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The Impact and Quality of the Surgery-First Approach for Orthognathic Treatment

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Abstract

Background

High-quality healthcare aims to deliver patient-centred service that adapts to the clinical needs. The aim of this study was to evaluate the impact and quality of orthognathic surgery, using validated questionnaires from patients (Patient Reported Outcome Measures -PROMs) and clinicians (Quality Outcomes in Oral and Maxillofacial Surgery -QOMS).

Materials and Method

This prospective cohort study was conducted in patients who received orthognathic treatment, according to the Surgery First Approach, between 2023 and 2025. Two questionnaires were used in the study; PROMS, which incorporated the Orthognathic Quality of Life Questionnaires (OQOL), and was completed pre-surgery, and at four to eight weeks and one-year post-surgery; and QOMS, which was completed by clinicians pre-surgery, and at six months and one-year post-surgery. It was hypothesised that a large effect would be found, and a sample of 31 patients would ensure that the study was powered appropriately at 80%. Chi-squared and Fisher's exact tests were applied to assess associations between PROMs and QOMs.

Results

Thirty-three patients (mean age 26.6 ± 9.0 years) were included in the study. Surgery improved patients' reported quality of life, facial aesthetics, and oral function. Pre-operatively, 25 patients reported being 'very dissatisfied' or 'dissatisfied' with facial appearance. At one-year post-surgery, all patients reported being 'satisfied' or 'very satisfied' with their facial appearance, and total OQOL scores improved substantially, reducing from 40.4 pre-treatment to 20.0, indicating significant long-term improvement in function, aesthetics, psychological status, and overall quality-of-life. Two patients required return to theatre (RTT) but, within 30 days, both patients demonstrated reductions in OQOL scores from baseline to post-operative assessments, indicating that RTT did not negatively affect overall quality of life outcomes. A statistically significant association was observed between clinicians' and patients'

perceptions regarding facial aesthetic improvement as a primary indication for surgery (p=0.007). However, alignment of perception was less evident concerning improving function as an indication for surgery (p=0.078). Both patients and clinicians reported agreement at one year post-operatively on improved function (p=0.017), but the agreement on improved aesthetics did not reach statistical significance (p=0.069).

Conclusions

The Surgery-First Approach to orthognathic treatment yields measurable improvements in patient-reported, and clinician-assessed, outcomes. The PROMS and QOMS questionnaires are useful tools for the evaluation of the quality of orthognathic service delivery.

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Author's Declaration

I declare that this thesis has been composed solely by myself and that it has not been submitted, in whole or in part, for any other degree or professional qualification except as specified.

Except where stated otherwise by reference or acknowledgment, the work presented is entirely my own.

List of Abbreviations

ABBREVIATION	EXPLANATION
3D	Three Dimensions
AC	Aesthetic Component Of IOTN
AHRQ	Agency For Healthcare Research And Quality
AP	Anteroposterior
BAOMS	British Association Of Oral And Maxillofacial Surgeons
BOS	British Orthodontic Society
BSSO	Bilateral Sagittal Split Osteotomy
CBCT	Cone Beam Computerised Tomography
CFR	Code Of Federal Regulation
CL+/-P	Cleft Lip And/ Or Palate
COG	Consultant Orthodontists' Group
COS	Core Outcome Set
CRO	Clinician Reported Outcome
CT	Computerised Tomography
DFD	Dentofacial Deformity
DHC	Dental Health Component Of IOTN
EBD	Evidence Based Dentistry
EDC	Electronic Data Capture

FISMAA	Federal Information Security Modernization Act
GDPR	General Data Protect Regulation
GSI	Global Severity Index
HIPAA	Health Insurance Portability And Accountability Act
HIPAA	Health Insurance Portability And Accountability Act
IOFTN	Index Of Orthognathic Functional Treatment Need
IOTN	Index Of Orthodontic Treatment Need
IV	Intravenous
MD	Multi-Disciplinary
MVLS	College Of Medical, Veterinary & Life Sciences
NHS	National Health Service
NHS GGC	National Health Service Greater Glasgow And Clyde
NOQ	Northwick Park Orthognathic Questionnaire
OFA	Orthodontics First Approach
OGS	Orthognathic Surgery
OHIP	Oral Health Impact Profile
OHRQOL	Oral Health Related Quality Of Life
OMFS	Oral And Maxillofacial Surgery
OPG	Orthopantomogram

OSA	Obstructive Sleep Apnoea
PCA	Principle Component Analysis
PROMS	Patient Reported Outcome Measures
QOMS	Quality Outcomes In Oral And Maxillofacial Surgery
QQLQ	Orthognathic Quality Of Life Questionnaire
RCP	Retruded Contact Position
REDCAP	Research Electronic Data Capture
RTT	Return To Theatre
SD	Standard Deviation
SF-36	36 Item Short Form Survey
SFA	Surgery First Approach
SOOQ	Surgical Orthodontic Outcome Questionnaire
TSP	Two-Dimensional Planning
TVSP	Three-Dimensional Virtual Surgical Planning
UK	United Kingdom
USA	United States Of America
VAS	Visual Analogue Scale
WHO	World Health Organisation

Chapter 2 Introduction

2.1 Background

Orthognathic treatment is an umbrella term for a group of treatment modalities which involves orthodontic treatment combined with jaw surgery. It aims to correct facial abnormalities to improve function and/or alter the facial profile to improve aesthetics (Naini et al. 2006). It is estimated that around 3,000 patients undergo orthognathic surgery (OGS) each year in the UK with over 90% stating that it has improved their overall health (BOS 2016).

Patients with a dentofacial deformity (DFD) require comprehensive and effective care with a multi-disciplinary approach. Specialties involved include orthodontics, oral and maxillofacial surgery (OMFS), clinical psychology and oral surgery. Highly skilled technicians are also involved in three-dimensional (3D) planning providing invaluable input. The duration of treatment for the conventional orthognathic treatment pathway involving pre-surgical orthodontics followed by surgery, also termed the Orthodontics-First Approach (OFA) is approximately 32.5 months. One of the perceived benefits of the Surgery-First Approach (SFA), which avoids orthodontic decompensation prior to surgery, is the shorter treatment duration which has been reported as 10.2 months (Anwar et al. 2022).

Orthognathic patients have a high burden of care, with the average number of appointments for OFA and SFA being reported as 24 and 14 respectively (Anwar et al. 2022). For OFA, pre-surgery orthodontics usually takes 12-18 months. Following surgery, patients remain in hospital for one-to-three days and then require two to four weeks off work for a full-recovery. The post-surgery orthodontic treatment usually takes six months, and patients are then followed-up for five years (British Orthodontic Society, n.d).

DFD can have detrimental impact on patients' speech, mastication, and quality of life. Cunningham et al., (2000) reported that patients with a DFD had a lower body image perception than those without.

The concept of Evidence Based Dentistry (EBD) is that individualised, patient-centred treatment should consider the most up-to-date evidence, the clinicians experience, and the patients views (Sellars 2020). Although the need for orthognathic treatment is based on the patients concerns, assessment tools often give little emphasis to patient perception and quality-of life. An example of this is the Index for Orthognathic Functional Treatment Need (IOFTN), which is a tool used to assess the eligibility for patients for treatment under the National Health Service (NHS). The IOFTN is an objective tool recorded by the clinician without patient input. Patient Recorded Health Outcomes are being more frequently used within medicine and dentistry. The use of conventional outcome measures, reported by clinicians, often have very little meaning and significance to patients. Patient Reported Outcome Measures (PROMs) are based on the philosophy that treatment should aim to improve patients' quality of life as well as improving overall health (Esperão et al. 2010).

An understanding of PROMS and how closely these are associated with Quality Outcomes in Oral and Maxillofacial Surgery (QOMS) will help inform clinicians' if their views are aligned with patients and therefore this project should (a) improve communication between patients and clinicians and (b) shape the care of orthognathic patients in the future.

2.2 Orthognathic Surgery

2.2.1 Orthognathic Surgery in UK

Orthognathic patients have a high burden of care, and it has been reported to cost the NHS approximately £6,456 (± £613.80 standard deviation) per patient (Nandhra et al. 2014).

2.2.2 Prevalence

The prevalence of DFD varies depending on geographic location, however it is estimated that approximately 5% of the UK or USA population have a DFD which is not fully correctable with orthodontic treatment alone (Posnick 2014).

In 2017-2018, the British Orthodontic Society conducted a national audit on orthognathic acceptance criteria and information provided to orthognathic patients before embarking on treatment. It included data from 69 hospital

orthodontic departments within the UK and found that the prevalence of malocclusions of those attending the initial multidisciplinary clinics were: class III (50.55%), class II division I (40.7%), class II division II (4.6%) and class I (4.2%) (Ireland et al. 2019).

The incidence of class III malocclusions varies with geographic location, race, and ethnic background with an approximated global prevalence of 0-26.7% (Hardy et al. 2012). The prevalence is higher in Chinese and Malaysian populations with an estimated incidence of 16% and 17% respectively (Hardy et al. 2012) whilst there is a lower prevalence within European (2- 6%), Indian (0-5%), and Afro-Caribbean (10%) populations (Burgersdijk et al., 1991; Willems et al., 2001;Hardy et al., 2012).

The prevalence of class II division I incisor relationships is estimated at 20% (Todd and Lader 1988), and class II division II prevalence in UK children is around 10% (Foster and Walpole Day 1974). Vertical skeletal factors are likely to contribute to the aetiology of more severe class II division II incisor relationships (Brezniak et al. 2002) where there is increased overbite and almost or complete coverage of the lower incisors.

2.2.3 Motivation for Treatment

Orthognathic surgery is an elective procedure and patients' motivation for seeking treatment should be established from the outset (Proothi et al. 2010).

Studies have reported high satisfaction rates with surgery with 40-80% of patients reporting an improvement in function and 50-90% with appearance following OGS (Kiyak, West, et al., 1982; Kiyak & Bell, 1991; Laufer et al., 1976). The motivating factors for patients seeking OGS can broadly be categorized as aesthetic, psychosocial or functional (Cunningham & Johal, 2015).

There is some evidence to suggest that aesthetics is the main driver for patients embarking on treatment (Jacobson 1984; Flanary et al. 1985a; McKiernan et al. 1992; Rivera et al. 2000). However, the number of patients who are aesthetically motivated may be underreported as patients may try and conceal this during initial appointments and find it easier to discuss functional concerns. This may be due to the misconception that aesthetic concerns, might be

disregarded by the surgical team and affect their eligibility for NHS-funded treatment (Jensen 1978).

Not all patients who are offered orthognathic surgery will decide to proceed. Ayoub et al., found that patient's decision to proceed with OGS depends on their pre-surgical perception of their facial appearance (Ayoub et al. 2014a).

2.2.3.1 Aesthetics

How patients and clinicians view facial appearance may differ and it is important for clinicians to understand and document the patient's main concern to ensure that expectations can be managed accordingly.

Stereotyping, and the lack of social acceptance for what is perceived to be unattractive, the expression *'what is beautiful is good'* may explain why some orthognathic patients seek treatment to improve their facial appearance (Dion et al. 1972). Patient reported motivations for treatment include to a) improve dental appearance (Yu et al. 2013), b) minimise dental problems in the future and c) improve self-image/ confidence .

Males and females have been reported to have subtly different motivating factors, with females seeking to improve confidence and males hoping that orthognathic treatment would improve their social life (Williams et al., 2005).

2.2.3.2 Function

Many patients seek orthognathic treatment to improve function such as mastication and speech (Nurminen et al. 1999). However, changes in function following treatment can be difficult to measure objectively and often rely on patient-reported questionnaires Kiyak et al found that patients tend to report fewer functional problems following OGS. (Kiyak, McNeill, et al., 1982; Kiyak, West, et al., 1982). OGS in patients with anterior open bites and lack of occlusal contact can lead to an improvement in masticatory forces (Hunt and Cunningham 1997).

2.2.3.3 Oral Health

The relationship between straight teeth and oral health is complex, however, in the presence of adequate oral hygiene, there is no direct correlation between maligned teeth and caries/ periodontal disease (Hafez et al. 2012). Despite

there being no relationship between crowding and dental disease, 69% of patients reported a key motivating factor for embarking on OG treatment was to prevent future dental problems (Williams et al., 2005). The exception to this is that orthognathic treatment may re-establish periodontal stability in the case of a deep and traumatic overbite causing gingival stripping of anterior teeth or an anterior crossbite causing occlusal trauma (Seehra et al. 2009). However, the prevalence of class II division II malocclusions is around 10% in the UK (Houston et al. 1996), with only 4.2% of all patients seen at the initial multidisciplinary orthognathic clinic presenting with a class II division II malocclusion (Ireland et al. 2019). This may suggest that 'deep bite' patients represent a relatively small percentage of the surgical caseload and therefore dental health is unlikely to change for most patients following OGS.

2.3 Approaches to Orthognathic Treatment

2.3.1 Surgery First vs Orthodontics First Approaches

Orthodontic treatment prior to orthognathic surgery was uncommon prior to the 1960s until the desire from both patients and orthodontists to achieve the optimal aesthetic and occlusal result became significant factor in measuring treatment outcomes (Sharma et al. 2015). The conventional approach was introduced in the 1970s and involves pre-surgical orthodontics, orthognathic surgery, and post-surgery orthodontics (Proffit & White, 2011). The Surgery-First- Approach (SFA) was introduced in 1994, and the initial philosophy was that by carrying out surgery before orthodontic treatment, it may result in more efficient tooth movement due to initial correction of the soft tissues (Lee, 1994).

The SFA involves the surgery being carried out before orthodontic treatment (Benington et al. 2023). Traditional treatment with pre-surgical orthodontics involves dental decompensation to align, level, and maximise the intercuspation between the teeth to achieve the desired occlusion post-operatively (Bell & Creekmore, 1973; Proffit & Miguel, 1995). A well-fitting occlusion aids with location of the maxilla and mandible into the planned post-operative position. Additionally, the degree of incisor decompensation determines how much antero-posterior movement is possible of the jaws. However, the traditional approach of pre-surgical orthodontics has the clear disadvantages of worsening

of the patient's malocclusion and facial profile in the pre-surgical phase. This has shown to have significant implications in reduction of patient's quality of life prior to surgery (Saghafi et al. 2020).

SFA involves correction of the skeletal discrepancy first, before commencing a single course of orthodontic treatment (Anwar et al. 2022). This avoids the negative effects associated with dental decompensation and reduces the total treatment time (Yu et al., 2015;Choi et al., 2019). Answar et al, reported that the difference in treatment duration for SFA compared with the conventional approach was 22.5 months less for the SFA (Anwar et al. 2022).

A reported factor contributing to reduced treatment time with SFA proposed more rapid tooth movement in the immediate post-operative period due to increased cellular activity; there is a reduction of occlusal forces and interferences and within the corrected jaw relationship; and the soft tissues change following surgery aid decompensation (Liou et al. 2011; Yang et al. 2017). Despite the reported faster treatment time, there doesn't appear to be a significant difference in the overall number of appointments between SFA and OFA (O'Brien et al. 2009; Anwar et al. 2022). This may be due to more regular appointments required in the initial post-operative phase with the SFA patients (Hernández-Alfaro et al. 2014)- which is dependent on operator preference and the post-operative malocclusion.

Other perceived benefits of SFA are that patients awaiting surgery are not yet in active orthodontic treatment. OGS is elective and therefore can be subject to last-minute cancellations due to emergencies taking priority. One of the disadvantages of OFA, is that if there are any delays to the surgery, patients are in a compromised stage of treatment where their malocclusion may appear worse. This not only causes patient frustration and dissatisfaction (Pelo et al. 2017), but has been shown to negatively impact on quality-of-life (Saghafi et al. 2020). Additionally, the shorter duration of fixed-appliance treatment may reduce risks such as decalcification, root resorption and gingivitis (Hertanto et al. 2021). Hu et al. assessed the cost effectiveness of SFA compared to conventional OFA and did not find any significant differences in terms of cost of hospitalisation or orthodontics between the two approaches (Hu et al. 2021).

2.4 Risks of Surgery

Orthognathic surgery is generally considered safe with few reports of life-threatening complications, however, it does have several risks which patients should be counselled on. An understanding of the risks and benefits allows patients to make an informed decision which is an important part of valid consent (General Dental Council 2019).

A complication rate as high as 44.9% has been reported in a retrospective cohort study with 94 complication events in a total on 209 orthognathic procedures (Peleg et al. 2021). Reassuringly, most of these complications were regarded as short-term and required either little or no treatment. This section will outline the most common complications; however, it is out with the scope of this review to describe all complications in detail. To our knowledge, there are no published studies assessment the impact of complications arising from OGS on patient-reported quality of life.

2.4.1 Intra-Operative Complications

Intra-operative complications are those which occur during surgery and can include:

- Unfavourable bone separation (Steenen et al. 2016; Steenen and Becking 2016).
- Haemorrhage (Piñeiro-Aguilar et al. 2011).
- Iatrogenic damage to teeth (Ho et al. 2011).
- Nerve exposure (Gennaro et al. 2017).
- Soft tissue injury (Kim and Park 2007a).

A bad split has been referred to as ‘An unfavourable and un-anticipated pattern of the mandibular osteotomy fracture’ (Steenen and Becking 2016). The incidence of a bad splits varies from 0.2% to 14.6% per split site. Bad splits can cause reduction in bony healing, mechanical instability, bony sequestrate which can then increase the risk of subsequent infection (Panula et al. 2001).

2.4.2 Post-Operative Complications

Post-operative complications can be categorised into those occurring early (in the immediate post-operative period) and late (those occurring some-time after surgery). Early post-operative complications are those which occur up to one week following surgery. Late post-operative complications are those which occur after one week post-operatively (Peleg et al. 2021). Most of the post-operative complications tend to occur within the first four weeks following surgery (Chow et al. 2007).

The most reported post-operative complication is temporary loss of sensation (Agbaje et al. 2015; Peleg et al. 2021). Others include infection, malocclusion, temporomandibular joint dysfunction, condylar resorption, non-union of bone fragments, bony necrosis, soft tissue and periodontal injuries, nasal deformities, dental complications, those relating to the metal hardware, unsatisfactory result (from both surgical and patient perspective), and skeletal relapse (Chow et al., 2007b; Ho et al., 2011b; Kim & Park, 2007; Morris et al., 2007; Patel et al., 2007; Williams et al., 2012).

The reported complication rate for OGS varies within the literature. In a 15-year review of 1,294 patients undergoing orthognathic surgery, a total of 2,910 individual osteotomy procedures were performed (with multiple procedures often carried out during a single operation, e.g. maxillary, mandibular and genioplasty). The overall complication rate was 9.7%, with 7.4% related to post-operative infection (Chow et al. 2007).

Within a single-centre retrospective cohort study, where a ten-year review of 209 orthognathic surgeries was conducted, the most reported early post-operative complications were related to systematic effects such as reduced haemoglobin levels and increased swelling (Peleg et al. 2021). Of the 209 surgeries, there were 26 complications documented within the first week. Surgical site infections occurred in two cases, and both affected the mandible. There were 59 complications which occurred after the first week and 21 required return-to-theatre. There were nine incidences of patients experiencing loss of sensation. Of the nine, only one was considered permanent which was still present at one-year post-operatively. Of the eight which were transient,

four improved without treatment and the others were treated with light laser therapy. Seven patients experienced surgical relapse and five of these occurred following a bimaxillary osteotomy. Two patients felt they had vertical maxillary excess (VME) or also known as a 'gummy smile' following surgery, however both were treated non-surgically (Peleg et al. 2021).

2.4.2.1 Numbness

Temporary altered sensation can arise due to post-surgical inflammation, oedema, and physical trauma to the nerve (Westermark et al. 1998). It has been reported that patients that experience post-operative altered sensation may be less satisfied with treatment outcomes and therefore they should be adequately counselled on this risk before embarking on treatment (Forssell et al. 1998).

Numbness is a term used to describe an abnormal sensory experience that can occur with or without a stimulus (Nagai et al. 2023) The reported incidence of temporary and permanent numbness following OGS varies (Rennie et al. 2017). A retrospective report on the incidence of complications of 655 orthognathic patients found that 35% of patients who had a BSSO experienced some form of neurosensory deficit of the inferior alveolar nerve (Panula et al. 2001). 32% of these altered sensations, were described as mild and 3% caused significant disturbance. Within this report, older patients had higher incidences of post-operative altered sensation than younger. However, these results should be interpreted with caution as this retrospective report may underestimate the complication rates due to relying on contemporaneous clinical notes for data.

Whilst there is a clear relationship between pain and reduced quality of life, there is a less clear relationship between numbness and the impact of quality of life (Nagai et al. 2023). Rennie et al. found that in 78 patients who had a bilateral sagittal split osteotomy, 32% had objective numbness confirmed with two-point discrimination testing and 71% had perceived numbness following surgery but 70.9% reported that it did not impact on their daily life. Only 7% of those with a perceived neurosensory deficit, said that it affected their life 'a-lot' (Rennie et al. 2017).

2.4.2.2 Return to Theatre

A second orthognathic surgical procedure is sometimes indicated if the pre-surgical treatment objectives are not achieved - either functionally or aesthetically (Reyneke 2011). Due to the associated risks with a general anaesthetic, unplanned second procedures should be minimised (Little et al., 2021a; Gottschalk et al., 2011).

The reported Return to Theatre (RTT) rate is 2.4% following OGS and common reasons include post-operative malocclusion and metal work becoming loose requiring surgical removal (Panula et al. 2001). In a recent retrospective review of OGS in a single centre within the UK, conducted by Little et al., the RTT rate over a thirteen-year period was 3.6%. The most common reason was a post-operative malocclusion and most second procedures were carried out within the first four weeks following initial surgery. Of the thirteen patients RTT, seven initially underwent a Bimaxillary Osteotomy, four had a Bilateral Sagittal Split Osteotomy (BSSO) and one had a Le Fort I advancement. It was found that second procedures were more likely to involve the mandible than the maxilla (Little et al. 2021a). This may be explained by surgeons reporting that the mandibular repositioning is one of the biggest intra-operative challenges and the condylar position is a key component in determining the post-operative stability (Tabrizi et al. 2016). The second most common reason for requiring re-operation was septal deviation following a Le Fort I Osteotomy which had a prevalence of 1.5% (de Mol van Otterloo et al. 1991).

2.4.2.3 Infection

Infection following orthognathic surgery can lead to pain, longer hospital-stays, increased medical costs, and an increased risk of morbidity (Tan et al. 2011). The prevalence of post-operative infections is 5-33% (Guernsey and DeChamplain 1971; Willmar et al. 1979; Moser and Freihofer 1980; Martis and Karabouta 1984; McDonald 1990; Leira and Gilhuus-Moe 1991).

Surgical factors which may lead to an increased risk of post-operative infections are increased length of surgery, short-term antibiotic prophylaxis, extraction of third molars at time of surgery, unfavourable fragmentation/ fracture of bony segments (‘bad split’), and the type of surgical procedure. Patient factors which

may increase the risk are if the patient is immunocompromised, of older age, current smoker, and has poor oral hygiene (Zijderveld et al. 1999; Cheynet et al. 2001; Laskin 2003; Alpha et al. 2006; Theodossy et al. 2006; Chow et al. 2007b).

2.4.2.4 Removal of Metal Work

The removal of metal work following orthognathic surgery is controversial and the need for plate removal is debated in the literature (Alpert and Seligson 1996; Haug 1996). The incidence of patients requiring metal-work removal ranges from 5-20% (Francel et al. 1992; Tuovinen et al. 1994; Schmidt et al. 1998; Matthew and Frame 1999). Most often plates are removed as they have either became exposed, infected or the screws have become loose (Chow et al. 2007a).

2.4.2.5 Relapse

Relapse following surgery can occur in the immediate or late post-operative phase. However, changes occurring more than one year after surgery can only be partly attributed to surgical relapse as it is likely that skeletal growth, dentoalveolar compensation and bone remodelling also contribute. Skeletal changes occur over time in everyone, not just those who have underwent OGS, however in a five-year period following surgery, orthognathic patients were found to have greater skeletal changes than those who had not (Mihalik et al. 2003). Immediate relapse may be due to intra-operative challenges such as errors in positioning or inadequate fixation (de Haan et al. 2013).

Proffit describes a hierarchy of stability of surgical procedures (Figure 2-1). The degree of stability is not static after surgery i.e., in the first year following surgery, class II malocclusions are generally more stable than class III. However, this changes overtime – after one year class III malocclusions are more stable than class II (Proffit et al., 2007).

More than 90% of patients treated with maxillary impaction and mandibular advancement for class II have excellent results as both procedures are highly stable (Thomas et al. 1986; Turvey et al. 1988). Horizontal changes in the mandible are generally stable; however, most patients experience upward movement of gonion (by >2mm) due to mandibular remodelling. After one year, approximately 20% of patients who undergo a mandibular advancement will

experience some relapse with a reduction in mandibular length one-to-five years following surgery. When the mandible length is reduced surgically, only half of these patients will have a resultant increased overjet and this is due to dentoalveolar compensation and proclination of the lower incisors (Proffit et al., 2007).

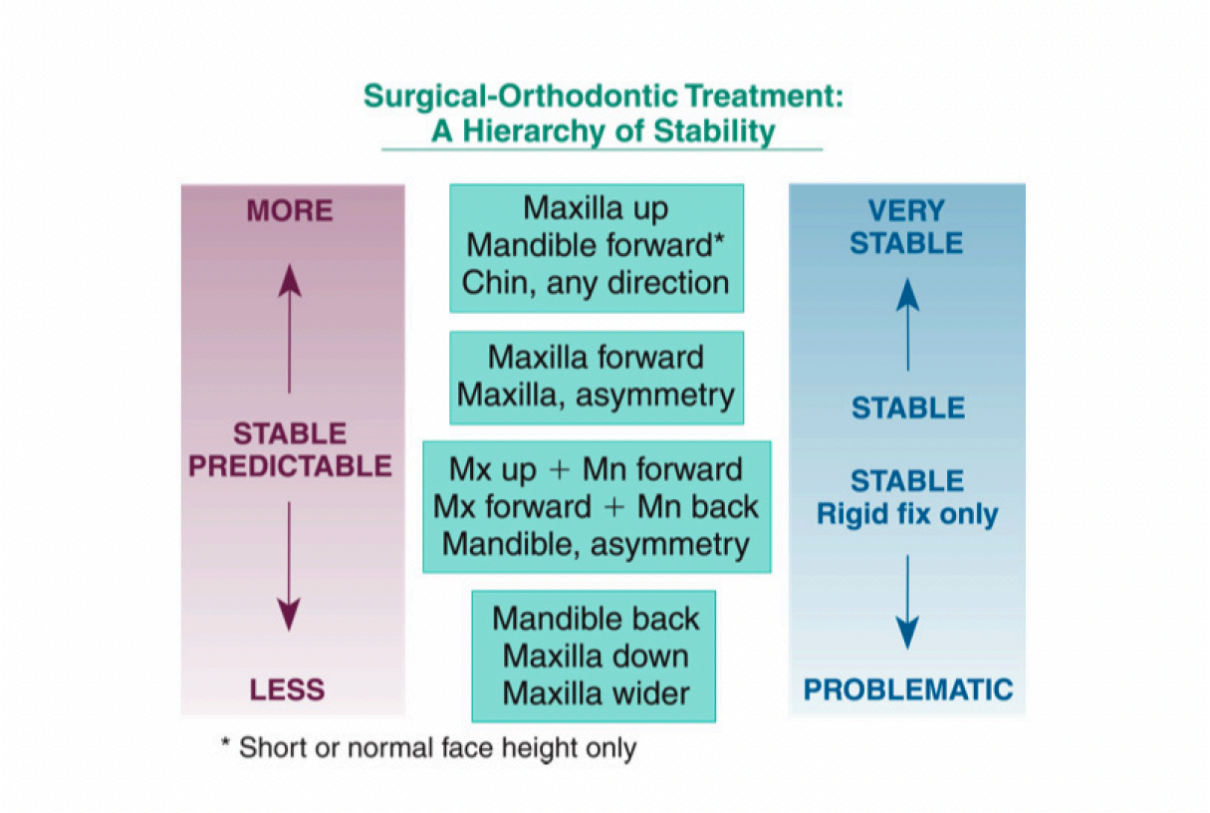

Figure 2-1 Hierarchy of Stability as Described by Proffit (Proffit et al. 2007)
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Isolated mandibular setbacks, downward movement of the maxilla and widening of the maxilla are unstable with a high relapse risk (Proffit et al. 1991; Bailey et al. 1997). Up to 50% of patients who undergo a mandibular setback and downward movement of the maxilla experience >2mm of post-surgical change and up to 20% have >4mm change. 30% of patients who undergo maxillary expansion will have relapse of >3mm. Downward movement of the maxilla is prone to relapse due to early occlusal forces causing upward displacement of the maxilla in the early post-operative period.

De Haan et al. assessed the relapse rate of class III deformities treated with (a) isolated BSSO alone and (b) BSSO in combination with a Le Fort I maxillary advancement. The incidence of clinically relevant relapse for mandibular set-

back procedures was 27% whilst maxillary procedures had a relapse rate of 21% (de Haan et al. 2013). Lateral Cephalograms were assessed from pre-treatment, post- surgery at one-three days and six months. Relapse, which was clinically relevant, as defined by Proffit (Proffit et al., 2000), was regression of the measurements and angles in the lateral cephalogram by more than 2mm and 2 degrees respectively towards their pre-treatment values. The severity of the initial deformity and the extent to which the mandible is set-back has influence on stability with larger setbacks having higher incidence of relapse.

Patients should be informed of the risk of relapse before undergoing orthognathic surgery. Reassuringly, despite the risks outlined above, most patients remain satisfied one year following surgery (Meger et al. 2021). However, there is a lack of studies which assess patient satisfaction in the long-term after one year.

2.5 Malocclusion

2.5.1 Aetiology of Malocclusion

Malocclusion has been described as ‘an appreciable deviation from normal occlusion’ (Houston and Tulley 1992) . In 1987, the World Health Organisation (WHO) included malocclusion in the category ‘Handicapping Dentofacial Anomaly’ which was described as ‘an anomaly causing disfigurement or impacting on function’ (Hassan 2007). A ‘normal’ occlusion can be described as a class I molar relationship with adequate alignment of the maxillary and mandibular dental arches. However, this only occurs in around 30-40% of the population (Mossey 1999).

The aetiology of malocclusion is considered multifactorial with the environment and genetics both playing an important role (Mossey 1999).

2.5.1.1 Genetics

Evidence from hereditary and twin studies confirm that there is a strong genetic influence in craniofacial development, and in particular, the orofacial structures (Mossey 1999). Studies have confirmed that there is a relationship between genetic heterogenicity and malocclusion. Populations that are genetically similar i.e. they possess homogenous genetics, have an increased prevalence of ‘normal’

occlusion; whilst those with greater heterogenicity, have increased incidence of malocclusion and dentofacial disproportion (Mossey 1999).

Familial and twin studies are important in understanding the role of genetics in the development of malocclusion (Korkhaus 1930; Markovic 1992). Monozygotic twins, provide invaluable information in understanding the environmental elements which influence malocclusion. Whilst dizygotic twins, (where only 50% of the gene complement is the same), allow researchers to understand the influence of both genetics and environment (Mossey 1999).

Studies have shown that vertical proportions are under greater genetic influence than other dimensions. Twin and triplet studies (Baker 1924; Markovic 1992; Mossey 1999) have shown that class II division 2 malocclusions run in certain families. Markovin (1992) examined the cephalometric radiographs in 114 patients with a deep bite comprising of 28 twin pairs and six triplet sets. 100% of the twin pairs had consistency with the malocclusion and approximately 90% of the dizygotic twins showed variation in their cephalometric measurements.

Class III malocclusions have been attributed to both genetic influence and environmental factors (Xue et al. 2010). The spectrum of severity is variable, and the aetiological factors can be dental, skeletal or a combination. In 75% of class III male Caucasian patients, the origin is most commonly skeletal with the patients likely to display either mandibular prognathism or maxillary retrognathism (Staudt and Kiliaridis 2009). The prevalence of class III malocclusions varies among ethnicities: 0-48.4% in Caucasians (Emrich et al. 1965), 10% in Japanese, (Nakasima et al. 1986), and 4.9% in Chinese populations (Zhang et al. 1991).

The influence of genetics on malocclusion and dentofacial disproportion is clinically relevant, particularly for class III patients, as often the appearance of a parent may indicate how a child or adolescent will grow. This may therefore influence the decision on whether to treat the patient with orthodontics alone in adolescence or monitor until growth is completed to assess the need for orthognathic surgery (Proffit & Phillips, 2003).

2.5.1.2 Environmental

The environment can affect how the facial bones and teeth grow in response to external pressures and forces (Proffit, 2000). Teeth are exposed continuously to pressures from mastication and soft tissues. The soft-tissue pressures from the cheeks, lip and tongue are lighter than those from mastication however, they act over a longer duration. It has been reported that the duration threshold in humans is six hours, and it is therefore reasonable to expect that the soft tissues may influence the position and movement of teeth. This is the case with dentoalveolar compensation as demonstrated by Alhammadi (Alhammadi 2019). In a retrospective study of 272 adults evaluating the effect of anteroposterior and vertical skeletal discrepancies on the inclination of the incisors, it was found that with increasing overjet, there is a greater incidence of maxillary incisor retroclination and mandibular incisor proclination to minimise the effects of anteroposterior skeletal and dental discrepancy. This study also confirmed that the anteroposterior discrepancy had the greater correlation to the dentoalveolar changes seen within their patient cohort (Alhammadi 2019).

2.5.1.3 Masticatory Function

Masticatory function can potentially affect dental development by two different mechanisms: a) higher forces and increased chewing duration can lead to enlarged jaws and dental arches; b) masticatory force has the potential to affect the eruption of teeth and therefore could influence the overjet, overbite and lower anterior facial height (Proffit, 2000).

Ethnic dentofacial variations may be partly attributed to dietary variations causing adaptation in masticatory function. There may be a link between a transition to modern diet and increased incidence of malocclusion. Malocclusion has been termed a ‘disease of civilization’ (Corruccini 1984) as one theory suggests that dental crowding may be partly due to an increase in the consumption of processed foods within modern-day diets requiring less masticatory force (Normando et al. 2011). Animal studies have demonstrated a clear change in the dentition when diet is altered (with soft versus hard foods) i.e., in pigs fed a soft diet there are resultant changes in the shape/ size of the jaws and the dental arches (Ciochon et al. 1997). However, this effect has not yet been as clearly demonstrated in humans.

2.5.2 Epidemiology

2.5.2.1 Malocclusion in West of Scotland

Malocclusion has been described by the WHO as the third most significant oral health issue and affects 39-93% of adolescents globally. The prevalence and type of malocclusion vary geographically with age and ethnicity. Although no data is available for the prevalence of malocclusions within the West of Scotland, the following figures have been reported for incidences of malocclusion in Europe (Lone et al. 2024):

- Class I: 46.8 ± 6.9%
- Class II: 25.1 ± 8.6%
- Class II(1): 16.1±5.7%
- Class II(2): 4.9 ± 2.6%
- Class III: 3.4 ± 2.6%

2.5.3 Indices

Indices are used in the dental and medical fields to measure variables and classify the severity of a condition (James et al. 2015). If employed correctly, they can help ensure that a conditions/illnesses are graded in a standardised and reproducible way. Within the NHS, indices are used for defining referral criteria, ensuring patients with the greatest need are prioritised (Ireland et al. 2014a), and assessing treatment outcomes (Sharabiani et al. 2012). They can help clinicians involved in vetting to ascertain if a patient is eligible for treatment when resources and funding are limited (Soh et al., 2018).

One of the most widely used indices within orthodontics is Index of Orthodontic Treatment Need (IOTN). This used to ensure that publicly funded treatment is available for only those with severe malocclusions and a high treatment need (Brook & Shaw, 1989).

2.5.3.1 Index of Orthodontic Treatment Need

The IOTN was introduced to prioritize the need for NHS orthodontic care based on both functional and psychological need for treatment. It was based and modified from an index used and implemented by the Swedish Dental Health

board (Linder-Aronson 1974). The IOTN has been in use within primary care since 2006 and earlier in secondary care (Holmes and Willmot 1996).

The IOTN is comprised of the Dental Health (DHC) and Aesthetic Components (AC) (Brook & Shaw, 1989). The DHC is a five-point scale and patients are allocated a score based on the highest scoring feature of their malocclusion (Borzabadi-Farahani 2011) and this is based on the acronym MOCDO (Missing teeth, Overjet, Crossbites, Displacement of contact points and Overbite) (Richmond et al. 1994). The aesthetic component is subjectively measured by comparing the malocclusion to a series of photographs labelled one-ten with increasing severity of malocclusion. NHS Treatment is reserved for those who score a four or above on the DHC or if an individual scores a three on the DHC, the AC should be greater than or equal to a score of six.

The IOTN is easy to use, and it is a valid, reliable and quick tool (Cardoso et al. 2011) which aids in budget planning and resource allocation (de Oliveira 2003). However, it has several pitfalls, one of which is that malocclusions which may be functionally indicated for orthognathic surgery are not captured within the IOTN. An example of this may be a case of Vertical Maxillary Excess (VME) or also referred to as a 'gummy smile', which in the absence of any occlusal abnormalities, may not score on the IOTN, however for comprehensive correction may require a combined surgical-orthodontic approach (Ireland et al. 2014b).

2.5.3.2 Index of Orthognathic Functional Treatment Need

The Index of Orthognathic Functional Treatment Need (IOFTN) was designed within the UK, and it measures similar features of the malocclusion to IOTN in addition to functional indications for OGS (Soh et al., 2018). Like the IOTN DHC, the IOFTN is a five-point scale where a score of five indicates a high need for orthognathic treatment.

In 2013, NHS England published guidance on Orthognathic Surgery commissioning and although this is no longer is place, it gives an indication on how IOFTN can be used to assess eligibility for NHS treatment. Patients had to fulfil the following (James et al. 2015b):

- IOFTN of four or five.

- Quality of life affected by the functional symptoms.
- Patents are fully grown and reached skeletal maturity.
- The multidisciplinary team could confirm that the patient's functional concerns could be addressed by orthognathic treatment.

Although the above criteria have been revoked, IOFTN still acts as a screening tool for NHS funded treatment. A national audit conducted by the BOS in 2017-18 recommended that 100% of orthognathic patients treated within the NHS should score have a IOFTN score of four or five unless there is a strong psychological justification or the patient had another condition not captured within the IOFTN i.e. Obstructive Sleep Apnoea (Ireland et al. 2019).

Like the IOTN, IOFTN is an accessible and simple tool which can be used to initially screen patients eligible for NHS Orthognathic treatment. However, it should not be used in isolation and the patient's clinical presentation, and psychological status are equally important to determine eligibility for treatment (Ireland et al. 2014).

2.6 Facial Deformity

2.6.1 Aetiology of Facial Deformity

DFD can be described as 'an abnormality of the jaws and dentition that may constitute a hazard to the maintenance of oral health and interfere with general well-being of the individual by adversely affecting dentofacial aesthetics, mandibular function or speech' (Proffit, 1991). Patients with a DFD may present to a variety of healthcare professionals with functional and/ or aesthetic concerns (Ryan et al. 2012).

2.6.2 Impact of Facial Deformity

The features of the dentofacial complex play an important role in in the ability of others to interpret, process and interact with an individual (Little, 2014). Physical attractiveness has been shown to be associated with a persons' overall life- satisfaction and attractive people tend to evoke more positive reactions from others (Urbatsch 2018).

The perception of human faces and the first impressions gained from looking at the face is an automatic process (Ritchie et al., 2017) with humans being able to

assess facial attractiveness in as little as one tenth of a second (Willis and Todorov 2006). The smile is one of the first facial features to be recognized and processed when meeting someone for the first time (Didier et al. 2019). Those with DFD tend to be perceived negatively by society and have problems with societal acceptance (Davis et al. 1998; Henson et al. 2011; Yu et al. 2014; Almedlej et al. 2020). People with a well-balanced profile with an aesthetic smile, tend to have greater confidence, a higher educational profile and possess higher intellect levels. Furthermore, attractive people have been shown to score higher in interviews when compared to less attractive individuals (Lorenzo et al. 2010). This is perhaps unsurprising if the impact of stereotyping within our modern-day culture is considered. For example, within children's cartoons, unintelligent characters are often conveyed by the physical characteristics of proclined upper incisors, increased overjet, and increased vertical proportions. Similarly, fictional characters which are portrayed negatively (such as witches) often have the characteristic facial features of maxillary hypoplasia and prognathism (Phillips et al. 1998).

A prospective study which aimed to assess the impact of moderate and severe malocclusions on first impressions, confirmed that DFD negatively impacts on societal acceptance and may impact negatively in a job-interview scenario (de Miranda et al. 2023). In this study, evaluators (who had a background in recruitment) were asked to assess the facial photographs of 20 patients before and after orthognathic treatment. They were asked how likely they were to hire the person and how they viewed them in terms of honesty, intelligence, and productivity. The results indicated that the pre-treatment images were scored more negatively and deemed less likely to be hired. Patients with a class III malocclusion were viewed the most negatively (de Miranda et al. 2023).

These findings are also supported by two other studies where 41 patients with a DFD were interviewed prior to their orthognathic surgery. More than 60% of patients reported that their personal life and more than 40% indicated that their social life was negatively impacted by their facial appearance (Barbosa et al., 1993; Garvill et al., 1992).

The face is one of the key features when defining physical attractiveness (Ren et al. 2021). There is a body of evidence to support the concept that facial and

physical attractiveness are desirable and advantageous in many aspects of life (Ren et al. 2021). Although the English idiom ‘don’t judge a book by its cover’ advises we should not base our impressions on someone’s physical appearance alone, as doing so may result in misperceptions, humans have difficulty adopting this mind-set (Zebrowitz, 2017). Erroneous judgements can arise from judging someone solely on their facial appearance and this can have detrimental implications not only to those being perceived negatively but also in wider social situations such as political elections (Olivola and Todorov 2010), financial rewards (Rule and Ambady 2011) and trial decisions made in court (Zebrowitz, 1997).

The ability to interpret, process, and understand information from someone else’s face is a skill that humans have developed and refined by repeated exposure to new faces daily (Little et al., 2011a).

2.6.3 Facial Attractiveness and Proportions

2.6.3.1 Systematically Evaluating Facial Aesthetics

The goal of the extra-oral examination is to assess which facial features may impede on facial harmony and balance.

Clinical assessment of the patients starts when the patients enter the consultation room as patients will more likely be adopt a natural posture when they are relaxed. Formal assessment should be conducted in both frontal and profile views (Naini, 2011a) with the patient in Natural Head Position (NHP), teeth in occlusion and lips relaxed.

One of the methods of evaluating the face is to assess the height to width ratio. The height (a measurement from trichion to menton) to bizygomatic width ratio should be 1.3:1 for females and 1.35:1 for males (Reyneke and Ferretti 2021). The bizygomatic distance should be approximately 30% more than the bigonial width.

The rule of fifths is often used to assess the transverse dimensions and assumes that an attractive face can be divided in the transverse plane into five equal parts which are the same width as one eye (Naini, 2011a). The landmarks for the rule of fifths are lateral helix of the ear and the medial and lateral canthi of the

eye (Figure 2-2). The outer canthus of the eye should generally coincide with the gonial angle of the mandible. The alar base width should be in the same vertical plane as the middle fifth (from inner canthus to inner canthus of the other eye).

To assess vertical facial proportions, the face can be split by horizontal lines parallel to trichion into thirds: (i) trichion to glabella, (ii) glabella to subnasale and (iii) subnasale to menton, and each should be equivalent in the vertical dimension. The lower third can be subdivided into the upper lip (which should be one third of the lower face) and the lower lip and chin (two thirds of the lower face). Lip length and competence are also importance features to assess, and an average upper lip is 20 ± 2 mm in females and 22 ± 2 mm in males

Figure 2-3).

Figure 2-2 Rule of Fifths to Assess Transverse Facial Proportions (Milutinovic et al. 2014)
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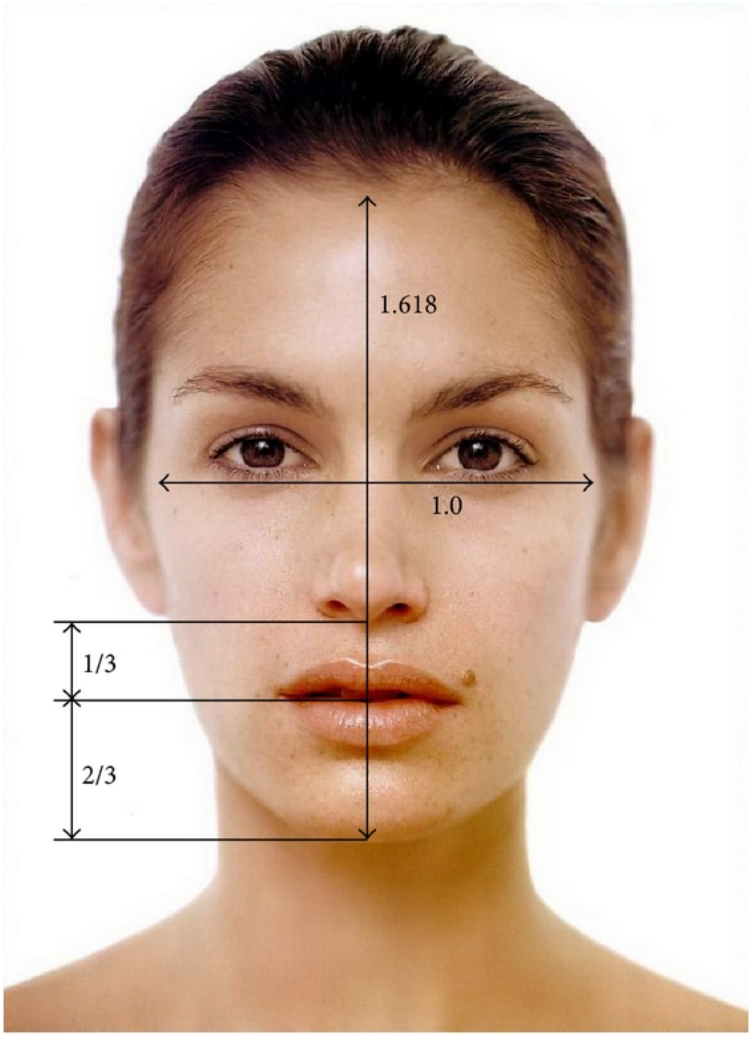

Figure 2-3 Vertical Thirds of the Face (Milutinovic et al. 2014)

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2.6.3.2 Golden Proportions

What makes a face attractive is subjective however it has been thought that aesthetic faces possess a degree of facial symmetry and harmony (Lombardi 1973). The 'ideal proportions' have also been termed Golden Proportions. This was first described in the fourth century by Euclid who described the golden proportion geometrically by dividing a line into two parts 'a' and 'b' and the proportion of 'a' and 'b' is equal to the proportion of the total length of the longer part. Golden Proportions value is 1.618 equal to 'phi' (Kaya et al., 2019). The incidence of golden proportions within the human body, particularly within the face was described by Ghkya. Ricketts then used golden proportions as a tool to aid rehabilitation planning of oral and maxillofacial region in his research where there is a particular focus on enhancing facial beauty (Ricketts 1982). In terms of how golden proportion has been used within facial aesthetics; the length of the face should be 1.618 x the width.

The importance of golden proportions has been debated within the literature (Tsao and Livingstone 2008). It has been suggested that when the face possesses the ideal proportions in line with the 'Golden Ratio', the brain can process it quicker and therefore it is more aesthetically pleasing (Londono et al. 2022).

2.6.3.3 Zero Meridian

Zero meridian was described by Mario Gonzalez-Ulloa, a Mexican plastic surgeon (Gonzalez Ulloa 1962). It has been used to assess facial profile, plan orthognathic surgery and assess surgical outcomes.

It is an imaginary line which is constructed by using two perpendicular reference lines: a) Frankfort or Horizontal line which extends from upper ridge of the External Auditory Meatus (EAM) to the inferior margin of the orbital ridge (IOM); (b) vertical line from Nasion. In faces which are more attractive, the angle between the vertical and horizontal lines ranges from 85-92 degrees and the individual segments of the face are aligned along the facial plane. The forehead, and pogonion should lie on the line. Point A typically lies 2-3mm ahead of Zero Meridian (Figure 2-4).

Zero Meridian is still used widely today in orthodontics and orthognathic surgical planning and has been adapted in response to evolving cultural and ethnic norms as well as an increased in knowledge on the influence of age, sex, ethnicity on cephalometric data (Naini, 2014).

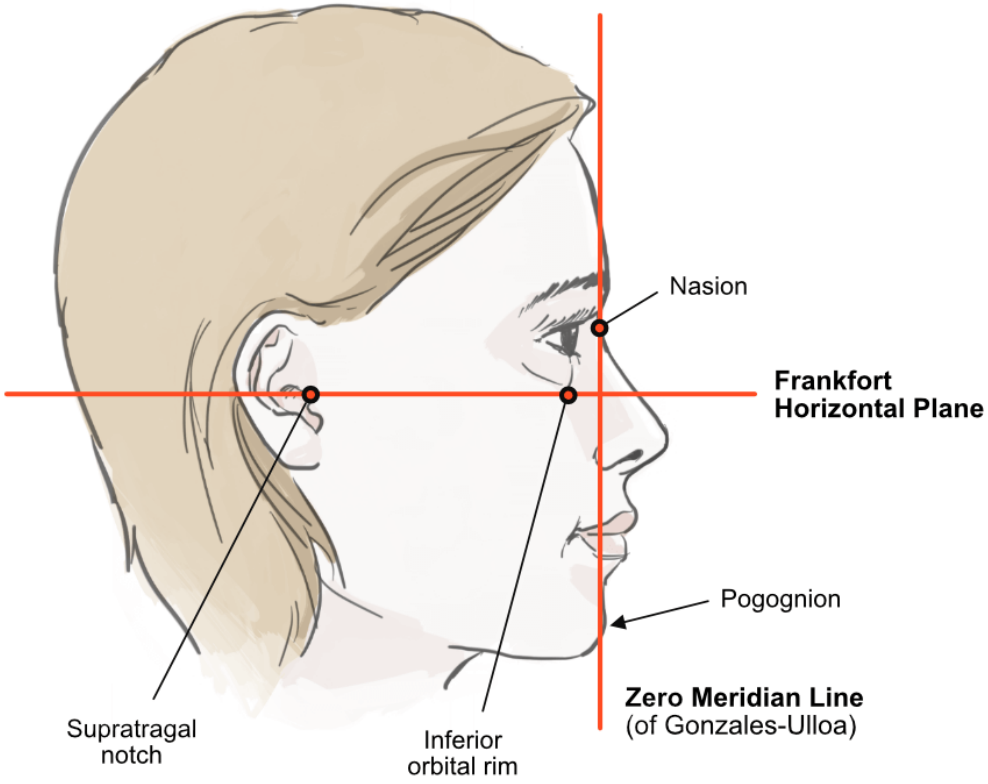

Figure 2-4 Zero Meridian as Described by Gonzalez (Gonzalez Ulloa 1962)
Permission to reproduce this image has been granted by Dr Kevan Lu (Lu 2022)

2.6.3.4 Ferretti- Reyneke Analysis

The Ferretti–Reyneke analysis is a soft tissue assessment used in orthognathic surgical planning to evaluate facial proportions, balance and harmony. It helps guide surgical movements based on soft tissue facial aesthetics.

The Ferretti Reyneke analysis separates the face into five soft tissue zones: forehead, oculonasal, maxillary-gnathic, mandibular gnathic and genial zone (Reyneke and Ferretti 2012). Each zone is assessed for disproportion, deficiency or excess and identification of whether and where surgical is required (Figure 2-5).

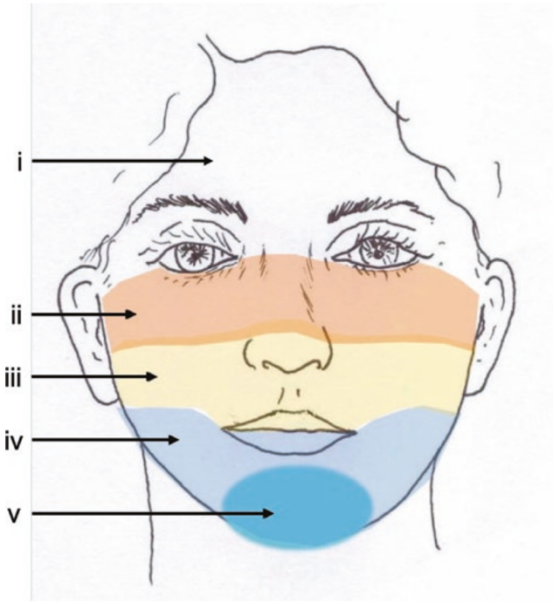

Figure 2-5 Ferretti Reyneke Analysis (Reyneke and Ferretti 2021)
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- (i) The forehead zone extends from trichion to glabella.
- (ii) Oculonasal zone starts at inferior border of the zygoma and extends up to the infraorbital foramen and onto the nose to the opposite side.
- (iii) Maxillary-gnathic zone starts at the inferior border of the oculonasal zone to the lower margin of the upper lip and angle of the mouth.
- (iv) Mandibular-gnathic zone extends from the inferior aspect of the maxillary gnathic area to mandibular lower border and labiomental fold.
- (v) Genial zone demarcates soft tissue chin.

2.6.4 Facial Attractiveness

The terms facial attractiveness and facial beauty are often thought to be interchangeable however there are differences in the definitions. The well-known proverb ‘beauty is in the eye of the beholder’ gives an indication of the subjectiveness of facial beauty which can evolve with time, age and differs between generations (Rhee and Koo 2007). Contrary to this, facial attractiveness is objective, and Bashour defines it as ‘time-static visual properties of a face in a photographic two-dimensional frontal repose image that are pleasing to the visual sense of an observer’ (Bashour 2006).

2.6.5 Laypeople vs Clinicians' Perception of Facial Attractiveness

Facial aesthetic preferences vary between clinicians and patients. There is conflicting evidence to suggest whether lay people or clinicians are more critical of facial appearance. Orthodontists and orthognathic surgeons are more likely to notice subtle facial anomalies and some features of the facial profile which go unnoticed by a patient (Cochrane et al., 1999; Maple et al., 2005; Phillips, Griffin, et al., 1995; Soh et al., 2005). However, Lauria et al found that laypeople were more critical of smile harmony than clinicians (Lauria et al. 2014). It has also been suggested that women are more critical than men when assessing specific characteristics of a smile including, gingival show, presence of an occlusal cant, crowding and the presence of golden proportions (Armalaite et al. 2018).

The specific features of the face which influence the overall attractiveness may also differ between clinicians and patients. This is demonstrated in an observational study where the overall attractiveness of 100 patients undergoing orthodontic treatment was assessed from pre-treatment photographs using a Visual Analogue Scale (VAS) by both clinicians and laypeople. The results from lay people indicated that there was a clear relationship between facial attractiveness and the chin, eyes, lips, hair, teeth and nose. The appearance of the chin resulted in a variation of facial attractiveness of 45.1%. When orthodontists assessed the photographs, there was correlation between facial attractiveness and lips, hair, chin, nose, and teeth. The lips resulted in variation of facial attractiveness by 62.2%. This study concluded that for lay people the chin is the major factor in determining facial attractiveness, whereas for orthodontists, the lips have greater significance. For both groups, the teeth contributed less to the overall variation in facial attractiveness than the chin and/ or lips (Ren et al. 2021b) . The results of this study suggest that overall attractiveness is influenced my multiple features of the face however for both patient's and individuals there may be one feature which has a greater influence in overall attractiveness and what may be the most obvious facial feature to the clinician may go unnoticed by a patient. However, a limitation of this study was that it was only Chinese patients' photographs were used for analysis and

patients were only included if they had what was perceived to be normal sized anterior teeth. Patients were excluded if they had periodontal disease, gingivitis, craniofacial abnormalities, or cavities in anterior teeth. As there is evidence that malocclusion and smile aesthetics influence the overall face attractiveness (Havens et al. 2010), this may have skewed the results of this study and therefore results should be interpreted with caution.

Orthodontists frequently use cephalometric tracings and compare the measured values to a set of averages which are considered normal. It is therefore surprising that there appears to be a poor correlation between cephalometric values and facial attractiveness (Jacobson 1984; Flanary et al. 1985a). Clinicians often place emphasis on the interpretation of measurements and values of Lateral Cephalograms, and this finding may suggest that whilst they are a useful tool, they should be used with caution and in combination with the clinical findings.

2.6.6 Digital Technology and Influence on Facial Attractiveness

Social media allows interaction with others and there is now more emphasis than ever placed on photographs and digital images as part of social media profiles.

Di Gesto et al confirmed by means of a questionnaire-based survey, that viewing images of celebrities on social media was closely related to patient's views and acceptance of facial surgery (Di Gesto et al. 2022). Browsing habits on social media can be useful in predicting the extent to which an individual experiences dissatisfaction with their appearance. Greater levels of body dissatisfaction are found with increased social media activity and specifically viewing, posting, or commenting on images which focus on the appearance of the individual or others (Meier & Gray, 2014;Arab et al., 2019). This highlights the need for clinicians to consider the influence of sociocultural factors in patients' decision to have surgery (Di Gesto et al. 2022) and they should seek to understand the motivating factors before commencing treatment.

Since the COVID-19 pandemic, there has been an increase in the use of video conferencing such as Zoom, Google Meet and Microsoft Teams (Souheyla 2022; Curry 2024; Iqbal 2024) and many people now view themselves on a face-front camera for several hours daily (Lu and Bartlett 2014). The term 'Zoom

dysmorphia' (Sarangi et al. 2022) has recently been used as an umbrella term to describe the impact of video applications on an individual's self-esteem and heightened awareness of subtle facial features (Rice et al. 2020; Rice et al. 2021). Front-facing cameras often display a zoomed-in and magnified image, and this can lead to distortion and subsequent scrutinization of one's appearance (Cristel et al. 2020). Those who use video-calls for up to one hour a day are more likely to dislike aspects of their facial appearance (Almutairi et al. 2022).

2.6.7 Facial Characteristics that Influence Attractiveness

There are differing views on why some faces are regarded as attractive. There is evidence to suggest that individual components of the face are closely related to the overall attractiveness. It has been shown that the presence of a malocclusion can negatively impact on overall facial attractiveness (Havens et al. 2010). In considering the occlusion in isolation, it has been reported that those with a well-fitting dentition are more pleasant, attractive, intellectual, and outgoing in comparison to those with a malocclusion (Olsen and Inglehart 2011).

There is evidence to suggest that overall facial attractiveness is not determined by individual facial components (Işıksal et al. 2006), rather it is assumed if an individual possesses a combination of several characteristics, this may result in a higher overall attractiveness (Little, 2014b; Little et al., 2011c). Although humans can quickly decide if they perceive a face attractive or unattractive, it is challenging for us to define what specific features of the face make it more aesthetic (Little et al., 2011c). Although facial attractiveness is subjective, there are several characteristics such as averageness, symmetry, skin texture/ colour, sexual dimorphism which are present in attractive faces (Little et al., 2011d; Rhodes, 2006). An attractive face is also considered to be symmetrical, harmonious, and well-balanced (Ren et al. 2021).

In a study conducted by Havens et al., where 20 lay people and 20 orthodontists evaluated pre and post orthodontic treatment posed-smile photographs for 48 white females, it was found that the presence of malocclusion can negatively affect facial aesthetics (Havens et al. 2010). Observers were asked to analyse three pre and post treatment photographs as follows: (i) smile only, (ii) face with no smile, (iii) face with smile. The pre-treatment photograph without the

smile visible was found to be more attractive than the smile photographs thus showing if the malocclusion is eliminated, facial attractiveness increases. There were no significant differences in the overall attractiveness of the three post-treatment photographs. There was agreement between lay people and orthodontists on the number of subjects which were attractive, however the degree to which the observers viewed the attractiveness differed. This study confirmed that the two most important features in influencing perceived facial attractiveness are harmony and the absence of malocclusion. Although there were differences in the degree of attractiveness scored by lay people and orthodontists, the two groups agreed on the key features which were important in smile assessment.

Johnstone et al. assessed the influence of deviations of the maxillary dental midline on smile aesthetics judged by both clinicians and lay people. In this study, a standard photograph of a female patient was duplicated and edited to alter the midline, and the viewers were asked to score the attractiveness of the smile. Results indicated that as the dental midline to facial midline discrepancy increased, the smile was scores less attractive. However, orthodontists were more likely to notice smaller deviations of the midline, and it was estimated that lay people are less likely to notice a centre line discrepancy of less than 2mm (Johnston 1999).

These studies highlight, in general that lay people agree in most-part with orthodontists on the key features of an attractive smile, however orthodontists may be more likely to detect to smaller imperfections.

2.6.8 Cultural Differences in Facial Aesthetics

There are variations in in what is considered attractive between certain societies and cultures (Langlois et al. 2000).

It is thought that what people believe to be attractive is learned from cultural norms and what is popular within their social groups. Within different populations, there is a preference towards certain facial features which tend to persist throughout generations. Facial norms vary significantly across different population groups and an example of this is that there is a preference towards

facial tattoos and scarification in some tribes whilst this would be viewed as unattractive by many western populations (Little, 2014).

2.6.9 Summary

DFD is multifactorial, and it can impact greatly on patients' psychological state and quality of life from childhood and continuing into adulthood (Cunningham & Johal, 2015). The problems patients with DFD may encounter can include, mastication difficulty leading to embarrassment, feeling self-conscious in public situations, social discrimination, stereotyping, and bulling (Seehra et al. 2011). Individuals believe their appearance can influence many aspects of their life such as education, career and interpersonal relationships (Cunningham & Johal, 2015). It may be assumed that more severe DFD may evoke more severe implications on one's mental and physical wellbeing, but this is not the case. It has been noted that some patients with more noticeable DFD can experience less social discrimination than those will a milder deformity (Macgregor 1970) .

The impact DFD has on quality of life is a key motivating factor for patients to seek treatment (Mayo et al. 1991). Whilst there may be variations within different cultures on what is considered attractive, it generally agreed that facial balance, harmony and symmetry are they key features in an attractive face (Little, 2014).

2.7 Diagnosis and Planning

This section will discuss the diagnosis and planning of orthognathic treatment. It will outline briefly extra-oral features which are pertinent however, it is out with the scope of this section to discuss all aspects of an orthodontic examination.

As the PROMS tool has a particular focus on measuring quality of life, expectations of treatment and patient satisfaction post-operatively, which are discussed in the pre-treatment psychology assessment, this is discussed in more detail. Within GGC, all patients undergoing OGS require a psychology assessment before OGS.

All cases within GGC are planned in three dimensionally and a brief outline of this has been included.

2.7.1 Clinical Assessment

DFD is one of the most difficult conditions to quantitively measure (Cohen and Jago 1976) due to the subjective nature of assessing facial attractiveness and aesthetics (Esperão et al. 2010). Clinical examination should be logical and structured to ensure all relevant information which is pertinent to the DFD is assessed. The initial consultation should begin with understanding the patient's presenting complaint/ main concerns; specifically, whether the patient is having any functional problems or aesthetic concerns (Ayoub et al. 2014b). A full medical, dental and social history should be taken. This may include asking questions regarding congenital or acquired, family history of malocclusion or facial dysmorphology, whether the malocclusion has worsened in recent years and cultural/racial backgrounds. In addition to carrying out a full facial assessment the patient's overall body-form and weight distribution should be assessed as the facial changes planned surgically should be in-keeping with the patient's body stature.

Facial assessment is carried out from the lateral, profile and front-on views with the patient in natural head position. The lateral examination of the patient allows assessment of the AP skeletal relationship, vertical dimensions (Frankfort mandibular plane angle, facial thirds), and individual component assessment such as paranasal region, lip and infra-orbital rims. The presence of transverse asymmetry and canting of the occlusal plane can be assessed from the frontal view. The worm's eye view can allow assessment of asymmetries of the mandible and alar base (Ayoub et al. 2014b). Intra-oral examination is also carried out; however, it is not within the scope of this project to detail this. Refer to the section on Facial Attractiveness and Proportions for further details on clinical examinations used.

2.7.2 Psychological Assessment

2.7.2.1 Symptom Checklist-90

The Symptom Checklist is a questionnaire comprising 90-items and it is used to assess psychological problems. Each item within the questionnaire is scored from 0-4 based on how much it bothers the patient (0= Not at all, 1= A little bit, 2= Moderately, 3=Quite a bit, 4= Extremely).

The scales assessed within the questionnaire are: Somatisation, Obsessive-compulsive, Interpersonal sensibility, Anxiety, Anger hostility, Phobic-Anxiety, Paranoid ideation, Psychoticism, Additional Items. The questionnaire has been revised and is now called 'The Symptom Checklist-90 Revised' (SCL90R) however this is not available for the public (Derogatis et al. 1976) A limitation of the SCL-90 is its questionable construct validity, with studies demonstrating significant overlap between subscales, which may indicate that whilst it provides a general overview of psychological distress it fails to recognise distinct symptom domains (Derogatis and Cleary 1977).

2.7.2.2 The Relationship between Psychological Status and Dentofacial Deformity

The question of whether orthognathic patients are more likely to experience psychological distress is particularly relevant due to the cosmetic and aesthetic nature of the treatment. The relationship between DFD and psychological status is complex. There is conflicting evidence on whether patients with a DFD experience greater levels of psychological stress than those without. An equally pertinent question is also whether orthognathic surgery improves the psychological profile for patients.

Phillips et al. assessed orthognathic patients pre-treatment and asked them to complete the '24-item Motives for Treatment questionnaire'. Each question was rated from (1) 'not at all a reason to' (4) 'very much a reason'. Items were grouped to form six dimensions. An average score of 3.0 or greater on a given dimension was considered a strong motivation. 135 patients completed the questionnaire and 16% wanted to improve their self-image and 4% were primarily motivated to improve oral function. In patients who elected to have orthognathic surgery, they scored an average of 3.0 or higher on the self-image and oral-function items (Phillips et al. 1997). As patients seeking orthognathic treatment are motivated for psychological and social reasons, it may be reasonable to assume that these patients may be more likely to initially experience negative emotions pre-treatment (Phillips et al. 1997; Phillips et al. 1998).

Within medicine, the impact of a physical illness or impairment on the psychological state of patients has been investigated and researchers within the

infertility field have proposed a 'Psychological Sequelae Model'. This suggests that, in certain circumstances, psychological state can be related to an individuals' physical health (Berg and Wilson 1990). In supporting this, a study examining the psychological status of 98 patients undergoing cosmetic surgery, found that the incidence of a psychiatric diagnosis was 72% (Edgerton et al. 1960). Another study confirmed that 53% of those seeking facial aesthetic procedures had some form of psychiatric disorder (Jacobson et al., 1960; Webb et al., 1965).

There is some evidence to suggest that people with a DFD experience no more psychological distress than those without. Flanary et al., (Flanary et al. 1990) conducted a two-year follow-up study which assessed the changes in personality traits of orthognathic patients over the course of their treatment journey. Patients were given questionnaires that assessed various psychological domains at the following time-points: one-four weeks before surgery and after surgery at one month, six months, one and two years. The results showed that before treatment, patients scored favourably in the psychological aspect of the questionnaire. 36% of patients scored out-with what was considered the psychologically stable range. Most of the variations in pre-treatment scores skewed toward a more positive psychological profile. It was also found that there was significant improvement in the patients' self-confidence and psychological status two years following orthognathic surgery. There was improvement in the following psychological domains: personality dimensions of general maladjustment ($p = 0.0000$), psychosis ($p = 0.0509$), personality disorder ($p = 0.0013$), neurosis ($p = 0.0003$), and personality integration ($p = 0.0232$). Although most patients scored within the average range for personality assessment pre-operatively, 36% of patients had tendencies towards personality disturbances (Phillips et al. 1998).

Conversely, a study which assessed the psychological status of 194 patients seeking treatment for DFD found that patient with a DFD experience more psychological distress than those without. Data was collected using the SCL-90 questionnaire which is 90 questions to screen for psychological distress. The Global Severity Index (GSI) was calculated which gives an indication on the number of symptoms and the severity of the impact on the psychological state. Approximately 25% of the patients met the criteria for a positive psychiatric

diagnosis. However, by eliminating some items on the questionnaire relating to interpersonal sensitivity ('feelings of personal inadequacy and inferiority') which may be related to a moderate-severe facial disharmony, the percentage of positive diagnoses reduced to 2%. The findings from this study suggest that orthognathic patients may experience higher levels of psychological distress however, as global Indices lacks the depth to diagnose complex psychiatric disorders, it may be appropriate that they are viewed as a screening tool to identify patients requiring further investigation (Phillips et al. 1998).

A more recent study by Ryan et al., also confirmed the above findings and concluded that patients with a DFD may be at increased risk of experiencing greater levels of psychological stress than those without (Ryan et al. 2012a). It has been suggested that one of the reasons that orthognathic patients may experience greater psychological instability is due to the impact of DFD on their social well-being. It is well documented that people with a DFD often lack confidence in social situations which leads to avoidance of interactions and feelings of difficulty to in being accepted into society (Newell and Marks 2000).

2.7.2.3 Psychological Status and Motivation for Treatment

Patients' motivation for undergoing orthognathic treatment varies however it is most often considered in the following domains: aesthetics, function and psychosocial reasons (Laufer et al. 1976; Ostler and Kiyak 1991; Zhou et al. 2001). Motivation for treatment can be driven by internal factors from the patient themselves or due to external pressure from others (Edgerton & Knorr, 1971). Children with DFD may experience 'playground harassment' from their peers (Shaw et al. 1980) and although bullying does not usually continue past adolescence, adults with DFD may also experience discrimination (Tagiuri 1969).

In a prospective study aiming to assess the motivation of 118 patients who had been offered orthognathic surgery, more than half of the patients reported that it was internally driven whilst 11% said that a clinician had made them aware of the problem and that had prompted them to seek treatment (Broder et al. 2000). Similar findings have also been reported by Williams et al who reported that a significant proportion of orthognathic patients had not noticed that they had dentofacial disproportion and were not expecting surgery to be discussed as

a treatment option at their initial orthodontic consultation (Williams et al., 2005).

Patient outcomes and satisfaction with orthognathic treatment are generally high however, there remains a small cohort of patients that are displeased with the results despite the clinicians feeling that a satisfactory result has been obtained (Chen et al., 2002; Cunningham et al., 1995).

There is conflicting evidence on whether the severity of the DFD has a greater impact on the quality of life for patients. A cross-sectional study conducted in a teaching hospital in the United Kingdom aimed to qualitatively explore and analyse the impact of DFD and understand patients' motivation for seeking treatment (Ryan et al. 2012a). Data collection was carried out prospectively by interviewing 18 orthognathic patients prior to commencing treatment. The motivation and the impact of patients' DFD on daily activities were both be categorised as practical (i.e., only impacting on function), psychological (including aesthetics and psychosocial implications) or a combination of the two. The reasons for seeking treatment ranged from completely internal to completely external. In most cases, they were motivated by the impact that the DFD had on their daily life. However, this study also found that in a small number of patients, the motivation did not relate to the severity of the DFD i.e. in some instances patients with a more severe facial deformity appeared less affected by it than those with a more minor facial disharmony. Motivation for treatment may therefore be closely linked to the interaction of relationships, personality traits and childhood experiences.

Choi et al. reported that with increased age and severity of malocclusion, the Oral Health related Quality of Life reduced (Choi et al., 2016). However, Hay (Hay 1970) reported that there was no relationship between the severity of malocclusion or degree of dentofacial disharmony and the extent of the psychological disorder. Although the severity of the malocclusion appears linked to the impact on quality of life, there is a less clear relationship between the severity of DFD and psychological health. Therefore, clinicians should not assume that because a patient has a mild DFD, they are less likely to be implicated psychologically than someone with a more severe DFD.

The motivating factor for patients' seeking treatment is important to establish at the initial consultation as this is a useful predictor in patient satisfaction following surgery. Unrealistic expectations from patients remain one of the main reasons for dissatisfaction following treatment and these should be addressed and managed accordingly from the outset (Cunningham, Hunt, et al., 1996). As described earlier, a patients' motivation is described as either external or internally driven. However, rather than these being regarded as two distinct entities where a patient falls into one category, it is now regarded as a spectrum where most patients' motivation lies somewhere in the middle (Ryan et al. 2012a).

2.7.2.4 Psychological Status and Surgical Outcomes

Patients' self-perception prior to OGS is a useful predictor in their likelihood of being satisfied following treatment (van Steenbergen et al. 1996). A thorough psychiatric history should be taken to ascertain if there is a history of previous psychiatric illnesses including anxiety and depression or a history of substance abuse (Cunningham & Feinmann, 1998). Hospital Anxiety and Depression scale can be a useful tool to aid clinicians (Zigmond and Snaith 1983).

A good surgical outcome does not always translate to a satisfied patient (Kiyak et al., 1984; Peterson & Topazian, 1976; van Steenbergen et al., 1996) as patients and clinicians may differ in their aesthetic goals (Albino et al. 1979; Bell et al. 1985; Kiyak and Zeitler 1988). Patients assess their face as-a-whole (Berscheid et al. 1973) whilst orthodontists tend to look at individual components of the dentofacial complex with a particular emphasis on profile, which patients pay less attention to (Albino et al. 1979).

The relationship between patients' experience of psychological distress and satisfaction with the treatment outcome is unclear. Some psychological states, such as neuroticism which is characterised by emotional instability (Widiger & Oltmanns, 2017), over reactivity (Phillips et al., 1995, 1998;) and self-consciousness (Widiger 2009) have been associated with greater levels of dissatisfaction following treatment (Phillips et al. 1998). Neuroticism has also been associated, in some cases, with greater patient experience of post-operative complications such a pain, swelling and paraesthesia (Kiyak et al., 1985, 1986). However, whether patients with a psychological diagnosis or an

unstable psychological state are less adaptable after surgery and therefore less satisfied remains unclear.

In a study carried out in Connecticut and New York, 54 orthognathic patients were issued a questionnaire before starting treatment. The aim of this study was to assess if psychological status, age, gender, socioeconomic status, and severity of facial disproportion influenced patients' satisfaction with their facial appearance pre-treatment. After all variables were assessed and analysed, self-perception was the only factor which influenced how happy patients were with their facial appearance. The severity of dentofacial disproportion assessed by orthodontists, was not related to patients' self-perception. Those who viewed themselves more positively tended to be more satisfied with the appearance of their face- irrespective of the severity of the disproportion (van Steenbergen et al. 1996). Patients' unhappiness with their appearance is likely multifactorial and one proposed reason is that they have behavioural adaptation in response to experiencing lack of societal acceptance throughout their life i.e. the patient's DFD becomes part of their personality (Kiyak et al., 1985; Stricker et al., 1979) and they develop coping mechanisms such as avoidance of certain situations.

Although this study only analysed patient perception with their appearance pre-treatment, it is suggested that those with negative self-concept are more likely to remain dissatisfied following treatment (van Steenbergen et al. 1996). Results from this should also be interpreted cautiously due to the small sample size and the return rate of less than 50% which may introduce nonresponse bias.

2.7.2.5 Summary: Psychological Input and Orthognathic Treatment

In summary, the relationship between psychological health and the presence of a DFD is complex. There is some evidence to suggest that dentofacial disharmony impacts negatively on patients' mental health and well-being and orthognathic patients tend to have higher levels of state anxiety (Cunningham, 2000). Although there is a link between increased severity of malocclusion and reduced quality of life (Choi et al., 2016b), there is a less clear relationship between severity of DFD and psychological state (van Steenbergen et al. 1996).

DFD can negatively affect individuals' body-image and some patients with extremely high expectations can often be disappointed with the outcome of OGS

(Cadogan and Bennun 2011a). Orthognathic treatment can alter a patient's psychological status which some patients struggle to adapt to post-operatively (Cadogan and Bennun 2011b).Clinical Psychologists have an important role in counselling patients and screening for those who may require further psychological input before proceeding with treatment (Taloumtzi et al. 2021).

2.7.3 Predication Planning

OGS should be planned to ensure reliable and predictable outcomes (Stokbro et al. 2014; Gaber et al. 2017). The treatment plan should be agreed between the surgeon, orthodontist and patient pre-operatively (Starch-Jensen et al. 2023). The patient's involvement in the planning stages is important to ensure that clinicians and patients are aligned in their expectations (Ayoub et al. 2014c).

2.7.3.1 Model Planning

Conventionally, model planning was used, and this was with the aid of two-dimensional radiographs (lateral cephalogram and orthopantomogram), articulated study models, a 'mock-up' of the surgical outcome and acrylic occlusal splints. Model planning was used for many years, and the results were acceptable and reproducible despite the process being time and labour intensive (Hammoudeh et al. 2015). However, there is potential for errors to be introduced with impression taking, facebow transfer, superimposition of 2D radiographs and these could lead to surgical inaccuracies (Sharifi et al. 2008). Additionally, model surgery gives no indication of the soft tissue changes (Ayoub et al. 2014c). Due to the inaccuracies reported with model planning, when treating complex cases of facial asymmetry and occlusal canting, the potential risk of error is increased and this may affect the predictability of the outcome (Alkhayer et al. 2020; Chen et al. 2021; Tondin et al. 2022).

2.7.3.2 Two-Dimensional Planning

Two-dimensional prediction planning can be done with the use of a lateral cephalogram superimposed with a profile photograph. Landmarks are used to allow accurate superimposition, and the computer software then plans the surgical movements starting with the position of the upper incisors. Model surgery should be used in conjunction with 2D computer planning to verify the

surgical plan and the desired skeletal movements should be within one millimetre using both methods.

Rustemeyer et al. conducted a retrospective comparative study to assess the difference between the predicted cephalometric changes and actual surgical movements when 2D planning software was used. The mean differences for measurements ranged from 1.3° (±1.1) to 2.2° (±1.6) for BSSO and 1.1° (±1.3) to 2.2° (±1.6) for Bimaxillary Osteotomy. For one case a difference of 8.5° was found but there were no differences in the predictability or accuracy for the surgical movements. This study concluded that 2D planning software remains a reliable tool for planning simple vertical and sagittal changes. However, for larger and more complex transverse changes three-dimensional planned may be more predictable (Rustemeyer et al. 2010).

2.7.3.3 Three-Dimensional Planning

Three-dimensional prediction planning has been used within orthognathic surgery for more than 35 years (Ayoub et al. 2014c). The advancements in technology have allowed surgery now to be largely planned using Computer Tomography (CT) and Cone Beam Computed Tomography (CBCT) which, in combination with 3D Surface Soft Tissue Capture and computer software allow three-dimensional surgical planning. A CBCT of the plaster models is obtained to allow 3D model production. The 3D image which can be visualised on a computer is the result of integration the CBCT, CBCT scanned models and the 3D photographs. Occlusal wafers can now be constructed by 3D printing. 3D planning software allows complex movements of the craniofacial complex to be visualised and planned accurately prior to surgery (Starch-Jensen et al. 2023). The software can import a CBCT to create a CT model and convert information from 2D or 3D photographs to the 3D CT skin surface. It allows patients to visualise the changes in their facial appearance, particularly with the aid of soft tissue superimposition. One of the pitfalls of CBCT is that the interface of soft tissue/air is not skin coloured, to overcome this 3D stereophotogrammetry can be used however, like the challenges with photograph/ cephalometric superimposition mentioned above, the soft tissue outlines of the 3D photographs and CBCT need to be identical. The two are merged to produce a CBCT scan with a soft tissue texture which resembles the patient (Ayoub et al. 2014c). 3D

planning may be more precise and lead to a reduction in inaccuracies in OGS (Alkhayer et al. 2020b). However, there are challenges with 3D software and one of the pitfalls is that when planning the post-surgery occlusion using virtual models, there is a lack of haptic feedback which is present with plaster models, and this can lead to difficulties with casts articulation. Almadi et al. compared the reliability and accuracy of free-hand articulation of digital versus physical dental models and found that the maximum digital errors in articulation were 0.76mm for translation and 1.83° for rotations which are clinically insignificant (Almadi et al. 2023). Alkhayer et al., concluded that errors of less than 2mm and 2°were considered acceptable for orthognathic surgical planning (Alkhayer et al. 2020a).

In a systematic review aiming to assess if there was a difference in the predictability of orthognathic planning with three-dimensional virtual surgical planning (TVSP) compared with two-dimensional planning (TSP), it was found that there appears to be accuracy between the planned and achieved surgical outcome with TVSP, however the results are inconsistent (Starch-Jensen et al. 2023). The primary outcome being measured was the accuracy of the surgery which was assessed by comparing the planned measurements (based on radiographs, CT, CBCT, photos) and the achieved outcome. Seven randomized control trials were included and there were no statistically significant differences in the soft tissue alignment between TVSP and TSP. Cephalometric points were used to assess the difference between the planned position of the jaws compared to the post-operative position and there was a statistically significant difference, with the TSP showing greater inaccuracies. Differences in the anteroposterior and vertical dimensions were 1.48 and 1.46mm respectively for the TVSP group. The same measurements were 2.29 and 2.07mm for the TSP group. Patient reported outcomes were compared in three of the seven studies and it was reported that patient satisfaction between TVSP and TSP were comparable. It is worth noting that this study excluded surgery-first patients and therefore the applicability to our patient cohort may be limited.

Awad et al., assessed the accuracy of soft tissue prediction planning with VSP software IPS CaseDesigner® (KLS Martin Group, Tuttlingen, Germany) in twenty patients having bimaxillary surgery. A four-month post-operative scan was compared to the prediction planned soft-tissue changes and the results indicated

that the predictions for the upper face (cheeks, nose, upper lip) were more accurate than for the lower face (lower cheek, lower lip and chin). The accuracy of the soft tissue prediction for the entire face varied and ranged from 69-96%. It was concluded that whilst the VSP software IPS CaseDesigner predicts post-operative soft tissue changes, it should be viewed only as an estimation, especially for the lower face. Further modifications and improvements to the software algorithm are needed to provide further accuracy (Awad et al. 2022).

Orthognathic surgery continues to evolve with increased knowledge on digital technology and it is of clear benefit to be able to show the predicted soft-tissue changes that will occur following surgery. Whilst 3D planning is reliable and predictable (Awad et al. 2022; Starch-Jensen et al. 2023), patients should be educated of the limitations and the margin of error with predicted soft tissue changes and how the surgical outcome may differ from the predicted planning.

In summary, the advancements in technology which allow OGS to be planned in 3D have clear benefits which include: (a) improving surgical accuracy, (b) aiding communication and discussion with the patient as they can visualise the outcome, (c) minimise intra-operative errors (Alkhayer et al. 2020).

2.8 Assessment of Outcomes

Healthcare systems aim to deliver care which is patient-centred and responsive to the needs of service-users (de Bienassis et al. 2022). There is an increased pressure from policymakers within the NHS to gain patient-perspective on their treatment using standardised, speciality-specific questionnaires. To produce meaningful data which can be interpreted and used to produce change, PROMS should provide clinically relevant information that accurately conveys how is patient feels (Mendlovic et al. 2022). A recent Cochrane review highlights the importance of PROMS in involving patients in their own care and aiding clinicians to make informed decisions regarding future care (Kendrick et al. 2016).

A structured literature search was undertaken to identify PROM tools which have been used in orthognathic surgery and focused on quality-of-life outcomes. Electronic databases including MEDLINE, Embase, and Scopus were searched using combinations of keywords such as “orthognathic surgery”, “surgery-first approach”, “patient-reported outcomes”, and “quality of life”. Although a

formal PICO framework was not used, the search strategy was able to comprehensively identify PROMs used within orthognathic patient cohorts. These tools were critically appraised with respect to their development process, validity, reliability and relevance to orthognathic patients. Generic tools (such as the Oral Health Impact Profile and Short Form Questionnaire) were considered less sensitive to orthognathic-specific changes, whereas instruments such as the OQLQ and FACE-Q demonstrated greater specificity to facial aesthetics and functional outcomes. Based on this appraisal, the British Orthodontic Society (BOS) questionnaire was selected for this study, as it incorporates elements of both FACE-Q and OQLQ, thereby providing a comprehensive and condition-specific assessment of patient-reported outcomes relevant to orthognathic surgery.

Tsichlaki et al., have outlined a Core Outcome Set (COS) for the use of clinical trials in orthodontic treatment. This is to address inconsistent reporting of outcomes. Tsichlaki et al. analysed 164 trials, qualitative interviews, a focus group with adolescents, and a two round international Delphi process to define seven core outcomes which have been agreed by orthodontists and patients. The outcomes cover four domains: (1) Perceived Health Status, (2) Clinical Outcomes, (3) Adverse Events, and (4) Delivery of Care. This helps to ensure standardisation in outcome reporting in orthodontic trials to improve comparability. Although the COS excludes orthognathic patients, the outcomes (especially stability, incisor relationship and alignment) are transferable to orthognathic research where similar variability exists. The authors recommend that these outcomes are a minimum data set to streamline future research and improving reporting consistency. Within this section, various PROMS tools are discussed which are historic (prior to the implementation of COS) (Tsichlaki et al. 2020).

2.8.1 Quantitative Data vs Qualitative Data

Assessing the impact of treatment on quality of life is an area that has gained increased interest within healthcare. There are more than 1000 new articles published in healthcare each year which contain the term ‘quality of life’ (Muldoon et al. 1998). To fully understand the success of an intervention, data collection should involve input from both clinicians and patients (Cunningham et

al., 2002). Patient perspectives on treatment outcomes are being increasingly used for evaluation of healthcare services and assessing patient care. They also provide valuable insight when assessing resource allocation (Jenkinson 1993).

Within the healthcare setting, there has been a recent interest in combining qualitative and quantitative data to assess the effectiveness of treatment outcomes (Bryman 1995). It has been suggested that by using both approaches, greater insight can be gained than either of the methods alone (Moffatt et al., 2006).

Most of the research on the psychological impact of DFD has been quantitative and involved the use of psychometric instruments and questionnaires (Cunningham, Crean, et al., 1996; Flanary et al., 1985). Whilst these methods provide useful information, they lack the depth that qualitative techniques can capture (Ryan et al. 2012).

Qualitative data has been used increasingly in the past 30 years within health care research by patient interviews and questionnaires. (Travess et al. 2004). Patient interviews allow patients to discuss answers to various questions verbally and speak freely, there is often increased depth and breadth of information gained than more rigid tools. In the case of semi-structured interviews, clinicians can ask patients to clarify and expand on their answers which overcome some of the limitations with structured tools (Kitzinger 1995). Questionnaires can be equally beneficial for qualitative data collection. They have several advantages including being less demanding on time and resources than interviews or focus groups. Online questionnaires also have the advantage of being easily exported into statistical software for analysis and interpretation (Tombs and Strange 2024).

Reports suggest qualitative data can ‘reach the parts other methods cannot reach’ (Mays and Pope 1995; Mays 2000) as it provides a holistic approach to patient-focused research. Qualitative research can be described as a social inquiry which is both naturalistic (it assesses events that occur in natural settings) and interpretive (how individuals understand the world) (Teherani et al. 2015). Qualitative research is invaluable in understanding a patients’ mindset, anticipations, attitudes, and incentives; all of which are important to a clinician in successfully treating a patient and managing their expectations

(Malterud 2001). Commonly adopted approaches to qualitative research are summarised in table one (Ritchie and Lewis 2003; Ryan et al. 2012a).

Table I. Approaches used in qualitative research[44]

Researcher	*Design*	*Methods*	*Analysis and output*
Studies the phenomenon from the perspective of those being studied	Is flexible and adaptive	Are flexible and sensitive to the situation	Answer questions such as what, why, how
Adopts a holistic approach	Is conducted in a real-world setting rather than in an experimental surrounding	Involve close contact between the researcher and those being studied	Are often complex
Maintains "empathic neutrality" and uses personal insight while sustaining a nonjudgmental position		Involve methods such as interviewing and observation	Identify theories arising from data rather than from a priori hypothesis

Table 1 Qualitative Research Approaches (Ryan et al. 2012a)
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2.8.2 Patient Reported Outcomes and Benefits of Orthognathic Surgery

Clinical Governance within the NHS has led to an increased focus on evaluating outcomes of treatment (Travess et al. 2004). The UK Governments have also indicated that the NHS should involve patients in decisions when planning future changes in care-delivery. Orthognathic outcomes have been investigated extensively since it was first introduced. Historical studies assessing OGS were focused on clinical outcomes recorded by clinicians (Nagar et al. 2023). However, what is considered a good surgical outcome, may not align with a satisfied patient. The disparity between patients and clinicians' views has been highlighted by Burne and Croucher who conducted a study in General Dental Practice and found that there was a lack of consistency between the two groups on what was important in the delivery of dental treatment (Burke and Croucher 1996).

PROMS were implemented by the NHS in 2009 and are used to assess the quality of care from a patient perspective. PROMS encompass all aspects of patients' medical condition, treatment, and overall experience. Specifically orthognathic PROMS aim to assess the patient's overall health, the impact of facial deformity on their quality of life and overall self-perception. It recorded by the patient without input from clinicians (Deshpande et al. 2011). Patient opinion forms an important aspect of 'person-centred care' where patients should feel that they are being listened to and treated respectfully (Health Foundation 2014).

Within orthodontics, historically many of the studies have analysed quantitative clinical outcomes, (Kallunki et al. 2021) and often patient reported outcomes are overlooked (Cunningham, 2020). A Cochrane review has confirmed the benefits of PROMS in healthcare which include (a) Improved communication between patients and clinicians, (b) Allowing clinicians to assess their performance and outcomes against their peers and (c) Providing valuable information for future qualitative research (Gibbons et al. 2021)..

PROMS data can also be used to inform the consent process as clinicians can use the information gained to understand what matters to patients (Urso-Baiarda et

al. 2015) and ensure that the patient's expectations are managed appropriately (Devlin and Appleby 2010).

In a study carried out to understand what information patients would like to know before surgery, it suggested that the following was of most important to patients: (Morley et al. 2013):

- Surgical options available (69%)
- What questions to ask the surgeon (67%)
- Preparation for the procedure (65%)
- How often is the procedure carried out? (62%)
- Limitations of the procedure (60%)

Studies also show how information from PROMs can be used to involve patients and encourage them to take ownership of their health care. Within the medical field, PROMs have been used to identify patients requiring a face-to-face appointment and steer the direction of the appointment based on their responses to a pre-consultation PROM questionnaire (Mejdahl et al. 2020). In a prospective, multi-perspective, qualitative study conducted by Mejdahl et al., epileptic patients due for out-patient follow-up were sent a PROM questionnaire before being issued an appointment. Each of the answers they submitted on survey were allocated a 'green', 'yellow', or 'red' indicator with red indicating that a follow-up appointment is required, yellow meaning that they may need contacted, and green indicating that no action is currently required. If a patient requested an appointment, this overruled the indicators. Patients reported that when they had completed the pre-appointment survey clinicians had greater insight into their concerns and felt that they were better prepared to discuss this. This study highlighted PROMS can be used prior to consultations to gain information on patient concerns and expectations as well as measuring treatment outcomes.

Several studies have been published within the last ten years assessing PROMS for orthognathic surgery using a number of tools which are discussed in this setion (Schwitzer et al. 2015; Campbell et al. 2018; Garg et al. 2018; Baniulyte and Esson 2024). Garg et al., found in a two-year follow-up of patients undergoing OGS that 97% were either very satisfied or satisfied. 89% of patients

reported an improvement in self-confidence and 74% would recommend the surgery to others (Garg et al. 2018). Baniulyte & Esson found that at two-years post-op, patients reported the main benefits from surgery were improved dental and facial appearance and greater satisfaction with their appearance in photographs and videos. 58% of patients reported altered sensation to the lower lip at two years however, it did not impact on patients' daily habits or overall quality of life (Baniulyte and Esson 2024)

The benefits of OGS are also confirmed by Meger et al., in a systematic review which found that OGS has a positive impact on overall quality of life for patients (Meger et al. 2021b). This section will outline various methods of collected patient opinion.

2.8.2.1 Patient Interviews

Structured interviews to gain patient perspective on orthodontic treatment outcomes have been used to gather information to help form PROM questionnaires (Cunningham et al., 2000).

Al Quraini et al. and Shah et al. used structured interviews to assess the benefits of orthodontic treatment. The positive effects of treatment which patients reported were i) behavioural change (patients are encouraged to maintain better oral hygiene), ii) improvement on dental health (appearance and function), and iii) overall impact on quality of life as they reported improved confidence and self-esteem (Al Quraini et al., 2019; Shah et al., 2019).

One of the pitfalls with interview-based studies is that patients may only give answers which they feel are socially acceptable and therefore some key and relevant information may be omitted (Hyman 1954).

2.8.2.2 Oral health Impact Profile

The Oral Health Impact Profile (OHIP) was developed by Slade et al (Slade and Spencer 1994) and has subsequently been condensed into 14 questions (OHIP-14) to assess pain and dysfunction caused by oral conditions. Tuk et al, used the OHIP-14 to assess the impact of orthognathic surgery on quality-of-life (Tuk et al. 2022) and found that there was a deterioration on Oral Health Related Quality of Life (OHRQoL) in the immediate post-operative phase but, after six

months, this improved from the baseline. One of the limitations of this study was that the initial questionnaire was conducted after orthodontic treatment had taken place, and the patients' malocclusion had been fully decompensated. Therefore, it is reasonable to assume that due to decompensation, their malocclusion may have been worse than at their initial presentation (Huang et al. 2016). This supports current findings within the literature that the pre-surgical orthodontic phase can worsen facial deformity and therefore impact on OHRQoL. However, as this study did not record baseline data prior to commencing orthodontic treatment it is difficult to draw any conclusions regarding the change OHQoL from pre-treatment to post-treatment.

The OHIP uses a weighting system where the weighting of each item on the questionnaire was determined by a panel of external judges. The Thurstone method was initially used to ascertain which questions in a pair yielded information which should be given greater weighting. The final overall score is determined by multiplying the allocated weighting of each item by the Likert response that the patient has answered. Scores for each scale are calculated by summing the results across all the items on the questionnaire (Locker et al. 2007). There are some concerns that the weighting which a clinician may give a question is different from that of a patient. Whilst external judges determining the weighting may make assumptions, the alternative option of asking participants to self-weight items, increases the length of time to complete the questionnaire and may lead to errors in responses and reduced response rates.

In addition to this, another significant limiting factor is that the OHIP form was initially designed to understand the impact of oral diseases for an ageing population, therefore it's applicability to generally young and medically fit, orthognathic patients, may be limited (Cunningham et al., 2002b).

2.8.2.3 Orthognathic Quality of Life Questionnaire

In accepting the limitations of the OHIP and its limited applicability to orthognathic patients, Cunningham et al., developed the Orthognathic Quality of Life questionnaire (OQLQ) (Cunningham et al., 2000, 2002c).

It has been widely used and consists of 22 questions (see Appendices) split into four categories (Eslamipour et al. 2017):

- Oral function- Items 2-6 and scores range from 0-20.
- Facial aesthetics/ aesthetic impact- Items 1, 7, 10, 11 and 14 and scores range from 0-20.
- Awareness of facial aesthetics- Items 15-22 and scores range from 0-32.
- Social implications- Items 15-22 and scores range from 0-32.

The questions are rated on a five-point Likert Scale with answers ranging from zero ("it does not bother me at all",) to four ("it bothers me a lot"). Following completion of the questionnaire, patients are allocated a score ranging from 0-88, with higher scores suggesting a poorer quality of life and lower scores indicates a better QOL. Since orthognathic treatment is elective and many patients undergo it to improve their aesthetics and function, it would be reasonable to expect a reduction in the score following orthognathic treatment. The OQLQ has shown to have good reliability and validity. It is quick and easy to complete, which encourages a high response rate (Cunningham et al., 2002b).

The OQOL was developed in three stages as follows:

i) generation of the questionnaire,
ii) reducing the questionnaire to include only relevant items,
iii) testing the tool on patients before its final implementation.

The initial questionnaire was formulated following a literature review and unstructured interviews with 25 patients, 10 oral and maxillofacial surgeons, and 15 orthodontists from hospitals throughout the UK. 15 patients had not yet started treatment, and 10 patients were in the initial treatment stage. Within the initial stage, a list of questions were developed to assess the impact of the orofacial deformity on the patient's quality of life. Interviews were conducted in a non-clinical setting by the same person and patients were asked to describe, in their own words, how their life was affected by their DFD. These statements were recorded, and after removal of repeated items, a list of 42 items/questions were made. During the second stage of item reduction, the 42 questions were issued to patients in in a written-questionnaire format, and they were asked to indicate which items had relevance when they were deciding whether to undergo orthognathic surgery. The items which were selected most often were then chosen for inclusion within the questionnaire. Items which were selected by 20% or less were eliminated as they were not considered useful at distinguishing

between patients. By this process, 22 items were selected for inclusion within the final tool.

The OQOL was the first tool to assess health-related quality of life for OGS. To ensure validity of the tool, several statistical analyses were used:

- Measurement of response frequencies – to ensure that the same answer wasn't being inserted repeatedly for any of the questions.
- Principle Component Analysis (PCA)- to assess the dimensionality of the data collected and to assess if the question had subscales.
- A measure of the internal consistency of the different dimensions of the questionnaire.
- Test-retest to assess the agreements between the scores.

The OQOL questionnaire has been used extensively in the literature to assess the outcomes of orthognathic surgery. In a prospective six-month follow-up study conducted by Murphy et al., 62 patients were recruited to complete OQOL and Visual Analogue Scales (VAS) pre-treatment and six months following surgery. After treatment, there was significant improvement in each of the domains of the OQOL. 93% reported their appearance had improved, 64% had increased masticatory function, 60% had improved comfort and 32% felt their speech improved (Murphy et al. 2011a). Soh and Narayanan confirmed these findings and concluded that the overall quality of life had improved following surgery however, they only found an improvement in three of the four domains at six months post-operatively. Oral function did not show a statistically significant change at six months whilst aesthetics, social aspects and patient awareness of the deformity all improved (Soh & Narayanan, 2015). Lee et al., commented on the temporary reduction in quality-of-life measures at six weeks post-operatively, however confirmed an improvement in the OQOL score at six months. Interesting, Lee et al., showed improvement in three of the four domains however these differed from the three domains described by Soh and Narayanan. The domains within this study which showed improvement at six months were: facial aesthetics, social aspects, and oral function.

2.8.2.4 Surgical Orthodontic Outcome Questionnaire

The aim of the Surgical Orthodontic Outcome Questionnaire was to develop a tool to specifically assess the quality of life of orthognathic patients pre- and post-surgery. The instrument is designed to capture the following: the impact of the DFD; the patient's motivating factors for seeking treatment; and the effect surgery has on the patient's quality of life (Locker et al. 2007). As previously mentioned with the OHIP, there are limitations when a panel of external judges determine the weighting allocated to items on a questionnaire. Therefore, when developing the SOOQ items were self-weighted which allows the weighted and unweighted versions of the tool to be compared.

The questionnaire was developed using several sources of information which included a literature review and existing tools which assessed health related quality of life e.g., OHIP and expert opinions.

It is comprised of 33 items, each of which are then sub-divided into two further questions (Locker et al. 2007). The five domains are:

- Functional issues prior to surgery (six questions).
- Functional issues after surgery (nine questions).
- Dental aesthetics (five questions).
- Facial aesthetics (four questions).
- Psychological wellbeing (nine questions).

Each question has two components: the leading questions ask about the frequency of symptoms or problem, and the follow-up question assesses to what extent the patient is bothered by it (an example is given in Figure 2-6). Responses to the frequency questions use unweighted Likert scales and weighted scores are applied to the follow-up questions. The questionnaire is completed at three time-points: pre-treatment, two-six months post-surgery and after two years post-op.

An example of a question from the Surgical Orthognathic Outcome Questionnaire is given below:

In the last few weeks…

Have you had difficulty chewing or biting foods like apples, corn on the cob or firm meat?

Never	Sometimes	Often	All the time

How much has it bothered you?

Not at all	A little	Quite a bit	Very much

Figure 2-6 Example from the Surgical Orthognathic Outcome Questionnaire (Locker et al. 2007)
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To evaluate the effect of weighted vs unweighted items in altering the reliability of the of the questionnaire, Locker et al., conducted a study where they recruited patients at different time-points: before commencing treatment, two-six months post-surgery and two years following surgery. For both the full questionnaire and a shortened version, the frequency questions were used to calculate unweighted scale scores and the follow-up 'bother' questions along with the frequency questions were used to calculate the weighted scores. Results indicated that the weighted and unweighted scores were able to differentiate between the patients completing the questionnaire at different time-points. When the weighted sub scale scores were assessed, there was increased reliability when compared to unweighted items. However, the authors concluded that items which were self-weighted did not significantly affect the validity of the SOOQ (Locker et al. 2007).

2.8.2.5 Short Form 36 (SF-36) Health Survey questionnaire

The Short Form 26 Health Survey questionnaire (SF-36) is used to evaluate health-related quality of life (Lins and Carvalho 2016). The questionnaire was first implemented in the USA and is now available in 120 languages (Burholt and Nash 2011). It is widely established, accounting for 10% of the published reports relating to QOL prior to 2000 (Garratt et al. 1993). It has been demonstrated to provide a representative measure of the health status in a diverse range of patients and additionally, patients report that it is easy to use.

The SF-36 measures eight domains: physical health, functional capacity, pain, overall general health, vitality, social aspects emotional health, and

psychological health. Following questionnaire completion, two separate scores are given (a) Physical Component Summary and (b) Mental Component Summary (Lins and Carvalho 2016). Norm-based Scores (NBS) can also be incorporated into the algorithm which provides information on trends and variations within certain groups and populations.

The SF-36 tool has been used for orthognathic patients to demonstrate the benefit of treatment on quality of life (Lee et al. 2008; Nicodemo et al. 2008; Al-Bitar et al. 2009; Miguel et al. 2014; Zamboni et al. 2019; Dong and Yates 2020). Nicodemo et al used the SF-36 questionnaire to assess if orthognathic treatment for class III deformities resulted in an improved quality of life. The questionnaire was completed in the thirty days leading up to surgery and at six-months post-operatively. There was no correlation between the extent of the skeletal deformity and the scores. There were statistically significant changes in four of the domains following surgery: emotional, physical, and social aspects, and general vitality. The scores for physical and social aspects increased following surgery for both men and women. Only females had a mean higher score in the emotional aspects after surgery regarding their performance at work and general daily activities. (Nicodemo et al. 2008).

One of the limitations of the SF-36 is that the survey is not specifically designed for patients undergoing orthognathic surgery and the generic questions lack specificity to the orofacial region. Post-operative altered sensation and its impact on patients' QOL is very important to orthognathic clinicians (Lee et al., 2011) and the SF-36 questionnaire does not provide this information.

2.8.2.6 Face- Q

FACE-Q is a validated PROM which assesses quality of life, psychosocial, and functional outcomes in patients who undergo aesthetic and reconstructive facial treatments, including OGS (Ottenhof et al., 2022; Chren et al., 1996). There are multiple domains and scales measured within FACE-Q which are:

1. Facial Appearance
2. Psychosocial Status
3. Function
4. Surgical Outcome and patient satisfaction

FACE-Q consists of 40 questions which are subdivided into categories: Appearance Appraisal scale, Quality of life scale, Adverse effect checklist, and Patient Experience scales. Each item is independent and aims to assess the patient's symptoms and perception of different facial areas (Klassen et al., 2015). Patients are asked to score each item from 0-100 with higher scores indicating a more positive outcome. The questionnaire can be adapted depending on the procedure, and the patient is only required to complete relevant aspects. Baseline information is provided by the pre-treatment questionnaire, and patients are then asked to complete it following treatment are various time-points depending on the procedure they have underwent.

FACE-Q was developed by both patients and clinicians using a mixed-method approach and initially 50 patients who had previously had cosmetic procedures were asked what questions may be useful to include within the questionnaire. The questionnaire was initially implemented in three independent studies and following analysis, the items which gave the most accurate indicator of the outcomes were included (Klassen et al., 2015).

FACE-Q has been used as a validated tool to assess outcomes and patient experiences of orthognathic surgery.

Denadai et al., used FACE-Q in a comparative study of patients, clinicians, and lay-persons perceptions in assessing the change in facial appearance and psychosocial features in orthognathic patients before and after treatment. Patients completed FACE-Q questionnaire pre- and post-treatment. The panel of assessors viewed the pre-and post-treatment photographs, and they also viewed those of a 'normal' cohort with no DFD. The panel was comprised of lay-observers, surgeons, and orthodontists. There was significant correlation between the FACE-Q questionnaire responses and the panel assessment of the overall facial appearance scale but not for the patient's satisfaction – specifically with the lower face, jawline, and lips. There was also no correlation between the FACE-Q psychosocial scales and the panel's interpretation of personality characteristics. This study demonstrates that, orthognathic treatment can lead to an improvement in quality of life and a positive change in facial appearance and psychosocial parameters. However, there is little or no

correlation between the FACE-Q tool and a panel assessment method. (Denadai et al. 2019).

In summary the FACE-Q tool is a validated tool which can detect important changes pre-and post-treatment for patients undergoing aesthetic and reconstructive facial treatments (Klassen, Cano, Schwitzer, et al., 2016). However, it has been designed for patients undergoing facial aesthetic treatments and therefore may limit its applicability to orthognathic patients with DFD.

2.8.2.7 Northwich Park Orthognathic Questionnaire

The Northwich Park Orthognathic Questionnaire (NOQ) is another PROM tool. It was developed in Northwich Park Hospital to evaluate patient's reasons for seeking orthognathic treatment and overall satisfaction in terms of function, psychological status and aesthetics (Al-Hadi et al. 2019). It consists of 91 questions split into seven categories and covers three themes. These are (i) Patient Outcomes, (ii) In-patient experience and (iii) Peri-operative experience. Question format varies and includes simple 'yes, no' answers, Likert and rating scales.

To ensure validity of the questionnaire, 118 post-surgery orthognathic patients were asked to complete the NOQ and 30 patients were then asked to complete it twice- six to twelve months apart. The reproducibility of responses was high – 92% of the 30 patients gave identical responses with an intra-class correlation coefficient of 0.96. Statistical analysis included an: (a) Principal Component Analysis (PCA) to assess if the questions can differentiate between patient's experiences and (b) Correlation Analysis to assess confounding information between questions. Some questions are asked multiple times in different formats to allow comparison and consistency of responses to be assessed (Chegini et al. 2022). This study confirmed that the NOQ is a validated tool to measure orthognathic patients' perception of their treatment and outcome.

The NOQ also collects data such as the treatment and surgery carried out and this information can be used by service evaluators to ensure gold-standard care and help improve services.

One of the limitations of this tool is that it is completed at one time-point by the patient following their surgery retrospectively i.e. In an initial study by Al-Had et al. to assess patient-satisfaction with orthognathic treatment using the NOQ, patients up to five-years post-op were asked to complete the survey (Al-Hadi et al. 2019). As questions relate to the patient's reasons for seeking treatment, initial consultation, post-operative complications and overall treatment experience, results may be skewed due to recall bias. As this is a 'one-time' questionnaire, this limits the interpretation of results in showing that orthognathic treatment improves QOL as there is a lack of baseline information to allow comparison.

Additionally, the questionnaire is lengthy comprising 91 questions which may limit response rates, however despite this, acceptability has high with a response rate of 91% in a small sample of 119 patients (Chegini et al. 2022). Cunningham et al. reported a response rate of 97% for the Orthognathic Quality of Life questionnaire (Cunningham et al., 2000) and this tool therefore gives comparable response rates.

In summary, the NOQ is a validated tool which captures data that other orthognathic-specific questionnaires such as the OQOL do not consider i.e., patient-perception on clinicians' communication and patients experience whilst in hospital in the peri- and post-operative period. As the NOQ has separate sections for each stage of treatment, patient perception can be quantified, and Al Hadi showed this using the NOQ by confirming that patients felt most informed about the orthodontic treatment (96.6%) and orthognathic surgery (94.1%) but felt less educated on how long treatment would take (83.1%) (Chegini et al. 2022).

2.8.2.8 Patient-centred Measure of the Process and Outcome of Orthognathic Treatment

Travess et al., developed a tool to measure the quality of orthognathic care in the South-West of England. This aimed to capture patient's perspective and views on the orthognathic care pathway and quality of care received (Travess et al. 2004). The questionnaire was developed in three stages:

(i) Focus group study.

(ii) Questionnaire development.

(iii) Measuring reliability and validity of questionnaire.

The focus groups were patients who had received orthognathic treatment between January 1995- December 2000 in hospitals in South-West England. The meetings were recorded, and the transcript then analysed by an independent party. Commonly occurring themes were then identified and used to construct the questionnaire. The number of questions allocated to a particular area reflected the weighting participants within the focus groups gave to a particular section. The questionnaire was piloted in 15 patients who had completed orthognathic treatment. To test the validity and reliability of the questionnaire, 46 patients (some of which had attended the focus group) took part in a pilot study. Subjects were sent two questionnaires three weeks apart to assess the test-retest reliability which had kappa scores for most questions which were greater than 0.4.

The authors acknowledge some of the limitations with this tool. Selection bias is expected in the focus group i.e. patients who attend these are likely to have views of one extreme or another (either very satisfied or dissatisfied with their outcome). In addition to this, significant time (up to three years) had elapsed from completion treatment to questionnaire submission. This may have impacted on patient's perception of treatment, and it is likely that information was forgotten or omitted. Despite these limitations, Travess et al have developed a valid and reliable tool to assess the outcome of treatment specific for orthognathic surgery.

2.8.2.9 Orthognathic Specific PROM used within this Study

An orthognathic-specific PROM tool has been developed by the British Orthodontic Society (BOS) and the British Association of Oral and Maxillofacial Surgeons (BAOMS) and is currently being implemented nationally and is being used within this study. It is a unique PROM which has been developed by both orthognathic surgeons and orthodontists to ensure that all relevant data is captured. The data collected from this will provide invaluable insight into the patient's perspective on treatment. In addition to this, information gained is

also useful in aiding NHS commissioners to make decisions regarding NHS funding for treatment and allocation of resources (BAOMS and BOS 2024).

This questionnaire consists of sections from OQOL and BODY-Q tools with additional questions. Part one of the survey consists of 22 questions from the Orthognathic Quality of Life Questionnaire (Cunningham et al., 2000, 2002a). Section two is multiple choice and asks about current satisfaction with facial and dental appearance. Part three asks 'In your current state of health, to what extent do you agree or disagree with the following statements?'. Answers are given in a Likert-scale response from Strongly Agree to Strongly Disagree. The first three sections are the same for all questionnaires completed pre- and post-operatively. In the immediate post-operative questionnaire, there is a section relating to the patient's opinion and perspective on the quality of care they have received – this is ten questions from BODY-Q questionnaire (Klassen et al. 2016b).

A systematic review conducted by Nagar et al., which aimed to assess the validity studies of PROMS, confirmed that the Orthognathic Quality of Life Questionnaire (OQLQ) has, to-date, been the most extensively tested orthognathic-specific PROM within the literature. Since the initial OQLQ was developed, there has been three other orthognathic-specific PROMS published. However, none of the more recent PROMs have been used to measure aesthetic, functional and/ or psychological outcomes for orthognathic patients (Nagar et al. 2023).

BODY-Q is a validated tool which has been subject to rigorous testing to ensure that it remains one of most reliable PROM for patients undergoing weight-loss and body contouring treatment (Dalaei et al. 2022). It has been subject to multiple field-tests in the UK, USA, Canada and has been psychometrically tested. BODY-Q usually consists of four independent domains which are measured, and these are appearance, health-related quality of life, eating concerns, and patient perception of the care given (Klassen et al. 2018). The literature highlights that BODY-Q is one of the tools for weight-loss patients with the highest levels of validation (Barone et al. 2018; de Vries et al. 2018).

In summary, the PROM tool being used within this study is comprised of (i) Orthognathic Quality of Life Questionnaire and (ii) BODY-Q. These are two of the

most validated and psychometrically tested PROMs which have been subject to thorough scrutiny and statistical analysis. This ensures that the data from this questionnaire is high-quality, reliable and allows meaningful, reproducible, and interpretable information to be gained.

2.8.2.10Summary of Patient Opinion Tools

Summary of Orthognathic Patient Opinion Tools

Tool	Developed by	Summary of data collected	Limitations
Patient Interviews	-	Patient experience data collected including oral health, self-esteem and confidence.	Patients may not disclose sensitive information.
Oral Health Impact Profile	Slade & Spencer (1994)	Measures oral health-related quality of life.	Not specific to orthognathic patients.
Orthognathic Quality of Life Questionnaire (OQOL)	Cunningham et al. (2000, 2002)	22-item orthognathic-specific PROM across four domains: oral function, facial aesthetics, awareness, social impact; Likert scoring (0–88).	The length of questionnaire can lead to lack of completion.
Surgical Orthodontic Outcome Questionnaire (SOOQ)	Locker et al. (2007)	33 items across 5 domains: pre/post function, dental & facial aesthetics, psychological wellbeing; includes frequency + “bother” (self-weighted).	Complex time consuming to complete.
Short Form -36 (SF-36)	Garratt et al. (1993); Lins & Carvalho (2016)	Generic health-related QOL tool; 8 domains (physical, emotional, social,	Not specific for orthognathic patients and lacks detail on

		pain, vitality, etc.); produces physical & mental summary scores.	facial concerns.
Face-Q	Klassen et al. (2015)	40-item modular PROM assessing facial appearance, psychosocial status, function, satisfaction; scored 0–100.	Designed for facial procedures and not specific to DFD.
Northwich Park Orthognathic Questionnaire (NOQ)	Northwick Park Hospital	91-item PROM covering outcomes, inpatient and peri-operative experience; includes functional, psychological, aesthetic and service-related data.	Time-consuming to complete and subject to recall bias.
Patient-centred Measure of Process & Outcome	Travess et al. (2004)	Focus-group–derived questionnaire assessing patient perspectives on care pathway and treatment outcomes.	Selection bias in focus groups.
BOS PROM including OQOL and Body-Q	British Orthodontic Society	Composite PROM: OQLQ + additional satisfaction and care questions + BODY-Q elements; captures QOL, satisfaction, and care experience pre/post-op.	Combined tools and specific for orthognathic patients.

Table 2 Summary of Patient Opinion Tools

2.8.3 Quality Outcomes in Oral and Maxillofacial Surgery (QOMS)

Quality Outcomes in Oral and Maxillofacial Surgery (QOMS) was introduced in 2018 and is a clinical effectiveness programme led and funded by the British

Association of Oral and Maxillofacial Surgeons (BAOMS). It is a speciality-wide, national programme which allows assessment of the standard of care provided and supports the continual improvement of care within OMFS (Morley et al. 2013). It is comprised of several audits to assess, improve and bench-mark OMFS subspecialties to ensure that care is standardised and continually improved see Figure 2-7 and Figure 2-8).

There are several nationally agreed questionnaires within QOMS for each of the OMFS sub-specialties. Questionnaires are completed by clinicians on standardised forms and uploaded to an online portal to allow national comparison. There is usually a designated person within each unit or hospital who is responsible for data collection. Questionnaires ask about the patients diagnosis, the surgical procedure completed, the level of the operator, post-operative complications and the clinicians' assessment of the patient's quality of life.

Each subspeciality within OMFS has a specifically designed QOMS which has been formulated in consultation with the subspeciality interest groups. The data is collected locally in each OMFS unit within the UK and managed by Barts Cancer Research UK centre at the Queen Mary University of London (BCC, QMUL). The data is stored electronically on the system Research Electronic Capture software (REDCap) (BAOMS 2023). QOMS is a quality assurance indicator as it allows surgeons to assess their performance against nationally and provides a method to identify indicators of high performance.

QOMS provides a way to ensure orthognathic treatment is patient-centred, which is a key factor of providing gold-standard healthcare. Additionally, there are cost and funding implications. Healthcare costs have exponentially risen and waiting times have been exacerbated due to the ongoing effects of the COVID-19 pandemic (BMA 2024). As healthcare commissioners are under continued pressure to ensure that funding and resources are focused in areas of healthcare with greatest need and for treatments which have a clear benefit to patients, the information gained from QOMS is valuable for planning future care provision in health boards (BAOMS 2024).

Measuring the quality of treatment is challenging due to the subjectiveness and to multidimensional nature of what one may consider 'quality treatment' to be.

The agency for Healthcare Research and Quality (AHRQ) has provided the definition of quality as 'doing the right thing for the right patient, at the right time, in the right way to achieve the best possible results' (Agency for Healthcare Research and Quality 2017).

The aims of QOMS are to produce information relating to the quality-of-care patients receive across Oral and Maxillofacial surgical subspecialties. The information collected from QOMS will allow clinicians to assess their current practice and implement appropriate changes to improve the service they provide. Particularly for orthognathic patients, it will provide insight into the long-term follow-up and importantly whether surgery has led to an improvement on their overall quality of life (BAOMS 2024).

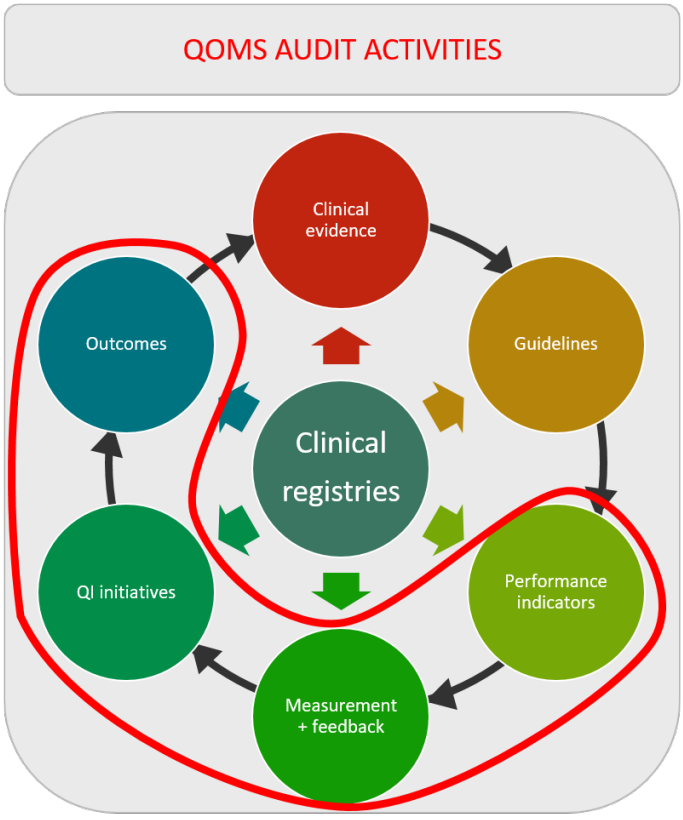

Figure 2-7. QOMS- Use of Clinical Registries for Audit and Quality Improvement Activities (BAOMS 2024)
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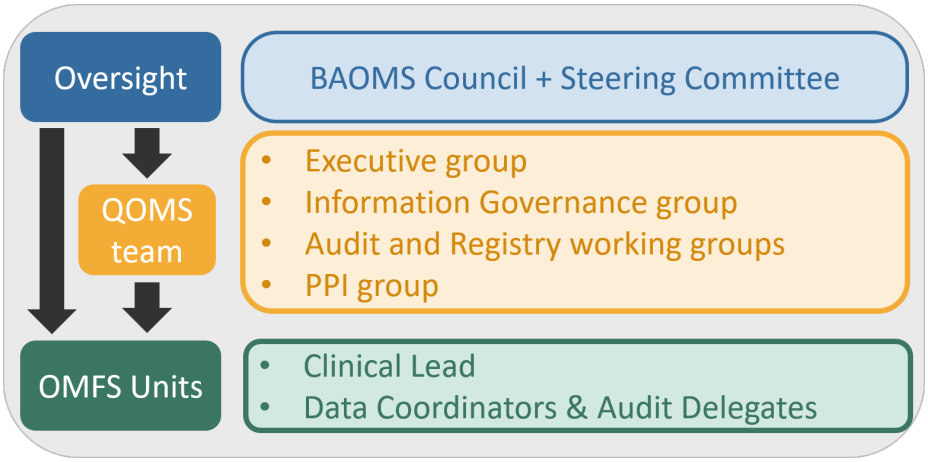

Figure 2-8. Structure of the QOMS Project (BAOMS 2024)
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2.8.4 Association between PROMS and QOMS

As orthognathic treatment is primarily patient-led, PROMS provide valuable insight into the motivating factors for patients seeking treatment, the improvement in quality of life after treatment and the patients' overall treatment experience. Within the literature, there have been multiple PROMs tools described, however the OQOL is the most widely used, likely due to the validity (Nagar et al. 2023) and ease of use by patients and clinicians.

The continuation of the provision OGS funded by the National Health Service relies on the specialty being able to demonstrate the cost effectiveness and clear benefit to benefits. Quality Outcome Measures are important are a way to quality assuring treatment and demonstrating the outcomes of orthognathic surgery (Ho et al. 2021). However, the relationship between PROMS and Quality Outcome Measured recorded by the clinician, to our knowledge, has not yet been investigated.

In the most recent 2020/21 QOMS report published by BAOMS, the effects of the COVID-19 pandemic and the implications of this on orthognathic surgery was discussed (70-100% reduction in activity during the pandemic). In the eight units participating in QOMS, the number of orthognathic procedures carried out ranged from 10-180 per year. For the surgeries that were completed, the complication rate was low and the return to theatre rate within 30 days was 2% (British Association of Oral and Maxillofacial Surgeons 2023).

2.8.5 Summary

Although other studies have individually analysed Patient Reported Outcomes and Quality Outcomes for orthognathic surgery, to our knowledge there are no studies assessing if there is a relationship between PROMS and QOMS.

Chapter 3 Rationale and Aims

3.1 Rationale for this Study

Currently there is lack of research in assessing PROMS and Quality Outcomes for Surgery-First Orthognathic treatment.

Understanding both patient opinion and clinician perspectives are important in the delivery of gold-standard care and allowing service providers to continually improve NHS funded treatment. By collecting data from the two cohorts, this will provide a comprehensive overview of the treatment delivery and outcomes which is representative of both patients and care-providers.

Additionally, there may be differences in what clinicians and patients perceive to be important in treatment delivery (Burke and Croucher 1996) and what clinicians may consider to be an optimal outcome may not translate to an equivalent level of patient satisfaction. Clinicians who understand how their views align (or not) with those of their patients will be able to offer a more patient-centred approach to delivery of care.

In summary, assessing PROMS and QOMS individually and the relationship between the two will allow understanding of surgical outcomes, patient experience and, if the clinicians perceptions are aligned with patients; all of which are important for managing expectations and ensuring patient-satisfaction.

3.2 Study Aims

The aim of this study was to assess the quality of care and the patient-reported outcomes of the surgery-first approach to orthognathic treatment, using the Patient Reported Outcome Tool (validated by BOS and BAOMS) and a Quality Outcome Measure questionnaire. A secondary objective was the evaluation of the relationship between the data derived from the two questionnaires.

The primary aims were:

(1). To determine how patients' satisfaction with their facial and dental appearance changed throughout SFA orthognathic treatment at the following

time-points: (a) pre-treatment, (b) four-eight weeks post-surgery, (c) one-year post-surgery (using questions within the Patient Opinion Questionnaire used within this study).

(2). To determine PROMS (specifically, the OQOL questionnaire) for SFA orthognathic treatment at three time-points (a) pre-treatment, (b) four-eight weeks post-surgery, (c) one-year post-surgery.

(3). To determine clinicians' perceptions on the patients' (a) dysfunction, (b) psychological deficit, (c) dysmorphology, (d) dentofacial deformity, (e) impact on quality-of-life at three time-points (pre-treatment, six-months post-surgery, one-year post-surgery) using a validated QOMS tool.

Secondary Aim: To explore the relationship between PROMS and clinician perceptions. Specifically, the following was assessed:

(i) Patients' concern and clinicians' indication for treatment (in terms of aesthetics) pre-treatment.

(ii) Patients' concern and clinicians' indication for treatment (in terms of dysfunction) pre-treatment.

(iii) Patients' satisfaction with facial appearance and the severity of the dysmorphology recorded by clinicians pre-treatment.

(iv) Patient self-reported chewing problems and the severity of dysfunction recorded by clinicians pre-treatment.

(v) The direction of improvement in function from patients and clinicians from pre-treatment to one-year post-surgery.

(vi) The direction of improvement in facial aesthetics from patients and clinicians from pre-treatment to one-year post-surgery.

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3.3 Null Hypothesis

The null hypotheses are:

(iv) There is no relationship between patients' concern and clinicians' indication for treatment (in terms of aesthetics) pre-treatment.

(v) There is no relationship between patients' concern and clinicians' indication for treatment (in terms of dysfunction) pre-treatment

(vi) There is no relationship between patients' satisfaction with facial appearance and the severity of the dysmorphology recorded by clinicians pre-treatment.

(vii) There is no relationship between patient self-reported chewing problems and the severity of dysfunction recorded by clinicians pre-treatment.

(viii) There is no relationship between the direction of improvement in function from patients and clinicians from pre-treatment to one-year post-surgery.

(ix) There is no relationship between the direction of improvement in facial aesthetics from patients and clinicians from pre-treatment to one-year post-surgery.

Chapter 4 Methodology

4.1 Study Design

This prospective cohort study was carried out to assess the outcomes of orthognathic treatment with the Surgery-First Approach.

4.2 Ethics Approval

Ethics approval for this study was gained locally from the NHS Greater Glasgow and Clyde Clinical Governance committee and from the University of Glasgow MVLS Research Committee (MVLS Project Reference: 200240008) (see Chapter 7).

As this was initially a Clinical Governance Project, the NHS Clinical Governance Committee approved the project for questionnaire-based data collection and preliminary data assessment. Approval was gained from the University of Glasgow for secondary data analysis (assessing the relationship between the two questionnaires).

4.3 Recruitment

4.3.1 Clinicians

Clinicians who conducted their dentofacial clinics at Glasgow Dental Hospital were approached and asked for their participation in the study. Following agreement, the Principle Investigator then arranged to attend each of the clinics to ensure contemporaneous data collection. All three of the surgeons who were approached agreed to participate.

4.3.2 Patients

Patients were recruited between October 2023 and December 2024, and the final one-year follow-up questionnaires were completed by December 2025.

Patients were recruited from the combined multidisciplinary dentofacial clinics, which they were already attending as part of their orthognathic treatment. All patients who fulfilled the inclusion criteria and who had a provisional Orthognathic Surgery date within three months were approached. The Principal

Investigator attended the clinics to approach patients and ensure consistency in the information provided. Initially, verbal information was given and when the patient agreed they were provided with a written consent form which outlined the study design in further detail (see section 7.3). Patients were made aware that their decision to take part did not influence their treatment. Where the Principal Investigator was on leave or unable to attend the clinic, the Consultant Orthodontist or Surgeon at the clinic approached the patient.

4.4 Sample Size Calculation

The sample size calculation is affected by the study design, effect size, standard deviation and desired power of study (Florey 1993; Fritz et al. 2012).

The equation below was used to determine the sample size for this study. This relates to the null hypothesis that there is no relationship between Clinician Reported Indications for surgery and treatment outcomes and Patient Reported Indications for surgery and treatment outcomes.

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2}{w^2}$$

$Z_{1-\alpha/2} = 1.96$ for a 5% significance level

$Z_{1-\beta} = 0.84$ for 80% power

w represents Cohen's effect size.

As there was no published data assessing the relationship between Patient Reported Outcomes and Surgeon Reported Outcomes for SFA Orthognathic treatment, it was hypothesised that a large effect size would be found. According to Cohen's conventions, a *w* value of 0.5 was chosen to correspond to a large effect size (Sullivan and Feinn 2012). A sample size of 31 participants was calculated to ensure that the study was powered appropriately at 80% (0.80). Additionally, there was a limit in the number of patients available, due to the limited number having the SFA within the recruitment period.

4.5 Subject Selection Process

The following inclusion and exclusion criteria were applied.

4.5.1 Inclusion Criteria

- Diagnosis of DFD by multi-disciplinary team and agreement to proceed with Surgery-First Approach.
- Index of Orthognathic Functional Treatment Need (IOFTN) score of 4 or 5.
- Consented to participate in study.

4.5.2 Exclusion criteria

- Patients who have previously had an orthognathic surgical procedure before completing the pre-treatment questionnaire.
- Orthodontics-First Approach
- Craniofacial syndromes.

Data were collected at Glasgow Dental Hospital and School on the MDT orthognathic clinics.

4.6 Materials

4.6.1 Questionnaires

4.6.1.1 PROMS

There are three PROMS questionnaires used in this study (i) Pre-surgery, (ii) Four-eight weeks post-surgery and, (iii) One-year post-surgery, with subtle differences in the sections which reflect the stage of treatment (see Chapter 7). This is a validated tool developed by the BOS and within the PROM, there are different questionnaires which have been discussed in earlier chapters. There is no published guidance on how the Orthognathic-Specific PROM tool used within this study was developed.

The questionnaires were not modified by the research group and were presented in their original form to the patients.

(i) Pre-surgery questionnaire

- Section 1: Orthognathic Quality of Life Questionnaire (2.8.2.3).
- Section 2: Facial/ Dental satisfaction and numbness.

(ii) Four-eight weeks post-surgery questionnaire

- Section 1: Orthognathic Quality of Life Questionnaire
- Section 2: Body-Q (see 2.8.2.6) asks the patient's opinion on the information that they have received from the clinical team. Please note, the questionnaire states Body-Q however, from analysis it appears to be Face-Q (which has been discussed in 2.8.2.6)
- Section 3: Facial/ Dental satisfaction and numbness.

(iii) One-year post-surgery questionnaire

- Section 1: Orthognathic Quality of Life Questionnaire.
- Section 2: Facial/ Dental satisfaction and numbness with an additional question which asks if the patient recommend this treatment to another person.

All sections use Likert scales which are psychometric, ordinal scales and are usually presented horizontally with verbal, graduated responses, which are usually symmetrical around a neutral middle response (Likert 1952).

4.6.1.2 Clinician Perspectives

Clinician Perspectives were gained using QOMS which is a standardised form categorized into four data collection instruments (see section 0):

1. Demographics and surgery – completed pre-surgery.
2. Orthodontic Treatment- completed pre-surgery.
3. Return to theatre & Readmission- completed post-surgery.
    - Was the patient unexpectedly returned to theatre within 30 days of the surgery?

- Was the patient unexpectedly readmitted within 90-days of the surgery?

4. Follow-up visits- completed at six months and one-year post-surgery.

The QOMS forms used several question types including multiple choice and rating scales. Likert scales are used for clinicians to rate their perception of certain aspects of DFD, including dysfunction, psychological impact, dysmorphology, DFD and impact on quality of life. The Likert scales are represented as an unmarked 10cm line with values ranging from 0-100 (see Figure 4-1). Higher scores indicate greater severity of the measured parameter i.e., a lower rating of dysmorphology would indicate the clinician interprets the patient to have a milder skeletal deformity whilst a higher score would indicate a greater severity of DFD. It is the clinician's subjective interpretation of each parameter which is scored. The mark on the Likert Scale was measured with a ruler to produce a numerical value i.e., 2.7cm gave a Likert Score of 27. This was then uploaded electronically to the REDCap (Research Electronic Data Capture) software package.

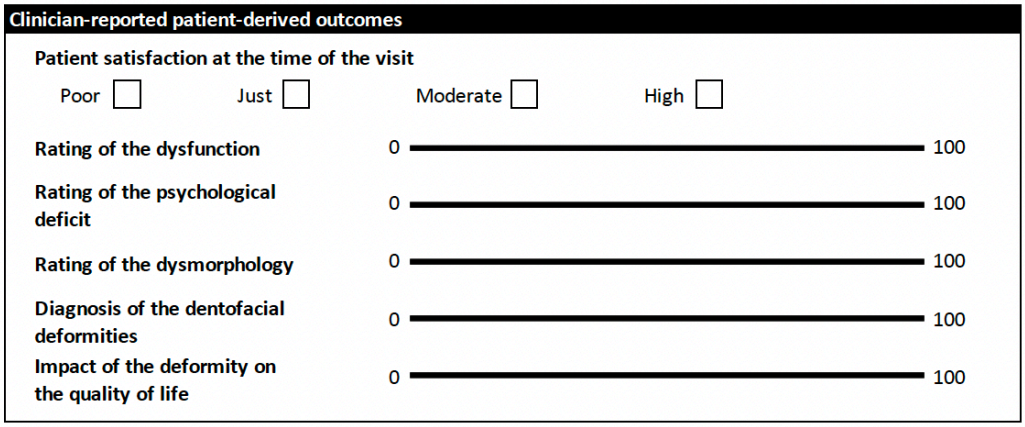

Figure 4-1Clinician Reported Patient Derived Outcomes from QOMS

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The VAS scorings were completed by clinicians scoring an unmarked line from 0-100 on paper QOMS forms. A numerical value was assigned to each Visual Analogue Reading by measuring with a ruler the distance from '0' to the clinician's marking (a line measuring 1.5cm, provides a score of 15). The scores were then transferred to REDCap by one designated person. To assess intra-examiner reliability and ensure calibration, the measurements were repeated for a sample of ten different Visual Analogue Scales to ensure the same scores

were recorded each time. In all ten cases (100%), the same scores were replicated proving repeatability and accuracy within the scores. To minimise variation, this was completed by one person only.

4.6.1.3 Linking Patient and Clinician Responses

The individual questionnaires from patients and clinicians were analysed thoroughly to assess similarity between question-types which could be used to link the two questionnaires. This was carried out by three researchers over a several meetings to allow time for discussion and to resolve any disagreements.

Table 3 illustrates what questions were used for each of the secondary objectives.

	Information from PROM	**Information from QOMS**
Patients' concern and clinicians' indication for treatment (in terms of aesthetics) pre-treatment.	Question: '*How satisfied are you with how your* ***face looks at the moment****?'* In section 2 of the questionnaire.	Surgeon Reported **Dysmorphology** in section *'Clinician reported patient derived outcomes'*
Patients' concern and clinicians' indication for treatment (in terms of dysfunction) pre-treatment	Question 14: '*I have* ***problems biting*** '*in* Section 1 of questionnaire.	Surgeon Reported **Dysfunction** in section *'Clinician reported patient derived outcomes'*
Patients' satisfaction with facial appearance and the severity of the dysmorphology recorded by clinicians pre-treatment.	Question: '*How satisfied are you with how your* ***face looks at the moment****?'* In section 2 of questionnaire.	Surgeon Reported **Dysmorphology** in section *'Clinician reported patient derived outcomes'*
Patient self-reported chewing problems and	Question 15: '*I have* ***problems chewing'*** in	Surgeon Reported **Dysmorphology** in section

the severity of dysfunction recorded by clinicians pre-treatment.	Section 1 of questionnaire.	*'Clinician reported patient derived outcomes'*
The direction of improvement in function from patients and clinicians from pre-treatment to one-year post-surgery.	**Oral Function component of the OQOL** which consists of several questions from section 1 and is scored out of 20.	Surgeon Reported **Dysmorphology** in section *'Clinician reported patient derived outcomes'*
The direction of improvement in facial aesthetics from patients and clinicians from pre-treatment to one-year post-surgery	**Facial Aesthetics component of the OQOL** which consists of several questions from section 1 and is scores out of 20	Surgeon Reported **Dysmorphology** in section *'Clinician reported patient derived outcomes'*

Table 3 Linking of Patient and Clinician Questionnaires

4.6.2 Software

Data were managed using REDCap, which is an online database system developed by Vanderbilt University in 2004 (Patridge and Bardyn 2018). It was initially developed by a group of researchers who required a way to store research data which was secure and compliant with HIPAA standards.

REDCap is web-based software and workflow system that allows collection of data, storage of databases, and analysis of research data in a secure and organised way. It uses metadata-driven electronic data capture (EDC) to streamline database design.

It is compliant with regulatory requirements such as Code of Federal Regulation (CFR) Part 11, Federal Information Security Modernization Act (FISMA), Health Insurance Portability and Accountability Act (HIPAA), and General Data Protection Regulation (GDPR) (Harris et al. 2009; Harris et al. 2019).

Initially, clinicians completed paper copies of the QOMS form for convenience, and this was then transferred by one dedicated person to REDCap. Paper copies of the questionnaires were retained in a secure folder within a secure, dedicated area. In line with Ethical approval from the University of Glasgow, paper copies of the data will also be retained for ten years.

PROMS forms were also stored and available electronically on REDCap. They were completed by patients on their mobile device by scanning a QR code and then automatically uploaded to the same software. Paper copies were available and if required, the answers were also uploaded by one dedicated person.

4.6.3 Data Storage

Data was stored on REDCap, which runs on Mac and Windows operating systems. Access to the data was required multi-factor authentication, thereby enhancing security and will be retained for ten years.

4.7 Data Collection

4.7.1 Consent

Written consent was obtained after patients were provided with verbal and written information about the study. All participants within this study agreed to their data being analysed.

4.7.2 Data Collection Protocol

Data collection was carried out at Glasgow Dental Hospital and School for audit purposes as part of two ongoing nationally agreed projects that were initiated and lead by BOS and BAOMS. Data collection was the responsibility of the principal investigator.

4.7.2.1 PROMS Data Collection

Patients completed PROMS questionnaires at three time-intervals: pre-surgery, and at four-eight weeks, and one-year post-surgery. After agreeing to participate and giving their consent, patients were assigned a unique identifier number which was sequentially generated by the Principal Investigator starting from 001. Patients then scanned a QR code on their mobile device to access the questionnaire, inserted their identifier before completing and submitting the survey. The same unique identifier was inserted to the three PROMS forms completed by the patient to allow each patient's QOMS and pre- and post-treatment PROMS questionnaires to be identified.

Patients were given the option to have the questions read aloud via the audio function of the digital questionnaire. Support was offered to patients who sought clarity regarding the questions.

4.7.2.2 QOMS Data Collection

QOMS forms were initially collected on paper at the following time intervals: pre-surgery, post-operatively at one week, thirty days, six months and one year. The data were then transferred to REDCap by one person. Forms were completed at the time of, or immediately after, the patient's clinical appointment to ensure contemporaneous data collection.

4.8 Data Processing

Data were pseudo-anonymised. Each patient was assigned a unique identifier which was inserted on their PROMS and QOMS questionnaires. The data were stored on an Excel file on an NHS encrypted USB drive to allow statistical analysis. These data were also accessible via the University's One Drive.

For data and statistical analysis, only the identifiers (i.e., no identifiable information) were uploaded into the statistical software.

An excel spreadsheet, which contained patient-identifiable information was stored on a password-protected NHS computer and only the Principal Investigator had access to this.

4.9 Data Analysis

Following data collection of PROMS and QOMS at the appropriate time intervals, data were uploaded into a Microsoft excel spreadsheet to allow assessment of variables for each questionnaire. Data were then imported to SPSS software for statistical analysis.

4.10 Missing Data

Four patients failed to complete all questionnaires. Reasons for dropout included one patient emigrating and three patients scanning the QR code but failing to complete the questionnaire. Of the four, one patient completed the pre-operative questionnaire only and three patients completed the baseline and initial post-operative questionnaire but failed to complete the one-year post-surgery questionnaire. All questionnaires were included within the PROMS results. However, the four patients who did not complete all questionnaires were excluded from the analysis which compared clinicians' and patients' views at one-year post-surgery.

All fields in the online patient questionnaire were required before it could be submitted and if any questions were blank, they were prompted to complete missing fields before submission. This ensured that all submitted questionnaires were completely fully.

The questionnaires used within this study had been in circulation for some time before this study started, however, only those completed form the study start date were included to ensure consistency and standardisation in the data collection protocol.

Completion of QOMS questionnaire was overseen by the PI to ensure all questions were completed.

4.11 Statistical Methodology

4.11.1 Assessment of Normality

The data from both questionnaires were ordinal and primarily generated from Likert scales. Normality tests are not usually required for ordinal data, since it is generally assumed that they are not normally distributed and therefore non-parametric tests are considered the most appropriate method for analysis (Bishop and Herron 2015).

Ranked data reduces the impact of outliers and unusual distributions. However, in ranking data, information regarding the size of the difference between scores can be lost. It is for this reason that non-parametric tests can be less statistically powerful that the parametric equivalent (Field 2018).

4.11.2 Descriptive Statistics

Descriptive statistics were guided by a Statistician at the University of Glasgow. If the data were normally distributed, they would be described in terms of the mean and standard deviation. However, as they were assumed to be non-normally distributed, the median was used to assess central tendency and interquartile range used to assess data dispersion (Gosall and Gosall 2015).

4.11.2.1 Pearson Chi-Squared Test

The Pearson Chi-squared (X^2) test is a non-parametric statistical test used to assess the association between categorical variables. It assesses whether the observed frequencies in each category are different from the expected frequencies that would occur if the two variables were independent. If $p < 0.05$ (a statistically significant Chi-squared value), there was a significant association between the two variables (McHugh 2013). In instances where expected cell

counts were small (less than five cases in each category), Fisher's exact test was used in addition to the Chi-squared test as it provides a more accurate measurement of significance for small or unevenly distributed samples. It was used when the expected frequency of one of more of the cells was less than five (Beukelman and Brunner 2016).

To disclose agreements or potential disparities between the data collected from the two questionnaires, the following parameters were assessed:

(1) Patients' concerns and surgeon's indications for treatment (in terms of aesthetics) pre-treatment.

A Chi-squared test was completed between (a) Surgeon reported pre-treatment dysmorphology- yes or no , and (b) Patient satisfaction with pre-treatment facial appearance- yes or no.

The surgeon recorded on the QOMS form if there was dysmorphology by marking a line on an unmarked Likert Scale from 0-100. If the score was $\geq$ 1 then this indicated that there was some degree of dysmorphology. For input into SPSS, numerical values were applied as follows:

1= Dysmorphology recorded

2= No dysmorphology recorded

In the PROMS questionnaire, the patients were asked to rank how satisfied they were with their facial appearance. Answers included Very Dissatisfied, Dissatisfied, Satisfied, Very Satisfied. Patients who answered either 'Dissatisfied' or 'Very Dissatisfied' were deemed to have some aesthetic concern regarding their appearance. For statistical analysis the following numerical values were applied,

1= Facial concern reported by patient (Answered either dissatisfied or very dissatisfied)

2= No facial concern reported by patient (Answered satisfied or very satisfied).

(2). Patients' satisfaction with pre-treatment facial appearance and clinicians' perception of the severity of the facial dysmorphology pre-treatment.

Clinicians recorded their perception of the degree of dysmorphology on the Likert scales with answers ranging from 0-100. For statistical analysis, the answers were categorised as follows:

- Likert score 1-25 was given a score of 4 (very mild dysmorphology)
- Likert score 26-50 was given a score of 3 (mild dysmorphology)
- Likert score 51-75 was given a score of 2 (moderate dysmorphology)
- Likert score 76-100 was given a score of 1 (severe dysmorphology)

Patients were asked how satisfied they were with their facial appearance. Answers included: Very Dissatisfied, Dissatisfied, Satisfied, Very Satisfied. The following scoring was applied:

- Very dissatisfied was given a score of 1
- Dissatisfied was given a score of 2
- Satisfied was given a score of 3
- Very Satisfied was given a score of 4

Patient and clinician data was imputed to SPSS with each patient having two scores – (a) A score ranging from 1-4 from clinicians and (b) A score of ranging 1-4 from their self-reported answers.

A Chi-squared test was carried out between the two scales to assess the association.

(3) Patients' concerns pre-treatment and surgeons' indications for surgery pre-treatment (in terms of dysfunction).

A Chi-squared test was completed between (a) Surgeon reported dysfunction- yes or no, and (b) do patients have problems biting- yes or no.

The surgeon recorded within the QOMS form if there was dysfunction by scoring a line on an unmarked Likert Scale from 0-100. If the score was $\geq$ 1 then this indicated that there was some degree of dysfunction.

The patients answered on the PROMS tool if they had ever had problems biting and the answers ranged from 'Not Applicable' to '4' indicating that they were greatly bothered by it. Any score of 1,2,3, or 4 indicated that that the patient had a functional concern and 'yes' was entered to SPSS.

(4). Patients' pre-treatment concerns regarding chewing problems and clinicians' perception of severity of dysfunction pre-treatment.

The surgeons scoring on the range of 0-100 for dysfunction was converted into four categories as follows:

- Likert score 1-25 was given a score of 1 (very mild dysfunction)
- Likert score 26-50 was given a score of 2 (mild dysfunction)
- Likert score 51-75 was given a score of 3 (moderate dysfunction)
- Likert score 76-100 was given a score of 4 (severe dysfunction)

The patients' answer to the question 'I have problems chewing' were as follows:

- Not applicable – no score applied
- Score 1 'It bothers me a little'
- Score 2: 'it bothers me quite a lot
- Score 3: 'it bothers me, buts less that a lot'
- Score 4: 'It bothers me a lot'

Each patient had a score of 1-4 from both patients and clinicians regarding their baseline dysfunction and a Chi-squared and Fisher's exact test were carried out between the two variables.

(5). The perception of improvement in function from patients and clinicians one-year post-surgery.

- The pre-treatment and post-treatment Oral Function component of the OQOL questionnaire (/20) was converted to a percentage. The percentage change from pre- to post- treatment was calculated and entered into SPSS software. A reduction in percentage indicated an improvement in the patient's oral function.

- The clinicians' scoring of the patient's dysfunction on the range of 0-100 was also converted to percentages and the change from pre- to post-treatment was calculated. A reduction in the percentage indicated an improvement in the patient's oral function. This percentage change was entered into SPSS software.

- A Chi-squared test was carried out between the two percentage changes to ascertain if there was any association between the two.

(6). The perception of improvement in facial aesthetics from patients and clinicians one-year post surgery.

- The pre-treatment and post-treatment Facial Aesthetics component of the OQOL questionnaire (/20) was converted to a percentage. The percentage change from pre- to post- treatment was calculated and entered into SPSS software. A reduction in percentage indicated an improvement in the patient's facial aesthetics

- The clinicians scores for the patient's facial appearance on the range from 0-100 were also converted to percentages and the change from pre- to post- treatment was calculated. A reduction in the percentage indicated an improvement in the patient's overall facial aesthetics. This percentage change was imputed to SPSS software.

- A Chi-squared test was carried out between the two derived percentages to ascertain if there was any association between them.

Chapter 5 Results

5.1 Participant Flow-Chart

The participant flow-chart is outlined in Figure 5-1.

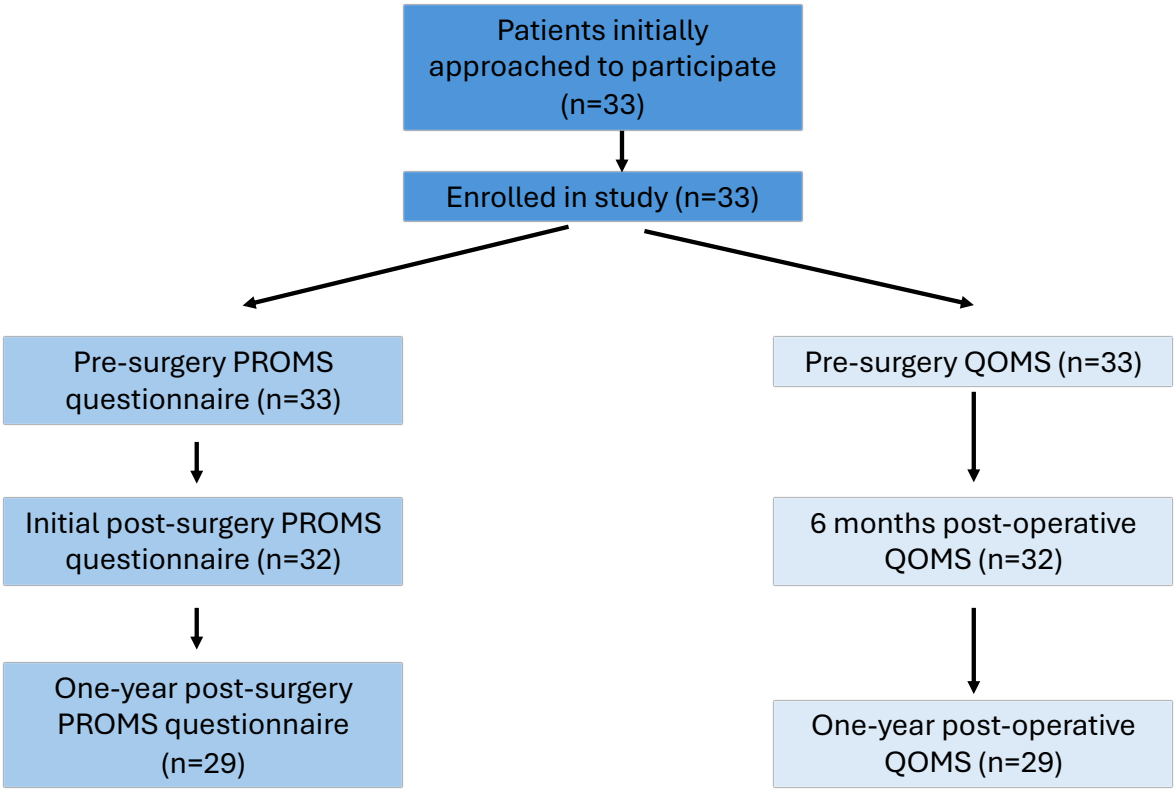

Figure 5-1 Participant Flow-Chart

5.2 Participant Baseline Characteristics

33 patients initially agreed to participate and were recruited. Four patients failed to complete all questionnaires giving a dropout rate of 12.1%. One patient did not complete the four-eight-week post-operative questionnaire as he failed to attend his initial appointments following surgery. Baseline characteristics are given in Table 4.

All patients had orthodontic treatment carried out within Glasgow Dental Hospital and School and orthognathic surgery was carried out in the Queen Elizabeth University Hospital in Glasgow.

Patients recruited were eligible for orthognathic treatment with IOFTN of 4/5. The mean age of patients was 26.6 $\pm$ 9. 20 were female and 13 were male. Of a

total of 33 surgeries, 10 were a Le Fort I Osteotomy only, 9 were a Bilateral Sagittal Split Mandibular Osteotomy, 14 were Bimaxillary procedures.

Baseline characteristic	Total (n=33)
Age at time of surgery (Mean ± SD)	26.6 ± 9.0
Gender – Females (n, %)	20, 61.0%
Gender- Males (n, %)	13, 39.0%
Approach – Surgery First (n, %)	33, 100.0%
Approach- Conventional Orthodontics first (n, %)	0, 0.0%
Surgery- Bilateral Sagittal Split Osteotomy only (n, %)	10, 30.0%
Surgery- Le Fort I Osteotomy only (n, %)	9, 27.0%
Surgery- Bimaxillary osteotomy (n, %)	14, 43.0 %

Table 4 Baseline Characteristics

The patient's initial complaint and the pre-treatment facial characteristics are outlined in Table 5.

Baseline Presentation	Total (n=33)
Patient's complaint- dysmorphology (n, %)	11, 33.3%
Patient's complaint- dysfunction (n, %)	7, 21.2%
Patient's complaint- dysmorphology and dysfunction (n, %)	15, 45.5%
Maxilla- Normal (n, %)	9, 27.3%
Maxilla- Hypoplastic. Retrognathic (n, %)	18, 54.5%
Maxilla- Prognathism (n, %)	4, 12.2%
Maxilla- Vertical Deficiency (n, %)	0, 0.0%
Maxilla-Vertical Excess (n, %)	1, 3.0%
Maxilla- Asymmetry: (n, %)	0, 0.0%
Maxilla- AOB (n, %)	1, 3.0%
Mandible- Normal	9, 27.3%
Mandible- Prognathism	10, 30.5%
Mandible- Retrognathism:	13, 39.6%
Mandible- Hemi-mandibular elongation	1, 2.6%
Mandible- Hemifacial Microsomia	0, 0%

Chin- Normal	25, 75.8%
Chin- Progenic	0, 0.0%
Chin- Retrogenic	5, 15.2%
Chin- Vertical excess	0, 0.0%
Chin-Deficiency	0, 0.0%
Chin-Asymmetry	3, 9.0%
Condyle- Normal	32, 97.0%
Condyle- Resorption	0, 0.0%
Condyle- Hyperplasia	0, 0.0%
Condyle- Atrophy	0, 0.0%
Condyle- Vertical Excess	0, 0.0%
Condyle- Deficiency	0, 0.0%
Condyle- Asymmetry	1, 3.0%

Table 5 Baseline Pre-Treatment Presentation

Table 3 illustrates that most patients' initial complaint was both dysmorphology and dysfunction (15 out of 33), with 11 reporting only dysmorphology seven only reporting dysfunction.Most patients (18) had a hypoplastic maxilla and 13 had a retrognathic mandible. All patients other than one had normal condyles.

5.3 PROMS

5.3.1 Satisfaction with Facial and Dental Appearance

Patients' satisfaction with facial and dental appearance pre- and post-treatment at four-eight weeks and one year are illustrated in Table 6 and Table 7.

	Very Dissatisfied (n, %)	Dissatisfied (n, %)	Satisfied (n, %)	Very Satisfied (n, %)
Pre-surgery (n=33)	3, 9%	22, 67%	7, 21%	1, 3%
Four-Eight weeks following surgery (n=32)	0, 0%	5, 16%	22, 68%	5, 16%
One year following surgery (n=29)	0, 0%	0, 0%	14, 48%	15, 52%

Table 6 Change in Satisfaction with Facial Appearance

Patients' satisfaction with their facial appearance was initially low with 25 of 33 patients answering either 'Very Dissatisfied' or 'Dissatisfied'. The number of patients dissatisfied with their facial appearance reduced to 5 in initial post-operative period. One year following orthognathic surgery, it reduced further to 0. All 29 patients one-year post-surgery were either 'Satisfied' or 'Very Satisfied' with their facial appearance.

	Very Dissatisfied (n, %)	Dissatisfied (n, %)	Satisfied (n, %)	Very Satisfied (n, %)
Pre-surgery (n=33)	14, 43.0%	15, 45.0%	4, 12.0%	0, 0.0%
Four-Eight weeks following surgery (n=32)	0, 0.0%	6, 19.0%	21, 65.0%	5, 16.0%
One year following surgery (n=29)	0, 0%	1, 3%	11, 38%	17, 59%

Table 7 Change in Satisfaction with Dental Appearance

29 patients were either very-dissatisfied or dissatisfied with their dental appearance pre-surgery. This reduced significantly to 6 patients in the initial post-operative period. One year following surgery, one patient was dissatisfied with their dental appearance and 28 were either satisfied or very satisfied.

	Yes (%)	No (%)
Pre-operative, do you have any numbness? (n=33)	1, 3.0%	32, 97.0%
Four-Eight weeks post-operative- do you have any numbness? (n=32)	28, 88.0%	4, 12.0%
One-year post-operative do you have any numbness? (n=29)	14, 48%	15, 52%

Table 8 Presence of Numbness Pre- and Post-Operatively

	Not Applicable (%)	Not at all (%)	A little (%)	A lot (%)
Pre-operative- How much does the numbness concern you? (n=33)	32, 97.0%	0, 0.0%	1, 3.0%	0, 0.0%
Four-Eight weeks post-operative -How much does the numbness concern you? (n=32)	4, 13.0%	1, 3.0%	15, 47.0%	12, 37.0%
One-year post-operative -How much does the numbness concern you? (n=29)	17, 59.0%	0, 0.0%	5, 17.0%	7, 24.0%

Table 9 How Much Numbness Concerns Patients

The number of patients with pre- and post-operative numbness and the extent to which it bothered them is shown in Table 8 and Table 9. One patient had pre-operative numbness and 28 had numbness in the initial post-operative period. Of the 28, 12 were bothered a lot by it, 15 were a little bothered and one was not bothered. 14 patients had numbness one-year following surgery and 5 were bothered a little by it and 7 were bothered a lot by it.

5.3.2 Orthognathic Quality of Life Questionnaire Scores

Table 10 and Table 11 outline the subscales and summary scores for the Orthognathic Quality of Life Questionnaire pre- and post- surgery

The Orthognathic Quality of Life Questionnaire is the first section in PROMS and consists of 22 questions. Answers include N/A which means that the issue covered by the statement does not bother the patient, 1 means that the issue bothers the patient a little, 2&3 lie between a little and a lot and 4 means that the issue covered in the statement bothers the patient a lot. The questionnaire is scored from 0-88 with a higher score indicating a greater negative impact on quality of life.

The pre- and post-treatment OQOL scores around outlined in the tables below.

Pre- treatment Results for OQoL (n=33)

Orthognathic Quality of Life Measure	Lowest Score	Highest Score	Median	Mean	Standard Deviation
OQoL Social Aspects of Deformity (/32)	0.0	29.0	12.0	13.0	6.9
QOoL Oral Function (/20)	0.0	19.0	11.0	9.9	5.5
OQoL Facial Aesthetics (/20)	0.0	20.0	10.0	8.9	6.1
OQoL Awareness of Deformity (/16)	0.0	16.0	8.0	8.9	5.2
OQoL total score (/88)	**0.0**	**77.0**	**42.0**	**40.4**	**21.1**

Table 10 Pre-Treatment OQOL Scores

The baseline OQOL questionnaires indicated significant impairment across all four domains. The total score (out of a maximum of 88) ranged from 0-77 with a mean of 40.4 (SD = 21.1) and median of 42.0 indicating huge variability in the pre-treatment overall quality of life.

Initial post-treatment results for OQoL (n=32)

Orthognathic Quality of Life Measure	Minimum score	Maximum Score	Median	Mean	Standard Deviation
OQoL Social Aspects of Deformity (/32)	0.0	29.0	14.0	14.0	8.5
QOoL Oral Function (/20)	0.0	15.0	8.0	7.8	4.3
OQoL Facial Aesthetics (/20)	0.0	17.0	6.0	7.0	4.5
OQoL Awareness of Deformity (/16)	0.0	16.0	7.0	7.2	3.9
OQoL total score (/88)	**1.0**	**73.0**	**37.0**	**36.1**	**18.9**

Table 11 Initial Post-Treatment OQOL of Scores (Four-Eight Weeks Post-Surgery)

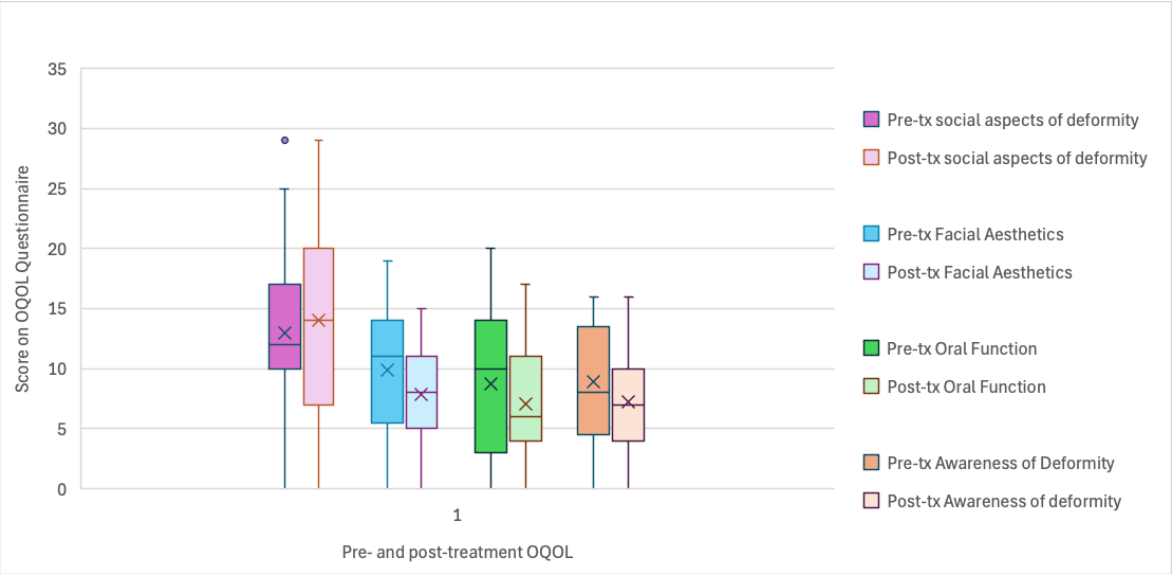

Figure 5-2 Box-Whisker Plot Showing the Pre- and Four-Eight Weeks Post-Treatment OQOL Scores

The pre-treatment and initial post-treatment OQOL are depicted in Figure 5-2 and the comparison shows significant improvements across most domains. The total OQoL mean score reduced from 42.0 to 37.0, indicating an overall improvement in quality of life in the initial post-operative period. Significant reductions in scores were observed in the Awareness of Deformity (from a mean of 8.9 to 7.2), Facial Aesthetics (8.9 to 7.0), and Oral Function (9.9 to 7.8) domains, reflecting positive changes in appearance and function post-surgery.

In the ‘Social Aspects of Deformity’ section, the mean increased from 13.0 to 14.0.

One-Year Post- Treatment Results for OQoL (n=29)

Orthognathic Quality of Life Measure	Lowest Score	Highest Score	Median	Mean	Standard Deviation
OQoL Social Aspects of Deformity (/32)	0.0	22.0	5.5	7.5	6.5
QOoL Oral Function (/20)	0.0	23.0	5.0	4.2	3.8
OQoL Facial Aesthetics (/20)	0.0	12.0	5.0	4.2	3.9
OQoL Awareness of Deformity (/16)	0.0	11.0	4.0	4.0	3.5
OQoL total score (/88)	**0.0**	**57.0**	**20.5**	**20.0**	**16.5**

Table 12 One-Year Post-Operative OQOL Scores

5.3.3 Change in OQOL Scores

The change in mean scores for the domains assessed in the OQOL were assessed and are shown in Table 13.

	Pre-treatment (n=33)	Four-eight weeks post-op (n=32)	One-year post-op (n=29)
Social Aspects of Deformity	13.0	14.0	7.5
Facial Aesthetics	8.9	7.8	4.2
Oral Function	9.9	7.0	4.2
Awareness of deformity	8.9	7.2	4.0
Total OQOL Score	40.4	36.1	20.0

Table 13 Change in Mean OQOL Scores

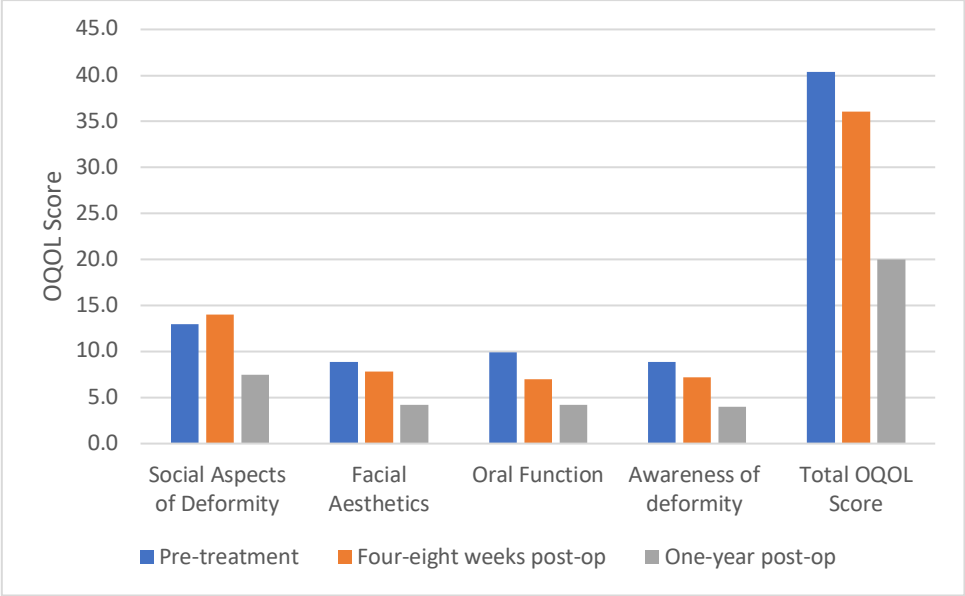

Figure 5-3 Chart Showing the Change in Mean OQOL Scores

The change in OQOL scores has improved across all domains from pre-treatment to one-year post-operatively (Figure 5-3 and Figure 5-4). The total OQOL mean score reduced significantly from 40.5 pre-treatment to 20.0 one year following surgery.

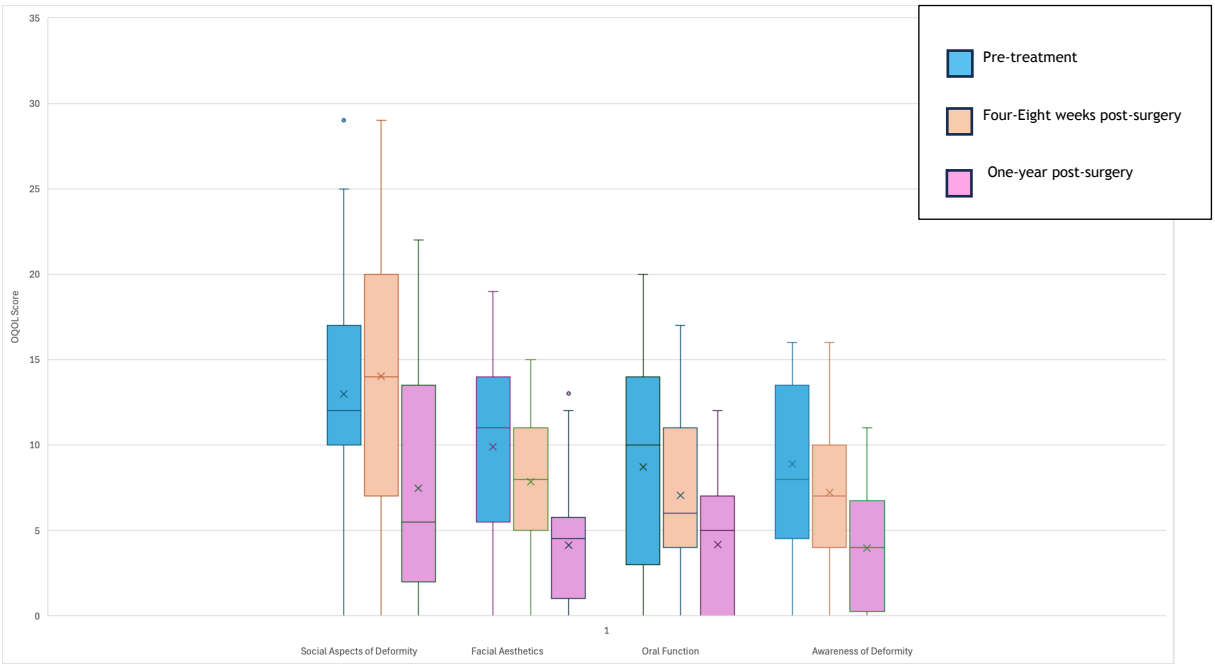

Figure 5-4 Box and Whisker Plot Showing Change in OQOL Scores

The overall OQOL scores were assessed on an individual bases from pre-treatment to one-year post treatment. Out of the 29 which were analysed at one-year follow-up, 26 overall OQOL trended down from pre—treatment to one-year post surgery. One remained the same (baseline score was low) and two patients had a slight upward trend.

5.4 QOMS

Clinicians were asked to score the following on Likert Scales (0-100) at three time-points- (1) pre-treatment, (2) six months post-surgery and (3) one-year post-surgery:

- Dysfunction
- Rate of psychological deficit
- Dysmorphology
- Diagnosis of DFD
- Impact on quality of life

The descriptive statistics for this are given in Table 14 and illustrated in Figure 5-5.

5.4.1 QOMS Pre-Treatment Likert Scales

	Lowest Score	Highest Score	Mean	Standard Deviation	Median	Interquartile range
Rate of dysfunction	7.0	98.0	55.7	22.1	57.0	22.0
Rate of psychological deficit	12.0	85.0	41.2	22.5	49.0	38.0
Rate of dysmorphology	13.0	83.0	52.7	19.2	59.0	32.0
Diagnosis of dentofacial deformity	24.0	88.0	55.5	15.8	58.0	14.0
Impact on quality-of-life	11.0	70.0	48.2	16.5	53.0	20.0

Table 14 Descriptive Statistics for Pre-treatment QOMS Likert Scales (n=33)

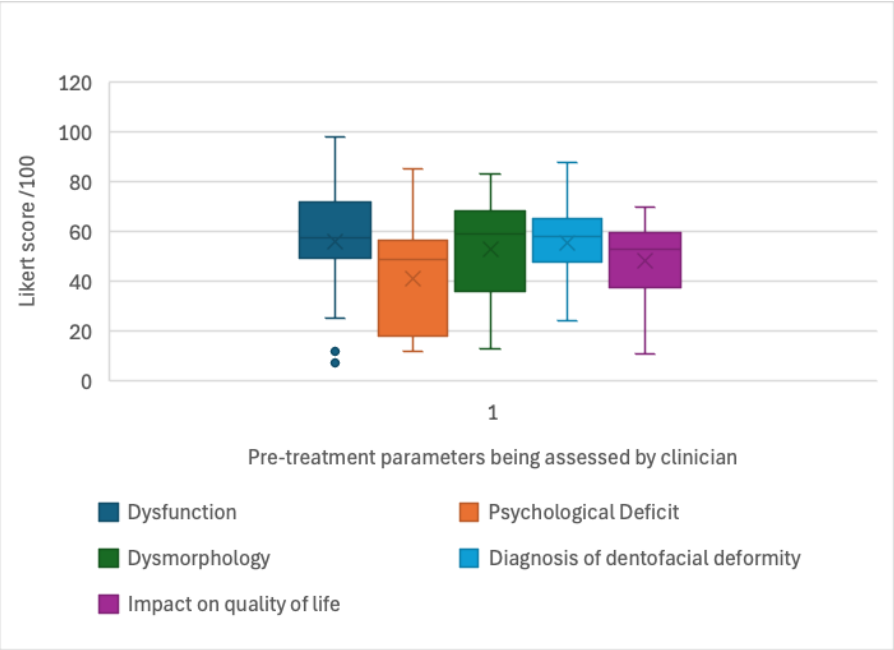

Figure 5-5 Box and Whisker Showing Pre-Treatment QOMS Scores

5.4.2 QOMS Post-Treatment Likert Scales

The six-months post-treatment Likert scales are illustrated in Table 15 and Figure 5-6.

	Lowest Score	Highest Score	Mean	Standard Deviation	Median	Interquartile range
Rate of dysfunction	0	70.0	16.1	17.9	9.5	14.5
Rate of psychological deficit	0	69.0	8.8	11.8	7.0	5.0
Rate of dysmorphology	0	41.0	9.2	8.6	7.0	6.0
Diagnosis of dentofacial deformity	0	42.0	8.9	8.5	6.0	5.0
Impact on quality-of-life	0	55.0	7.9	9.3	6.0	3.5

Table 15 Six Months Post-Treatment QOMS Likert Scale Values (n=32)

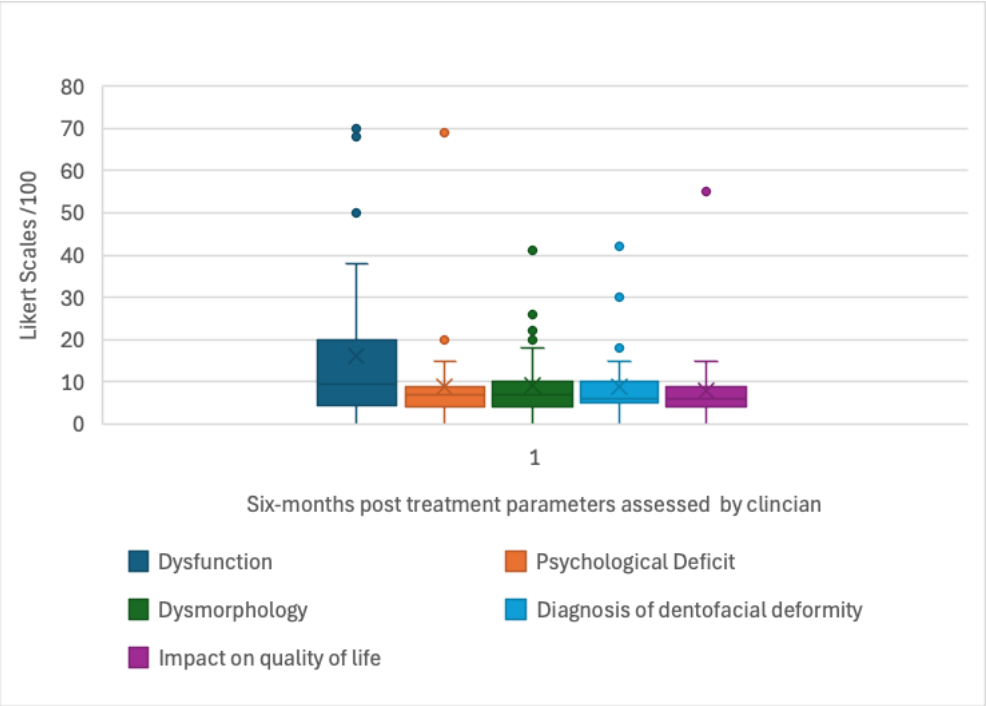

Figure 5-6 Box and Whisker Showing Six-Months Post-Treatment QOMS Scores

The one-year post-operative QOMS score are illustrated in Table 16.

	Minimum Score	Maximum Score	Mean	Standard Deviation	Median	Interquartile range
Rate of dysfunction	0	50	11.5	12.4	7.0	11.0
Rate of psychological deficit	0	50	8.3	9.5	5.0	7.0
Rate of dysmorphology	0	50	7.7	9.4	5.0	5.0
Diagnosis of dentofacial deformity	0	30	6.9	6.2	5.0	4.0
Impact on quality-of-life	0	50	9.4	12.3	5.0	4.0

Table 16 One-Year post-operative QOMS Likert Scale Values (n=29)

The change in QOMS Likert scales are illustrated in Figure 5-7.

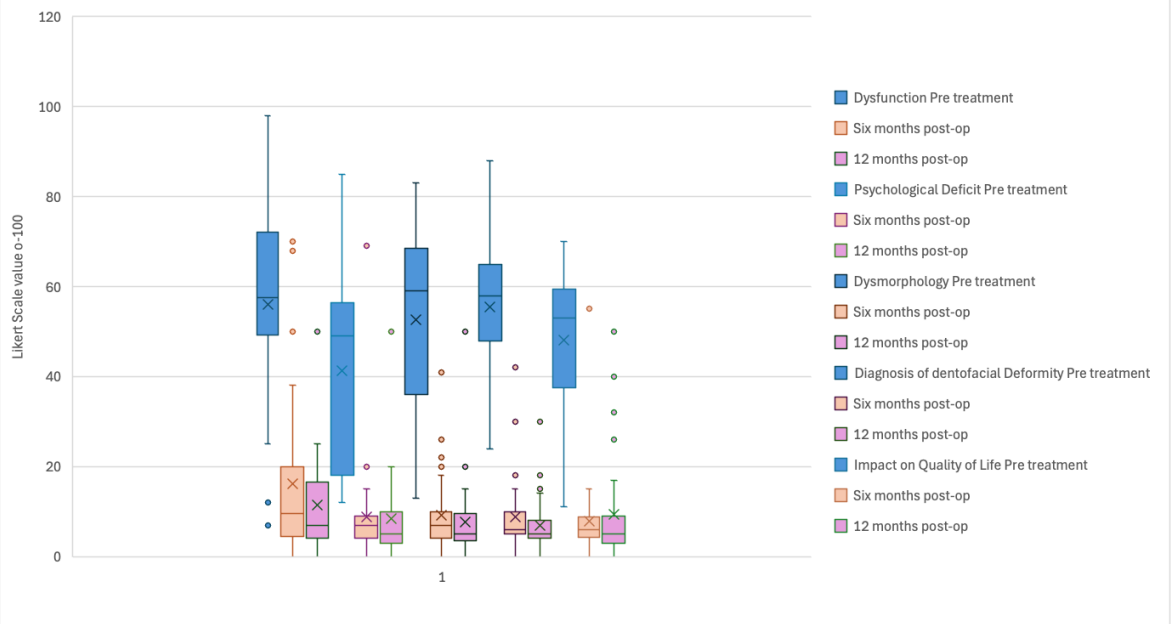

Figure 5-7 Box and Whisker Plot Showing Changes in QOMS Likert Scales

5.5 Readmission and Return to Theatre

The Return to Theatre (RTT) for this cohort was 6.0% (two patients).

30 days RTT:

- One patient required a second surgical procedure for adjustment of the osteotomy segment.

90 days RTT:

- None.

6 months RTT:

- One patient required removal of infected plate

One-year RTT:

- None.

Despite requiring a second surgical procedure, the OQOL scores for the two patients still reduced from baseline to post-operatively indicating that returning to theatre did not affect the post-operative quality of life.

5.6 Association

Our secondary objective was to disclose agreements and potential disparities between the data collected from the two questionnaires, which included the following parameters:

(i) Patients' concern and clinicians' indication for treatment (in terms of aesthetics) pre-treatment.

(ii) Patients' concern and clinicians' indication for treatment (in terms of dysfunction) pre-treatment.

(iii) Patients' satisfaction with facial appearance and the severity of the dysmorphology recorded by clinicians pre-treatment.

(iv) Patient self-reported chewing problems and the severity of dysfunction recorded by clinicians pre-treatment.

(v) The direction of improvement in function from patients and clinicians from pre-treatment to one-year post-surgery.

(vi) The direction of improvement in facial aesthetics from patients and clinicians from pre-treatment to one-year post-surgery. See section 4.11 for methodology.

Cross tabulations have been included for the following:

- Agreement between Patients' Satisfaction with Facial Appearance and Clinicians' Perception of the Severity of the Facial Dysmorphology.
- Agreement between Patients' Concerns Regarding Chewing Problems and Clinicians' Perception of Severity of Dysfunction.
- Relationship between the Perception of Improvement in Function from Patients and Clinicians.
- Relationship between the Perception of Improvement in Facial Aesthetics from Patients and Clinicians.

5.6.1 Agreement Between Patients' Concerns and Surgeons' Indications for Treatment (in Terms of Aesthetics) Pre-Treatment

A Chi squared test between (i) surgeon reported dysmorphology: yes or no. (ii) are patients currently satisfied with their facial appearance- yes or no (see Table 17).

	Value	df	Sig. (2-sided)
Pearson Chi-squared	12.682	1	<0.001
Fisher's exact	-	-	0.007

Linear-by Linear Association	12.298	1	<0.001

Table 17 Chi-Squared Test and Fisher's Exact to Assess the Agreement in Indication for Surgery (Dysmorphology) between Patients and Surgeons (n=33)

The Pearson Chi-squared value = 12.68, $p < .001$, is highly significant and indicates that there is a significant relationship between the patients' concern about their facial appearance, and the surgeons' perception of dysmorphology The Fisher's exact test ($p = .007$,) is still significant, which confirms this agreement between the two groups. The Linear-by-Linear Association test showed a significant linear relationship between patients' and surgeons' responses.

5.6.2 Agreement Between Patients' Satisfaction with Facial Appearance and Clinicians' Perception of the Severity of the Facial Dysmorphology Pre-Treatment

The surgeons dysmorphology scores (0-100) were converted into four categories as follows:

- Likert score 1-25 was given a score of 4 (very mild dysmorphology)
- Likert score 26-50 was given a score of 3 (mild dysmorphology)
- Likert score 51-75 was given a score of 2 (moderate dysmorphology)
- Likert score 76-100 was given a score of 1 (severe dysmorphology)

The patients' satisfaction with their facial appearance was ranked as follows:

- Very dissatisfied was given a score of 1
- Dissatisfied was given a score of 2
- Satisfied was given a score of 3
- Very Satisfied was given a score of 4

i.e., a higher Likert score indicated greater dysmorphology and this was assigned a lower ranking on the 1-4 scale. Patients answering 'very dissatisfied' were assigned a score of 1. This ensured that on the two scales, lower scores indicated more severe dysmorphology and greater dissatisfaction respectively.

The cross tabulation is given in Table 18 and the association is illustrated in Table 19.

	Dysmorphology severity recorded by clinicians				
Patient Satisfaction	Severe	Moderate	Mild	Very Mild	Total
Very Dissatisfied	0	0	0	1	1
Dissatisfied	0	2	2	3	7
Satisfied	4	13	3	2	22
Very Satisfied	0	2	1	0	3
Total	4	17	6	6	33

Table 18 Crosstabulation of Patients Baseline Satisfaction with Facial Appearance and Clinicians Dysmorphology Scores

Test	**Value**	**df**	**Sig. (2-sided)**
Pearson Chi-squared	12.407	9	0.191
Likelihood Ratio	12.560	9	0.184
Fisher-Freeman=Halton exact Test	-	-	0.169
Linear-by-Linear Association	6.314	1	0.012
N of Valid cases	33		

Table 19 Association Between Patients Baseline Satisfaction with Facial Appearance and Surgeons Dysmorphology Score

The relationship between patients' satisfaction with their facial appearance and the severity of their dysmorphology scored by clinicians was not statistically significant ($p>0.05$). The Linear-by-Linear association assesses the trend between the two which suggests that there is a significant linear trend – as clinicians dysmorphology rating increases, patient satisfaction decreases ($p=0.012$). However, as the minimum expected count is only 0.12 and 93.8% of cells have expected counts of <5 this violates one of the key assumptions of the Chi- squared test.

Overall, these findings suggests that there is general alignment between clinician dysmorphology ratings and patients' satisfaction with facial appearance, however due to the very small sample size and low expected cell counts, the results should be interpreted with caution.

5.6.3 Agreement Between Patients' Concerns Regarding Chewing Problems and Clinicians' Perception of Severity of Dysfunction Pre-Treatment

The surgeons scoring of dysfunctions 0-100 was converted into four categories as follows:

- Likert score 1-25 was given a score of 1 (very mild dysfunction)
- Likert score 26-50 was given a score of 2 (mild dysfunction)
- Likert score 51-75 was given a score of 3 (moderate dysfunction)
- Likert score 76-100 was given a score of 4 (severe dysfunction)

The patients' answer to the question 'I have problems chewing' were as follows:

- Not applicable – no score applied
- Score 1 'It bothers me a little'
- Score 2: 'it bothers me quite a lot
- Score 3: 'it bothers me, buts less that a lot'

- Score 4: ‘It bothers me a lot’

A higher dysfunction score from clinicians indicated that they perceived the patient to have more chewing problems. A higher score on the patient scale indicated that they were bothered significantly by chewing problems. The cross tabulation is given Table 20.

	Dysfunction Severity				
Satisfaction	Very Mild Dysfunction	Mild Dysfunction	Moderate Dysfunction	Severe Dysfunction	Total
Bothers the patient a little	1	1	3	1	6
Bothers the patient more than a little	2	1	3	2	8
Bothers the patient quite a lot	0	1	4	1	6
Bothers the patient a lot	1	2	3	1	7
Total	4	5	13	5	27

Table 20 Crosstabulation of Patients Self-Reported Chewing Problems with Clinicians’ Dysfunction Scores

Test	Value	df	Sig. (2-sided)
Pearson Chi-squared	2.957	9	0.985
Likelihood Ratio	3.657	9	0.932
Fisher-Freeman=Halton exact Test	3.753	-	0.169
Linear-by-Linear Association	0.001	1	0.978
N of Valid cases	27		

Table 21 Association Between Patients Baseline Self-Reported Chewing Problems and Surgeons' Dysfunction Scores

The number of valid cases for assessing the association between the clinician scoring of dysfunctions and the patients self-reported chewing problems was 27 as six patients answered, 'Not Applicable' and therefore could not be included within this analysis (see Table 21).

There is no statistically significant relationship between clinician's dysfunction scores and patient-reported chewing problems (p=0.985). As all cells, have expected less counts of less than five, this violates one of the Chi-squared assumptions and it is unlikely that this statistical test is reliable. The Linear-by-Linear association also indicates that there is no consistent pattern between the two measures (p=0.978).

Due to the few valid cases included within this analysis (n=27), it indicates that no association could be detected in this small sample however ideally should be repeated with a larger sample size.

5.6.4 Agreement Between Patients' Concerns and Surgeons' Indications for Treatment (in Terms of Dysfunction) Pre-Treatment

A Chi-squared test was carried out to assess the association between (i) Surgeon reporting dysfunction as an indication for surgery (yes or no) and (ii) patients having problems with biting (yes or no) (Table 22).

	Value	df	Sig. (2-sided)
Pearson Chi-squared	5.215	1	<0.001
Fisher's exact	-	-	0.078
Linear-by Linear Association	5.057	1	<0.025

Table 22 Chi-Squared Test to Assess the Agreement in Indication for Surgery (Dysfunction) Between Patients and Surgeons (n=33)

There is a statistically significant association between the two variables (at the 0.05 level). The Pearson Chi-squared = 5.215, df = 1, p <0.001, indicates statistical significance. However, 50% of cells have expected counts less than five which means that the data is sparse (some response combinations are rare) and this violates one of the assumptions of the Chi-squared test, which can make the p-value less reliable. Therefore, Fisher's exact test, was used which is more reliable for smaller samples. The p value from the Fisher's exact Test was 0.078, which is not significant at the .05 level. The Linear-by-Linear Association test supported the presence of a significant linear relationship between patients' and surgeons' responses.

In summary, a Chi-squared test showed an association between patient and surgeons reporting that dysfunction was an indication for surgery, x^2 (1, N=33) = 5.22, p <0.001. However, Fisher's exact Test was also considered (p = .078) and this suggested that the association did not reach statistical significance when a small sample size was accounted for.

5.6.5 Relationship Between the Perception of Improvement in Function from Patients and Clinicians One-Year Post Surgery

The percentage change in oral function scores (from pre-to one-year post-treatment) were calculated for both clinician and patients. A percentage reduction indicates an improvement in oral function, and this was imputed as a "yes" to SPSS. If the percentage increased from pre-to-post treatment, this indicates a reduction in oral function and was imputed as a "no".

Numerical values were assigned to allow statistical analysis. 'Yes' was represented by 1.0 and 'No' was indicated by 2.0. The cross tabulation is outlined in Table 23.

Was there improvement in function following OGS?

	Clinician: Yes	Clinician: No	Total
Patient: Yes	21	6	27
Patient: No	0	2	2
Total	21	8	29

Table 23 Cross Tabulation: Improvement in Function Following OGS n=29

The results indicate that 21 out of 27 patients who felt that OGS improved their function, was also rated as improved by the clinician. Six patients reported functional improvement, but the clinician did not agree. Two patients answered that there was no improvement and the clinician also rated them as no improvement. Overall, there is a strong tendency for both groups to agree.

	Value	df	Sig. (2-sided)
Pearson Chi-squared	15.651	2	<0.001
Fisher-Freeman Halton exact	-	-	0.017
Linear-by-Linear Association	-	1	<0.001

Table 24 Chi-Squared and Fishers Exact test for Improvement in Function n=29

The Pearson Chi-squared test showed that there was strong agreement between clinician and patient assessments of functional improvement ($p < 0.001$). However, 66.7% had expected cell counts of <5 which violates one of the assumptions of the Chi-squared tests. Therefore, a Fishers exact test was used which also indicates there was a statistically significant association between the two groups for functional improvement following SFA OGS (Table 24).

5.6.6 Relationship Between the Perception of Improvement in Facial Aesthetics from Patients and Clinicians One-Year Post Surgery

The percentage change in facial aesthetics scores (from pre-to post- treatment) were calculated for both clinician and patients. A percentage reduction indicates an improvement in facial appearance, and this was imputed as a "yes" to SPSS. If the percentage increased from pre-to-post treatment, this indicated worsening of facial aesthetics and was imputed as a "no".

Numerical values were assigned to allow statistical analysis. 'Yes' was represented by 1.0 and 'No' was indicated by 2.0. The cross tabulation is outlined in Table 25.

	Was there improvement in facial aesthetics following OGS?		
	Clinician: Yes	Clinician: No	Total
Patient: Yes	28	0	28
Patient: No	1	0	1
Total	29	0	29

Table 25 Cross Tabulation: Improvement in Facial Aesthetics Following OGS n=29

The clinicians felt that all patients had some degree of improvement in facial aesthetics following OGS. One patient felt that there was no improvement and the clinician disagreed. This shows that there is very strong agreement between clinicians and patients about facial aesthetic improvement following OGS.

	Value	df	Sig. (2-sided)
Pearson Chi-squared	13.982	1	<0.001
Fisher's exact	-	-	0.069
Linear-by-Linear Association	-	1	<0.001

Table 26 Chi-Squared and Fishers Exact Test for Improvement in Facial Aesthetics n=29

The Pearson Chi-squared test is significant ($p < 0.001$), suggesting a strong association between patient and clinician ratings of aesthetic improvement. However, 75% of cells have expected counts less than 5, which violates the Chi-squared assumption. The Fisher's exact test ($p = 0.069$) is more appropriate for small sample sizes and low cell counts and this is not significant at the 0.05 level. It does, however, indicate a trend toward significance. The Linear-by-Linear Association ($p<0.001$) suggests a constant directional relationship that patients and clinicians agree in their assessments (Table 26).

Chapter 6 Discussion and Conclusions

6.1 Discussion

The aim of this study was to assess the quality of care and the patient-reported outcomes of the surgery-first approach to orthognathic treatment, using the PROMS and QOMS questionnaires. A secondary objective was the evaluation of the relationship between the data derived from the two questionnaires. Understanding if there is a relationship between PROMS and QOMS will help improve future care for orthognathic patients in allowing clinicians to understand if their clinical observations are aligned with the patient's views.

Various PROM tools have been used within OGS for several years and provide information on patients' quality of life, self-perception, and interaction in society. The QOMS questionnaire measures the complication rates, and aspects of the DFD from a clinician perspective. Both PROMS and QOMS share a common objective of assessing the quality of treatment and, when the two tools are analysed, this ensures standardised delivery of orthognathic care to meet both patients' and clinicians' expectations (Ashford et al. 2015; Bily et al. 2022).

Understanding the relationship between PROMS and QOMS will allow clinicians to have a comprehensive understanding of what matters to patients. This will guide discussions during the consent process to help patients make informed decisions. It will help clinicians tailor discussions, treatment plans, and interventions to meet the individual needs of patients. It will also provide information for those involved in developing PROMS and QOMS tools in ascertaining if the questionnaires accurately capture both clinician and patient-reported data.

6.2 Study Design and Subject Selection

This longitudinal prospective study is based on validated questionnaires, which were developed specifically to record outcome measures of orthognathic treatment. Although the prevalence of dentofacial deformities amenable to OGS is generally low (approximately 5% in UK/ USA populations) (Posnick 2014b), due to strict referral criteria in GDH and an established orthognathic service within NHS GGC, prospective data collection was possible in this study. This allowed

the data collection at specific time points (Song and Chung 2010) and reduced recall bias. (Talari and Goyal 2020).

The subject selection process outlines that patients with craniofacial syndromes were excluded from this study. Patients with craniofacial syndromes may have additional facial features unrelated to the DFD which are not corrected with orthognathic surgery and therefore would have introduced variance within our sample.

Patients who had previously had OGS were also excluded. Re-do OGS is often a more extensive operation in terms of technical challenges due to scarring and the position of bone fragments (Reyneke 2011b). Primary OGS usually aims to improve sagittal skeletal disproportions, whereas repeat orthognathic surgery is often required to correct asymmetry, relapse, unacceptable aesthetic outcomes, Obstructive Sleep Apnoea (OSA) and malposition within the maxilla and/ or mandible following the initial surgery, (Choi et al., 2023; Wu et al., 2019). The baseline data for patients having repeat OGS would therefore be difficult to compare with those having primary surgery and by only including those having surgery for the first time, this ensures a homogenous initial baseline data sample. Therefore, patients who have previously had an orthognathic surgical procedure before the start of the present study were excluded however, patients who returned to theatre (RTT) following their initial surgery who had already been included, continued to be included within the study.

The British Orthodontic Society has suggested, based on a national audit in 2017-18, that 100% of all patients receiving NHS funded orthognathic treatment should score an IOFTN score of a 4 or 5 unless there is justified psychological reasons or other diagnoses not captured within the IOFTN i.e. OSA (Ireland et al. 2019) and this was therefore defined within the inclusion criteria

6.3 Questionnaires

6.3.1 Quality Outcomes in Oral and Maxillofacial Surgery (QOMS)

The orthognathic QOMS questionnaire uses a variety of question styles including multiple choice, free text, and Visual Analogue Scales (VAS). It is out with the scope of this section to detail the pros and cons of all question styles used within

the questionnaire. However, as the Visual Analogue Scales have been used extensively and questions using the VAS have been analysed within our results, this will be discussed in more detail.

Hayes and Patterson reported that VAS, which has also been referred to as the graphic rating method, allows the rater to 'make as fine a discrimination of merit as he chooses' (Hayes and Patterson 1921). Clinicians are asked to rate the following on a scale of 0-100 using the VAS: the patient's level of dysfunction, psychological deficit, dysmorphology, diagnosis of DFD, and impact of the deformity on quality of life. The VAS is a tool to measure and record subjective items which are scored on an unmarked line representing a continuum (Klimek et al. 2017). Data derived from VAS is regarded as scaled intervals i.e. intervals of the same size are interpreted as equal-sized differences. In contrast, categorical questions produce ordinal data which reflects a hierarchy. However, it is not possible to ascertain the differences between the two categories. The VAS used within this survey had no interval markings and it has been reported that unmarked VAS have greater accuracy and reduced inter- and intra-person variability when compared to scales that have interval markings (García-Pérez and Alcalá-Quintana 2022).

As discussed in the methodology, one designated person was responsible for conversion of the measurements from the VAS to a numerical value and imputed to REDCap. A potential issue may arise if the person was consistently wrong in doing this. Ideally, two people would have recruited to do this (duplicating the measurements) and assessing inter-rater variability.

6.3.2 Patient Reported Outcome Measures

The PROM questionnaires are currently being implemented as part of a national project by The British Orthodontic Society. The questionnaires were implemented in October 2023 and are based on previous validated outcome measure tools (BAOMS and BOS 2024). Section two of the post-operative PROM forms have been adapted from Body-Q; a validated questionnaire initially designed for assessing outcomes for weight-loss surgical procedures (Klassen, Cano, Alderman, et al., 2016).

The PROM questionnaire utilises Likert and ordinal scale responses. Likert scales are easy to use and interpret (Guyatt et al. 1987; Laerhoven et al. 2004) by both patients and clinicians. Dourado et al., confirmed this when comparing the opinions of orthodontists, lay people and OMFS surgeons in assessing facial appearance using Likert Scales and VAS. Approximately 75% of the examiners preferred the Likert scale as they felt that it represented their opinions accurately and found the tool easy to use. The two scales were shown to be substantially correlated and show similar results irrespective of the occupation or gender of the assessor (Dourado et al. 2021).

The answers from the PROM questionnaires range from 1-4, with a rating of 1 indicating that the issue covered in the statement bothers the patient only slightly, and 4 indicating that it bothers them greatly. It is a common finding that answers at the ends of Likert scales are typically chosen less than central choices, which causes an 'anchor effect' (Guilford 1954). If Likert scales are considered interval data, respondents may perceive the interval scales at the extreme ends (i.e. the lowest and highest ends) as further apart than the scales within the middle answers. This therefore suggests that Likert scale data cannot be considered as interval data and therefore do not meet the assumptions for parametric tests.

In our study, whilst PROMS used Likert scales to assess patient's self-consciousness, confidence, and satisfaction with their facial appearance, the VAS was used by clinicians within the QOMS questionnaire.

One of the problems associated with ordinal data is that non-parametric tests are usually more appropriate for statistical analysis. Non-parametric tests may lack power when compared to parametric tests (Hayes and Patterson 1921; Siegel and Castellan 1988). Non-parametric data assumes that the data is not normally distributed and may therefore be less likely to detect a statistically significant result. Despite these pitfalls, non-parametric tests were the most appropriate method to analyse the data produced by the questionnaires within this study. They allowed the categorical data to be analysed in its current format whereas, if a parametric test had been used, it would have required scores to be assigned to each category of answers with the assumption that the difference between categories is fixed (Whitley and Ball 2002).

6.4 Discussion of Results

6.4.1 Participant Baseline Characteristics

This study initially involved 33 participants, and the baseline characteristics are illustrated in Table 4. All patients who took part within this study had a diagnosis of DFD amenable to correction with SFA OGS. The percentage of surgery types is also reflective of other studies. Within this group, 10 underwent a BSSO (30%), nine had a Le Fort I Osteotomy, 14 (27%) had a Bimaxillary procedure (43%) and this is similar to other studies assessing orthognathic outcomes (Cirignaco et al. 2026).

The sample size calculation indicated that this study was adequately powered to detect only a large effect size (*w* value of 0.5) at 0.80 (80%) in the relationship between PROMS and QOMS data, with 31 patients being required.

Patients were recruited when their proposed date for surgery was within three months of the date of initial questionnaire completion. For a minority of patients whose surgery was not carried out on the planned day due to unforeseen circumstances (i.e., illness, cancelled theatre lists etc) the time between initial questionnaire completion and surgery-date may have been slightly longer than three months.

Twenty of the participants were female and this is consistent with other research which confirms that females may be more likely to seek orthognathic treatment than males (Bailey et al., 2001; Cunningham & Moles, 2009; Espeland et al., 2007). Eleven patients were in the 19-21 age category, which is similar to other cohort studies (Peacock et al. 2014).

6.4.2 Post-Operative PROMS Results

25 of 33 patients were ‘Very Dissatisfied’ and ‘Dissatisfied’ with their facial appearance initially. This reduced to five at four-eight weeks post-operatively and it reduced to zero at one-year post-surgery. All 29 patients who completed the one-year post-operative questionnaires were satisfied with their facial appearance following OGS which agrees with previous studies demonstrating patients’ improved self-perception following OGS (Alkaabi et al., 2025).

Patients were asked, within the OQOL questionnaire, whether they ever felt depressed regarding their appearance, and they were asked rate their answer on a Likert Scale from 'Not applicable', indicating no signs of depression, to a score of 4, indicating that they were bothered a lot by depression. In the pre-treatment questionnaire, 15 patients answered either 'Not Applicable' or 1, ten scored 2 and seven scored a 3/4. Post-operatively, there was a tendency for patients to score lower on this scale with 20 answering 'Not applicable' or 1, eight scoring 2 and four scoring 3/4. This indicates that, within our study, orthognathic treatment improved facial appearance, with minimal residual psychological deficit.

Analysis of the Orthognathic Quality of Life Questionnaire (OQOL) within the PROMS questionnaire showed that the mean overall OQOL scores reduced from 40.4 (baseline) to 36.1 (initial post-operative period). This improvement in quality of life has been demonstrated in other studies (Gabardo et al. 2019). However, at four to eight weeks following surgery, the 'Social Aspects of deformity' mean scores increased slightly from 13.0 to 14.0. Possible reasons for this deterioration are swelling/bruising, post-operative depression and psychological adjustment (Frost and Peterson 1991; NHS Tayside 2024; Zhou et al. 2024). This temporary deterioration in social interaction during the initial pre-operative period has also been shown by a previous study in a group of West of Scotland orthognathic patients (Finlay et al. 1995).

6.4.3 One Year Follow-up OQLQ Results

The one-year follow-up PROMS results confirmed that there was a reduction in scores for all domains in the OQLQ indicating an improvement in quality of life. The mean OQLQ score dropped from 40.5 (baseline) to 20.0 which is comparable to the findings of other studies. Sun et al. found that, in a group of Chinese orthognathic patients, the OQOL scores reduced from 40.4 $\pm$ 17.6 to 24.4 $\pm$ 13.6 five to seven months following surgery (Sun et al. 2018). Murphy et al. found a mean reduction in OQLQ scores from 36.9 to 25.6 six months following surgery (Murphy et al. 2011b).

Although the overall trend indicated a positive improvement for all domains assessed in the OQOL, the individual results indicate that for two patients, the total OQOL increased from pre-treatment to one-year post-surgery. The slight

upward trend observed in these two patients may be attributed to a mismatch between patient expectations and perceived outcomes, particularly in those primarily motivated by functional improvement rather than aesthetics. In these cases, there may be limited perceived aesthetic benefit following OGS. Additionally, post-operative sensory changes or difficulty adapting to facial changes may negatively influence OQOL scores. Additionally, low baseline scores may result in a 'floor effect', where minimal variation appears as a deterioration.

Our findings agree with those of a systematic review, which demonstrated that OGS significantly improves the quality-of-life for patients using both the OQLQ and OHIP-14 questionnaires (Alkaabi et al. 2025a). As our study demonstrated that there were improved scores for all domains within the OQLQ, it suggests that the benefits of OGS within this patient cohort were functional, social, psychological and aesthetic (De Araujo et al. 2020).

6.4.4 Readmission and Return to Theatre

Two patients returned to theatre (RTT rate 6.0%), which is comparable to others, who reported that 3.6% patients required an unexpected second procedure in a thirteen-year follow-up study with a plate-removal rate of 3.2% (Little et al. 2015; Little et al. 2021b).

For the patients who required RTT, the OQOL scores reduced post-operatively from baseline, indicating an improved QoL despite requiring an unplanned second surgical procedure. This may be, in part, because the two patients had high baseline OQOL scores (77/88, 52/88) and therefore, even with two surgeries, showed a positive overall post-operative trajectory. It is important to emphasise that patients were consented for the possibility of a second surgical procedure to deal with potential complications. Therefore, they were not unduly concerned at having to undergo further surgery. Moreover, the magnitude of improvement of facial appearance and oral function was marked, and the second procedure did not have any negative impact on the overall outcome.

6.4.5 Indications for Treatment; Agreement Between Surgeons and Patients

The Chi-squared test showed that surgeons and patients agreed that improvement in facial aesthetics was an indication for orthognathic surgery (Pearson's $x^2 = 12.68$, $p < 0.001$; Fisher's exact $p = 0.007$). This is reassuring, in that patients and surgeons share the same surgical objectives, and focused concerns, which can only improve confidence and minimise post-operative disagreements.

For improving function as an indication for surgery, a weaker non-statistically significant association was observed (Pearson's $x^2 = 5.22$, $p = 0.022$; Fisher's exact $p = 0.078$). While surgeons and patients often agreed about functional concerns, the significance level was weaker than for aesthetic motivations, and some discrepancy existed between patient self-reported functional problems and surgeons' assessment of functional indications for surgery. This may be due to the complex nature of assessing functional deficits and the lack of sensitive tools to evaluate this objectively.

The significant association in aesthetic motivations indicates clear alignment in the expectations of surgeons and patients, whereas the weaker relationship for functional reasons suggests some variations in their views of functional needs. This highlights that, whilst aesthetic goals are mutually understood, functional concerns may require clearer communication to ensure that both perceptions are aligned before a patient has OGS.

6.4.6 Association Between Severity of Clinician Reported Dysmorphology and Patient Satisfaction with Facial Appearance (Pre-Treatment)

Patients' satisfaction with their facial appearance were assessed in combination with the surgeons' perception of the dysmorphology pre-treatment. The cross tabulation indicated that most patients (22/33) were satisfied with their baseline facial appearance, whilst clinicians rated those same people (13/33) as having moderate dysmorphology. Very few patients were 'dissatisfied or 'very dissatisfied' with their facial appearance, although they were rated by clinicians as having moderate or severe dysmorphology. This may be due to the wide

variation in the perception of dysmorphology among patients and surgeons. It is also important to highlight that the psychological status of the patients has a clear impact on the perception of the facial appearance and the related dysmorphology.

The Linear-by-Linear Association confirmed that there was a significant trend for dysmorphology scores to increase, while patient satisfaction scores decreased. However, the individual scores indicated that clinicians were more critical of facial appearance than patients. These findings agree with the view that professionals with an orthodontic background are more critical of facial appearance (Monk et al. 2025).

The results indicated that, from the limited sample size, there was general alignment between the clinicians' dysmorphology scores and the patients' overall satisfaction with their facial appearance. However, a Chi-squared test showed the association between the two to be non-significant statistically.

6.4.7 Association Between Severity of Clinician Reported Dysfunction and Patients Self-Reported Chewing Problems (Pre-Treatment)

The cross tabulation for patient reported chewing problems and clinicians' assessment of dysfunction showed that there was a discrepancy between the two evaluations. While clinicians rated many patients as having mild-moderate dysfunction, patients often reported being bothered significantly by their chewing problems. Almost half of the patients (13/27) answered that they are bothered 'quite a lot' or 'a lot' about their chewing, but the clinicians only scored 5 patients out of 27 as having severe dysfunction. This suggests that patients perceive their level of functional impairment to be more severe than the clinicians.

The lack of relationship between the two may highlight that the multifactorial nature of mastication and patients' experience can be influenced by other factors such as social interaction which may not be fully captured by clinical evaluation alone. This may be due to the lack of universal sensitive instruments to measure functional impairment. Previous studies have highlighted similar discrepancies between clinician-assessments and patient-reported outcomes in

oral function, emphasizing that subjective patient experiences may encompass quality of life aspects that objective tools do not (Fan et al. 2021).

6.4.8 Association Between Surgeons and Patients in terms of Functional Improvement One-Year Following OGS

The cross-tabulation for the improvement of function at one-year post-surgery from patients' and surgeons' perspective showed that there was general agreement between the two groups regarding functional improvement following OGS. However, six patients reported improved function, when the clinician had recorded a worse/ same score. This may be due to clinicians under-estimating the level of dysfunction pre-treatment and therefore a significant improvement in their post-operative score was not observed. It could also be caused by difficulty in clinicians assessing function objectively and they may have assumed that as many patients still had fixed-appliances in situ, that there may have been some degree of residual functional impairment (Johal et al. 2024).

The association between patient-reported and surgeon-measured improvement in function scores was assessed using a Chi-squared test of independence. This test was selected because both variables were categorical and the goal was to determine whether the two assessments of function were related. The results indicate a statistically significant association between patient and surgeon ratings of improvement in function (x^2, N = 29) = 15.65, $p < 0.001$). As the minimum cell count was <5, a Fisher-Freeman-Halton exact test was also applied, and this confirmed the significant association (p=0.017).

The statistically significant association between patient-reported and surgeon-measured improvement in function suggests a strong level of agreement between subjective and objective assessments of improvement in function. This alignment between treating clinicians and patients is important in shared decision making and evaluating treatment outcomes. It also reinforces the validity of clinicians' assessments being a true reflection of patients' experiences. However, this finding should be interpreted carefully, due to the small sample size (n=29), due to four patients dropping out.

6.4.9 Association Between Patients and Surgeons in terms of Aesthetic Improvements One-Year Following OGS

The agreement between surgeons and patients in terms of aesthetic improvement following surgery showed a strong trend towards association, although statistical significance was not achieved. Although the Pearson Chi-squared test indicated a significant association between the two, the Fisher's exact test was considered a more appropriate test for this dataset, and this yielded a non-significant result ($p = 0.069$). Both patients and clinicians agree that facial appearance improves following OGS (as demonstrated by PROMS and QOMS). However, there may be some variability between the groups about the extent to which appearance improved. Pre-treatment, clinicians were slightly more critical of the facial appearance but, at one-year post-surgery, clinicians viewed the patient's facial appearance more positively than the patients. This may be in part due to a cognitive bias which may exist in surgeons grading the quality of their own work and this may lead to inaccuracies in the dysmorphology ratings (Karnick et al. 2021).

The near-significant trend highlights that both patients and clinicians have a comparable level of recognition regarding the aesthetic improvements produced by orthognathic surgery. The lack of statistical significance may be caused by the small sample size and limited variability within responses, both of which reduce statistical power. Future research involving larger and more diverse cohorts could clarify whether this apparent agreement remains consistent across different patient demographics, surgical procedures, and aesthetic priorities.

6.5 Potential Limitations

Studies which assess orthognathic outcomes are often limited by a small sample size due to the low prevalence (approximately 5% in UK/ USA population) of dentofacial disproportions requiring OGS (Posnick 2014a). It is estimated that in the UK, 3000 patients undergo combined OGS and orthodontics each year (British Orthodontic Society. 2016). Clinical research analysing rarer conditions can pose several challenges such as difficulties with patient recruitment, lack of funding for research, and the more complex study designs (Griggs et al. 2009). This was

further exacerbated in this study, as it was limited to patients treated with the Surgery-First Approach.

Challenges with patient recruitment were further exacerbated due to the stringent time-points which the questionnaires had to be adhered to. For example, one of the patients emigrated overseas mid-treatment and, although he continued his follow-up treatment within Glasgow, the appointments were less regular. To overcome this, he was emailed the QR code to allow questionnaire completion if his face-to-face appointments did not coincide with the appropriate time-points. Despite this, four patients did not complete the one-year post-operative questionnaires giving a drop-out rate of 12%.

This study was powered at 80% on the assumption that there would be a large effect size, and this indicated that 31 patients were required. However, only 29 patients were included in post-operative analyses due to drop-outs. This shortfall may reduce the statistical power of the study and increase the probability of a type II error. The number of patients included within the analysis for the indication for surgery was 33 and therefore this was adequately powered. Subsequent studies should recruit larger samples to detect small to medium effect sizes.

Additionally, multiple tests were carried out on the data and this increases this risk of obtaining a type I error (false positive). A Bonferroni correction could have been used which is a method of avoiding false positives when several statistical tests are used. The rule is usually dividing 0.05 by the number of tests carried out.

Patients were recruited immediately before surgery, and this was part of the reason for excluding patients who had the Orthodontics-First Approach. All OFA patients would have already undergone decompensation at the time of the initial questionnaire, and this would have introduced variability within the results. This group of patients should be considered in future studies.

The heterogeneity of the sample is reflected in the surgical approaches included within the sample. Nine patients had maxillary surgery only, ten had mandibular procedures only and 14 had bimaxillary surgery. Recruiting a sample with the same number of patients in each group would have allowed a more reliable

comparison and would have minimised the variability between the groups. Unfortunately, due to the time constraints, this was not possible.

The inherent limitation of the QOMS questionnaire is that it is completed by the treating surgeon. This may result in an overestimation of the quality of the outcome and an underreporting of complications. This could have been overcome by QOMS being completed by clinicians not directly involved in the care of the patients who were blinded to the surgical approach and the surgeon/orthodontist carrying out the treatment. However, this was not practical in the setting of an NHS hospital unit.

Another limitation related to the conversion of the VAS to categories. The VAS were measured in millimetres and converted into categories (e.g. very mild, mild/moderate/severe) and this may reduce precision and create artificial thresholds which do not exist (Lund et al. 2005).

Other challenges were that the patients were only followed up for one year following orthognathic surgery. In most cases, relapse occurs within the first six months or one year (Inchingolo et al. 2023). Therefore, this should be represented within the data collection. However, as one of the factors being assessed within the PROM survey is the change in quality-of-life following orthognathic treatment, it would be interesting to explore if these changes are maintained long-term i.e. up to five years operatively.

6.6 Recommendations for Future Research

A recommendation for future research is to assess the relationship between PROMS and objectively measured QOMS by an independent clinician not involved in the care of the patient and therefore blinded to (a) the treatment plan, (b) the orthodontist and surgeon carrying out the care, and (c) the surgery carried out. The patient's dysmorphology could be scored from 3D clinical photographs. However, the assessment of the patient's dysfunction, psychological status, and quality of life would likely require one-to-one structured interviews. This may therefore create challenges with patient and clinician recruitment.

This study analysed outcomes from questionnaires completed by patients at one year post-operatively. A future research project could assess the association

between long-term stability of surgical outcome and patient satisfaction. Patients are followed up within Glasgow Dental Hospital for five years following orthognathic treatment and therefore it is feasible that the PROM questionnaire could be issued when patients are attending their routine orthognathic review appointments.

There is a significant amount of data recorded from both the PROMS questionnaire and the QOMS tool which have not been reported within this study due to time limitations. Additional studies could analyse the other components of these questionnaires which have not yet been explored.

This study only assessed Surgery-First-Approach outcomes. Research comparing OFA to SFA would provide clinically relevant information to allow surgeons to make informed decisions regarding patient perception on both approaches.

Correlation between surgical morbidity and satisfaction could also be analysed more extensively. This research might help the patients in their decision-making process regarding whether to proceed with surgery.

A multi-centre study is recommended, which would allow homogenous samples to be compared. Patients could be categorized according to the treatment approach (OFA or SFA) and the surgical procedure (BSSO, Le Fort I Osteotomy, Bimaxillary) (Das 2022)

6.7 Conclusions

PROMS confirmed that there was an improvement in patient satisfaction with facial and dental appearance and overall quality of life, as measured by the Orthognathic Quality of Life Questionnaire (OQOL). The OQOL scores improved at one-year post-surgery across all domains and all of patients were satisfied with their facial appearance.

The orthognathic QOMS questionnaire also confirmed that there was improvement in all domains at one year following OGS.

A strong and statistically significant association was found between patients' and clinicians' aesthetic motivation for orthognathic treatment. The relationship between clinicians' and patients' functional motivations for surgery was weaker,

indicating that there were some differences in perception between the two groups.

Clinicians were more critical of facial appearance than patients pre-operatively, but both surgeons and patients agreed that OGS improved facial appearance.

There was no significant association between patient reported chewing problems and clinician-rated dysfunction. Patients often reported greater functional impairment than was recorded by the clinicians. However, both groups agreed that there was improvement in function following SFA OGS.

This study confirmed that SFA for orthognathic treatment improved patients' function, facial aesthetics, and overall quality of life. The results have highlighted the benefit of PROMS and QOMS in ensuring that both subjective and objective findings are considered when evaluating treatment outcomes.

Chapter 7 Appendices

7.1 GGC Health Board Approval

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7.2 MVLS College Ethics Committee

30th September 2024

MVLS College Ethics Committee

Project Title: The relationship between Patient Reported Outcome Measures (PROMs) and Quality Outcome Measures (QOMs) in Orthognathic treatment of dentofacial deformities?
Project No: 200240008

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- Project end date: End December 2025
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: https://www.gla.ac.uk/media/media_490311_en.pdf
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.
- For projects requiring the use of an online questionnaire, the University has an Online Surveys account for research. To request access, see the University's application procedure at https://www.gla.ac.uk/research/strategy/ourpolicies/useofonlinesurveystoolforresearch/.

Yours sincerely

Jesse Dawson
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Professor of Stroke Medicine
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7.3 Consent Form

Patient sticker

BAOMS BOS Orthognathic PROM project - Consent form

Before signing this consent form, please read carefully the accompanying patient information leaflet (version: 2.0, Date: 18/01/2024) and ask your clinical team any questions you may have. Once you are satisfied, please complete the consent form below if you are happy to consent to the collection of your personal information – note you must initial all boxes to be eligible to take part.

Please **initial** or tick the boxes below

1. I confirm that I am the patient and that at the time of signing this consent form, I am at least 16 years of age or more. ☐
2. I confirm that I have read the participant information leaflet (version 1.6, date: 01/02/2022). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. If I choose to withdraw, I understand that no further information will be collected about me and that I will no longer be asked to complete questionnaire for this project. ☐
4. I understand that the information collected may be used and shared to support secondary analysis. ☐
5. I understand that my name will be collected as part of the consent process. Consent forms will be kept in the hospital where it was collected and will not be shared with any other organisations. No identifiable information will be collected as part of the questionnaire. ☐
6. I AGREE to take part in this project and for my information to be collected. ☐

Patient's name and signature:

To be completed by the Person taking consent: I confirm that I have discussed the collection and storage of information for the BAOMS BOS Orthognathic PROM project.

Name and signature of the person taking consent: **Date of consent:**

For more information, please contact: BAOMS | Royal College of Surgeons of England, 38/43 Lincoln's Inn Fields, London WC2A 3PE | E: goms@baoms.org.uk | W: https://bit.ly/goms-at-baoms

The original of this form should be kept in the patient's note and one copy should be given to the patient.

Version: 2.0 *Date: 18/01/2024*

7.4 PROMS Questionnaires

7.4.1 Pre-Surgery Questionnaire

BAOMS BOS Orthognathic PROM

Patient pseudo-identifier

Today's date (DD/MM/YYYY)

This questionnaire relates to any concerns you may have about your face and teeth and should be completed PRIOR to the start of your orthognathic treatment.

About you

You are / identify as... Female ☐ Male ☐ Other ☐ I prefer not to say ☐

You are ☐☐ years old

Section 1 - Orthognathic Quality of Life Questionnaire

Please read the following statements carefully and select N/A or 1, 2, 3, 4 where:

- N/A means the issue covered by the statement either does not apply to you or it does not bother you at all
- 1 means the issue covered in the statement bothers you a little
- 4 means the issue covered in the statement bothers you a lot
- 2 & 3 lie in between a little and a lot.

1. I try to cover my mouth when I meet people for the first time	N/A	1	2	3	4
2. I worry about meeting people for the first time	N/A	1	2	3	4
3. I worry that people will make hurtful comments about my appearance	N/A	1	2	3	4
4. I lack confidence when I am out socially	N/A	1	2	3	4
5. I do not like smiling when I meet people	N/A	1	2	3	4
6. I sometimes get depressed about my appearance	N/A	1	2	3	4
7. I sometimes think that people are staring at me	N/A	1	2	3	4
8. Comments about my appearance really upset me, even when I know people are only joking	N/A	1	2	3	4
9. I am self-conscious about the appearance of my teeth	N/A	1	2	3	4
10. I don't like seeing a side view of my face (profile)	N/A	1	2	3	4
11. I dislike having my photograph taken	N/A	1	2	3	4
12. I dislike being seen on video	N/A	1	2	3	4
13. I am self-conscious about my facial appearance	N/A	1	2	3	4
14. I have problems biting	N/A	1	2	3	4
15. I have problems chewing	N/A	1	2	3	4

16. There are some foods I avoid eating because the way my teeth meet makes it difficult	N/A	1	2	3	4
17. I don't like eating in public places	N/A	1	2	3	4
18. I get pains in my face or jaw	N/A	1	2	3	4
19. I spend a lot of time studying my face in the mirror	N/A	1	2	3	4
20. I spend a lot of time studying my teeth in the mirror	N/A	1	2	3	4
21. I often stare at other people's teeth	N/A	1	2	3	4
22. I often stare at other people's faces	N/A	1	2	3	4

Section 2. modified V8

How satisfied are you with how your face looks at the moment?

Very satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied ☐

How satisfied are you with how your teeth look at the moment?

Very satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied ☐

Do you have any numbness, tingling or altered sensations? **Y** ☐ **N** ☐

If yes, where is it? (Tick all that apply)

	Top Lip	Bottom lip	Tongue		
Left	☐	☐	☐	Chin	☐
Right	☐	☐	☐	Palate / Roof of mouth	☐
				Other (give details below)	☐

If yes, how much does it concern you? A lot ☐ A little ☐ Not at all ☐

7.4.2 Four-Eight Weeks Following Surgery Questionnaire

BAOMS BOS Orthognathic PROM

Patient pseudo-identifier

Today's date (DD/MM/YYYY)

This questionnaire relates to any concerns you may have about your face and teeth and should be completed 4-8 weeks AFTER your surgery.

About you

You are / identify as... Female ☐ Male ☐ Other ☐ I prefer not to say ☐

You are ☐☐ years old

Has your treatment been impacted by the COVID-19 pandemic? Y ☐ N ☐

If 'Yes', which part of your treatment was impacted? (Tick all that apply)

- Your initial consultation ☐
- Your orthodontic treatment (braces) ☐
- Your surgery ☐

Did you have orthodontic treatment (i.e. treatment to realign your teeth) before you had surgery?

- I had orthodontic treatment prior to surgery ☐
- I had surgery first and no orthodontic treatment ☐

How long did your orthodontic treatment last? (approximately in months) ☐☐

Section 1 - Orthognathic Quality of Life Questionnaire

Please read the following statements carefully and select N/A or 1, 2, 3, 4 where:
- N/A means the issue covered by the statement either does not apply to you or it does not bother you at all
- 1 means the issue covered in the statement bothers you a little
- 4 means the issue covered in the statement bothers you a lot
- 2 & 3 lie in between a little and a lot.

1. I try to cover my mouth when I meet people for the first time	N/A	1	2	3	4
2. I worry about meeting people for the first time	N/A	1	2	3	4
3. I worry that people will make hurtful comments about my appearance	N/A	1	2	3	4
4. I lack confidence when I am out socially	N/A	1	2	3	4
5. I do not like smiling when I meet people	N/A	1	2	3	4
6. I sometimes get depressed about my appearance	N/A	1	2	3	4
7. I sometimes think that people are staring at me	N/A	1	2	3	4

8. Comments about my appearance really upset me, even when I know people are only joking	N/A	1	2	3	4
9. I am self-conscious about the appearance of my teeth	N/A	1	2	3	4
10. I don't like seeing a side view of my face (profile)	N/A	1	2	3	4
11. I dislike having my photograph taken	N/A	1	2	3	4
12. I dislike being seen on video	N/A	1	2	3	4
13. I am self-conscious about my facial appearance	N/A	1	2	3	4
14. I have problems biting	N/A	1	2	3	4
15. I have problems chewing	N/A	1	2	3	4
16. There are some foods I avoid eating because the way my teeth meet makes it difficult	N/A	1	2	3	4
17. I don't like eating in public places	N/A	1	2	3	4
18. I get pains in my face or jaw	N/A	1	2	3	4
19. I spend a lot of time studying my face in the mirror	N/A	1	2	3	4
20. I spend a lot of time studying my teeth in the mirror	N/A	1	2	3	4
21. I often stare at other people's teeth	N/A	1	2	3	4
22. I often stare at other people's faces	N/A	1	2	3	4

Section 2 - BODY-Q(TM) - SATISFACTION WITH INFORMATION

Provide only one answer per line. These questions ask about information you received from your medical team (e.g. surgeon, nurse, other staff) **about your jaw surgery procedure**. How **satisfied or dissatisfied** were you with the information you received in relation to the following:

	Very dissatisfied	Somewhat dissatisfied	Somewhat dissatisfied	Very dissatisfied
How well your questions were answered?	☐	☐	☐	☐
The amount of written information they gave you to read?	☐	☐	☐	☐
The activities you should avoid during your recovery?	☐	☐	☐	☐
How the surgery would be done?	☐	☐	☐	☐
The amount of time it would take to heal and recover?	☐	☐	☐	☐
Options for how the surgery could be done?	☐	☐	☐	☐
The kinds of complications that could happen?	☐	☐	☐	☐
What other patients like you experience after surgery?	☐	☐	☐	☐
How long it would take for you to feel like yourself again?	☐	☐	☐	☐

How much pain you might feel during your recovery? ☐ ☐ ☐ ☐

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Section 3. modified V8

Do you currently have fixed braces on your teeth? Y N

How long have they been in place?
0-1 month ☐ 1-6 months ☐
6-12 months ☐ More than 12 months ☐

How satisfied are you with how your face looks at the moment?
Very satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied ☐

How satisfied are you with how your teeth look at the moment?
Very satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied ☐

Do you have any numbness, tingling or altered sensations? Y N

If yes, where is it? (Tick all that apply)

	Top Lip	Bottom lip	Tongue
Left	☐	☐	☐
Right	☐	☐	☐

Chin ☐
Palate / Roof of mouth ☐
Other (give details below) ☐

If yes, how much does it concern you? A lot ☐ A little ☐ Not at all ☐

7.4.3 One-Year Post-Operative Questionnaire

BAOMS BOS Orthognathic PROM

Patient pseudo-identifier

Today's date (DD/MM/YYYY)

This questionnaire relates to any concerns you may have about your face and teeth and should be completed 1 year AFTER your surgery.

About you

You are / identify as... Female ☐ Male ☐ Other ☐ I prefer not to say ☐

You are ☐☐ years old

Section 1 - Orthognathic Quality of Life Questionnaire

Please read the following statements carefully and select N/A or 1, 2, 3, 4 where:

- N/A means the issue covered by the statement either does not apply to you or it does not bother you at all
- 1 means the issue covered in the statement bothers you a little
- 4 means the issue covered in the statement bothers you a lot
- 2 & 3 lie in between a little and a lot.

1. I try to cover my mouth when I meet people for the first time	N/A	1	2	3	4
2. I worry about meeting people for the first time	N/A	1	2	3	4
3. I worry that people will make hurtful comments about my appearance	N/A	1	2	3	4
4. I lack confidence when I am out socially	N/A	1	2	3	4
5. I do not like smiling when I meet people	N/A	1	2	3	4
6. I sometimes get depressed about my appearance	N/A	1	2	3	4
7. I sometimes think that people are staring at me	N/A	1	2	3	4
8. Comments about my appearance really upset me, even when I know people are only joking	N/A	1	2	3	4
9. I am self-conscious about the appearance of my teeth	N/A	1	2	3	4
10. I don't like seeing a side view of my face (profile)	N/A	1	2	3	4
11. I dislike having my photograph taken	N/A	1	2	3	4
12. I dislike being seen on video	N/A	1	2	3	4
13. I am self-conscious about my facial appearance	N/A	1	2	3	4
14. I have problems biting	N/A	1	2	3	4
15. I have problems chewing	N/A	1	2	3	4

16. There are some foods I avoid eating because the way my teeth meet makes it difficult	N/A	1	2	3	4
17. I don't like eating in public places	N/A	1	2	3	4
18. I get pains in my face or jaw	N/A	1	2	3	4
19. I spend a lot of time studying my face in the mirror	N/A	1	2	3	4
20. I spend a lot of time studying my teeth in the mirror	N/A	1	2	3	4
21. I often stare at other people's teeth	N/A	1	2	3	4
22. I often stare at other people's faces	N/A	1	2	3	4

Section 2. modified V8

Do you currently have fixed braces on your teeth? Y ☐ N ☐

How long have they been in place? 0-1 month ☐ 1-6 months ☐ 6-12 months ☐ More than 12 months ☐

How satisfied are you with how your face looks at the moment?

Very satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied ☐

How satisfied are you with how your teeth look at the moment?

Very satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied ☐

Do you have any numbness, tingling or altered sensations? Y ☐ N ☐

If yes, where is it? (Tick all that apply)

	Top Lip	Bottom lip	Tongue
Left	☐	☐	☐
Right	☐	☐	☐

Chin ☐

Palate / Roof of mouth ☐

Other give details below) ☐

If yes, how much does it concern you? A lot ☐ A little ☐ Not at all ☐

Would you recommend your treatment to another patient? Y ☐ N ☐

Do you have any further comments or suggestions for improvements to our service?

7.5 QOMS Questionnaire

7.5.1 Initial QOMS Questionnaire

QOMS - Orthognathic CRF
Clinical data

Quality Outcomes in Oral and Maxillofacial Surgery
BAOMS Saving Faces

Record Identification

Local ID | REDCap record ID

Patient identifiable information

NHS, CHI or Admission number
Date of birth D D M M Y Y
Date of index procedure D D M M Y Y
Postcode
Sex at birth Female ☐ Male ☐ Intermediate ☐ Unknown ☐

Pre-admission

Presenting complaints Dysfunction ☐ Dysmorphology ☐

Abnormal jaw movements ☐	Breathing problems ☐	Facial appearance ☐
TMJ pain or dysfunction ☐	Sleep problems ☐	Dental appearance ☐
Eating problems ☐	Speech problems ☐	Other (give details below) ☐
Other (give details in box) ☐		

Underlying association/cause?

Cleft palate or Cleft lip and palate (CLP) ☐ | Craniofacial syndrome ☐ | Post trauma ☐ | None of the above ☐

Did you use any of the following diagnostic aids?

Study model ☐ | 2D photos ☐ | 3D photos ☐
Intra-oral scanner and virtual model ☐ | None of the above ☐

Did you have use of the following radiograph?

2D (Lateral cephalographs, OPT) ☐ | CT ☐ | CBCT ☐ | None of the above ☐

Facial deformities

Maxilla	Hypoplasia / retrognathism ☐	Vertical deficiency ☐
	Prognathism ☐	Asymmetry ☐
	Vertical excess ☐	Anterior open bite (AOB) ☐
		None of the above ☐

QOMS - Orthognathic CRF
Clinical data

Record Identification

Local ID ☐☐☐☐☐☐☐☐☐☐ **REDCap record ID** ☐☐☐☐☐☐☐☐☐☐

Mandible Prognathism ☐ Retrognathism ☐ Hemi-mandibular elongation ☐ Hemifacial microsomia ☐

Condyle Resorption ☐ Hyperplasia ☐ Atrophy ☐ Fracture ☐ Normal ☐

Chin position Normogenic ☐ Progenic ☐ Retrogenic ☐ Vertical excess ☐
Deficiency ☐ Asymmetry ☐

Index of Orthognathic Functional Treatment Need (IOFTN)? N/A ☐

5 Very great need for treatment ☐
- 5.1 Defect of cleft lip and palate and other craniofacial anomalies ☐
- 5.2 Increased overjet ≥ 9mm ☐
- 5.3 Reverse overjet ≥ 3mm ☐
- 5.4 Open bite ≥ 4mm ☐
- 5.5 Complete scissors bite affecting whole buccal segment(s) with signs of functional disturbance and/or occlusal trauma ☐
- 5.6 Sleep apnoea not amenable to other treatments such as MAD or CPAP (as determined by sleep studies) ☐
- 5.7 Skeletal anomalies with occlusal disturbance as a result of trauma or pathology ☐

4 Great need for treatment ☐
- 4.2 Increased overjet ≥ 6mm and ≤ 9mm ☐
- 4.3 Reverse overjet ≥ 0mm and < 3mm with functional difficulties ☐
- 4.4 Open bite < 4mm with functional difficulties ☐
- 4.8 Increased overbite with evidence of dental or soft tissue trauma ☐
- 4.9 Upper labial segment gingival exposure ≥3mm at rest ☐
- 4.10 Facial asymmetry associated with occlusal disturbance ☐

3 Moderate need for treatment ☐
- 3.3 Reverse overjet ≥ 0mm and < 3mm with no functional difficulties ☐
- 3.4 Open bite < 4mm with no functional difficulties ☐
- 3.9 Upper labial segment gingival exposure <3mm at rest, but with evidence of gingival/periodontal effects ☐
- 3.10 Facial asymmetry with no occlusal disturbance ☐

QOMS - Orthognathic CRF
Clinical data

Quality Outcomes in Oral and Maxillofacial Surgery
BAOMS Saving Faces

Record Identification

Local ID | | | | | | | | | | |

REDCap record ID | | | | | | | | | | |

Clinician-reported patient-derived outcomes

Rating of the dysfunction	0 ———	100
Rating of the psychological deficit	0 ———	100
Rating of the dysmorphology	0 ———	100
Diagnosis of the dentofacial deformities	0 ———	100
Impact of the deformity on the quality of life	0 ———	100

Diagnosis of the case (e.g., Class III skeletal base III due to maxillary hypoplasia complicated by mandibular asymmetry and AOB)

Surgical matrix

Orthodontic treatment None - N/A ☐ Pre surgical ☐ Post surgical ☐ Pre & post surgical ☐

Date of start of orthodontic treatment D D M M Y Y

Date of patient being ready for surgery D D M M Y Y

Prediction planning method(s) used?

Standard articulator ☐ 2D digital planning ☐ 3D-virtual digital planning ☐

Surgical guides used to guide the occlusion during surgery?

Articular based wafer ☐ 3D printed wafer ☐ 3D printed plates ☐

None ☐

7.5.2 Initial Post-Operative QOMS Questionnaire

QOMS - Orthognathic CRF
Clinical data

Quality Outcomes in Oral and Maxillofacial Surgery
BAOMS Saving Faces The Facial Surgery Research Foundation

Record Identification

Local ID ☐☐☐☐☐☐☐☐☐☐ **REDCap record ID** ☐☐☐☐☐☐☐☐☐☐

Surgery and discharge

Grade of the surgeons performing the surgery

Operating	Consultant	☐	**Assisting**	Consultant	☐
	Specialist registrar	☐		Specialist registrar	☐
	Associate specialist	☐		Associate specialist	☐
	Junior doctor	☐		Junior doctor	☐

Surgical procedures

Le Fort I (V10.4) ☐	Sagittal split osteotomy ☐	Vertical sub sigmoid ☐
Genioplasty (V19.2) ☐	Inverted L osteotomy ☐	
Segmental maxillary osteotomy ☐		Segmental mandibular osteotomy ☐
Le Fort II (V10.3) ☐	Le Fort III (V10.2) ☐	Mandibular body osteotomy ☐
Kufner procedure ☐	Malar onlays (medpore) ☐	Widening of the zygoma ☐
Bone graft rib ☐	Bone graft iliac ☐	Distraction osteogenesis ☐
TMJ replacement ☐		Other (give details below) ☐

Other surgical procedure(s)

Was any third molar removed? No ☐ Yes, prior to surgery ☐ Yes, during surgery ☐

Mandibular fixation N/A ☐ Bicortical screws ☐ Plates ☐ Inter-maxillary fixation (IMF) ☐

Maxillary fixation Bendable plates ☐ 3D-printed plates ☐ N/A ☐

Intra-operative complication(s)

No intra-operative complication ☐	Unfavourable separation of the maxilla ☐
Excessive haemorrhage, >500ml ☐	Transection of ID nerve ☐
Unfavourable sagittal split of the mandible ☐	Genioplasty complication ☐
Injury to teeth or roots ☐	Other (give details below) ☐

Other intra-operative complications

QOMS - Orthognathic CRF
Clinical data

Record Identification

Local ID | | | | | | | | | | |

REDCap record ID | | | | | | | | | | |

Indicate the nature and severity of postoperative complications

No postoperative complications	☐	Septal deviation	☐
Bleeding	☐	Infection	☐
Incorrect occlusion	☐	Other (give details below)	☐

Other postoperative complication(s)

Did the patient need to return to theatre? Y ☐ N ☐

Date of discharge D D M M Y Y

Comment

QOMS - Orthognathic CRF
Clinical data

Quality Outcomes in Oral and Maxillofacial Surgery
BAOMS Saving Faces

Record Identification

Local ID | | | | | | | | | | | **REDCap record ID** | | | | | | | | | | |

30-day return to theatre post-surgery

Did the patient return to theatre unexpectedly within 30 days after index surgery? Y N

Date of return to theatre D D M M Y Y *(If the patient went back several to theatre, indicate the earliest occurrence.)*

Indicate the reason(s) for return to theatre

Occlusal adjustment ☐ Septoplasty revision ☐ Haemorrhage ☐

Infected / exposed / fractured plates ☐ Genioplasty revision ☐ Other (give details below) ☐

Other reason(s) for return to theatre

90-day readmission pot surgery

Was the patient unexpectedly readmitted within 90 days of index surgery? Y N

Date of readmission D D M M Y Y *(If the patient was readmitted >1, indicate the earliest occurrence.)*

Indicate the reason(s) for readmission

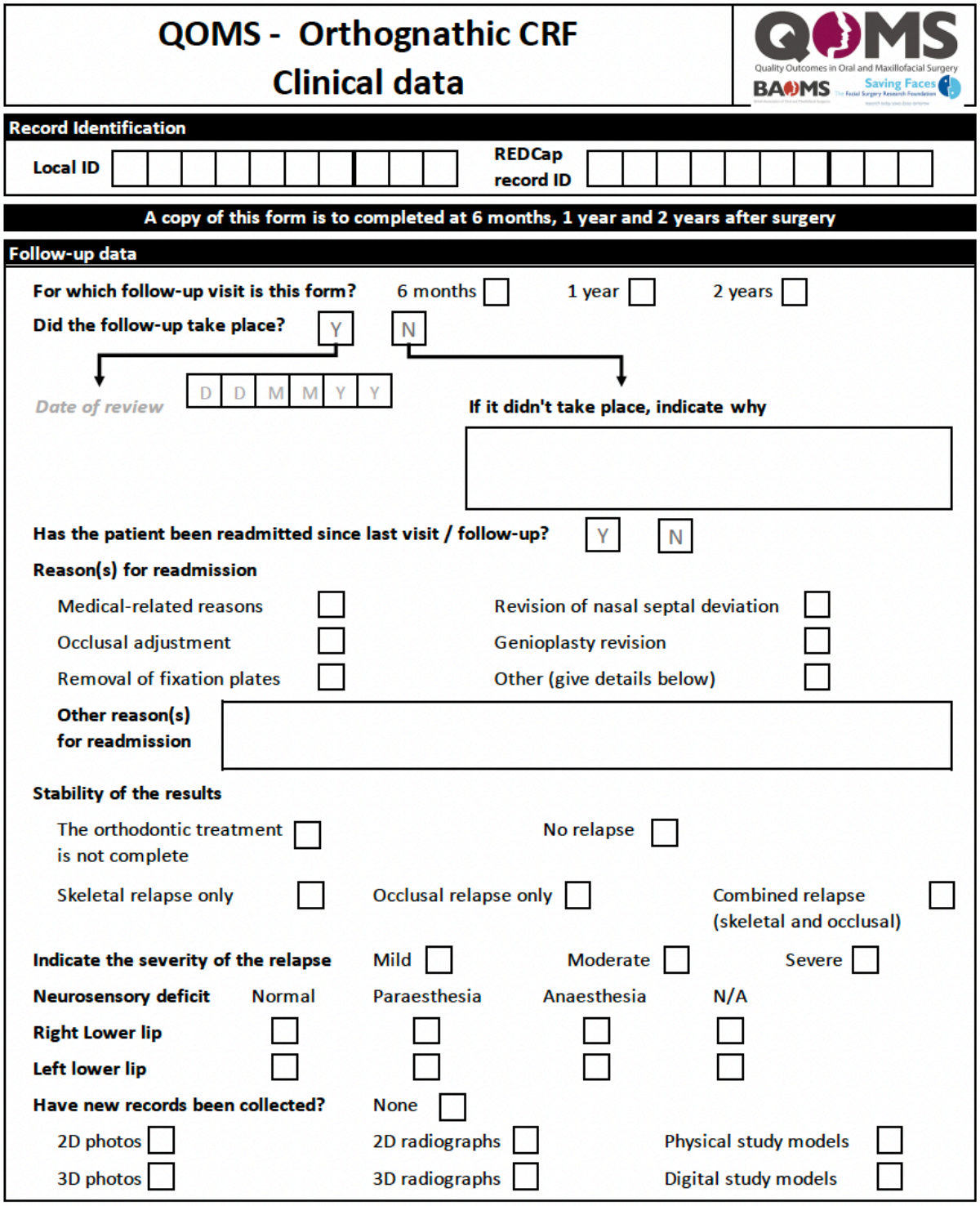
Occlusal adjustment ☐ Septoplasty revision ☐

Infected / exposed / fractured plates ☐ Genioplasty revision ☐ Other (give details below) ☐

Other reason(s) for readmission

Comment

7.5.3 Six-Month and One-Year QOMS Forms



QOMS - Orthognathic CRF
Clinical data

Quality Outcomes in Oral and Maxillofacial Surgery
BAOMS Saving Faces

Record Identification

Local ID | | | | | | | | | | |

REDCap record ID | | | | | | | | | | |

A copy of this form is to completed at 6 months, 1 year and 2 years after surgery

Follow-up data

For which follow-up visit is this form? 6 months ☐ 1 year ☐ 2 years ☐

Did the follow-up take place? Y ☐ N ☐

Date of review D D M M Y Y

If it didn't take place, indicate why

Has the patient been readmitted since last visit / follow-up? Y ☐ N ☐

Reason(s) for readmission

- Medical-related reasons ☐
- Occlusal adjustment ☐
- Removal of fixation plates ☐
- Revision of nasal septal deviation ☐
- Genioplasty revision ☐
- Other (give details below) ☐

Other reason(s) for readmission

Stability of the results

- The orthodontic treatment is not complete ☐
- No relapse ☐
- Skeletal relapse only ☐
- Occlusal relapse only ☐
- Combined relapse (skeletal and occlusal) ☐

Indicate the severity of the relapse Mild ☐ Moderate ☐ Severe ☐

Neurosensory deficit	Normal	Paraesthesia	Anaesthesia	N/A
Right Lower lip	☐	☐	☐	☐
Left lower lip	☐	☐	☐	☐

Have new records been collected? None ☐

- 2D photos ☐
- 2D radiographs ☐
- Physical study models ☐
- 3D photos ☐
- 3D radiographs ☐
- Digital study models ☐

QOMS - Orthognathic CRF
Clinical data

Record Identification

Local ID | | | | | | | | | | |

REDCap record ID | | | | | | | | | | |

Improvement of quality of life (To be completed by the clinician)

Confidence	Y	N	Better facial appearance	Y	N
Interaction in the society	Y	N	Better chewing	Y	N

Clinician-reported patient-derived outcomes

Patient satisfaction at the time of the visit

Poor ☐ Just ☐ Moderate ☐ High ☐

Rating of the dysfunction	0	100
Rating of the psychological deficit	0	100
Rating of the dysmorphology	0	100
Diagnosis of the dentofacial deformities	0	100
Impact of the deformity on the quality of life	0	100

Comment

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