

A follow-up study investigating changes in oral health-related quality of life (OHRQoL) in patients undergoing orthodontic treatment for Class II division 1 malocclusion: A longitudinal study

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DECLARATION

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SUMMARY

The aim of the study is to evaluate the impact of orthodontic treatment on OHRQoL in children with Class II division 1 malocclusion. A common treatment modality in this cohort of patients is the use of functional appliances to reduce the overjet followed by a second phase of treatment with fixed appliances to detail the occlusion. This is the first prospective cohort study investigating periodic changes in OHRQoL in children who are undergoing two phases of treatment. Secondary objectives included assessment of the level of agreement in rating the children's OHRQoL between parents and children, examination of the relationship between the perceived and normative aesthetic treatment needs and how the former relates to OHRQoL.

A consecutive sample of 74 patients aged 11-14 years with a 5a Index of Orthodontic Treatment Need (IOTN) was recruited. The children and their parents were asked to fill short forms of the Child Perception Questionnaire (CPQ11-14) and the Parental-Caregiver Perception Questionnaire (P-CPQ), respectively at four time points of the children's orthodontic treatment: T1 (prior to starting treatment), T2 (at the end of the functional appliance phase), T3 (following six months with upper and lower fixed appliances) and T4 (at the end of treatment, three months post-debond). Prior to starting the fixed appliance phase, the children were asked to score their corresponding Aesthetic Component (AC) of IOTN. A calibrated clinician also rated the AC of the children to represent the normative aesthetic treatment need.

A total of 46 pairs of children and parents completed the questionnaires at the four time points. At the end of treatment, repeated measures analysis of variance (ANOVA) model has shown a statistically significant improvement ($P < 0.05$) in the overall CPQ11-14 scores particularly in the emotional and social well-being sub-domains compared to pre-treatment scores. Across the four time points of measurement, the intraclass correlation coefficient ($ICC > 0.5$) indicates a moderate level of agreement between parents and children in rating the children's OHRQoL. Poorer levels of agreement are observed at the emotional and social well-being dimensions ($ICC < 0.5$) with the parents scoring higher mean values. The ICC between the self-reported AC of IOTN and those rated by the clinician reveals a moderate to a high level of agreement ($ICC\ 0.529-0.767$). The spearman correlation test ($\rho = 0.062$) found no statistically significant correlation between self-reported AC of IOTN ratings and CPQ11-14 scores ($p = 0.69$).

Conclusion

- Orthodontic treatment of Class II division 1 in children is associated with improvement in OHRQoL particularly in the emotional and social well-beings dimensions.
- Parents tend to overestimate the emotional and social impact malocclusion and orthodontic treatment have on their children's OHRQoL.
- The children are found to be as conscious of their aesthetic treatment need, as clinicians would be.
- The subjective aesthetic treatment need does not relate to OHRQoL (as measured by CPQ11-14) suggesting several other factors other than dental aesthetics might play a role in influencing the subjective treatment need.

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1 LITERATURE REVIEW

1.1 Introduction

Proffit defines malocclusion as any deviation from the ideal occlusal scheme described by Angle (Proffit, 2013).

The World Health Organization (WHO) does not classify malocclusion as disease but rather a set of dental variations that can influence the quality of life (WHO, 2004). Therefore, orthodontic treatment, unlike other medical interventions, does not cure malocclusion but rather aims to correct to an arbitrary norm (O'Brien et al 1998). It can be argued that many people seek orthodontic treatment not because of the actual impairment or the effect of malocclusion on the tissues of the oral cavity but because of the effects of the aesthetic impairment of the malocclusion. Hence malocclusion and its correction becomes a quality of life issue (Liu et al., 2009).

Shaw (1981) has shown that children with dentofacial abnormalities in the anterior zone were perceived to be less desirable and less intelligent by their peers and lay adults relative to children with normal dental appearance who were perceived to be better looking. Prominent upper teeth as seen in children with Class II division 1 malocclusion have been associated with an increased incidence rate of school teasing and poorer oral health related quality of life compared to children with no malocclusion (Johal et al., 2007; Seehra et al., 2011). These findings suggest that children with increased overjet might have a higher psychosocial orthodontic treatment need.

Orthodontic treatment need is usually assessed by the use of objective measures such as Index of Orthodontic Treatment Need (IOTN). However, there is evidence that such measures are not always in agreement with the treatment need as perceived by the patient. One study has found that a high percentage of adolescents with a normative treatment need did not have perceived need for orthodontic treatment. In contrast, 12% were not satisfied with their malocclusion despite having only slight normative need (de Oliveira and Sheiham, 2003). Therefore, the severity of the malocclusion does not always relate to a psychosocial treatment need. This evidence highlights the role of oral health related quality of life measures which can be used to complement normative indices in assessing orthodontic treatment need to maximize treatment benefit and manage patient expectations (O'Brien et al, 2007).

In addition, providing orthodontic treatment for various malocclusions places a global burden on resources. Therefore better understanding of perceived treatment need could perhaps allow for more appropriate allocation of public funds since many health services employ normative indices only, such as IOTN, to assess treatment need and determine eligibility for state-funded orthodontic treatment.

1.2 Malocclusion

1.2.1 Definition

The World Health Organization (WHO) includes malocclusion under the sub-heading handicapping dento-facial anomalies, where an anomaly is defined as that which causes impediment to function and disfigurement, which could negatively

impact the physical and/or emotional well-being, in which case, treatment might be required (WHO, 2004).

Houston et al (1992) simply defines malocclusion as deviation from the ideal occlusion that may be considered aesthetically unsatisfactory. Profitt (2013) associates malocclusion with either malalignment within the arch where the position of a tooth deviates from the smooth curve of line due to tipping, displacement or rotations, etc; or discrepancy in the relationship of the dental arches relative to the normal occlusion in any of the three planes of space.

1.2.2 Prevalence

The prevalence of malocclusion and orthodontic treatment need have been surveyed on a national level in various populations with global estimates of more than 70% (Liu, 2009). In Ireland, approximately one third of 12- and 15-year-olds were found to have a definite orthodontic treatment need as assessed by the Dental Health Component (DHC) of the IOTN (Whelton et al., 2006). Similarly, the 2003 U.K. Child Dental Health Survey found that 35% of 12-year-olds had an IOTN DHC score of 4 or 5 with an Aesthetic Component (AC) of 8-10 (Chestnut et al., 2006). A national survey conducted in the U.S. on a sample of 7000 children and adults revealed that up to 59% of each of the three racial groups included in the sample were indicated for orthodontic treatment according to the IOTN (Profitt et al., 1998).

1.3 Class II Division 1 Malocclusion

1.3.1 Definition and prevalence

British Standard Classification of Malocclusion (BS4492 1982) classifies the incisor relationship as Class II division 1 malocclusion when the lower incisal edges lie posterior to the cingulum plateau of the upper incisors and there is an increase in overjet and the upper central incisors are usually proclined (British Standards, 1983)

Class II division 1 is one of the most common malocclusions with a reported prevalence ranging from 12.5 % to 27% of English school children (Haynes, 1970; Foster and Day, 1974). Different etiological factors have been implicated in Class II division 1 malocclusion such as lower lip entrapment, digit sucking habits and crowding. Nonetheless, mandibular skeletal retrusion was found to be the most commonly associated factor with Class II malocclusions (McNamara, 1981).

1.3.2 Treatment Modalities

The treatment of Class II division 1 malocclusion generally falls under one of the following three categories; the choice of which depends on the age of the patient, the severity of the underlying skeletal discrepancy, the etiology of the malocclusion, the compliance of the patient and the growth potential.

Growth modification/functional appliance therapy

In a growing patients with mild/moderate skeletal Class II skeletal pattern and average or reduced vertical proportions, the cephalocaudal growth gradient of the jaws can be utilized to reduce the overjet and achieve ideal buccal and incisor segment relationships. Treatment is generally divided into two phases. In phase I,

functional appliances are used in isolation or in combination with headgear. Phase II would entail the use of fixed appliances to relieve any crowding and detail the occlusion. In a patient with a favorable mandibular growth pattern, functional appliances are effective in reducing large overjets. The evidence in the literature suggests that their mode of action of action is primarily dentoalveolar with a small amount of maxillary restraint (O'Brien et al., 2003a).

Orthodontic camouflage with fixed appliances

This option is generally considered in non-growing patients with mild/moderate skeletal Class II discrepancy. It would typically involve upper arch extractions to create space to allow for the retraction of the upper anterior segment and subsequently reducing the overjet.

Combined surgical and fixed appliance treatment

This option might be ideal for non-growing patients with severe skeletal discrepancy in the anteroposterior or the vertical dimension. The main aim of this treatment is to correct the underlying skeletal discrepancy thereby improving the facial and dental aesthetics.

1.3.3 Rationale for treatment

An increased overjet is considered a risk factor for upper incisor trauma. In an epidemiological survey, it was found that children with an overjet greater than 9 mm are approximately twice as much at risk of sustaining trauma to their upper incisor teeth relative to children with overjet less than 9mm by the age of 12 years (Todd, 1985). A recently updated Cochrane systematic review concluded that there is moderate quality evidence to suggest that early functional appliance therapy treatment during the mixed dentition is likely to reduce the incidence of trauma by

40% compared to treatment provided later during adolescence (Batista et al., 2018).

An increased overjet is thought to have a long-term psychosocial impact. A 15-year follow-up study of Danish adolescents who had no access to orthodontic care reported that certain malocclusions such as increased overjets and overbites can have a negative impact on body image and self-concept during adolescence extending into adulthood. In addition, a higher incidence of teasing at school was also observed in adolescents with malocclusion, almost 7 times more often compared to subjects with no malocclusion (Helm et al., 1985).

Similarly, Seehra et al (2011) found a strong association between increased incidence of bullying, low self-esteem and Class II division 1 malocclusion in a sample of 336 participants aged between 10-14 years. At a later follow-up study of the same sample, 78% of the bullied participants reported that the bullying stopped following the start of orthodontic treatment (Seehra et al., 2013). The authors concluded that orthodontic treatment might have a positive psychosocial benefit in bullied patients with malocclusions.

Early functional appliance therapy during the mixed dentition was found to lead to a transient increase in self-esteem in Class II division 1 patients. While it might be beneficial for some patients, it would need to be weighed against the added treatment cost and time associated with early functional appliance therapy (O'Brien et al., 2003a).

1.4 Oral Health Related Quality of Life

1.4.1 Terminology

Quality of life (QoL): defined as “a person’s sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her” (Becker et al., 1993). Alternatively, the WHO (2004) defines QoL, as individuals’ “perceptions of their position in life in the context of culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns.” It is a broad concept that often encompasses a multitude of human experiences such as employment, poverty, living conditions, job satisfaction, etc (Patrick, 1993). Therefore, it should be used with caution when discussing oral health related quality of life (OHRQoL) or health related quality of life (HRQoL), as quality of life may not be necessarily captured by measures that address only one aspect of it.

Health related quality of life (HQoL): refers to the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions (Testa and Simonson, 1996).

Oral health: As defined in the *Oral Health Strategy of England* “oral health is a standard of health of the oral and related tissues which enables an individual to eat, speak and socialize without active disease, discomfort or embarrassment and which contributes to general well-being” (Kent, 1998).

OHRQoL: “The impact of oral diseases and disorders on aspects of everyday life that a patient or person values, that are of sufficient magnitude, in terms of frequency, severity or duration to affect their experience and perception of their

life overall.” Locker and Allen (2007) noted that a precise definition was needed to critically and carefully address the questionnaires/tools used in OHRQoL assessment. They recognized that many of these tools were not fully addressing the concepts they set out to measure. While the tools measure the frequency or the severity of the impact, many fail to determine the value of the impact to the individual.

1.4.2 Historic Overview

In 1946, the WHO introduced a more holistic definition of health that takes into account the physical, mental and social well-being (WHO, 1948). In response, there has been a growing shift from bio-medical conceptualization of health to a bio-psychosocial one where the outcome of disease or pathology is not judged by the mere absence of it but by its impact on the physical, social and emotional and social functioning of the individual.

This transition was followed by the emergence of the concepts “quality of life” and “HRQoL” in the medical literature by the 1960s (Alzoubi et al., 2017). Medical advances over the years have led to a paradigm shift in health care from focusing on survival to prevention, diagnosis and treatment of chronic disease and thus objective parameters such as mortality and morbidity rates could not be used as the sole indicators to reflect on the health status of a population or the effectiveness of health care systems (Gift and Atchison, 1995).

The importance of a more holistic approach to health by using QoL and HRQoL measures has been well established in the literature. An initiative by the US Department of Health and Human Services (Healthy People 2020) highlighted the

importance of HRQoL measures; clinicians and public health officials in the US are implementing such measures to develop better understanding of the effects of chronic illness, treatments, and short- and long-term disabilities. Such measures can be used to identify and prioritize health issues, facilitate communication and shared clinical decision making between patients and clinicians and to monitor changes or responses to treatment (Slade, 2002).

This late emergence could be attributed to the lack of awareness of the impact of oral health on QoL (Bennadi and Reddy, 2013). The oral cavity was viewed as a distinct anatomical entity disassociated from the body and the individual, and aside from oral cancers, oral diseases were viewed as having no impact on social life (Davis, 1976). This notion was challenged by Gift and Atchison in 1995, who conceptualized oral health as an integral part of general health. They asserted that the oral cavity contributes to HRQoL at a basic biologic level “through protection from systemic infection, chewing and swallowing and at a more social and psychological level through self-esteem, self-expression, communication and facial aesthetics.” Simply put, when oral health is compromised, the overall health and the quality of life might be adversely affected. In fact, several articles in the late 1980s and early 1990s have shown oral diseases can undermine the emotional and psychosocial well-being of individuals (Cushing et al., 1986; Reisine et al., 1989; Gift et al., 1992).

With the development of the concept of OHRQoL and instruments to measure it, there has been a recent spike in the interest of the OHRQoL within the field of orthodontics; a simple search of PubMed has garnered over 200 articles linking orthodontics to OHRQoL. Orthodontic treatment, unlike other medical

interventions, does not cure malocclusion but rather aims to correct to an arbitrary norm (O'Brien et al 1998). Perhaps, since many of the conditions that orthodontic treatment corrects are asymptomatic and people might seek treatment for aesthetic improvement of their dentofacial appearance and subsequent improvement of their psychosocial well-being, subjective measures such as OHRQoL become necessary to clearly address patient concerns and evaluate the success of treatment or even the need for orthodontic intervention (Cunningham and Hunt, 2001).

1.4.3 Health Models

Given the multidimensional construct of the HRQoL and OHRQoL, several theoretical models have appeared to lay the framework to postulate the relationship between health/oral health and QoL as modulated by several domains. In this section, two of the most popular conceptual health/oral health models will be explored.

Wilson and Cleary (1995)

In this model (Figure 1), different measures of health outcomes are divided across five levels: biological and physiological factors, symptoms, functioning, general health perceptions, and overall quality of life. The five levels are arranged on a continuum of increasing complexity; such that biological and physiological factors are at one end linked to quality of life on the other end through a series of increasingly complex and integrated measures as modulated by environmental and personal factors.

The model is designed in a way that as one moves across the levels from left to right, the concepts become more integrated with a greater number of inputs that are beyond the control of clinicians and health care systems. The arrows do not necessarily mean a reciprocal relationship and the absence of arrows between non-adjacent boxes/levels does not necessarily imply the lack of one (Wilson and Cleary, 1995).

This model is effective in providing a more holistic overview of the impact of disease, as it links bio-medical measures to psychosocial ones through a causal relationship while appreciating the complexity of the interplay of individual and environmental factors. There is evidence of the success of the application of this model in chronic oral health conditions (Williams et al., 1998; Baker et al., 2007).

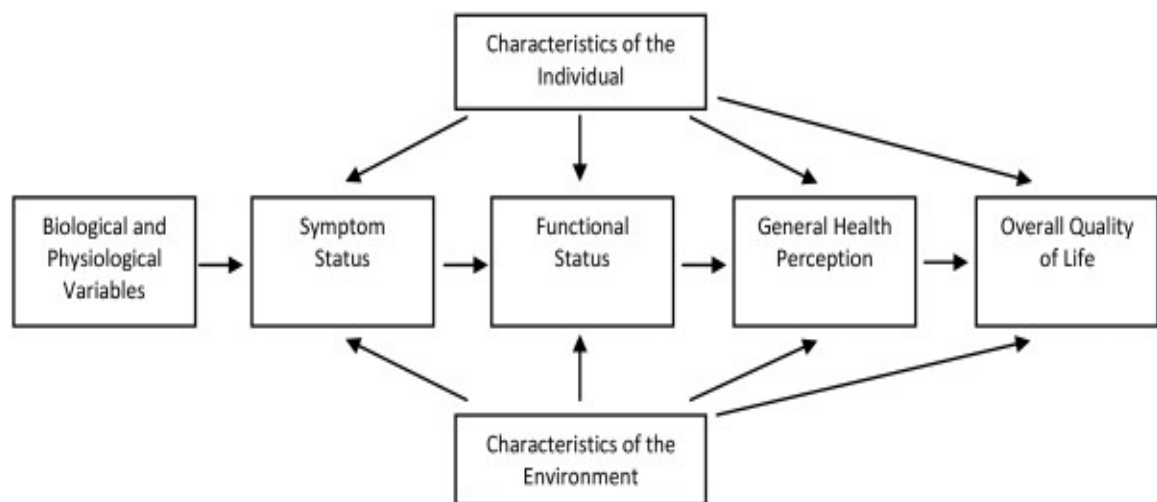


Figure 1 Wilson and Cleary (1995)

Locker conceptual model (1988)

This model (Figure 2) is based on the WHO international classification of impairment, disability and handicap (ICIDH) first proposed in 1980 (WHO, 2004),

which aimed to identify the biological and psychosocial consequences of disease and conceptualize them within an integrated framework where a causal relationship is implied between the consequences.

Impairment is the immediate biomedical outcome of the disease at the organ level; disability reflects the functional difficulty in carrying out daily activities at the individual level; and handicap reflects the difficulties experienced by the individual at a societal level (the “overall” impact) as a result of the disability/impairment as tempered by the surrounding circumstances.

Locker (Locker, 1988) later adapted this model to oral diseases to predict the number of ways and the pathways through which individuals can be affected. Similar to the Wilson and Cleary model, there is a hierarchy of the experience of oral disease across five levels (consequences) where the impact “progresses” from a biological level to the level of the individual then ultimately impacting psychosocial aspects.

This framework has been seminal in the development of a number of OHRQoL measures whose reliability and validity have been proven (Allen, 2003; Slade and Spencer, 1994; Leao and Sheiham, 1996) and while Locker’s model provides a better understanding of the consequences of oral disease, it only provides an implicit link to quality of life. Locker in his paper (2004) suggested that an adoption of a modified version of the Wilson and Cleary model provides a broader concept of health where OH is explicitly linked to QoL.

Very few studies (Baker et al., 2007; Nuttall et al., 2006; Yamaga et al., 2018) have attempted to provide empirical evidence of the model and as such, it is often

viewed as a theoretical framework. Further, malocclusion may not relate to the pathways hypothesized in the framework for the following reasons: 1. Malocclusion is not a disease per se and orthodontic treatment does not “cure” it but only attempts to correct to an arbitrary norm (O'Brien et al., 1998). 2. Unlike most oral diseases, malocclusion is often asymptomatic and relates to aesthetics and might not necessarily to relate to the pain and function and functional limitation domains (Rusanen et al., 2010). One study has found that a modified version of the model where functional limitation is linked to pain and discomfort was more predictive of the relationship between the domains than the original model and hence provides a better understanding of the impact of malocclusion on OHRQoL (Masood et al., 2015).

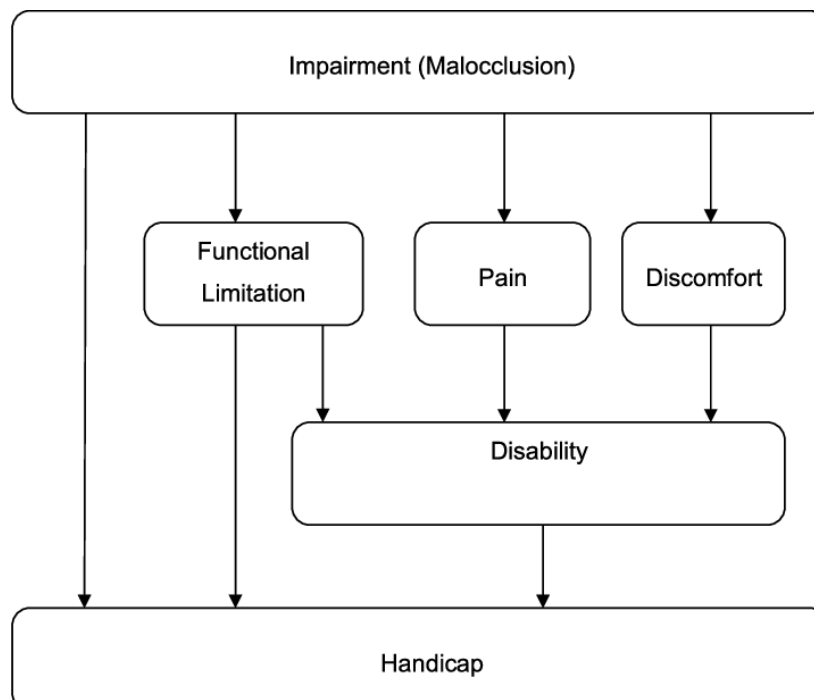


Figure 2 Locker conceptual model (1988)

1.4.4 Measures of OHRQoL: Overview

Development of an OHRQoL measure broadly follows a three stage process: identifying a conceptual framework, undergoing the technical procedures to formulating the measure and finally understanding the scope of the application of the measure (Locker, 1996). The measure is required to be valid and reliable. Ideally, it should also be discriminative (able to distinguish between individuals across a gradient of health levels) and evaluative (able to detect meaningful changes over time).

Slade has identified three categories of OHRQoL measure: social indicators (the burden of oral disease at a community level such as missed work days), global ratings and multi-item questionnaires (Slade, 2002). The latter two are used concurrently in most current OHRQoL measures.

While multi-item questionnaires provide a description of the subjective oral health status by measuring the frequency and the severity of oral disease across the functional and psychosocial domains, global ratings assign value to the importance of these domains to the individuals' OHRQoL, reflecting their overall perception of the impact of oral disease (Locker and Allen, 2007). Global rating is usually a broad generic question, the answer to which is a composite of the values, concerns, beliefs, and relative importance of the domains to the individual. It is particularly useful as a validity check when a new measure is being developed (Benson et al., 2016).

Further, multi-item questionnaires can be generic (e.g. Oral Health Impact Profile (OHIP)) or condition specific such as those developed for cancer patients (Terrell

et al., 1997) or patients with dento-facial deformities (Cunningham et al., 2000). Generic measures allow comparison between different populations where as specific measures might be more sensitive to subtle changes over time that could be of clinical relevance and therefore have better responsiveness.

Measures can also be culture specific or age specific. UK-OHRQoL is an example of a culture specific tool (McGrath and Bedi, 2002). Age specific measures for adults include Geriatric Oral Health Assessment Index which is designed for older adults (Atchison and Dolan, 1990). Several OHRQoL measures have been developed for children. These include Child Perception Questionnaire (CPQ), the Early Childhood Oral Health Impact Score (ECOHIS), Pediatric Oral Health-Related Quality of Life (POQL), Child Oral Impacts on Daily Performances (Child-OIDP), and the Child Oral Health Impact Profile (COHIP) (Genderson et al., 2013). Most recently, the Malocclusion Impact Questionnaire (MIH) has been developed for adolescents, which is also condition specific (Patel et al., 2016).

Locker and Allen (2007) critically appraised some of the most commonly used tools of OHRQoL measures by adhering to a set of criteria derived from Guyatt and Cook (Guyatt and Cook, 1994) to verify whether these tools address the constructs they are set out to measure. They concluded that while the tools are patient centered and cover aspects of importance to patients; they fail to establish an explicit link to quality of life. Locker and Allen (2007) suggested the incorporation of more global ratings, which provides more meaning to the scored data and allows highly individualized data to be grouped for analysis.

1.5 Child Oral Health Related Quality of Life

1.5.1 Development and Testing of Child Perception Questionnaire (CPQ11-14)

Children undergo continuous emotional, physical and cognitive development. Therefore, their awareness of their health and its psychosocial impact and the ability to understand and answer questions related to their health is age dependent. By the age of 11-12, children have a clear understanding of complex emotions such as worry, shame and jealousy. They also begin to experience the effect of peer crowds (Hetherington EM, 1999). Previous research of HRQoL of children used parents' responses as proxies but the parents' knowledge of the psychosocial impact of their child's health may be limited and thus may not reflect accurately the child's health status in relation to quality of life (Levi RB, 1999).

Jokovic was the first to develop an OHRQoL measure specific for children of three different age groups: 6-7, 8-10, 11-14 years old (Jokovic et al., 2002). The child-perception questionnaire (CPQ11-14) is a 36-item questionnaire. It measures the negative impact of a wide range of dental, oral and oro-facial conditions on OHRQoL across four domains: oral symptoms (6 items), functional limitations (9 items), emotional well-being (9 items), and social well-being (12 items covering the subdomains: peer interaction, schooling, and leisure activities).

It asks questions in relation to the frequency of the problem in the past three months. The response options are: "Never" = 0; "Once/twice" = 1; "Sometimes" = 2; "Often" = 3; and "Every day/almost every day" = 4. The impact of which is assessed by the use of two global ratings "Would you say that the health of your teeth, lips, jaws and mouth is...?" and "How much does the condition of your teeth, lips, jaws

or mouth affect your life overall?”. The range of scores is 0-144, with higher scores indicating poorer OHRQol.

Items were developed through a two-stage process as described by Guyatt and Juniper (Juniper EF, 1996). First, a review of the existing child health and oral health measures generated a pool of 46 items across the four domains of oral health. Second, the items were then examined for their clarity, comprehensiveness and relevance by a panel of experts comprised of 17 health professionals who treat children with oral and oro-facial disorders and 33 parents of child patients with these conditions. This resulted in a modified pool of 50 items, which was then assessed by conducting in depth interviews with 11 child patients from three different clinical groups, all aged 11-14 years: children with dental diseases (primarily caries), orthodontic disorders, and orofacial conditions (primarily cleft lip and/or palate).

Through face-to-face interviews with 83 children from the three clinical groups, an item-impact study was used to select items for the final questionnaire, where the frequency and the importance of each item is assessed and accordingly given an impact score. Asking the child if in the past three months they had experienced the problem in relation to their oral health assesses frequency. If the child responds positively, the importance of the item is rated on a 4-point Likert scale ranging from 0 (“Does not bother me at all”) to 4 (“Bothers me very much”).

Correlational and discriminative validity of the questionnaire was tested through a sample size of 123 children. The questionnaire was found to be discriminative across the three different groups with children belonging to the oro-facial group reporting the highest scores and the pedodontic (dental diseases) groups reporting

the lowest scores. Further, significant correlation was found between the two global ratings (measures HRQoL) and the questionnaire scores (measures health status).

A short version of the questionnaire was developed to reduce the respondent's burden, thus facilitating the application of the questionnaire in dental health surveys and clinical settings. The 16-item questionnaire was found to have similar validity and discriminative properties as the 37-item questionnaire (Jokovic et al., 2006). The score range is 0-64.

The CPQ11-14 has been validated by a number of studies (Do and Spencer, 2008; O'Brien et al., 2006; Marshman et al., 2005). A study of 430 children in New Zealand showed a distinct gradient in mean CPQ11-14 scores as varied by malocclusion severity with the gradient being clearer for the emotional and the social well-being domain scores (Foster Page et al., 2005). Similarly, O'Brien et al (2007) reported statistically significant difference between the malocclusion and control total CPQ11-14 scores in the emotional and social well-being domains. However, in this study, the CPQ scores did not differentiate between the different types of malocclusion: crowding, hypodontia, or an increased overjet (O'Brien et al., 2007). Johal (2007) noted that one important limitation of the questionnaire is that it is not condition specific and therefore, the impact of the score could be due to oral health conditions other than malocclusion (Johal et al., 2007). Further, (Marshman et al., 2010) reported that some of the questions in the CPQ11-14 may not be relevant to adolescents with malocclusion, emphasizing the need to develop malocclusion-specific OHRQoL measure. Although Locker and colleagues provided evidence that the CPQ11-14 is sensitive to objective and subjective variations in

malocclusion severity and hence can be applied to patients seeking orthodontic treatment, the findings were based on a small clinical sample (Locker et al., 2007).

The responsiveness of the questionnaire has also been evaluated. In a study of 45 children with malocclusion, the results have shown that the CPQ11-14 has the sensitivity to detect moderate changes in OHRQoL scores as the patients were followed throughout their orthodontic treatment (Agou et al., 2008). In another study of 101 children with malocclusion, the CPQ11-14 reflected a moderate effect size in the OHRQoL scores after 12 months of orthodontic treatment (Abreu et al., 2014). Indeed, CPQ11-14 has been used in several longitudinal studies investigating the effect of orthodontic treatment on OHRQoL (Abreu et al., 2018; Chen et al., 2009; Zhang et al., 2008; Jaeken et al., 2018; Healey et al., 2016).

1.5.2 Development and Testing Parent-Caregiver perception Questionnaire (P-CPQ)

P-CPQ is a component of child oral health related quality of life (CHORQoL) developed in conjunction with the CPQ for parents of 6-14 year old children (Jokovic et al., 2003b). Parents are often regarded as the primary decision makers in regards to their children's health and may have a significant influence in determining their children's treatment needs. Therefore, health care may cater to the parents' needs rather than the children. It has been stated that parents often play a role for children seeking orthodontic treatment (Stricker, 1970). Indeed, in one study, 63-67% of parents reported pressurizing their children to seek orthodontic treatment (Wędrychowska-Szulc and Syryńska, 2010). In addition, parents' information about their children may be limited particularly in activities occurring outside the home (Jokovic et al., 2004). Therefore the purpose of the P-CPQ

is not to serve as a proxy but rather to be complimentary with the information provided by the CPQ.

The same process of development was followed as that of the CPQ11-14, 31 items were selected from a preliminary pool of 47 items through an item impact study. The validity of the questionnaire was confirmed by testing it on a sample of 231 parents. It was able to discriminate among the three clinical groups of children: paedodontic, orthodontic and orofacial with higher scores corresponding to the increased severity of the oral condition (Jokovic et al., 2003b).

Several studies have reported on the level of agreement between parents and children with conflicting results (Abreu et al., 2015b; Abreu et al., 2015a; Barbosa Tde and Gaviao, 2015; Jokovic et al., 2003a; Benson et al., 2010; Zhang et al., 2007; Ferreira et al., 2012).

Benson et al (2010) has found a good level of agreement in OHRQoL scores between children with malocclusion and mothers, although mothers tended to overestimate the emotional impact of malocclusion. Jokovic et al (2003) and Ferreira et al (2012) both noted that the level of agreement was lower in older adolescents.

Further, in one study the levels of agreement between mothers, fathers and children was found to be poor at the individual unit with children reporting lower CPQ scores. Children had differing views from their parents and both parents also had different opinions (Zhang et al., 2007). One possible explanation for the inconsistent data is that different studies were carried out in different countries; cultural factors might play a role in influencing the parent/child dynamics

(Ferreira et al., 2012). Abreu et al (2015) has found a poor level of agreement between children and parents particularly in the social and emotional subscales with the children reporting higher scores; concluding that parents tend to have limited knowledge of the influence of malocclusion on their children's OHRQoL but this finding does not undermine the importance of parental reports.

1.6 Malocclusion and orthodontic treatment need

Frequently, objective clinical measures such as the dental health component (DHC) (Brook and Shaw, 1989) and aesthetic component (AC) of Index of Orthodontic Treatment Need (IOTN) (Evans and Shaw, 1987) are used to assess treatment need. Public health services in some countries rely on these objective tools to determine eligibility for state funded orthodontic treatment. However, it is often cited that one of the major drawbacks of solely depending on normative measures is that it fails to take into account the patients' perception of their malocclusion and thus might deny treatment to children with psychosocial need (de Oliveira and Sheiham, 2004).

The literature continues to record discrepancies between objective and subjective treatment needs. De Oliveira and Sheiham, in their study of 1675 Brazilian adolescents using Oral Impacts on Daily Performances (OIDP) as a subjective measure found that despite a strong association between OHRQoL scores and IOTN, 12.5% of adolescents were dissatisfied with the appearance of their teeth despite having no or slight treatment need as measured by the IOTN. They also reported that half of adolescents who had clinical treatment need were satisfied with the appearance of their teeth (de Oliveira and Sheiham, 2003). This is in agreement with the 2013 UK National Child Dental Health survey where 20% and

9% of 12 and 15 year old children respectively were satisfied with the appearance of their teeth despite a clear objective need for treatment. The survey also reported that a large proportion of children with subjective treatment need were not deemed eligible for state funded orthodontic treatment based on their IOTN (Tsakos et al., 2013). Other studies reported similar results (Birkeland et al., 1996; Ahmed et al., 2001).

It is worth noting that some studies equate perceived dental appearance with subjective treatment need (Birkeland et al., 1996; Ahmed et al., 2001; Tsakos et al., 2013; Grzywacz, 2003). Several authors noted that dental appearance, while it could be one of the factors, does not necessarily reflect subjective treatment need. The desire for orthodontic treatment might be influenced by other factors such as the popularity of braces among peers or parental pressure or psychological status (Kragt et al., 2017; Kok et al., 2004; Agou et al., 2011). In one study of 204 children in the UK, CPQ11-14 scores showed a stronger co-correlation in relation to orthodontic concerns (assessed by two questions) relative to self-perceived AC scores and therefore OHRQoL measures could be a better predictor of subjective orthodontic treatment need (Kok et al., 2004). Agou et al (2011) has further argued that the OHRQoL of patients with a low psychological well-being (PWB) status is likely to get worse if their malocclusion is left untreated reflecting a higher treatment need and perhaps their treatment should be prioritized over patients with high PWB. This argument along with the inconsistencies found in the literature between normative and subjective treatment needs clearly highlights the importance of implementing patient based tools with psychometric properties to compliment clinical measures in reflecting orthodontic treatment needs.

1.7 Impact of malocclusion on OHRQoL

The association between malocclusion and OHRQoL has been extensively studied in the literature. A 15-year follow-up study concluded that malocclusion could negatively impact body image and self-concept not only in adolescence but also in adulthood. Subjects with untreated severe malocclusions particularly increased overjet and spacing reported feelings of dissatisfaction with their own dental appearance (Helm et al., 1985).

One of the earlier literature reviews concluded, that while it is generally thought that malocclusion can have a negative impact on perceived attractiveness and intelligence, there has been conflicting evidence in the literature and as such, the association could not be determined clearly (Zhang et al., 2006). Since then, several high quality studies have been carried out investigating the impact of malocclusion on OHRQoL.

In a study of 783 of school children aged 12-13 years old in New Zealand, malocclusion was found to have negative impact on OHRQoL particularly in the emotional and social well-being subscales (Ukra et al., 2013). Similar results were reported in another study of 632 Brazilian school children, with higher OHRQoL scores reported in children with more severe malocclusions as measured by the dental aesthetic index (Scapini et al., 2013).

Further, specific malocclusion traits have been associated with poorer OHRQoL. In one study, 90 children were divided across 3 groups according to the type of their malocclusion: increased overjet (> 6mm), spacing and control. No difference in the CPQ scores were found between the first two groups but both reported

significantly higher CPQ scores relative to the control (Johal et al., 2007). These findings are supported by a systematic review, which concluded there is high quality evidence that severe malocclusions, especially those impacting the aesthetic zone (diastema, increased overjet and anterior crowding) have negative effects on OHRQoL in children and adolescents (Dimberg et al., 2015).

A meta-analysis of 40 cross-sectional studies examining the association between malocclusion and OHRQoL in children and adolescents has noted that studies in different countries showed different levels of association between malocclusion and OHRQoL, suggesting that cultural factors might have an influence on the way individuals perceive their malocclusion (Kragt et al., 2016). Indeed, the WHO defines quality of life of individuals within the contexts of culture and “value systems in which they live...” (WHO, 2004). Therefore, it would not be surprising that the effect of malocclusion on OHRQoL is modified by culture.

The authors have also found that age played a major role, children older than 14 years were more likely to experience the impact of their malocclusion on OHRQoL. In contrast, no association was found in younger age groups. It is worth noting, that among the studies included in the meta-analysis, a high level of heterogeneity was present. Nevertheless, the authors advise that longitudinal cohort studies following subjects from the age of 8 years to adulthood would provide a clearer understanding of age as a modulating factor in the relationship between malocclusion and OHRQoL (Kragt et al., 2016).

There is a tendency for the impact of malocclusion to be manifested in the social and emotional domains, more so than other domains, with only small difference in the overall OHRQoL scores (Kragt et al., 2016). One possible explanation is that

orthodontic conditions are generally considered asymptomatic (O'Brien et al., 1998), and given that most current OHRQoL measures have domains addressing physical symptoms along with psycho-social domains, the difference is likely to be small if it is only seen in few questions. Agou et al (2011) has shown that the emotional well-being and social well-being subscales of OHRQoL were more likely to be influenced than the oral symptoms and functional limitation subscales by the children's psychological well-being (PWB). This raises the question: Should different weights be assigned to different domains?

1.8 Impact of orthodontic treatment on OHRQoL

If malocclusion has been associated with poorer OHRQoL scores, it is only logical to hypothesize that orthodontic treatment would improve OHRQoL. Shaw et al (1981) has stated that one of the reasons for undergoing orthodontic treatment is improvement in aesthetics and a subsequent improvement of psychological well-being. To date, many studies have investigated the effect of orthodontic treatment on OHRQoL.

A recent systematic review has identified over 1500 studies reporting the changes in OHRQoL in patients undergoing orthodontic treatment (Javidi et al., 2017). A study of 1675 Brazilian adolescents has found that treated subjects were 1.85 times less likely to experience negative oral impact on their daily activities and thus reported better OHRQoL (de Oliveira and Sheiham, 2004). Similarly, Feu et al (2013) reported improvement in OHRQoL scores of adolescents after 2 years of starting orthodontic treatment compared to untreated controls. Both studies utilized the OHIP-14 measure in assessing OHRQoL.

A study of 118 Canadian children aged 11-14 years old reported that treated children had significant reductions in their CPQ11-14 scores compared to untreated children of similar age, sex and dental condition (Agou et al., 2011). Another well-designed study, where patients have been followed for a period of 21 months after the end of orthodontic treatment reported positive changes in their OHRQoL; however, this was not reflected immediately following debond (Healey et al., 2016). The difference could be accounted to patients requiring time to adjust to their new occlusion and for the potential psychosocial gains to reflect on their interactions with the external environment (Agou et al., 2011). Nevertheless, Jaeken et al (2018) reported positive changes in OHRQoL of 11-16 year olds at only 1 month following debond when compared to pretreatment data despite OHRQoL declining during treatment.

While the above studies focused primarily on OHRQoL changes following the end of orthodontic treatment, it is important to investigate changes during treatment, especially following the insertion of orthodontic appliances, so as to help patients to understand the consequences of treatment and manage their expectations (Brosens et al., 2014). In a study of 250 Chinese adolescents, patients' OHRQoL deteriorated following placement of fixed appliances, with the lowest levels reported after one week where there was an adverse impact on physical pain and psychological discomfort. After one week, consistent improvement in OHRQoL was observed (Chen et al., 2009). A similar trend was noted in other studies (Brosens et al., 2014; Zhang et al., 2008; Healey et al., 2016).

Moreover, only few OHRQoL studies controlled the type of appliance used (Healey et al., 2016; Chen et al., 2009; Zhang et al., 2008; Kadkhoda et al., 2011). Fixed or

functional appliances have been associated with higher levels of discomfort relative to removable appliances (Stewart et al., 1997; Sergl et al., 2000). Weidel and Bondemark (2016) compared removable and fixed appliances in children undergoing orthodontic treatment and found that removable appliances were more likely to have adverse effects on school and leisure activities whereas fixed appliances caused higher levels of pain initially with more difficulty in eating and chewing. Kadkhoda et al (2011) compared the impact of functional appliances and headgear on OHRQoL between two adolescent groups with Class II division 1 malocclusion and found no difference between both groups. However, this study reported OHRQoL at one time point only; short and long term assessment of OHRQL changes is more likely to provided a clearer comparison between the two appliances. Similarly, Alzoubi et al (2017) compared changes in OHRQoL between two groups of participants aged between 10-16 years with Class II division 1 malocclusion. One group received Twin Block removable functional appliances while the other group received fixed appliances. The OHRQoL was quantified using the OHIP-14 questionnaire. No difference in OHRQoL changes was found between both groups at the end of treatment with both reporting positive changes relative to pretreatment OHRQoL scores. The observation period was approximately 25 months but it was not made clear if the twin-block group progressed to fixed appliances treatment

The general trend across the literature is improvement in OHRQoL following orthodontic treatment during childhood. Findings of a recent meta-analysis of 6 studies confirmed there is moderate quality evidence that orthodontic treatment during childhood leads to improvement in OHRQoL, although whether this change

is sustained to adulthood remains unclear. The authors called for more longitudinal high quality studies (Javidi et al., 2017).

It is important to approach the association between orthodontic treatment and OHRQoL as studied in the literature with caution. Doubts have been expressed whether orthodontic treatment or untreated malocclusion contribute to any significant psychosocial impact in later life in the context of other psychosocial variables (Kenealy et al., 2007; Shaw et al., 2007). Agou et al (2011) results have shown a significant difference in CPQ scores between treated children and untreated controls. However, when those results were analyzed such that a confounding psychological factor such as psychological well-being (PWB) was controlled for, orthodontic treatment contribution to the change in CPQ scores was found to be non-significant except for the emotional well being domain. An interesting finding was that children with higher PWB initially were more likely to show significant improvement in their OHRQoL regardless of their treatment status whereas OHRQoL of untreated children with low initial PWB scores worsened across the duration of the study. Therefore, when analyzing OHRQoL changes as an orthodontic treatment outcome, it would be ideal to account for the modulating effects of other psychosocial variables (Brosens et al., 2014; Agou et al., 2011; Kenealy et al., 2007; Shaw et al., 2007).

2 AIMS AND NULL HYPOTHESIS

2.1 Aim

The aim of the study is to evaluate the impact of orthodontic treatment on OHRQoL in children with Class II division 1 malocclusion.

2.2 Specific Objectives

- To assess changes in OHRQOL in patients undergoing functional and fixed appliance treatment for Class II division 1 malocclusion (Primary outcome).
- To assess the level of agreement in OHRQoL between parents and children undergoing functional and fixed appliance therapy for Class II division 1 malocclusion.
- To assess the relationship between the perceived (self-reported AC of IOTN) and normative aesthetic treatment needs (clinician-reported AC of IOTN) and to establish the relationship between the former and CPQ11-14 scores.

2.3 Null Hypothesis

Orthodontic treatment of children with Class II division 1 malocclusion is not associated with an improvement of their OHRQoL.

3 MATERIALS AND METHODS

3.1 Study Design

This was a prospective cohort study where a convenience consecutive sampling method was employed.

Patients with a Class II Division 1 malocclusion (IOTN 5a), requiring functional appliance treatment attending the Health Service Executive (HSE) orthodontic regional unit of St. James's Hospital who satisfied the inclusion and exclusion criteria were asked to participate in the original study (Al-Jumah, 2017). All participants from the original study who required fixed appliances following the end of their functional appliance therapy were contacted to be possibly enrolled in the current study where they would be followed until the end of their fixed appliance treatment. The COHRQoL questionnaires were collected at four different time points where the subject pairs (child and parent) were followed from the start of their functional appliance therapy (phase I) until the end of their fixed appliance therapy (phase II).

3.2 Ethical Approval (Appendix 1)

The ethical committee of the Faculty of Health Sciences of Trinity College Dublin approved the follow-up of the participants until the end of their fixed appliance therapy.

3.3 Subjects

3.3.1 Selection Criteria

Inclusion Criteria

The inclusion criteria as set for the original study/Phase I (Al-Jumah, 2017) are as follows

- Patients categorized as 5a according to the Dental Health Component (DHC) of IOTN (Index of Orthodontics Treatment Need)
- Patients identified as being suitable for Twin-Block Appliance (TBA) therapy as determined by the treating orthodontist.
- Patients aged 11-14 years old.
- Good motivation to maintain oral hygiene and undergo orthodontic treatment.

The inclusion criteria as set for the current study/Phase II are as follows

- Patients from phase I identified as being suitable to receive upper and lower fixed appliance therapy following the completion of their functional appliance therapy.

Exclusion Criteria

- Patients with craniofacial syndromes.
- Children who declined to participate.
- Children who have received orthodontic treatment prior to Phase I.
- Children aged older than 14 year old at the start of Phase I.
- Subjects receiving fixed appliance therapy for one arch only.

3.3.2 Sample Size

The sample used was a convenience sample from the original study (Al-Jumah, 2017). A power analysis was performed to confirm a sufficient number of participants existed to detect an estimated medium effect of 0.25 with an alpha value of 0.05, and a power of 80% for repeated measures ANOVA. This data analysis using G*Power determined a sample size of 45 was needed (Faul et al., 2007). All children (N=58) from the original study who completed their functional appliance therapy were included in the present study to allow for attrition.

3.3.3 Recruitment

Subjects for both phases of the study were recruited from the HSE regional orthodontic unit of St. James's Hospital: Dublin, Ireland.

Phase I(Al-Jumah, 2017)

Eligible subjects who satisfied the selection criteria for Phase I were asked to participate at the assessment visit. A member of the research team provided verbal explanation of the study details. Subjects were also provided with information leaflets detailing the aims and the characteristics of the study. For each parent and child pair, a signed written consent and a written assent forms were obtained respectively. Furthermore, prospective participants were assured that they were under no obligation to participate in the study and no prejudice would be held against the children or the parents nor would the quality of care be adversely affected if they chose not to participate in the study. A total of 74 pairs of children and their parents were recruited for original study/phase I. All children participants received the same design of the twin-block appliance (modified Clark).

Phase II

Participants from phase I, who completed their functional appliance therapy and were due to receive upper and lower fixed appliances were asked to extend their participation to provide the follow-up data for the current study until the completion of their orthodontic treatment. A similar informed consent process was followed as outlined above (Appendix 2; Appendix 3). A total of 58 participants agreed to continue being followed until the end of their orthodontic treatment.

3.4 Measures

The short versions of the Child Perception Questionnaire (CPQ11-14) and the Parental-Caregiver questionnaire (P-CPQ) were employed to measure changes in the children's oral health related quality of life (OHRQoL) as assessed by the child and the parent respectively. The normative and the perceived aesthetic treatment need were assessed using the Aesthetic Component (AC) of IOTN as rated by a calibrated clinician and the children, respectively (Evans and Shaw, 1987).

The CPQ11-14 and the P-CPQ are components of the Child Oral Health Related Quality of Life originally developed by Jokovic in 2002 and 2003 respectively. Shorter versions of both questionnaires were later developed (Thomson et al., 2013; Jokovic et al., 2006). The development and the testing of the CPQ11-14 and P-CPQ were discussed extensively in the literature review section, a brief overview is provided in the sections below.

3.4.1 Child Perception Questionnaire (CPQ11-14) (Appendix 5).

Components and Scoring

The short version of the CPQ11-14 is 16-item questionnaire that quantifies OHRQoL across four domains: oral symptoms, functional limitation, emotional well-being and social well being. Each domain is assessed by four questions in relation to the frequency of the problem in the past three months. The response options are: “Never” = 0; “Once/twice” = 1; “Sometimes” = 2; “Often” = 3; and “Every day/almost every day” = 4. The overall range of scores is 0-64, with a range of 0-16 to each domain.

Validity and Testing

The CPQ11-14 has been validated against global ratings by a number of studies in children with malocclusions (Do and Spencer, 2008; O'Brien et al., 2006; Marshman et al., 2005).

The responsiveness of the questionnaire has also been evaluated (Agou et al., 2008); the ability of the questionnaire to detect changes over time has rendered it suitable to be used in longitudinal studies investigating the effect of orthodontic treatment on OHRQoL (Abreu et al., 2018; Chen et al., 2009; Zhang et al., 2008; Jaeken et al., 2018; Healey et al., 2016).

Limitations

Johal (2007) noted that one important limitation of the questionnaire is that it is not condition specific and therefore, the impact of the score could be due to oral health conditions other than malocclusion. Further, doubts have been expressed about the questionnaire's discriminative ability to differentiate between the different types of malocclusion (O'Brien et al., 2007)

3.4.2 Parental-Caregiver Questionnaire (P-CPQ) (Appendix 6).

Components and Scoring: short version

Similar to the CPQ11-14, the short version of P-CPQ is a 16-item questionnaire divided equally across the aforementioned subdomains

Validity and testing

The full 31-item P-CPQ version has been validated by Jokovic (2003). The short version has been validated in children with early childhood caries and its association with poorer OHRQoL (Thomson et al., 2013).

Limitations

The short version of the P-CPQ has not been validated for children with malocclusions or receiving orthodontic treatment. However, the purpose of this study

3.4.3 Aesthetic Component of IOTN (Appendix 7)

Components and scoring

A series of 10 color photographs arranged on a continuum of attractiveness with grade 1 being the most attractive and grade 10 the least attractive (Evans and Shaw, 1987). The treatment need can be classified as follows: 1-4 no need/low, 5-6-7 moderate/borderline and 8,9, 10 high (Richmond et al, 1994).

Validity and testing

The AC component of IOTN has been validated against laypersons (Stenvik et al., 1997). It has been shown to have good level of agreement between children referred for orthodontic treatment and a random sample of 11-12 year old school children (Brook and Shaw, 1989).

Limitations

The dental development differs across the 10 photographs, which might influence judgments among clinicians and patients. Doubts have been expressed in the ranking order of the photographs. Concerns were also raised that there is not enough distinction between the different photographs particularly between those that are considered of low and moderate needs (Johansson and Follin, 2005).

3.5 Data Collection

The CPQ11-14 and the P-CPQ questionnaires were administered to the child and parents pairs at four time points: Prior to the functional appliance therapy (T1), at the end of the functional appliance treatment (T2), 6 months into fixed appliances (T3) and at the end of treatment (3 months following debond)(T4). The questionnaires were completed at the orthodontic clinic during which the parent and the child were separated whenever possible to avoid any potential confounding influence they might have on each other's answers. Gender and age were recorded for every child and a specific identification number was assigned to each pair. The questionnaires were collected in paper format, which was then transferred into a SurveyMonkey™ questionnaire by the lead investigator.

The perceived aesthetic treatment need at T2 was evaluated by the AC of the IOTN where the children were asked to choose a photograph in a series of 10 that, in their opinion, best resembled the attractiveness of their anterior teeth. The treating clinicians were asked to take a frontal intraoral photo of the participants prior to the start of the fixed appliance therapy and accordingly, the AC of the IOTN was also rated by a calibrated clinician.

3.6 Statistical Analysis

The statistical analysis was carried out using SPSS (Statistical package for social sciences) version 25 (SPSS Inc, Chicago, USA). The tests conducted are as follows:

- *Distribution of age, gender and ethnicity*: Descriptive statistics.
- *Changes in CPQ11-14 scores with time*: Repeated measures ANOVA (The data was visualized for normal distribution, using Q-Q plot and was found to be normally distributed at the four time points) is used to examine changes across the time periods T4-T1, T2-T1, T3-T2 and T4-T2
- *Difference between CPQ 11-14 and P-CPQ scores*: Paired T-tests is used at every time point.
- *The level of agreement between parents and children at the four time points*: Intraclass correlation coefficient (ICC) is used at every time point.
- *The level of agreement between child and clinician for the aesthetic treatment need*: ICC is used prior to starting the fixed appliance therapy.
- *Correlation between CPQ11-14 and AC scores*: Spearman correlation.

4 RESULTS

Seventy-four subject pairs of children and parents were enrolled in the original study (Al-Jumah, 2017). Of these, 46 have completed the CORQOL questionnaires data across the four time points of data collection (Figure 3).

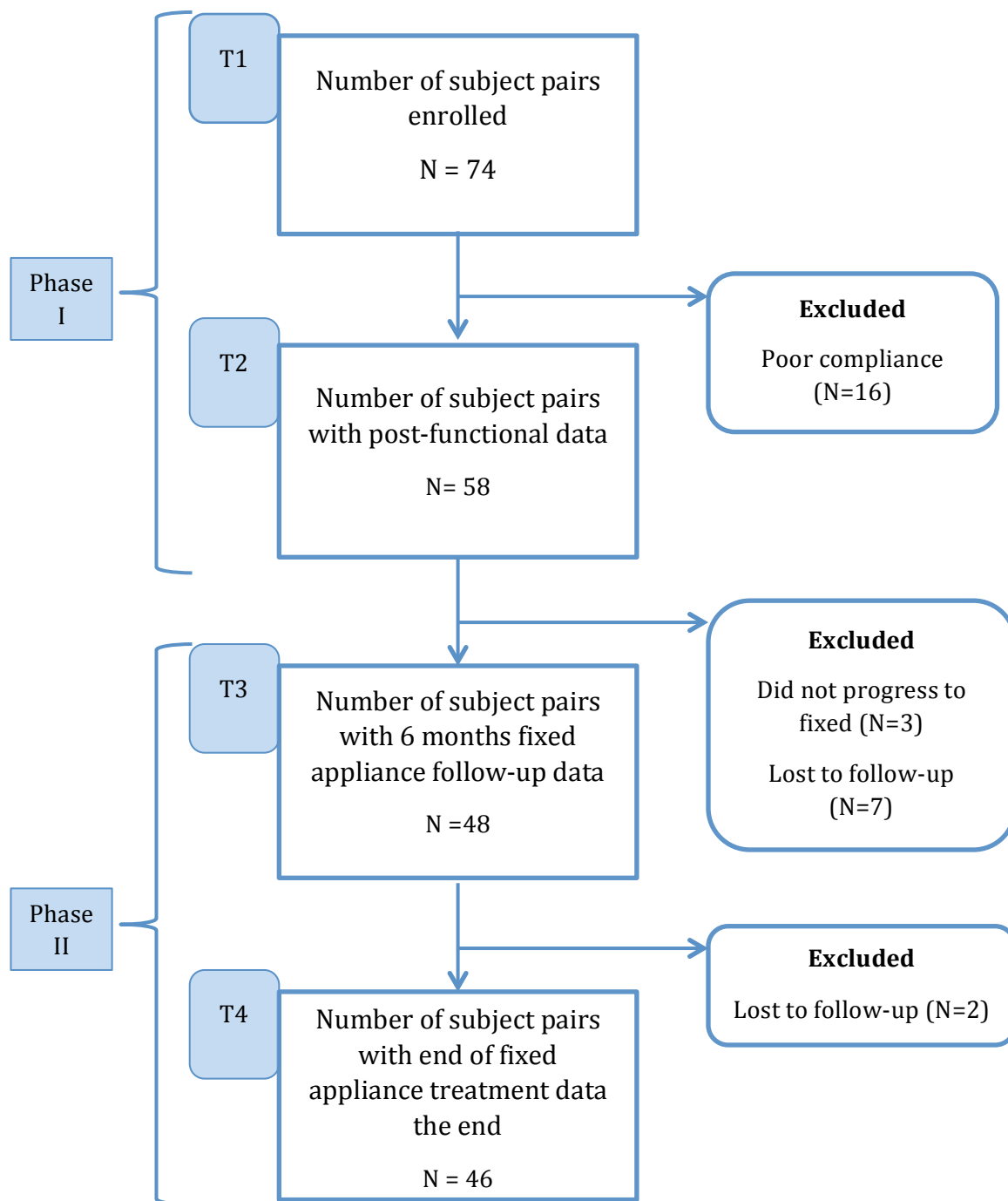


Figure 3 Study flow diagram

4.1 Baseline Sample Characteristics

The baseline characteristics as represented by age, gender and ethnicity of the final and recruited sample at T1 is summarized in the table below. The mean age of the children in the final sample was 12.74 years (SD=0.905) with 41.3% of the sample being girls. The recruited sample had a mean age of 12.77 years (SD=0.96), with girls representing 45.9% of the sample.

Table 1 Sample Characteristics of the final and recruited samples at T1

	Final Sample N =46	Recruited Sample N=74
Age at T1 (years)		
11	N=4 (8.7%)	N=8 (10.8%)
12	N=14 (30.4%)	N=20 (27.0%)
13	N=18 (39.1%)	N=27 (36.5%)
14	N=10 (21.7%)	N=19 (25.7%)
Gender		
Female	N=19 (41.3%)	N=34 (45.9%)
Male	N=27 (58.7%)	N=40 (54.1%)
Ethnicity		
Caucasian	N=40(87%)	N=63 (85.1%)
Other	N=6 (13%)	N=9 (14.9%)

4.2 Changes in OHRQoL (CPQ11-14) over time

Table 2 demonstrates the mean values of the overall and the sub-domain CPQ11-14 scores. Table 3 shows the results of the repeated measures ANOVA test where the overall and sub-domain CPQ11-14 scores are compared across the four time points of data collection. A statistically significant difference in the overall score, the emotional well-being and social well-being subscales is found between the pre-treatment and post-treatment CPQ11-14 scores with medium to large effect sizes. The results depict a trend where the emotional and social well-beings of the participants seem to improve with the progression of the orthodontic treatment as displayed by figures 7 and 8. Neither the functional limitations nor the oral symptoms showed a statistically significant difference across the four time points of measurement (Figure 5 and Figure 6).

Table 2 Mean scores of the CPQ11-14

T1, Pre-treatment; T2, End of functional; T3, Six months with fixed appliances; T4, Post-treatment. SD, standard deviation.

Effect size for ANOVA (Faul et al.,2007): A value of less than 0.25 is considered small, between 0.25 and 0.4 is considered medium and greater than 0.4 is large.

	T1	T2	T3	T4	Effect Size
Overall score					
Mean (SD)	15.05 (8.037)	14.43 (8.24)	12.94 (7.95)	10.24 (5.029)	0.235
Median	15.00	13.00	12.00	10.00	
Range	1-36	1-36	1-30	1-23	
Oral Symptoms					
Mean (SD)	4.74 (2.43)	4.68 (2.25)	5.06 (2.70)	4.48 (2.07)	0.084
Median	5.00	4.00	5.00	4.50	
Range	0-11	0-11	0-11	0-8	
Functional limitations					
Mean (SD)	2.34 (2.61)	3.07 (2.32)	3.00 (2.59)	2.27 (1.74)	0.173
Median	2.00	3.00	2.00	2.00	
Range	0-11	0-9	0-8	0-8	
Emotional well-being					
Mean (SD)	4.62 (3.65)	3.23 (3.58)	2.60 (2.68)	2.18 (2.40)	0.293
Median	4.00	3.00	2.00	2.0	
Range	0-16	0-12	0-10	0-10	
Social well-being					
Mean (SD)	3.35 (2.63)	3.54 (2.56)	2.28 (1.93)	1.88 (1.91)	0.326
Median	3.00	3.00	2.00	1.40	
Range	0-11	0-11	0-7	0-7	

Table 3 Comparison of CPQ11-14 subscale and total scores across four time-points.*Difference statistically significant at $p=0.05$; SD, Standard deviation

	Post-treatment/Pre-treatment (T4-T1)	End of functional/Pre-treatment (T2-T1)	Six months with fixed /End of functional (T3-T2)	Post-treatment/End of functional (T4-T2)
Overall score				
<i>P</i> -value	0.011*	1.000	0.864	0.056
Mean difference	-4.408	0.528	-1.590	-3.880
Oral symptoms				
<i>P</i> -value	1.000	1.000	1.000	1.000
Mean difference	-0.306	-0.59	0.380	-0.247
Functional limitations				
<i>P</i> -Value	1.000	0.488	1.000	1.000
Mean difference	-0.046	0.732	-0.070	-0.779
Emotional well-being				
<i>P</i> -value	0.001*	0.048*	1.000	0.335
Mean difference	-2.601	-1.394	-0.632	-1.207
Social well-being				
<i>P</i> -value	0.006*	1.000	0.039*	0.002*
Mean difference	-1.456	-0.193	-1.267	-1.648

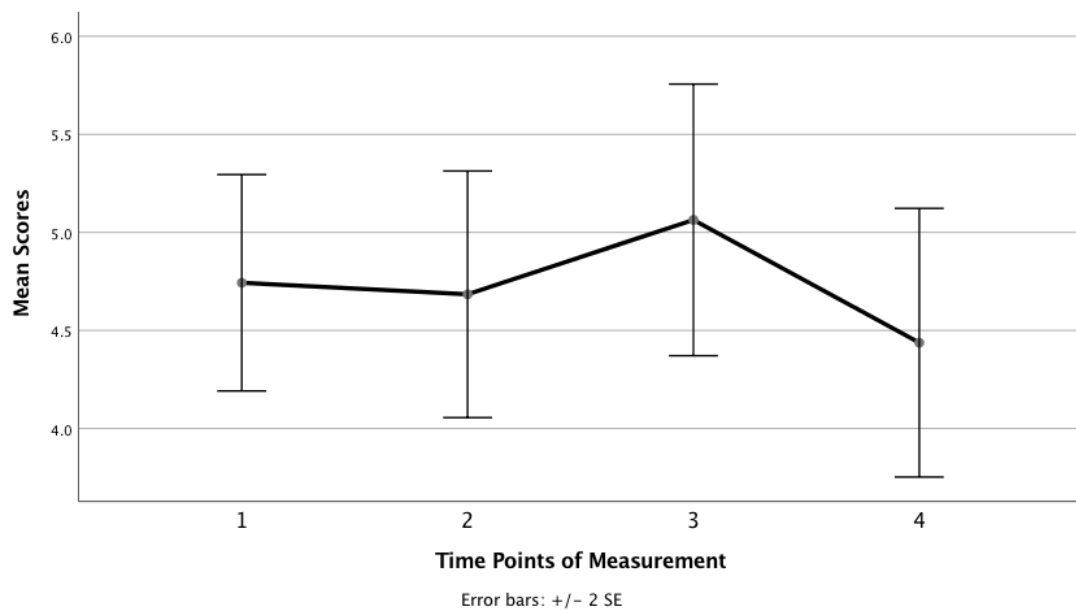


Figure 4 Changes in CPQ11-14 overall score across the four time-points of measurement.

Error bars represent standard error (SE). Statistical significance ($p < 0.05$) is found between T4 and T1.

T1, Pre-treatment; T2, End of functional; T3, Six months with fixed appliances; T4, Post-treatment.

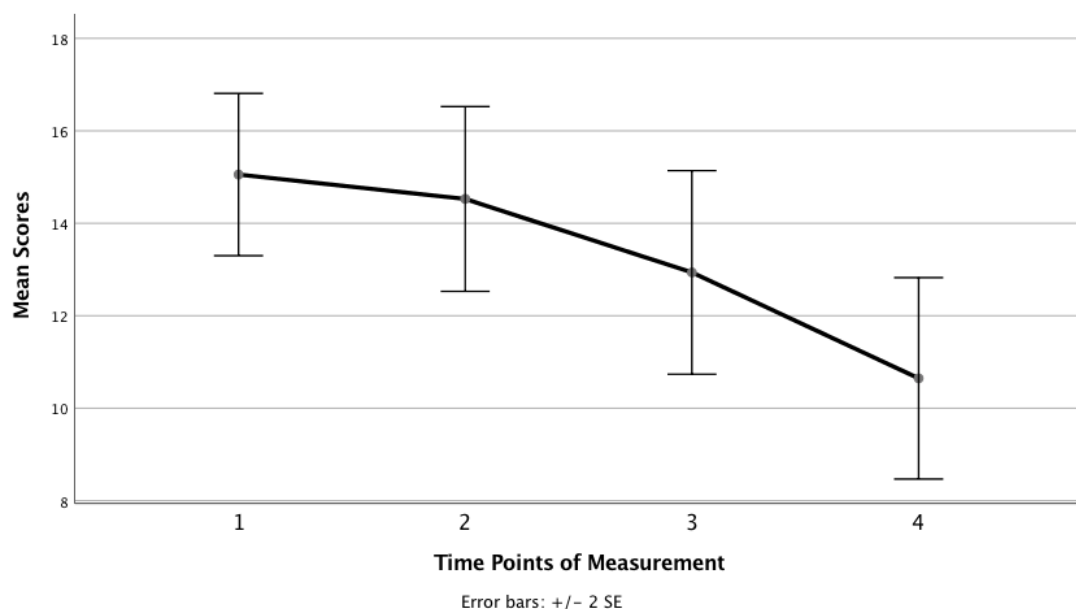


Figure 5 Changes in the CPQ11-14 oral symptom subscale across the four time points of measurement.

Error bars represent standard error (SE). No statistical significance ($p > 0.05$) is found between any of the time points.

T1, Pre-treatment; T2, End of functional; T3, Six months with fixed appliances; T4, Post-treatment.

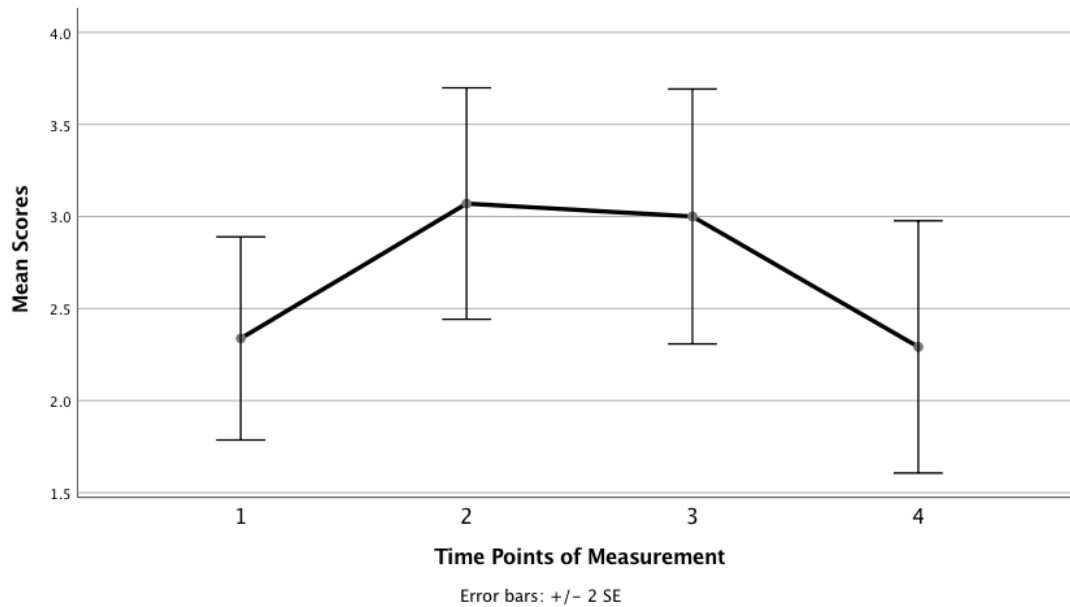


Figure 6 Changes in the CPQ11-14 functional limitation subscale across the four time points of measurement.

Error bars represent standard error (SE). No statistical significance ($p > 0.05$) is found between any of the time points.

T1, Pre-treatment; T2, End of functional; T3, Six months with fixed appliances; T4, Post-treatment.

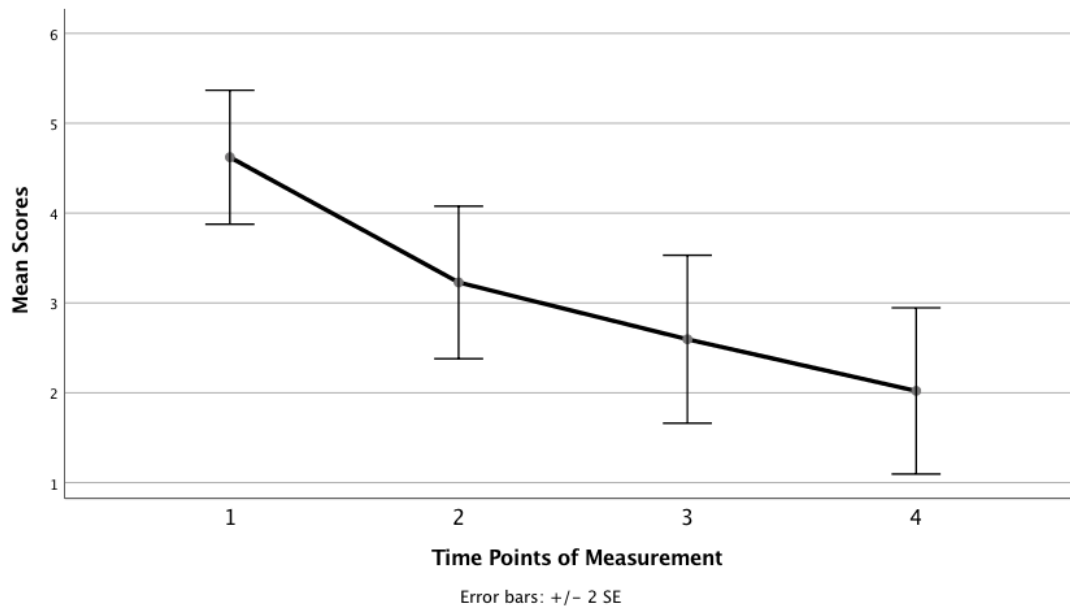


Figure 7 Changes in the CPQ11-14 emotional well-being subscale across the four time points of measurement.

Error bars represent standard error (SE). Statistical significance is found across three time periods: T2 - T1, T3 - T1, and T4 - T1.

T1, Pre-treatment; T2, End of functional; T3, Six months with fixed appliances; T4, Post-treatment.

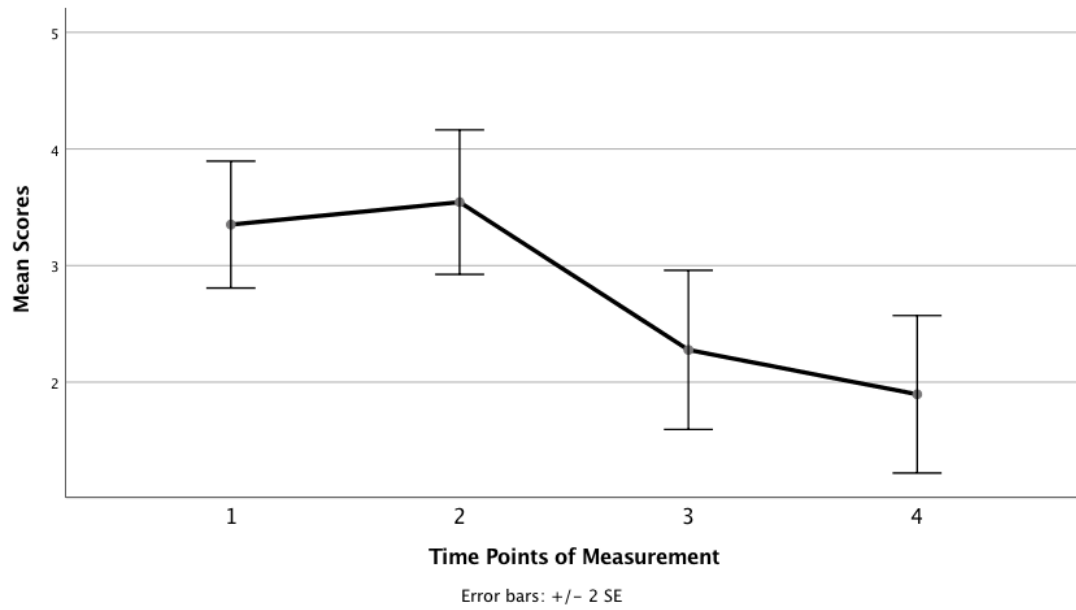


Figure 8 Changes in the CPQ11-14 social well-being subscale across the four time points of measurement.

Error bars represent standard error (SE). Statistical significance is found across three time periods: T4 -T1, T4 - T2. and T3-T1.

T1, Pre-treatment; T2, End of functional; T3, Six months with fixed appliances; T4, Post-treatment.

4.3 Levels of agreement in rating OHRQoL between parents and children

Tables 4-7 display the means of the Parental-Caregiver Perception Questionnaire (P-CPQ) and the CPQ11-14 scores. Each table presents one particular time point of measurement. The tables also show the results of the intraclass correlation test (ICC) between PCPQ and CPQ11-14 overall and subdomain scores. Poor, moderate and high levels of agreement are indicated when reported ICC values are less than 0.5, 0.75, and greater than 0.90, respectively (Koo and Li, 2016). At T1, there was a statistically significant difference between parents and children among the overall score, emotional and the social well-being subdomains ($P < 0.05$), with the latter two showing a poor level of agreement ($ICC < 0.5$). In each of these instances, the parents reported higher scores. The highest level of agreement is observed at the functional limitation subdomain with an ICC value of 0.708.

Generally, moderate levels of agreement are found between parents and children with the highest being observed at the functional limitation subdomain ($ICC = 0.714$) at the post-functional time point. Statistically significant difference is noted only in the emotional well-being subdomain at T2 ($P = 0.026$), with the parents reporting higher scores, despite a moderate level of agreement ($ICC > 0.5$); suggesting that some parents significantly overestimate the negative impact of malocclusion on the emotional well-being of their children.

At T3 and T4, the functional limitation subdomain showed the highest level of agreement with ICC values 0.695 and 0.581, respectively. Poor levels of agreement are observed in the emotional, social well-beings and oral symptoms subdomains at both time points.

Table 4 Agreement between parent and child questionnaires scores prior to starting treatment.

*P value <0.5 (paired t-test); ICC, Intraclass coefficient; SD, Standard deviation.

	CHILD	PARENT	Mean	P value	ICC
	Mean (SD)	Mean (SD)	Difference		value
			Parent- Child		
Overall score	15.05(8.037)	17.35(9.04)	2.30	0.034*	0.602
Oral symptoms	4.74 (2.43)	4.08(2.41)	-0.662	0.059	0.387
Functional limitation	2.34 (2.61)	2.14(2.50)	-0.203	0.450	0.748
Emotional well-being	4.62 (3.65)	6.18 (3.71)	1.554	0.003*	0.448
Social well-being	3.35 (2.63)	4.96(3.22)	1.608	0.001*	0.363

Table 5 Agreement between parent and child questionnaires scores at the end of functional.

**P* value <0.5 (paired t-test); ICC, Intraclass coefficient; SD, Standard deviation

	Child	Parent	Mean	P value	ICC
	Mean (SD)	Mean (SD)	Difference		value
			Parent-Child		
Overall score	14.28 (8.39)	15.10(9.0)	0.127	0.247	0.522
Oral symptoms	4.68 (2.25)	4.11 (2.64)	0.828	0.176	0.264
Functional limitation	3.07(2.32)	2.86(3.00)	-0.211	0.702	0.714
Emotional well-being	3.23(3.58)	4.54(4.08)	1.316	0.026*	0.508
Social well-being	3.54(2.56)	3.63(3.50)	0.088	0.893	0.226

Table 6 Agreement between parent and child questionnaire scores at 6 months after placement of fixed appliances.

*P value <0.5 (paired t-test); ICC, Intraclass coefficient; SD, Standard deviation.

	Child	Parent	Mean	P value	ICC
	Mean (SD)	Mean (SD)	Difference		value
			Parent-Child		
Overall score	12.94 (7.95)	13.89 (8.83)	0.957	0.219	0.517
Oral symptoms	5.06 (2.70)	4.36 (2.55)	-0.702	0.966	0.341
Functional limitation	3.00 (2.59)	3.02 (2.40)	0.021	0.537	0.695
Emotional well-being	2.60 (2.68)	2.96 (2.97)	0.362	0.537	0.384
Social well-being	2.28 (1.93)	3.55 (2.98)	1.277	0.005*	0.420

Table 7 Agreement between parent and child questionnaire scores at the end of the fixed appliance treatment.

**P* value <0.5 (paired t-test); ICC, Intraclass coefficient; SD, Standard deviation.

	Child	Parent	Mean	P-value	ICC
	Mean (SD)	Mean (SD)	Difference		value
			Parent-Child		
Overall score	10.24(5.03)	9.98 (5.32)	-0.26	0.225	0.502
Oral symptoms	4.48 (2.07)	4.02(2.08)	-0.46	0.368	0.487
Functional limitation	2.27 (1.74)	2.28(1.81)	0.043	0.902	0.581
Emotional well-being	2.18 (2.40)	1.87(1.97)	-0.264	0.511	0.435
Social well-being	1.88 (1.91)	1.81(2.05)	-0.21	0.958	0.369

4.4 Levels of agreement between the normative and perceived aesthetic treatment need at T2

Table 8 shows the distribution of the normative and the perceived aesthetic treatment need of the children at T2 as rated by the children themselves and an expert. No statistically significant difference is observed between the expert and the children mean scores ($P=0.669$) with the scores showing a moderate level of

agreement (ICC = 0.597). When gender is accounted for, a higher level of agreement is noted with girls (ICC =0.767) compared to boys (ICC = 0.529).

The magnitude of the Spearman's correlation between the aesthetic scores self – reported by the children and the overall CPQ11-14 score was found to be weak ($r_s=0.062$) and of no statistical significance $p=0.69$).

Table 8 Distribution and levels of agreement between the normative and the perceived aesthetic treatment need.

No/low treatment need, AC scores 1-4; Moderate/high treatment need, AC scores 5-10

*Paired t-test significance $p<0.05$

	Normative need (assessed by clinician)	Perceived treatment need (Self reported by the children)
AC score category		
No/low treatment need	83%	85.1%
Moderate/high treatment need	17%	14.9%
Mean (SD)	3.49 (1.545)	3.38(1.609)
P value*	0.669	
ICC	Sample 0.597 (Female 0.767, Male 0.529)	

5 DISCUSSION

Malocclusion particularly Class II division 1 is thought to have a negative impact on the psychosocial health of adolescents which can extend into adulthood (Helm et al., 1985). Adolescents with certain occlusal traits such as an increased overjet of more than 6 mm and spacing are more so associated with poorer OHRQoL scores compared to subjects with no malocclusion (Johal et al., 2007).

Hence, patients with increased overjets might receive a significant psychosocial benefit from orthodontic treatment. Therefore, the utilization of subjective measures such as patient reported outcomes compliment objective indices in the assessment of orthodontic treatment need and benefits in patients with Class II division 1 malocclusion. OHRQoL measures also equip clinicians with a clearer understanding of the reasons behind seeking orthodontic treatment and consequently leading to better communication with patients and management of treatment expectations.

This study primarily set out to measure the impact of orthodontic treatment on the OHRQoL of adolescents with Class II division 1 malocclusion. Secondary objectives included assessing the level of agreement between parents and children in rating OHRQoL and finally, investigating the discrepancy between the normative and the perceived treatment needs.

5.1 The impact of orthodontic treatment on OHRQoL

The findings of this study have shown that orthodontic treatment is associated with improvement in OHRQoL scores particularly in the emotional and the social well-being dimensions. This is not surprising, given that in the literature, there is high quality evidence to suggest that subjects with malocclusion report poorer OHRQoL scores particularly in these two dimensions (Dimberg et al., 2015). These findings are in agreement with a recent systematic review investigating the impact of orthodontic appliances on OHRQoL; Javidi et al (2017) carried out a meta-analysis of 6 studies concluding that there is moderate quality evidence to suggest that orthodontic treatment during adolescence has a positive impact on the emotional and social well-being dimensions. It remains unclear if the apparent benefit in the emotional and social well-being will be sustained to adulthood. A 20-year follow-up study in the U.K. revealed that there was no long-term negative psychosocial implication for participants who never received orthodontic treatment despite a prior objective treatment need as children (Kenealy et al., 2007).

A closer look of the CPQ11-14 scores during treatment exhibits a trend where OHRQoL improves with the progression of treatment with the oral symptoms and functional limitation scores being more or less constant throughout the treatment. This is in contrast to previous research, which has shown OHRQoL scores tend to deteriorate during orthodontic treatment particularly in the oral symptoms and functional limitations sub-domains (Zhang et al., 2008; Chen et al., 2009). Zhang et al and Chen et al observed worsening of the scores during the first month of fixed appliance treatment with a consistent improvement afterwards. In the current

study, CPQ11-14 scores are reported 6 months after placement of fixed appliances, which might have provided the patients with enough time to adjust to the appliances.

Conversely, a recent systematic review could not find a statistical difference in OHRQoL scores between orthodontic and non-orthodontic subjects, but the authors argue that it is possible OHRQoL scores of orthodontic groups normalized following treatment and hence if there is any difference, it could not be detected (Javidi et al., 2017). Similarly, a 3-year follow-up of 11-12 year old school children in the U.K. who had no prior history of orthodontic treatment at baseline reported no statistical difference in the change of CPQ 11-14 scores between those who received treatment during the observation period and those who did not. OHRQoL seemed to improve for both groups, but it was not clear if there was a difference between the CPQ of both of these groups either at baseline or at the end of the study (Benson et al., 2015).

Only two studies investigated the impact of orthodontic treatment in Class II division 1 patients. Kadkhoda et al (2011) compared headgear and functional appliances at one time point during treatment to a non-malocclusion group and Alzoubi et al (2007) compared two appliances: functional and fixed in two groups of adolescents. In the latter study, both groups showed moderate improvements in OHRQoL scores, but the observation period for the functional group was not clear or whether some of the patients in that group received a second phase of fixed appliances treatment. In the current study, a greater magnitude of improvement in the CPQ11-14 scores is observed during phase II (fixed appliances) relative to phase I (functional appliance). This could be attributed to achieving better

alignment of the dentition with fixed appliances during phase II and therefore better dental aesthetics, although the literature is conflicted on the relationship between dental aesthetics and OHRQoL (Kok et al., 2004; Ahmed et al., 2001; Kragt et al., 2017).

The lack of a control group in the present study makes it difficult to isolate the effect orthodontic treatment has on OHRQoL. An ideal control group would include participants of a similar malocclusion and baseline characteristics. Such a group could be attained from the national waiting list for orthodontic treatment. However, an overjet greater than 6mm is classified as a high treatment need according to the Dental Health Component of ITON and is associated with a reported higher incidence of trauma and bullying (Todd, 1985; Seehra et al., 2011). Therefore, it is not feasible nor is it ethical for treatment to be withheld for the duration of the study. Nonetheless, studies with similar age and gender distributions as the current study reported improvements in OHRQoL scores following orthodontic treatment when compared to untreated controls recruited from waiting lists for orthodontic treatment (Agou et al., 2011; Feu et al., 2013; Abreu et al., 2018).

It is important to interpret the results of the current study and those that have shown significant difference compared to untreated controls with caution, as an association does not imply causation. Agou et al (2011) investigated changes in OHRQoL of 118 adolescents, where 74 received orthodontic treatment and 44 were untreated controls recruited from a waiting list. The results have shown that the improvement in the CPQ11-14 scores was significantly better for the treatment group; however, when the psychological well-being (PWB) was controlled for, the

statistical difference in the CPQ scores was eliminated suggesting that children with better PWB will show improvement in their OHRQoL regardless of their treatment status. Thus, it is possible that some children can show improvement in their OHRQoL as they get older even when their malocclusion is left untreated. Whether this assumption can be extended to children with Class II division1 malocclusion remains unclear, as they are often postulated to have a greater psychosocial treatment need (Seehra et al., 2011).

5.2 Levels of agreement in rating OHRQoL between parents and children

The study assessed the levels of agreement between parents and children in rating OHRQoL scores across the four time points. The short version of the P-CPQ was chosen over the 31-item version as it included only the items that are in common to those in the CPQ11-14. This served the purpose of providing the necessary data to assess the levels of agreement between parents and children, whilst reducing the respondents' burden.

Generally, the results indicate a moderate level of agreement, although lower levels are observed in the emotional and social-wellbeing domains with the parents overestimating the emotional impact of the malocclusion. This is in agreement with previous research (Barbosa Tde and Gaviao, 2015).

A study of 90 English child and mother pairs found high levels of agreement in the objective subscales only. The study concluded that mothers tend to over-report the emotional impact of the malocclusion supporting the findings of the present one (Benson et al., 2010). In contrast, a Canadian study of 42 mother and child pairs

found that children reported higher scores compared with their mothers (Jokovic et al., 2003a). Their sample included children with orofacial conditions who may experience a more negative impact on their OHRQoL compared to children with malocclusions only as in the current study.

Emotional and social well-being items such as “How often has your child avoided smiling or laughing when around other children?” “...because of his or her teeth, lips, mouth, or jaws, how often has your child been irritable or frustrated?” “...shy or embarrassed?” tend to relate to activities outside the home environment where parents might have a limited knowledge on; whereas functional limitation questions tend to enquire about activities that the children are likely to carry-out in the presence of family such as difficulty to say any words or eat certain food. Therefore, it is not surprising that a high level of agreement is found in the functional domain compared to the emotional and social well-being domains.

The findings of another study with a large sample of 906 Brazilian mother and child pairs showed lower levels of agreement across all the subscales compared to the current one (Ferreira et al., 2012). The authors noted that cultural factors might have contributed to the disagreement of the results with that of previous research (Benson et al., 2010; Jokovic et al., 2003a).

The levels of agreement remained consistent across the four time points, as the children are getting older. This contradicts the findings of Jokovic et al (2003) and Ferriera et al (2012) who reported poorer levels of agreement among older adolescents. In these studies, none of the children have received orthodontic treatment, unlike the current one. It is possible that parents by regularly accompanying their children’s orthodontic appointments are kept aware of some

aspects of their children's malocclusion, particularly those relating to functional limitations.

5.3 Levels of agreement between the normative and perceived treatment need

The present study reports a moderate to a high level of agreement between expert and children AC scores. This is in contradiction to previous research where poor levels are often found with children being significantly less critical of their aesthetic appearance compared to clinicians (Birkeland et al., 1996; Hamdan, 2004; Ghijselings et al., 2014). The sample investigated in the current study includes patients being treated at the orthodontic clinic who are expecting to receive fixed appliances, where the orthodontic treatment had been discussed thoroughly with the child and the parent. It can be argued that the children have garnered enough orthodontic knowledge of their malocclusion and therefore would be more critical of their dental aesthetic appearance compared to other studies that have excluded subjects with a previous history of orthodontic treatment. Indeed, a study where half of the sample was receiving orthodontic treatment has found moderate levels of agreement between AC scores rated by patients and those by clinicians (Grzywacz, 2003).

No significant correlation was found between the two subjective measures: CPQ11-14 scores and self-reported AC scores. Several authors have noted that dental appearance, while it could be one of the factors, does not necessarily reflect subjective treatment need. The desire for orthodontic treatment might be influenced by other factors such as the popularity of braces among peers or parental pressure or psychological status (Kragt et al., 2017; Kok et al., 2004; Agou et al., 2011). In one study of 204 children in the UK, CPQ11-14 scores showed a

stronger co-correlation in relation to orthodontic concerns (assessed by two questions) relative to self-perceived AC scores and therefore OHRQoL measures could be a better predictor of subjective orthodontic treatment need (Kok et al., 2004).

5.4 Strengths and Limitations

This study employed the use of validated questionnaires to assess changes in OHRQoL over time. The psychometric properties of the CPQ11-14 have been tested and validated by a number of studies in children with malocclusion (Do and Spencer, 2008; O'Brien et al., 2006; Marshman et al., 2005). The responsiveness of the questionnaire has also been evaluated (Agou et al., 2008); the ability of the questionnaire to detect changes over time has made it suitable to be used in longitudinal studies investigating the effect of orthodontic treatment on OHRQoL (Abreu et al., 2018; Chen et al., 2009; Zhang et al., 2008; Jaeken et al., 2018; Healey et al., 2016).

This is first prospective study investigating periodic changes in OHRQoL in Class II division 1 patients who are undergoing two phases of treatment. This cohort of patients is suspected to have a greater psychosocial treatment need compared to other malocclusions (Johal et al., 2007; Helm et al., 1985) and therefore the effect of orthodontic treatment might transcend beyond the objective correction of the malocclusion. Supplementing objective clinical measure with ones reported by the patients provides clinicians with a clearer assessment of treatment expectations, needs and outcomes.

Nonetheless, the study has a few weaknesses. Firstly, a high attrition rate of 37% was observed. Twin-block appliance is generally associated with 30% failure due to lack of compliance (O'Brien et al., 2003b). In the present study, this percentage was found to be 22%, contributing to more than half of the lost participants. In addition, 12 participants were lost to follow-up. This study was conducted under “real-life” settings where orthodontic treatment was administered by experienced orthodontists in the public health service. Whilst this increases the generalizability of the results, it also hampers the data collection process where sometimes, it was not feasible to administer the questionnaires due to either patient related or clinician related time constraints despite the lead investigator’s efforts in closely monitoring the data collection process.

The lack of an untreated control group limits the certainty in the interpretation of the cause behind the observed change in OHRQoL. However, for ethical reasons, treatment cannot be withheld from adolescents when there is a clear objective treatment need. Lastly, no data was collected on other potential influences on OHRQoL; self-esteem and physiological well-being have been shown to modulate changes in OHRQoL (Brosens et al., 2014; Agou et al., 2011).

6 CONCLUSIONS

- Orthodontic treatment is associated with improvement in OHRQoL scores particularly in the emotional and the social well-being subdomains in Class II division 1 patients receiving two phases of treatment: functional and fixed appliances therapy.
- There was a moderate level of agreement between parents and children's ratings of the children's OHRQoL with higher levels being observed at the functional limitation subdomain and lower levels in the emotional and social-wellbeing domains. The parents tended to overestimate the emotional impact of the malocclusion.
- The children were found to be as conscious of their aesthetic treatment need, as clinicians would be.
- The subjective aesthetic treatment need does not relate to OHRQoL (as measured by CPQ11-14) suggesting several other factors other than dental aesthetics might play a role in influencing the subjective treatment need.

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8 APPENDICES

Appendix 1 Ethical Approval Letter



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Hadil Khraishi
School of Dental Science
Dublin Dental University Hospital
Trinity College Lincoln Place
Dublin 2
Ireland

Date: 28th November 2017

Ref: 171005

Title of Study: A follow-up study investigating changes in oral health-related quality of life (OHRQoL) in patients undergoing orthodontic treatment for Class II division 1 malocclusion: A longitudinal study.

Dear Hadil,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in October 2017. We are pleased to inform you that the above project has ethical approval to proceed.

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Prof. Brian O'Connell'.

Prof. Brian O'Connell
Chairperson
Faculty Research Ethics Committee

Appendix 2 Invitation Letter



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin



Invitation letter:

Dear Sir/Madam,

We would like to invite you and your child to consider taking part in a study, which Dr. Hadil Khraishi from the Dublin Dental University Hospital, Trinity College Dublin is undertaking as part of her postgraduate research in orthodontics. Dr Khraishi wants to collect information about the benefit of orthodontic treatment. She would also like your child and yourself to complete a questionnaire about the impact of orthodontic treatment on the oral health related quality of life.

You and your child can read more about the study in the information sheet provided and if you want to ask questions about the study, Dr Khraishi contact details are supplied below. If you are interested in taking part then Dr Khraishi will meet you on your first appointment following the functional appliance therapy.

This study will be a continuation of the original study commenced by Dr Fatmah Aljumah that you and your child agreed to participate in.

If you are interested in taking part in the study, then please contact her as follows:

- (1) Telephone contact 016127210
- (2) Email hadil.khraishi@dental.tcd.ie
- (3) By filling in the form below and handing it in personally to one of the staff.
- (4) By post, put the slip below, in the envelope supplied.

Thank you for your interest in this project

We are interested in taking part or learning more about the study with Dr. Hadil Khraishi and we are willing for her to contact us.

PARTICIPANT NAME:

SIGNATURE:

PARENT NAME:

SIGNATURE:

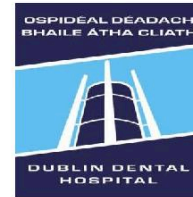
Telephone Number

E-mail :

Appendix 3 Patient Information Leaflet



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin



PATIENT INFORMATION LEAFLET

Title of the study: A follow-up study investigating changes in oral health-related quality of life (OHRQoL) in patients undergoing orthodontic treatment for Class II division 1 malocclusion: A longitudinal study

Principal investigator: Dr. Hadil Khraishi

Introduction

I am Dr. Hadil Khraishi from Dublin Dental University Hospital, Trinity College. I am carrying out research about the impact of orthodontic intervention on the oral health related quality of life and bullying among adolescents as a part of my postgraduate research with Trinity College Dublin. My study will be a continuation of Dr. Fatmah Aljumah's study, and so if you agree to participate in the continuation, you will be asked to fill out the same set of questionnaires as you did before with Dr. Aljumah.

I would like to invite **you and your child** to join this postgraduate research study. The purpose of this study is to collect information about the benefit of orthodontic treatment, to assess the effect of orthodontic intervention on oral health related quality of life.

Choosing not to take part in this study will not affect/change the treatment that you will be provided. Before you decide whether you and your child want to take part, it is important for you to understand, why the research is being done and what your participation will involve. Please take time to read the following information carefully. Ask Dr Khraishi if there is anything that is not clear or if you would like more information.

The study Details

As per Dr. Aljumah's study, I will ask you and your child to complete a questionnaire. The questionnaire will be collected at 6 months following the placement of fixed appliances and at the end of treatment. The questionnaire is validated and is used commonly and is the exact same one used in Dr. Aljumah's study. The questionnaire will take no more than ten minutes to complete and it will remain confidential as part of the study. In addition to the questionnaire, I will ask to take impressions at the aforementioned time intervals, the purpose of which is to monitor changes in your child's malocclusion.

Eligibility:

Children aged between 11-15 years, undergoing fixed appliance treatment following functional appliance, are eligible to take part in this study. The child must be accompanied by a parent at every visit.

Confidentiality:

Your identity and your child's will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group

Risks

The patient may disclose personal, sensitive information that could be upsetting. A specialized counselor will be provided to the patient if requested. Where a participant is identified as being bullied, the parent will be informed and a report will be sent to the parent. They would be advised to contact school and enquire about the schools anti-bullying policy.

Voluntary participation:

It is up to you and your child to decide whether to participate in this research. If you decide not to participate in this study, there will be no difference in quality or availability of care from staff.

Further information:

If you have any questions or require more information about this study, please contact the researcher using the following details:

Dr.Hadil Khraishi

Dublin Dental University Hospital, Trinity College Dublin, Lincoln Place, Dublin 2. [Tel:016127210](tel:016127210) or email hadil.khraishi@dental.tcd.ie

Appendix 4 Consent Form



CONSENT FORM

Please complete this form for study continuation after you have read the Information Sheet and listened to an explanation about the research

PROJECT TITLE: A follow-up study investigating changes in oral health-related quality of life (OHRQoL) in patients undergoing orthodontic treatment for Class II division 1 malocclusion: A longitudinal study

Principal investigator: Dr Hadil Khraishi

Thank you for considering taking part in this research. The person who is organizing the research must explain the project to you before you agree to participate. If you have any questions arising from the information sheet or the explanation already given to you, please ask the researcher before you decide whether to consent. You will be given a copy of this consent form.

You and your child understand that if you decide at any time during the research that you no longer wish to participate in this study, you can notify the researcher involved and withdraw from it immediately without giving any reason. Furthermore you understand that you will be able to withdraw any data pertaining to you, up to the point of publication.

My child and I are agreeing to participate in a research project which is being carried out by Dr. Hadil Khraishi as part of her postgraduate research with Dublin Dental University Hospital.

The study is designed to investigate the benefit of orthodontic treatment and the impact of orthodontic treatment on quality of life among adolescents and their parents. It will be a continuation of Dr. Fatima Aljuma study. We agree to participate in the questionnaire survey. Any information or data which is obtained from me during this research will be treated confidentially and stored securely. Data from this research project may be published in future:

Declaration

We have read the information leaflet for this project and I understand the contents. We had the opportunity to ask questions and all my questions have been answered to my satisfaction. We freely and voluntarily agree to be part of this study, though without prejudice to my legal and ethical rights. We understand that we may withdraw from the study at any time and we have received a copy of this agreement.

PARTICIPANT NAME:

PARTICIPANT SIGNATURE:

DATE:

PARENT NAME :

SIGNATURE:

DATE:

|

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent

INVESTIGATOR SIGNATURE:

DATE

Appendix 5 CPQ11-14

* 1. Patient identifier

* 2. Time of questionnaire

- ☐ Pre Functional
- ☐ During Functional
- ☐ Post Functional
- ☐ Six Months with fixed
- ☐ Twelve Months with fixed
- ☐ Post fixed

3. Age

* 4. Gender

- ☐ Female
- ☐ Male

* 5. What is your ethnic origin ?(UK and Ireland Specific)

- ☐ White British
- ☐ White Irish
- ☐ Other white background (please give details below)
- ☐ Mixed white and black Caribbean
- ☐ Mixed white and black African
- ☐ Mixed white and black Asian
- ☐ Mixed white and other background (please give details below)
- ☐ Asian
- ☐ Asian British
- ☐ Asian Irish
- ☐ Asian Indian
- ☐ Asian Pakistani
- ☐ Asian Bangladeshi
- ☐ Other Asian background (please give details below)
- ☐ Black
- ☐ Black British
- ☐ Black Irish
- ☐ Black Caribbean
- ☐ Black African
- ☐ Other Black Background (please give details below)
- ☐ Chinese
- ☐ Middle Eastern
- ☐ Prefer not to answer

Other (please specify)

**So if you don't mind I am going to ask you a few questions about your mouth.
theres a choice of answers and you can choose to answer never, once or twice, sometimes,
often, everyday or if you are not sure you can say don't know.
ok off we go**

* 6. In the past 3 months, how often have you had sores in your mouth?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer this

* 7. In the past 3 months, how often have you had bad breath ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer this

* 8. In the past 3 months, how often have you had food stuck in between your teeth?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 9. In the past 3 months, how often have you had difficulty biting or chewing food like apples, corn on the cob or steak ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 10. In the past 3 months, how often have you found it difficult to drink or eat hot or cold foods?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 11. In the past 3 months, how often have you had difficulty saying any words?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 12. In the past 3 months, how often have you had trouble sleeping ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 13. In the past 3 months, how often have you had pain in your teeth, lips, jaws or mouth ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 14. In the past 3 months, how often have you had taken longer than others to eat a meal?

- ☐ Never
- ☐ Once or twice
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 15. In the past 3 months, how often have you felt irritable or frustrated?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer this

* 16. In the past 3 months, how often have you felt shy or embarrassed?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 17. In the past 3 months, how often have you been upset ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 16. In the past 3 months, how often have you felt shy or embarrassed?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 17. In the past 3 months, how often have you been upset ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 18. In the past 3 months, how often have you been concerned what other people think about your teeth, lips, mouth or jaws?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 19. In the past 3 months, how often have you avoided smiling or laughing when around other children?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 20. In the past 3 months, how often have you not wanted to speak to speak or read out loud in class?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 21. In the past 3 months, how often have you had other children ask you questions about your teeth, lips, jaws , mouth or braces ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

23. In the past 3 months, how often have other children teased you or called your names about your teeth , lips , jaw , mouth or braces ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer this

* 24. Did that bother you ?

- ☐ Not at all
- ☐ Very little
- ☐ Some
- ☐ A lot
- ☐ Very much
- ☐ Don't know
- ☐ Prefer not to answer this

*25. What did they tease you about? (you can choose more than one answer)

- ☐ Teeth
- ☐ Lips
- ☐ Jaws
- ☐ Mouth
- ☐ Braces
- ☐ Other

Appendix 6 P-CPQ

* 1. Patient identifier

* 2. TIME OF QUESTIONNAIRE

☐ PRIOR TO STARTING

☐ DURING THEFUNCTIONAL

☐ POST FUNCTIONAL

☐ Six months with fixed

☐ Twelve months with fixed

☐ Post Fixed

* 3. Can you confirm that you are.....parent

☐ MOTHER

☐ FATHER

- ☐ 4. What is your ethnic origin?(UK and Ireland specific)
- ☐ White British
- ☐ White Irish
- ☐ Other White background (please give details below)
- ☐ Mixed white and black Caribbean
- ☐ Mixed white and black african
- ☐ Mixed white and black Asian
- ☐ Mixed white and other background (please give details below)
- ☐ Asian
- ☐ Asian British
- ☐ Asian Irish
- ☐ Asian Indian
- ☐ Asian Pakistani
- ☐ Asian Bangladeshi
- ☐ Other Asian background(please give details below)
- ☐ Black
- ☐ Black British
- ☐ Black Irish
- ☐ Black Caribbean
- ☐ Black African
- ☐ Other Black background (please give details below)
- ☐ Chinese
- ☐ Middle Eastern

☐ Prefer not to answer Other (please specify)

* 5. In the past 3 months, how often has your child had sores in his/her mouth?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer

* 6. In the past 3 months, how often has your child had bad breath ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer

* 7. In the past 3 months, how often has your child had food stuck in between his/her teeth?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 8. In the past 3 months, how often has your child had difficulty biting or chewing food like apples, corn on the cob or steak ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 9. In the past 3 months, how often has your child found it difficult to drink or eat hot or cold foods?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 10. In the past 3 months, how often has your child had difficulty saying any words?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 11. In the past 3 months, how often has your child had trouble sleeping ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 12. In the past 3 months, how often has your child had pain in his/her teeth, lips, jaws or mouth ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* In the past 3 months, how often has your child had taken longer than others to eat a meal?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer

* 14. In the past 3 months, how often has your child felt irritable or frustrated?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day
- ☐ Don't know
- ☐ Prefer not to answer

* 15. In the past 3 months, how often has your child felt shy or embarrassed?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 16. In the past 3 months, how often has your child been upset ?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 17. In the past 3 months, how often has your child been concerned what other people think about his/her teeth, lips, mouth or jaws?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 18. In the past 3 months, how often has your child avoided smiling or laughing when around other children?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 19. In the past 3 months, how often has your child not wanted to speak to speak or read out loud in class?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 20. In the past 3 months, how often has your child had other children ask him/her questions about his/her teeth, lips, jaws or mouth?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

* 21. Did that bother your child ?

- ☐ Not at all
- ☐ Very little
- ☐ Some
- ☐ A lot
- ☐ Very much
- ☐ Don't know
- ☐ Prefer not to answer

22. In the past 3 months, how often have other children teased your child or called him/her names?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost everyday
- ☐ Don't know
- ☐ Prefer not to answer

Appendix 7 AC Component of IOTN

Patient Identifier

Gender

- ☐ Male
☐ Female

Clinician's Score of the AC of IOTN

Here is series of 10 photographs showing a range of dental attractiveness, number 1 is the most and number 10 the least attractive arrangement of teeth. Where would you put your teeth on this scale?

Answer with the photo's number:

