OF PATIENTS' PERCEPTIONS OF MATERIAL RISKS FOR ORTHOGNATHIC SURGERY.

By

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Abstract

Aim: There are a limited number of publications which have qualitatively investigated the treatment journey and the risk based decision-making process of patients undergoing orthognathic surgery following the Montgomery versus Lanarkshire Health Board (2015) legal ruling. Therefore, the aim of the study is to carry out qualitative research to ascertain the perception of risks during decision-making in a group of patients who have undergone orthognathic surgery. The goal is to improve the consent process of this elective procedure and better tailor this for each individual patient and improve their overall experience.

Design: The aims of this study were to evaluate patients' perception and their lived experiences qualitatively, using focus groups and one to one interviews.

Methods: Patients who had undergone bimaxillary orthognathic surgery were recruited from review clinics at Birmingham Dental Hospital and School. Recruitment began in September 2021 and was completed by December 2021. All patients were approached by an orthodontic registrar (SMS). Twenty-three participants were initially identified and of those fifteen were interviewed. Ten of the participants interviewed were female and five were male. Ages ranged from twenty-three years to forty-three years old. The range of surgery dates was from October 2017 to December 2019.

Results: Two domains were identified, the first domain investigated perceptions of risk involved in orthognathic surgery. The second domain looked at the impact of orthognathic surgery on patients' psychosocial well-being and considerations during the consent process.

The first domain based on three main themes were identified from the interviews centring on the patient’s perceived risks to orthognathic surgery: sources of information about orthognathic surgery, surgical risk and setting and format of how risks should be presented. For the second domain, again three themes; physical effects of surgery and its impact on patients' psychosocial well-being, non-physical effects of surgery and its impact on patients' psychosocial well-being, and impact of surgery necessitating support.

Conclusions: This study has found that patients need to be informed of the overall experience of the treatment journey, providing realistic and accurate information prior to starting treatment. Previous patients are a valuable source in supporting future patients in the consent process. Clinicians should be aware that what may seem of importance to them may not be the same for patients. Patients should be aware of the pain, swelling, nerve injury, difficulty eating and drinking, and the difficulties that may arise in the initial postoperative recovery period. They should also be given a realistic idea of their final facial appearance. This knowledge may lead to greater patient satisfaction and most importantly mentally prepare these patients to reduce the negative implications on their psychosocial well-being. This research has identified the importance of the patient’s social network, dieticians, and psychologists in the treatment pathway. The findings of this study can inform future quantitative studies in which further research is required to look at how this new setting and format should be employed to improve the consent process for these patients as well as developing a comprehensive list of risks from both a clinicians and patient perspective.

LIST OF FIGURES

LIST OF TABLES

TABLE OF CONTENTS

Contents

CHAPTER 1

LITERATURE REVIEW

1.1 INTRODUCTION

Orthognathic surgery is performed to change the position of the maxilla and/or mandible in order to correct a skeletal disharmony (Khechoyan, 2013). This treatment modality is for patients in which their malocclusion is not suitable for treatment by orthodontic camouflage due to the severity of their malocclusion or for patients who are beyond growth modification. Patients can present with concerns regarding their facial appearance as well as functional difficulties (Khechoyan, 2013). These facial deformities can have an impact on speech or mastication, occlusal trauma, soft tissue trauma, skeletal asymmetries, and sleep apnoea. This treatment is provided by a multidisciplinary team. The aims of surgery are to optimise facial aesthetics, address functional needs, improve mental health and ultimately to attain an overall improvement in the patient's quality of life.

1.2 HISTORY OF ORTHOGNATHIC SURGERY

Historically, the study of facial aesthetics has always been an interest to painters, sculptors, and philosophers. In the 13th century Thomas Aquinas made a statement regarding the concept of aesthetics: 'the senses delight in things duly proportioned'; explaining how beauty and mathematics are interlinked and aesthetics is measurable (Goldstein, 1997). Initially, surgery was carried out solely on the mandible, however this was unsuccessful in severe malocclusions as they often required double jaw surgery. This led to surgeries involving both the maxilla and mandible to achieve facial balance and harmony and this was possible for all malocclusions (Bell et al., 1985).

Even though there are many theoretical advantages of orthognathic surgery, it has been previously viewed as a radical, dangerous and unpredictable treatment option, and it was only during the last four or five decades that the concept of this surgery has won the acceptance of Oral and Maxillofacial surgeons as well as Orthodontists (Naini and Gill, 2017). The first recorded orthognathic surgery was performed by Simon Hullihen in 1848 without pre-surgical orthodontic treatment. The patient had experienced extensive burns when younger resulting in a protrusive mandibular alveolar segment. A sub-apical osteotomy was used to correct the anterior open bite. Since then, many additional procedures and approaches have been established (Aziz, 2004). The first osteotomy combined with orthodontic treatment was carried out by Edward Angle and the surgeon Vilray Blair in a patient with Mandibular Prognathism (Whipple, 1898).

It was in 1921 when the first Le Fort I osteotomy procedure was carried out by Herman Wassmund to correct a dentofacial disharmony (Wassmun and Leipzig, 1927). The technique became widely accepted for the correction of dentofacial disharmony in Europe and the United States, however, its stability was still questionable. This led to the importance of including the orthodontist in orthognathic surgery planning (Converse and Horowitz, 1969). Since then, there has been a wider acceptance of incorporating orthodontics pre- and post-operatively to achieve an optimal and stable result. Popularity of the Le Fort I surgery has resulted in the introduction of the ‘two jaw’ surgery which is a bilateral sagittal split osteotomy alongside a Le Fort I surgical procedure (Buchanan and Hyman, 2013).

Currently orthognathic surgery involves orthodontic treatment before the surgical procedure. This involves upper and lower fixed appliances which remain in place during the surgery as well as a brief period after the surgery to achieve the desired occlusion. A multidisciplinary team approach is imperative to execute predictable outcomes. These outcomes are now better achieved with the advances in technology including, using 3-dimensional (3D) virtual surgical planning (VSP) to simulate the end result of the surgery (Naini and Gill, 2017). In 2015, in the United Kingdom, it was approximated that there were potentially 250,000 patients who could have benefitted from orthognathic surgery (Cunningham and Johal, 2015).

1.3 THE ORTHOGNATHIC TREATMENT JOURNEY

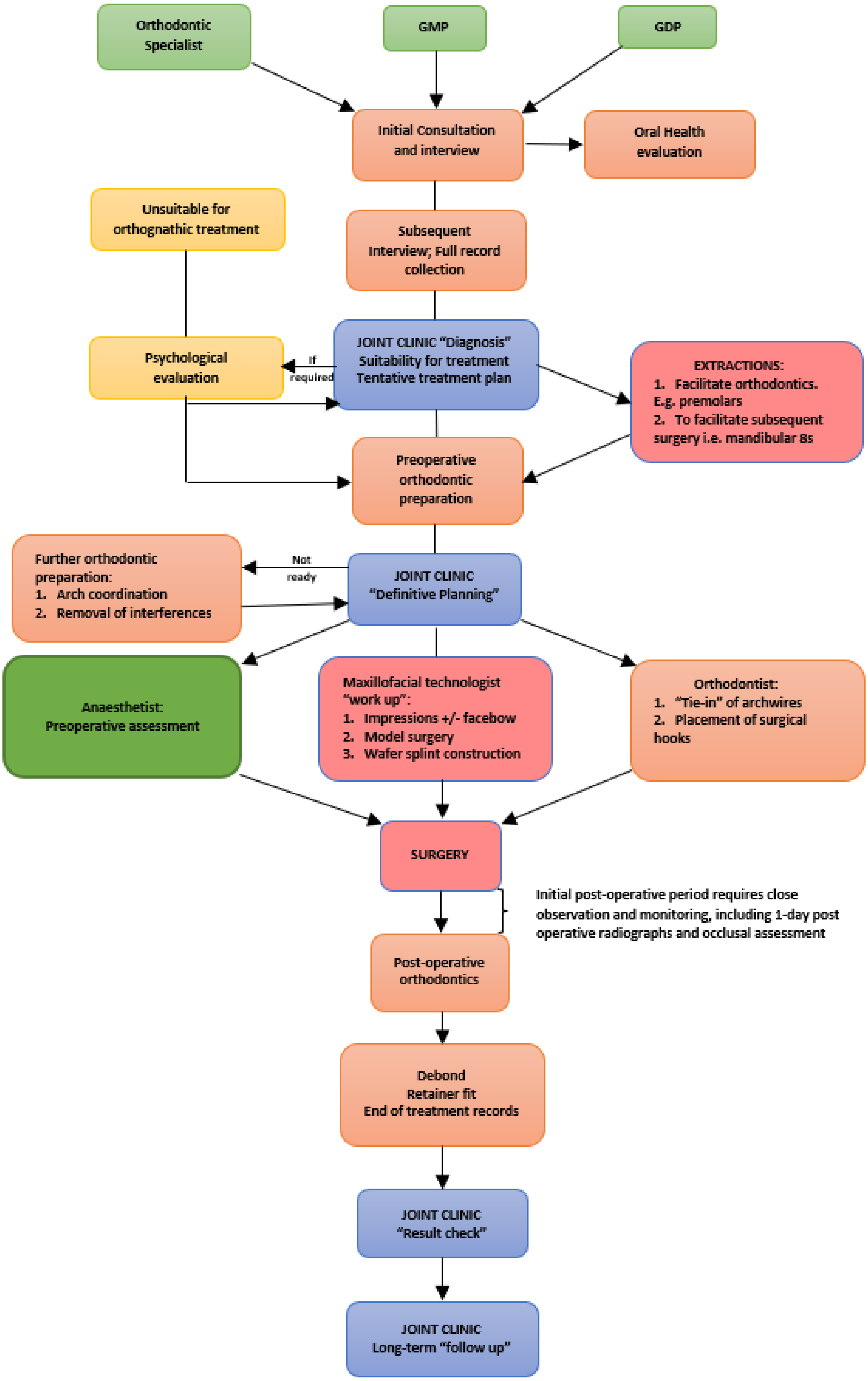
Over recent years, the treatment care pathway for orthognathic surgery has become more established and involves many different specialties. These should include a consultant maxillofacial surgeon, consultant orthodontist, ideally a clinical psychologist/liaison psychiatrist, dental technician, specialist orthognathic nurse, specialist maxillofacial dietician, speech and language therapist, consultant anaesthetist and occasionally a restorative specialist (Naini and Gill, 2017).

Treatment is usually timed when facial growth is complete or significantly slowing down (Achal et al., 2018). This is usually around 17 to 18 years in females and 18 to 19 years in males. These are generic time points so it is necessary to assess each patients growth with the use of growth charts as growth patterns can greatly vary (Ursi et al., 1993). Possible considerations could be the use of hand-wrist radiographs to assess skeletal maturity by looking at the phalanges and metacarpal bones using Tanner-Whitehouse 3 (TW3) methods (Tanner, 1983). Although reliable, one needs to take consideration of the increased exposure of patients to radiation. The general dental practitioner usually refers the patient to tertiary care where the patient is assessed for suitability for orthognathic treatment. The Index of Orthognathic Functional Treatment Need (IOFTN) is used to determine whether the patient is eligible to be treated under the National Health Service (Ireland et al., 2014).

A multidisciplinary clinic (MDT clinic) is required to ensure successful treatment planning and for patients with more complex craniofacial disharmonies, further specialities are involved such as craniofacial surgeons and ear, nose and throat surgeons (Khechoyan, 2013). During the assessment the patient's presenting complaints and concerns are identified as well as the patient's psychological well-being. The potential treatment options are then discussed alongside the risks and benefits for each option and information leaflets are given regarding orthognathic surgery. The patient is also informed whether they would be feasible for this surgery and a provisional plan formulated.

Patients should also be informed of the approximate treatment journey duration as patients often lose compliance with orthodontic treatment after they have had the surgery (Kiyak et al., 1982). Firstly, any dental treatment that is required prior to orthognathic treatment such as restorations, periodontal treatment and orthodontic extractions is discussed and arranged. The patient is then notified of the pre-surgical orthodontic treatment duration which is approximately 1-2 years (Luther et al., 2003) and the requirement to attend follow-up MDT clinics. There is then a discussion regarding the orthognathic surgery as well as explaining what it will entail including the recovery period of around 6 weeks. Following this the patient will undergo post-surgical orthodontic treatment which takes up to a year and this information is also relayed to the patient (Luther et al., 2007), Figure 1.1. Lastly, there are two established methods of information delivery which the patient is directed to: the British Orthodontic Society (BOS) website 'Your Jaw Surgery' as well a leaflet produced by BOS entitled 'Orthognathic surgery' (British Orthodontic Society (BOS), 2014).

Figure 1.1 Orthognathic surgery pathway (adapted from Naini and Gill (2017))



1.4 INDICATIONS FOR ORTHOGNATHIC TREATMENT

Three main objectives of orthognathic surgery which are ‘improved aesthetics and dentofacial function in a stable manner leading to an improved health-related quality of life’ (Naini and Gill, 2017). Therefore, clinical effectiveness is whether this surgery achieves these treatment objectives.

A cross-sectional survey was carried out on four Orthognathic departments in Yorkshire which involved questionnaires and interviews of patients (Stirling et al., 2007). The most common reasons reported to have elective surgery was to improve the ‘bite’ and to improve the appearance of their teeth. Patient’s also expressed concerns regarding their facial appearance and that this affected their behaviour and self-esteem. Less common reasons were given such as ‘chewing’ problems, socialising and speech problems, pain in their joints, headaches and general health problems (Stirling et al., 2007).

Qualitative research has shown that patients who were mainly concerned with their facial appearance had improved self-confidence following orthognathic surgery (Ryan et al., 2012). Pre-surgery patients reported a feeling of victimisation and being punished unfairly because of their facial disharmony. This further highlighted the importance of dentofacial disharmony and its impact on the quality of life of this group of individuals.

It is also important to note that the severity of the dentofacial disharmony does not necessarily relate to a greater impact of the patient’s quality of life. Individuals with a mild deformity were shown to have the lowest self-esteem’ (Lansdown et al., 1991). This reiterates the fact that clinicians must consider each patient’s concern so that these can be addressed but at the same time to be able to identify patients with a psychiatric disorder, such as Body Dysmorphic Disorder (BDD) (American Psychiatric Association, 1994). These cohort of patients are overly obsessive with a certain aspect of their appearance in which they may not have a facial disharmony or their disharmony may be minor (Vulink et al., 2008). These patients tend to be oblivious to their unrealistic concerns and they often tend to not be satisfied with the outcome of their surgical procedure (Vulink et al., 2008). Most of these patients seek out other clinicians for further advice and treatment (Phillips, 1991; Veale et al., 1996). They can also become litigious or violent (Vulink et al., 2008). It has also been found that quarter of oral and maxillofacial patients meet the criteria for a psychiatric disorder (Phillips et al., 1998) therefore it is important to be aware of this when assessing the patient's concerns.

1.5 AIMS OF ORTHOGNATHIC SURGERY

1.5.1 Improve dentofacial aesthetics

The main motivational factor for patients seeking Orthognathic surgery is an improvement in their dentofacial appearance (Naini and Gill, 2017). It is therefore not surprising that this is well documented in the literature given that increasing emphasis on facial aesthetics in society (Flanary et al., 1985; Stirling et al., 2007; Williams et al., 2005). From a patient's perspective aesthetic considerations can often be of greater importance than functional problems (Obwegeser, 1969).

1.5.2 Improve function

Previous studies have reported functional concerns were the main reason for patients seeking orthognathic surgery (Alanko et al., 2010; Proothi et al., 2010). A systematic review found 33-60% of patients report that functional concerns were their primary motivation (Alanko et al., 2010). Stirling et al. (2007) also found that the second most frequent reason that patients sought treatment was due to difficulty eating. Some of the functional problems patients may present with include incising food, mastication, deglutition, traumatic occlusion, attrition, sleep apnoea, temporomandibular joint dysfunction, drooling and speech (Naini and Gill, 2017). Patients with anterior open bites often report difficulty incising food with their anterior teeth and tend to find it embarrassing when eating publicly (Naini and Gill, 2017). This is also common with patients who have Class III malocclusions and lateral open bites. Another concern which is becoming more frequently reported is the inability to snorkel or dive for individuals with anterior open bites (Naini and Gill, 2017). Patients may also present with trauma as their functional problem in terms of biting their tongue and this occurs when the maxillary width is markedly constricted. Patients may also have an anterior occlusion which leads to stripping of the mucosa (Naini and Gill, 2017).

As well as direct functional problems, indirect effects of the malocclusion may be reported as a problem, for example sleep apnoea. Orthognathic surgery may improve these patients' quality of life by widening the airway as a result of advancement jaw surgery (Naini and Gill, 2017). Temporomandibular joint dysfunction (TMD) is also a functional problem patients seek to address through surgery. However, the links between TMD and dental occlusal problems are not evidence based, and it is important to note that the aetiology of TMD is usually multifactorial. Therefore it is imperative to warn these patients that surgery will not necessarily improve their TMD and in certain cases their symptoms may worsen (Naini and Gill, 2017).

1.5.3 Improve psychosocial well-being and quality of life

It is unfortunate that those patients who have dentofacial disharmony can be perceived differently in today's society which may lead to a reduction in their quality of life (Cunningham and Johal, 2015). Health is defined as a 'state of complete physical, mental and social well-being not merely the absence of disease' by the World Health Organisation (WHO). The measurement of health must also include an approximation of well-being and quality of life (World Health Organisation, 1997). This explains why a significant number of studies highlight the negative effects of dentofacial disharmony and the subsequent improvement in patients' quality of life following treatment (Cunningham et al., 1996; Lee et al., 2007; Alanko et al., 2010; Rusanen et al., 2010; Ryan et al., 2012). Systematic reviews have shown that those patients who undergo surgery have a subsequent improvement in their social outlook (Hunt et al., 2001) and improved well-being (Alanko et al., 2010).

1.6 PATIENT INVOLVEMENT

Since the Darzi Report (2008), there has been a greater emphasis in adopting a patient-centred approach to healthcare and using Patient Reported Outcome Measures (PROMs) when assessing the quality of the outcomes of treatment (Department of Health, 2008). The quality of healthcare has now been redefined to incorporate clinical effectiveness, patient safety and experience. This is particularly important as NHS funds are now limited more than ever. However, in a recent study, Cunningham et al. (2003) demonstrated the monetary cost-effectiveness of orthognathic treatment, based on cost per quality-adjusted life-year (QALY).

This demonstrates the value for money orthognathic treatment provides, which showed that Orthognathic treatment had positive outcomes for a relatively small cost in comparison to other surgical procedures that are carried out in the United Kingdom. The National Institute for Health and Care Excellence (NICE) recently introduced guidance to reinforce the importance of individualised care and that this involves giving the patient the opportunity to 'discuss their needs and preferences' (National Institute for Health and Care Excellence (NICE), 2012). Therefore, to reach this standard of care it is paramount to address why a patient is seeking this treatment modality. A qualitative study illustrated that motivating factors for seeking treatment may not necessarily be related to impact of the dentofacial disharmony but in fact there can be other underlying factors such as personality traits and childhood upbringing (Ryan et al., 2012). This further illustrates the importance of clinicians treating patients on an individual basis which has been shown to be a key predictor of patient satisfaction (Kiyak et al., 1982).

1.7 RISKS OF ORTHOGNATHIC SURGERY

All surgical procedures carry an element of risk, it is essential that the benefits as well as the risks are discussed with the patient. Information that is told to the patient before treatment is considered as professional advice, however any information given after the procedure may be considered as an excuse by the patient (Makin, 2017). Therefore, the clinician should be clear and specific about the potential risks even if it were to deter the patient from going ahead with treatment. Orthognathic surgery demands patient compliance, and the orthodontic/surgical pathway is incredibly tasking for any patient, however the morbidity of this surgery is low and generally temporary (Naini and Gill, 2017). Sousa and Turrini (2012) undertook an in-depth systematic literature review of the complications of orthognathic surgery based on 23 studies meeting the inclusion criteria, with 8390 patients. The review found approximately 12% of patients had altered sensation, 3.4% infection, 2.5% fixation problems and 1.8% unfavourable fracture during the osteotomy. This was a similar to a previous study where the incidence of infection was noted at 2% (Sousa and Turrini, 2012). Lannetti et al. (2013) reviewed 3236 patients and found irreversible sensory deficits in 2% of patients, but reversible sensory lip deficit in 19% of patients. There has also been a recent report of two cases of patients losing their tear reflex after maxillary orthognathic surgery and therefore there is a rare risk of the pterygopalatine ganglion being injured during a Le Fort I osteotomy (Kang et al., 2014). Although significant complications are rare with Orthognathic surgery, it is paramount to make the patient aware of these risks. Certain risks are attributed to the orthodontic treatment which are root resorption, decalcification and gingivitis (Travess et al., 2004). In addition to this relapse is a risk and therefore long-term retention is required.

Surgical complications are dependent on the surgical procedure and involve short-term and long-term risks. Normally, those that are short-term are postoperative discomfort, pain, oedema, trismus, difficulty eating, bleeding, infection, general anaesthesia affects and those that may be long-term can be injury to the inferior dental nerve resulting in temporary/permanent altered sensation to the lips, chin, cheeks, tongue, palate and gingiva. Facial swelling can take at least six months to resolve and therefore the outcome of surgery cannot be determined until this has occurred (Day and Robert, 2006). A previous qualitative study investigated complications of orthognathic surgeons amongst oral and maxillofacial surgeons (de Santana Santos et al., 2012). The surgeons were asked, via a questionnaire regarding these complications, and reported that the most frequent complication was nerve damage in relation to surgery to the mandible. Nerve damage was also the most common complication with surgery to the maxilla (40%), followed by haemorrhage (29%).

1.7.1 Blood loss

Bloods loss is a complication of any invasive surgery, and every attempt should be made to control blood loss, bearing in mind orthognathic surgery is an elective procedure. Controlling blood flow reduces the need for a blood transfusion which in turns avoids the risk of reaction to the transmission or the transmission of blood-borne pathogens (Khechoyan, 2013). This is achieved via hypotensive anaesthesia which leads to an improved quality of surgical field and reduced blood loss (Precious et al., 1996). Blood transfusions are rarely required for single jaw surgeries (Khechoyan, 2013). On the contrary, 30% of double jaw surgeries require blood transfusions (Samman et al., 1996). Around a quarter of patients who had surgery to maxilla only, required one or more units of blood transfusion (Hegtvedt et al., 1987). Occasionally during a Le Fort I maxillary osteotomy, uncontrolled haemorrhage can occur and patients need to have been consented for an autologous blood transfusion prior to surgery (Khechoyan, 2013). Profuse haemorrhage with a mandibular osteotomy is a rare occurrence. For most patients consenting to a blood transfusion will be a matter of routine. However, for same faith groups i.e., Jehovah's Witnesses, this may not be possible and can lead to eviction from their religious communities.

1.7.2 Nerve damage

The inferior alveolar nerve during surgery to the mandible can be stretched but it is rarely lacerated and injury to the facial or lingual nerve is rare (Khechoyan, 2013). The healing process when this occurs is reliant on several factors including then types of surgery, the type of injury and individual variations in the response to healing. The incidence of permanent altered sensation as a result of inferior alveolar nerve injury is approximately 10% (Cunningham and Johal, 2015). With mandibular bilateral sagittal split osteotomy (BSSO), paraesthesia of the lower lip is the most common complication. The incidence of this varies from 9%−85% and is also affected by age (Gianni et al., 2002; Westermark et al., 1998). The prevalence is also affected by the extent of the mandibular advancement (da Costa Senior et al., 2020), the position of inferior alveolar nerve and whether there is a lateral course of the inferior alveolar nerve (Yamauchi et al., 2012), length of the mandibular angle (Yamauchi et al., 2012), the manipulation of the nerve during surgery (da Costa Senior et al., 2020), the surgeons' experience (Kobayashi et al., 2006), concomitant procedures (Choi et al., 2013), the method of fixation (Yeo et al., 2016) and type of surgery (Gianni et al., 2002; Kobayashi et al., 2006). The prevalence of altered sensation between the ages of 18−31 years is around 17%, although patients above the age of 31 years have a higher incidence of 29% (Gianni et al., 2002; Westermark et al., 1998).

1.7.3 Infection

Infection is rare complication as patients are administered prophylactic pre-operative and intraoperative antibiotics as well as intravenous antibiotics during admission and they are given oral antibiotics when discharged (Khechoyan, 2013). It is therefore not surprising that the literature shows the low prevalence of plate infection following a Le Fort I osteotomy at around 1.4% (Schmidt et al., 1998). The incidence of plate infection following a bilateral sagittal split osteotomy over two years is around 16% whereby removal of the plate is carried out under general anaesthetic (Theodossy et al., 2006).

1.7.4 Other complications

Less common complications include temporomandibular joint pain and an unfavourable fracture at the sagittal split osteotomy site. Temporomandibular joint (TMJ) pain or degeneration are at a higher incidence with patients whom have a dentofacial disharmony than the general population (Johnson, 1997). However it is difficult to predict whether orthodontic treatment or orthognathic treatment can worsen TMJ pain (Khechoyan, 2013). Progressive condylar resorption is a rare consequence of long-term relapse that may follow single or double jaw surgery. The cause is poorly understood but often occurs in young female patients with initial Class II malocclusions (Khechoyan, 2013).

The risk of unfavourable fractures during sagittal splits is rare with it being less than 2% (Khechoyan, 2013). This occurs due to a technical complication or if the bone is malformed and is termed as a 'bad split' which is then treated with reduction and internal fixation (Khechoyan, 2013). Patients should be warned about this complication which may require a further surgical procedure or extend the patient's recovery.

1.8 CONSENT

Consent represents one of the key principles of the General Dental Council's standards (General Dental Council, 2013). Therefore, it is a requirement by regulatory bodies and by law that informed consent is obtained and is valid for every patient being treated. Touching a patient without their consent would be seen as battery and would be dealt with under the tort of battery. Valid consent is when consent is 'given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question' (Department of Health, 2012). Consent is informed when a competent patient understands the nature of the procedure they are undergoing and the reason as to why this is being carried out. They need to understand the risks and benefits of an intervention as well as alternative options available. They are then able to use this information to make their decision regarding their treatment and communicate this across without coercion (Department of Health, 2012). The patient subsequently has the capacity to consent if they can understand and retain the information given to them, as well as weighing the risks and benefits of the procedure (Sharma and Chate, 2011).

Consent begins with the tort of battery (Naini and Gill, 2017). This involves deliberate and unpermitted contact with another person even if this does lead to harm. A patient's medical or dental consent therefore differentiates between permitted and unpermitted clinical contact. However this should be distinguished from dental malpractice which results in a claim of negligence rather than tort of battery (Raab, 2004). The Department of Health states that 'if the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid' (Department of Health, 2001). The General Dental Council guidance also suggests that the patients should be given information they need to help them make an informed decision (General Dental Council, 2013).

1.8.1 Legality of informed consent

The consent process is a considerable challenge in medical and dental practice. It is important to highlight that litigation against the medical and dental profession is on the rise (Lewis et al., 2006). Dental Protection Limited have commented that 'a dentist in the United Kingdom is nearly twice as likely to receive a claim for clinical negligence compared to just ten years ago and a full time dentist can now expect to receive two claims over a typical year' (Dental Protection Limited., 2018). It should be noted that in 2018/2019 the NHS Litigation Authority

(NHSLA) reported that negligence claims are starting to plateau and have been largely stable for the last two years although the ‘cost of harm’ increased to approximately £9 billion (NHS Litagation Authority, 2019).

Currently, there are no set regulations which clearly state how much information patients should be given regarding the risks of their treatment. Previously in the United Kingdom the standard of care has been based on the Bolam test. This establishes whether a clinician’s practice is accepted as proper by a responsible body of contemporary medical men skilled in that particular art (Bolam v Friern Hospital Management Committee, 1957). The depth of information to be provided regarding risks disclosure was governed by the House of Lords decision of Sidaway (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985). Therefore not only does the particular practice has to be accepted as proper by a responsible body of medical opinion, but that the body of opinion has to be reasonable and responsible (Bolitho v City and Hackney Health Authority, 1998), and that the opinion should be logical (Boynton S., 2006). Later on in 1999 it was ruled by the Court of Appeal that the responsibility lies with the clinicians to make known any significant risks which could affect the judgement of a reasonable patient (Pearce v United Bristol Healthcare NHS Trust, 1999).

In 2004, Lord Steyn in Chester v Ashfar stipulated that, ‘In modern law, medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery’ (Chester v Afshar, 2004). Therefore, clinicians should inform patients of any complications to treatment even if the risk is small. In a recent case of Olloson v Lee, a patient was consented for a vasectomy and was told that ‘the likelihood of chronic pain occurring was small, but greater than the rare and remote risks of early and late failure’ of the vasectomy (Olloson v Lee, 2019). The patient was informed that the pain could affect their lifestyle and that the range of this pain could be mild to severe with a chance of affecting the patient in the long-term. Unfortunately, the patient then developed chronic scrotal pain following the procedure and a claim was raised against the doctor as the patient felt that the risks were not adequately discussed. The judge subsequently decided that the percentage of the risks were not necessary and that it was sufficient to describe the risk as being ‘small’ which is an ‘an everyday word which encompassed and satisfactorily conveyed the risk’. The conclusion was that the patient could ask for further clarification when they are informed a risk is ‘small’ otherwise it is only necessary to provide information of the procedure and the risks involved (Olloson v Lee, 2019).

In 1992 the High Court of Australia ruled that, ‘A risk is material if in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it’ (Roger v Whitaker, 1992). Therefore, it seems that there is a large variation with regards to which risks are acceptable amongst judges. Furthermore the standards of risks informed seem to shift with what is deemed reasonable by the clinician and what is deemed reasonable by the patient (Brands, 2006). There has therefore been a move away from medical paternalism towards more patient-centred treatment with the term ‘enlightened consent’ being projected. This highlights that patients need to be given sufficient information to help them understand a certain procedure (Dental Protection Limited).

Consent came to prominence again in the in the Montgomery case (Montgomery v. Lanarkshire Health Board, 2015a). In 1999, Mrs Montgomery was an expectant mother who also had diabetes mellitus, these patients tend to be at higher risk of their babies having shoulder dystocia during natural birth as the babies are larger than normal. This risk was not explained to the patient as it was deemed as a ‘small’ risk. Unfortunately, during labour the babies shoulder became stuck leading to the child being born with cerebral palsy and quadriplegia. Mrs Montgomery therefore argued that should this risk have been known to her she would have opted for an elective caesarean section. The Supreme Court ruling ruled that a reasonable patient would have attached significance to the risk of shoulder dystocia and should have been told if there was a possibility of avoiding this complication by having a caesarean. This ruling of material risk now represents a considerable change in the medical law in United Kingdom (Convie et al., 2018).

Following the Montgomery case it was highlighted that a patient has to be informed of what they would consider to be a material risk: ‘The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.’ ‘The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it’ (Montgomery v. Lanarkshire Health Board, 2015a). This would suggest that patients need to know the material risks of orthognathic surgery, then decide on the amount of risk they are willing to take. In other words, is the risk of the event happening enough to make them decline surgery. Therefore, the surgeon and patient need to have a thorough discussion of the risks of surgery that allows the surgeon to understand what the material risks are for a particular patient, and then to give them the information to be able to agree to or decline surgery.

Dunn et al. (2019) argues that the Montgomery ruling correctly implies clinicians are legally obliged to address patients' autonomy and well-being when consenting patients to treatment. The UK Supreme Court concluded that the information that is material to a patient's decision should be judged in reference to a new two-limbed test founded on the notions of the 'reasonable person' and the 'particular patient' (Dunn et al., 2019). The rationale behind this is that the law now takes into consideration the respect for the patient's autonomy in the process of obtaining consent (Dunn et al., 2019). 'Therapeutic privilege' however is an exception to the two-limbed test (Dunn et al., 2019; Montgomery v. Lanarkshire Health Board, 2015b). This refers to an interpretation of what a 'reasonable person in the patient's position' would require not to be told due to possible impact on the patient's well-being (Dunn et al., 2019).

Mazur, (2009) discusses the 'subjective patient standard' in which the clinician should give information that the patient requests to be informed of. This will undoubtedly have substantial impact on clinical practice however it further highlights the importance of an in-depth conversation with the patient when obtaining valid consent and that the responsibility lies with the clinician to be thorough with the consent process. This is a legal and ethical obligation upon all health care professionals.

1.9 CONSENT IN ORTHOGNATHIC SURGERY

As discussed previously as orthognathic surgery involves orthodontics and maxillofacial surgery only those clinicians who are experienced in both disciplines can normally obtain consent. This is where a multidisciplinary clinical setting makes it convenient for this discussion to take place where both specialities come together to manage these patients (Naini and Gill, 2017).

The consent process does not necessarily occur during one visit but can be carried out across several visits and this also gives the opportunity for the patient to review the soft tissue predictions of their potential surgical outcomes (Naini and Gill, 2017). This gives patients the chance to consider the options available, the implications of the treatment modality and the opportunity to clarify any questions they may have before deciding. It is important to highlight that this surgical procedure is elective and its primary outcome is an improvement in the patient's quality of life as opposed to a procedure to treat disease or pathology. Therefore the discussion between the patient and clinician should reflect this (Naini and Gill, 2017).

In elective surgery it is difficult to discuss the risks of general anaesthesia (GA). Although the risk of anaesthetic death is without doubt a catastrophic consequence in a patient who is generally fit and well, the risk remains to be very rare, approximately 1 death in 100,000 GA's. Given that around 3 million GA's are given each year, this means that approximately 30 fit and healthy people a year die as a result of the GA. On the other hand, it clearly is one risk a reasonable patient would want to know about given that the surgery is elective rather than a lifesaving procedure. The argument put forward by paternalistic clinicians who would want to withhold such information or not emphasise it is that the disclosure of such information could result in the patient not undergoing a procedure that they could potentially benefit from (Raab, 2004). Those in favour of patient enlightenment would say that if the patient is informed that this anaesthetic risk is very small in comparison to life event risks, that are accepted daily, for example the risk of dying in a road accident in any year in the U.K. approaches 1 in 20,000. In this respect such information that would supposedly deter patients may in fact give them reassurance (Naini and Gill, 2017).

Sharma and Chate (2011) carried out a cross sectional written questionnaire-based study assessing the knowledge and understanding of informed consent amongst orthodontic trainees in the United Kingdom. Surprisingly there was a low number of complete responses to specific questions in the following areas – 'Explanations patients need from clinicians prior to obtaining consent; How to fully judge if a patient is capable of consenting; How to manage a patient incapable of giving consent; The legal status of fathers consenting on behalf of their children; Whether consent forms have to be re-signed if the start of treatment is delayed by six months or more and responsibility for obtaining consent for dental treatment under general anaesthesia'. This further highlighted that there was a high number of incomplete answers to questions amongst the trainees which determined their knowledge of law with regards to informed consent (Sharma and Chate, 2011). This was similar to their study carried out in 2008 amongst orthodontic consultants (Chate, 2008). Similarly a lack of knowledge was identified in the following areas: 'What explanations patients need from clinicians in order for them to give consent, How to fully judge if a patient is capable of giving consent, How to manage a patient deemed incapable of giving consent, The legal status of fathers consenting on behalf of their children, Whether consent forms have to be re-signed if the start of treatment is delayed by six months or more, and that Dentists referring a patient for treatment requiring a general anaesthetic have the same duty to receive consent for the anaesthesia as do the clinicians who will be performing the surgical procedure' (Chate, 2008). Therefore, there is room for improvement in terms of the consent process for both Consultant orthodontists and orthodontic trainees. Furthermore, it is evident that there is an apparent need to develop and support the consent process at all levels of clinical engagement and this encompasses all staff grades.

1.10 THE CONSENT PROCESS

As mentioned previously for consent to be valid patients need to understand the harms and benefits of an intervention as well as alternative options available. They must also be able to use this information to make their decision and then relay this information back to the consenting individual (Department of Health, 2012). This is in the form of a conversation between the clinician and the patient and utilising decision-making aids such as a patient information leaflet titled 'Orthognathic surgery' or directed to the British Orthodontic Society (BOS) website 'Your Jaw Surgery' for further information (British Orthodontic Society (BOS), 2014). 'Decision aids' have improved the consent process (Stacey et al., 2017). A recent Cochrane review of 'Decision aids for patients facing health treatment and screening decisions' found high quality evidence suggesting that patients who were presented with decision aids felt more comfortable and better informed with regards to their options as well as this decreasing decisional conflicts (Stacey et al., (2017). Another systematic review of randomised controlled trials looked at interventions to improve adherence amongst orthodontic patients (Aljabaa et al., 2015). Although this study was reviewing orthodontic patients, it is evident that spending time with patients including written information improves adherence to intervention. Stacey et al. (2017) found that using decision aids increased the accuracy in the patient's risk perceptions compared to when decisions aids were not used. However, interestingly there were no adverse effects on health outcomes or satisfaction. This was similar to the findings of a Cochrane review of interventions to promote informed consent for invasive procedures. In this review the interventions that were utilised to improve consent, reliably enhanced patient knowledge which is an important prerequisite for informed consent (Kinnersley et al., 2013). The shortcomings were that both studies reported high levels of heterogeneity in outcomes, which in turn made it hard to formulate subsequent comparisons. Therefore, it is not clear as to which specific interventions are most effective, although work towards improving information delivery will without doubt benefit patients. Further research is required to ascertain the measurable outcomes which inform the quality of informed consent and then subsequently develop a standardised tool to measure these.

1.11 QUALITATIVE RESEARCH

1.11.1 Focus groups

Focus groups have been utilised in qualitative research especially in medicine and now increasingly in dental research (Curtin, 2016). Focus groups are able to inform and shape a proposed clinical research topic by encouraging group discussion on a particular topic (Goodman and Evans, 2015). While focus group methodology is not identified to a specific qualitative methodology, it is being progressively used in healthcare research as they are valuable in studying collection outlooks and experiences (Gill and Baillie, 2018). This in turn can shed light on in-depth data and highlight agreements as well as inconsistencies between the groups (Goodman and Evans, 2015). Focus groups can be used in isolation or with other methodologies such as interviews to enrich understanding as well as provide alternative perspectives (Goodman and Evans, 2015).

The social interaction between the participants can lead to a meaningful discussion in which useful data can be extrapolated. Although focus groups are incredibly useful they can be difficult to manage in particular with sensitive topics that certain participants may not wish to discuss as a group (Gill and Baillie, 2018). They are mostly carried out face to face but can also be carried out virtually (Fielding et al., 2017). Using online platforms, data collection can be synchronous (such as online discussions in real time) or asynchronous (such as email discussions in non-real time) which does not happen in traditional face-to-face groups (Gill and Baillie, 2018).

1.11.2 Usability of focus groups

An consolidative review was carried out to evaluate the use of focus groups within dental research (Curtin, 2016). The study found three key points from the six papers that were included in the review: different focus groups methods, focus group-based research had benefits for dentistry and quality controls needed to be employed in setting up and running the focus groups. The qualitative review found that focus groups can enhance qualitative research. However, it was important for the researchers to carry out advanced preparation and that they have sound theoretical knowledge as well as experience to facilitate group discussion. As well as this, they should have sound knowledge of the group dynamics and have excellent communication. This is also supported by Shaha et al. (2011) who reiterates this finding.

1.11.3 Focus group considerations

There are key considerations that need to be considered when using focus group methods. If they are undertaken face-to-face then one must consider how many participants are required and how many groups are required for a single study (Gill and Baillie, 2018). There is no definitive answer and varies amongst different studies as they largely depend on what is being researched and how in-depth the discussions are required to be (Shaha et al., 2011; Gill and Baillie, 2018). The ideal group size is between six to eight participants but can also work adequately with around three to four participants (Gill et al., 2008). It should be noted, however, that smaller groups could mean that the discussions are limited and larger groups could make the conversations more difficult to organise. It is also worth noting to recruit two to three participants more than the desired number to allow for participants who do not attend or withdraw from the study (Gill and Baillie, 2018).

For online focus groups similar considerations need to be taken. Synchronous online focus groups will involve approximately three to eight participants and non-synchronous groups can have as many as ten to thirty participants as the discussion does not occur at the same time (Poynter, 2010). When the participants in the group know each other such as work colleagues, this then facilitates their recruitment as they tend to have shared experiences and their familiarity facilitates a discussion as well as them having the ability to challenge each other without them taking offense (Gill et al., 2008). On the other hand, if there are existing hierarchies within the group or a potential power imbalance then in this case it would be best to have ‘stranger groups’ which is essentially participants not knowing each other in order to allow them to speak up (Barbour and Kitzinger, 1999).

1.11.4 Focus group management

Normally, face to face focus groups are carried out by two researchers, a moderator and an observer. The moderator facilitates the group discussion and the observer monitors the group dynamics which is paramount for data analysis (Goodman and Evans, 2015). The venue should be carried out at a convenient location for the participants and the in a quiet area free of any disruptions (Gill and Baillie, 2018). Another consideration to have is the timing of the interviews which should be appropriate to encourage attendance which may be out of work hours. Ethical considerations should also be applied with online focus groups such as informed consent and encrypted data storage (Gill and Baillie, 2018). Before the focus group discussions begin the researchers should introduce themselves, establish rapport with the participants and help them feel comfortable. This should in turn lead to a more in-depth discussion. The researchers should clarify what their research aims are and lay out ‘ground rules’ to assist the discussion. These rules are to reinforce that the discussions are confidential, that all the participants will have the opportunity to speak and that only one person can speak at one time. It will be reiterated that all views and opinions are to be respected and challenging opinions are welcomed (Gill et al., 2008; Shaha, et al., 2011; Goodman and Evans, 2015). They may then use a topic guide to facilitate the discussion.

To have a precise account of the discussions that have taken place, focus groups must be recorded and this is usually carried out with an audio recorder. Video recording can also be possible however this may be intrusive to some which can have a negative effect on the group dynamics (Gill et al., 2008). At the end of the discussion, the researchers should summarise the points made and reflect on the discussion (Goodman and Evans, 2015).

Some discussions can give rise to sensitive issues in which case the participants may require support to navigate through these. Therefore, they can be reminded that a referral to a third party is available at the end of the discussion. Some participants may no longer want to be included in the study as they feel the discussions did not reflect their views. This is uncommon, however should this arise then it is important to give them the opportunity to discuss their concerns and offer them the option to withdraw from the study (Gill and Baillie, 2018).

Focus groups and individual interviews are often chosen as the preferred qualitative method for data collection, as opposed to participant observation as it was felt this would extract rich information on the participants lived experiences. Whereas participant observation looks at 'developing a sustained relationship with people while they go about their normal activities' (Bachman and Schutt, 2019). Although theoretically their behaviours can be observed, it was important to gain an understanding of their interpretation of their behaviours and this can only be effectively done through interviews. It is also important to have both semi-structured one-to-one interviews as well as focus groups. This is because focus groups can 'increase the validity of attitude measurement by revealing what people say when presenting their opinions in group context' (Bachman and Schutt, 2019). Therefore, they encourage interaction between participants, generating discussion and eliciting their perspectives of the risks of orthognathic surgery. Participants would then bounce off each other and prompt another in discussing their experiences. The added benefit of semi-structured interviews, however, would mean there would be in-depth insights which reflects the individual's perception of their experience and not be influenced by other opinions if they were in a group. Another advantage of this qualitative design was that it gave us a greater depth of data with a smaller number of participants.

1.12 QUALITATIVE RESEARCH STUDYING PATIENTS UNDERGOING ORTHOGNATHIC SURGERY

Qualitative research has been described as an approach for 'systematic collection, organisation and interpretation of textual information used to explore social phenomena as experienced by individuals themselves, in their natural context' (Malterud, 2001). Qualitative research uses methods of analysis that are difficult to measure quantitatively and are designed to identify the thoughts and experiences of individuals rather than numerical data. There are a limited number of publications which have qualitatively investigated the decision-making process patients undergoing orthognathic surgery (Paul et al., 2022; Lee, 2014; Bradley et al., 2020; Stirling et al., 2007; Broder et al., 2000)

Patients' experience of decision-making for orthognathic treatment has recently been reported (Paul et al., 2022). Face to face interviews were carried out for patients who have had orthognathic surgery at a teaching hospital in the United Kingdom. Twenty-two participants were recruited at different stages of their treatment journey: at the decision-making stage, 6-to-8-week post-surgery and 1 to 2 years post-surgery. Data analysis was carried out using grounded theory methodology including open and selective coding. The study found that dental care professionals had a fundamental role in the decision-making process and supporting patients in this journey to improve the patient experience. Six key aspects were identified in this process: ‘awareness about the underlying dentofacial problems and treatment options available, the information available about the treatment, the temporality of when surgery would be undertaken, the motivations and expectation of patients, social support, and fear of the surgery, hospitalization, and potentially disliking the new facial appearance’. The study concluded that the decision-making process is complex and is greatly influenced by dental care professionals.

A retrospective audit assessing the level of knowledge of patients who had had orthognathic has raised several deficiencies (Lee, 2014). Four questions were related to the current orthognathic information leaflet, how patients preferred information delivery, their use of websites and their hospital experience. The areas where patients felt they needed additional information were on recovery time, possibility of wiring jaw together, postoperative dietary requirements and possibility of relapse.

A third study investigated the patient reported experience and outcomes in relation to orthodontic treatment, however the authors felt it was useful to refer to this study as it evaluated patient experience which can be extrapolated to patients undergoing orthognathic surgery (Bradley et al., 2020). This was a cross-sectional survey and data were collected using the Orthodontic Patient Treatment Impact Questionnaire (OPTIQ), a validated 12-item measure with questions relating to pre-treatment experience, impact of treatment and outcome from treatment. They found that the OPTIQ is a useful patient-reported tool to identify pre-treatment concerns and expectations, treatment experience and outcome which can also be used to evaluate patient experience who have undergone orthognathic surgery.

Stirling et al. (2007) looked at a cross sectional survey of 61 participants with both post-operative and prospective samples using a questionnaire to assess patient demographics, dental history and psychopathology (anxiety, satisfaction with self, body satisfaction, facial appearance). Additional interviews were conducted which questioned their reasons for and experiences of orthognathic treatment. The study concluded that some patients do not appear to be making informed decisions about their treatment and that the reasons given for having treatment were to improve their 'bite', as well as gaining a more normal facial appearance. Around 50% of the participants made negative comments regarding the service, with some reporting staff communications made them feel worse and the knowledge of the surgery’s risks and benefits were poor. Although this study picked up on what patients were concerned about during the decision-making process it failed to identify the factors that influenced decision-making.

The final study, however, further investigated this (Broder et al., 2000). They conducted focus group interviews of orthodontic treatment versus orthognathic surgery, looking at post-operative patients only. Emerging themes highlighted the key role of patient-clinician communication and interpersonal skills in supporting decision-making, the availability of support and the patient's readiness for change.

All studies identified that decision-making is complex and multidimensional. Overall, further qualitative research is required to ascertain the perception of risks and their impact on the decision-making process. Qualitative methodology allows the researcher to obtain in depth descriptions to explore perception of risks in this group of patients during decision-making.

1.13 SUMMARY

It is evident from the narrative literature review that orthognathic surgery has a long and complex treatment pathway. The main aims of the surgery are to improve dentofacial aesthetics, function as well as psychosocial well-being and quality of life. The quality of healthcare has now been redefined to include patient experience, patient safety and clinical effectiveness. In order to reach this standard of care it is paramount to address why a patient is seeking this treatment modality. Motivating factors for seeking treatment may not necessarily be related to impact of the dentofacial disharmony but in fact there can be other underlying factors such as childhood upbringing and personality traits (Ryan et al., 2012). This illustrates the importance of clinicians to treat patients on an individual basis. This starts by involving the patient at every opportunity as this ultimately improves patient satisfaction.

Orthognathic surgery is a complex procedure which involves risks and comorbidities that a patient should not take lightly when weighing up whether they would like to go ahead with surgery. Following Montgomery v Lanarkshire Health Board it was highlighted that a patient has to be informed of what they would consider to be a material risk (Montgomery v. Lanarkshire Health Board, 2015a). Following this ruling, the UK Supreme Court concluded that this should be judged by reference to a new two-limbed test founded on the notions of the 'reasonable person' and the 'particular patient' (Dunn et al., 2019). Respecting patients' autonomy is therefore now the centralised approach in obtaining consent from patients. The 'subjective patient standard' in which the clinician should provide information that a particular patient would want to know has also been highlighted (Mazur et al., 2009). Above all, health care professionals have a legal and ethical duty of care to ensure that patients are adequately informed about the procedure they are consenting to.

CHAPTER 2

AIM AND OBJECTIVES

2.1 AIM

There are a limited number of publications which have qualitatively investigated the treatment journey and the risk based decision-making process of patients undergoing orthognathic surgery following the Montgomery versus Lanarkshire Health Board (2015) legal ruling. Therefore, the aim of the study is to carry out qualitative research to ascertain the perception of risks during decision-making in a group of patients who have undergone orthognathic surgery. The goal is to improve the consent process of this elective procedure and better tailor this for each individual patient and improve their overall experience.

2.2 OBJECTIVES

The objective of this research is to lay the groundwork for a structured approach for orthognathic surgeons in carrying out conversations about risks and taking consent prior to surgery and improve the patient journey.

- To identify the patients’ perception of the care pathway
- To identify the range of perceptions the patients have with respect to the risks
- To identify the range of attitudes of patients to the risks to be taken
- To identify those risks of particular importance to these patients

CHAPTER 3

METHODOLOGY

3.1 RATIONALE BEHIND THE STUDY DESIGN

The aims of this study were to evaluate patients' perception and their lived experiences and therefore this is best captured qualitatively using focus groups and one to one interviews.

3.2 ETHICAL APPROVAL

Ethical approval was granted by the HRA and Health and Care Research Wales (HCRW) on the 24th November 2020, REC reference number 20/NW/0433 (Appendix 1). Research and development approval was obtained from Birmingham Community Healthcare NHS Trust on 15th September 2021 (Appendix 2).

3.2.1 Ethical considerations

The participants were given the opportunity to speak to the researcher if they had any questions regarding the study. They were also informed that their participation is voluntary and that they can opt to leave at any point.

Participants sometimes disclosed personal and upsetting experiences during the interviews. The interviewer ensured that those participants who were emotionally distressed had time to recompose and checked with them if they would like to continue or discontinue the interview. Verbal consent was gained again to ensure they were happy to proceed with the interview. Participants were signposted to counselling services should they need so.

3.3 SETTING

The interviews were carried out using Microsoft Teams at a time convenient to the participants and was conducted by two researchers (SMS and BK). Microsoft Teams is a secure platform which is in line with Data Protection as required by this study and was provided by Birmingham Community Healthcare NHS Foundation Trust. They were conducted in a non-clinical setting at the participants residence which is important as the setting will ultimately impact the content of the results. Preparation was carried out prior to the interviews to ensure the speakerphone was working and that there was good internet connection. Clear instructions were sent to the participants to explain how to connect onto the platform and they were notified beforehand that they would require an electronic device such as laptops or phone.

3.4 CONSENT

The participants were given an informed consent form (ICF) during their clinical appointment (Appendix 4). Those who expressed interest to join the study were contacted two weeks after the referral. At this point they were informed to sign the consent form and return this by post or online via secured NHS encrypted e-mail to the researcher (SMS). A hard copy was printed, and this document was placed in the Investigator Site File (ISF). Each participant was given the opportunity to ask questions regarding the study before signing and returning the ICF to the researcher. The researcher adequately explained the aims, anticipated benefits, and potential hazards of taking part in the project to the participants. It was also stressed that participation is voluntary and that the participant was free to refuse to take part and may withdraw from the project at any time without giving a reason. It was also explained to the participants that for focus groups they will be offered a shopping voucher to compensate them for their time and for the one-to-one interviews, the participants were also offered a shopping voucher. On the day of the interviews prior to conducting the interviews the participants were also asked to give verbal consent that they are happy to participate in the study.

3.5 THEORETICAL POSITION

Braun and Clarke (2006) state the importance of recognising the theoretical position and values when it comes to analysing the data. It proves difficult to evaluate research without knowing which lens the data has been interpreted with and the perspective that informed the analysis. The thematic analysis can either be a realist method looking at 'experiences, meanings and the reality of participants' or a constructionist method which examines the ways in which 'events, realities, meanings, experiences' are the effects of 'a range of discourses operating within society' (Braun and Clarke, 2006). For the current study the realist method has been predominately utilised as the aim was to better understand orthognathic patients' perception of risks and how their lived experiences may shape the consent process. Therefore, a methodology was required that would help better understand patients' perception of risks and how they felt about the consent process. Consequently, the stance of the researcher is important to recognise and within this constructivism method it is important to also apply the principles of reflexivity.

3.6 STUDY PARTICIPANTS

This was a qualitative, semi-structured interview-based study of adults who have undergone orthognathic surgery at Birmingham Dental Hospital and Queen Elizabeth Hospital, United Kingdom.

Potential participants who satisfied the inclusion criteria (see below) were invited to become involved in the research by their treating clinician (Consultants and Specialist Trainee Registrar) at Birmingham Dental Hospital and School. If they expressed an interest, the researcher (SMS) briefly informed them about the research, and they were given a participant information sheet

(PIS) (Appendix 3). This gave details around the aims of the study, what the research involved and the duration of the interviews. It was outlined to the patients at this point that their involvement will be anonymous and that participating will not impact their care in any way. Lastly, they were given an informed consent form (ICF) to read and discuss with others in their own time (Appendix 4).

The patients were asked verbally, to give consent to pass their name and preferred method of contact (email, address, or telephone number) to the research team and a note of this was made in the medical notes. A log of all participants referred to the research team along with their referral site was kept by the research team as part of the site file. A member of the research team (SMS) then contacted the potential participants via their contact information two weeks after referral. An option was given to the participants to either carry out a one-to-one interview, to be part of a focus group or if they had no preference this was also noted. A virtual appointment was then made for the potential participants who expressed interest to join the study.

Inclusion criteria

- Patients aged 18 to 60 years old.
- Patients who had undergone orthognathic Surgery.
- Orthognathic surgery which involved surgery to both the maxilla and mandible.

Exclusion criteria

- Patients under 18 years of age and over 60 years old.
- Patients lacking capacity and unable to consent.

- Patients with craniofacial syndromes with significant co-morbidities that would impact on healthcare provision.
- Patient's first language is not English.

3.7 SAMPLE SIZE

It is impossible to state exactly how many patients need to be interviewed in qualitative research of this type and no previous studies existed so a formal sample size calculation could not be carried out. However, the sample size was based on similar studies (before the research) and were guided by the concept of saturation (during the research) as well as the number of patients who may fulfil the inclusion criteria. Holton and Walsh (2017) explain that the point of saturation is reached when 'constant comparison of conceptual indicators in the data to the point where additional indicators yield no further theoretical specification or elaboration'. The sample size was therefore determined by the point of theoretical saturation whereby no further new themes emerged. This cannot be determined prior to beginning the data collection.

3.8 DATA COLLECTION

Prior to commencing the interview, the aims of the study were explained to the participants, and they were given the opportunity to ask any questions that they may have. Further assurances were given regarding confidentiality and their involvement in this study would not impact their care. Data protection was also discussed and at this point the participants. Once any concerns were addressed, they participants were asked to give verbal consent.

Interviews were conducted at the interviewee's convenience, which were in the evening and weekends, for people who work during weekdays. A topic guide was developed, using information from a thorough review of the literature to ensure the interviews were carried out in a consistent manner (Appendix 5). This indicated the expected areas to cover by the interviewers and prompt questions were included to encourage discussion. It is important to note that although a topic guide was used to outline a framework, the interviews were kept flexible and exploratory depending on the lived experiences of the participants. Emerging themes were added to the guide cumulatively as part of an iterative process by sharing findings from earlier interviews to encourage reflexivity.

The interviews were recorded with the participants' consent, and they were assured that only audio was being recorded and not video to further ensure anonymity. The audio was recorded and stored on an encrypted digital voice recorder. These are the same digital recording devices that are used for dictating patient letters by NHS clinical staff. They were kept securely and were only accessible by the research team. Each device had a unique access code. The recordings were then transferred from the device onto an NHS password protected PC within 7 days. The data on the digital recorder was automatically deleted following transfer onto the NHS PC. These recordings were then transcribed using Microsoft Word®. The recordings, once transcribed, were then re-examined for accuracy and adjustments made if required.

3.9 DATA HANDLING AND RECORD KEEPING

3.9.1 Patient information

Patient related information was anonymised due to patient confidentiality and was stored in accordance with the Data Protection Act 1998. All research forms were labelled with a unique patient identification code, which is linked to their NHS number through a patient identification log kept in the site file. All paper forms were kept in a secure, locked filling cabinet in a locked room with restricted access, located at Birmingham Dental Hospital. All digital records were stored on a password protected NHS server. The audio data of the focus groups and one-to-one interviews were recorded and stored on encrypted digital voice recorders. They were kept securely and were only accessible by the research team. Each device had a unique access code. The recordings were then transferred from the device onto an NHS password protected PC within 7 days. The data on the digital recorder was automatically deleted following transfer onto the NHS PC.

3.9.2 Archiving

All essential project documentation and source documents (e.g. signed Informed Consent Forms and Investigator Site Files) will be retained for at least 10 years by University of Birmingham Research Archive in accordance to the University of Birmingham Code of Practice for Research.

3.10 ANALYSIS

3.10.1 Thematic analysis as a method for data analysis

'Thematic analysis is a method for identifying, analysing, and reporting patterns (themes) within data' (Braun and Clarke, 2006). It enables to organise data to be set in 'rich detail' due to its flexibility through theoretical freedom. It involves searching across the data set to find repeated patterns of meaning. Thematic analysis is useful in this study as it allows the researchers to interpret the participants perspectives in terms of their perception of risk and lived experiences. It is also not bound to pre-existing theoretical frameworks such as grounded theory and so can be used as part of the constructivist method. Theoretical frameworks assume what the data represents however a good thematic analysis makes this transparent (Braun and Clarke, 2006).

3.10.2 Data analysis

Thematic analysis was used in accordance with guidelines outlined by Braun and Clarke (2006) to analyse the transcripts. Table 3.1 outlines the steps utilised in the analysis phase as per the Braun and Clarke (2006) guidelines.

Firstly, the researcher (SMS) read the transcript several times to become familiar with the data set. Codes were then identified on NVivo software to assist data organisation. Codes are a feature of the data that stands out to the researcher and is referred as 'the most basic segment, or element, of the raw data or information that can be assessed in a meaningful way regarding the phenomenon' (Boyatzis, 1998).

Once the codes were identified they were grouped into potential themes. A theme unified certain behaviours and perceptions by capturing a patterned response within the data set (Braun and Clarke, 2006). The process was assisted with visual representation by carrying out a written mind map with post it notes whereby the codes can be played around with and organised into.

Table 3.1 Key phases of thematic analysis

Phase	Description
Familiarisation with the data set	Transcription, reading and rereading the data, noting down initial ideas.
Generation of the initial codes	Coding interesting features of the data systematically, collating data relevant to each code.
Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme.
Reviewing themes	Ensuring the themes correspond to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic map.
Defining and naming themes	Ongoing analysis to refine the specifics of each theme and the overall story the analysis tells, generating clear definitions and names for each theme.
Producing the report	Selection of vivid extract examples, final analysis of selected extracts, relating back to the research question and literature.

Adapted from Braun and Clarke (2006)

theme piles. Meetings were held to review the coding and to reach consensus with the themes identified. Through these discussions new coding and themes were added. Once a thematic map was created, the specifics of each theme was refined and the overall story that the analysis was pointing towards.

Clear definitions were generated, and the names of each theme were finalised amongst the researchers. Each theme was distinct from other themes and relevant to the research question. There were, however, themes that emerged that did not answer the research question, nonetheless it was felt that they required addressing. This can often occur in qualitative research and is outlined by Braun and Clarke (2006) whereby the specific research question can evolve during the coding process. This maps onto the 'inductive approach' as opposed to the 'theoretical approach'. The second domain of the research question that emerged was how orthognathic surgery impacted the participants psychosocial well-being and what should be considered during the consent process as a result of their lived experiences. Therefore, the research question was refined as the research progressed. Data analysis occurred simultaneously with the interviews until no new themes were identified. The point of saturation was ultimately decided upon by the researcher (SMS).

CHAPTER 4

RESULTS

4.1 SAMPLE DEMOGRAPHICS

Patients who had undergone bimaxillary orthognathic surgery were recruited from review clinics at Birmingham Dental Hospital. Recruitment began in September 2021 and was completed by December 2021. All patients were approached by an orthodontic registrar (SMS). Twenty-three participants were initially identified and of those fifteen were interviewed, Figure 4.1. Ten of the participants interviewed were female and five were male. Ages ranged from twenty-three years to forty-three years old. The range of surgery dates was from October 2017 to December 2019.

4.2 DATA COLLECTION

Participants were given a unique code to describe their gender M = male / F = female, age in years and then a numerical identifier. For example (M25-1) describes a twenty-five-year-old male with identifier 1. There were in total four participants who carried out a one-to-one interview and three focus groups altogether consisting of eleven participants, Table 4.1.

4.3 THEMATIC ANALYSIS

Data collection and thematic analysis occurred simultaneously until saturation was achieved and no new themes emerged (Morse, 2015). These characteristics are identified from the underlying theoretical theme as the data increases in these categories. It was therefore agreed that there was sufficient material to underpin answering the research question. The transcripts underwent an extensive and iterative coding process of which two domains were identified. The first domain investigated perceptions of risk involved in orthognathic surgery pertaining to the research question. The second domain looked at the impact of orthognathic surgery on patients' psychosocial well-being and considerations during the consent process. Both domains

Figure 4.1 Participant flowchart

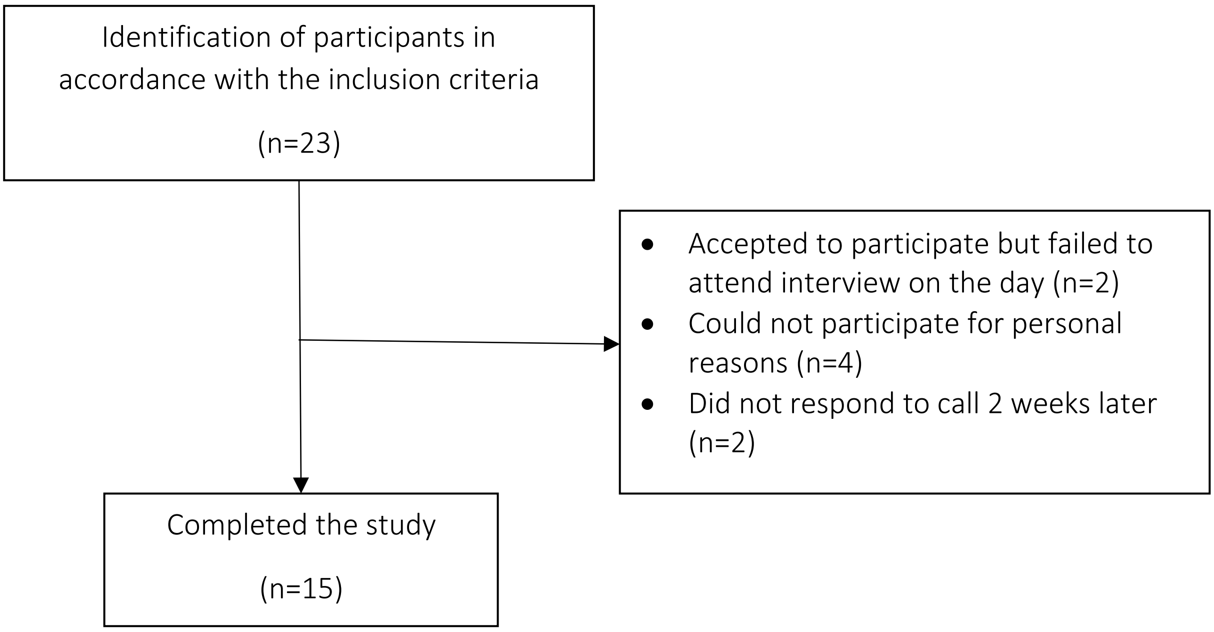


Table 4.1 Identifiers of participants

Type of Interview	Participants
One to one interview 1	F31-1
One to one interview 2	F43-2
One to one interview 3	F27-3
One to one interview 4	M29-4
Focus group 1	F26-5, M24-6, F24-7
Focus group 2	F23-8, M26-9, F27-10, M25-11
Focus group 3	F27-12, F25-13, F30-14, F24-15

identified three themes each. The themes and sub-themes are presented in Figure 4.2 and Figure 4.3.

4.4 PERCEPTIONS OF RISK INVOLVED IN ORTHOGNATHIC SURGERY

Three main themes were identified from the interviews centring on the patient’s perceived risks to orthognathic surgery:

1. Sources of information about orthognathic surgery
2. Surgical risk
3. Setting and format of how risks should be presented

4.4.1 THEME 1: SOURCES OF INFORMATION ABOUT ORTHOGNATHIC SURGERY

Patients sought information concerning orthognathic surgery in a variety of ways. These will be reported with quotes from the interviews to illustrate the different approaches. The primary source of information was obtained via the internet, various formats such as the British Orthodontic Society website (British Orthodontic Society (BOS), 2014), Instagram, YouTube and online forums were used.

4.4.1.1 British Orthodontic Society website

Following clinical assessment many participants were directed towards the British Orthodontic Society (BOS) videos on orthognathic surgery. These videos are the standard resource recommended by clinicians to patients - ‘Your Jaw Surgery’ (British Orthodontic Society, 2014). There were mixed reviews on the benefit of this information. Some individuals reported the information was beneficial,

Figure 4.2 Themes and sub-themes identified for domain one: Perceptions of risk involved in Orthognathic surgery

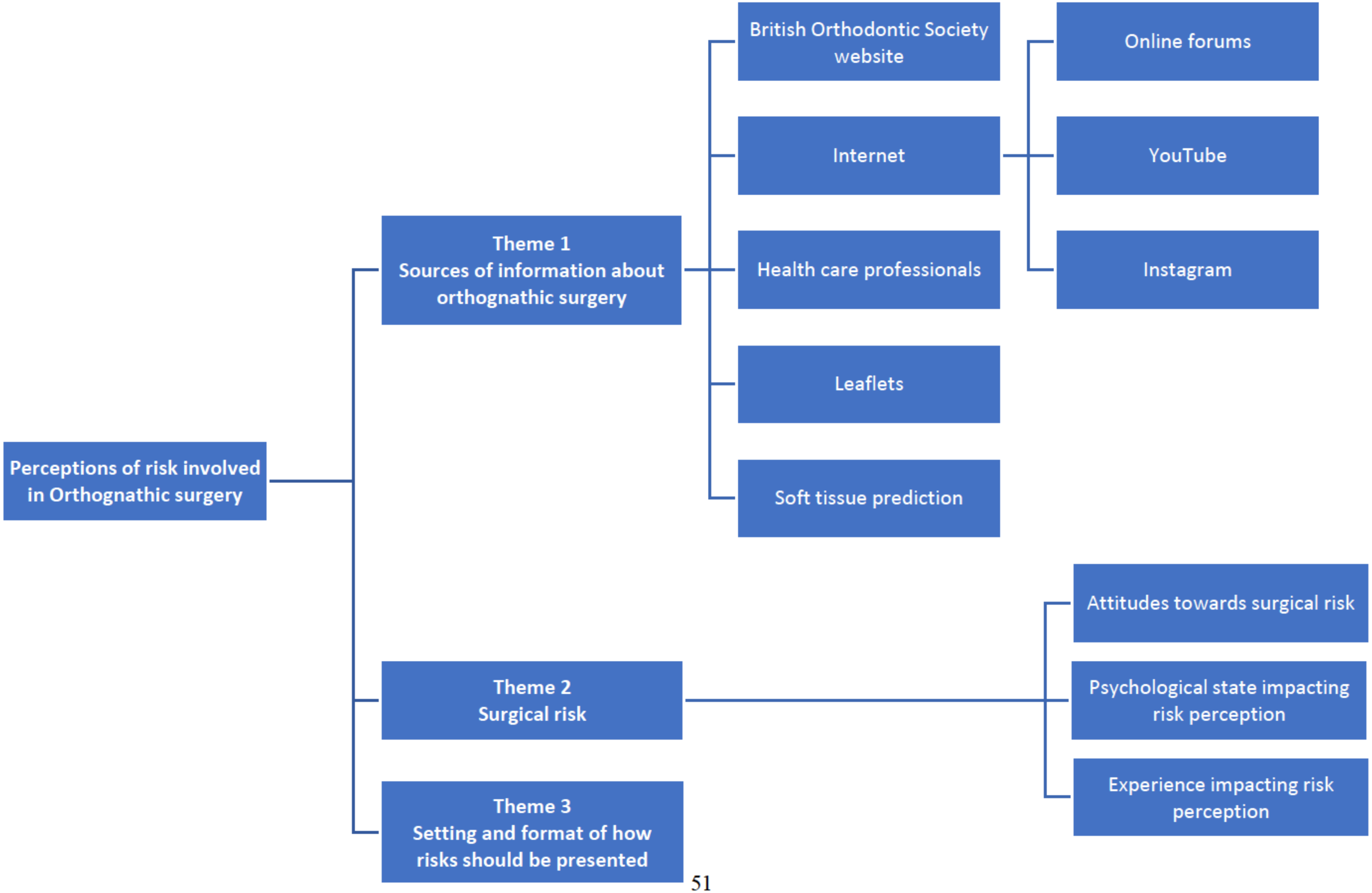
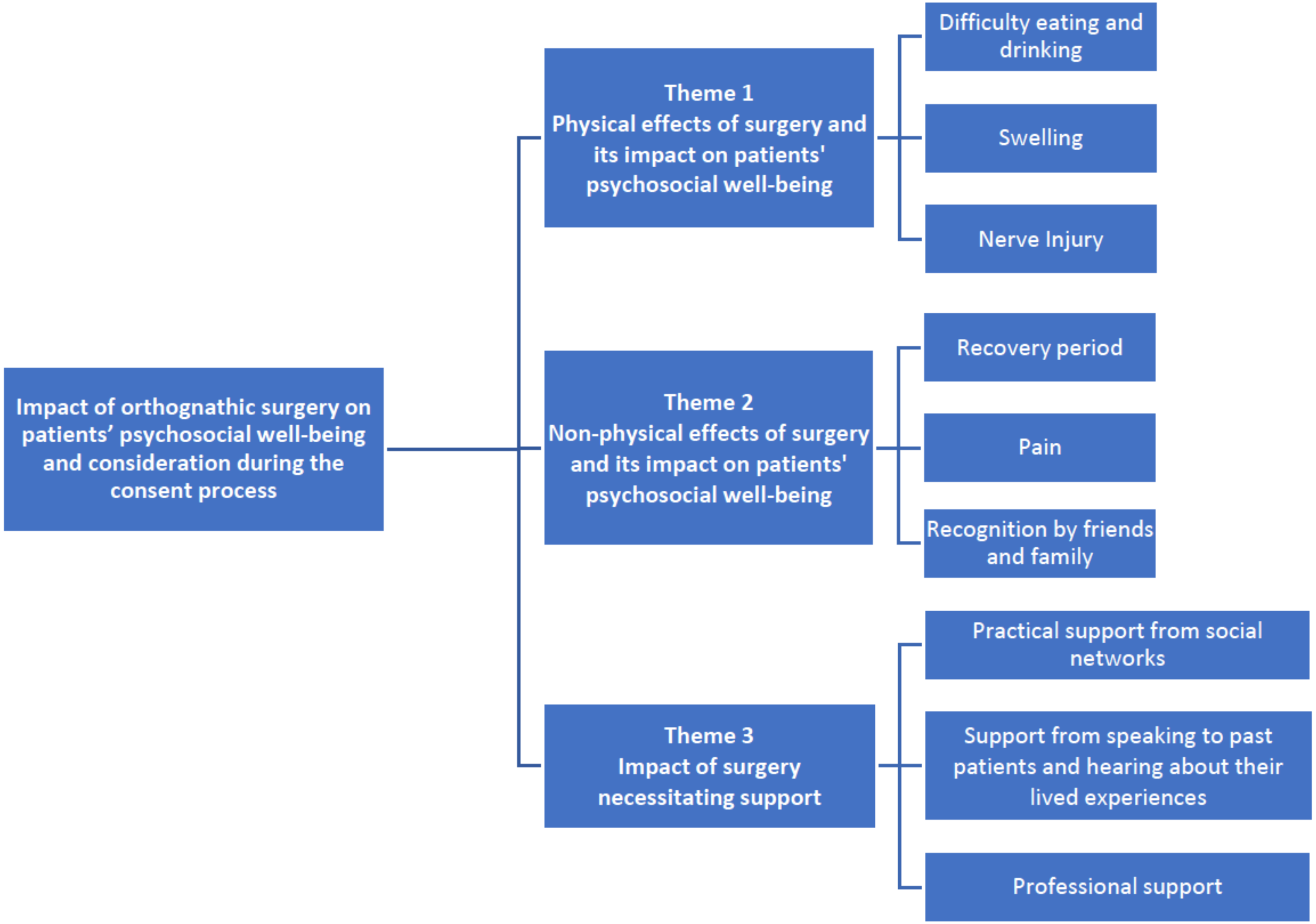


Figure 4.3 Themes and sub-themes identified for domain two - Impact of Orthognathic surgery on patients’ psychosocial well-being and considerations during the consent process



> *'I watched the video quite early on and I think that really prepped me.'* (F23-8)

Whilst, to others it seemed that the videos gave a positive bias towards surgery.

> *'So, I looked at that and I looked at people that had already had the surgery done and listened to their experiences and what they had done and how their recovery process is going. So, as I was watching that, people had really good experiences. So, then that really enticed me more to go for it.'* (F27-3)

However, there were several participants who felt that the presented information did not give a true representation of the treatment journey.

> *'I felt like it was all sugar coated, to be honest, like no one was really being honest.'* (F27-3)
>
> *'There are some cases where you need to know where it hasn't been successful so then you can make your mind up with what you want to do. And, you know, then that that puts everything into perspective, so then you know what to expect.'* (F27-3)

Some participants mentioned that the "lived experience" of a past patient who has gone through the journey would have been more helpful.

> *'I found the YouTube videos more helpful because it was a lived experience. Each showed that they got better eventually. It showed they got better and that was reassuring for me.'* (F26-5)

One participant expressed shock over her recovery period as the videos did not illustrate the degree of post-surgical swelling that could occur and did not provide enough information regarding the post-surgery period.

> *'Even to the point of one of the videos that we were given just beforehand, it showed this guy and the next day he went to see his doctor and he was sat upright, and he had hardly any swelling. Obviously, he couldn't really open his mouth. He wasn't talking very much. But I was expecting it to be like that. And then the next day, I was lying in a hospital bed. I had to stay an extra day than they'd originally said, because I couldn't eat. I was way more swollen than I thought I was ever going to be.'* (F30-14)

Other participants reported the content to be frightening.

> *'I was given a website to look at. I didn't look at it until a lot after but when I looked at it, it was scary.'* (F26-5)

Therefore, there are mixed feelings when it comes to utilising this website resource to aid risk assessment and depicting an unclear picture of what the journey entails.

4.4.1.2 Internet

4.4.1.2.1 Online forums

Some patients referred to accessing a Facebook support group which helped guide them throughout the journey and better prepare them of the risks involved. One participant explained how she found this resource supportive, realistic in terms of giving a true picture of the treatment journey and a resource where past patients could be contacted. These groups were named 'Orthognathic Surgery Support' and 'Jaw Surgery Group Support'.

> *'I came across a Facebook support group... It was only for UK patients. A lot of the international groups again was the butterfly effect, the before and after, quite Americanised and not really what I was looking for. But the UK group, again, because there was a lot of us who have had the NHS experience it was very moderate. A lot of support given was about the appointments, where you might be at, the honesty of it with people sharing their good and bad experiences without it being sensationalised. It was a really good support group without sensationalism, which you do get in a lot of other groups.'* (F43-2)

> *'I felt I needed to talk to other people that were experiencing this and going through it. It was what this group gave without the sensationalism of competition in groups like that. It just escalates but this one wasn't like that it was very practical and very supportive.'* (F43-2)

In addition, this group provided practical information, such as a list of items required by patients during their stay in hospital, which is not normally mentioned by clinicians.

> *'It was daft things like people would say post-surgery this is a list of equipment that the hospital didn't tell you about but it would be invaluable to you. A lot of the time it was. Sometimes it wasn't because we all recover in different ways. It was things like you might have cushions you might want. If you can't swallow for example, somebody suggested getting a spray bottle. When you first recover from having jaw surgery, the nurses give you water in a cup, well I couldn't drink from a straw and I needed water post-surgery. The suggestion was a spray bottle basically that you take on holiday and put the water in that because even if you can't drink it, you're getting something that*

> *you need in recovery and if you ever needed to chat with somebody there's always someone there to respond to you.’* (F43-2)

She explains that it is a very convenient resource to access as you can have the support you require any time of day as opposed to having to wait to speak to a clinician to discuss any concerns.

> *‘I think day to day people prefer to use something they can just dip into as and when it suits them.’* (F43-2)

> *‘I must say I spent many a time in the Dental Hospital waiting room really wanting to tell other people about this… I think if that's something you can do, it would help a lot of people. They can choose to do it, look at it. If they don't want it, they don't have to look at it.’* (F43-2)

Some mentioned they accessed American forums and would have preferred if they had access to a U.K. based forum to help support them through their journey.

> *‘. So yeah, so I suppose a UK specific or an NHS specific forum would be really useful.’* (F31-1)

4.4.1.2.2 YouTube

Several participants utilised YouTube as a platform to seek information and expressed how lived experiences were useful and easier to relate to.

> *'I was watching a lot of people who had jaw surgery, and I was watching their recovery. I found that very helpful. I was watching it before, but then I was also watching it after I had it, because I was so alert couldn't sleep so I was awake all the time.'* (F26-5)

> *'Then I also went on YouTube and looked at other people's stories and that really helped to see their process. So it kind of prepared me for it beforehand.'* (F23-8)

> *'I used to sit there and watch videos all night on YouTube of people who have had the surgery and stuff you know, just getting their experience, is it worth it or not worth it. 99% of people have said it has changed their lives, which it has done mine.'* (M29-4)

4.4.1.2.3 Instagram

Instagram was consistently popular amongst the participants for information gathering, which is not particularly surprising given the young age cohort of the participants.

> *'I found an Instagram page of somebody who had just had surgery like a few weeks before. So I followed her and used to see everything that she was posting, because she was a couple of weeks ahead of me, it was quite nice to see that it's really bad at the moment, but actually, it does get better. So I found that really helpful just for reassurance really.'* (F27-12)

> *'When you can see somebody else who's had the same thing done, and they're swollen as well, you kind of know what to expect, because they always say, oh you're going to be swollen, but it's difficult to know how swollen you're actually going to be. And she*

> *would say that, Oh, it's difficult to eat because your chin feels numb and your mouth feels like it's not in the right place. It makes you feel a bit better.'* (F27-12)

Participants referred to having 'Instagram stories' to better prepare them of what is to come.

> *'If there was a little clip of someone who was willing to share their story and their process online, that kind of thing would have really, definitely helped me to have a sense of what was actually coming. As opposed to just the NHS speak on what the recovery will be.'* (F31-1)

The internet is a vast digital resource and social media is a huge influence in particular accessing live 'stories' on Instagram where individuals considering orthognathic surgery can follow a patient's journey by the hour. In addition, Facebook forums provide an environment where individuals can post a question, reaching out for support any time of day.

4.4.1.3 Health care professionals

Not many participants referred to surgeons to seek information regarding their surgery which was surprising as these are the clinicians that they will see on a regular basis during the multi-disciplinary clinics and their stay in hospital.

> *'There's a bit of a disjoint in that you get some information from the orthodontist, and then you hardly ever see the surgeon.'* (F30-14)

> *'I didn't feel like making the decision to go on the waiting list was informed by very much other than people going yeah, you're sort of eligible.'* (F31-1)

Many participants found the information they sought regarding the surgery was from predominately from their orthodontist.

> *'I actually didn't feel I got very much information from Birmingham Dental Hospital until I finally got to the top of the waiting list. And then when I was in the care of ***, my orthodontist, then I felt like I got a lot of information because *** was very good at communicating about everything. But before then, I didn't have a lot of information.'* (F31-1)

Some were completely reliant on their surgeon and avoided seeking any further information.

> *'But beyond that, when they gave me a leaflet and said, try this website and have a look at this and have a look at that, I just didn't do all of that only because I knew I was having it regardless. At the end of the day, I am in good hands if God forbid anything went wrong. They are the specialists. They know what they're doing.'* (F25-13)

Clinicians are fundamental to aid patients in assessing the risks of the surgery and the intricacies of the patient journey. Some participants placed their trust entirely with the treating Team and avoided learning about the surgery.

4.4.1.4 Leaflets

Many participants mentioned that they had access to leaflets, however they did not find this helpful and that it did not address their concerns.

> *'The consultant gave me medical information from the NHS. That wasn't something I was referred to, that wouldn't have been appropriate. But they did give a little booklet*

> *that had some information in but I wouldn't really say the NHS has a lot of information or support there in terms of what I felt I needed.'* (F43-2)

> *'I don't feel like I knew very much at all. I had all the leaflets on like the standard risks and the risk of numbness and etc. But like a really good example was the next day I blew my nose. I didn't know that I wasn't meant to blow my nose and there was blood everywhere.'* (F30-14)

> *'To be honest I didn't look through the leaflets. Because it was just like a whole bunch of information that was given to me and I was like, okay.'* (F24-15)

This further shows that this should only be a supplementary aid in decision making and should not be relied upon entirely.

4.4.1.5 Soft tissue predictions

Software is currently available to assist in planning orthognathic surgery. This software can also include prediction models to predict soft tissue surgical outcomes. Participants were asked whether this would have helped them in the decision-making process and whether seeing and discussing these images would have better prepare them mentally for the facial changes following surgery. All the participants indicated they would have liked to see these images and it would have helped in the decision-making process. However, none of the participants in the group were shown the soft tissue prediction images at any point of their treatment journey.

> *'If they were able to do that before the surgery, that would have been very helpful as well…then I could see and focus more on oh, this is what I'm going to look like when it's done.'* (F27-3)

> *'I think maybe a more accurate representation of what you're going to look like afterwards would be helpful so that you don't look in the mirror and you're oh, my goodness, my chin is like down here and I didn't expect that.'* (F30-14)

It is evident that resources such as the internet, British Orthodontic Society website and soft tissue prediction imaging can improve patient experience of Orthognathic surgery by gaining an in depth understanding of what risks pertain to this treatment modality. There seems to be room for improvement when it comes to utilising leaflets as a resource as well as better access to clinicians and surgical soft tissues predictions.

4.4.2 THEME 2: SURGICAL RISK

4.4.2.1 Attitudes towards surgical risk

A previous study reported a 3.2% chance of devitalisation of anterior teeth with maxillary osteotomies (Mesgarzadeh et al., 2010). When the participants were asked whether they would have still opted for surgery if they were told there was a risk of damaging their upper incisors there were varying responses. Some participants had the attitude of delegating the decision of their care to the health care professionals and avoiding having to consciously weigh the risks and benefits of the surgery.

> *'In my situation, it was something I'd have to do regardless and so I left it in the hands of them. But if it was an option, I probably would have backed out but it's because I wasn't given the option. I just thought, you know what, they're the experts at the end*

> *of the day and they wouldn't recommend it to me if I didn't need it, or if they didn’t think in the future it was going to get worse.’* (F25-13)

Some individuals demonstrated that they were prepared to take the risk and weighed up whether the complication was something they were willing to accept.

> *‘It all just got to the point that for me, you could have told me anything and it wouldn't put me off because I would have weighed it up against the statistical likelihood about that happening and I would have still taken the chance that I was in the 90% that that would not happen to.’* (F43-2)

> *‘I still would have had the operation because I know you can survive without 4 teeth.’* (M24-6)

One participant stated that had she known there was a risk to damaging her anterior teeth she would not have gone ahead with the surgery.

> *‘I don't think I would risk that. Again, that was never told to me either.’* (F27-3)

In weighing up risk, the risk of the event occurring should be discussed with the patient as well as the impact of the risk. Regarding orthognathic surgery, the risks of loss of a segment or entire jaw and death under GA are a small risk, but the impact on the patient and their family are potentially life changing. Maxillary orthognathic surgery is at higher risk of ischaemic complications (Ho et al., 2011; Lanigan et al., 1990). A recent case report showed a rare complication of post-operative avascular necrosis of the maxilla (Teemul et al., 2017). When the participants were asked whether they would still consider having the surgery if they were told there is a risk of losing their maxilla, they all unanimously said that they would not.

> *'I would have probably rather died than to have my jaw gone.'* (F26-5)

When asked regarding the risk of death as a result of the GA, there was a mixed response depending on each participant's attitude towards risk. However, all participants unanimously agreed that this risk should be known to the patient during the consent process.

> *'It might put some people off unfortunately. But what if you as the surgeon didn't communicate that to the patient. What if that patient did then die and what would be the consequence for the surgeon if the family said that hadn't been explained to use? I don't think there's a way around. For some people that would horrify them but for me, I think you go and have your ears pinned back or anything, that would still be a consequence.'* (F43-2)

> *'Yeah, I was basically told all the symptoms of what could happen but at that point in my life I said, listen, I don't really care. I'm ready to die to get the surgery.'* (M29-4)

> *'Obviously, just before my surgery, I was having literally heart palpitations, because my dad's cousin had previously had an operation and died on the operation table. So I was thinking that's gonna happen to me. But I was still up for it and ready to go and going to do it. I kind of knew there was a chance of that.'* (F26-5)

The outcomes of this theme showed that many participants were not fully aware of the complications that could have occurred with orthognathic surgery. Some participants were under the impression that they needed surgery and there were no alternatives and therefore there was no need for them to weigh the risks against the benefits. Others were content with the clinician making the right decision for them and therefore placed their trust in the surgeon's ability. Only a few participants reported willingness to accept perioperative mortality risk when given hypothetical scenarios and again this was reasoned by the fact that they have placed their trust with their treating clinician and the perception of having no alternative. It was clear some patients would appreciate knowing all the risks entailed with the surgery so they can decide. The final group were willing to accept any complication provided the surgery corrected their facial deformity. The mental state of this group and their ability to consent could be undermined as a result of their overwhelming desire to have surgery.

4.4.2.2 Psychological state impacting risk perception

There was a recurring theme that participants were willing to take any risk to have the surgery regardless of any detrimental outcomes. The participants often compared the risks to the psychological impact their appearance had had on them and that nothing would have deterred them from having the surgery.

> *'Honestly there's not a single risk, not a single depth of anxiety would have stopped me getting the surgery. Nothing really deterred me at all.'* (M25-11)

> *'This is something wanted since I was young......So, nothing would have stopped it from happening.'* (M24-3)

One participant explained that they were willing to accept low levels of risks given the fact he had to suffer with a significant number of years of bullying due to his facial appearance.

> *'If you'd have said it's 50:50 or 90:10 that you go blind, then maybe I would have kind of reconsidered. When you're handed a leaflet that says there's a 1 in 10,000 chance of these things happening, and I've just had a decade of being bullied….'* (M25-11)

There were many participants who described their low mental state as debilitating. They believed surgery would solve their problems, improve their mental well-being and therefore perceived the risks as necessary in order to achieve their desired outcome.

> *'It didn't put me off the surgery I must say because at that point I was so low I would have said yes to anything.'* (F43-2)

> *'I don't think I could have got much lower…. There wasn't any other outcome or side effects for me that would have put me off at that point. I was that low and that desperate.'* (F43-2)

Some participants explained that due to their current psychological state they struggled to rationalise their thoughts and weighing the risks against the benefits.

> *'With my psychological state at the time, it's hard to rationalise my thinking, but thinking back then I probably would have weighed it up with the statistical likelihood. I am taking this decision knowing you have told me this.'* (F43-2)

> *'… I would have took the risk anyway because I was ready to give up… there are dark places and then giving up completely and I was on that line.'* (M29-4)

Some participants admitted that they would have lied in order to not jeopardise them not having surgery. This raises an interesting dilemma that if patients resort to lying in order to have surgery, then do they have the mental capacity to rationally weigh the risks and benefits and make an informed decision. Alternatively, it could mean that they are willing to accept a high level of risk due to their perception of having no alternative option or desperation for surgery.

> *‘If someone asked me a question and I thought they were trying to catch me out to prevent the surgery, I would have answered it how I believed it should have been answered because I thought I had to get this surgery done. So even if I had to lie to get it done… I've got to say what I need to say to get the surgery done.’* (M29-4)

For the majority of participants, their facial appearance contributed to varied negative emotions such as shame, embarrassment, self-consciousness, insecurities, mental breakdowns, bullying and suicidal thoughts. It was apparent that these emotional states and the comments of others played a key role in their perception of surgical risk. Rather than surgery being elective it seems as though the risk of surgery is something they must accept regardless of how significant that risk may be in order to correct facial visible difference.

> *‘But to me it didn't feel elective. I almost felt if I can't get access to treatment, although I never have thought of killing myself, but how black and low and ashamed and constantly having no worth it was a thought I came to. I never felt it was a choice to have the operation. It didn't feel like that because I don't have a choice because I cannot carry on having these thoughts.’* (F43-2)

> *'I was basically told all the symptoms of what could happen but at that point in my life I said, listen, I don't really care. I'm ready to die to get the surgery. So that was the mindset I was at. Which is not a good mindset. But I thought you know what, there's no point in me living anymore.'* (M29-4)

> *'I just sat in that chair and asked my children to leave the room. It was a complete breakdown in the chair and I said to him I know it sounds silly but if you don't do something I will be in trouble. I am utterly utterly miserable, and I think it was possibly more the fact that I couldn't even hold it together add that happened probably 4 or 5 more times.'* (F43-2)

> *'I'm not going to use the word suicidal, that suggests I had feelings of self-harm and I didn't but sometimes I was very low and didn't want to wake up and I think that is not just a cosmetic issue. When people say they are having jaw surgery, it is far more than that.'* (F43-2)

Participants often referred to how society made them feel different and that they were judging them by their facial appearance and a large aspect of this was mental abuse.

> *'For me, I was training to be a teacher. And young children can be quite abrupt with how they mention things. I didn't realise it at first myself but when I was in placement a lot the children were like miss, why are your teeth like that? Why is your face like that? So, I thought if a child's telling you then it does kind of give you a bit of a confidence drop. If I want to continue in this career, maybe I'll have to get it done.'* (F24-15)

> *'I used to actually get picked on at school and I used to get called goofy all the time. So that did have a massive effect on me. I didn't used to eat out in public. Anything that involves some sort of human interaction I didn't do because I didn't want to smile, I didn't want to talk. Before I never used to do any of that… But it did have a massive impact on my confidence and how I was around people.'* (F24-7)

> *'In my journey, there was a couple of occasions that I come home from school, and I literally, I punched myself in the face. Because I wanted to break my own jaw. Getting the bus, I used to wait for the second bus to avoid getting on the one with all the kids. Sit at the back of the class. Not many friends. When you're that age, your brain is a sponge and everything is absorbed, and you carry it with you in life and now a role as a locker manager at work, I have these small team meetings now and I am still to this day paranoid about being the front speaker, and it's really something I have to control and cope with. Even just talking about now my heart is racing.'* (M25-11)

> *'It's only now that I fully admit I was bullied… In school, I failed all my exams. I couldn't even go into the exam hall. I was always in the back picture. I had no friends. I was just a complete lone wolf.'* (M25-11)

There were some participants who rationalised accepting the risk of death because they were mentally struggling, which shows their psychological state has a huge impact in evaluating risk. To these participants they would rather not be living with the deformity that they had and so the risk of death was not significant for them.

> *'I was willing to (accept the risk of death) at the time because I was suffering.'* (F27-3)

It seems to be that the psychological state of the participants at the time of their decision making played a huge role in how they were perceiving the risks of the surgery. Those who have been significantly mentally impacted by their facial deformities had the attitude of accepting any risk the surgery entails. For the majority for participants, their facial appearance contributed to varied negative emotions such as shame, embarrassment, self-consciousness, insecurities, mental breakdowns, bullying and suicidal thoughts. Participants alluded to the fact that these negative emotions led to a low mental state which was debilitating for them. The social repercussions that they had to suffer during their time in school and in the workplace led them to believe surgery would solve their problems and improve the mental well-being. Therefore, they viewed the risks as something they had to accept regardless of the significance of this risk due to their perception of having no alternative option or desperation to have the surgery.

4.4.2.3 Experience impacting risk perception

Some participants described themselves as 'naïve' when they were given information regarding surgery and the risks it involved. This meant that it impacted their decision making whether it was to have or not have surgery.

> *'Earlier when I was 19 I was quite naive. If a medical professional tells you it is not really that bad, there's nothing wrong and it's a terrible operation, at that point I hadn't had the next 13, 14, 15 years of life experience.'* (F43-2)

> *'If I had a hospital say to me, would you come up and, you know, take some counselling, because we believe you are going to struggle with your jaw, I would have laughed at them and not took it because I was so young and naïve.'* (M29-4)
>
> *'Actually, I think it was really quite bad that I had that as an option because I think actually part of my decision for going ahead with it was something to do with my impressionable mindset when I was a young woman. Because I think at that age, you're so concerned about your appearance and you're so concerned about looking different that someone suggesting to you don't worry, you can have surgery and you will look different to how you currently look. I think that's a really tempting offer when you're that age… It suggests to me that it relies mainly on men, looking at impressionable young people going, your face could be better, you know what I mean? Like, it seems to me, an odd way to offer any kind of elective surgery on the NHS' (*F31-1)

It appears that the age or experiences of the participants impacted their ability to perceive the various risks of surgery. The younger generation acknowledged that they were naive when it came to decision making and therefore they relied on placing their trust with their treating clinician.

4.4.3 THEME 3: SETTING AND FORMAT OF HOW RISKS SHOULD BE PRESENTED

It was clear that the participants unanimously wanted clinicians to inform them of all the risks involved with orthognathic surgery.

> *'Unfortunately, it's not important until it happens to you. As surgeons you have no control over that. But I would always say list everything, talk about everything and then it's up to the patient to decide. Because by not doing that, people cannot then give their*

informed consent… I also think, if you could go through all of that, if you can look at all of those risk and checks and balances and still come to the conclusion that the surgery is right for you, then the surgery is probably right for you. If you've got anybody that's hesitant and in doubt, it possibly isn't right for them at this point in their life.' (F43-2)

'I'd improve that by actually stating every possible side effect that could happen. I mean I didn't know about the whole teeth going missing and the jaw. I didn't know any of that. As much as listening to everybody's journey on that website, it was brilliant. It was successful for them. But, you know, there are some cases where you need to know where it hasn't been successful so then you can make your mind up with what you want to do… that puts everything into perspective, so then you know what to expect. Luckily, none of those side effects happened to me. But if it had, then anyone would be questioning the person who gave you the information which then can get these people into a lot of trouble.' (F27-3)

Some felt that the information should be given in a detailed conversation as opposed to a list of risks that are read out.

'I do feel the process and how was told was a very quick process and it was like a tick box thing. I feel like it should have been a bit more kind of conversational… I remember going in and going out and feeling like I still did not have all the answers.' (F27-10)

'I don't think you fully understand. So it would be nice to have a conversation, even if it's somebody breaking down the basics to you. But I felt I was in and out. Every time I went in, I had more questions when I left. And it would have been nice to kind of have that kind of discussion.' (F26-5)

In addition to this, the participants preferred for this conversation to be carried out in a non-clinical environment so that they are in a comfortable setting to retrieve the information and ask any questions they may have. Several participants felt that the discussion was not in depth and too brief to their liking.

> *'When they're asking at the time about the risks and stuff, you can't think of stuff on the spot. So maybe if it was like sitting in non-clinical environment, I'd probably have a bit more time to think about the risks, or I can ask more questions. Whereas when they're asking me on the spot, I might only think of one or two things.'* (F24-15)
>
> *'Yeah, because when you're in a chair, it's like you're being told information. Whereas when you're on the same level, psychologically, on two chairs. So you're both equal, it's more of a conversation... It's difficult to take all of it in when you sat in the chair, and you've got people looking at you. You need time to go and think about it.'* (F25-13)

It is clear that patients would like to be informed of the risks in a detailed conversation, ideally a non-clinical environment and would have appreciated knowing all of the risks entailed.

In summary, there are three main themes that were identified from the one-to-one interviews and focus groups on how patients perceive risk pertained to orthognathic surgery. This is impacted by various information seeking methods to aid risk assessment, different attitudes to risk taking and the setting as well as format as to how the risks of this treatment modality is presented.

4.5 IMPACT OF ORTHOGNATHIC SURGERY ON PATIENTS’ PSYCHOSOCIAL WELL-BEING AND CONSIDERATION DURING THE CONSENT PROCESS

Not only does the discussion of risks pertaining to this treatment modality serve the decision-making process which has been discussed in the first domain above, it also gave rise to the second domain which is the general considerations for orthognathic surgery and the preparation for what may happen after the surgery. It was apparent during the interviews, that the risks of adverse effects such as pain and swelling described during the consent process did not marry up with the participants’ lived experiences and impact on their psychosocial well-being after the surgery. The second domain that emerged gave rise to 3 themes:

1. Physical effects of surgery and its impact on patients' psychosocial well-being.
2. Non-physical effects of surgery and its impact on patients' psychosocial well-being.
3. Impact of surgery necessitating support.

4.5.1 THEME 1: PHYSICAL EFFECTS OF SURGERY AND ITS IMPACT ON PATIENTS' PSYCHOSOCIAL WELL-BEING.

It was evident that the physical effects of orthognathic surgery left an impact on the participants psychosocial well-being. This was predominately difficulty in eating and drinking, swelling and nerve injury. Although these risks were discussed with patients prior to surgery, they felt that these points were not described in sufficient detail, with their actual lived experience not matching the descriptions given by the clinicians.

4.5.1.1 Difficulty eating and drinking

This was the most common physical effect of surgery that the participants mentioned during their recovery period. Some noted the need to have someone with them during their stay in hospital to help them eat and drink.

> *‘I couldn't even take the Fortisips so I actually used a syringe and had it like that. But what they did was the nurses came and they just put it on the side and they would walk away.* (F24-7)

> *‘If you're underweight anyway, then obviously, these things could have quite a major impact on you after surgery, so they're not kind of risks. I suppose they're kind of just stuff that you wish you'd been told beforehand.’* (F27-10)

> *‘I had my tonsils out and that was worse. But this surgery was really bad for much, much longer. I think it was like six weeks. I think the effect on my mental health, was like week two, week three. We then started looking at restaurant menus when all you've been eating is yoghurts and stuff for the last couple of week.’* (M25-11)

> *‘They didn't give a specific menu to what I should have when I come out of surgery because I chose what I wanted under the impression that they were going to puree it. They gave me food that you would chew and I couldn't chew at the time. I could only swallow. So I felt like that was not useful to me at all.’* (F27-3)

> *'You haven't got a nurse by your side who's constantly giving you something as simple as water every few hours, and you can be then left for several hours and not being able to drink yourself because you can't physically do it yourself.'* (F23-8)

It was clear that the inability to eat and drink had a toll on their physical and mental well-being during the recovery phase.

> *'I had nothing in my stomach and obviously everyone knows when you take painkillers your stomach needs to be relatively full. So I was just being sick. And because my mouth was shut, I was being sick… through a small gap. It was the holiday season as well, something like 23rd December. I had family round and I was just upstairs feeling miserable by myself. I couldn't eat anything. It was a horrible time.'* (M25-11)

> *'I don't think they really emphasised to me that actually it's not about how you feel and how painful it is to eat, it's about if you eat and chew…. And that it is really six weeks without chewing anything. That's a long time to be eating soup. I think for me, that was the biggest thing the food.'* (F27-12)

> *'The eating, that's the biggest issue. It took like two hours to eat porridge. By the time you've eaten breakfast, you've got to do your mouthwash and then start on lunch and you just need someone to make it for you and make it a healthy nutritious meal.'* (F30-14)

Some mentioned they were not aware of dissolvable medication that would have helped them significantly with pain relief as they could not swallow tablets after their surgery.

> *'Because I stayed the extra day, they gave me tablets of Co-codamol and Ibuprofen, which I was struggling to fit into this little hole that I could make my mouth. And then I'm stuck because how am I supposed to put this in my mouth and swallow it and put water in my mouth to help me swallow it? I struggled a lot with that. But because I had worked in a pharmacy, I knew that I get a pill crusher, so I had to crush all my tablets and mix them with water and then try and get it all in a syringe so I could take it.'* (F24-15)

Difficulty eating and drinking came as a shock during the recovery period and the participants would have appreciated if this was reiterated to them. The effect of this had a huge impact on their physical and mental well-being as it seems to be such a debilitating aspect of the recovery phase.

4.5.1.2 Swelling

Many participants were unaware that they would experience significant swelling and for some this made them insecure to leave their homes for several weeks after the surgery.

> *'So after a week, everyone stopped coming. The swelling was still there and I just wasn't comfortable in how I felt. Honestly, some days it was so depressing. Like, oh, my God, is this going to be forever? Is it never going to go? I think they don't tell you also about that part, like it can make you feel really s***. At the time, like I said, I'd just graduated, I was looking for jobs and stuff but then I really didn't want to go to the interviews. I don't know what people are going to think about me and stuff... I think on the third weekend my sister said to go to Tesco.... I was like, hah, everyone's gonna stare at me...*

> *She's like, you're not going to come to help me then I don't know where to leave the shopping - I was that insecure.'* (F25-13)

> *'But the thing with me is that my swelling took ages to go away. I don't even know how long it took to go away. To be honest, thinking about it, I was not too great. Because I was living independently, I had to go out a lot and I would get stared at. So I think that was another thing for me was a bit like people are staring at me because of how I look and that was a bit sad. I knew it was gonna get better, but it made me feel like s***.'* (F24-7)

> *'When I came round after the surgery, my face was fine, had no swelling, or anything. But the next day, my mouth just ballooned. It was really like out there. I was black and blue and I didn't realise the extent of it.'* (F27-3)

Some went as far as feeling a deep sense of regret of choosing to have surgery due to the extent of swelling and how they looked.

> *'The second day I was regretting it. I kept saying I regret getting this done because of the way I looked, and the amount of pain that I was in as well which didn't help at the time.'* (F27-3)

The amount of swelling was underestimated by the participants and the realisation that the extent of this varies amongst individuals came as a shock to many. Participants explained that they would have appreciated a more realistic description of how swollen they would be as this risk impacted them significantly both physically and emotionally with several participants not willing to leave their home and be seen in this way. To some they were regretting having the surgery and they were not prepared to be in this state.

4.5.1.3 Nerve injury

Several participants mentioned experiencing altered sensation as a result of the surgery. A recurring theme which emerged was that the participants felt the altered sensation they experienced was not as described. Several described the sensation as a ‘tingle’.

> *‘It was a tingle. It didn't feel the same, but it's not like when you have a local anaesthetic. It's not quite that numb but it's just different, if that makes sense.’* (M26-9)
>
> *‘I can't really feel it, but I can feel my gums will start tingling. So, if I try to eat anything harder than mashed potato on that side, my gums will start to hurt and I feel like there's a lot of pressure.’* (F24-15)
>
> *‘It's like when you're sat on your leg for a long time, and it goes dead. All of a sudden when you try to get back up and the feelings come back, it's that tingle.’* (M26-9)
>
> *‘I've heard someone else to describe it as it's like having an injection at the dentist and then when the injection starts to wear off, you start to slowly getting that tingly sensation, that's what it feels like but permanently.’* (F27-10)

Some described that the nerve injury had had an impact on them socially such as when eating publicly or kissing and this ultimately led to negative emotions which were embarrassing.

> *'…I'll be brushing my teeth and I'll just have toothpaste all over my chin and not really realised that it's there. … kissing my boyfriend at the time - now fiancé - is completely different to how it was before. I think for him, he doesn't notice any difference but for me, I guess it's just completely different.'* (F30-14)

> *'… since the surgery where I've ended up with something on my face, my friend has had to tell me hey, FYI because I can't feel it right. Normally, if you've got like a rice kernel stuck to the side of your chin, you know?... No one told me about accidentally looking a lot less socially acceptable when I'm eating. I'm not sure but like kissing is very different now so that's a bit of a shame. Yeah, so I think patients should consider that in the future.'* (F31-1)

In addition, there was also a mention of female participants in particular experiencing difficulty placing make-up.

> *'But I felt that there was a lot of things that they didn't tell me about that in hindsight, I wish they had… like trying to put lip gloss or lipstick. I couldn't eat without a mirror for a good few months without stabbing myself in the chin with the fork, just because it wasn't where I was used to it being. So again, I didn't want to eat in public.* (F27-12)

There was also a mention that the nerve injury resulted in difficulty brushing and compromising toothbrushing.

> *'What I find really irritating is that when you brush your teeth normally, you're very careful to sort of brush the gum line on the inside of your mouth when you're brushing. But since the surgery, because it's so numb, I don't really notice if I've brushed the gum*

> *line on the inside of my mouth because it's just something I can't feel anymore…'* (F31-1)

A few described the nerve injury giving them significant pain and debilitating their everyday activities.

> *'I suffered with about 3 months' worth of nerve damage. That was the most horrific pain and discomfort I think I have ever experienced in my life. That was far worse than the jaw surgery. I was quite fortunate that for me it did eventually go.'* (M29-4)
>
> *'I have permanent paraesthesia in my jaw. It basically feels like a really strange sensation. I can feel it but I can't feel it. I get altered sensation, but I am learning to live with that. That's what I thought they were talking about but lingual nerve damage is very different from paraesthesia and partial feeling and partial numbness that I still have in my lower jaw. Maybe a bit of information about what the difference is between the two. If you're feeling this in your tongue, like somebody is using a lighter against your nerve that is actually setting your tongue on fire, that could be lingual nerve damage. Because I didn't know what it was and I was checking Google and then I had to speak to the surgeon on my follow up but again, the response was quite nonchalant - oh that will be that. I thought have you ever had that pain, do you know how bad it is and I've had two children!'* (F43-2)

Despite the impact of this risk psychosocially, most of the participants stated that they would have still gone ahead with the surgery however a better description and the negative connotations associated with this risk would have helped them prepare mentally.

> *'So I would have still gone ahead with it even if I knew I was going to have the lack of feeling now.'* (F30-14)

However, there are some who said the nerve injury has changed their mind about having surgery.

> *'I was made aware of a few risks, but not as many as I would have hoped. So I was told about the fact that there's a potential for altered sensation or permanent numbness. But I was told it was 10% of patients. It's actually higher. As far as I have heard, I think it's more like 20%. And I think that would, that would have changed my mind because I do have altered sensation now and a bit of permanent numbness. I mean it's like, you know, you learn to live with lots of things. Right. But I think if I'd known the results, I might not have done it. So I would have liked to know that it was 20% rather than 10%.'* (F31-1)

The description of altered sensation as a risk needs to be re-defined as several participants described different experiences when it came to their nerve injury. Several alluded to the fact that it felt more like a 'tingle' and gave the description of when local anaesthesia wears off when you have had an injection at their dentist. The psychosocial repercussions of this risk impacted the participants significantly and some of these consequences were developing gingivitis due to lack of sensation when brushing, difficulty placing make-up on, different sensations when kissing and the embarrassment of food left on their lips/cheek when eating socially with them not being aware of this incident. Surprisingly some participants described significant pain associated to the nerve injury and would have appreciated being warned about this.

Other physical effects of the surgery that were briefly mentioned by the participants in which they were informed about were nosebleeds, infected plates, sinus infections, nose becoming larger, blood clots and root damage.

4.5.2 THEME 2: NON-PHYSICAL EFFECTS OF SURGERY AND ITS IMPACT ON PATIENTS' PSYCHOSOCIAL WELL-BEING.

There were also non-physical effects such as the recovery period, change in face recognition and pain that do not get listed as risks per se during the consent process, yet they had a significant impact on the patients' psychosocial well-being, and these should be explored further when discussing this treatment modality with patients.

4.5.2.1 Recovery period

The duration of the recovery period was something that many participants explained they were not prepared for and found the experience came as a shock to them.

> *'It was a shock to me ...I would stress to those patients that they really need to be aware of either having extra support which is definitely needed or planning in advance; cooking meals and putting them in the freezer because there will be times you don't have energy to cook.... Another thing is when you go to bed, make sure all of your medication is next to you. Make sure you have water, tablets, pain relief, whatever you need by your bed at night. Sometimes people don't think about that. I was that ill there was some nights I don't think I could've gone downstairs to get water and tablets.'* (F43-2)

Several referred to a negative experience in hospital which did not help with the recovery period.

> *'Hospital is really not a good place for recovery. It's a good place to be monitored. But actually, there's a lot of light, you know, the lights go on at like 6am. People come around and do your bloods at like, 6am. You know, when you've just fallen asleep, like, there's so much noise, you've been woken every five minutes with something else, and all you need to do asleep. The space isn't comfortable. There's nowhere to do anything. You know, it's just torture. Yeah, so actually trying to get out and home is probably your best bet so that you can actually lie down and recover properly in sleep. But yeah, making sure that I was ready to go home, I didn't feel like I got really any communication from any of the staff on the ward on that. And it was just a lot of people coming in and doing stuff to you without ever really knowing what was going on. Like random medications being put on your table, but no one helping you to actually make sure you take it, things like that. From what I remember, I mean, it was a hazy time. But yeah, I think my mom was quite insistent that she stayed. And I'm sure that puts a lot of people off. I think it really did help having someone who was there just to help me.'* (F31-1)

One participant went as far as describing the recovery period being worse than the bullying he experienced which highlights the toll this surgery takes on patients' psychosocial being.

> *'I was bullied profusely in school and school wasn't a nice time for me. To be honest, the recovery period was probably worse'* (M25-11)

Another participant explained that the recovery period led to depression and that she struggled to leave her home.

> *'I have never had depression even when I was left with my 2 children on my own. But after the surgery it was almost like agoraphobia. I didn't like leaving the house. I felt*

> *really uncomfortable being outside. I just wanted to be in the house. When the surgeon said after five weeks you can go back to work, I thought I work with 94 year olds (as a nursing home carer) and I have to talk from 8am to 5.30pm with virtually no break and I don't feel ready.'* (F43-2)

Several said they felt an overwhelming sense of exhaustion after their surgery which they were not mentally prepared for.

> *'The initial week you really feel so tired and so drained because you're not eating anything, that you haven't got the energy to go downstairs and get the painkillers or get the food….I don't know how anybody would do it with kids…. I wouldn't have been able to go back to work before the four weeks. I was too tired. I didn't muster going to the supermarket until the week before I went back to work and even just going to the supermarket that was my activity for the day and then it was time to just rest and chill.'* (F27-12)

> *'I would say the fatigue, maybe, because obviously you're having less intake, you're not eating as much so you're going to be more tired. So I expected it because you're eating this, but I didn't know it was going to hit me as hard.'* (F27-10)

Several participants mentioned they were not prepared for the fact that they would struggle to talk during the recovery phase and the toll that took on them mentally.

> *'I found not being able to talk after the surgery. I'm not a talker, obviously. I just I carry on as I go. But I think after the surgery because my throat was that dry, I couldn't obviously talk. My jaw was shut. So when the nurse came around and asked if I wanted*

> *a drink, I couldn't say yes or no, just "mmmm" . But I didn't know how I was going to be after the surgery. I knew that obviously I wouldn't be able to talk because I have my jaw closed so I bought like a little pad, you know, the whiteboards then I give that to my family. So I could write down stuff instead of talking. I had my mum here anyway, so she was alright in supporting me. But I think it's a lot harder if you were on your own, especially if you can't talk.'* (F27-10)

> *'It took quite a while. I would say it took around a good six to eight weeks before I started to have my normal voice again. I couldn't talk properly to everyone. I used sign languages for yes, no, bye. Every time I said something to someone, it was what did you say? And then it's just I'll write you down the text, I'll text you what I said. In fact, when I was interacting with my sisters, I'm texting away, like go get me this from the shops, go get that and whatever. So it was really hard to communicate.... It's the pain. When you're talking and moving your jaw you can just feel the pain.'* (M26-9)

> *'I actually physically couldn't talk. I tried to talk. I actually couldn't talk because everything was just so swollen that I couldn't speak. I remember being on air (oxygen) as well because I was saying in my head I can't breathe, I can't breathe. Obviously, I couldn't speak but I was on air (oxygen).'* (F26-3)

The significance of the recovery period came as a shock to all the participants. They felt the duration of the recovery period was downplayed by the clinicians. The experience of the hospital stay was also associated with negative experiences by many and several came to the realisation that they needed more support from the nursing team or preferring to have their recovery in their homes with the reinforcement of vital support from their family and larger social networks. It was apparent that the recovery had a significant impact on their psychosocial well-being due to their inability to eat, talk and the overwhelming sense of exhaustion leading to post-surgical depression for some participants.

4.5.2.2 Pain

Several participants felt that the risk of 'post-operative pain' was overlooked and should have been described in more detail especially where day three post-surgery seemed to be the most difficult.

> *'I left hospital and I think I was probably still on a lot of painkillers, and I was yeah, this is fine, I'll go home. Then day three hit me like a ton of bricks and I felt dreadful. And then you kind of get back there again but then but I found that maybe by day 10 I went down again, just because by then I was absolutely fed up. And then when I spoke to the surgeon about it, he said oh yeah, it's completely normal. Well, it would have been nice to know that before what to expect about feeling up and down.'* (F25-13)

> *'So, when you when you realise how painful it actually is, I think by the third day, I got really, really low. And I think actually, I had heard that the third day is the worst. But I definitely had a moment of like, Oh, God, what have I done kind of thing. And it was really, really hard.'* (F31-1)

> *'The pain is bad. The first night I was in hospital, I couldn't sleep all night. Then when I come back home, they said to sleep on your back, but my face felt heavy constantly. And then whenever I did try and sleep on the side, that side would end up being swollen. So,*

> *I literally used a neck pillow for a week or something just to make sure I didn't sleep on my side. My face was just constantly throbbing all the time.'* (F24-15)

4.5.2.3 Recognition by friends and family

Several participants struggled mentally with their new facial appearance and looking different after the surgery. Although they were happy with the result, they were not prepared mentally that their facial recognition may change amongst their family and friends.

> *'What I found as well, when I was watching YouTube, a lot of people said that they had gone through an identity crisis. I found that very interesting. Because when you wake up and you're swollen, it's not you. Do you know what I mean? So you have that, like, this is not me kind of thing. So it takes a while to get used to yourself again.'* (F24-7)

> *'I think even though you've had the operation, for a long time after you still are conscious about the way that you look. Even though you look better and you're more confident, it's just that in your head, you're still like oh no I can't show my teeth. It is weird. I worked in a pub and I went back after a long period of time, and everyone was kind of like, is that you? Is that you? And I'm like yeah, it's really me, I'm here. So I think it is weird because people notice you and they don't know notice you in a way.'* (F27-10)

> *'I found a lot of people didn't recognise me afterwards. That's not always a bad thing. But people I knew from school, or like I haven't seen in a few years and didn't know I was having surgery, would walk past me in the street and not recognise me, which is a bit strange… Initially, you think, they're just ignoring me. Then people would say no, it's*

> *because you looked completely different. But I think that was something I'd like to know. I don't think it would change the outcome. I still would have had the surgery. Like all the things that I'm going to say now that I wish I'd known, I'd have had it anyway, but I think it would just be nice to know'*. (F27-12)
>
> *'Then you get sent home and you're happy and that but after a few months, you've got a new face in the mirror and it's like there is no one to talk to about it, like before the surgery but there is no one to talk to or understands after the surgery. Your brain is trying to figure out what's going on, you know because you've had your face rearranged and there isn't a lot of support, you know to talk to someone but at the same time, what can you really talk about? It's a tough one. I don't know…What I would say about counselling is that I was left alone with myself, and I had to look in the mirror and ask myself why had I done it. You know what I mean, I didn't know I had to come to terms with who I was basically, it's like you were reborn again. It's so weird I can't explain it.'* (M29-4)

The concept of dealing with a new facial appearance was difficult for many. Not being recognised by loved ones and their community had a psychological impact on these patients. This aspect of this journey needs counselling and support to better prepare them mentally of the changes to come which we will be discussing later on.

Therefore, the three common non-physical effects of having this surgery that participants referred to in the interviews and focus groups was the recovery period, change in face recognition and the pain they experienced. This had a significant impact on the patients' psychosocial well-being, and should be explored in further detail when discussing this treatment modality with patients.

4.5.3 THEME 3: IMPACT OF SURGERY NECESSITATING SUPPORT

The need for support was a consistent theme that emerged during this study. The lack of support had a huge impact on the participants psychosocial well-being and this needs to be addressed in the consent process if a patient were to undergo such life-changing surgery where from the participants' accounts it became apparent that the recovery period was debilitating for them. This type of support could be from their social networks (family and friends), professional support from health care providers and speaking to past patients to better understand their lived experiences which can be a powerful relatable tool.

4.5.3.1 Practical support from social networks

Nearly all the participants commented that having the support of their family and friends helped them significantly during the recovery phase and that it was not stressed enough in pre-surgery discussions.

> *'I think for me, they did ask me, and I said, it's just me. And then all I got told was you should have somebody there. That was the end of it.'* (F26-5)

> *'And I think I was lucky enough that I had my parents who were able to cook for me and look after me. But I certainly couldn't have looked after myself. So if you don't have someone in your life, who can cook for you, puree a whole bunch of stuff and try and squeeze it down your throat with a syringe, you're in a bad place, because it's almost impossible to do anything yourself for like a month.'* (F31-1)

> *'Luckily, I had my mum to look after me, she'd got all the medication in liquid forms. She actually brought pyjamas that I could put easily over my head. I think little tips like that can make someone's journey a lot easier.'* (F23-8)

Some noted the considerations to have in place if you were a carer.

> *'Even if you've got a partner, that partner needs to look after the kids. You need to have that and be prepared for childcare and stuff like that, because you just wouldn't recover as well I don't think and you'd struggle more.'* (F27-12)

Those who were not fortunate enough to have this support system at home, were impacted by this.

> *'I wasn't happy with myself, so I did find myself in a very dark place. It would have been nice to have some sort of support system around me. But I think a support system around me in general, I never had that. But it would have been nice to have that extra person to talk about the surgery or whatnot…And even after my surgery, I was in a very dark place because I didn't have people around me. I didn't have that support system. Like I think I almost fainted a few times at home because I couldn't physically eat. I couldn't do much for myself. I feel like the bit of information I feel they should give to patients is how much it can affect you after.'* (F24-7)

It is therefore clear that support from the patient's social networks is paramount in particular with this treatment modality.

4.5.3.2 Support from speaking to past patients and hearing about their lived experiences

Several participants commented on how useful it would have been for them if they were given the opportunity to speak to past patients who have undergone orthognathic surgery due to their relatability.

> *'I think there's a bit of a disconnect between kind of yourself and a dentist or orthodontist. They're kind of looking over you… but I think more than anything you need somebody who's had the surgery, I think that's the most important thing. And if the psychiatrist has ever had the surgery, then it's two birds with one stone.'* (F24-7)

> *'Then, you know, it doesn't have to be formal. And you know, people will just say how it is. I mean, the recovery process, they told me it would be around 3-6 months that you'd recover. I felt like it was longer. I didn't feel like I recovered fully in that short space of time.'* (F27-3)

> *'I think it would have been nice as well if I was at the hospital and I could speak to someone who had previously had the surgery. You know, someone who would understand and give me an insight on how they found it and where they are now and, you know, what it's like when you get to the end, how your life changes. That would be nice.'* (M29-4)

> *'I'm yet to meet anybody that was in the same position as me just have a conversation with. But I think if I had spoken to somebody that had the operation because they might tell me things.'* (M26-9)

4.5.3.3 Professional support

There were many references made to how the participants would have benefitted from the input of a psychologist/psychiatrist to counsel them before and after the surgery.

> *'Speaking to someone, like a psychologist, or someone who has a mental health background, just so that people have a sense that they're being looked after, in terms of the fact that they might feel different about the results of the surgery than they were expecting. Because I don't feel that either my orthodontist or my surgeon, were the people able to have those conversations with me. And that was a real shame… I would have found it beneficial if there's like an informal room or setting where you have like a separate room to discuss the consent process somewhere away from the clinical environment, having also a psychologist or psychiatrist throughout your journey before and after surgery... It's like if someone like me had come in at the age of 14, saying, I'm being bullied because of my face, which was all true at the time, then perhaps a psychological assessment would have been more appropriate than someone just going yeah, your face could look better.'* (F31-1)

> *'…. I just felt like there was just too much going on at the time… The support was still kind of there. But then it was just like, really you have to get on with it…. I think after speaking to you today, it has become really helpful. And I do think that patients that go through surgery like that should have that someone to speak to afterwards just to sort of make them feel better and get some advice if they need it.'* (F27-3)

> *'There's no one to talk to. I used to enjoy going to see my surgeon, but he just explained to me we've done this and this, how are you feeling and that was it.'* (M29-4)

In addition to this there were references made inferring that they would have benefitted from speaking to dietician as difficulty eating was the most debilitating aspect of the recovery phase.

> *'I think all patients should have that access to that service. Because afterwards, you really struggle with eating, and perhaps that's also something as well that you need to be prepared for mentally before the surgery if you were given just information about that.'* (F27-3)

> *'Perhaps, having someone who is like a dietician afterwards, that you can see and that can help you get through that process getting used to kind of swallowing solids and just getting you on to kind of like a diet plan because that's part of the recovery as well as the nutritional food and allowing you to heal through that. So, you know, eating is delaying that recovery process.'* (F23-8)

Lastly, several participants mentioned they would have appreciated support from the nursing staff during their hospital stay to help them with their recovery period.

> *'And actually, if my mum and sister hadn't stayed outside of visiting hours, which I don't think the nurses were happy with. But unless if she hadn't been able to do that, I wouldn't have drank any water for like 12 hours - there was no one there to make sure that you're drinking anything. I think they had one nurse for like an insane amount of beds and I'm sure that person was just very stressed. But I did think when you're recovering, you really cannot do anything, especially directly post-surgery, you need to at least be given some water or some opportunity to take something and yeah, it was pretty bad. Even getting discharged was pretty bad as well, like, just waiting for someone to come and do the processing took like a whole 12 hours.'* (F31-1)

It is evident that the impact of Orthognathic surgery on patients’ psychosocial well-being and consideration during the consent process necessitated support from the participants social networks, professional support in the form of dieticians, clinical psychologists, nursing staff during their recovery phase in hospital as well as support from speaking to past patients and hearing about their lived experiences. These findings inform future quantitative studies in which further research is required to look at how this level of support can be implemented to improve this life changing journey.

In summary, there are three main themes that were identified in this second domain from the one-to-one interviews and focus groups that were carried out. The second domain revealed that orthognathic surgery had a significant impact on patients’ psychosocial well-being and that certain considerations need to take place during the consent process because of this. Both physical and non-physical effects of the surgery had an impact on the patients' psychosocial well-being and there was a clear necessity for support during this life changing journey.

CHAPTER 5

DISCUSSION

5.1 DISCUSSION

This qualitative, semi-structured interview-based study is the first to explore patients' perception of material risks for orthognathic surgery in the United Kingdom. Orthognathic surgery is a complex treatment pathway, and the journey is life-changing with a significant impact on patients' psychosocial well-being. As an elective surgical procedure, it requires a considerable amount of decision-making before patients choose to embark on this challenging journey. Patients need to know the material risks of orthognathic surgery, then decide on the amount of risk they are willing to take. For example, is the risk of the complication enough to make them decline surgery or are they tolerant of the risk and proceed with surgery? Therefore, this research set out with the aims of laying the groundwork for a structured approach for orthognathic surgeons to have conversations around risks and take informed consent prior to surgery. This would ensure patients are fully informed of the treatment journey and the potential complications. By carrying out qualitative research, through interviews, the patients' perceptions of risk, their attitudes towards taking risks and which risks were particularly salient to them were explored. In total 6 themes were identified which are discussed below:

1. Sources of information about orthognathic surgery.
2. Surgical risk.
3. Setting and format of how risks should be presented.
4. Physical effects of surgery and its impact on patients' psychosocial well-being.
5. Non-physical effects of surgery and its impact on patients' psychosocial well-being.
6. Impact of surgery necessitating support.

5.2 SOURCES OF INFORMATION ABOUT ORTHOGNATHIC SURGERY

Patients seek information regarding orthognathic surgery in various ways. Most patients expressed the preference of speaking to individuals who have undergone similar surgery. They found ways in doing this by accessing online forums, social media sites such as Facebook groups and Instagram, as well as YouTube. They expressed the benefit of establishing a connection with these patients. Broder et al. (2000) found that patients who spoke to someone who had had similar surgery were 'significant facilitators' in their decision-making process. This was further reiterated in a qualitative study which identified that information from other patients was valued highly as was seen as more reliable and honest (Patel et al., 2017). The orthognathic team at the Eastman Dental Hospital developed and evaluated a new style of multidisciplinary clinic to increase patient satisfaction in the decision-making process. One aspect included the opportunity for individuals considering surgery to meet patients who had undergone surgery to 'ask questions that clinicians may find it difficult to answer due to lack of personal experience of the treatment itself' (Ryan et al., 2011). This interaction was shown to contribute to the improvement in patient satisfaction. Furthermore, former studies have highlighted that internet forums are often used by patients to gain support from past patients who have undergone a similar procedure (Bhamrah et al., 2015; Paul et al., 2022). A previous study has shown that patients preferred using information from digital media resources, including internet videos and establishing contacts through social networks (Patel et al., 2017). As a matter of routine, the internet has now become the default source for most information, especially for the current generation. However, the material on the internet is not regulated and as such clinicians need to ensure that the information individuals are accessing is appropriate and "policed". The reason patients have stated as to why they access the internet for additional information was due to a lack of information given by clinicians which is important make note of (Bhamrah et al., 2015).

To provide individuals with an insight of the treatment journey the British Orthodontic Society (BOS), together with maxillofacial surgeons, have developed a DVD titled ‘A Patient Guide to Orthognathic Surgery’. The DVD was a precursor to the BOS website ‘Your Jaw Surgery’ which is available on the BOS website (British Orthodontic Society (BOS), 2014). Flett et al. (2014) undertook a qualitative study to gain the opinions of orthognathic patients on the influence the BOS DVD had on their decision-making process. Even though the participants found the DVD useful they reported areas of improvements and suggested an additional section on ‘tips and hints about recovery after the surgery’ would have been helpful. They also reported that younger patients preferred receiving information from peers of their own age. This is in agreement with the present study’s findings in that patients found the BOS videos were of limited value compared to the internet for the information retrieval on orthognathic surgery. Individuals felt that the videos did not give a realistic view of the treatment journey. A similar finding was reported by Kettle et al. (2017) in which patients remark that the British Orthodontic Society online information resource conveys a positive view of the long-term benefits of this procedure. It is important to note that this may give a skewed image of what the procedure in fact entails. Furthermore, in this present study patients preferred to know more about the non-physical effects of surgery to prepare themselves better mentally, especially during the recovery period and for the videos to be more realistic on what to expect.

Patients in the present study found leaflets unhelpful and felt that it overwhelmed them with information which they felt was irrelevant at the time. Interestingly in a previous randomised control trial patients were allocated to the British Orthodontic Society patient information leaflet or a patient information website and the latter was found to give more information about the surgery in comparison (O'Connell, 2016). This agreed with the present study which found patients criticised the BOS leaflets as being too generalised when it came to support the decision-making process.

Given that improvement in facial aesthetics is one of the primary drivers for orthognathic surgery, none of the patients interviewed in the present study were shown simulated computer images of the anticipated surgical outcome. Interestingly, all the participants unanimously agreed that this would have helped them in their decision to undertake surgery. This visual information could facilitate the discussion process and encourage debate and communication between the surgical team and the patient. In addition, it will better prepare patient's mentally to deal with their 'new face'. Some participants commented that they were not fully aware of the risks of nasal changes following surgery, which 3D virtual planning would demonstrate. However, there has always been concerns with the accuracy of computerised prediction software and whether showing surgical prediction images will increase a patients' expectations of treatment (Magro-Filho et al., 2010). In a recent study, utilising 3D prediction planning, most patients felt that their surgical soft tissue changes was better than the predictions given to them (Hertanto et al., 2021). Phillips et al. (2001) also contradicts the current findings and found no improvement on patients' decision-making when they were shown computerised treatment simulation. However, involving the patients in the planning process has been shown to increase the patient's satisfaction of the post-surgical outcome. In addition, it has been shown that 3D prediction planning motivates patients to undergo surgery and enhances their confidence in their decision (Hertanto et al., 2021).

5.3 SURGICAL RISK

It was clear from this study that the attitudes to risk taking varied amongst the participants. Many participants were not fully aware of the numerous complications that can occur with orthognathic surgery and the decision made was mainly based on the desire to correct their facial deformity. Even though patients were "willing to have surgery at any risk" they all unanimously said that they would not risk having the surgery if they knew loss of the maxilla was a risk. This raises an interesting point, if patients do not know the risks attached to orthognathic surgery and the potential impact it may have on them, they can only decide based on information they have at hand. Following Montgomery v Lanarkshire Health Board [2015] UKSC 11, it is necessary upon clinicians to inform patients of the material risks pertaining to their surgery. "The test of materiality is whether a reasonable person in the patient's position would be likely to attach significance to the risk. Also, whether the doctor was or should reasonably be aware that the particular patient would be likely to attach significance to it." Even though the likelihood of the loss of the maxilla is rare, there is still a risk, and this risk needs to be explained to the patient, especially given the fact that none would have had the surgery.

More likely occurrences, i.e., loss of vitality of one or more incisors following Le Fort I osteotomes, evoked a varied response. This shows there is individual variability when it comes to being risk tolerant or being risk averse. Some individuals are more likely to accept risk and followed whatever treatment is suggested by their treating clinician on the assumption there was no alternative, rather than resorting to themselves to weigh the risks. These participants indicated that they trust their surgeon's ability and that their clinicians were competent enough to decide on their behalf. This was also reported in a qualitive study that examined patients' attitudes to risk in lung cancer surgery and found that patients preferred to rely on their clinicians to make decisions regarding their treatment (Powell et al., 2015). Only a few participants reported willingness to accept perioperative mortality risk when given hypothetical scenarios and again this was reasoned with the fact that they have placed their trust with their treating clinician and the assumption of having no alternative. Studies have shown individuals with a higher cognitive ability are less risk averse (Lilleholt, 2019). Some studies have linked age as a factor when it comes to risk aversion and risk tolerance, with adolescences being described as a period of 'heightened risk-taking' (Paulsen et al., 2012). This was demonstrated in the present study where participants acknowledged that they were 'naive' when they were given information regarding surgery which impacted their decision-making. For those who demonstrated risk aversion, it was clear that these patients would appreciate knowing all the risks entailed with this surgery. Some patients adopted a "paternalistic" approach to the decision-making process and were under the impression that "doctor knows best". Whilst this approach may be acceptable in some procedures, emergency interventions, that are in the patient's best interest, it is no longer acceptable for routine and elective procedures. This reinforces the need to make sure the patient is involved in the decision-making process and is fully aware of material risks.

Some participants had the attitude of active risk avoidance by delegating the decision of their care to the clinician. Miller and Mangan (1983) defined two groups of people: "monitors" (information seekers) and "blunters" (information avoiders). Monitors are highly attentive and sensitized, and tend to amplify threats", whilst 'blunters avoid and minimize the same threats'. This type of behaviour was also shown in the present study where some participants avoided having to think about the risks and put their trust entirely to the clinician with the attitude that the surgeon was acting in their best interests and so they would be ‘safe’ under their care. Ryan et al. (2011) explains that patients tend to suppress information that may cause them anxiety, i.e., death under GA, and tend to remember information which encourages them to have the surgical procedure. This may explain why some individuals do not respond to high impact risks and have a “blocking” strategy as a coping mechanism to find the courage to have the surgery.

There were different attitudes when it came to assessing the risks of surgery. Some participants were risk averse, whereas others were more risk tolerant given the potential of achieving a favourable outcome. Generally, the participants were aware and accepting of the risks of pain, bleeding, and infection as these were generic across many different surgical procedures. More specific risks of maxillary osteotomies, such as devitalisation of teeth, loss of vitality of the maxilla and death under a general anaesthetic were less familiar to the group but had the potential to influence the decision-making process. When carrying out a generic risk assessment the first steps of the process involve identifying the risk and who is at risk. The next step is the likelihood that the risk will occur and finally the consequences of the risk. The same process could be used in orthognathic surgery risk using a risk matrix, where,

(Likelihood of risk) x (Consequence of risk) = Level of risk

Figure 5.1 shows a potential risk matrix for orthognathic surgery. For example, the likelihood of loss of an upper incisor, or incisors, during a Le Fort I osteotomy is unlikely; the consequences would be minor for some patients and potentially perceived as a low level of

Figure 5.1 Potential risk matrix for orthognathic surgery

Likelihood of event occurring		Consequence of event				
		Insignificant	Minor	Moderate	Major	Catastrophic
	Almost certain	Medium	Medium	High	High	High
	Likely	Low	Medium	Medium	High	High
	Possible	Low	Medium	Medium	High	High
	Unlikely	Low	Low	Medium	Medium	High
	Rare	Low	Low	Low	Low	High

Worked examples

- Likelihood of having problems with eating and speech are almost certain, consequences are minor (if normal weight), therefore medium risk.
- Likelihood of having problems with eating and speech are almost certain, consequences are major (if underweight), therefore high risk.
- Likelihood of loss maxilla integrity following a Le Fort I osteotomy is rare, consequence catastrophic, therefore high risk.

risk. To others the consequence would be major and prevent them from having surgery and therefore would be perceived as a high level of risk for that individual.

It is clear from this study that the patients' psychological state has a huge impact on how they perceive risks. The participants often noted that nothing would have deterred them from having the surgery because of how they have been mentally impacted by their facial visible difference. There were many participants that described their low mental state as debilitating, which made them believe that surgery would solve their problems and improve the mental well-being. Some participants explained that in their pre-operative psychological state they struggled to rationalise the risks and therefore their cognitive reasoning was impaired. This was further extended to some participants acknowledging that they would have to lie to not jeopardise having the surgery. If patients' mental states are resorting to lying to have the surgery, then that would question their frame of mind for decision making. This could indirectly affect the individual's ability to consent as they may not have comprehended the information given or utilise this information for the decision-making process. In other words, it could be argued they lack the capacity to consent. The self-confessed mental impairment may mean that the individual is unable to make a specific decision about surgery necessary in the 2-stage test of capacity set out in the Mental Capacity Act (2005).

Facial attractiveness appears to be correlated to psychologic distress and a strong underlying motivator for treatment. This was evident with patients recounting emotionally painful interpersonal experiences such as bullying. For most participants, their facial appearance contributed to various negative emotions such as shame, embarrassment, self-consciousness, insecurities, and suicidal thoughts. It is apparent that these emotional states played a role in how they perceived the risks of surgery. Rather than surgery being optional, with weighing the risk versus benefit of the surgery, it becomes as if the surgery was a necessity and the risks were something they must take regardless irrespective of the consequences. Focus group and one-to-one interview findings support that treatment-seeking behaviours were largely associated to social and aesthetic concerns that impacted patients' daily lives.

There is possibly an age-related difference that patients desire in terms of shared decision making and the extent of information given. Often the participants mentioned that they were too young to decide for themselves and placed their trust in their clinician because of their lack in life-experience. They seemed to be oblivious to the risks of surgery and a few did not even consider them. A similar response has been previously highlighted where patients under the age of 50 years had a greater desire to receive information about general anaesthesia than those who were older (Lonsdale and Hutchison, 1991).

5.4 SETTING AND FORMAT OF HOW RISKS SHOULD BE PRESENTED

It was clear that the participants unanimously wanted clinicians to inform them of all the risks involved with orthognathic surgery. They felt that the information should be given in a detailed conversation as opposed to a list of risks read out to them. In addition to this the participants preferred that this conversation should be carried out in a non-clinical environment so that they are comfortable in retrieving the information and ask any questions they may have. Several participants felt that the discussion was not in depth and too brief to their liking. This conversational type of method in relaying information was incorporated in a 'new style orthognathic clinic' study that found that this improved satisfaction amongst the patients in them understanding the information given. In addition, the patients felt they were given enough time to ask questions in a non-threatening environment (Ryan et al., 2011).

The second aspect of this study was a domain that emerged which did not necessarily address the research question, but it was felt it was an important finding and requires highlighting to improve the consent process. It was apparent during the interviews that the risks described to the patients did not coincide with their lived experience and impact on their psychosocial well-being.

5.5 PHYSICAL EFFECTS OF SURGERY AND ITS IMPACT ON PATIENTS' PSYCHOSOCIAL WELL-BEING

The findings of the study suggest that often the expected complications of the surgery are played down by the clinician which then subsequently leads to the patient be unable to cope with the complication. This was also a similar finding in a cross-sectional survey which used interview and questionnaire methods in four orthognathic treatment services in Yorkshire (Stirling et al., 2007). Sixty-one patients who had had orthognathic surgery reported they found awareness of the surgical risks was poor, with about half of the patients reporting their knowledge was poor which led to them not making informed decisions and not fully meeting their needs. Zhou et al. (2001) evaluated the association between patients' psychologic status pre-operatively and post-surgical adaptation and experience of the surgery. '44% of patients had more pain, 57% had more numbness, and 73% had more swelling than expected' (Zhou et al., 2001). Interestingly satisfaction of the outcome increased over a 2-year period but 8% of the patients regretted having had surgery, largely due to their facial changes were not as they envisioned. Therefore, the perceived risks given to patients do not always align with the information that is communicated by the clinician prior to the surgery.

One physical effect of surgery was difficulty with eating and drinking which has been discussed previously. Another physical effect was that many patients were distressed by the extent of post-operative swelling. Acute facial oedema tends to resolve in the first 3 weeks post-surgery and it has been shown that rigid internal fixation reduces oedema by 6 to 8 weeks (Khechoyan, 2013). Holman et al. (1995) found that the more positive family and friends were in terms of their reaction to the patient's appearance post-operatively, the most satisfied the patient was (Holman et al., 1995). This further reiterates that counselling the patient's social support group is paramount in their recovery. Not only do patients need to be warned of the risks of surgery but so do their friends and family. A negative or inappropriate comment about the patient's post-surgical facial appearance may have long term psychological effects. It is important to note, that pain, swelling and loss of sensation impacted patients' immediately after the surgery but this did not affect patient satisfaction, however, in the long term.

The third physical effect of surgery that patients reported was nerve injury. A recurring theme that emerged was that the participants felt the altered sensation they experienced was not as described and so this changed the perception of this risk. Several seemed to describe the sensation as a 'tingle' or the feeling when local anaesthetic begins to wear off. A few, however, described intense pain that they were not prepared for. All the participants explained how this consequence of surgery impacted their psychosocial well-being. It had a negative implication on social interactions such as kissing, eating out in public, losing the sensation when food is left on their lip, tooth-brushing and placing make-up. Although the majority state they would have still gone ahead with the surgery after experiencing nerve injury, however, a better description and the negative connotations associated with this risk may have helped them prepare mentally. It is important to note that there were participants who after experiencing this risk have changed their mind regarding having surgery carried out which shows the significance of this morbidity. This is contradictory to other studies which found this complication had no effect on patient satisfaction, and patients seem to adapt to this complication. It appears there is a broad variation in the impact of this complication on patients. This may be related to managing patient expectations with the acceptance of a numb lip as a positive trade-off against an improvement in facial aesthetic and function.

5.6 NON-PHYSICAL EFFECTS OF SURGERY AND ITS IMPACT ON PATIENTS' PSYCHOSOCIAL WELL-BEING

All the patients reported that the recovery period affected their psychosocial well-being to some extent. They were impacted by the duration of their recovery, negative experiences associated with the level of care during their hospital admission, inability to speak and overwhelmed by the exhaustion the recovery entailed. Some participants described their experience to leading to ‘dark places’, ‘depression’, ‘worse than the bullying’ and ‘struggling to leave home’. Several participants felt that the risk of ‘pain’ was underemphasised and should have been described in more detail especially around day 3 post-surgery where situation became the most difficult. This contributed to the negative impact of their mental well-being. Recently, postsurgical depression has been recognised as a legitimate complication of Orthognathic surgery despite it receiving little acknowledgement in the past (Nicodemo et al., 2008). It seems from this study that patients were experiencing a transitory state of mind, following surgery, which requires clinicians who are adequately trained in counselling to address. Therefore, orthodontists and oral and maxillofacial surgeons who are responsible for the patient they are treating have a duty of care to identify the symptoms of this mental illness and refer them when necessary to a psychologist following discussions with the patient and their family. It is important for these clinicians to liaise with the psychologist to improve patients' recovery. Psychological support pre-treatment through the treatment journey has been reported as being acceptable and beneficial from a patient's perspective (Selvaraj et al., 2019). The orthodontist should also identify any other stressful periods in the patient's life that may contribute to the anxiety and depression during the recovery period seen as they continue to see the patient a further 2 years after the surgery. It is important to note that patients with rigid fixation show instant psychological rebound and reduced signs of depression in comparison to patients who required intermaxillary fixation 5 to 10 years ago (Graber et al., 2017).

Several participants struggled mentally with looking differently after the surgery. Although they were happy with the final result, they were not mentally prepared with not being recognised by their family and friends. Adaptation to facial appearance change was a key theme that emerged in this study. Graber et al. (2017) explains that negative emotional responses rarely occur with mandibular setback/advancement procedures as they change the patient's profile. This may be due patients being satisfied with the outcome or may be a result of not being aware of their facial profile. This has been highlighted in a recent study which found around only 50% of patients, undergoing surgical correction of class III skeletal patterns, were able to correctly identify their presurgical facial profile (Franks et al., 2022). Whereas Le Fort procedures alter the frontal facial appearance significantly and immediately, so patients need to adapt to this new appearance. This can only be shown using 3D prediction planning which requires a cone beam computed tomography scan, 3D photorealistic soft tissue capture, intra-oral scans, and the appropriate software. It is also noted from this study that these unexpected facial changes had an impact on their self-esteem. It has been previously reported that patients' self-esteem declined significantly following the 9 month post operative interval (Kiyak et al. 1991). Therefore, health care professionals who are responsible for the care of these patients following this period should be aware of the emotional highs and lows during this period. A psychologist is imperative to intercept significant emotional problems that may arise, and these professionals are aware of the needs of the orthognathic patient.

5.7 IMPACT OF SURGERY NECESSITATING SUPPORT

Nearly all the participants commented that having the support of their family and friends significantly helped them during the recovery phase. The need to access this additional support was not stressed enough by the team preoperatively and arrangements need to be made if the patient is a carer or has any other commitments. This is in line with a prospective longitudinal study which looked at the relationship between interpersonal support and patient satisfaction (Holman et al., 1995). The study concluded that availability of support from the patient's support group was associated with the patient's satisfaction in the early post-operative period. Finding that pre-operative support is associated with post-operative satisfaction has important clinical implications and further highlights the importance of support through the patient's social networks. It is paramount that the patient is not treated in isolation of their support group and that they should be involved throughout this journey. This means that alongside diagnosis, patients should be evaluated for their level of support at home and potentially these individuals should be included in the consultation process. This is becoming more important as patients are often discharged from hospital earlier to free up hospital beds and prevent hospital acquired infections. With the current lack of social care and community health care it falls on the shoulders of family and friends to support postoperative patients in their own homes. Clinicians should advise patients' support group that the 'psychological healing process continues well beyond the early postoperative months' and that their role is crucial in facilitating this process (Holman et al., 1995). If it is made aware to the clinician that the patient's support network is not available or when they are unsupportive of the patient having surgery, then implications of this lack of support should be discussed with the patient with a possible referral to a psychologist or a delay in surgery if that is felt to be appropriate.

Professional support was another source in patients' information seeking to assess the risks of surgery. Two additional areas of support that patients particularly felt would have helped them in their journey were psychologists and dieticians. The combination of the two highlighted that social support was a key factor in improving their psychosocial well-being which in turn facilitates a quicker road to recovery. The importance of this psychological preparation should not be under estimated (Khechoyan, 2013). Not only is it important to discuss with the patient their motivation for surgery, but more importantly counselling the patient about the main complications and the duration of recovery. The patient should also be informed about the sudden lifestyle changes of up to 6 weeks following the surgery. Khechoyan (2013) notes that patients will suffer acute mood shifts during this period and that patients should be forewarned about these mood changes. Patients who have persistent postoperative depression and any difficulty to adjusting to their new facial appearance may they need to be referred to specialised professional counselling. This preparation is paramount, and involves in depth communication between the patient and the clinician. It is clear in the present study that patients were not always entirely psychologically prepared for the surgical sequelae, yet they were not offered access to the support service. This could have led to a catastrophic psychological impact with some participants having suicidal thoughts in the short term following surgery. Lack of funding and an increase in mental health issues, with an overburdened system, is probably a factor why patients do not have routine access to this service.

The dietician was another health care professional that all the participants felt they would have benefitted from seeing. Difficulty eating and drinking in the early phases of recovery, had a huge impact on their mental well-being. Having someone in their social network for support during this phase was important and a delegated caregiver is crucial to monitor the patients calorie intake (Khechoyan, 2013). The dietician provides support by prescribing the type and consistency of food depending on the patient's recovery stage and the progress of their functional adaptation. Paul et al. (2022) found that functional adaption was one of the key coping behaviours that had an impact on patients' experience of their surgery. Patients make varied functional adaptations post-surgery due to swelling and bruising and so it is advised for the patient to be referred to the dietician to guide them post-surgery. Also, as the jaws are often secured with heavy elastics, the dietician givens advice on the suitability of the consistency of food which is largely a liquid diet in the early days. Patients often reported they were prescribed pain medication in the form of solid tablets and so were unable to take these. They also often recalled negative experiences whereby food was left by the support team during their stay in hospital when it was not appropriate for them to have. One participant went as far as saying sucking on a straw was not possible for them due to the pain that it caused and so required the use of a syringe in the early stages. An experienced dietician can guide the patient and liaise with the clinical team being an essential mediator on what is appropriate for the patient. It goes without saying that nutrition is a key contributor to the healing and recovery process. Sufficient calorie intake, which includes protein, is paramount post-operatively to combat the catabolic metabolism reaction to stress following the operation (Khechoyan, 2013). Therefore, the patient’s nutritional requirements are increased yet their jaw function is impaired, and this is exacerbated with prolonged postoperative maxillomandibular fixation.

The works of Gabor Maté has revealed that human beings’ upbringing and any childhood adversity they may have faced has an impact on their mental health and undermines their general emotional balance (Maté, 2011). This is significant when interviewing different participants, as it became apparent that they all recovered differently and those who had troubled childhoods or experienced stress seem to have suffered more throughout the treatment journey. It becomes imperative that when clinicians are diagnosing these patients to not just look at the facial deformity that requires correcting, but that this face is part of a human being and some of their concerns may also have underlying psychosomatic influences. The nervous system, immune system, and hormonal apparatus is a psychosomatic unit. The state of the nervous system determines the state of the world as we perceive it. Because the unshakeable unit of our emotional system and the brains emotional circuit with the mind and body we cannot address correcting this facial deformity in isolation without expecting patients to be impacted differently. Patients often feel dismissed because clinicians do not recognise the unity of the mind and body. Therefore, when treating these patients with this life-changing treatment modality it is imperative to gain a detailed history of their social background and those who have experienced childhood adversity, chronic stress, traumas in their workplace must have added support throughout this journey.

It is important to understand how patients perceive the risks of orthognathic surgery and the impact this surgery may have on their psychosocial well-being; this needs to be considered during the consent process.

5.8 LIMITATIONS OF THE RESEARCH

Fifteen participants were recruited, ten females and five males. It has been reported in the literature that there are small gender differences in expressing emotion, with women showing greater emotional expressivity (Chaplin, 2015). Although in this study both females and males were able to express positive and negative emotions to a similar degree.

The ages of the participants ranged from twenty-three years to forty-three years old. This age range is smaller than a previous report in the U.K with the age ranging from sixteen years to sixty-two years and the mean age at 24.6 years (Ireland et al., 2019). The range of surgery dates was from October 2017 to December 2019. There were limitations in recruiting a cohort of participants with more recent surgeries due to COVID-19 and so it should be noted that this may affect their selective recall although most participants had their surgeries carried out in 2019. In addition, this research is a snapshot of patient experience from one orthognathic team which make the results less generalisation. However, the general method of running a multi-disciplinary clinic is fairly similar across the Hospital teams in NHS England.

Another limitation of this study was the length of time that lapsed from the point of the participants' surgery to when they had the interviews. It is important to note that this may have impacted their selective recall although most participants had their surgeries carried out in 2019. The participation dropout rate was 35%. Therefore, self-selection of participants that have stronger opinions or were impacted in the extremities by the surgery be it negatively or positively. There was a large range of ages of the participants and so from different walks of life and hence a diverse range of experiences. The ratio of female to male participants was 2:1. It has been reported in the literature that there are small gender differences in expressing emotion with women showing greater emotional expressivity (Chaplin, 2015). Although in this study it was felt that both females and males were able to express positive and negative emotions to a similar degree. Lastly, although data saturation was achieved during thematic analysis, a larger sample may have reflected a wider range of patient perceptions and experiences.

5.8.1 Relationship between the researchers and participants

The Critical Appraisal Skills Programme (2018) outlines a checklist as an appraisal tool for qualitative research which ensures quality in qualitative research. One aspect looks at is the role of the researcher and the potential bias that can be introduced in the study during formulation of the research question and data collection.

Self-selection may have been introduced during data collection in the focus groups interviewing process by the participants. It should be highlighted that they may have imposed a certain 'story' that they wanted to tell due to their personal experiences which may have influenced other participants of the same group to support these lived experiences. Particular perspectives can dominate if certain personalities are able to voice their strong interest and opinions during the focus group interviews. These can be an advantage as they contribute rich data. However, depending on the group dynamics, there can be a challenge with strong characters who may prevent more timid contributors from vocalising their concerns. This is where it is important for the researcher to regulate the group discussion and give others an opportunity to speak. Another aspect of selection bias in this study that should be addressed is the use of the virtual platform Microsoft Teams which could have potentially deterred individuals without access to the technology and excluded participants of a lower socio-economic status or the older generation who may not be familiar with such platforms. This was addressed during the recruitment phase where it was clearly explained to the potential participants that either telephone or the virtual platform can be used for the interview and a step-by-step guide was given for those who did not have previous access to Microsoft Teams.

Researcher bias may occur during data collection and analysis of the data set and it is important to apply the principles of reflexivity to acknowledge the perspective of the researcher can potentially influence the research (Pope and Mays, 2020). As the researcher (SMS) is an orthodontic registrar there is potential, where her insight in this field, could shape the researcher’s expectations by asking certain questions and prompting certain responses during the interviews. Therefore, it was important to be reflexive by asking open ended questions and using the topic guide to merely prompt the participants. During the analysis, again the researcher’s knowledge in this field may introduce preconceptions when searching the data set for codes by possibly overlooking unexpected answers. This bias was minimised by having a second researcher (AL) involved in the analysis of the data whose expertise is in another field. This enhances the theoretical sensitivity and interpretation of the data to reduce bias. It was also important to remain objective during the data analysis and maintain an open mind to new themes emerging that may not necessarily be answering the research question which was demonstrated in this study. Lastly, by using the NVivo software this promoted transparency of the data set and coding.

CHAPTER 6

CONCLUSIONS

6.1 CONCLUSIONS

This study begins to provide the clinician with a clearer insight to the patients' perception of risks and the impact surgery has on their psychosocial well-being which may give rise to considerations during the consent process:

- Improving information giving during consultations. Wherever possible, giving opportunities for patients to speak to past patients be it by formulating an online resource, improving the BOS videos or bringing past patients onto the consultation clinics.
- Including three-dimensional (3D) soft tissue prediction imaging during the consultation process.
- Recognition by the clinician that providing information should be simple and conversational, as well as carried out in a non-threatening non-clinical environment.
- Screening patients for past psychological distress and gauging whether they are risk adverse or risk tolerant.
- Ensure the patients have the mental capacity to consent.
- Ensuring that both physical and non-physical risks of orthognathic surgery are explained to the patients, giving details of potential psychosocial implications on their well-being in particular during the first 9 months of their recovery phase.
- Expanding the team approach in the care of the patient by involving a clinical psychologist and dietician.
- Ensuring that the patient is not treated in isolation of their support group and involving them throughout the journey. Alongside diagnosis, patients should be evaluated for their level of support at home and these individuals should be included in their

consultations. In the case where patients cannot identify their support systems this should be red flagged and prioritised to have a psychologist alongside their care.

This study has found that patients need to be informed of the overall experience of the treatment journey. It has highlighted that the consent process should not merely include direct surgical risks but should also include other less well documented risks, such as the indirect psychological risks and the need for a positive support group during the recovery period. Failure to discuss these later risks with patients undergoing orthognathic surgery may result in a negative experience and may have a longer-term psychological impact. It is important to provide patients with realistic and accurate information prior to the start of their orthognathic treatment and past patients are paramount in contributing to the consent process. Clinicians should be aware that what may seem of importance to them may not be the same for patients. Patients should be aware of the pain, swelling, nerve injury, difficulty eating and drinking, and the difficulties that may arise in the initial postoperative recovery period. They should also be given a realistic idea of their final facial appearance. This knowledge will lead to greater patient satisfaction and most importantly mentally prepare these patients to reduce negative implications on their psychosocial well-being. This research has identified the importance of the patient’s social network, dieticians, and psychologists in the duration of their treatment pathway. The findings of this study can inform future quantitative studies in which further research is required to look at how this new setting and format should be employed to improve the consent process for these patients as well as developing a comprehensive list of risks from both a clinicians and patient perspective.

CHAPTER 7

REFERENCES

7.1 REFERENCES

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CHAPTER 8

APPENDICES

8.1 Appendix 1: Ethical approval granted by the HRA and Health and Care Research Wales (HCRW) on the 24th November 2020

Ymchwil Iechyd
a Gofal Cymru
Health and Care
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24 November 2020

Dear Mrs Mohammed Saed & Professor Khambay

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

Study title:	**An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery.**
IRAS project ID:	**281494**
Protocol number:	**RG_20-075**
REC reference:	**20/NW/0433**
Sponsor	**University of Birmingham**

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.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

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 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) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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 standard conditions 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.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

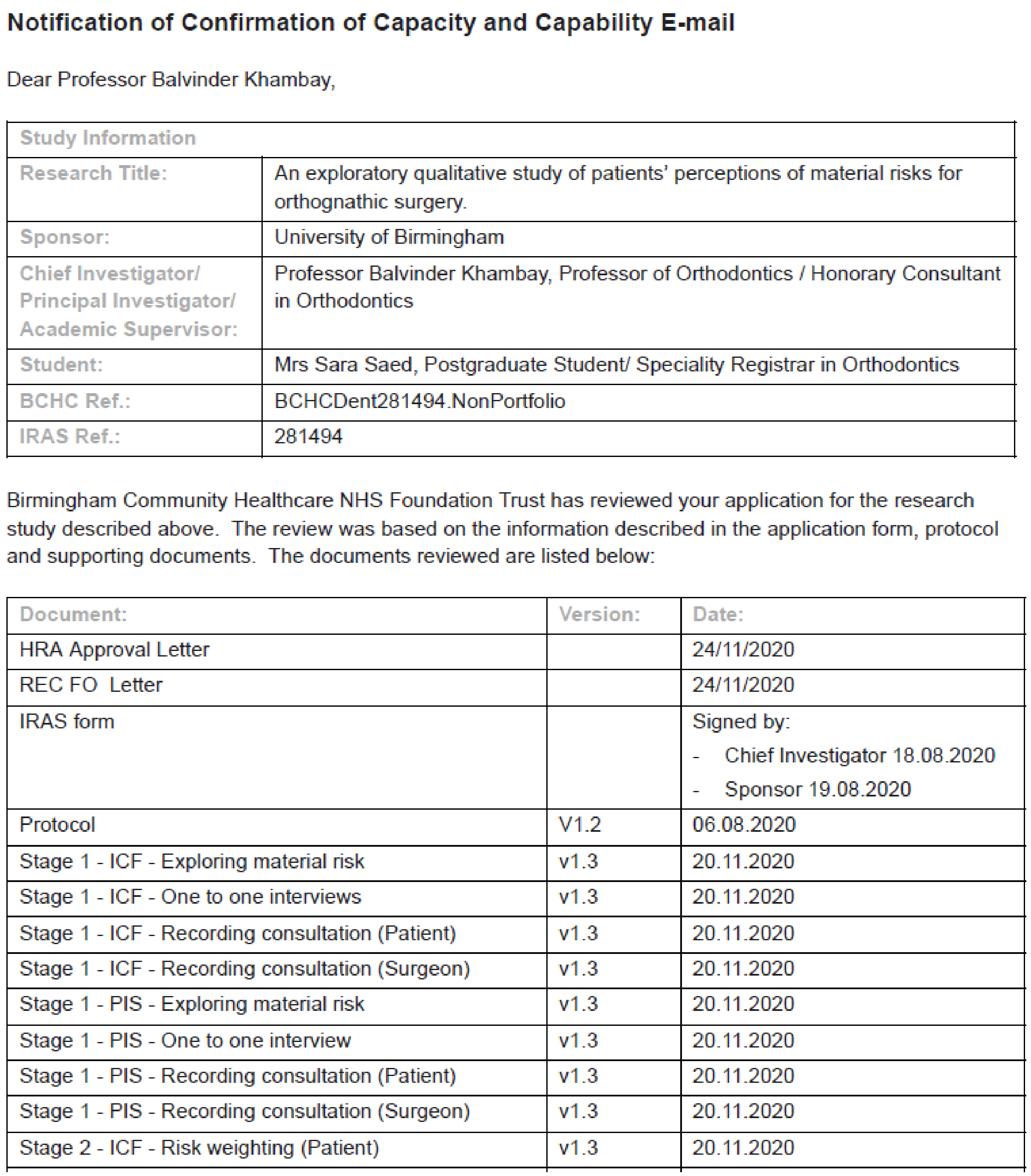
Your IRAS project ID is **281494**. Please quote this on all correspondence.

Yours sincerely,
Rachel Katzenellenbogen
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: Dr Birgit Whitman

8.2 Appendix 2: Research and development approval obtained from Birmingham Community Healthcare NHS Trust on 15th September 2021



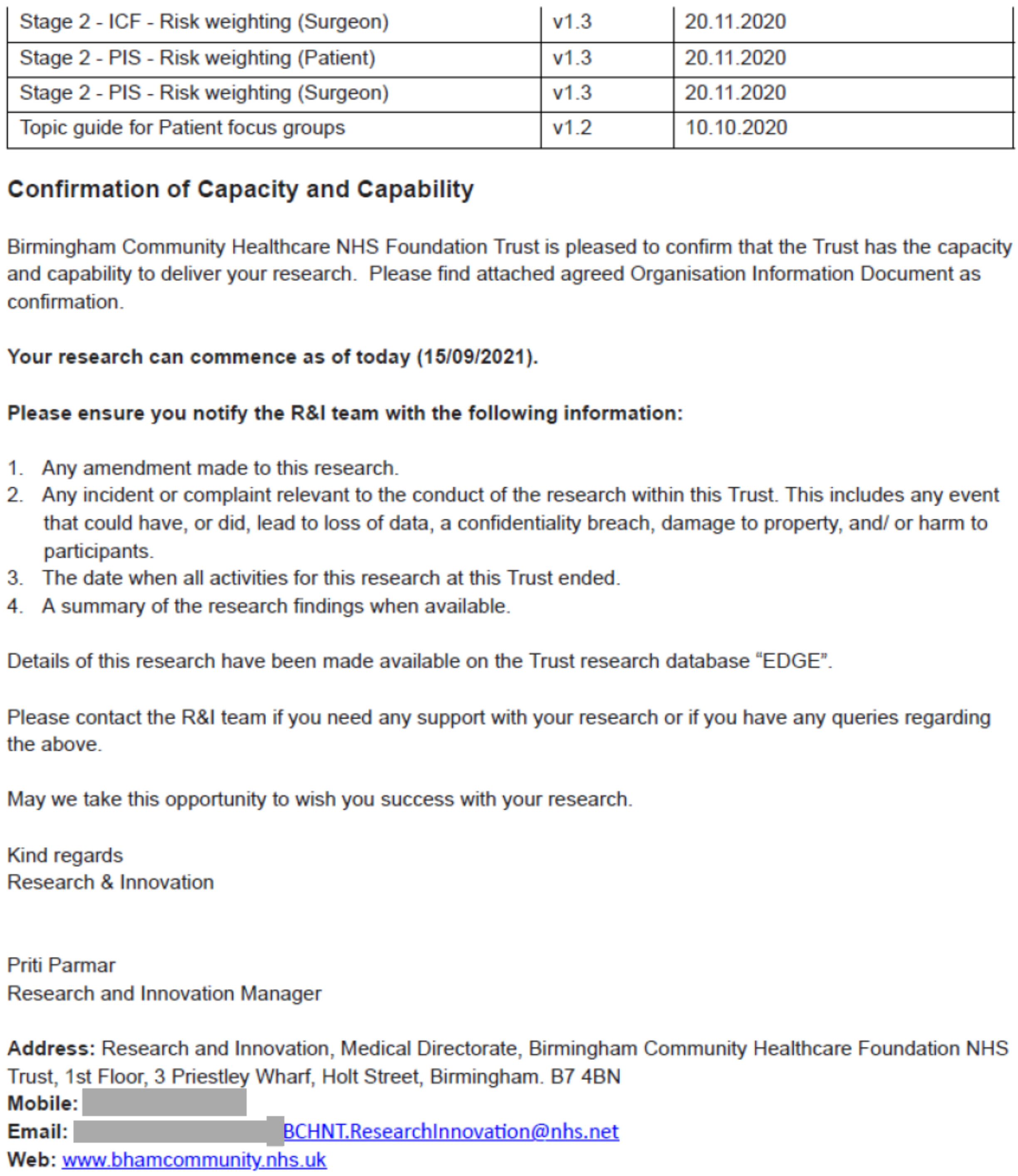
Notification of Confirmation of Capacity and Capability E-mail

Dear Professor Balvinder Khambay,

Study Information	
Research Title:	An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery.
Sponsor:	University of Birmingham
Chief Investigator/ Principal Investigator/ Academic Supervisor:	Professor Balvinder Khambay, Professor of Orthodontics / Honorary Consultant in Orthodontics
Student:	Mrs Sara Saed, Postgraduate Student/ Speciality Registrar in Orthodontics
BCHC Ref.:	BCHCDent281494.NonPortfolio
IRAS Ref.:	281494

Birmingham Community Healthcare NHS Foundation Trust has reviewed your application for the research study described above. The review was based on the information described in the application form, protocol and supporting documents. The documents reviewed are listed below:

Document:	**Version:**	**Date:**
HRA Approval Letter		24/11/2020
REC FO Letter		24/11/2020
IRAS form		Signed by: - Chief Investigator 18.08.2020 - Sponsor 19.08.2020
Protocol	V1.2	06.08.2020
Stage 1 - ICF - Exploring material risk	v1.3	20.11.2020
Stage 1 - ICF - One to one interviews	v1.3	20.11.2020
Stage 1 - ICF - Recording consultation (Patient)	v1.3	20.11.2020
Stage 1 - ICF - Recording consultation (Surgeon)	v1.3	20.11.2020
Stage 1 - PIS - Exploring material risk	v1.3	20.11.2020
Stage 1 - PIS - One to one interview	v1.3	20.11.2020
Stage 1 - PIS - Recording consultation (Patient)	v1.3	20.11.2020
Stage 1 - PIS - Recording consultation (Surgeon)	v1.3	20.11.2020
Stage 2 - ICF - Risk weighting (Patient)	v1.3	20.11.2020



Stage 2 - ICF - Risk weighting (Surgeon)	v1.3	20.11.2020
Stage 2 - PIS - Risk weighting (Patient)	v1.3	20.11.2020
Stage 2 - PIS - Risk weighting (Surgeon)	v1.3	20.11.2020
Topic guide for Patient focus groups	v1.2	10.10.2020

Confirmation of Capacity and Capability

Birmingham Community Healthcare NHS Foundation Trust is pleased to confirm that the Trust has the capacity and capability to deliver your research. Please find attached agreed Organisation Information Document as confirmation.

Your research can commence as of today (15/09/2021).

Please ensure you notify the R&I team with the following information:

1. Any amendment made to this research.
2. Any incident or complaint relevant to the conduct of the research within this Trust. This includes any event that could have, or did, lead to loss of data, a confidentiality breach, damage to property, and/ or harm to participants.
3. The date when all activities for this research at this Trust ended.
4. A summary of the research findings when available.

Details of this research have been made available on the Trust research database "EDGE".

Please contact the R&I team if you need any support with your research or if you have any queries regarding the above.

May we take this opportunity to wish you success with your research.

Kind regards
Research & Innovation

Priti Parmar
Research and Innovation Manager

Address: Research and Innovation, Medical Directorate, Birmingham Community Healthcare Foundation NHS Trust, 1st Floor, 3 Priestley Wharf, Holt Street, Birmingham. B7 4BN
Mobile: [redacted]
Email: [redacted] BCHNT.ResearchInnovation@nhs.net
Web: www.bhamcommunity.nhs.uk

8.3 Appendix 3: Participant information sheet (PIS)

Birmingham Community Healthcare NHS
NHS Foundation Trust

UNIVERSITY OF
BIRMINGHAM

Patient Information Sheet

An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery.

Stage 1: Exploring material risk (Post-surgical Patient Focus groups)

Version 1.3

20th November 2020

Sponsor Reference: RG_20-075

IRAS: 281494

You can speak to a member of the research team for further information about participation requirements for this research.

If you change your mind later about taking part, you can withdraw permission at any time without giving a reason

Enquiries & Correspondence:

This research is sponsored by the University of Birmingham.
The Chief Investigator of this study is Professor Balvinder Khambay.
If you want to discuss this study further, please call 0121 466 5522
or email dentistryresearch@contacts.bham.ac.uk

Birmingham Dental Hospital
5 Mill Pool Way
Birmingham
B5 7EG

Patient Information Sheet

Focus group

An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery

Researcher: Prof Balvinder Khambay

I would like you to take part in the study but before you decide, please read the following information and think about if you would like to be involved. One of my research students will help me run this project and the results of this study will contribute to an educational project i.e. a research degree.

What is the purpose of this study?

Patients that have opted for jaw surgery have to weigh up the risks and benefits of treatment before making a decision on whether to have surgery or not. From a surgeons point of view we are aware of the main surgical risks – pain, bleeding and infection, but there are many other minor risks. What we don't know is which risks are important to you, as a patient, and which ones might make you stop and reconsider whether surgery is right for you?

In this study, I am looking at what risks are important to people who have had or are about to have jaw surgery. I am also looking at the language used to give information to people during their consultation.

The information that I get from listening to the consultations will help me use the right language when I make a questionnaire or ask people about the risks in having jaw surgery. I hope the results of the study will help us give similar patients the right information to help them make a decision about having jaw surgery.

Who is doing the study?

I am an NHS Consultant and Professor of Orthodontics at the Birmingham Dental Hospital & School. One of my research students will help me run this project and the results of this study will contribute to an educational project i.e. a research degree.

Who is being asked to participate?

I am asking patients who have had jaw surgery, and come to the hospital, for Orthodontic treatment to be involved in the study.

What will be involved if I take part in this study?

For this part of the study, I am looking for people who would like to participant in a group discussion to talk about their experience of jaw surgery. The group would include another 4 or 5 individuals who have also had jaw surgery.

If you decide to participate in the study, you will be asked to sign a consent form. We will then arrange a date and time for the focus group. This will either be at the Birmingham Dental Hospital or it will take place online.

Some people may find it easier to speak on an individual basis rather than in a group setting. We can arrange for you to have a more detailed talk, with my research student and myself, about your jaw surgery. This talk can happen either face-to-face at the Dental Hospital, over the telephone or online depending on what suits you best.

The focus groups and follow up call will be audio recorded, transcribed into written text and kept for at least 10 years according to the University of Birmingham Code Of Practice for Research on a secure server. In addition any direct quotes will be anonymised before being used in a publication or journal.

If following the focus group and / or individual interviews you are feeling emotionally distressed, please free to contact me (details at the end of this leaflet) and I will arrange to speak to you or arrange for a referral to the appropriate individual with in the NHS.

What are the advantages and disadvantages of taking part?

Although there might not be a direct benefit to you, I hope the results of the study will help us decide on what risks should be told to patients undergoing jaw surgery in the future. I will be able to let you know what I find out if you are interested at the end of the study.

The only disadvantage of taking part is that it will take up some of your time to attend the discussion group. The discussion will last 2-3 hours and can be arranged outside work time. If I arrange a face-to-face meeting I will provide refreshments and there is an allowance of £10 to cover travel costs. You will also receive a £30 shopping voucher for participation. If the group meeting are online then you will only receive a £30 shopping voucher for participation

How will we use information about you?

We will need to use information from you for this research project.

- You are free to withdraw from the study at any time without needing to give a reason. You will have two weeks after you have withdrawn to request any data is destroyed. After this point, any data collected may still be used for research purposes.
- Information will be kept strictly confidential and they will not be identifiable in any of the results published. Withdrawal from the study would not affect your care in the future.
- This information will include your initials, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- Any information that could show who you are will be held safely with strict limits on who can access it.
- Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. We make sure that when we write reports about the study in a way that no-one can work out that you took part in the study.
- The results of this study will contribute to an educational project i.e. a research degree.
- If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer, Mr. Ben Pumphrey, Head of Legal Services / Data Protection Officer, 3 Priestley Wharf, Holt Street, Birmingham Science Park, Birmingham, West Midlands, B7 4BN.

What will happen to the results of the study?

The results will be presented to other Orthodontists and Surgeons to allow everyone to benefit from the research. However, all findings will be anonymous so your results will not be able to be identified. You can find out the results of the study by contacting me (contact details on title page). The results of this study will contribute to an educational project i.e. a research degree.

Who has reviewed this study?

This study has been given ethical approval by the University of Birmingham and the NHS Research Committee.

"The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage."

What are your choices about how your information is used?
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by asking one of the research team.

Complaints
If you have any concerns or complaints please contact

Mr John Turner
Consultant Orthodontist
Orthodontics Department
Tel: 0121 466 5038

If you agree, I will contact you in two week via telephone to see if you are willing to participate in the study.

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

Birmingham Community Healthcare NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

Patient Information Sheet

An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery.

Stage 1: One to one interviews (Post-surgical)

Version 1.3

20th November 2020

Sponsor Reference: RG_20-075

IRAS: 281494

You can speak to a member of the research team for further information about participation requirements for this research.

If you change your mind later about taking part, you can withdraw permission at any time without giving a reason

Enquiries & Correspondence:

This research is sponsored by the University of Birmingham.
The Chief Investigator of this study is Professor Balvinder Khambay.
If you want to discuss this study further, please call 0121 466 5522
or email dentistryresearch@contacts.bham.ac.uk

Birmingham Dental Hospital
5 Mill Pool Way
Birmingham
B5 7EG

Patient Information Sheet

One to one interviews

An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery

Researcher: Prof Balvinder Khambay

I would like you to take part in the study but before you decide, please read the following information and think about if you would like to be involved. One of my research students will help me run this project and the results of this study will contribute to an educational project i.e. a research degree.

What is the purpose of this study?

Patients that have opted for jaw surgery have to weigh up the risks and benefits of treatment before making a decision on whether to have surgery or not. From a surgeons point of view we are aware of the main surgical risks – pain, bleeding and infection, but there are many other minor risks. What we don't know is which risks are important to you, as a patient, and which ones might make you stop and reconsider whether surgery is right for you?

In my study, I am looking at what risks are important to people who have had or are about to have jaw surgery. The information that I get from the one to one discussions will help to determine which additional risks should be discussed with patients considering jaw surgery. I hope the results of the study will help us give similar patients the right information to help them make a decision about having jaw surgery.

Who is doing the study?

I am an NHS Consultant and Professor of Orthodontics at the Birmingham Dental Hospital & School. One of my research students will help me run this project and the results of this study will contribute to an educational project i.e. a research degree.

Who is being asked to participate?

I am asking patients who have had jaw surgery, and come to the hospital, for Orthodontic treatment to be involved in the study.

What will be involved if I take part in this study?

For this part of the study, I am looking for people who would like to participant in a one to one discussion to talk about their experience of jaw surgery.

If you decide to participate in the study, you will be asked to sign a consent form. We will then arrange a date and time for the discussion. This will either be at the Birmingham Dental Hospital or it will take place online or over the phone.

What are the advantages and disadvantages of taking part?

Although there might not be a direct benefit to you, I hope the results of the study will help us decide on what risks should be told to patients undergoing jaw surgery in the future. I will be able to let you know what I find out if you are interested at the end of the study.

The only disadvantage of taking part is that it will take up some of your time for the face to face interview. The interview will last about 1-2 hours and can be arranged outside work time. If I arrange a face-to-face meeting I will provide refreshments and there is an allowance of £10 to cover travel costs. You will also receive a £10 shopping voucher for participation. If the discussion takes place online or over the phone then you will only receive a £10 shopping voucher for participation. The discussion will be audio recorded.

How will we use information about you?
We will need to use information from you for this research project.

- You are free to withdraw from the study at any time without needing to give a reason. You will have two weeks after you have withdrawn to request any data is destroyed. After this point, any data collected may still be used for research purposes.
- Information will be kept strictly confidential and they will not be identifiable in any of the results published. Withdrawal from the study would not affect your care in the future.
- This information will include your initials, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- Any information that could show who you are will be held safely with strict limits on who can access it.
- Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. We make sure that when we write reports about the study in a way that no-one can work out that you took part in the study.
- The results of this study will contribute to an educational project i.e. a research degree.
- If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer, Mr. Ben Pumphrey, Head of Legal Services / Data Protection Officer, 3 Priestley Wharf, Holt Street, Birmingham Science Park, Birmingham, West Midlands, B7 4BN.

What will happen to the results of the study?
The results will be presented to other Orthodontists and Surgeons to allow everyone to benefit from the research. However, all findings will be anonymous so your results will not be able to be identified. You can find out the results of the study by contacting me (contact details on title page). The results of this study will contribute to an educational project i.e. a research degree.

Who has reviewed this study?
This study has been given ethical approval by the University of Birmingham and the NHS Research Committee.

"The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage."

What are your choices about how your information is used?
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by asking one of the research team.

Complaints
If you have any concerns or complaints please contact

Mr John Turner
Consultant Orthodontist
Orthodontics Department
Tel: 0121 466 5038

If you agree, I will contact you in two week via telephone to see if you are willing to participate in the study.

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

8.4 Appendix 4: Informed consent form (ICS)

Birmingham Community Healthcare NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

Consent Form

An exploratory qualitative study of patients’ perceptions of material risks for orthognathic surgery.

Stage 1: Exploring material risk (Post-surgical Patient Focus groups)

Version 1.3

20th November 2020

Sponsor Reference: RG_20-075

IRAS: 281494

You can speak to a member of the research team for further information about participation requirements for this research.

If you change your mind later about taking part, you can withdraw permission at any time without giving a reason

Enquiries & Correspondence:

This research is sponsored by the University of Birmingham.
The Chief Investigator of this study is Professor Balvinder Khambay.
If you want to discuss this study further, please call 0121 466 5522 or email [redacted] or dentistryresearch@contacts.bham.ac.uk

Birmingham Dental Hospital
5 Mill Pool Way
Birmingham
B5 7EG

Patient Identification Number:

CONSENT FORM

TO BE COMPLETED BY THE PATIENT

Participation in Research Study

Title of Project: An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery. Stage 1: Exploring material risk (Post-surgical Patient Focus groups).

Name of Researcher: Prof Balvinder Khambay

	Please initial box
1. I confirm that I have read and understand the Patient Information Sheet dated 20th November 2020, version 1.3 for the above study. I have had chance to think about it, ask questions and any questions have been answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I can withdraw at any time without giving reason. This will not affect my Orthodontic care.	☐
3. I understand that the data collected during the study might be looked at by other researchers from the University of Birmingham or regulatory authorities. I give permission for these individuals to have access to the information.	☐
4. I agree to take part in the focus group and I understand that it will be audio recorded.	☐
5. I agree to any anonymous quotes being used in a publication / journal.	☐
6. I agree to my contact details being stored in order to be contacted for a follow up interview after the focus group.	☐
7. I agree to take part in the above study.	☐
8. I understand that following the focus group and / or individual interviews if I am feeling emotionally distressed I can contact the research team (details at the front of this leaflet).	☐
9. I understand that information on unsafe practice could be escalated, if they have not yet been reported through the usual procedures.	☐

Print your name ____

Signature ______________________________ Date ______________

Name of Person Taking Consent __________________________________

Signature ______________________________ Date ______________

Thank you for your help.

Consent Form

An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery.

Stage 1: One to one interviews (Post-surgical Patient Focus groups)

Version 1.3

20th November 2020

Sponsor Reference: RG_20-075

IRAS: 281494

You can speak to a member of the research team for further information about participation requirements for this research.

If you change your mind later about taking part, you can withdraw permission at any time without giving a reason

Enquiries & Correspondence:

This research is sponsored by the University of Birmingham.
The Chief Investigator of this study is Professor Balvinder Khambay.
If you want to discuss this study further, please call 0121 466 5522 or email [redacted] or dentistryresearch@contacts.bham.ac.uk

Birmingham Dental Hospital
5 Mill Pool Way
Birmingham
B5 7EG

Version 1.3 - Consent for participation – One to one interview 20th November 2020

Patient Identification Number:

CONSENT FORM

TO BE COMPLETED BY THE PATIENT

Participation in Research Study

Title of Project: An exploratory qualitative study of patients' perceptions of material risks for orthognathic surgery. Stage 1: One to one interviews (Post-surgical Patient Focus groups).

Name of Researcher: Prof Balvinder Khambay

	Please initial box
1. I confirm that I have read and understand the Patient Information Sheet dated 20th November 2020, version 1.3 for the above study. I have had chance to Think about it, ask questions and any questions have been answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I can withdraw at any time without giving reason. This will not affect my Orthodontic care.	☐
3. I understand that the data collected during the study might be looked at by other researchers from the University of Birmingham or regulatory authorities. I give permission for these individuals to have access to the information.	☐
4. I agree to take part in the interview and I understand it will be audio recorded.	☐
5. I agree to any anonymous quotes being used in a publication / journal.	☐
6. I agree to take part in the above study.	☐
7. I understand that following the focus group and / or individual interviews if I am feeling emotionally distressed I can contact the research team (details at the front of this leaflet).	☐
8. I understand that information on unsafe practice could be escalated, if they have not yet been reported through the usual procedures.	☐

Print your name ____

Signature _________________________________ Date _____________

Name of Person Taking Consent___________________________________

Signature _________________________________ Date _____________

Thank you for your help

IRAS Number: 281494 Copies: 1 - participant copy; 1 - site file; 1 - medical records

Appendix 5: Topic guide

Topic guide for focus groups

1. **How did you find out you may benefit from jaw surgery?**

Prompt questions:
- Did your dentist tell you?
- Did the orthodontist tell you?
- Do other people in your family have it?
- What did you think/ feel when you were told you might benefit from jaw surgery?

2. **What concerns / problems did you have?**

Prompt questions:
- Did you have any problems eating?
- Were you worried about how your teeth look?
- Are you self-conscious about your teeth?
- Are you self-conscious about the way you look?
- Have you ever been teased/bullied about the appearance of your teeth or face?

3. **What kind of treatments were you told you might be able to have?**

Prompt questions:
- Were you told you could do nothing?
- Were you told you could just have your teeth straightened and accept the facial appearance as is was today?
- Were you told your bite might worsen before surgery?
- Were you told your facial appearance might worsen before surgery?
- Were you told the end result was permanent?

4. **Where did get information about treatment choices?**

Prompt questions:
- Did the dentist/orthodontist give you information?
- Did you talk to your family?
- Did you ask friends what they thought?
- Did you look on the internet?
- Were you given enough information to decide which treatment was best for you?
- Was the explanation of different options clear?

5. **What did you think about when you were deciding if treatment would be a benefit to you?**

Prompt questions:
- Did you think about the final result, in terms of how it looks?
- Were you worried about how well you would be able to bite food?
- Were you worried about how you would look after surgery?

- How did you know what you were going to look like after surgery?
- Did you think about how long it would take or how much work you would miss?
- Do you think about how far you would need to travel and whether you would be able to get to appointments easily?

6. **What is important to you in treatment of you jaw position?**

Prompt questions:

- Is it important that the final result looks good?
- Is it important that you can bite into food easily?
- Did you want treatment that would not need a lot of maintenance in the future?

7. **How involved do you feel you were in making decisions about your treatment?**

Prompt questions:

- How much time was spent discussing the options?
- Did you understand what all the options meant?
- Would you make the same choice again now you have started treatment?
- Do you think in the future you would like to be more or less involved in making the decisions about your treatment?
- Do you feel you made the right choice?

8. **What risks were you told about surgery?**

Prompt questions:

- Were you told about numbness and where?
- Did you understand what was meant by “numbness”?
- Were you told infection?
- Were you told about swelling?
- What took you by surprise?
- What would you warn future patients about?
- Did features of your bite or face change that you did not expect?