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Psychosocial and physiological assessments of orthognathic patients

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Thesis submitted to University College Cork in partial fulfilment of the requirements for the DClinDent (Orthodontics)

National University of Ireland, Cork

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LIST OF ABBREVIATIONS

- AC – Aesthetic Component of IOTN
- BFNES – Brief Fear of Negative Evaluation Scale
- BMI - Body Mass Index
- CUDSH – Cork University Dental School and Hospital
- DD - Dentofacial deformity
- DHC – Dental Health Component of IOTN
- HSE - Health Service Executive, Ireland
- IOTN - Index of Orthodontic Treatment Need
- IOFTN - Index of Orthognathic Functional Treatment Need
- NHS - National Health service, UK
- OHIP-14 - Oral Health Impact Profile
- OHR - Oral Health Related
- OQLQ - Orthognathic Quality of Life Questionnaire
- % - per cent
- QoL - Quality of Life
- RCS- Royal College of Surgeons
- RPC - Raphy Paul Cheruvathur (Main researcher)
- RoI- Republic of Ireland
- SD - Standard Deviation

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ABSTRACT

Aims

The primary aim was to compare, in the RoI, generic oral health-related quality of life (OHIP-14), condition-specific quality of life (OQLQ), the fear of negative evaluation (BFNES) and self-reported BMI of patients seeking surgical-orthodontic correction of their malocclusion versus those of the general population.

A secondary aim was to assess the IOFTN in the orthognathic cohort and to investigate any correlation between the functional domain of OQLQ and IOFTN.

Materials and Methods

Orthognathic patients prior to commencing pre-surgical orthodontics from five regional HSE orthodontic units within the RoI and randomly selected age-matched subjects from the general population were invited to complete a telephone interview. Participants were asked questions regarding general characteristics and then asked to respond to the validated questionnaires OHIP-14, OQLQ, and BFNES. IOFTN grades of the orthognathic sample were also assessed.

Results

Eighty orthognathic patients (39 males; 41 females) with an overall mean age of 17.5 (SD 1.6) years and 213 subjects from the general population (95 males; 118 females) with an overall mean age of 17.8 (SD 1.5) years completed a telephone interview. Orthognathic patients had significantly higher mean scores for OHIP-14, OQLQ and S-BFNES than the

general population ($p < 0.001$). The mean score of OHIP-14 for the orthognathic patients and the general population were 14 (SD 8.6) and 5 (SD 5.9) respectively. Corresponding group scores for OQLQ were 40.9 (SD 19.3) and 19.9 (SD 14.9), and for S-BFNES were 23.2 (SD 7.2) and 18.8 (SD 8.1). Females had higher overall OQLQ and S-BFNES scores than males in both groups ($p < 0.0001$).

There was no significant difference in the distribution of self-reported BMI categories between the groups ($p = 0.8931$).

More than 90 per cent of the orthognathic sample were in IOFTN grade 4 and grade 5 showing 'great' and 'very great' functional need for surgery respectively. No association was found between the functional domain of OQLQ and IOFTN categories ($p=0.5530$).

Conclusion

Orthognathic patients reported significantly poorer oral-health related and condition-specific quality of life as well as higher levels of social anxiety than the general population. Females in both groups had higher scores than males for OQLQ and S-BFNES. There was no correlation between the functional domain of OQLQ and IOFTN.

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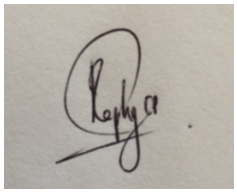
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DECLARATION

I hereby declare that the work described in the thesis, except where otherwise mentioned, is my own and has not been submitted previously as a requirement for a degree or a diploma at the this or any other institution.



Raphy Paul Cheruvathur

CHAPTER ONE

INTRODUCTION

1. Introduction

Combined orthodontic-surgical (orthognathic) treatment is a well-established treatment modality for the correction of moderate to severe dentofacial deformities. These have aesthetic, functional, and psychosocial impacts. Those individuals whose facial morphology differs markedly from the average may often be perceived differently and experience a poorer quality of life (QoL) (Cunningham & Johal, 2015). The World Health Organisation (WHO) defines health as "A state of complete physical, mental, and social wellbeing not merely the absence of disease…"(WHO, 1998). Various approaches have been used to assess QoL including the use of generic health, generic oral health and condition-specific measures. The presence of a facial disfigurement may also be associated with elevated fear of negative evaluation and orthognathic patients could be at an increased risk of Social Anxiety Disorder regardless of age, gender and severity of the deformity (Ryan et al., 2016). Besides, patients with dentofacial deformities often report with functional and masticatory difficulties.

Generic oral health is most commonly measured using a 14-item short form version of the Oral Health Impact Profile (OHIP-14). A condition-specific quality of life measure was developed in the last decade for orthognathic patients using a 22-item Orthognathic Quality of Life Questionnaire (OQLQ). The social anxiety is mostly measured using BFNES (Brief Fear of Negative Evaluation Scale). The Index of Orthognathic Functional Treatment Need (IOFTN) has recently been introduced to reflect the functional indications of treatment need for orthognathic patients.

The studies that have assessed some of the above QoL measures are mostly single-centred. Most have no general population comparison group, a wide age range of subjects, no sample size calculation and vary in the timing of data collection. The patient's perception of QoL is often culture-dependent, and the study results from one part of the world cannot be applied directly to another part. No data exist in the Republic of Ireland (RoI) in relation to any of these QoL measures for either patients seeking surgical-orthodontic treatment or for the general population. This study addresses this deficiency in the literature.

This prospective multi-centre study assessed psychosocial and physiological aspects of orthognathic patients versus an age-matched control group in the RoI.

CHAPTER TWO

LITERATURE REVIEW

2. Literature Review

2.1 Search Strategy

This literature review was conducted using advanced search options in search engines as 'PubMed' and 'Google Scholar' and the search strategy as detailed below:

- Orthognathic Surgery AND patient satisfaction OR quality of life OR life quality OR psychosocial OR psychological OR psychiatric OR patient expectations OR Social anxiety OR Body Mass Index (BMI) OR Functional OR IOFTN
- Dentofacial deformity AND patient satisfaction OR quality of life OR life quality OR psychosocial OR psychological OR psychiatric OR patient expectations OR Social anxiety OR Body Mass Index (BMI) OR Functional OR IOFTN
- Orthodontic-surgical AND patient satisfaction OR quality of life OR life quality OR psychosocial OR psychological OR psychiatric OR patient expectations OR Social anxiety OR Body Mass Index (BMI) OR Functional OR IOFTN
- Orthosurgical AND patient satisfaction OR quality of life OR life quality OR psychosocial OR psychological OR psychiatric OR patient expectations OR Social anxiety OR Body Mass Index (BMI) OR Functional OR IOFTN

2.2 Overview

This literature review will start with a brief overview of orthognathic surgical procedures. It will then focus principally on psychosocial, physiological and treatment need aspects.

2.3 Orthognathic Surgery

Orthognathic surgery, a term originating from the Greek words “orthos” (straight) and “gnathos” (jaw), is considered to be a specialist branch of oral and maxillofacial surgery carried out to correct a dentofacial deformity. It involves pre-surgical orthodontics with fixed appliances followed by surgery to reposition the jaws to achieve a more harmonious facial skeleton. Orthognathic surgery aims to attain an improvement in the facial form and occlusal function by correcting skeletal, aesthetic and occlusal aspects.

2.3.1 Indications

Principal indications for orthognathic surgery are as follows:

- To improve facial and dental aesthetics, in patients with moderate to severe anteroposterior, vertical and transverse problems (Laufer et al., 1976).
- To improve function, mastication and speech (Stirling et al., 2007; Proothi et al., 2010).
- To correct a traumatic and increased overbite that cannot be addressed by conventional orthodontics.
- Condylar hyperplasia, progressive condylar resorption and rheumatoid arthritis.

A less common indication is:

- To increase the airway in patients with obstructive sleep apnoea (Islam et al., 2014).

2.3.2 Prevalence

The prevalence of dentofacial deformity in the UK and USA is around five per cent. Twice as many females seek orthognathic consultation compared to males, and similarly more subjects with Class III malocclusion and long face seek opinion (Sandy et al., 2001). As per the 2013 commissioning guide by RCS England (Hunt, 2015), there are almost 3000 procedures per year in England with a population of 53 million. Assuming similar demands in the RoI, it can be extrapolated that there may be 241 procedures per year with a population of 4.7 million. There are differences, however, in the eligibility criteria to access free treatment for orthognathic surgical procedures within the NHS in England and under the HSE in RoI; this extrapolation, therefore, may not be accurate.

2.4 Procedures

The various types of maxillary and mandibular surgical procedures along with the indication (s) for each are given briefly below:

2.4.1 Maxillary Surgery

2.4.1.1 Le Fort I maxillary advancement

Indication:

- Treatment of maxillary hypoplasia, Class III skeletal bases.

2.4.1.2 Le Fort I maxillary impaction

Indication:

- An excessive gingival display on smiling/ vertical maxillary excess

- An anterior open bite of skeletal aetiology.

2.4.1.3 Surgically Assisted Rapid Palatal Expansion (SARPE)

Indication:

- To treat transverse maxillary deficiency/ posterior crossbite
- To widen a narrow, high-arched palate often associated with oral clefts.

2.4.1.4 Le Fort II osteotomy

Indication:

- The treatment of nasomaxillary hypoplasia where the deficiency is at the infra-orbital margins.

2.4.1.5 Le Fort III (Kufner) osteotomy

Indication:

- Severe hypo-development of the middle third of the face with flattening of the suborbital area and cheekbones.

2.4.1.6 Segmental Le Fort I osteotomy

Indication:

- One-stage correction of the transverse maxillary deficiency
- Correction of anterior open bite where there is an obvious discrepancy in the occlusal planes of the labial and buccal segments
- Correction of severe anterior vertical maxillary excess or deficiency (Malik et al., 2016).

2.4.2 Mandibular Surgery

2.4.2.1 Bilateral sagittal split ramus osteotomy (BSSO)

Indication

- Mandibular advancement (less than 10 -12 mm).
- Mandibular set back (less than 7-8 mm).
- Correction of asymmetry (minor).

2.4.2.2 Vertical Sub-sigmoid Osteotomy (VSO)

Indication

- Large mandibular setback/correction of mandibular sagittal excess
- Mandibular sagittal excess with slight amounts of open bite

2.4.3 Combined Procedures

2.4.3.1 Bimaxillary Osteotomy

Many patients require surgery to both jaws to correct the underlying skeletal discrepancy. These include procedures outlined above.

2.4.4 Additional Procedure- Genioplasty

A genioplasty may be used to correct abnormal chin prominence. It may be undertaken in combination with other surgical procedures or in isolation.

2.4.4.1 Reduction genioplasty:

Vertical reduction genioplasty

- To reduce the height of the lower facial third

Horizontal reduction genioplasty

- Used for correction of anteroposterior chin excess

2.4.4.2 Augmentation genioplasty

Vertical augmentation

- To increase the vertical height of the chin

Horizontal augmentation. (sliding or double sliding genioplasty)

- Used for correction of anteroposterior chin deficiency.

2.5 Psychosocial aspects related to Orthognathic surgery

This research project assessed OHRQoL (Oral Health-Related Quality of Life) and social anxiety of orthognathic patients versus a general population sample. In this section, the impact of dentofacial deformities on psychosocial aspects for patients undergoing orthognathic treatment will be discussed. The three qualitative instruments used in our research to measure these psychosocial aspects will then be considered in detail

Dentofacial deformities and psychosocial aspects

Dentofacial deformities may lead to social and psychologic problems(Phillips, Bennett and Broder, 1998). In this stereotyping society, people are biased toward those with better facial appearance. Legal interactions, finding jobs and marriage are all found to be influenced by personal physical features. Patients with dentofacial deformities face problems of adjustment and social adaptation, with negative consequences to their mental health (Flanary, 1992). Patients are reported to underperform in school, college or the workplace and to have difficulty forming relationships (Garvill et al., 1992). The decision to proceed with orthognathic treatment is complex and often involves external influences, including the views and opinions of friends, family and healthcare professionals.

A dentofacial deformity may have a significant impact on a person's life, and this might not solely be related to the defect itself but reflect the person's past experiences, psychological constitution and personality. As a result, the degree of impact is not necessarily proportional to the extent of the deformity (Ryan et al., 2012a).

Proffit et al. (2003) stated that the primary reason for treatment of dentofacial problems is to improve the quality of life (QoL), but traditionally this has not always been included as an outcome measure of orthognathic research.

Quality of life (QoL) and HRQoL

The World Health Organisation defines the quality of life (QoL) as “an individual's perception of their position in life in the context of the culture and the value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships and their relationships to salient features of their environment” (WHO, 1998). The quality of life, specifically in relation to an individual’s health, is often called "health-related quality of life (HRQoL)”.

Quality of life assessment

QoL assessment has become a rapidly expanding area of research in the fields of medicine and dentistry over the past 20 years. Questions on QoL enable us to evaluate treatment needs, doctor-patient relationships and to weigh the risk and benefits of various treatment options as part of informed consent (Kiyak, 2000). In recent years, there has been a paradigm shift in favour of assessing patient-centred outcomes after surgical interventions (Lee et al., 2008).

In orthognathic surgery, it has been shown that patients who reported unexpected effects following surgery were more likely to be dissatisfied with the treatment (Cunningham et

al., 1996). Hence, it is essential to determine the effects of orthognathic surgery on patients' QoL in order to adequately inform them of what to expect from treatment.

It is also important to establish and compare the impact of various dental and dentofacial conditions on patient's QoL to determine and prioritise treatment need, especially where public healthcare resources are limited (Allen, 2003).

Instruments developed to measure QoL

The growing demand for measures of oral health-related QoL has led to the development of a variety of instruments as listed by (Tajima et al., 2007):

- Oral Health Impact Profile (OHIP)
- The Social Impacts of Dental Disease
- The Geriatric Oral Health Assessment Index
- The Dental Impact Profile
- The Oral Health-Related Quality of Life Measure
- The Dental Impact of Daily Living (DIDL) and
- The Subjective Oral Health Status Indicators (SOHSI).

All these instruments were originally developed for use with an ageing population (Cunningham et al.,2002). Currently, the best known among QoL measures is the Oral Health Impact Profile or OHIP (Slade, 1997; Slade, 1998).

2.5.1 Measurement of Generic Health-related QoL

Generic health measures are instruments intended to assess the impact of different health states on QoL irrespective of the underlying disease or condition (Hayes, 1998). Generic instruments, for example, the 36-item Short-Form Health Survey (SF-36) (Ware et al., 1992) or the EuroQoL (EuroQoL Group, 1990) are not sensitive to changes in oral health and exhibit limited construct validity (Bowling, 1997). Such measures may be insensitive to the subtle differences between different health states/conditions; thus, generic oral health and condition-specific measures have been developed.

Validity is the extent to which a test measures what it is supposed to and the classical model, as described by Gosall and Gosall (2012) divides validity into construct, content, criterion and face validity. Construct validity is the extent to which the test measures a theoretical construct by a specific measuring device or procedure. Content validity is the extent to which the test measures variables that are related to the parameter which should be measured by the test. Criterion validity is used to demonstrate the accuracy of a measure or procedure by comparing it with another measure or procedure that has been demonstrated to be valid. Face validity is the extent to which the test, on superficial consideration, measures what it is supposed to measure.

The validity of the design of experimental research studies are assessed using internal and external validity. Internal validity estimates to what extent the study measures what it sets out to measure. External validity estimates to what extent the results of the study can be generalised to a wider population (Gosall and Gosall, 2012).

2.5.2 Measurement of Generic Oral Health-related QoL (OHIP)

The demand to measure the oral health-related quality-of-life led to the development of several instruments. The most widely used instrument is oral health impact profile (OHIP), which measures an individual's perceptions of the social impact of oral disorders on well-being. This exists in the original format (OHIP-49) and a shortened form (OHIP-14). The latter was devised for settings where the full battery of 49 questions might be inappropriate (Slade, 1997).

The 14 items of the OHIP-14 questionnaire contribute to seven domains (two items per domain): functional limitation(OH-1, OH-2),physical pain(OH-3, OH-4), psychological discomfort(OH-5, OH-6, OH-10),physical disability(OH-7, OH-8, OH-14), psychological disability(OH-9), social disability(OH-11, OH-12) and handicap(OH-13).

Responses for each item are made on a Likert-type scale and coded as:

0 = 'never', 1 = 'hardly ever', 2 = 'occasionally', 3 = 'fairly often' and 4 = 'very often'.

Overall OHIP-14 scores can range from 0 to 56, where 0 indicates no impact and 56 indicates the worst impact of one's oral health on QoL. Individual domain scores can be calculated by summating responses to the items within a domain and can range from 0 to 8 (Slade, 1997).

Studies which have used OHIP-14 only to assess QoL in orthognathic patients are listed in Table 2.1. Those which used OHIP-14 and OQLQ are listed in Table 2.2. Studies which evaluated QoL using OQLQ only are given in Table 2.3.

2.5.2.1 Review summary of OHIP-14 studies (Table 2.1 and Table 2.2)

Since the development of a shorter version of OHIP-14 by Slade (1997), so far twenty-three studies have assessed OHIP-14 in patients undergoing orthognathic surgery or in patients with dentofacial deformities. We have included all studies relevant to our area of interest and excluded studies which assessed OHIP-14 in orthodontics, OHIP-14 in a 'surgery-first' approach and the few studies that have used OHIP-49.

These twenty-three studies have been conducted around the world in different ethnic groups: Nordic countries (Finland-3; Sweden -1), Rest of Europe (Germany-3), South America (Brazil-6), Middle East (Iran-2; Turkey-1), South Asia (India-1; Nepal-1), East Asia (China -3), Southeast Asia (Singapore-1) and one study was conducted in New Zealand.

The study designs used were very heterogeneous including variation in inclusion criteria, the time points of data collection, the age range of subjects and differing questionnaires used along with OHIP-14. The time point of data collection varied from pre-orthodontics, pre-surgery and at different points post-surgery. In some studies, especially the ones conducted in Oral and Maxillofacial units, there is lack of clarity in the term "pre-treatment" as to whether it is pre-orthodontics or pre-surgery.

In almost all studies data were collected prospectively except in the study by Wee & Poon (2014) where data were collected retrospectively. Six studies were cross-sectional and the rest were longitudinal with data collected at different time points in the orthodontic-orthognathic surgery treatment pathway. Among the cross-sectional studies, some collected data only at 'pre-surgery' (Lee et al., 2007; Migliorucci et al., 2015), one study

collected data pre-orthodontics (Frejman et al.,2013), one collected data post-surgery (Schmidt et al., 2013) and two studies collected data from separate cohorts of pre-orthodontics, pre-surgery and post-surgery groups at one time point (Garcia Esperão et al., 2010; Palomares et al., 2016).

Most of the studies were conducted in the single centre except one which collected data from two centres (Silva et al.,2016) and two collected data from three centres (Kavin et al., 2012; Palomares et al.,2016). None of the multi-centre studies has nationwide coverage.

Most studies have been conducted among a broad age range of subjects varying from 22 to 34 years to 18 to 66 years.

Only four studies had a control group. Lee et al. (2007) used a control group made up of 76 ‘asymptomatic wisdom teeth consultation patients without dentofacial deformity’. Frejman et al. (2013) used a control group of 34 patients with ‘general harmony of the profile angle and normal occlusion (untreated or treated with orthodontia)’. Kilinc & Ertas (2015) used 30 participants with ‘Class I skeletal structure and good dentofacial harmony' whereas Corso et al. (2016) had 60 patients in the control group comprising of ‘patients not suffering from any dentofacial deformities’. No studies had a true general population control group. Among all these studies only Frejman et al. (2013) included a sample size calculation.

Amongst the studies with no control group, Wee & Poon (2014) reported a power calculation and Palomares et al. (2016) conducted a sample size calculation. No other studies report a sample size calculation.

Some studies used the English version of the OHIP-14 questionnaire while others had it translated and adapted to their own language.

Table 2.1: Comparative studies of orthognathic patientswhich used OHIP-14.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Silvola 2016 Finland P, L S	Ortho only N= 20 N=64 18: 46 37.5 18-64	Orthognathic N=44	• (T1) Pre-surgery • (T2) Post-op 3 years	• OHIP-14 (Finnish) • Facial pain-VAS • TMD severity Ai Di dysfunction indices	• Orthodontic and orthognathic tx of severe malocclusion seems to improve OHRQoL via decreased facial pain in adults with pre-existing functional problems.
Corso 2016 Brazil P, L S	Orthognathic group with DD N=30 6: 24 29.4 (9.3)	Control -No DD* Q at T0 only N=60 12: 48 23.5 yr	• T0- pre-surgery 1 wk • T1-post-op 1 mo • T2-post-op 3 mo	• Weighted OHIP-14 (Brazilian)	• At T0 the surgery group had pre-existing negative perception regarding OHRQoL greater extent than controls • Perception of QoL poorer in women with DD. • QoL improved 3 months post-op.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Baherimoghaddam 2016 Iran P, L S	Class II N=28 12:16 25.1 (3.4) Class III N=30 19:11 21.3 (2.7)	Same group followed up	• T0 baseline • T1 pre-surgery • T2 post-op 6 mo • T3 post-debond 12 mo	• OHIP-14 (Persian)	• Class II and Class III patients had significant improvements in OHIP-14 domains; changes markedly different between patients with Class II and Class III malocclusion.
Antoun 2015 New Zealand P, L S	Severe malocclusion grp N=30	Non syn CLP N=24 Orthognathic N=29 15:14	• Pre-Ortho • Post-tx	• OHIP-14	• Orthognathic subjects have poor baseline OHRQoL, but benefit most from treatment compared with severe malocclusion and cleft patients.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Migliorucci 2015 Brazil P, C S	Facial Pattern I N=12 Total N=36 27.2 18-40	Facial Pattern II N=12 Facial Pattern III N=12	Pre-surgery	• OHIP-14 • MBGR protocol	• Those with DD had more impact on QoL than those without. • Higher occurrence of changes in the performance of orofacial functions (OFFs) for Facial Patterns II and III, compared to Pattern I and QoL in individuals with DD. • Relationship between scores in protocols MBGR and OHIP-14, the worse the OFFs, the worse the QoL in cases of DD.
Tabrizi 2014 Iran P, L S	Pre-surgery N=28 10:18	Post-op 4 mo	• Pre-surgery • Post-op 4 mo	• OHIP-14 (Persian)	• OHRQoL significantly improved following orthognathic tx. • QoLnot significantly different among patients with different reasons (aesthetic, functional, or both) for treatment.
Silvola 2014 Finland P, L S	Ortho-only N=14 Total N=52 16: 36 18-61	Orthognathic N=38	• Pre-tx • Post-tx 3.1 (1.22) years	• OHIP-14 (Finnish) • VAS • IOTN AC	• Treatment improved the OHRQoL, psychological discomfort and psychological disability.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Goelzer 2014 Brazil P, L S	Orthognathic with DD N=74 25:49 28.0 (9.0) 15-53	Longitudinal follow up	• Pre-surgery (T0) • Post-op 4-6 mo (T1)	• OHIP-14	• Class III- benefited in all domains • Class I - improvement in psychological disability domain • Class II - benefit in all domains except functional limitation.
Schmidt 2013 Germany P, C S	1-2 years post-retention N=28 6:28	No comparison group	• Post-retention 1-2 yrs	• OHIP-G14 (German) • OHIP-G	• Skeletal malocclusion patients have lower OHRQoL than the general population.
Frejman 2013 Brazil P, C S	ClassII and Class III DD N=34 27.56	Control* (harmony of profile angle and normal occlusion) N=34	• Pre-tx	• OHIP-14 • RSES • GHDS	• Those with DD, tend to more negative OHRQoL than those without. • Those with DD, lower self-esteem compared with people without. • Depression seemsunaffected by DD.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Silvola 2012 Finland P, L S	Ortho only N=15 Total N=51 16: 35 36.4	Orthognathic N=36	• Pre-tx • Post-tx 2.8 years	• OHIP-14 (Finnish) • PAR	• Prevalence of oral impacts reported 'fairly often' or 'often' was 7-fold higher pre-tx than post-tx. • Post-tx, oral impacts declined to the level of general population. • Improved occlusion, a favourable effect on the OHRQoL.
Rustemeyer 2012 Germany P, L S	Pre-Ortho N=30 Class III 13:17 24.3 (4.5)	Post-op	• Pre-Ortho 6.2 (1.2) mo pre-surgery • Post-op 8.3 (1.2) mo	• OHIP-14 • Ceph	• Postsurgical reduction of labio-mental angle and reduced accentuation of chin after mandibular setback directly linked to reduced psychological discomfort in patients' QoL.
Rustemeyer 2012 Germany P, L S	Pre-Ortho N=50 20: 30 26.9 (9.9) 18-52	Post-op N=50	• Pre-Ortho 9.1 (2.4) mo pre-surgery. • Post-op 12.1 (1.4) mo	• OHIP-14 • AD-2	• Functional and psychosocial benefits after treatment. • If aesthetic facial improvement post-op, benefit generally high, and functional problems only secondary. • Improvement of psychosocial aspects and aesthetics emphasised when comparing surgical with alternative options.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Garcia Esperao 2010 Brazil P, C S	Pre-ortho N=20	Pre-surgical (separate grp) N=70 Post-surgical (separate grp) N=27	• Pre-ortho • Pre-surgical • Post-op	• OHIP-14 (Brazilian)	• Pre-tx most negative QoL compared with pre-surgery and post-surgery. • Females report greater impact than males at all stages.

P: Prospective, R: Retrospective, L: Longitudinal, S: single centre, M: multi-centre, QoL: Quality of Life, Tx: Treatment, Post-op: Post-surgery, wk: week(s), mo: Months, yrs: years, DD: Dentofacial deformity, OFF: Orofacial functions, SD: standard deviation
*Studies with a control group highlighted in blue colour.

Table 2.2: Comparative studies of orthognathic patients which used both OHIP-14 and OQLQ.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Chaurasia 2017 Nepal P, L S	Pre-surgery N=14 9: 5 21.78 (2.29)	Post- op 8-12 mo	• Pre- surgery • Post-op 8-12 mo	• OQLQ • OHIP-14 • SF-36	• Significant decrease in OHIP and OQLQ scores post-surgery.
Silva et al 2016 Sweden P, L M (2)	Pre-surgery group N=50 44%:56% 22.7 18-66	Same patients followed up	• Pre-surgery. • Post-op6 wks. • Post-op6 mo	• OHIP-14 (Swedish) • OQLQ (Swedish)	• OHIP14 and OQLQ -significant improvement in QoL over time. • Men tended to have lower scores pre-op, but gender seemed not to be an important factor post-op. • Higher OQLQ scores if problems at school, work, social life due to facial appearance. • When facial appearance main factor for tx greatest decrease in total OQLQ score 6 mo post-op.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Palomares et al 2016 Brazil P, C M (3)	Total N=254 107: 147 18-50 (4 separate groups) 1. Pre-ortho N=65 27: 38 26.6 (8.3)	2. Pre-surgical N= 75 37: 38 24.8 (6.8) 3. Post-op N= 62 24: 38 27.9 (8.1), 4. Retention N=52 19: 33 30.1 (8.8)	• Pre-ortho • Pre-surgical- at least 6 mo of ortho tx. • Post-op at least 3 mo. • Post completion 6 mo– Retention.	• OHIP-14(Brazilian) • OQLQ(Brazilian) • IOTN • Oral examination	• OQLQ - retention phase most positive, followed by postsurgical, presurgical, and initial phases. • OHIP-14 - best in retention phase, followed by presurgical, postsurgical, and initial phases. • Significant correlations between higher OQLQ scores and crowding, anterior crossbite, open bite, concave profile, Angle Class III, and edge-to-edge overjet. • Females- more negative impact on OHRQoL, primarily; dental function and social aspects.
Kilinc et al 2015 Turkey P, C S	Post-op.Class III grpN=30 15: 15 Mono-maxillary grp (n=11) 23.18 (2.71) Bi-maxillary grp (n=19) 22.73 (4.52)	Control*- Class I skeletal with no DD N=30 15: 15 21.96 (1.88)	• From 9-42 mo post-op	• OQLQ • OHIP-14 • SF-36	• OQLQ QoL levels after surgery in mono and bimaxillary groups were similar to those without DD except for oral function in the bimaxillary group. • OHIP QoL was low compared with those without DD.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Wee 2014 Singapore R, L S	Pre-surgery Class III/ N=41 23:18 20.2 17-32	Post-op 2 yrs	• Pre-surgery • Post-op 2 yrs	• OQLQ • OHIP-14	• Neurosensory disturbances that might be related to BSSO did not affect QoL of Class III skeletal patients significantly as all QoL scores improved two years after surgery.
Kavin 2012 India P, L M (3)	Pre-surgery N=14/ VME 26 22-34	Post-op 2 mo Post-op 6 mo	• Pre-surgery • Post-op 2 mo • Post-op 6 mo	• OQLQ • OHIP-14	• OQLQ and OHIP-14 followed same pattern of scores with only little change/slight decrease in score 2 months post-op and huge improvement in QoL 6 months post-op.
Choi 2010 China P, L S	Pre-surgery N=32 10:22 23.94	Same group followed up	• T0- pre-surgery • T1- post-op 6 wks • T2- post-op 6 mo • T3- post-ortho tx 6 mo	• SF-36 • OHIP-1 • OQLQ	• OHIP-T0 21.34 (10.08), T3 6.50 (9.54) • OQLQ-T0 44.72 (17.80), T3 20.69 (16.69) • Deterioration immediate post-op then continuous improvement in OHIP and OQLQ scores from 6 months after surgery to the completion of all treatment. Best time-QoL assessment is at least 1 year after all tx is completed.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusions
Lee 2008 China P, L S	Pre-surgery N=36 11: 25 23.25 (6.60)	Same group followed up.	• Pre-surgical (Immediately before surgery) T0 • Post op 6 wk T1 • Post-op 6 mo T2	• SF-36 • OHIP-14 • OQLQ	• OHIP-T0 20.97 (10.99), T2 12.75 (10.50) • OQLQ-T0 42.53 (18.16), T2 28.11 (14.31) • At (T1) marked deterioration in QoL. • By (T2), improvement in QoL was evident compared to T0
Lee 2007 Hong Kong China P, C S	Pre-surgery N=76 28: 48 21.5 (14-41)	asymptomatic wisdom teeth consult* N=76 36: 40 26.2 (16-45) yr	• Pre-surgery	• SF-36 • OHIP-14 • OQLQ	• OHIP Control 9.92 (8.88) Case 14.96 (9.23) • OQLQ Control21.37 (13.67) Case 37.63 (20.24) • Those with DD have poorer QoL than those without.

P: Prospective, R: Retrospective, L: Longitudinal, S: single centre, M: multicentre, QoL: Quality of Life, Tx: Treatment, Post-op: Post-surgery, wk: week(s), mo: Months, yrs: years, DD: Dentofacial deformity, OFF: Orofacial functions, SD: standard deviation
*Studies with a control group highlighted in blue colour.

Table 2.3: Comparative studies of orthognathic patients which used OQLQ

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Catt 2018 UK P, C M (4)	(2 separate groups) Pre-Ortho N=73 28:45 21.2 (8.11)	Post-op 2 yr N=78 22:56 27.6 (10.21)	• Pre-Ortho • Another group of post-op 2 yr	• OQLQ • CAT-T	• Pre-tx patients -reduced QoL (facial aesthetics, oral function, social well-being). More pronounced in females • 2 yr post-op grp better QoL scores both females and males overall and in all the subdomains.
Asfour 2018 Kuwait R, L M (2)	Post-op 6mo - 7yrs N=66 24: 42 25.1 (3.9)	No control grp	• Post-op 6 mo - 7 years	• OQLQ (Arabic) • VAS	• QoL of patients with DD improved significantly post-op. • Lower OQLQ score differences between pre- and post-surgery in female patients than in male patients • No significant difference between male and female patient scores.
Tamme 2017 Germany R, L S	Post-op grp (3-10 years) N=65 21: 44 24	Control group-gender and age-matched (no other info)* N=65	• Post-op 3-10 years	• OQLQ –G • SF-36 • 35 Qs	• Continue to experience difficulties post-op; social needs -functional limitations and the assessment of one's appearance. • No baseline data, so cannot rule out whether they had problems before surgery and not consequence of the therapy.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Eslamipour 2017 Iran P, L S	Pre-surgery Bimaxillary osteotomies N=43 13: 30 18-40	Post-op 3 wks Post-op 3 mo Post-op 6 mo	• Pre-surgery • Post-op 3 wk • Post-op 3 mo • Post-op 6 mo	• OQLQ	• Reduction in OQLQ and all subdomains mean scores over the trajectory of treatment. • Women's overall QoL score in all four domains (notably, in emotional and social subscales), poorer status compared with men, pre-op. • Women's QoL, a remarkable improvement in all 4 aspects, in the same range as men post-op.
Alanko 2017 Finland P, L M (2)	T0-before start of tx T1-after first ortho exam T2- T4 T5-1 yr post-op N=22 6: 16 36 18-54	1st-year Uni students attending the dental examination (female only)* N=22 0: 22 25 19-49	• Pre-ortho • After 1st ortho exam • 3 times during tx • Post-op 1 yr	• OQLQ • SCL-90 • RSES • AAQ II • Structured diary • S & J Body image Q	• After the placement of orthodontic appliances T2, QoL was lower. • QoL improved from T2 to T5 • At T5, OQLQ scores were comparable to or even better than those of control subjects.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Jung 2016 Korea P, C S	Class II N=37 24.5(4.3) N=136 Female only 24.3 18-30	Class III N=47 24.5(7.7) Minor Malocclusion Group (MMG) N= 52 22.3(2.8)	• Pre-Ortho	• OQLQ • Rosenberg's	• Class II and Class III females, no difference in the OQLQ scores • Both groups, low QoL compared to minor malocclusion group. • Asymmetry group, no difference in OQLQ scores.
Stagles 2016 UK P, C S	Pre-ortho N=102 26%: 74% 21 16-59yr	N/A	• Pre-Ortho / Prior to consultation in the combined clinic	• IOFTN • ICON • Ceph • OQLQ	• Poorer esthetics and functional complaints are associated with large increased or reverse overjets • Being female increases OQLQ by 15.6 points compared to males. • Overjet increase by 1mm away from normal values, resulting in a 1.5 increase in OQLQ score. • OQLQ functional domain significant associations seen with overjet, overbite and IOFTN score. • IOFTN category a significant predictor for the overall OQLQ score.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Soh 2015 India P, L S	Pre-surgery N=66 28: 38 23.4 18-30	Post-op 6 mo	• Pre-surgery • Post-op 6 mo	• OQLQ	• 'Minimal clinically important difference' was calculated as one half of standard deviation above the total score. From this sample, it was determined to be 44.14. • Post-op overall improvement in QoL across all four domains.
Bortoluzzi 2015 Brazil P, C M (2)	Pre-ortho N=53 53 23:30 28.9 (9.7) 15-52	No control	• Before the start of any tx	• SF-36 • OHIP-49 • OQLQ • VAS- QoL	• More pronounced impact in female patient's QoL in domains of OQLQ (oral function, awareness of facial deformity and facial aesthetics) and OHIP (physical pain, psychological discomfort, psychological disability and handicap) • The older the patient, greater the negative impact on QoL mainly in facial aesthetics and oral function domains.
Walid A. Abdullah 2015 Saudi Arabia P, L S	Pre-surgery N=17 5: 12 M 25 (20-37) F 21.3 (19-27)	No control	• Immediate pre-surgery • Post-op 1 yr	• OQLQ (Arabic)	• Improved QoL post-op evident in all four OQLQ domains. • Difference in social aspects domain greatest.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Alanko 2014 Finland P, C M (2)	Pre-surgery N=60 16: 44 17-61 yr	1st yr Uni students who attended dental examination* N=29 1: 28 19-49 yr	• Pre-surgery	• BIQ • OQLQ • RSES • AAQ II • SCL90 • Structured Diary • IOTN AC	• Pre-surgery group's OQLQ poorer than that of controls except in social aspects of DD.
Murphy 2011 Ireland P, L M (2)	Pre-surgery N=62 27:35 21.6 yr 18-38 yr	Same group followed up N=52	• Pre-surgery. • Post-op 6 mo.	• OQLQ • VAS • GTS (post-op)	• Appearance showed the largest impact on the analysis of change in QoL using OQLQ. • Positive impact on the patient's facial appearance and oral function, improved self-confidence.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Khadka et al 2011 China P, L S	Grp A. Immediate pre-surgery after ortho tx. N=110 33: 77 22.86 (18-34)	Grp B. Immediately pre-surgery with no ortho tx (square faces/prominent zygoma) N=42 5: 37 27.21 (20-37)	• Pre-op surgery (within 30days) • Post-op (6-8 mo)	• SF-36 • OQLQ	• Pre-op, there was significant difference in the oral function and facial esthetics components between group A and group B. • Post-op only the oral function component showed a significant difference.
Al- Ahmad 2009 Jordan P, C S	Pre-surgery N=36 11: 25 21.9 (17-33) Post-op N=35 12: 23 24.5 (17-33) Declined surgery N=35 10: 25 23.1 (15-43)	Control (patients attending routine clinics-normal occ, no DD)* N=37 12: 25 17-40 yr Total N=143 (4 separate groups)	• Pre-surgery • Post-op • Declined surgery grp • Control grp	• SF- 36 • OQLQ	• Condition-specific OQLQ showed better discriminator ability than the generic SF-36 • Surgery declined group of patients seemed to adjust to their deformity, thus maintaining levels of QoL similar to normal individuals.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Bock et al 2009 Germany P, C S	Pre- ortho N=50 25: 25 27.9 (7.9) 16-50 yr	No control	• Pre-Ortho	• OQLQ-G (German)	• Most of the patients in this study mentioned aesthetic and functional reasons for treatment (n = 27, 54%) or primarily health-related restrictions (n = 19, 38%). Only four (8%) gave purely aesthetic reasons.
Al-Bitar et al 2009 Jordan P, C M (2)	Pre-Ortho N=38 17: 21 16-31	No control	• Pre-Ortho	• SF-36 • OQLQ	• Between Jordanian and British samples, OQLQ differed only for the function domain. • Functional problems in the Jordanian sample appear to have a greater impact on QoL.
Tajima et al 2007 Japan P, C S	Surgery grp N=61 21: 40 28.8 (16-40) Non-surgery grp N=66 12: 54 22.8 (16-41)	Normal occlusion, no DD* N=66 28: 38 22.0 (19-31)	• 1st visit • Pre-orthodontics	• SF-36 • SOHSI • OQLQ (VAS 0-10) • Severity score (SS)	• In all domains of OQLQ, surgical group differed compared with Control and Non-surgical group. • Study is unique as compared QoL of a group who choose to try nonsurgical orthodontics for their malocclusion.

Author Year Country Study-design Centres	Test Sample M: F Mean Age (SD) yrs Age Range (yrs)	Comparison Sample M: F Mean Age (SD) yrs Age Range (yrs)	Data collection	Questionnaires	Conclusion
Cunningham 2002 UK P, L S	Pre-ortho N=62 23: 39 21.92	Same group followed up	• T1- pre-ortho • T2- pre-surg • T3- 6-8 wks after removal of ortho appliances	• OQLQ • VAS • SF-36	• Good evidence for validity, reliability and responsiveness of the OQLQ.

P: Prospective, R: Retrospective, L: Longitudinal, S: single centre, M: multicentre, QoL: Quality of Life, Tx: Treatment, Post-op: Post-surgery, wk: week(s),mo: Months,yrs: years, DD: Dentofacial deformity, OFF: Orofacial functions, SD: standard deviation
*Studies with a control group highlighted in blue colour.

2.5.3 Measurement of Condition-specific QoL

Condition-specific measures have been developed to specifically assess the impact of a particular disease or condition on QoL. Condition-specific measures focus on a particular problem and are more responsive to small but clinically significant changes in health.

Cunningham et al. (2000) developed a condition-specific instrument to measure the QoL of patients with severe dentofacial deformity. The instrument content was derived through literature review and focused interviews with patients and clinicians. The resulting instrument was tested for internal consistency and test-retest reliability. The instrument is known as the orthognathic quality of life questionnaire (OQLQ).

The OQLQ has 22 statements divided into four principal components:

- First component-social aspects of deformity (15-22)
- Second component-facial aesthetics (1, 7, 10, 11, 14)
- Third component-oral function (2-6)
- Fourth component-awareness of facial deformities (8, 9, 12, 13).

The responses are marked on a four-point scale according to how much the issue covered by the statement bothers the respondent.

1= bothers you a little and on the higher end of the scale

4= bothers you a lot.

2 and 3=lie between these statements.

0= not applicable, does not bother at all

A total OQLQ score can range from 0 to 88. A lower score indicates better QoL; a higher score indicates poorer QoL.

2.5.3.1 Review summary of OQLQ studies (Table 2.2 and Table 2.3)

Twenty-seven studies have assessed psychosocial aspects of orthognathic patients using OQLQ. The studies included in Table 2.2 and Table 2.3 does not include studies conducted primarily for translation, cross-cultural adaptation, validity and reliability of OQLQ; these studies will be discussed separately.

These twenty-seven studies have been conducted in East Asia (China-4; Japan-1;Korea-1), South Asia (India -2; Nepal-1), South-East Asia (Singapore-1), Middle-East (Jordan-2; Saudi-; Iran-1; Kuwait-1;Turkey-1), Nordic countries (Finland-2; Sweden-1), Rest of Europe (UK -2; Ireland-1; Italy-1; Germany-3) and South America (Brazil-3).

All studies display heterogeneity in various aspects of study design. The composition of the sample, the time point of data collection, the age range of the subjects and the other questionnaires used alongside OQLQ, differed in each study. The time of data collection varied from pre-orthodontics, pre-surgery and at different time points post-surgery. Some studies recruited from those attending oral and maxillofacial clinics or combined clinics and it was often not clear whether the initial sample was pre-orthodontics or pre-surgery.

In almost all of the studies, the OQLQ questionnaire data were collected prospectively, although in some studies data were collected from groups who had surgery completed a few years previously (Tamme *et al.*, 2017; Al-Asfour, Waheedi and Koshy, 2018). One of

the subgroups in the study by Al-Ahmad et al. (2009), OQLQ data were collected up to 7 years postoperatively, which raises questions about the extent of recall bias.

Some studies were cross-sectional and assessed different cohorts at a single time point, while others were longitudinal with the same group followed up and the data collected at various stages. Some cross-sectional studies assessed a pre-orthodontics or a pre-surgical group and a separate post-surgical group. Overall sixteen studies were longitudinal, and eleven were cross-sectional in study design. Among the cross-sectional studies, data were collected pre-orthodontics in eight studies and pre-surgery in three studies.

Among longitudinal studies, only three were started with participants prior to orthodontic treatment, eleven were started prior to orthognathic surgery and three longitudinal studies followed up patients at different time periods post-surgery. All these studies followed the participants to the completion of treatment. Out of the total twenty-seven studies, data were collected pre-orthodontics for ten, and pre-surgery for fourteen and post-surgery for three.

All studies had both male and female subjects with a slight predominance of female subjects in the sample, except for Jung (2016) which collected data only from female subjects.

All studies had a broad age range for the sample with the largest being 18-66 years. The age-range from the youngest subject to the oldest in these studies varied from 12 to 48 years. Subjects from different age groups with dentofacial deformity potentially can have significant differences in their response to psychosocial questionnaires.

Seven studies had control groups. Two Finnish studies (Alanko et al., 2014, 2017) used '1st-year university students who attended dental clinics' as the control groups. 'Class I patients and patients with normal occlusion with no dentofacial deformity' were used as a control group by Kilinc & Ertas (2015) and Tajima et al. (2007). Al-Ahmad et al. (2009) used 'patients attending routine dental clinics with no dentofacial deformity' while Lee et al. (2007) used 'asymptomatic wisdom teeth consultation patients without dentofacial deformity'. Although Tamme et al. (2017) used a control group, no further information was available in their publication. None of the studies had an age-matched true general population control group.

Seven studies were conducted in multiple centres and the others were single centre studies. Among the multicentre studies, six studies were conducted in two centres, and one had three centres (Palomares et al., 2016) and one had four centres (Catt et al., 2018). Only three studies report a sample size calculation (Jung, 2016; Palomares et al., 2016; Wee & Poon, 2014).

Some studies had used OQLQ in the English language in the original format while others had it translated into their native language and culturally adapted it before data were collected. Cunningham et al. (2002) first conducted the validity and responsiveness assessments of OQLQ. Bock et al. (2009) translated, adapted and validated OQLQ in German. Three studies, two in Brazil (Araújo et al., 2013; Coutinho Baldoto Gava et al., 2013) and one in Serbia (Vucic et al.,2016) have assessed the version of OQLQ translated into their native language with regard to validity and reliability.

The mean time to complete the questionnaire was assessed in one study and was 3.5 minutes (range, 2.0-8.0 minutes) (Vucic et al., 2016).

Almost all of the published studies collected data, by patients self-completing the OQLQ questionnaire before appointments, or it was sent to them by post. In the study by Khadka et al. (2011) during their follow-up, 15 patients were unable to complete the questionnaire personally, and therefore a telephone interview was conducted.

Three studies (Feu et al., 2017; Pelo et al., 2017; Zingler et al., 2017) assessed changes in QoL in a 'surgery-first' cohort compared to traditional 'orthodontics-first' approach. Feu et al. (2017) reported that early orthognathic surgery negatively influenced patient cooperation after surgery because patients had already achieved many of the improvements they were seeking.

2.5.3.2 Influence of various independent variables on OQLQ scores: Gender, Age

Multiple studies have explored the correlation between gender and OQLQ scores. Conflicting findings have been found regarding OQLQ score and gender, but most studies reported females with lower QoL and higher OQLQ scores. Choi et al. (2010) found no significant difference between male and female OQLQ scores.

Silva et al. (2016) showed that gender was correlated with the baseline OQLQ score, with men tending to have lower scores (better QoL) pre-operatively. Gender seemed not to be an influential factor after surgery. Patients who reported facial appearance as the primary factor for seeking treatment had the greatest decrease in total OQLQ score between baseline and six months postoperatively.

The impact of dentofacial deformity (DD) on QoL was more pronounced in female patients prior to having surgery (Bortoluzzi et al., 2015) with significant differences between male and female patients observed in some domains of OQLQ (oral function, awareness of facial deformity and facial aesthetics) and OHIP (physical pain, psychological discomfort, psychological disability and handicap).

Comparable results have been shown in another study with overall QoL score in females across all four domains before surgery (notably, in emotional and social subscales) showing a poorer status compared with males (Eslamipour et al., 2017). Women's QoL, however, achieved a remarkable improvement after the surgery in all four aspects and was in the same range as men. Palomares et al. (2016) also demonstrated that females had a more negative OHRQoL, primarily regarding dental function and social aspects.

Although in the study by Al-Asfour et al. (2018), the response pattern generally showed lower OQLQ score differences between pre- and post-surgery in females than in males, this was not statistically significant.

Jung (2016) explored differences among females with Class II or Class III malocclusion compared to minor malocclusions. No significant differences were found in the OQLQ scores between the Class II and Class III groups, but both groups showed significant impairment in QoL compared to the minor malocclusion group.

Only one study explored the age difference in OQLQ scores. The older the patient is, the greater is the negative impact on QoL mainly in the facial aesthetics and oral function domains (Bortoluzzi et al., 2015).

2.5.3.3 Influence of Culture/Ethnicity and Funding for treatment on OQLQ scores:

Al-Ahmad et al. (2009) compared a Jordanian sample with a British sample using OQLQ and showed no statistically significant differences for three of the four domains: dentofacial aesthetics, social aspects or awareness of dentofacial aesthetics. There was, however, a significant difference for QoL related to the domain for oral function. The Jordanian group had a slightly higher mean value for function and hence poorer QoL compared to the British cohort. This finding may be due to differences in culture or funding, where Jordanian patients are more comfortable justifying their need for treatment based on function rather than aesthetics.

2.5.4 Orthognathic patients and Social Anxiety

As social anxiety is evaluated in this study reported here, this will now be defined.

Social anxiety disorder (SAD) has been defined as 'an enduring fear of social situations where the individual may be subject to evaluation by others' (Carleton et al., 2011). It is the most common type of anxiety disorder, with a prevalence of up to 18 per cent in the general population (Kessler et al., 2005). Fear of negative evaluation is said to be the trademark of social anxiety, as this fear often leads to irrational and exaggerated anxiety in social situations (Weeks et al., 2005). The presence of a facial disfigurement may be associated with elevated fear of negative evaluation, and orthognathic patients could be at an increased risk of Social Anxiety Disorder (SAD) regardless of age, gender and severity of the deformity (Ryan et al., 2016).This may be a factor motivating orthognathic patients to seek treatment (Rumsey and Harcourt, 2004). Different self-reported questionnaires are used in research to evaluate social anxiety.

The Fear of Negative Evaluation Scale (FNE) is a self-reported questionnaire that was designed to assess this construct, and that has been widely used for this purpose (Watson and Friend, 1969). The FNE was divided into two scales, one worded in a straightforward manner (FNE-S) and the other consists of reverse worded items (FNE-R).

The only study which assessed fear of negative evaluation directly in orthognathic patients using the original 30-item Fear of Negative Evaluation Scale (FNES)found that patients had a lower fear of negative evaluation than norms (Lovius et al., 1990).It has been argued that its length (30 items, scored true or false) may tax respondents' patience and endurance. So a short form (BFNES) was introduced by Leary (1983).

2.5.4.1 Brief Fear of Negative Evaluation scale (BFNES)

BFNES consists of 12 items, eight of the items are positively scored, and four are negatively scored (items 2, 4, 7, and 10), in order to reduce the risk of response bias (Rodebaugh et al., 2011). Recent research has suggested using the original 12-item scale (O-BFNES) but including only the eight straightforward (S-BFNES) items in calculating the final score (Carleton et al., 2011; Rodebaugh et al., 2011).

Ryan et al. (2016) conducted a prospective cross-sectional questionnaire study using BFNES among an orthognathic cohort in a single UK centre and a national general population control group. Data from the orthognathic patients were collected before the start of orthodontic treatment. The mean S-BFNES score was 15.59 (SD7.67) and 24.21 (SD 8.41) for the general population and the orthognathic group respectively. The general population sample showed females exhibited a significantly higher score compared to males and a trend towards BFNES scores decreasing with age. In the orthognathic sample,

the influence of gender and age was not statistically significant. The authors concluded that orthognathic patients exhibited significantly higher levels of fear of negative evaluation than the general population and the magnitude of the difference is likely to be clinically meaningful.

Multi-centre studies have been recommended by the authors to increase the generalizability of the findings. In that study, the general population sample was also not screened for the presence of dentofacial deformity.

2.5.5 Orthognathic patients and Body Mass Index

BMI was also recorded in the present study to explore any associations with high or low BMI and psychosocial aspects among orthognathic patients.

Body Mass Index (BMI) may be assessed objectively by recording weight and height or may be self-reported to the following categories: underweight <18.5 kg/m2, normal 18.5 to <25kg/m2, overweight 25 to <30 kg/m2, obese 30 to <35/m2 and morbidly obese > 35kg/m2 (Bjorntorp et al., 2000).

A study conducted by Santos et al. (2014) using silhouette scales and measuring the actual height and weight of school students suggested agreement and association between different indicators of body image and BMI in adolescents. A general tendency to experience negative emotions was associated with higher BMI, whereas a general tendency to be organised and disciplined was associated with lower BMI (Sutin and Terracciano, 2016). Physical activity, for example, has been linked to personality: Individuals high in Extraversion, Conscientiousness, or Emotional Stability tend to engage in more physical

activity than individuals who score lower on these traits (Rhodes & Smith, 2006; Wilson & Dishman, 2015).

Self-reported body weight and height data are easy and cost-effective to obtain (Stunkard and Albaum, 1981) but often viewed as a study limitation and considered insufficiently accurate for research studies. Findings by Quick et al. (2015) indicate that self-reported body weight and height of young adults can be fairly accurate, and their use is supported when direct measurements are not feasible.

2.5.5.1 Orthodontic patients and BMI/Obesity

Among orthodontic patients, an increased BMI has been shown to be a risk factor for less cooperation, longer treatment duration and more oral health-related problems during multi-bracket treatment, indicating that these patients require special attention during orthodontic therapy (Von Bremen et al., 2016). Another study by Von Bremen et al. (2013) study showed no differences in PAR score reduction between normal-weight and overweight multi-bracket patients. Patients with an increased BMI did not cooperate as well during treatment and had slightly longer treatment durations with more appointments than adolescents with a normal BMI. Schott & Ludwig (2014), however, found that BMI did not influence wear time or behaviour of removable orthodontic appliances by comparing obese to normal weight young patients.

Saloom et al. (2017) conducted a prospective clinical study investigated tooth alignment in obese and normal-weight patients undergoing fixed-appliance orthodontic treatment. Obese patients needed less time to achieve tooth alignment compared with normal-weight patients, but this was no significant. After adjusting for confounders, the rate of

orthodontic tooth movement was significantly higher in obese patients compared with normal-weight patients. A pro inflammatory obese state can influence orthodontic tooth movement, with significant associations between levels of specific biomarkers within the GCF of obese patients.

2.5.5.2 BMI & Orthognathic surgery

Patients seeking surgical-orthodontic treatment have been shown to have altered body image (Cunningham and Feinmann, 1998; Cunningham et al., 2000) which may well impact on their BMI. Vulink et al. (2008) showed that 17 per cent of patients had excessive concerns about their appearance before orthognathic surgery and 10 per cent of patients screened positive for body-dysmorphic disorder.

Neeley et al. (2009) examined patients undergoing orthognathic surgical correction for Class II skeletal malocclusions and assessed outcomes in relation to BMI. That study showed that obese and overweight patients have different responses to mandibular advancement with rigid fixation compared to normal or thin patients. The authors advocated orthodontists and surgeons to treat obese patients having orthognathic surgery more appropriately.

Only one previous short-term observational study (Hammond et al., 2015) recorded BMI pre- and post-orthognathic correction. The authors recommended closer psychosocial and dietetic support for those patients who have a low, normal or underweight BMI.

2.6 Orthognathic patients and Functional need for treatment.

Orthognathic surgery may also be indicated for functional needs. These were examined in the present study.

2.6.1 IOFTN

The Index of Orthognathic Functional Treatment Need (IOFTN) has recently been developed to reflect the functional indications of treatment need for orthognathic patients (Ireland et al., 2014).

Although widely used, there are some limitations of the Index of Orthodontic Treatment Need (IOTN). In the case of the Aesthetic Component (AC) of the index, it comprises only Class I and Class II incisor relationships. In the case of DHC, some of the functional indications for orthognathic treatment are not included or might be classified differently if the malocclusion were not treatable with orthodontics alone.

The Index of Orthognathic Functional Treatment Need (IOFTN) was developed to overcome the limitations of IOTN by using, wherever possible, the same traits as used in the IOTN DHC but with modifications and additions to include orthognathic treatment needs. The Index reflects the functional indications of treatment need for orthognathic patients and assists in prioritising public resources for orthognathic surgery. This created an index that was familiar to those using the IOTN which is valid, reliable and quick and easy to use. IOFTN is used to assess objective treatment need, with the single most severe occlusal or facial trait scored categorically from 1 to 5.

Several retrospective studies, and only one prospective study, have been conducted using IOFTN.

A retrospective UK study of 78 subjects found the most prevalent IOFTN score was 5.2 (29.5%), followed by 5.3 (15.5%), 4.2 (13%) and 4.3 (11.5%) (Harrington et al., 2015). The authors concluded that the index is a reliable tool to identify patients in need of orthognathic surgery and can be used in resource allocation for patients with highest functional needs.

In a sample of 103 Iranian subjects who had orthognathic surgery, an IOFTN score of 5.3 (27.2%) was the most prevalent, followed by 4.2(19.4%), 4.3(13.6%), 4.10 (12.6%) and 5.2 (8.7%) (Borzabadi-Farahani et al., 2016).

Retrospective studies in the UK (Barber et al., 2017), New Zealand (Fowler et al., 2018) and Malaysia (Soh et al., 2018) found that approximately 90 per cent of orthognathic patients were in IOFTN category 4 and 5 and that there was no association between OHIP-14 and IOFTN (Fowler et al., 2018).

The only prospective study which was conducted in the UK found that IOFTN was significantly associated with the functional domain of OQLQ (Stagles et al., 2016). The OQLQ functional domain also had significant associations with overjet and overbite. The IOFTN category was a significant predictor for the overall OQLQ score, with category 5 patients scoring a mean of 10.0 points (95 per cent CI) more than category 4. The IOFTN also adequately prioritised those patients with the greatest functional disadvantage and the authors recommend that it should be used routinely.

CHAPTER THREE

AIMS AND NULL HYPOTHESES

3. Aims and Null Hypotheses

3.1 Aims

Primary

- To compare, in the RoI, generic oral health-related quality of life (OHIP-14), condition-specific quality of life (OQLQ), the fear of negative evaluation (BFNES) and self-reported BMI of patient's seeking surgical-orthodontic correction of their malocclusion versus those of the general population.

Secondary

- To assess the IOFTN in the orthognathic cohort.
- To investigate any correlation between the functional domain of OQLQ and IOFTN.

3.2 Null hypotheses

Primary

- There is no difference in generic and condition-specific oral health-related quality of life, fear of negative evaluation and self-reported BMI of patient's seeking surgical-orthodontic correction of their malocclusion versus those of the general population.

Secondary

- There is no correlation between the functional domain of OQLQ and IOFTN in the orthognathic cohort.

CHAPTER FOUR

MATERIALS AND METHODS

4. Materials and Methods

4.1 Study Design

This was a multicentre case-control study.

4.2 Ethics

Ethical approval was received from the Clinical Research Ethics Committee of the Cork University Teaching Hospital (Ref: ECM 4 (k) dated 05-07-2016; modified date 08-03-2018) (Appendix A).

4.3 Development of Telephone Survey

The telephone interview was identified as the most feasible way to gather data from the general population. To achieve uniformity in the methodology of data collection between the orthognathic group and the general population group, we used telephone interviews for the orthognathic group as well.

A telephone interview script was designed and a pilot study was conducted to assess the duration of the telephone survey as well as to remove any ambiguities in the questions. The survey comprised the following questions:

- General questions regarding age range, gender, ethnicity, educational level and self-reported BMI
- OHIP-14
- OQLQ
- BFNES.

RPC conducted telephone interviews of the orthognathic cohort. Amarach (Dublin, RoI), a national market research agency in RoI, conducted the telephone interviews of the general population cohort. For both groups, the telephone interviews were conducted in the same manner. The investigator who conducted the telephone interviews of the orthognathic cohort had undergone preliminary training in telephone surveys, provided by a market research company (IPSOS MRBI, Dublin). The telephone interview script was reviewed and modified following recommendations from the research manager at the head office of IPSOS MRBI, Dublin. The main researcher (RPC) received one-to-one training on conducting a telephone survey. Training also included an opportunity to listen to the live telephone survey process at the centre.

The modified draft version of the telephone script was used to pilot the full telephone interview on seven adults (four females and three males) from CUDSH staff and students. Each participant gave feedback; the order and the content of the telephone script were modified accordingly. This resulted in the final telephone script and the data collection sheet for the telephone survey; each interview took on average 8 to 10 minutes. Following the pilot study, the feedback was a preference to have OQLQ questions before the OHIP-14. The main researcher (RPC) started telephone interviews in July 2016. RPC and Amarach used the same final telephone script and data collection sheet. The final order of the telephone survey for the questionnaires was as follows:

- OQLQ
- OHIP-14
- BFNES

4.4 Sample size calculation

4.4.1 Orthognathic patient group - sample size calculation

As no study had assessed all the variables recorded in our study, the sample size for OHIP-14 and OQLQ was based on Lee et al. (2007). That study was able to detect clinically meaningful differences with a power of 80 per cent ($p<0.05$) in OHIP-14 and OQLQ scores between the orthognathic and control groups, with a sample size of 76 participants in each group.

For BFNES, a sample size of 46 orthognathic patients was needed to detect a difference in means of 10 per cent on the S-BFNES scale (3.2 points) using an unpaired t-test with a power of 80 per cent at the 5 per cent level of significance (Rodebaugh et al., 2011). Based on this, Ryan et al. (2016) recruited 61 patients to detect a clinically relevant difference between an orthognathic and general population group in their study.

A sample size of 80 subjects was recruited to allow for some incomplete questionnaires (particularly for OHIP-14 and OQLQ) in the orthognathic patient group.

4.4.2 General population group sample size calculation

The interim analysis of the first 56 patients from our orthognathic cohort identified an equal distribution of males and females with a mean age of 17.9±1.7 years. We, therefore, requested Amarach to identify a random sample of subjects within the 16 to 20 years age range with approximately equal gender distribution across the country.

No previous study had assessed all the variables recorded in our study.

The clinically significant difference in OHIP-14 score was set at 25per cent of the total score based on clinical experience and scores from previously published data. With the orthognathic sample size set at 80 and the OHIP-14 score of 14.14 (SD 8.81) from our interim results, the general population group sample size was calculated to require 136 subjects.

The clinically significant difference in OQLQ score was set at 20per cent of the total score based on clinical experience and scores from previously published data. With the orthognathic sample size set at 80 and the OQLQ score of 40.0 (SD 20.16) from our interim results, the general population group sample size was calculated to require 130 subjects.

A sample size of 212 subjects from the general population was required to detect a clinically significant difference in means of 10per cent on the BFNES scale between the orthognathic group and the general population group based on mean scores (29.72±9.39) from previously published data by Ryan et al. (2016).

We recruited 213 subjects from the general population which would give a power of 80per cent at the 5per cent level of significance.

4.5 Samples and recruitment

Consultant orthodontists and Consultant Oral and Maxillofacial surgeons from five centres in the RoI who supervised the management of orthognathic patients at combined orthodontic-surgical clinics were contacted and invited to participate in the research.

The five centres were:

- Cork University Dental School and Hospital (CUDSH)
- St Finbarr's Hospital, Cork
- University Hospital Waterford
- Merlin Park University Hospital, Galway
- St James's Hospital, Dublin

The contact clinician in each unit received a copy of the protocol, ethics approval and questionnaires. An agreement was obtained from all consultants to conduct the study using patients under their care.

4.5.1 Inclusion and Exclusion criteria

4.5.1.1 Orthognathic group

Inclusion criteria:

- Patients accepted for combined orthodontic-surgical treatment but have not yet commenced pre-surgical orthodontics
- Age ≥16 years
- Able to give informed consent.

Exclusion criteria:

- Patients with congenital craniofacial anomalies (e.g. due to syndromes or cleft lip and/or palate)
- Patients younger than 16 years
- Patients unable to give informed consent
- Patients who have previously received orthognathic treatment
- Reported or exhibited psychosocial disorders
- Patients undergoing combined orthodontic-surgical treatment who paid privately.

4.5.1.2 General population group

Inclusion criteria:

- Age ≥16 years
- Able to give informed consent

Exclusion criteria:

- Previous orthognathic or cosmetic surgery.

4.5.2 Orthognathic group data collection

Eighty consecutive patients, who were referred by orthodontists and attended the combined orthodontic-surgical planning clinic at CUDSH or one of the four Regional HSE centres, and who met the inclusion and exclusion criteria, were invited to participate in a telephone interview by the main researcher (RPC). RPC visited each unit, met the new patients after their joint orthodontic-surgical planning clinic and obtained informed consent from willing participants. None of the participants had yet commenced pre-surgical orthodontics.

Patients were provided with a brief overview of the research project and then requested to read the written patient information sheet regarding the study. Written informed consent was obtained from patients who were willing to take part. Parents were actively encouraged to participate in the consent process, if in attendance at the combined orthodontic-surgical clinic, and the main researcher (RPC) addressed any queries. Patients were requested to provide the most suitable contact telephone number and to indicate the most appropriate time to be contacted.

A reminder text message was sent 10 to 30 minutes before making the telephone interview. Verbal consent was obtained from the patient prior to each telephone survey. Patients were advised that they could decide to withdraw consent midway through the telephone survey if desired with no detriment to their treatment. Participants were assured that their responses would remain confidential and anonymous. Participants were informed some responses might sound personal and that it was acceptable not to answer if they wished to do so. During the survey, patients were given time to answer each question and if they were unsure, the question and options were repeated slowly. At the conclusion of the survey, each patient was asked if they wanted their name entered into a prize draw, to win €250. Following recruitment, data were entered into a data collection sheet with the subject identified by a unique ID number only.

4.5.3 General population group data collection

A rigorous methodology was used to achieve the best possible response rate and sample size including making up to eight attempts by telephone. Amarach employed two strategies

to recruit participants within the field period; random number generation and field interviewer recruited participants. In both cases, respondents were recruited at random but based on the exclusion criteria given and with the requirement for a country-wide spread of participants. Subjects in the general population group were asked the area of the country in which they lived. Soft quotas were set at the beginning for age, gender and region (Dublin, Rest of Leinster, Munster, Connaught/Ulster).

Interviewers recruited respondents by asking them their age and checking whether they satisfied the inclusion criteria. Multiple field interviewers covering set geographic areas, approached people within their extended networks and panels. Parental consent was sought before those under the age of 18 were approached. In such cases, often the interviewer or participant recruiter would have visited the home first. Once parental consent was given, then those under 18 were asked for their consent to participate.

Participants recruited by random number generation were asked their age, and in the case where a parent answered the telephone, they were asked whether they had a son/daughter between the ages of 16 and 20 years. Verbal parental consent was obtained for all participants under 18 years and none of the participants withdrew their consent mid-way through the survey. Participants were given the option to enter their name into a prize draw, where there were four prizes of one4all vouchers: one prize of €200, one of €100 and two prizes of €50.

4.6 Instruments used and data recorded

Participants were asked general questions regarding age, gender, ethnicity, education and to self-report BMI. They were then asked to answer three questionnaires in the order

recommended by the pilot study: OQLQ, OHIP-14 and BFNES. For the orthognathic group, patient records were examined by RPC to determine the IOFTN score and malocclusion type.

4.6.1 OHIP-14

Generic oral health is most commonly measured using a 14-item short form version of the Oral Health Impact Profile (OHIP-14) (Appendix C).

This is comprised of seven individual domains (two items per domain):

- Functional limitation (items 1, 2)
- Physical pain (items 3, 4)
- Psychological discomfort (items 5, 6)
- Physical disability (item 7, 8)
- Psychological disability (item 9, 10)
- Social disability (item 11, 12) and
- Handicap (item 13, 14).

Responses for each item were made on a Likert-type scale and coded as:

0 = ‘never’,

1 = ‘hardly ever’,

2 = ‘occasionally’,

3 = ‘fairly often’ and

4 = ‘very often’.

Overall OHIP-14 scores can range from 0 to 56 where 0 indicates no impact and 56 indicates the worst impact of one’s oral health on QoL.

Individual domain scores were calculated by summating responses to the items within a domain and can range from 0 to 8.

4.6.2 OQLQ

This is a condition-specific 22-item Orthognathic Quality of Life Questionnaire (OQLQ) (Cunningham, Garratt and Hunt, 2000). (Appendix B)

The 22 items contribute to four domains:

- Facial aesthetics (items 1, 7, 10, 11, 14 scoring 0– 20),
- Oral function (items 2–6 scoring 0–20),
- Awareness of dentofacial aesthetics (items 8, 9, 12, 13 scoring 0–16) and
- Social aspects of dentofacial deformity (items 15–22 scoring 0–32).

The responses were marked either NA (not applicable) or on a four-point scale according to how much the issue covered by the statement bothered the respondent.

1 = 'means it bothers you a little' and

4 = 'means it bothers you a lot';

2 and 3 = 'lie between these statements'.

0 = NA = 'means the statement does not apply to you or does not bother you'.

A total OQLQ score range from 0 to 88. A lower score indicates better QoL, and a higher score indicates poorer QoL. Individual domain scores were calculated by summating responses to the items within a domain.

4.6.3 BFNES

The BFNES (Brief Fear of Negative Evaluation Scale) measures the core construct in social anxiety and is thought to be the most commonly used measure of social anxiety in clinical studies. (Appendix D)

BFNES consists of 12 items, scored from 1-5:

1 = not at all characteristic of me

2 = slightly characteristic of me

3 = moderately characteristic of me

4 = very characteristic of me

5 = extremely characteristic of me

- Original 12 item score / O-BFNES (items 1-12) / score (12–60)
- Eight of the items are positively scored, and four are negatively scored (items 2, 4, 7, and 10), to reduce the risk of response bias.
- 8 straightforward items / S-BFNES (items 1, 3, 5, 6, 8, 9, 11, 12) / score (8-40)
- Total scores were calculated by summating responses to the items (S-BFNES).

4.6.4 BMI

Self-reported BMI was recorded using the following categories:

- Underweight<18.5 kg/m ^{2}
- Normal 18.5 to <25 kg/m ^{2}
- Overweight 25 to <30 kg/m ^{2}
- Obese 30 to <35 kg/m ^{2} and
- Morbidly obese ≥35 kg/m ^{2}

This information was collected as part of the general questions asked of participants. The question was worded as below:

Which category would you choose to describe your body mass index?

a. Underweight
b. Normal
c. Overweight
d. Obese
e. Morbidly obese

4.6.5 IOFTN

The Index of Orthognathic Functional Treatment Need (IOFTN) was used to reflect the functional indications of treatment-need for orthognathic patients.

IOFTN is based on a five-point scale ranging from Very Great Need for Treatment (5) through to No Need for treatment (1).

Five major categories consist of individual sub-categories. (Appendix E)

- No Need for treatment
- Mild Need for Treatment
- Moderate Need for treatment
- Great Need for Treatment
- Very Great Need for Treatment

4.7 Reliability tests

4.7.1 BMI

To gain an insight into how objective and subjective measures compare for BMI assessment in the orthognathic sample, 11 randomly selected patients (14 percent) had their height and weight recorded using a stadiometer (Model: 213, Seca,) and digital

weighing machine (WB-150MA, TANITA Corporation). Comparison between self-reported BMI and objective measurements was undertaken.

4.7.2 IOFTN

- The main researcher (RPC) assessed pre-treatment study models and referred to clinical photographs and clinical assessment notes to determine the IOFTN score.
- To determine intra-examiner reliability in IOFTN assessment, the records of 21 patients (26 per cent) reviewed initially were re-examined three months later.

4.8 Statistical analyses

Statistical Analyses

The statistical analyses were undertaken using SAS for Windows Version9.4 (SAS Institute Inc., NC, USA).

The statistical tests used are summarised in Table 4.1

Table 4.1: Statistical tests and analyses

	Statistical Analyses
Self-reported BMI	• Chi-squared tests
OHIP-14	• Overall score – Mean and SD for each group • Individual domain scores for groups • Tested for normality • ANOVA • Multiple linear regression - to find the influence of group, gender, Ethnicity, BMI, Education, and Age on the OHIP-14 score and domain scores.
OQLQ	• Overall score– Mean and SD for each group • Individual domain scores for groups • Tested for normality • ANOVA • Multiple linear regression - to find the influence of group, gender, Ethnicity, BMI, Education, and Age on the OQLQ score and domain scores. • Multiple linear regression - to find the influence of group, gender, Ethnicity, BMI, Education, and Age on the OQLQ functional domain score.
BFNES	• Overall score – Mean and SD for each group • Tested for normality • ANOVA • Multiple linear regression – to find the influence of group, gender, Ethnicity, BMI, Education, and Age on the S-BFNES score.
IOFTN	• Mean and SD of categories • Mean and SD of subcategories • Multiple linear regression with IOFTN as independent factor • Intra-operator reliability

CHAPTER FIVE

RESULTS

5. Results

5.1 Demographic data

Eighty patients (41 females; 39 males) with a mean age of 17.5(SD1.6) years were recruited to the orthognathic group between July 2016 to January 2018. The general population sample comprised of 213 subjects (159 females; 139 males) with a mean age of 17.8(SD 1.5) years (Table 5.1).

Most of the orthognathic and general population group were in 'secondary education' (85 per cent and 68 per cent respectively), but more of the general population group (30 percent) were in third level education compared to the orthognathic group (10 per cent). Over 90 per cent of subjects in both groups were of Irish origin.

In the orthognathic sample, the breakdown of the orthognathic patients by recruitment site and of the general population by provinces is given in Table 5.2. Most of the orthognathic sample was recruited between CUDSH (26%) and University Hospital Waterford (35%). The general population sample covered 24 out of 26 counties in the RoI. Dublin had the largest number of recruits (n=59) followed by Cork (n=26) and Galway (n=25).

In the orthognathic group, a mix of malocclusions was observed, with Class III being most prevalent (65%) followed by Class II division 1 (33%) (Table 5.3). Of the 80 patients in the orthognathic group, 91 per cent were in categories 4 or 5 of IOFTN indicating 'great' and 'very great' functional need for orthognathic surgery respectively.

Table 5.1: Characteristics of the orthognathic group and the general population group.

Characteristics	**Orthognathic, N=80(%)**	**General population, N= 213 (%)**
Gender		
Female	41 (51)	118 (55)
Male	39 (49)	95 (45)
Age in years [range, mean (SD)]	16-25, 17.5 (1.6)	16-20, 17.8 (1.5)
Education		
Primary	4 (5)	5 (2)
Secondary	68 (85)	144 (68)
Tertiary	8 (10)	64 (30)
Ethnicity		
Irish	73 (91)	200 (94)
British	1 (1)	2 (1)
Other White	0	1 (0)
Black / African/ Caribbean	4 (5)	2 (1)
Mixed	2 (3)	3 (1)
Other	0	5 (2)

Table 5.2: Geographic distribution of the orthognathic and the general population sample by region in RoI.

HSE units in RoI	**Orthognathic sample, n=80(%)**
CUDSH, Cork	21 (26)
St Finbarr's, Cork	9 (11)
University Hospital, Waterford	28 (35)
Merlin Park University Hospital, Galway	14 (18)
St James's Hospital, Dublin	8 (10)
Provinces of RoI (counties)	**General population sample, n=213(%)**
Leinster (11)	108(50.5)
Ulster (3)	17(8)
Munster (6)	54(26)
Connaught (4)	34(15.5)

Table 5.3: Malocclusion and IOFTN categories of the orthognathic sample

Malocclusion	**N=80 (%)**	**IOFTN**		**N=80 (%)**
		IOFTN main categories	IOFTN subcategories	
Class I	1 (1)	3	3.3	6 (8)
Class II division1	26 (33)		3.4	1 (1)
Class II division2	1 (1)	4	4.1	4 (5)
Class III	52 (65)		4.2	5 (6)
			4.3	20 (25)
			4.8	1 (1)
		5	5.2	19 (24)
			5.3	15 (19)
			5.4	9 (11)

5.2 BMI (Self- reported)

BMI category was self-reported as 'normal' by 84 per cent of the orthognathic group and by 85 per cent of the general population group. The breakdown of the orthognathic and general population samples by self-reported BMI category is given in Table 5.4. There was no significant difference in the distribution of self-reported BMI between the groups ($p = 0.8931$).

5.2.1 Reliability of self-reported BMI vs Measured BMI

Self-reported BMI and actual BMI were compared in a sample of 11 orthognathic patients. One patient self-reported BMI as normal when the actual BMI was overweight. The other 10 patients classified their self-reported BMI the same as the actual BMI indicating a 91per cent agreement between self-reported BMI and measured BMI in these 11 patients.

Table 5.4: Distribution of self-reported BMI categories among orthognathic and general population samples

	BMI (Self-reported)		
Group	**Underweight (%)**	**Normal weight (%)**	**Overweight (%)**
Orthognathic	4 (5)	67 (84)	9 (11)
General population	11 (5)	182 (85)	20 (9)

5.3 Generic oral health-related QoL: OHIP-14

The mean overall OHIP-14 score was 14 (SD 8.6) and 5.0 (SD 5.9) for the orthognathic patients and the general population group respectively ($p < 0.0001$).

At the domain level, there were significant differences between the two groups in all seven domains within functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap (all $p < 0.0001$; Table 5.5).

For the domain of physical disability, group ($p < 0.0001$) and gender ($p < 0.0022$) were significant independent predictors. Also, combined group and gender was found to be a significant predictor ($p=0.0301$). For males, the mean OHIP-14 scores were not significantly different between the orthognathic group (0.7) and the general population group (0.3) ($p = 0.1000$). The mean OHIP-14 scores for these groups for females differed significantly (1.5 and 0.4 respectively; $p < 0.0001$; Table 5.6)

Multiple linear regressions of overall OHIP-14 and the individual seven domains indicated that group (orthognathic or general population) was a significant independent predictor of OHIP score ($p < 0.0001$). Outcomes for multiple linear regression analyses is for all questionnaires are given in Table 5.10.

Table 5.5: Comparison of mean OHP-14 scores between orthognathic and general population groups

	Orthognathic (SD)	**General population (SD)**	**P value**
OHIP-14			
Overall OHIP-14 score [0–56]	14 (8.6)	5.0 (5.9)	$p < 0.0001$
Domains			
Functional limitation [0–8]	1.5 (1.6)	0.4 (0.9)	$p < 0.0001$
Physical pain [0–8]	2.2 (1.7)	1.2 (1.6)	$p < 0.0001$
Psychological discomfort [0–8]	3.1 (2.2)	1.3 (1.6)	$p < 0.0001$
Physical disability [0–8]	1.1 (1.7)	0.4 (0.9)	$p < 0.0001$
Psychological disability [0–8]	3.0 (2.1)	0.8 (1.2)	$p < 0.0001$
Social disability [0–8]	1.7 (1.6)	0.5 (1.0)	$p < 0.0001$
Handicap [0–8]	1.5 (1.4)	0.3 (0.7)	$p < 0.0001$

Table 5.6: Comparison of mean OHIP-14scores for males (M) and females (F) between orthognathic and general population groups

	Gender	Orthognathic (SD)	General population (SD)	Gender P value
OHIP-14 Overall score				
OHIP-14 score [0–56]	M F	12.1 (8.2) 15.8 (8.8)	4.4 (4.9) 5.4 (6.6)	p < 0.0889
Domains				
Functional limitation [0–8]	M F	1.6 (1.6) 1.5 (1.6)	0.3 (0.7) 0.5 (1.0)	p < 0.7074
Physical pain [0–8]	M F	1.9 (1.8) 2.4 (1.7)	1.0 (1.3) 1.3 (1.8)	p < 0.2631
Psychological discomfort [0–8]	M F	2.8 (2.4) 3.4 (1.9)	1.2 (1.3) 1.4 (1.8)	p < 0.1807
Physical disability [0–8]	M F	0.7 (1.4) 1.5 (1.8)	0.3 (0.6) 0.4 (1.1)	p < 0.0022
Psychological disability [0–8]	M F	2.7 (2.2) 3.2 (2.2)	0.7 (1.1) 1.0 (1.3)	p < 0.0177
Social disability [0–8]	M F	1.3 (1.5) 2.1 (1.6)	0.6 (1.0) 0.5 (1.1)	p < 0.5500
Handicap [0–8]	M F	1.1 (1.2) 1.8 (1.6)	0.3 (0.7) 0.3 (0.8)	p < 0.1992

5.4 Condition-specific QoL: OQLQ

The mean overall OQLQ score was 40.9 (SD 19.3) and 19.9 (SD 14.9) for the orthognathic patients and general population group respectively ($p < 0.0001$). There were significant differences in all the four domains within social, facial aesthetics, oral function and awareness between the two groups (all $p < 0.0001$; Table 5.7). Females had higher overall OQLQ scores and individual domain scores than males in both groups ($p < 0.0001$) (Table 5.8; Table 5.10). In the orthognathic group the overall mean OQLQ score for females 44.8 (19.5) was eight points higher than that for male subjects 36.7 (18.5). In the individual domains, 'social aspects of dentofacial deformity' had the greatest difference between the genders (Table 5.8).

Table 5.7: Comparison of mean OQLQ scores between orthognathic and general population groups

	Orthognathic (SD)	**General population (SD)**	**P value**
OQLQ			
Overall OQLQ score [0–88]	40.9 (19.3)	19.9 (14.9)	$p < 0.0001$
Domains			
Social [0–32]	12.2 (7.5)	5.8 (5.0)	$p < 0.0001$
Facial aesthetics [0–20]	10.0 (4.6)	4.4 (3.7)	$p < 0.0001$
Oral function [0–20]	9.3 (5.0)	4.9 (4.4)	$p < 0.0001$
Awareness [0–16]	9.3 (4.2)	4.9 93.9)	$p < 0.0001$

Table 5.8: Comparison of mean OQLQ scores among males (M) and females (F) between orthognathic and general population groups

	Gender	Orthognathic (SD)	General population (SD)	P value
OQLQ				
OQLQ score [0–88]	M F	36.7 (18.5) 44.8 (19.5)	13.5 (0.8) 25.1 (15.7)	$p < 0.0001$
Domains				
Social [0–32]	M F	11 (7.1) 13.4 (7.7)	4.3 (3.9) 7.1 (5.4)	$p < 0.0001$
Facial aesthetics [0–20]	M F	9.1 (4.4) 10.9 (4.7)	3.0 (2.9) 5.5 (3.8)	$p < 0.0001$
Oral function [0–20]	M F	8.3 (5.2) 10.3 (4.7)	3.0 (3.0) 6.3 (4.8)	$p < 0.0001$
Awareness [0–16]	M F	8.4 (4.1) 10.2 (4.2)	3.3 (3.0) 6.1 (4.0)	$p < 0.0001$

5.5 Straightforward BFNES (S-BFNES)

The mean S-BFNES score was 23.2 (SD 7.2) and 18.8 (SD 8.1) for the orthognathic group and the general population group respectively ($p < 0.0001$; Table 5.9). Females had higher S-BFNES scores than males in both groups ($p < 0.0001$; Table 5.9).

Multiple linear regression indicated that group (orthognathic or general population) and gender were significant independent predictors of S- BFNES ($p < 0.0001$; Table 5.10). In the orthognathic group, the mean S-BFNES score for females was 23.9 (6.6) while in males the mean score was 22.5 (7.9). In the general population group, the S-BFNES sores for males was16.2 (7.3) which is considerably less than the mean score of 20.9 (8.1) for female subjects (Table 5.9).

Table 5.9: Comparison of mean S-BFNES scores among males (M) and females (F) between orthognathic and general population groups

	Gender	Orthognathic (SD)	General population (SD)	P value
S- BFNES **Overall mean score**		23.2 (7.2)	18.8 (8.1)	$p < 0.0001$
S-BFNES [8-40]	M F	22.5 (7.9) 23.9 (6.6)	16.2 (7.3) 20.9 (8.1)	$p < 0.0001$

Table 5.10: Multiple linear regression exploring the association between the group, gender, ethnicity, BMI, education, age and OHIP-14, OQLQ and S-BFNES scores

Dependent variable	Independent variables						
	Group P value	**Gender P value**	**Ethnicity P value**	**BMI (self) P value**	**Education P value**	**Age P value**	**Group* Gender**
OHIP-14 score	< 0.0001	0.0889	0.6633	0.8833	0.8045	0.7303	
Functional limitation	< 0.0001	0.7074	0.7866	0.5219	0.6040	0.1423	
Physical pain	< 0.0001	0.2631	0.3523	0.7101	0.6238	0.2160	
Psychological discomfort	< 0.0001	0.1807	0.6814	0.6135	0.3698	0.1547	
Physical disability	< 0.0001	0.0022	0.8187	0.6321	0.7814	0.2396	0.0301
Psychological disability	< 0.0001	0.0177	0.2106	0.5370	0.9275	0.6390	
Social disability	< 0.0001	0.5500	0.4366	0.5342	0.4604	0.9786	
Handicap	< 0.0001	0.1992	0.6712	0.8675	0.4440	0.3449	
OQLQ score	< 0.0001	< 0.0001	0.3830	0.7872	0.4348	0.6524	
Social	< 0.0001	< 0.0001	0.3998	0.9060	0.1209	0.2600	
Facial aesthetics	< 0.0001	< 0.0001	0.3955	0.4571	0.1599	0.7258	
Oral function	< 0.0001	< 0.0001	0.4107	0.5398	0.9981	0.5631	
Awareness	< 0.0001	< 0.0001	0.1375	0.8122	0.8450	0.8695	
S BFNES	< 0.0001	< 0.0001	0.1820	0.1238	0.7704	0.1226	

5.6 IOFTN

Of the 80 patients in the orthognathic group, 91 per cent were in categories 4 or 5 of IOFTN indicating 'great' and 'very great' functional need for orthognathic surgery respectively.

The IOFTN subcategories corresponding to 'reverse overjet' were most prevalent with 20 subjects in subcategory 4.3 and 15 subjects in subcategory 5.3. This is followed by 'increased overjet' with 19 subjects in subcategory 5.2 and 'open bite' with nine subjects in subcategory 5.4 (Table 5.3)

The mean OHIP-14, mean OQLQ and mean S-BFNES scores did not increase progressively with the severity of IOFTN categories (Table 5.13) or subcategories (Table 5.14). For example, mean OQLQ score for IOFTN category 3 was 35.4(19.7) which increased in IOFTN category 4 to 42.9(20.7) but slightly decreased in IOFTN category 5 to 40.3 (18.5).

Multiple linear regression was used to explore any association between mean OHIP-14, mean OQLQ, mean OQLQ-functional domain and mean S-BFNES score as dependent variables and IOFTN categories of 3, 4 and 5 (Table 5.11) and subcategories 4.3, 5.2, 5.3 (Table 5.12) as independent variables. IOFTN (3, 4, 5) or subcategories of IOFTN (4.3, 5.2, 5.3) were not found to be independent predictors for mean OHIP, mean OQLQ, mean OQLQ-functional domain or mean S-BFNES scores.

Multiple linear regressions indicated that IOFTN (categories and subcategories), group (orthognathic or general population), gender, ethnicity, education or age were not significant independent predictors of mean OHIP, OQLQ and S- BFNES scores.

No association was found between the functional domain of OQLQ as the dependent variable and the IOFTN categories (p=0.5530) and subcategories (p=0.6096) as independent variables.

5.6.1 Intra-operator Reliability of IOFTN

The reliability of IOFTN was very good, with Kappa scores of 0.94 for intra-operator testing. The percentage agreement was 95 per cent.

Table 5.11: Multiple linear regression showing an association of IOFTN categories 3, 4, 5, gender, ethnicity, BMI, education, age as independent variables and OHIP-14, OQLQ and S-BFNES scores as the dependent variables.

Independent Variables	Dependent Variables		
	OHIP	**OQLQ**	**S-BFNES**
IOFTN 3,4,5	0.5722	0.3600	0.1493
Gender	0.1493	0.1090	0.5759
Ethnicity	0.7545	0.2261	0.0801
BMI (self)	0.9736	0.9660	0.7277
Education	0.7949	0.5409	0.7995
Age	0.9987	0.8385	0.3732

Table 5.12: Multiple linear regression showing an association of IOFTN subcategories 4.3, 5.2, 5.3, gender, ethnicity, BMI, education, age as independent variables and OHIP-14, OQLQ and S-BFNES scores as the dependent variables.

Independent Variables	Dependent Variables		
	OHIP	**OQLQ**	**S-BFNES**
IOFTN 4.3,5.2,5.3	0.1818	0.6573	0.2793
Gender	0.0805	0.3384	0.6435
Ethnicity	0.7234	0.4277	0.3950
BMI (self)	0.8898	0.4891	0.3191
Education	0.8329	0.6120	0.8844
Age	0.7456	0.4993	0.0818

Table 5.13: Mean OHIP, mean OQLQ and mean S-BFNES score for IOFTN categories 3,4,5

IOFTN category	Mean OHIP-14(SD)score	Mean OQLQ (SD) score	Mean S-BFNES (SD) score
3(n=7)	13.6(12.5)	35.4(19.7)	21.1(4.9)
4(n=30)	15.1(9.2)	42.9(20.7)	24.5(8.1)
5(n=43)	13.2(7.6)	40.3(18.5)	23.2(7.2)

Table 5.14: Mean OHIP, mean OQLQ and mean S-BFNES score for IOFTN subcategories (4.3,5.2,5.3)

IOFTN subcategory	Mean OHIP-14 (SD)score	Mean OQLQ (SD) score	Mean S-BFNES (SD)score
4.3(n=20)	15.2(8.1)	45.8(20.9)	25.4(7.7)
5.2(n=19)	11.3(7.7)	39.2(22.0)	21.5(6.2)
5.3(n=15)	14.9(5.4)	39.9(16.5)	24.5(6.9)

CHAPTER SIX

DISCUSSION

6. Discussion

This was a prospective multi-centre case control study to compare, in the RoI, generic oral health-related quality of life (OHIP-14), condition-specific quality of life (OQLQ), fear of negative evaluation (BFNES) and self-reported BMI of patients seeking surgical-orthodontic correction of their malocclusion versus those of the general population. The orthognathic group was recruited at combined orthodontic-surgical planning clinics before the start of any pre-surgical orthodontics. The general population group was recruited from a randomly selected age-matched sample within the RoI using a market research agency.

Prospective sample

Except for the study by Wee & Poon (2014) where data were collected retrospectively, most studies including the present study which assessed OHIP-14, collected data prospectively. In almost all OQLQ studies, data were also collected prospectively, although some studies had subgroups where data were collected retrospectively (Al-Ahmad *et al.*, 2009; Tamme *et al.*, 2017; Al-Asfour, Waheedi and Koshy, 2018). These retrospective samples are subject to selection bias. The only previous study (Ryan et al., 2016) which assessed BFNES for orthognathic patients also collected data prospectively for both the orthognathic and the general population groups. Our study used prospective samples to eliminate the risks of introducing type I error.

Instruments used

Our study is the only study which has assessed OHIP-14, OQLQ and BFNES in orthognathic and general population samples.

There are nine studies which used both the OHIP-14 questionnaire and OQLQ with orthognathic patients (Table 2.2). There are 14 studies which used the OHIP-14 questionnaire (Table 2.1), and 18 studies which used the OQLQ (Table 2.3) either alone or along with other instruments. Of those studies which assessed QoL prior to the placement of any orthodontic appliance, nine studies used OHIP-14 and OQLQ.

Time of assessment for orthognathic sample: Pre-orthodontics

The assessment of QoL and social anxiety among patients can be influenced by orthodontic appliances and changes in tooth position or pain because of treatment mechanics. It has been reported that QoL decreases immediately after placement of orthodontic appliances (Johal et al., 2015). In our study data were collected at one-time point, before any orthodontic appliances were placed.

Study design

In this study, we used a cross-sectional study design. Among former studies which used the OHIP-14 questionnaire in orthognathic patients before the start of pre-surgical orthodontics, three studies were cross-sectional and the rest were longitudinal with data collected at different time points in the orthodontic-orthognathic treatment pathway. Of the three cross-sectional studies, two studies collected data from three separate cohorts at the following time points: pre-orthodontics, pre-surgery and post-surgery (Garcia Esperão et al., 2010; Palomares et al., 2016)and one study (Frejman et al., 2013) assessed OHIP-14 pre-orthodontics only.

Among OQLQ studies which assessed orthognathic patients before the start of pre-surgical orthodontics, eight studies were cross-sectional and two were longitudinal studies.

The only previous study using BFNES in orthognathic patients by Ryan et al. (2016) had a cross-sectional study design.

Multi-centre nationwide sample with a control group

Orthognathic group

In our study, the orthognathic sample was collected from five HSE orthodontic units spread throughout the RoI. Multi centre studies have been recommended by authors of the earlier research in QoL to improve the generalisability of the findings. This study is the first among OHRQoL studies with an orthognathic sample from more than four centres. Among studies which assessed an orthognathic sample before the start of pre-surgical orthodontics, only one study which used OHIP-14 questionnaire was multi-centre involving three centres (Palomares, Celeste and Miguel, 2016). For the other studies data were collected from a single centre. Among OQLQ studies, which assessed an orthognathic sample before the start of pre-surgical orthodontics, three were conducted in two centres (Al-Bitar et al., 2009; Bortoluzzi et al., 2015; Alanko et al., 2017), one in three centres (Palomares et al., 2016), and another in four centres (Catt et al., 2018). For the study using the BFNES questionnaire, Ryan et al. (2016) collected data from a single UK centre.

The present study is the only study with a nationwide distribution for both the orthognathic group and the general population group for OQLQ, OHIP-14 and BFNES.

General population control group

Our general population sample (n=213) had a nationwide spread covering twenty-four out of twenty-six counties in the RoI. There is no previous study which used OHIP-14 or OQLQ with a true age-matched general population control group.

Among the studies which used OHIP-14 questionnaire in an orthognathic sample before the start of pre-surgical orthodontics, only one study had a control group (Frejman et al., 2013), which consisted of 34 dental patients with the harmony of profile angle and normal occlusion. Among the rest of the studies which used the OHIP-14 questionnaire, three had a control group. Those control groups comprised of 76 subjects with asymptomatic wisdom teeth and no dentofacial deformity (Lee et al.,2007), 30 dental patients with 'Class I skeletal structure and good dentofacial harmony' (Kilinc and Ertas, 2015) and 60 patients not suffering from any dentofacial deformities (Corso et al., 2016).

Among the OQLQ studies, which assessed an orthognathic sample before the start of pre-surgical orthodontics, only one study had a control group (Alanko et al., 2017) which consisted of 22 1st-year female university students who attended dental clinics. Other OQLQ studies had a control group made up of 29 1st-year university students who attended dental clinics (Alanko et al., 2014), 30 Class I patients (Kilinc & Ertas 2015), 66 Class I subjects with normal occlusion and no dentofacial deformity(Tajima et al. 2007), 37 patients attending routine dental clinics with no dentofacial deformity(Al-Ahmad et al., 2009) and 76 asymptomatic wisdom teeth consultation patients without dentofacial deformity (Lee, McGrath and Samman, 2007).

For the BFNES, a nationwide sample of 1196 subjects was used for the control group in a UK study in 2016 (Ryan et al., 2016). Unlike that study, in our general population sample, we used a screening question to exclude patients who had undergone previous orthognathic or cosmetic surgery.

Gender

Almost all studies published in relation to QoL of orthognathic patients (OHIP-14 and OQLQ) had slight female predominance (Table 2.1-2.3). Wee & Poon (2014) had a slight predominance of males and the study by Jung (2016) had a female-only sample. Our study sample is similar to previous studies with a slight predominance of females in the orthognathic group (51%) and the general population group (55%).

Age range, Mean age

In the present study, the age range of the orthognathic patients and of the general population group was 16 to 25 years and 16 to 20 years respectively. The mean age of these samples were 17.5± 1.6 years and 17.8 ± 1.3 years.

Most studies to date which used the OHIP-14 questionnaire and OQLQ have a broad age range varying from 22 to 34 years to 18 to 66 years. The BFNES study had an age range from 16 to 64 years for the orthognathic group and 16 to over 75 years for the general population group (Ryan et al., 2016). Subjects from a diverse group of age-ranges with dentofacial deformity potentially can have significant differences in their response to psychosocial questionnaires and this could introduce bias when making direct comparisons.

Ethnicity

In our study sample, 91 per cent of the orthognathic group and 94 per cent of the general population group were of Irish ethnic origin, making a total Caucasian sample of 94 per cent. The influence of culture and ethnicity on QoL assessments has been previously documented (Al-Ahmad et al., 2009). Compared to previous studies, the higher proportion of single ethnicity (Caucasian) gives a less biased assessment of QoL between the orthognathic and the general population groups.

The studies which used the OHIP-14 questionnaire to collect data at the pre-orthodontics phase have been conducted in Brazil (Garcia Esperão *et al.*, 2010; Frejman *et al.*, 2013; Palomares, Celeste and Miguel, 2016), Europe (Rustemeyer et al., 2012; Silvola et al., 2012; Silvola et al., 2014), Iran (Baherimoghaddam et al., 2016) and New Zealand (Antoun et al., 2015).

Similarly, the OQLQ studies which collected data pre-orthodontics were undertaken in Brazil (Bortoluzzi *et al.*, 2015; Palomares, Celeste and Miguel, 2016), Europe (Cunningham et al., 2002; Stagles et al., 2016; Bock et al., 2009; Alanko et al., 2017), Korea (Jung, 2016) and Jordan (Al-Bitar et al., 2009).

In the study assessing BFNES by Ryan et al. (2016), 18 different ethnicities were included in the sample; there was no statistical difference in BFNES scores between the British and non-British groups. Among the British group, the percentage of Caucasian subjects was not reported.

Sample size calculation

A sample size calculation for the orthognathic group (n=80) and the general population group (n=212) was carried out for the present study. Among studies which used the OHIP-14 questionnaire to assess an orthognathic sample before the start of pre-surgical orthodontics, two studies discuss a sample size calculation (Frejman *et al.*, 2013; Palomares, Celeste and Miguel, 2016). Frejman et al. (2013) had 34 subjects in both groups. Among pre-orthodontics OQLQ studies, two studies (Jung, 2016; Palomares, Celeste and Miguel, 2016) had a sample size calculation. Jung (2016) had 37 subjects in the Class II group and 47 subjects in the Class III group while Palomares et al. (2016) had 65 subjects in the pre-orthodontics group. The only previous study for BFNES (Ryan et al., 2016) had a sample size calculation of 61 subjects for the orthognathic group and 1196 subjects for the general population sample. A sample size calculation in our study will have reduced type II errors and the chances of rejecting the null hypothesis.

Funding for treatment

Our orthognathic group was recruited from HSE units where patients do not pay for treatment, and we excluded patients who have treatment privately funded from our sample.

For the studies which used the OHIP-14 questionnaire and OQLQ pre-orthodontics, no other study has specified whether the patient sample had to pay privately for orthognathic surgery or whether it was publicly funded.

In the study evaluating BFNES by Ryan et al. (2016) subjects had treatment publicly funded through the NHS in the UK.

OHIP-14 score

There was a statistically significant difference between the mean OHIP-14 scores for the orthognathic (14±8.6) and general population (5.0±5.9) groups (p<0001). The orthognathic group had a higher mean score indicating poorer QoL. This difference in scores was significant in all seven subdomains of OHIP-14.

In the OHIP-14 subdomain of 'Physical Disability', females had poorer QoL than males. The mean scores were 1.5 for female patients and 0.4 for females in the general population (p <0.0001). There was no statistically significant influence of gender in any other domain. Multiple linear regression showed no effect of ethnicity, BMI, education or age on OHIP-14 scores.

The OHIP-14 score recorded in our orthognathic group is similar to that recorded in previous studies. The only previous study with a pre-orthodontics orthognathic sample and a control group, also found a significant difference between the orthognathic(16.0) and the control group (3.0) (p<0.001) (Frejman et al., 2013). Their OHIP-14 scores recorded in that study are very similar to ours, although the mean age (27.2 years) and proportion of patients with Class III malocclusion (88.2%) were higher than those of our study samples.

Other studies which also used OHIP-14 at the pre-orthodontics phase but with no control group had scores as follows: 18.3 (Silvola et al., 2014); 19.52 (SD 9.62)(Antoun et al., 2015); Class II-19.18 and Class III-19.86 (Baherimoghaddam et al., 2016) and 16.9 (SD 12.2) (Palomares, Celeste and Miguel, 2016). These scores are similar to, but on average

lower than, those recorded in our study. Differences are likely to be due to variation in ethnicity, the age range of the samples, whether privately or publicly funded and culture.

OQLQ score

There was a statistically significant difference between the orthognathic (40.9±19.3) and the general population group (19.9±14.9) ($p < 0.0001$). The orthognathic group had poorer QoL. There is only one previous study which used OQLQ with a pre-orthodontic group and a control group of 1st-year university students (Alanko et al., 2017). The mean OQLQ score of the latter (21.09±17.27) was similar to that recorded in our study, but the mean OQLQ score of their orthognathic group (31.38±20.71) was lower than in the present study.

Other studies with a pre-orthodontic orthognathic sample had a very similar mean score to that recorded in the study reported here; 43.77 (Cunningham et al.,2002), 43.5 (Palomares, Celeste and Miguel, 2016) and 39.32 (Catt et al., 2018). Three studies had a slightly higher mean OQLQ score than ours: 50.6 (Al-Bitar et al., 2009), 48.15 (Bock, Odemar and Fuhrmann, 2009) and 53.5 (Stagles, Popat and Rogers, 2016). One study had a marginally lower score than ours: 35.3 (Bortoluzzi et al., 2015).

In our study, there was a statistically significant difference between males and females ($p < 0.0001$) with females having poorer QoL. A possible explanation for this may be that females were more concerned about their appearance than males. The age of the subjects is another factor to consider. Unlike other studies, our study sample was limited to 16-25 year old's in the orthognathic group and to 16-20 year old's in the general population group.

Females in these age ranges may be more sensitive to the impact of dentofacial deformities on their QoL.

There were significant differences in scores between the orthognathic and the general population groups and between the genders in all the four domains of OQLQ.

Multiple linear regression showed no effect of ethnicity, BMI, education or age on OQLQ scores.

S-BFNES

There was a statistically significant difference between the mean S-BFNES score recorded for the orthognathic group (23.2±7.2) and the general population group (18.8 ±8.1) ($p < 0.0001$). The orthognathic group had increased social anxiety. These scores were very similar to those reported by Ryan et al. (2016) which evaluated S-BFNES among orthognathic patients (24.21±8.41) and a general population sample (15.59±7.67) in the UK. Our study is the first to record S-BFNES data for the general population in the RoI.

Although statistically significant, the difference between the orthognathic and the general population group mean score was smaller in our study (around 5 points) compared to that of the UK study (around 8-9 points). This could be because our general population sample was smaller (213 versus 1196) and had higher social anxiety. These two studies had a different ethnic mix and different mean age.

In our study females had higher social anxiety than males ($p < 0.0001$). This is similar to previous studies which reported higher scores for females (Duke *et al.*, 2006; Bilge and Kelecioğlu, 2008; Ryan *et al.*, 2016).

Multiple linear regression showed no effect of ethnicity, BMI, education or age on S-BFNES scores.

Self-reported BMI

Similar percentage distribution of self-reported BMI categories was recorded in the orthognathic and the general population group. In both groups, five percent were reckoned to be underweight, 84 to 85 per cent were normal weight, and 9 to 11 percent overweight. No patients were self-reported as "Obese" or "Morbidly obese" in either group. There are no comparable data which have assessed the distribution of self-reported BMI categories among orthognathic patients before having orthodontic appliances placed. Hammond et al. (2015) measured actual BMI in their pre-surgical group and approximately 50 per cent of subjects were of normal weight.

Malocclusion

Our study sample has a predominance of Class III malocclusion (65%) followed by Class II division 1 (33%). This follows the general trend with more Class III patients seeking orthognathic surgery than any other malocclusion category (Harrington, Gallagher and Borzabadi-Farahani, 2015; Borzabadi-Farahani, Eslamipour and Shahmoradi, 2016; Soh *et al.*, 2018).

IOFTN

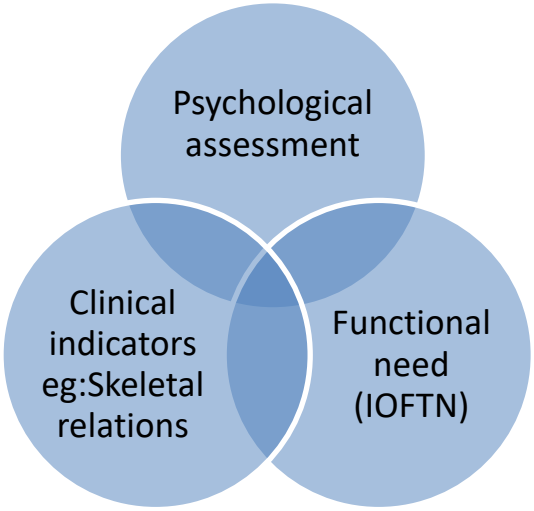
More than 90 percent of orthognathic patients were in IOFTN grade 4 or 5 which is in agreement with previous studies (Harrington, Gallagher and Borzabadi-Farahani, 2015; Borzabadi-Farahani, Eslamipour and Shahmoradi, 2016; Shah *et al.*, 2016; Fowler *et al.*, 2018; Soh *et al.*, 2018).

There was no association of IOFTN categories or subcategories (4.3, 5.2, 5.3) with the mean OHIP-14, OQLQ and mean S-BFNES scores. This agrees with the findings of Fowler et al. (2018) who found no association between mean OHIP-14 scores and IOFTN. This, however, is contrary to the study by Stagles et al. (2016) which found that IOFTN was significantly associated with the functional domain of OQLQ, overjet and overbite.

" IOFTN relates only to the **functional** need for treatment and should be used in combination with appropriate psychological and other clinical indicators" (Ireland et al., 2014).

Recent studies (Shah et al., 2016; Soh et al., 2018) recommend the need to include psychosocial assessment so that patients who fall into the lower functional categories are not automatically excluded from this potentially life-changing treatment (Figure 6.1).

Figure 6.1: Orthognathic treatment need components



Once an average OQLQ score or a range for a given population can be established, and if the score is higher than average for a given patient, then arrangements can be made to see the patient in a combined clinic with a clinical psychologist or consider referral to a psychologist familiar with dentofacial deformities.

Strengths of the present study:

- Prospective data collection
- Sample size calculation
- Multicentre study with nationwide sample for both groups
- Age matched randomly selected general population control group
- Similar mean age for both groups
- Single ethnicity for more than 90 per cent of subjects
- Time of data collection for the orthognathic group before any orthodontic appliances placed
- Use of previously validated questionnaires.

Short comings of the present study:

- Cross-sectional design with no longitudinal follow-up
- The state of mind of the subject at the time of receiving the telephone call could affect the results.

Suggestions for future research:

The following could be explored in future research:

- A longitudinal evaluation of QoL (Generic and condition specific) following orthognathic surgery, with ideally follow-up to 2 years post-surgery.
- A longitudinal evaluation of IOFTN following orthognathic surgery.
- Comparison of IOFTN with longitudinal changes in QoL.

CHAPTER SEVEN

CONCLUSIONS

7. Conclusions

The aims and null hypotheses were given in Chapter 3. The conclusions together with the impact of the results on the null hypotheses are given below.

Aim 1:

To compare, in the RoI, generic oral health-related quality of life (OHIP-14), condition-specific quality of life (OQLQ), the fear of negative evaluation (BFNES) and self-reported BMI of patients seeking surgical-orthodontic correction of their malocclusion versus those of the general population.

Conclusion:

- Orthognathic patients experienced significantly poorer generic oral-health related and condition-specific quality of life as well as significantly higher levels of social anxiety than the general population.
- Females had higher mean OQLQ and mean S-BFNES scores than males.
- There was no significant difference in the distribution of self-reported BMI categories between the orthognathic group and the general population group.

Null hypothesis 1:

There is no difference between the generic and condition-specific oral health-related quality of life measure, fear of negative evaluation and self-reported BMI of patients

seeking surgical-orthodontic correction of their malocclusion versus those of the general population.

- The null hypothesis is rejected for the generic and condition-specific oral health-related quality of life measures and fear of negative evaluation.
- The null hypothesis is accepted for self-reported BMI.

Aim 2:

To assess the IOFTN in the orthognathic cohort and to investigate any correlation between the functional domain of OQLQ and IOFTN.

Conclusion:

- Overall 91 per cent of the orthognathic sample was categorised as either IOFTN grade 4 or IOFTN grade 5 showing ‘great’ or ‘very great’ functional need respectively.
- No association was found between the functional domain of OQLQ and IOFTN categories.

Null hypothesis 2:

There is no correlation between the functional domain of OQLQ and IOFTN in the orthognathic cohort.

- The null hypothesis is accepted.

CHAPTER EIGHT

APPENDICES

8. Appendices

8.1 Appendix A

UCC

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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our ref: ECM 4 (k) 05/07/16

6th July 2016

Professor Declan Millett
Professor of Orthodontics
Cork University Dental School and Hospital
Wilton
Cork

Re: Psychosocial and physiological components of orthognathic patients.

Dear Professor Millett

Expedited approval is granted to carry out the above study at:

- Cork University Hospital and Dental School.

The following documents have been approved:

- Signed Application Form
- Study Protocol Version 1
- Patient Information Sheet
- Study Questionnaire
- Consent Form
- CV for Chief Investigator.

We note that the co-investigators involved in this study will be:

- Postgraduate Students enrolled in DClinDent (Orthodontics) and Niamh Kelly, 3D Imaging Assistant.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospital

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

8.2 Appendix B

OQLQ Questionnaire (Orthognathic Quality of Life Questionnaire)

(Please listen to 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	**2**	**3**	**4**	
	N /A	Bothers you a little			Bothers you 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

2

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

8.3 Appendix C

Oral Health Impact Profile (OHIP 14)

OHIP-14					
In the last six months	Never	Hardly ever	Occasionally	Fairly often	Very often
1) Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?					
2) Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?					
3) Have you had painful aching in your mouth?					
4) Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?					
5) Have you been worried by dental problems?					
6) Have you felt tense because of problems with your teeth, mouth or dentures?					
7) Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?					
8) Have you had to interrupt meals because of problems with your teeth, mouth or dentures?					
9) Have you found it difficult to relax because of problems with your teeth, mouth or dentures?					
10) Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?					
11) Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?					
12) Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?					
13) Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?					
14) Have you been totally unable to function because of problems with your teeth, mouth or dentures?					

4

8.4 Appendix D

BFNES questionnaire (Brief Fear of Negative Evaluation Scale)

(Listen to each of the following statements carefully and indicate how characteristic it is of you by choosing the number that is most appropriate according to the following scale:)

1 = Not at all characteristic of me
2 = Slightly characteristic of me
3 = Moderately characteristic of me
4 = Very characteristic of me
5 = Extremely characteristic of me

1. I worry about what other people will think of me even when I know it doesn't make any difference.	1	2	3	4	5
2. I am unconcerned even if I know people are forming an unfavorable impression of me.	1	2	3	4	5
3. I am frequently afraid of other people noticing my shortcomings.	1	2	3	4	5
4. I rarely worry about what kind of impression I am making on someone.	1	2	3	4	5
5. I am afraid others will not approve of me.	1	2	3	4	5
6. I am afraid that people will find fault with me.	1	2	3	4	5
7. Other people's opinions of me do not bother me.	1	2	3	4	5
8. When I am talking to someone, I worry about what they may be thinking about me.	1	2	3	4	5
9. I am usually worried about what kind of impression I make.	1	2	3	4	5
10. If I know someone is judging me, it has little effect on me.	1	2	3	4	5
11. Sometimes I think I am too concerned with what other people think of me.	1	2	3	4	5
12. I often worry that I will say or do the wrong things.	1	2	3	4	5

5

8.5 Appendix E

JO June 2014 Open Access Index of Orthognathic Functional Treatment Need 79

Index of Orthognathic Functional Treatment Need

This index applies to those malocclusions that are **not amenable to orthodontic treatment alone, due to skeletal deformity,** and will ordinarily apply to those patients who will have completed facial growth prior to surgery (commonly 18 years of age and older). It relates only to the **functional** need for treatment and should be used in combination with appropriate psychological and other clinical indicators.

5. Very Great Need for Treatment
5.1 Defects of cleft lip and palate and other craniofacial anomalies
5.2 Increased overjet greater than 9 mm
5.3 Reverse overjet ≥ 3 mm
5.4 Open bite ≥ 4 mm
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 ≥ 6 mm and ≤ 9 mm
4.3 Reverse overjet ≥ 0 mm and < 3 mm with functional difficulties
4.4 Open bite < 4 mm 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 ≥ 0 mm and < 3 mm with no functional difficulties
3.4 Open bite < 4 mm 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
2. Mild Need for Treatment
2.8 Increased overbite but no evidence of dental or soft tissue trauma
2.9 Upper labial segment gingival exposure < 3mm at rest with no evidence of gingival/periodontal effects
2.11 Marked occlusal cant with no effect on the occlusion
1. No Need for treatment
1.12 Speech difficulties
1.13 Treatment purely for TMD
1.14 Occlusal features not classified above

Figure 1 The Index of Orthognathic Functional Treatment Need (IOFTN)

Downloaded by [British Orthodontic Society] at 22:12 02 April 2016

8.6 Appendix F

If you are OK I am going to start with asking **5 general questions**

1. Could you please choose what **age group** you come under?
    a. 16-24, 25-34, 35-44, 45-54, 55-64, >65

2. (Gender: Male/female)

3. How would you describe your ethnicity?
    a. Irish/British/Other white background/Asian/Chinese/Black African Caribbean/Mixed ethnic group/Refused/Don't know

4. Which category would you choose to describe your body mass index?
    a. Underweight
    b. Normal
    c. Overweight
    d. Obese
    e. Morbidly obese

5. What is your Highest Educational level so far?
    a. Primary school level b) secondary school level c) 3rd level

CHAPTER NINE

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