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Children and Adolescents and Modified Twin block for Class II division 1 malocclusion compared to controls: quantitative and qualitative analyses

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Thesis submitted to University College Cork in partial fulfilment of the requirements for the

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LIST OF ABBREVISATIONS USED IN THE TEXT

AC	Aesthetic Component
COHIP	Child Oral Health Impact Profile
C-ODIP	Child Oral Impacts on Daily Performance
COHQoL	Child Oral Health Quality of Life
CPQ	Child Perception Questionnaire
CUDSH	Cork University Dental School and Hospital
CVM	Cervical Vertebral Maturation
DAI	Dental Aesthetic Index
DHC	Dental Health Component
EWB	Emotional Well-Being
FL	Functional Well-Being
HSE	Health Service Executive
IOTN	Index of Orthodontic Treatment Need
MIQ	Malocclusion Impact Questionnaire
MTB	Modified Twin Block
OASIS	Oral Aesthetic Subjective Impact Scale
OHRQoL	Oral Health Related Quality of Life
OS	Oral Symptoms
QoL	Quality of Life
QoL	Quality of Life
RCT	Randomised Control Trial
SCAN	Standard Continuum of Aesthetic Need
SD	Standard deviation
SWB	Social Well-Being
TBA	Twin Block Appliance
2D	Two-dimensional
3D	Three-dimensional
4D	Four-dimensional

ABSTRACT

Aims

- To evaluate the impact Modified Twin Block (MTB) treatment has on oral health related quality of life (OHRQoL), self-esteem, self-perception of aesthetic treatment need and 3D soft tissue facial changes in children with Class II division 1 malocclusion (II/1M) compared to children with II/1M awaiting treatment who served as controls.
- To assess the effect MTB treatment has on family quality of life (QoL) and on both the parent's perception of their child's OHRQoL and aesthetic treatment need compared to controls.
- To assess the level of agreement of child OHRQoL and perception of aesthetic treatment need by child and parent between groups.

Materials and methods

Following ethical approval, 60 subjects (31 males; 29 females) received MTB treatment (MTB group) and 47 subjects (22 males; 25 females) with II/1M awaiting treatment served as controls (Control group). At baseline (T1) and following MTB treatment/recall (T2) all subjects completed the Child Perception Questionnaire (CPQ_{11-14}), Child Health Questionnaire short from (CHQ-CF45) and self-assessed aesthetic treatment need (IOTN-AC). Each child also had a 3D facial image captured at rest. At the same time points, a parent of each child completed the Parent-Caregiver Perception Questionnaire (P-CPQ) and assessed their child's aesthetic treatment need (IOTN-AC). Comparisons of patient demographics were made using ANOVA and Chi-square tests. ANOVA was used for comparisons in CPQ, P-CPQ, CHQ-CF45 and 3D soft tissue facial changes at T1 and T2 between groups and paired t-tests were used within both groups. Bowker's symmetry test was used to compare IOTN-AC within groups and Fisher's Exact test was used between groups. ANOVA was used to test for associations between CPQ, CHQ, IOTN-AC, and 3D soft tissue facial change.

Results

Forty-two subjects (20 males; 22 females) completed MTB treatment (average duration 8.5 months; range 5-12 months) and 35 untreated II/1M subjects (15 males; 20 females) were recalled after an average time of 11 months (range 9-13 months). At T1, groups

were similar in age (p=0.1402) and gender (p=0.2973) but overjet in the MTB group was slightly greater (p=0.0016). At T2, there was a significant improvement in the MTB group in overall OHRQoL (p<0.0001) and self-perception of aesthetic treatment need (p=0.018) but there was no change in self-esteem (p=0.144). Significant improvements occurred in family QoL (p=0.0001), in parent's perception of both their child's OHRQoL (p<0.0001) and aesthetic treatment need (p<0.0001). In the MTB and Control groups and at both time points, the level of agreement between child and parent perception of the child's OHRQoL was poor with parents rating it worse [MTB group T1, p=0.0001; T2, p=0.003]; [Control group T1, p=0.001; T2, p=0.008]. At T1, parents rated the aesthetic treatment need to be greater than their child in the MTB group (p=0.054) and Control group (p=0.04). At T2, the level of agreement between the child and parent in their aesthetic treatment need was similar (p=0.262) but in the MTB group children perceived their aesthetic treatment need to be greater than their parents (p=0.019). From T1 to T2, significant 3D soft tissue changes occurred at Pogonion in the MTB group 4.26 mm (p= 0.001) and in the Control group 3.29 mm (p=0.002) but the mean difference between the groups (0.97 mm; p=0.011) was not clinically significant.

Conclusions

- MTB treatment significantly improved the OHRQoL and self-perception of aesthetic treatment need in children with II/1M but had no significant impact on self-esteem or 3D soft tissue facial changes compared to controls.
- MTB treatment significantly improved the family QoL and both the parent's perception of their child's OHRQoL and aesthetic treatment need compared to controls.
- In children following MTB treatment or awaiting treatment, poor agreement existed between the child and parent perception of OHRQoL and aesthetic treatment need.

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To Harper- you are the sun that never fades and the moon that never wanes.

DECLARATION

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

_____

Caroline O'Dwyer

CHAPTER ONE

INTRODUCTION

1 Introduction

Class II division 1 malocclusion (II/1M), with prominent upper incisors and an increased overjet, affects about 30% of children and adolescents (Whelton et al., 2002; O'Brien et al., 2009b). It is commonly associated with bullying and incisor trauma (Burden et al., 2001; Seehra et al., 2011) as well as poor oral health related quality of life (OHRQoL) in the child and the family (Johal et al., 2007).

Growth modification in II/1M with a functional appliance has been shown to improve OHRQoL (Alzoubi et al., 2017; Khraishi et al., 2019), self-esteem (O'Brien et al., 2003a) and dentofacial aesthetics (O'Brien et al., 2009a; O'Brien et al., 2009b). The Twin Block (TBA) is the most popular functional appliance in the UK and Republic of Ireland (RoI) (Chadwick et al., 1998; Gill et al., 2005; Campbell et al., 2013). It is a two-part removable appliance that postures the lower jaw forward by interlocking inclined bite planes and is well tolerated by patients (Clark, 1988; Clark, 2010). Treatment with a TBA principally effects the lower face (Singh and Clark, 2003; Varlık et al., 2008, Yıldırım et al., 2021). These improvements occur through combined effects on the orofacial soft tissues and muscles of mastication producing dentoalveolar and skeletal changes and are most effective during the pubertal growth period (Baccetti et al., 2000; Proffit et al., 2006; Ehsani et al., 2015).

Three-dimensional (3D) imaging is effective at monitoring the soft tissue effects of TBA treatment (Flores-Mir, 2006) but as yet, the changes brought about by this appliance and those that occur due to normal growth have not been separated.

This project compares Caucasian children with II/1M treated with a modified Twin block appliance (MTB) to children with II/1M awaiting treatment who served as controls with respect to the following outcomes:

- OHRQoL
- Self-esteem
- Self-perception of the aesthetic treatment need
- Three-dimensional (3D) soft tissue facial changes.

Comparisons are also made between parent groups and with their child with respect to:

- Family QoL
- Parental perception of the child's OHRQoL
- Parental perception of the child's aesthetic treatment need.

To the authors knowledge, no similar study has been conducted with these outcomes. This study aims to address these deficiencies.

For the purpose of this thesis ‘child’ refers to the children and adolescent participants. and ‘parent’ refers to the legal guardian/care giver of the participant.

CHAPTER TWO

LITERATURE REVIEW

2 Literature Review

This literature review will address in turn;

- II/1M with respect to incidence, aetiology and treatment need including child and parental perception of aesthetic treatment need;
- Functional appliances with a focus on the TBA/MTB;
- Craniofacial growth and soft tissue changes in untreated II/1M and following TBA/MTB treatment;
- Facial imaging in orthodontics;
- Child OHRQoL, Child Perception Questionnaire (CPQ_{11-14}) and Parental-Caregiver Perception Questionnaire (P-CPQ) with impact of II/1M before and after MTB treatment on OHRQoL;
- Self-esteem in children, Child Health Questionnaire-short form (CHQ-CF45) and impact of II/1M before and after MTB treatment on self-esteem;
- Association between OHRQoL, self-esteem and aesthetic treatment need in the child.

2.1 Search Strategy

An electronic database search was conducted for literature published from January 1st 1951 to May 1st 2021 with no language restrictions. The search was not confined to full text articles. The search strategy for each database is summarized in Appendix 1. The bibliographies of relevant studies were also scanned and a search of the grey literature was undertaken.

2.2 Class II division 1 malocclusion (II/1M)

2.2.1 Definition

The British Standards Institute (1983) defined II/1M as "The lower incisor edges lie palatal to the cingulum plateau of the upper incisors, the upper incisors are proclined or of average inclination, with an increased overjet" (British Standards Institution, 1983) [1]

2.2.2 Incidence of II/1M in children

II/1M affects approximately 30% of children in Ireland, with 12.2% having an overjet greater than 6mm and 2.5% of 12-year-olds having an overjet greater than 10mm (Whelton et al., 2006).

2.2.3 Aetiology of II/1M

II/1M has a multifactorial aetiology with skeletal, soft tissue, dentoalveolar and environmental influences (Bishara, 2006). A retrognathic mandible is the most common cause of the Class II skeletal relationship (Moyers et al., 1980; McNamara, 1981) but it may also be caused by a combination of maxillary protrusion and mandibular retrognathia or more rarely maxillary protrusion alone (Moyers et al., 1980; McNamara, 1981; Ferrario et al., 1994; Ngan et al., 1997; Bishara, 2006).

As the soft tissues are related to the underlying skeletal pattern, children with II/1M often have a lip trap, lip incompetence and an adaptive swallowing pattern (Lee, 1999). This tends to exacerbate the dentoalveolar relationship (Bishara et al., 1995; Lee, 1999; Bishara, 2006) with proclined upper incisors, retroclined lower incisors and an increased overjet (Bishara et al., 1995). An environmental aetiology such as a non-nutritive habit may be the cause or a contributory factor in II/1M (Pădure et al., 2012).

[1] Permission to reproduce extracts from British Standards is granted by BSI. British Standards can be obtained in PDF or hard copy formats from the BSI online shop: www.bisgroup.com/Shop or by contacting BSI Customer Services for hardcopies only: Tel: +44(0)2089969001, Email: cservices@bsigroup.com

2.2.4 Treatment Need

2.2.4.1 Psychosocial implications

Bullying among 10-14-year-old children owing to malocclusion is reported at 12.8% (Seehra et al., 2011) and this has been linked to low self-esteem and poor OHRQoL (Kilpelainen et al., 1993; DiBiase and Sandler, 2001; Seehra et al., 2011; Fabian et al., 2018). Adolescents with an increased overjet are 5.5 times more likely to report teasing (Shaw et al., 1985; Kilpelainen et al., 1993; Burden and Pine., 1995; Seehra et al., 2013; Nandakumar et al., 2019) and 14% of Irish children aged 10-14 years have reported being bullied due to their II/1M (Al-Jumah et al., 2017).

2.2.4.2 Trauma

An increased overjet and lip incompetence greatly increases the risk of incisor trauma (Rego et al., 2017; Schatz et al., 2020), with the incidence being doubled and even tripled compared to those with an average overjet (Petti, 2015; Thiruvenkatachari et al., 2015; Batista et al., 2018; Macey et al., 2020). It is often a parental reason for seeking treatment (Arraj et al., 2019; Shah et al., 2019). An overjet over 6mm is deemed to have a "great" or "very great" need for treatment according to the dental health component (DHC) of the Index of Orthodontic Treatment Need (IOTN) due to the risk of incisor trauma (Brook and Shaw, 1989). A modified version of this index is used in the RoI to determine eligibility for orthodontic treatment within the Health Service Executive (HSE) (Health Service Executive, 2007).

2.2.4.3 Functional impairments

Difficulty when eating has been reported among those with prominent incisors and some evidence shows that after correction masticatory ability improves (Zhang et al., 2006). There is also a link between mis-articulation and an increased overjet (Subtelny et al., 1972) but no evidence demonstrates speech improvement following correction (Laine, 1992; Johnson and Sandy, 1999).

2.2.4.4 Aesthetics

Characteristically there is a convex facial profile (Johnston et al., 2005), acute nasolabial angle, a decreased mentolabial angle, recessive chin, a short chin-to-neck length, retrusive lower lip and lip incompetence (Bishara et al., 1995; Bishara, 2006; Rego et al., 2017).

There is a strong association between teeth being visible at rest and poor facial appearance (O'Brien et al., 2009a). Furthermore, Nabarrette et al. (2021) reported that an increased overjet had the most negative impact on a child's perception of dental appearance when compared to other occlusal anomalies. This is a significant factor that motivates children and parents to seek orthodontic treatment (Espeland et al., 1993; Kilpelainen et al., 1993; Seehra et al., 2013).

A number of tools exist to record the perception of aesthetic treatment need such as the Dental Aesthetic Index (DAI), Index of Orthodontic Treatment need (IOTN-AC), Oral Aesthetic Subjective Impact Scale (OASIS) and the Standardized Continuum of Aesthetic Need (SCAN). In this study the aesthetic treatment need was self-assessed by the child and by the parent according to the IOTN-AC. This attempts to evaluate the psychosocial needs of a person based on dental attractiveness. It is based on a series of 10 frontal occlusal photographs, with a gradual reduction in dental aesthetics, with 1 being "most aesthetic" to 10 being "least aesthetic". The AC is a subjective measure (Brook and Shaw, 1989; Younis et al., 1997; Cooper et al., 2000) and II/1M often has a high aesthetic treatment need measured by this (Campbell et al., 2020).

2.2.4.5 Child and Parent perception of aesthetic treatment need

A systematic review reported a lack of agreement between the child and parent perception of aesthetic treatment need in children with malocclusion (Livas and Delli, 2013). In a mixed malocclusion group, Benson et al. (2010) observed that parent's perceived their child's aesthetic treatment need greater than their child's perception. Children with II/1M were 1.54 times more likely to have aesthetic concern compared to other anterior malocclusions (Nabarrette et al., 2021). Few studies, however, have assessed the child and parent perception of aesthetic treatment need in children with II/1M. Among those studies, children with a severe II/1M and their parents had a good level of agreement and rated their malocclusion in the highest aesthetic treatment need category (Espeland et al., 1993; Campbell et al., 2020). de Sousa et al. (2016) using a dichotomous scale observed that 30% of children and their parents perceived a definite aesthetic need for treatment in children with an overjet greater than 3mm. Following MTB treatment, Campbell et al. (2020) observed good agreement between the child and parent and the most commonly chosen image was '3' indicating a low aesthetic treatment need. Similarly, Khraishi et al. (2019) assessed the self-perception of aesthetic treatment need following MTB treatment

and reported 83% of children perceived a low aesthetic treatment need. A parental or pre-treatment rating was not available for comparison.

2.3 Functional appliances

This project used a MTB for growth modification treatment in children with II/1M. This section will now address functional appliances, focusing on the TBA/MTB.

2.3.1 Definition and background

Functional appliances alter the skeletal and dental relationships using forces generated by the stretching of facial muscles, fascia and periodontium (Bishara and Ziaja, 1989; Mills, 1991).

2.3.2 Original and modified Twin Block appliance

The TBA is a popular functional appliance and is considered by patients to be the most acceptable and comfortable functional appliance to wear (Illing et al., 1998). The overall success rate is 65% (Pacha, 2020) with a range of compliance rates reported between 60-95% (Illing et al., 1998; Toth and McNamara, 1999; Chintakanon et al., 2000; Harradine and Gale, 2000; Mills and McCulloch, 2000; O'Brien et al., 2003b; Banks et al., 2004; Clark, 2010a; Clark, 2010b).

The original design and mode of action is described by Dr William Clark (Clark, 1988). It was developed from the double plate of Schwartz and Pierre Robin mono-block (Clark, 1982). The TBA is a two-part removable functional appliance that works by posturing the lower jaw forward and has its most significant effect on the lower third of the face (Singh and Clark, 2003; Varlık et al., 2008). It stretches the orofacial soft tissues and muscles of mastication leading to favourable tooth movement and facial growth modification (Baccetti et al., 2000; Mills and McCullough 2000; Baysal and Uysal, 2013a; Proffit, 2006). It is prescribed to be worn full-time to take full advantage of the muscles of mastication and oro-facial soft tissues during normal daily function, such as mastication (Clark, 1988; Clark, 2019).

The TBA is a versatile appliance and various design modifications have been described to minimise the dento-alveolar effects and enhance skeletal changes (Table 1). These include no labial bow (Yaqoob et al., 2012), reduced height of the posterior bite blocks (Gill and Lee, 2005), incorporation of torqueing spurs (Harradine and Gale 2000), use of

southend clasps on the upper and lower incisors (Trenouth and Desmond, 2012) or use in conjunction with fixed appliances (Clark, 2011) or headgear (Parkin et al. 2001). Importantly, the removal of the labial bow had no deleterious dentoalveolar or skeletal effects (Yaqoob et al., 2012). That design was adopted in this research project.

Table 1 Studies that assessed the effects of modified designs of the Twin Block appliance

Author, year	Design	Conclusions
Harradine and Gale, (2000)	Compared TBA with an upper labial bow vs TBA with upper incisor torquing spurs	• Torqueing spurs substantially reduced upper incisor retroclination and extrusion with slightly more favourable lower jaw growth.
Parkin et al., (2001)	Use of TBA with headgear and torquing springs vs TBA with labial bow	• Effectively controlled vertical and sagittal maxillary growth, greater skeletal Class II correction. • Less retroclination of maxillary incisors with torquing springs.
Gill and Lee, (2005)	"mini-block" TBA: with posterior bite block of reduced vertical height, incremental advancement, upper incisor torqueing springs	• Progressive mandibular advancement not associated with more significant mandibular skeletal change.
Clark, (2011)	TBA combined with fixed appliances	• Integrated functional appliance therapy with fixed appliance by bonding pre-formed blocks directly to teeth.
Trenouth and Desmond, (2012)	Use of a Southend clasp on the upper and lower incisors	• Greater control over the axial inclinations, reduced tipping, less maxillary incisor retroclination and mandibular incisor proclination
Yaqoob et al., (2012)	TBA with and without maxillary labial bow	• Maxillary labial bow had no influence on dentoalveolar or skeletal changes, or rate of overjet reduction

2.3.3 The mode of action and the effects of the TBA/MTB in II/1M

The mode of action of the TBA or MTB in children is widely disputed and five systematic reviews have evaluated this. Those that specifically report on the TBA/MTB are summarised in Table 2. Two systematic reviews focused on dentoalveolar and skeletal effects (Cozza et al., 2006; Santamaria-Villegas et al., 2017), two included soft tissue changes (Koretsi et al., 2015; Perinetti et al., 2015) and one review only evaluated soft tissue changes (Flores-Mir and Major, 2006).

The TBA/MTB aim to improve the facial profile and dentofacial aesthetics by addressing the underlying Class II skeletal discrepancy, remove any aberrant soft tissue function to create a more favourable soft tissue relationship and correct the dento-skeletal discrepancy to achieve a Class I incisor relationship (Quintao et al., 2006). Baccetti et al. (2000) observed a considerable skeletal change with the use of a TBA in those aged 11-14 years coinciding with the pubertal growth spurt. While there are many methods to aid in the prediction of timing of the pubertal growth spurt, including the more commonly used chronological age and peak height velocity, it is difficult to accurately predict (Songra et al., 2017). More recently a strong correlation was found to exist between cervical vertebral maturation (CVM) stage III and peak mandibular growth occurring a year after (Franchi et al., 2021). O'Brien et al. (2003b) also observed a notable skeletal change which contributed to 27% of the reduction in overjet and 41% improvement in the molar relationship. Skeletal effects are through a combination of maxillary restraint as well as supplemental mandibular growth (Cozza et al., 2006; Kortesi et al., 2015; Pertinetti et al., 2015).

The dentoalveolar effects are through a combination of retroclination of the upper incisors, movement of the upper posterior teeth distally, proclination of the lower incisors as well as mesial movement of the mandibular dentition which aims to correct the Class II relationship (Proffit et al., 2018). Soft tissue changes include removal of a lip trap, improved lip competence (Quintao et al., 2006; Salloum et al., 2018) and reduced facial convexity (Morris et al., 1998).

Treatment is deemed a success by patients and their family when not only dental appearance but also facial appearance improves (Sarver and Ackerman, 2000; Sarver and Ackerman, 2003).

Table 2 Systematic reviews that assessed effects of RFA in children with II/1M; outcomes focuses on the TBA / MTB

Study, year	Studies	Outcome: Skeletal/Dental/Soft tissue
Cozza et al. (2006)	RCTs, L, P CCTs, R CCTs	• TBA produced 0.23 mm/month supplemental mandibular growth • Supplemental growth greater during pubertal growth spurt
Flores-Mir and Major, (2006)	P, CT	• No significant changes in the facial angles, nose, lower lip, upper lip, soft tissue menton
Koretsi et al. (2015)	P, RCT, N-RCT	• MTB treatment effective in the short term, main effects dentoalveolar and soft tissue rather than skeletal • Minimal stimulation of mandibular growth or restriction of maxillary growth
Perinetti et al. (2015)	RCTs, CCT's,	• No significant soft tissue changes • Overjet reduction and correction of molar relationship: distal movement of maxillary molars, mesial movement of mandibular molars, mandibular incisor proclination, • Pre-pubertal: Mandibular length 0.95 mm (0.38 – 1.51) • Post-pubertal: Mandibular length 2.91 mm (2.04 – 3.79)
Santamaria-Villegas et al. (2017)	CCTs, RCT.	• Increase in mandibular length 1.80 mm

RFA, Removable Functional Appliances P, Prospective, R, Retrospective, CT, Clinical trial, RCT, Randomised control trial, N-RCT, non-randomised control trial, CCT, Clinical controlled trial, L, Longitudinal, TBA, Twin Block appliance, MTB, Modified Twin Block, Co, Condylion, Gn, Gnathion, Po, Pogonion

2.4 Craniofacial soft tissue growth and development in II/1M

Studies in untreated II/1M assessing the growth and development of craniofacial structures observed that the facial profile increased in convexity (Carter, 1987; Chung and Wong, 2002). The main changes with soft tissue growth and development are centred around the mid- to lower third of the face (Subtelny, 1959). The most considerable change occurs with the nose, chin and lips (Subtelny, 1961; Ferrario et al., 2000).

The relationship between the soft tissues of the face change during growth. The changes in the nose and chin are largely related to the underlying skeletal development with the other structures diverging from the underlying skeleton. There is a greater rate and duration of nasal growth compared to the other facial structures, and it is this disproportionate rate of growth that accounts for the convex appearance (Subtelny, 1961).

Soft tissue growth also exhibits sexual dimorphism (Mamandras., 1984; Prahl-Andersen et al., 1995) with males having a more prominent chin due to the thickness at pogonion (Prahl-Andersen et al., 1995) and a thicker upper lip (Ferrario et al., 2000). In females, the nasolabial angle decreases to a greater extent (Prahl-Andersen et al., 1995) and the growth velocity of the lips decreases earlier than in males.

2.4.1 Soft tissue changes in children following TBA/MTB treatment

The evidence surrounding soft tissue changes and treatment with a TBA/MTB remains controversial. So far, soft tissue changes brought about by TBA/MTB treatment and those that occurred due to normal growth have not been separated due to the lack of incorporation of a control group into the study design. Several systematic reviews have assessed the soft tissue changes that occur following treatment with a TBA/MTB using two dimensional (2D) and three dimensional (3D) assessments (Table 2). (Flores-Mir and Major, 2006; Pertinetti et al., 2015; Koretsi et al., 2015). No significant soft tissue facial changes were reported. Changes of less than 2 mm at pogonion are thought not to be clinically significant (Cozza et al., 2006; Salloum et al., 2018).

2.4.1.1 Soft tissue changes with 2D assessment

Broadbent (1931) used both lateral and antero-posterior cephalometry to record the 3D nature of the cranium but these are only 2D representations with inherent limitations so a real 3D image cannot be produced (Moyers and Bookstein, 1979; Bourne et al, 2001; McIntyre and Mossey, 2003; Hajeer et al., 2004; Cho, 2009). Studies using 2D

cephalometry assessment in II/1M before and after TBA/MTB treatment have observed a favourable facial soft tissue relationship following treatment, with soft tissue pogonion advancing and a reduction in facial convexity (Singh, 2002; Singh and Clark, 2003; Quintao et al., 2006; Varlık et al., 2008; Baysal and Uysal, 2013b).

2.4.1.2 Soft tissue changes with 3D assessment

Only five studies, using 3D techniques, have assessed the soft tissue changes in II/1M following TBA/MTB treatment (Table 3). These have indicated that TBA/MTB treatment significantly improved the soft tissue facial morphology primarily with advancements in soft tissue pogonion of 3-7mm (Morris et al., 1998; McDonagh et al., 2001; Sharma and Lee; 2005; Salloum et al, 2018, Yıldırım et al., 2021). Only Morris et al. (1998) had an untreated control group as a comparison and no significant difference was observed in that group over the observation period.

2.4.2 Soft tissue changes with 4D assessment

More recently, 4D technology has been used to document facial movement dynamics and variation in facial expression in children with II/1M following MTB treatment compared to children with II/1M awaiting treatment. This demonstrated that facial expression normalised following MTB treatment and overjet reduction correlated with a more significant reduction in the distance between subnasale to lower lip during mouth opening (Stergiopulos et al., 2019).

Table 3 Studies assessing 3D soft tissue changes following TBA/MTB treatment

Reference	3D technique	Design	Cohort	Conclusion (TBA only)
Morris et al. (1998)	3D laser scanning	P, CT	TBA 6M, 16F Bionator 9M, 9F, Bass 7M, 6F Control group 13M, 7F 8-15 years 9 months	• Upper lip position remained stable • Increase in lower lip protrusion, lower lip length, LAFH, TAFH • Labiomental fold reduced by 2.1 (SD 4.7) mm • Ls to E line reduced by 1.6 (SD 2.5) mm • No significant changes in untreated control group
McDonagh et al. (2001)	3D Optical surface scanning	P, O.	TBA 7M, 5F; Bass 6M, 11F, TBA + Hg,6M 7F 10-14 years 10 months	• Forward movement of the chin point by 1-3 mm • Increase in LAFH of 5-7 mm
Sharma and Lee (2005)	3D Optical laser scanning	P, CT	TBA 35 M, F, mini-block 35M, F 10-14 years 12 months	• Soft tissue Po advanced by a median of 4.0 mm, • Soft tissue anterior face height increased by a median of 4.4mm
Salloum et al. (2018)	3D stereophotogrammetry	P, O	MTB 29M, 18F, 11-14 years 9 (SD 3.8) months	• Soft tissue Po advanced 4.12 (SD 3.03) mm F, 4.13 (SD 2.13) mm M • No correlation between soft tissue changes and overjet reduction
Yıldırım et al. (2021)	CBCT	R	TBA 16 M, 14 F 11-14 years 7.4 months	• Lower lip advancement: T_0 83.24 (SD 5.89) T_1 85.31 (SD 6.31); Po advancement: T_0 74.99 (SD 6.22) T_1 77.13 (SD 7.31)

P, prospective, O, observational, R, retrospective CT, clinical trial, 3D, three dimensional, FA, functional appliance, MTB, modified twin block appliance, TBA, twin block appliance, LAFH: lower anterior face height; TAFH: total anterior face height; Hg, Headgear, F, female, M, male, Li, Labiale Inferius, S, sella, Ls, labiale superiorus, E line-Rickett E- line, Po-pogonion, Gn-gnathion

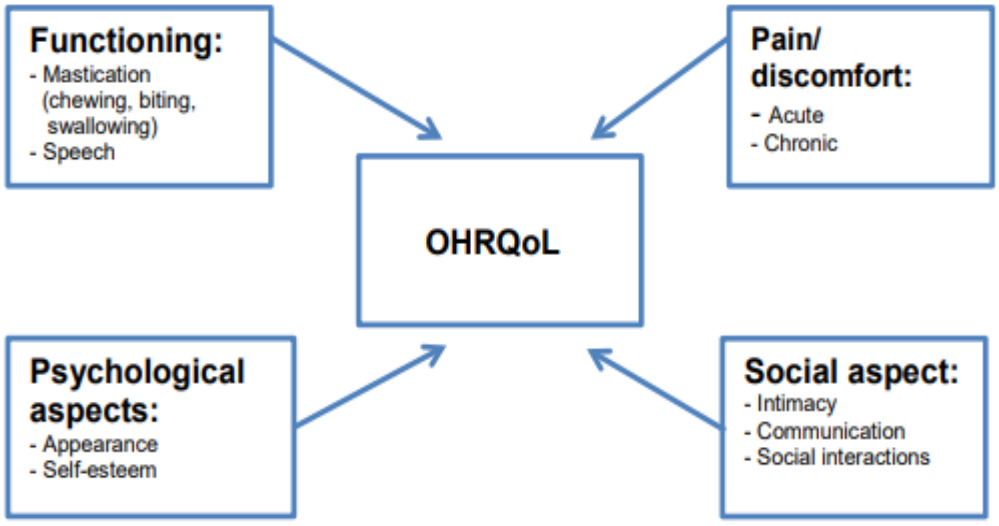
2.5 OHRQoL

2.5.1 Definition and background

Oral health has recently been defined as multifaceted and includes not only the absence of disease and pain but also the ability to speak, smile, convey a range of emotions through facial expression with confidence and this is a fundamental component of overall health including physical and mental wellbeing (Glick et al., 2016). Malocclusion has been associated with poor OHRQoL (Feu et al., 2013). Increasingly patient perspectives are being accounted for among orthodontic studies (Tsichlaki et al., 2018) and it is necessary to measure these before and after orthodontic treatment to provide an understanding of what may be achieved (Tsichlaki and O'Brien., 2014).

OHRQoL consists of four domains: oral symptoms (OS), functional limitations (FL), emotional well-being (EWB) and social well-being (SWB) (Figure 1).

Figure 1 Four Domains of OHRQoL



2.5.2 Child OHRQoL

A single standardised questionnaire to assess OHRQoL in children is not suitable as there are developmental differences from the ages of 6-14 years (Jokovic et al., 2002; McGrath et al., 2004). OHRQoL questionnaires are used to gain an insight into the perspectives of children before, during and after orthodontic treatment to assess how malocclusion impacts their life and whether orthodontic treatment has a positive or negative effect (Benson et al., 2010; Zaror et al., 2019). Sun et al. (2018) reported deterioration in

OHRQoL from 12 to 15 years, with this age group being more affected by malocclusion than older children. De Baets et al. (2012) observed that OHRQoL was better when treatment need is low; and that those with a more severe malocclusion had a poorer OHRQoL.

2.5.3 Child Perception Questionnaire (CPQ $_{11\text{-}14}$)

2.5.3.1 Development and background

CPQ$_{11\text{-}14}$ consists of 37 items organised into four health domains: OS, FL, EWB and SWB. It exists in short form to facilitate use clinically and for research (Jokovic et al., 2002; Jokovic et al., 2006). It is a valid and reproducible tool, specific for children aged between 11-14 years (Jokovic et al., 2002; Marshman et al., 2005; Jokovic, 2006; Kadkhoda. 2011; Ferrando-Magraner et al., 2019; Stamm et al., 2020). It is recommended to use CPQ$_{11\text{-}14}$ with the P-CPQ (Zaror et al., 2019) as the latter assessment provides useful information that complements the CPQ report (Jokovic et al., 2003a; Barbosa and Gaviao, 2008).

2.5.4 Parental-Caregiver Perception Questionnaire (P- CPQ)

2.5.4.1 Development and background

The P-CPQ is based on a previous model described by Guyatt et al. (1986). It mirrors the CPQ$_{11\text{-}14}$ questionnaire and is reliable and valid (Jokovic et al., 2003b). It consists of 31 items divided into four health domains: OS, FL, EWB and SWB (Jokovic et al., 2003b). It also includes the family impact scale which consists of 14 items and gives an insight on how the malocclusion impacts the quality of life (QoL) of the family (Locker et al., 2002).

2.5.5 OHRQoL among children with II/1M before and after treatment

There seems to be unequivocal evidence from systematic reviews that children with malocclusion (Table 4) and more specifically with II/1M (Table 5) have a poorer OHRQoL compared to those with no malocclusion. Kragt et al. (2016) reported that children with malocclusion were 1.74 times more likely to have a negative OHRQoL compared to those with no malocclusion; they also found that OHRQoL was affected by age, with children aged over 11 years more likely to be impacted.

An increased overjet appears to have the greatest impact on a child's OHRQoL (Liu et al., 2009; Dimberg et al., 2015; Kragt et al., 2016; Sun et al., 2018; De Stefani et al., 2019) particularly in the EWB and SWB domains (Fabian et al., 2018; De Stefani et al., 2019). It also has a deleterious impact on family QoL compared to no malocclusion (Johal et al., 2007). Following treatment of II/1M with TBA (O'Brien et al., 2003a) or with MTB (Alzoubi et al., 2017), the overall OHRQoL of the child improved as perceived by the child and their parent especially in the EWB domain (Khraishi et al., 2019). The most recent systematic review, Alrashed and Alquerban, (2021), concluded that those with severe malocclusion might have the worst levels of OHRQoL and these effects are influenced by age, culture and environment.

2.5.6 Level of agreement between child and parental perception of their child's OHRQoL

Among children with malocclusion, there are conflicting findings regarding the level of agreement between child and parental perception of their child's OHRQoL. In mixed malocclusion samples, good agreement has been identified between FL and OS domains (Zhang et al., 2007; Benson et al., 2010; Abreu et al., 2015) but poor agreement exists regarding EWB and SWB domains (Eiser and Morse, 2001; Zhang, 2007; Barbosa & Gaviao, 2008; Benson, 2010). It is commonly reported, however, that parents rate their child's overall OHRQoL poorer than the child, especially regarding EWB, SWB and OS domains (Jokovic et al., 2004; Zhang et al., 2007; Barbosa and Gaviao, 2008; Benson et al., 2010; Al-Jumah et al., 2017; Khraishi et al., 2019).

With regard to II/1M, CPQ and P-CPQ scores have been compared in an Irish cohort of children before and after MTB treatment (Al-Jumah et al., 2017). Before MTB treatment, there was a good level of agreement between the parent and child in the OS and FL domains with the overall OHRQoL, EWB and SWB being over-emphasised by the parent. Following MTB treatment, there was a better agreement in all aspects of the child's OHRQoL with both reporting a great improvement apart from EWB ($p=0.026$) (Al-Jumah et al., 2017).

Table 4 Systematic reviews that assess the OHRQoL in children with a malocclusion

Study, year	Included studies (n)	Level of Evidence	Conclusion and Suggestions
Liu et al. (2009)	23; CS, L	Moderate to high	• Modest but strong association between malocclusion and orthodontic treatment need with OHRQoL. • Need for appropriate assessment methods.
Dimberg et al. (2015)	6; CS	Moderate to high	• Anterior malocclusion negative impact on OHRQOL, especially EWB and SWB • Strong correlation between increased treatment need and poor OHRQoL
Kragt et al. (2016)	40; CS	Low to high	• Inverse association of malocclusion with OHRQOL • 1.74 times more likely to have a negative OHRQoL when malocclusion present • OHRQoL affected by age, >11 years more impacted, >14 years most impacted
Sun et al. (2018)	22; CS, P, C	Low to moderate	• Children with malocclusion could have oral functional limitations • Severe malocclusion could cause oral symptoms and poor EWB
Macey et al. (2020)	87; RCT, P, C, CS	Low quality	• Absence of evidence on effects of malocclusion and orthodontic treatment on OHRQoL
Alrashed and Alqerban (2021)	11; CS	Very low to moderate	• Severe levels of malocclusion might have worst levels of OHRQoL • Effects of malocclusion on OHRQoL influenced by age, culture and environment

N, number, CS, Cross-sectional, L, Longitudinal, RCT, Randomised Controlled Trial, C, Cohort, P, prospective, OHRQoL, Oral Health Related Quality of life, EWB, emotional well-being, SWB, social well-being

Table 5 Studies that assessed child with/without parent perception of child's OHRQoL in II/1M before and after TBA/MTB treatment

Study, year	Design, Cohort	Measurement	Conclusion
Untreated only			
Johal et al. (2007)	P, CS, UK. 49 M, 41 F (13-15 years) and a parent, II/1M, spacing, no malocclusion	CPQ 11-14, P-CPC	• II/1M and spaced dentition harm children and family OHRQoL
Seehra et al. (2011a)	P, CS, UK 201 M, 133 F (10-14 years) II/1, Class I, Class II/2, Class III M	CPQ 11-14	• II/1M and increased overbite associated with poor OHRQoL
Fabian et al. (2018)	P, C, Germany: 748 subjects (9.5 -15.5 years) II/1M, Deep bite	CPQ 11-14	• II/1M associated with poor OHRQoL especially EWB and SWB
Before and after treatment			
Al-Jumah et al. (2017)	P, C, RoI 32 M, 26 F (11-14 years) and a parent, II/1M	CPQ 11-14 (P-CPQ)	• Children and parents reported poor OHRQoL before MTB • Good level of agreement between child and parent perception of child OHRQoL in overall OHRQoL, FL&OS • MTB had a positive impact on children's OHRQoL
Khraishi et al. (2019)	P, C, RoI 27 M, 19 F (11-14 years) and a parent, II/1M	CPQ 11-14 (P-CPQ)	• Improvement in OHRQoL following MTB treatment • Moderate level of agreement between child and parent
Alzoubi et al. (2017)	P, RCT, Malta 20 M, 28F (11-14 years) II/1M	OHIP-14	• OHRQoL low before treatment • TBA treatment significantly improved OHRQoL

P, Prospective, CS, Cross-sectional study, C, Cohort, RCT, Randomised Clinical Trial, II/1M, Class II division 1 malocclusion, Class I, Class I malocclusion, Class II/2 M, Class II division 2 malocclusion, Class III M, Class III malocclusion, CPQ, child perception questionnaire CPQ, parental-child perception questionnaire, RoI, Republic of Ireland, EWB, emotional well-being, SWB, social well-being, OS, oral symptoms, FL, functional limitations

2.6 Self-Esteem

2.6.1 Definition and background

Self-esteem is a concept that relates to a person's feelings of self-worth (Rosenberg et al., 1995). It's development commences at an early age (Stein et al., 1998) and is affected by the person comparing themselves to their peers and by people's reactions towards them (Rosenberg et al., 1995). Adolescence is a period of development with multi-factorial influences on self-esteem. This leads children to make assumptions on their level of competence and how they fit in with society (Bernabe et al., 2008). A person's self-esteem may influence their perception of certain malocclusion traits (Agou et al., 2008). The impact dental appearance has on self-esteem varies between gender, social status, ethnicities and age, with advancing age leading to more self-awareness of one's image (Christopherson et al., 2009). Avondroodt et al. (2020) observed that self-esteem functioned as a stable construct during orthodontic treatment, with no change being observed before, during or after treatment.

It is necessary to measure both OHRQoL and self-esteem to be aware of the full impact malocclusion and orthodontic treatment have on psycho-social wellbeing (Benson et al., 2015). The relationship between self-esteem, OHRQoL and malocclusion have not been established with fluctuating findings in the literature (Dann et al., 1995; Onyeaso., 2003; Marques et al., 2005; Agou et al., 2008; Agou et al., 2011; Locker, 2007; Seehra et al., 2011; De Baets et al., 2012; Seehra et al., 2013; Benson et al., 2015).

2.6.2 Child Health Questionnaire short from (CHQ-CF45)

2.6.2.1 Development and background

The CHQ is recognised worldwide as a health-related quality of life instrument to evaluate children's self-esteem (Landgraf et al., 1996; Jokovic et al., 2002; Raat et al., 2005; O'Brien et al., 2006). In 2015, the short form of the CHQ questionnaire (CHQ-CF45) was developed which is valid and reliable in a Caucasian population (Landgraf et al., 2018). It measures 14 unique physical and psychosocial concepts grouped as follows: satisfaction with school and athletic ability; appearance; ability to get along with others and the family; and life overall (Raat et al., 2007).

2.6.3 Self-esteem of children with II/1M before and after treatment

Some studies (Table 6) have reported self-esteem to be poor in children with untreated II/1M (O'Brien et al., 2003a; O'Brien et al., 2009; Taibah and Al-Hummayani, 2017) with associated bullying affecting their self-esteem (Seehra et al., 2013a). In contrast, Dann et al., (1995) observed a high self-esteem in North American children with untreated II/1M which remained unchanged following functional appliance treatment. When TBA treatment was commenced early in a UK sample, self-esteem improved compared to an untreated control group (O'Brien et al. 2003a). This difference disappeared after the untreated control group had completed comprehensive orthodontic treatment, demonstrating that psychosocial benefits are equally effective irrespective of when treatment is provided (O'Brien et al., 2009b).

Table 6 Studies that assessed self-esteem among children with II/1M before and after treatment

Study, year	Time point	Design, Cohort	Measurement	Conclusion
Dann et al. (1995)	T1, T2	P, CS, L, MC, UK, 104 subjects (7-15 years) II/1M and 104 control	Piers-Harris	• II/1M not associated with low self-esteem • No change in self-esteem following functional appliance treatment
O'Brien et al. (2003a)	T1, T2	P, RCT, MC, UK, 62 F & 48 M MTB;55 F & 50 M controls (8-10 years) II/1M	Piers-Harris	• II/1M associated with low self-esteem • Self-esteem improved following TBA treatment
O'Brien et al. (2009b)	T1, T2	P, RCT, MC, UK, 54 (9.7 years) II/1M 73 (12. 1 years) II/1M	Piers-Harris	• II/1M associated with low self-esteem • Improvement in self-esteem in both groups following TBA treatment • No difference between both groups in self-esteem following comprehensive treatment
Seehra et al. (2013)	T1, T2	P, CS, UK, M 13, F 14 (11.2-13.8 years) 70% II/1M	Harter's Self Perception Profile	• No difference between the pre- and post-treatment scores
Taibah and Al-Hummayani (2017)	T1 only	P, CS, D, Saudi Arabian; M 328, F 558 (12-19 years) II/1M, crowding, spacing	Self-esteem measurement scale	• Overjet, spacing and crowding associated with the highest percentages of lower self-esteem.

P, prospective, L, longitudinal, CS, cross-sectional, MC, multicentre, RCT, randomised control trial, D, Descriptive, PWB, psychological well-being ,HG, headgear, FA, functional appliance, T1, pre-treatment, T2, post-treatment/ recall, Piers-Harris, Piers-Harris self-concept scale

2.6.4 Relationship between self-esteem, OHRQoL and self-perception of aesthetic treatment need

The relationship between self-esteem, OHRQoL and self-perception of aesthetic treatment need in those with malocclusion is complex and has not been defined (Table 7). Some have reported that a person's self-esteem influences their OHRQoL (Giddon, 1995; Benson et al., 2015). It has been observed that children with low self-esteem had poorer OHRQoL due to their malocclusion even when it was considered mild (Owens et al., 2006) whereas those with a severe malocclusion but a high self-esteem had a good OHRQoL (Onyeaso., 2003; Marques et al., 2005; Agou et al., 2008; Agou et al., 2011; De Baets et al., 2012). It has been suggested that a high self-esteem provides a psychological resource that protects a person from any negative effects that may incur from a malocclusion (Locker, 2007; Agou et al., 2011). Benson et al. (2015) demonstrated a cross-sectional and longitudinal association between self-esteem and OHRQoL, those with poor self-esteem had poor OHRQoL and vice versa.

A high self-perception of aesthetic treatment need has been linked to low self-esteem (Giddon, 1995; Avontroodt et al., 2020). Benson et al., (2015) observed in a mixed malocclusion cohort that a child's OHRQoL was related to the self-perception of aesthetic treatment need when assessed cross-sectionally but this relationship was not maintained longitudinally. Only two studies have assessed the interaction between self-perception of aesthetic treatment need according to IOTN-AC and both self-esteem and OHRQoL. Agou et al. (2008) found that a high self-perception of aesthetic treatment need and low self-esteem negatively impacted the child's overall OHRQoL especially in terms of EWB and SWB domains. On the other hand, Dos Santos et al. (2017) observed that a child's OHRQoL and self-perception of aesthetic treatment need were not related, but there was a significant relationship between self-esteem and self-perception of aesthetic treatment need. Those with a low self-esteem had a higher perceived aesthetic treatment need even when the malocclusion was mild.

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Table 7 Studies that assessed the relationship between Self-esteem and OHRQoL

Study	Design, Cohort	Measurements	Conclusions
Agou et al. (2008)	P, CSS 102 F, 97 M (11 to 14 years) mixed malocclusion	SE subscale-CHQ-CF87, CPQ $_{11-14}$, DAI	• 17% of variance in OHRQOL attributed to self-esteem; effects EWB SWB. • Low self-esteem had poorer OHRQoL compared to those with high self-esteem with the same malocclusion. • Self-esteem is salient determinant of OHRQoL in children seeking treatment.
Agou et al. (2011)	L, 74 treatment group, 44 untreated control, (11-14 years) Mixed malocclusion,	CPQ $_{11-14}$ PWB-c	• Children with high PWB report better OHRQOL regardless of orthodontic treatment. • Children with low PWB without treatment had worse OHRQOL • PWB contributed significantly to the variance in OHRQoL (26%).
Seehra et al. (2011)	P, CS, UK 201 M, 133 F (10-14 years) II/1, Class I, Class II/2, Class III M	CPQ$_{11-14}$ Harter's questionnaire	• II/1M, an increased overjet & increased overbite associated with bullying, poor self-esteem and poor OHRQoL • Not possible to make a direct relationship between OHRQoL and self-esteem
De Baets et al. (2012)	P, CS 113 M, 110 F (11-16 years) Mixed malocclusion	CPQ $_{11-14}$ Harter's Self-Perception Profile	• Higher the self-esteem had better the OHRQoL • OHRQoL, especially SWB & EWB, better if treatment need is lower • No evidence SE moderates relationship between OHRQoL and treatment need
Benson et al. (2015)	P, C, T1= 122M, 252F; T2= 89M, 180F; (11-12 years;) Mixed malocclusion	CPQ$_{11-14}$ CHQ-SF87	• Significant negative association between self-esteem and OHRQoL; those with low self-esteem had poorer OHRQoL

P, prospective, CSS, cross-sectional study, CPQ, child perception questionnaire, SE subscale-CHQ-CF87, self-esteem subscale of child health questionnaire-child self-report, DAI, dental aesthetic index, QoL , quality of life, OHRQoL, oral health related quality of life, PWB-c, psychological wellbeing-child, EWB, emotional wellbeing, SWB, social wellbeing

2.7 3D Facial imaging

With advancements in 3D technology there are many valid, reliable and simple techniques for assessing the soft tissue facial changes that occur naturally and with orthodontic treatment (Hajeer et al., 2004). The most commonly used procedures and their limitations are given in Table 8.

2.7.1 Stereophotogrammetry 3D imaging technique

Stereophotogrammetry is defined as "the science or art of obtaining reliable measurements" through photographs (American Society of Photogrammetry, 1966). Thalmann-Degan first used this technique in 1944 to record changes in the facial structure that occurred following orthodontic treatment (Burke and Beard, 1967). It can accurately reproduce the surface geometry of the face, and can map realistic colour and texture to produce a lifelike image. Sophisticated algorithms can produce an image to appear 3D on a 2D monitor. It is the most common non-invasive 3D imaging technique used in orthodontics and its use has been validated (Plooij et al., 2009; Dindaroğlu et al., 2016; Erten and Yilmaz, 2018). Facial images are captured in milliseconds and may be re-captured if required (Winder et al., 2008; Weinberg, 2019).

3D Stereophotogrammetry is the vision-based imaging system used in this project. Further details are provided in Section 5.7.

Table 8 3D imaging techniques, including vision-based, reported in the literature

Technique	Limitations
3D Cephalometry	Radiation exposure, poor soft tissue contour and definition, time-consuming procedure, difficulty locating landmarks
3D CT scanning	High radiation dosage, poor facial soft tissue resolution due to slice spacing, image distortion with intraoral metal objects
Cone Beam CT	Radiation exposure, unable to map out muscles structure and attachments, unable to produce colour and skin texture of scanned object
Stereolithography	High radiation exposure, inadequate soft tissue contour, expensive, experience required
3D Laser scanning	Slow, invasive, distortion if subject moves during process, safety concern due to eyes exposed to a laser beam, inability to capture soft tissue texture
Vision-based imaging	
3D Facial Morphometry	Time-consuming landmarking, challenging to reproduce landmarks, not possible to show appearance of natural facial soft tissues
Moire Topography	Better results on smooth contoured surfaces Changes to head position produce variations in fringe pattern
Structured Light Techniques	Image capture takes longer, unable to capture ear to ear facial model
3D Ultrasonography	Time-consuming, skillful operator needed, co-operative patients required, contact with soft tissue during data collection produces errors
3D Stereophotogrammetry	Tissue reflections, hair, eyebrow and curved surfaces such as eyes, ears and nose influence image processing, require experience for landmarking.

CHAPTER THREE

AIMS AND NULL HYPOTHESES

3 Aims and the null hypotheses

3.1 Aims

- To evaluate the impact Modified Twin Block (MTB) treatment has on oral health related quality of life (OHRQoL), self-esteem, self-perception of aesthetic treatment need and 3D soft tissue facial changes in children with Class II division 1 malocclusion (II/1M) compared to children with II/1M awaiting treatment who served as controls.
- To assess the effect MTB treatment has on family QoL and on both the parent's perception of their child's OHRQoL and aesthetic treatment need compared to controls.
- To assess the level of agreement of child OHRQoL and perception of aesthetic treatment need by child and parent between groups.

3.2 Null hypotheses

- There is no difference in OHRQoL, self-esteem, self-perception of aesthetic treatment need and 3D soft tissue facial changes in children with II/1M following MTB treatment or awaiting treatment.
- MTB treatment has no effect on family QoL or on both the parent's perception of the child's OHRQoL and aesthetic treatment need compared to controls.
- There is no difference in the level of agreement of child's OHRQoL and perception of aesthetic treatment need by child and parent between groups.

CHAPTER FOUR

PARTICIPANTS AND METHODS

4 Participants and Methods

4.1 Study Design

A prospective cohort study was carried out in the Postgraduate Orthodontic Unit at Cork University Dental School & Hospital (CUDSH), Ireland.

4.2 Sample size calculation

Using data from Johal et al., (2007), a sample size of 30 subjects per group (15 females and 15 males) was required to detect a clinically significant difference of 35% in the OHRQoL between the MTB treatment group and the untreated Control group with 80% power at $p<0.05$. Using data from Morris et al., (1998), 24 subjects per group were required to detect a clinically significant difference of 2 mm in soft tissue Pogonion between the MTB treatment group and the untreated Control group with 80% power at $p<0.05$. To allow for a dropout rate of up to 50% (Caldwell and Cook, 1999), we aimed to recruit 60 subjects per group.

4.3 Ethical approval

Ethical approval was obtained from the Clinical Research Ethics Committee of Cork Teaching Hospitals, University College Cork. (Appendix 2 and 3)

4.4 Participants

4.4.1 MTB group

From January 2019-January 2020, subjects aged 11-14 years requiring MTB treatment at the Postgraduate Orthodontic Unit, CUDSH, and a parent of each, were asked to participate. Henceforth, this group will be referred to as the MTB group.

4.4.2 Control group

From January 2019-January 2020 a convenience sample of consecutive subjects aged 11-14 years on the HSE Orthodontic treatment waiting list for MTB treatment at CUDSH and at St Finbarr's Hospital, Cork, and a parent of each, were asked to participate. All subjects were referred from HSE dental clinics. Henceforth, this group will be referred to as the Control group.

4.4.3 Parental group

A parent of each subject was asked to participate.

4.4.4 Consent

At their first appointment, each subject and their parent received verbal and written information regarding the purpose of the study and procedure involved. Informed consent was obtained after establishing that the inclusion (Table 9) and exclusion criteria (Table 10) were satisfied.

Table 9 Inclusion criteria

MTB Group	Control Group
Caucasian	Caucasian
Class II division 1 malocclusion	Class II division 1 malocclusion
Overjet > 6 mm	Overjet > 6 mm
11-14 years of age for the duration of treatment	11-14 years for the duration of observation
Eligible and motivated for MTB treatment	Patients on the HSE treatment waiting list

Table 10 Exclusion criteria

MTB Group	Control Group
Non-Caucasian	Non-Caucasian
Craniofacial anomaly or metabolic Disorder	Craniofacial anomaly or metabolic disorder
Previous orthodontic treatment	Previous orthodontic treatment
Not motivated for Twin Block Treatment	Commences orthodontic treatment prior to T2 to T2
< 11 years or > 14 years for duration treatment	<11 years or >14 years for duration of observation
Do not assent to take part	Unwilling to attend twice over ≈ 12 months

4.5 Outcomes

4.5.1 Data and time-points

For the MTB group, data were collected:

- On the day of fitting the MTB but prior to insertion (T1) and
- When a Class I incisor relationship was achieved with closure of the lateral open bites and with the appliance being worn at night only (T2).

For the Control group, data were collected:

- At baseline (T1) and
- At recall, approximately 12 months later, during which no orthodontic treatment was carried out (T2).

The following data were collected for subjects in both groups at T1 and T2 and all data were anonymized: Date at T1/T2, Gender, Date of birth, Age, Hospital number, Initial overjet, CPQ_{11-14}, CHQ-CF45, IOTN-AC and 3D facial image at rest. Each parent completed two questionnaires: P-CPQ and IOTN-AC. One researcher checked all questionnaires before the child and parent departed to ensure all items were completed correctly.

4.5.2 Treatment Protocol

The treatment protocol was standardised for all subjects. The bite registration for MTB construction was recorded using a Projet bite gauge with the mandible postured forward maximally (Orthocare (UK) Limited) (Figure 2). Where that was not possible, the postured bite was taken at 70% of the maximum protrusion and reactivation was carried out as required during treatment (Clark 2010a).

4.5.3 MTB Design

This was modified from the original design described by Clark (Figure 3) and had the following design features:

Upper appliance

- Adams' clasps on teeth 16, 14, 24, 26
- Midline expansion screw
- Acrylic baseplate

- Posterior inclined bite blocks covering molar teeth

Lower appliance

- Adams' clasps on teeth 46, 44, 34, 46
- Southend clasp on 31, 41
- Acrylic baseplate
- Posterior inclined bite blocks covering both premolars

4.5.4 Instructions regarding MTB wear and breakages

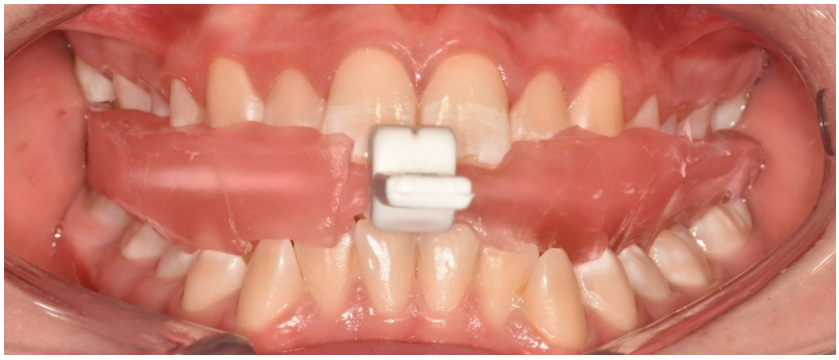
On fitting the MTB, participants received the usual written and verbal instructions adopted in the clinic. The importance of appliance wear was emphasized and participants were directed to wear the appliance full time including eating, except for contact sports, swimming, oral hygiene and appliance cleaning. When not wearing the appliance, it was advised to store it in the container provided to avoid damage. The upper midline expansion screw was turned as required for arch coordination. Clinic contact details were also provided for emergency care. For minor breakages, the MTB was repaired but for major breakages, a new MTB was made and returned to the patient within 7 days

Figure 2 Images of postured wax bite registration with Projet insitu

(a) Right buccal segment



(b) Edge to edge bite registration anterior

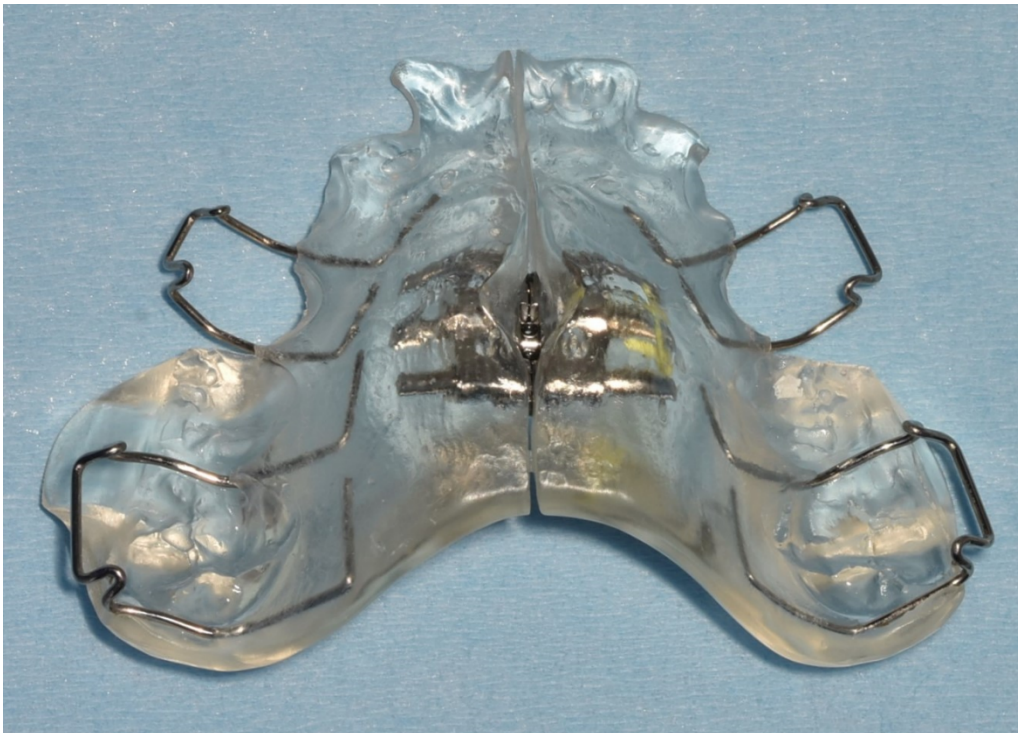


(c) Left buccal segment



Figure 3 Images of MTB design

(a) Upper appliance



(b) Lower appliance



4.6 Questionnaires

4.6.1 CPQ $_{11-14}$ questionnaire

Each question addressed the frequency of events experienced by the participant concerning the teeth, jaw and mouth over the preceding three months; the score ranges from never = 0, once or twice = 1, sometimes = 2, often = 3 and every day or almost every day = 4. The response summary score ranges from 0 to 64. A low score indicates an absence of problems and a subjective good OHRQoL. It also includes a global rating of the overall impact of oral health on the child's QoL, rated on a five-point scale from excellent to poor.

4.6.2 P-CPQ questionnaire

Each question addressed the frequency of events experienced by their child across the four domains. It also included the family impact scale assessed with 14 items. The scoring system matches that of the CPQ$_{11-14}$ questionnaire.

4.6.3 CHQ-CF45 questionnaire

Each question had 5 possible outcomes and was coded 1 = very badly to 5 = very good. Scoring was carried out according to the CHQ manual. Raw scores were generated by calculating the mean and then transformed to standardized scores from 0 to 100. Higher scores indicate higher self-esteem.

4.6.4 IOTN-AC

The child was asked to choose a photograph from the 10 images that resembled the appearance or level of attractiveness of their front teeth. The parent was also asked to choose a photograph that they thought resembled that of their child's dental appearance or level of attractiveness. The treatment need was classified as scores of 1-4 "no/low need", 5-7 "moderate/borderline" and 8-10 "definite" need (Richmond et al., 1994).

4.7 3D Facial images and analyses

4.7.1 Equipment and facility

The Di3D system was used to capture high resolution 3D surface images of the human face in a designated room (Figure 4).

Figure 4 3D imaging room



This system has the following components (Figure 5).

- Cameras: 4 Canon 1000D digital cameras initially and upgraded to a 6 Canon 1000D digital cameras
- Flash: 2 Esprit 500DX
- Computer: Dell Optiplex 980
- Supporting stand in which the two or three pairs of cameras are mounted 85cm apart and converging at 97 cm from the subject imaged.

Figure 5 The hardware components of the Di3D stereophotogrammetry system
(a) the flash; (b) the supporting stand and (c) the cameras

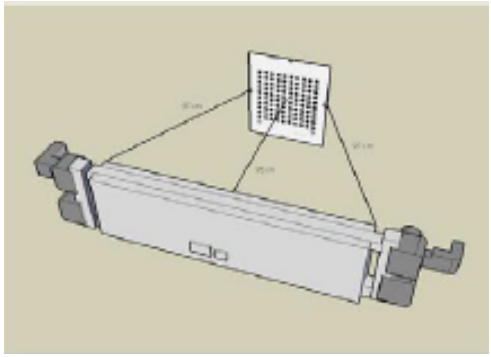


(a) (b) (c)

4.7.2 Calibration

Cameras were calibrated to ensure consistency and accuracy of all the images captured; six images were captured to accurately orient the cameras to each other. When the target object is of known dimension, the calibration process is done automatically. A matt white card with matt black spheres, located at known dimensions and distances was used for calibration (Figure 6). As the cameras were held on a rigid supporting stand, their orientation was not changed. The calibration process was done at the beginning of every week. Recalibration was only required if the camera orientation had been changed or settings such as focus and aperture had been adjusted.

Figure 6 Illustration of the matt placement to a pre-set distance from the camera configuration for accurate calibration



4.7.3 Scanning protocol

All 3D images were taken by one of two experienced operators. Subjects were familiarised with the scanning procedure. Images were taken with subjects seated in the centre of the Di3D system camera structure with all makeup removed, hair tied back with a hairband when necessary, the head in natural head position and teeth in occlusion. Subjects were asked to look straight ahead into their own eyes in a mirror and to remain still during image capture. Subjects followed the cue described by Zachrisson (1998) for "rest" position:

- Say Mississippi
- Swallow and say "N"

Rest position is the most reproducible facial expression (Johnston et al., 2003). Images were taken in this position at T1 and T2. Images were repeated 15 minutes after the initial image to check reproducibility.

4.7.4 Software

Images were captured and built using Di4DSnap and then landmarked in Di3DView.

4.7.5 Landmarks

A single trained and calibrated operator landmarked all the 3D images. To assess for intra-observer reproducibility a 10% of images were randomly selected and re-landmarked one month after the initial landmarking. The facial landmarks used were the ones suggested by Farkas (1994) and Sawyer et al. (2009b). All points are shown in Figure 7 and their definitions are given in Table 11.

Figure 7 3D image of a patient in this study showing the landmarks used

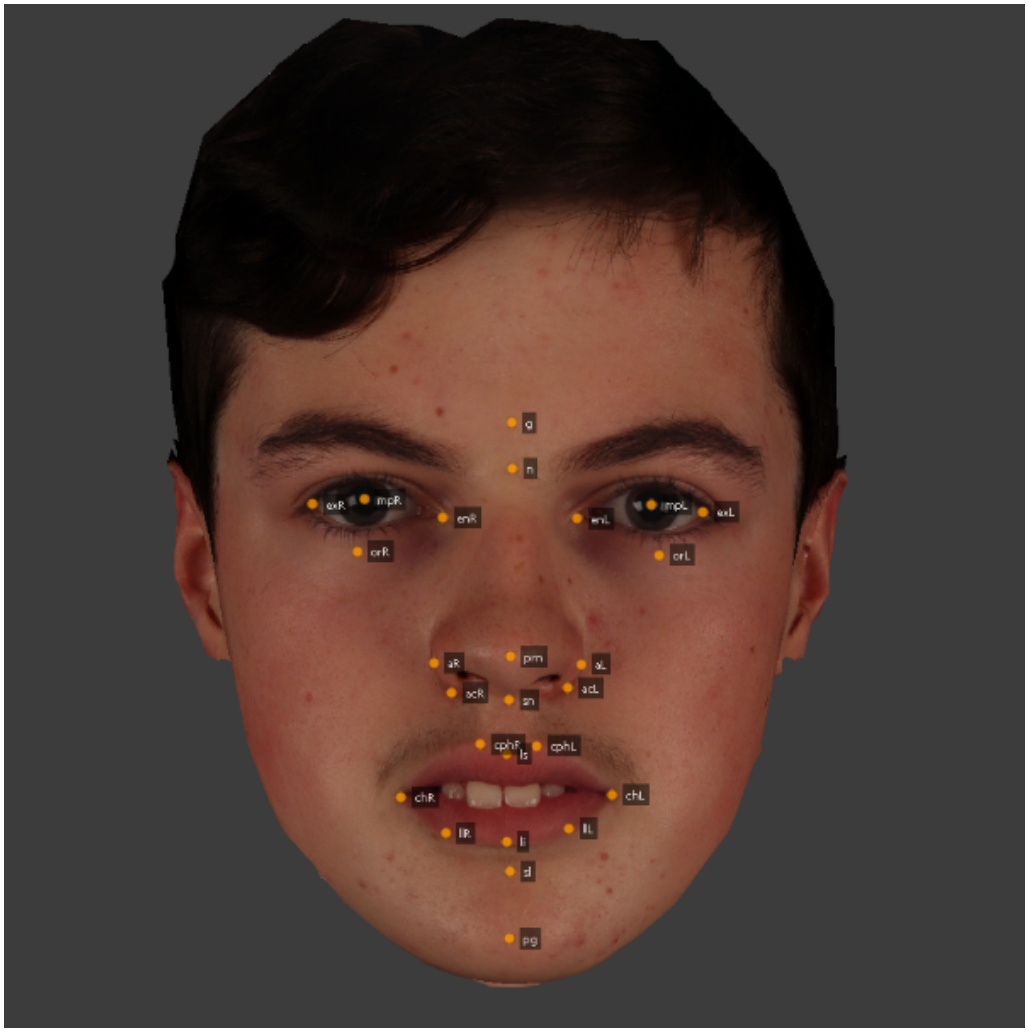


Table 11 Soft tissue facial landmarks

Glabella (g)	the most prominent midline point between eyebrows
Nasion (n)	the point in the midline of both nasal root and nasofrontal suture.
Right exocanthion (exR)	the outermost point on the commissure of the eye fissure on the right.
Mid pupil right (mpR)	the centre point of the right pupil.
Orbitale right (oR)	the lowest point on the lower margin of the right orbit.
Endocanthion right (enR)	the innermost point on the commissure of the eye fissure on the right.
Endocanthion left (enL)	the innermost point on the commissure of the eye fissure on the left.
Mid pupil left (mpL)	the centre point of the left pupil.
Orbitale left: (oL)	the lowest point on the lower margin of the left orbit.
Exocanthion left (exL)	the outermost point on the commissure of the eye fissure on the left.
Pronasale (prn)	the most protruded point of the apex nasi identified in the lateral view of the rest position of the head.
Subnasale (sn)	the midpoint of the angle where the lower nasal septum and the lips meet (the base of Columella).
Alar curvature right (acR)	the most lateral point in the curved baseline of the right ala.
Alar curvature left (acL)	the most lateral point in the curved baseline of the left ala.
Alare right (aR)	the marking level at the midportion of the right alae.
Alare left (aL)	the marking level at the midportion of the left alae.
Cheilion right (chR):	the outermost point of the right lip commissure.
Christa philltri right (cphR):	point on the right elevated margin of the philtrum just above the vermillion line.
Labiale superius (Ls)	the midpoint on the upper vermilion border.
Christa philltri left (cphL)	point on the left elevated margin of the philtrum just above the vermillion line.
Cheilion left (chL)	the outermost point of the left lip commissure.
Labiale inferius (li)	the lower border of the lower lip.
Lower lip right (llR)	located midway between cheilion right and labiale inferius.
Lower lip left (llL)	located midway between cheilion left and labiale inferius.
Sublabiale (sl)	the lower border of the lower lip or the upper border of the chin.

4.8 Statistical analyses

4.8.1 Demographics

Comparisons of patient demographics between groups and between completers and non-completers were made using analysis of variance (ANOVA) for numeric variables and the Chi-square test for categorical variables.

4.8.2 CPQ, P-CPQ, CHQ-CF45

Comparisons were made between completers and non-completers in CPQ, P-CPQ, CHQ-CF45 at T1 using ANOVA with group and gender as factors and age, overjet and scores as covariates. Within the MTB and Control groups, comparisons were made between T1 and T2 using paired t-tests. Comparisons were made between CPQ and P-CPQ at T1 and T2 between MTB and Control groups using ANOVA with group and gender as factors and age, overjet and scores at T1 as covariates.

4.8.3 Perception of Aesthetic Treatment need according to IOTN-AC

Within the MTB and Control groups the IOTN-AC was compared between T1 and T2 for children and parents separately, and between children and parents, using Bowker's symmetry test. The perception of aesthetic treatment need was compared between MTB groups at T2 using Fisher's Exact Test.

4.8.4 3D soft tissue facial landmark change

The 3D soft tissue facial landmark change between T1 and T2 were compared between MTB and Control groups using ANOVA with MTB group and gender as factors and age, time and overjet at T1 as covariates.

4.8.5 Associations between CPQ, CHQ-CF45, IOTN-AC and 3D soft tissue facial change

Bivariate analysis using ANOVA was used to test for associations between CPQ, CHQ-CF45, IOTN-AC and 3D soft tissue facial change.
All variables were summarised using descriptive statistics and/or frequency distributions. Data transformations were applied in ANOVA where required to normalise the residuals. The level of significance used was 5% and all statistical analyses were performed in SAS® (Version 9.4).

CHAPTER FIVE

RESULTS

5 Results

5.1 Participants

5.1.1 MTB Group

From January 2019 – January 2020, 60 subjects (31 males; 29 females) and their parent agreed to participate in this study. The non-compliance rate was 30% (11 males; 7 females). The final sample comprised of 42 subjects (20 males; 22 females) and their parent. The average duration of treatment was 8.5 months with a range of 5-12 months.

In the MTB group, 18 subjects (30%) failed to complete treatment due to unwillingness to wear the appliance (14 subjects), broken appliance (one subject), change of treatment plan (two subjects) and treatment completed elsewhere (one subject).

At T2, questionnaire data were available for 42 subjects and their parent; 3D images were available for 37 subjects (18 males; 19 females). The final images for five subjects were irretrievable due to a software upgrade.

5.1.2 Control group

Forty-seven subjects (22 males; 25 females) and their parent agreed to participate. Subjects were recalled on average at 11 months, with a range from 9-13 months. The dropout rate was 26% (7 males; 5 females). In the Control group, 12 subjects were not available at recall due to failure to attend for their follow-up appointment (11 subjects) and treatment commenced elsewhere (one subject).

At T2, data were available for 35 subjects (15 males; 20 females) and their parent.

Demographics of the final sample are summarised in Table 12. An intention-to-treat (ITT) and a per protocol analyses were undertaken. As there were no differences between the results with either analyses, results for the ITT analyses are presented here.

At T1, there were no significant differences between the groups in age or gender ($p=0.1402$; $p=0.2973$ respectively) but the overjet in the MTB group was slightly greater ($p=0.0016$). At T2, there were no significant differences between the groups apart from overjet which was significantly less in the MTB group (mean 3.1 mm) versus the Control group (mean 8.7 mm) ($p=0.0001$).

Table 12 Demographics for MTB and Control groups at T1 and T2

TIME	GROUP (n)	Female (n)	Male (n)	**Age** Mean (SD) (range) in years	**Overjet** Mean (SD) (range) in mm
T1	**MTB (60)**	29	31	12.6 (1.0) (11.0 - 14.2)	10.2 (1.7) (7 - 15)
	Control (47)	26	21	12.5 (0.7) (11 – 13. 8)	9.2 (1.5) (7 – 13)
	P value	0.133		0.297	**0.0016**
T2	**MTB (42)**	22	20	13.8 (0.8) (11.11 – 14.8)	3.1 (1.3) (1– 5)
	Control (35)	20	15	13.6 (0.9) (11.11 – 14.8)	8.7 (1.8) (4.5 – 13)
	P value	0.078		0.284	**0.0001**

5.2 Outcome measures

All comparisons between the MTB and Control groups were adjusted for age, gender and overjet.

5.2.1 Impact of II/1M on QHRQoL in MTB and Control groups at T1 and T2

At T1, there was no significant difference between the MTB or Control group in the overall OHRQoL (p=0.035) or in the individual domains; OS (p=0.0249), FL (p=0.005), EWB (p=0.626), SWB (p=0.171). Following treatment, there was a significant improvement in the overall OHRQoL (p=<0.0001) and in the OS (p=0.018), EWB (p=0.003) and SWB (p=0.0002) domains. There was no significant change in FL domain (p=0.1865). In the Control group, however, there was no significant change at recall in the overall OHRQoL (p=0.841) or across the four domains (all p values >0.05) (Table 13).

Table 13 Mean (SD) CPQ Domain and overall OHRQoL scores for MTB Group and Control Groups at T1 and T2

	MTB Group		**p-value**	**Control Group**		**p-value**
Domain	T1 mean (SD)	T2 mean (SD)	T2-T1	T1 mean (SD)	T2 (mean) SD	T2-T1
OS	4.3 (1.9)	3.5 (1.9)	**0.018**	5.1 (2.2)	4.2 (3.0)	0.841
FL	2.4 (2.1)	1.9 (1.9)	0.187	3.6 (3.2)	1.3 (2.4)	0.139
EWB	5.1 (4.8)	3.4 (4.3)	**0.003**	4.5 (3.9)	3.9 (4.3)	0.371
SWB	2.4 (2.0)	1.4 (2.0)	**0.0002**	2.1 (2.3)	1.6 (2.4)	0.089
Overall	14.2 (7.2)	10.2 (7.0)	**<0.0001**	15.4 (9.0)	12.5 (10.7)	0.841
MTB T1 vs Control T1						
Domains	OS	FL	EWB	SWB	Overall	
p-value	0.091	0.052	0.554	0.542	0.650	
MTB T2 vs Control T2						
p-value	0.212	0.225	0.613	0.691	0.261	

SD, Standard deviation, OS, Oral Symptoms, FL, Functional Limitations, EWB, Emotional Well Being,

5.2.2 Self-esteem of the MTB and Control group at T1 and T2

There was no statistically significant difference between groups at T1 (p=0.188) or at T2 (p=0.375). From T1 to T2, within the groups, there was a trend for the mean self-esteem score to reduce but this was not significant (MTB group p=0.144; Control group p=0.056) (Table 14).

Table 14 Mean (SD) for overall self-esteem in MTB and Control groups at T1 and T2

Group	T1 Mean (SD)	T2 Mean (SD)	p-value (T2-T1)
MTB	77.1 (9.0)[a]	75.3 (9.3)[b]	0.144
Control	75.5 (8.6)[c]	72.5 (9.2)[d]	0.056
p-value	*(c-a)*0.188[c-a]	*(d-b)*0.375[d-b]	

SD, Standard deviation

5.2.3 Aesthetic treatment need in MTB and Control groups at T1 and T2

In the MTB group (Table 15), 42% perceived a moderate-definite aesthetic treatment need at T1 with this improving following treatment (T2=26%) (p=0.018). In the Control group (Table 16), there was no significant change in those who perceived a moderate-definite aesthetic treatment need between T1 (29%) to T2 (31%) (p=0.881). Table 17 presents the comparison at T2 between the groups; none of the children in the MTB group perceived a definite aesthetic treatment need compared to 14% in the Control group (p=0.029).

Table 15 Comparison of the self-perceived aesthetic treatment need in the MTB group at T1 vs T2

	Aesthetic Treatment Need	MTB Group T2 Low n (%)	Moderate n (%)	Definite n (%)	Total n (%)
T1	Low n (%)	19 (40%)	5 (12%)	0	24 (57%)
	Moderate n (%)	6 (14%)	2 (5%)	0	8 (19%)
	Definite n (%)	6 (14%)	4 (9%)	0	10 (24%)
	Total n (%)	31 (68%)	11 (26%)	0	42 (100%)
P-value 0.018					

Aesthetic treatment need rated by IOTN-AC: Low AC 1-4, Moderate, AC 5-7, Definite, AC 8-10

Table 16 Comparison of self-perceived aesthetic treatment need in the Control group at T1 vs T2

	Aesthetic Treatment Need	Control Group T2 Low n (%)	Moderate n (%)	Definite n (%)	Total n (%)
T1	Low n (%)	21 (60%)	2 (6%)	2 (6%)	25 (72%)
	Moderate n (%)	1 (3%)	3 (8%)	2 (6%)	6 (17%)
	Definite n (%)	2 (6%)	1 (3%)	1 (3%)	4 (11%)
	Total n (%)	24 (69%)	6 (17%)	5 (15%)	35 (100%)
P-value=0.818					

Aesthetic treatment need rated by IOTN-AC: Low, AC 1-4, Moderate, AC 5-7, Definite, AC 8-10

Table 17 Comparison of self-perceived aesthetic treatment need in MTB group with Control group at T2

Aesthetic Treatment Need	MTB n (%)	Control n (%)	Total n (%)	p-value
Low n (%)	31 (74%)	24 (69%)	55 (71%)	
Moderate n (%)	11 (26%)	6 (17%)	17 (22%)	**0.029**
Definite n (%)	0 (0%)	5 (14%)	5 (7%)	
Total n (%)	42 (100%)	35 (100%)	77 (100%)	

Aesthetic treatment need rated by IOTN-AC: Low AC 1-4, Moderate AC 5-7, Definite AC 8-10

5.2.4 Relationship between OHRQoL, self-esteem, self-perception of aesthetic treatment need in MTB and Control groups at T1 and T2

In the MTB group, there was a moderate inverse association between the overall OHRQoL and self-esteem at T1 (r = - 0.53) whereas at T2 this was not significant (r = - 0.23). In the Control group, there was a low inverse association between self-esteem and overall OHRQoL at T1 (r = -0.43) whereas at T2 there was no association (r = - 0.13). In both groups, there was no significant association between the overall OHRQoL and self-perception of aesthetic treatment need at T1 (MTB r = + 0.21; Control r = 0.36) or at T2 (MTB r = + 0.11; Control = 0.39). Similarly, in the MTB and Control groups, there was no significant association between the self-esteem and self-perception of aesthetic treatment need at T1 (r = + 0.09; r = + 0.05) or T2 (r = + 0.27; r = + 0.21) respectively.

5.3.1 Parent perception of the child's OHRQoL in MTB and Control groups at T1 and T2

At T1, parents of children in the MTB and Control groups perceived their child to have poor OHRQoL. In the MTB group, parents reported the mean overall OHRQoL score to be almost twice that reported by parents in the Control group, 46.5 compared to 25.7 (p=0.0004) respectively. Following MTB treatment, there was a significant improvement in the parent's perception of their child's overall OHRQoL (p=<0.0001) especially in relation to FL (p=<0.0001), EWB (p=0.008), and SWB (p=<0.0001) domains. In contrast, at recall in the Control group, the parent's perception of their child's overall OHRQoL did not change significantly (p=0.721) or across the four individual domains (all p values > 0.05). When comparing both parental groups at T2, the parents of the Control group had a significantly poorer rating of their child's overall OHRQoL (p=0.0017) and across all four domains (all p-values < 0.05) (Table 18).

Table 18 Mean (SD) CPQ Domain and overall OHRQoL scores for Parents of the MTB and Control Groups T1 versus T2

	MTB Group		**P-value**	**Control Group**		**P-value**
Domain	T1, mean (SD)	T2, mean (SD)	T2-T1	T1, mean (SD)	T2, mean (SD)	T2-T1
OS	8.8 (5.4)	4.0 (2.5)	<0.0001	6.1 (4.0)	5.9 (4.8)	0.841
FL	9.6 (5.5)	6.6 (7.7)	<0.0001	7.0 (59)	4.4 (4.4)	0.696
EWB	15.7 (11.9)	3.9 (4.6)	0.008	7.7 (8.8)	7.2 (9.4)	0.65
SWB	12.4 (9.2)	3.4 (3.6)	<0.0001	5.0 (6.2)	4.7 (7.8)	0.853
Overall	46.5 (28.6)	15.7 (12.1)	<0.0001	25.7 (21.9)	24.5 (27.5)	0.721
MTB Group T1 vs Control Group T1						
Domains	OS	FL	EWB	SWB	Overall OHRQoL	
p-value	**0.0107**	**0.038**	**<0.0008**	**<0.0001**	**0.0004**	
MTB Group T2 vs Control Group T2						
P-value	**0.0015**	**0.0442**	**0.0097**	**0.0024**	**0.0017**	

SD, Standard Deviation, OS, Oral Symptoms, FL, Functional Limitations, EWB, Emotional Well Being, SWB, Social Well Being

5.3.2 Family QoL in MTB and Control groups at T1 and T2

At T1, the mean family QoL score in the MTB group (13.6) was significantly poorer than the mean family QoL in the Control group (6.9) (p=0.0008). Following MTB treatment, the family QoL improved substantially (p=0.0001). From T1 to T2, the mean QoL score in the Control group did not change significantly, 6.9 to 5.2 respectively. This was much poorer than the mean family QoL in the MTB group at T2 (2.4) (p=0.0024) (Table 19)

Table 19 Family QoL in the MTB and Control groups

Group	T1 Mean (SD)	T2 Mean (SD)	P Value (T2-T1)
MTB	13.6 (9.9)[a]	2.4 (2.3)	**0.0001**
Control	6.9 (7.5)[c]	5.2 (8.3)[d]	0.221
P-value	**0.0008**[c-a]	**0.0024** [d-b]	

SD, Standard Deviation

5.3.3 Parent perception of their child's aesthetic treatment need in MTB and Control groups at T1-T2

In the parents of the MTB group, 62% perceived a moderate to high aesthetic treatment need at T1 and this reduced to 12% at T2 (p=<0.0001) (Table 20). At T1, 40% of parents of the Control group perceived a moderate to high aesthetic treatment need and this increased to 57% at T2 (p=0.202) (Table 21).

Table 20 Parent perception of aesthetic treatment need in the MTB group at T1 and T2

	Perception Of Aesthetic Treatment Need	MTB Group T2 Low n (%)	Moderate n (%)	Definite n (%)	Total n(%)
T1	Low n (%)	16 (38%)	0	0	16 (38%)
	Moderate n (%)	15 (36%)	1 (2%)	0	16 (38%)
	Definite n (%)	6 (14%)	2 (5%)	2 (5%)	10 (24%)
	Total	37 (88%)	3 (7%)	2 (5%)	42 (100%)
	P value <0.001				

Aesthetic treatment need rated by IOTN-AC: Low, AC 1-4, Moderate AC 5-7, Definite AC 8-10

Table 21 Parent perception of aesthetic treatment need in the Control group at time points at T1 and T2

	Perception of Aesthetic Treatment Need	Control Group T2 Low n (%)	Moderate n (%)	Definite n (%)	Total n(%)
T1	Low n (%)	10 (29%)	4 (11%)	1 (3%)	15 (43%)
	Moderate n (%)	7 (20%)	2 (6%)	0	9 (26%)
	Definite n (%)	4 (11%)	2 (6%)	5 (14%)	11 (31%)
	Total n (%)	21 (60%)	8 (23%)	6 (17%)	35 (100%)
	P value = 0.202				

Aesthetic treatment need rated by IOTN-AC: Low, AC 1-4, Moderate AC 5-7, Definite AC 8-10

5.3.4 Self-perception and parental perception of their child's OHRQoL in MTB and Control groups at T1 and T2

At T1 in the MTB group, there was a significant difference between self-perception and parental perception on the child's OHRQoL. Parents overemphasised the negative impact that II/1M had on their child's overall OHRQoL and each of the domains (all p-values <0.0001). At T2, although children and parents reported a significant improvement in overall OHRQoL, parents still rated this to be lower than their child (p=0.003). Parents also reported that FL (p=0.0002), EWB (0.004) and SWB (0.003) domains were poorer. OS was the only domain where there was no significant difference (p = 0.314) (Table 22).

Similarly, in the Control group, parent's perception of their child's overall OHRQoL was significantly worse than their child's perception at T1 (p=0.0011) and T2 (p=0.008). This was also evident for FL (p=0.0005,0.004), EWB (p=0.006,0.017) and SWB (p=0.002,0.014) domains, respectively. OS was the only domain where there was no significant difference at T1 (p=0.1432) and T2 (p= 0.072) (Table 23).

Table 22 Comparison between self-perception and parent perception of the child's OHRQoL in the MTB group at T1 and T2

MTB Group						
	T1			T2		
Domain	Child Mean (SD)	Parent Mean (SD)	P-Value	Child Mean (SD)	Parent Mean (SD)	P-Value
OS	4.3 (1.9)	8.8 (5.4)	**<0.0001**	3.5 (1.6)	4.0 (2.5)	0.314
FL	2.4 (2.1)	9.6 (5.5)	**<0.0001**	1.9 (1.9)	6.6 (7.7)	**0.0002**
EWB	5.1 (4.8)	15.7 (11.9)	**<0.0001**	3.4 (4.3)	3.9 (4.6)	**0.0002**
SWB	2.4 (2.0)	12.4 (9.2)	**<0.0001**	1.4 (2.0)	3.4 (3.6)	**0.004**
Overall	14.2 (7.2)	46.5 (28.6)	**<0.0001**	10.2 (7.0)	15.7 (12.1)	**0.003**

SD = Standard Deviation, OS = Oral Symptoms, FL=Functional Limitation EWB=Emotional Well Being, SWB = Social Well Being

Table 23 Comparison between self-perception and parent perception of the child's OHRQoL in the Control group at T1 and T2

Control Group						
	T1			T2		
Domain	Child Mean (SD)	Parent Mean (SD)	P-Value	Child Mean (SD)	Parent Mean (SD)	P-Value
OS	5.1 (2.2)	6.1 (4.0)	0.143	4.2 (3.0)	5.9 (4.8)	**0.072**
FL	3.6 (3.2)	7.0 (59)	**0.0005**	1.3 (2.4)	4.4 (4.4)	**0.004**
EWB	4.5 (3.9)	7.7 (8.8)	**0.006**	3.9 (4.3)	7.2 (9.4)	**0.017**
SWB	2.1 (2.3)	5.0 (6.2)	**0.002**	1.6 (2.4)	4.7 (7.8)	**0.014**
Overall	15.4 (9.0)	25.7 (21.9)	**0.0011**	12.5 (10.7)	24.5 (27.5)	**0.008**

SD = Standard Deviation, OS = Oral Symptoms, FL=Functional Limitation EWB=Emotional Well Being, SWB = Social Well Being

5.3.5 Child and Parent Perception of Aesthetic Treatment Need in MTB and Control Groups at T1 and T2

At T1 in the MTB group, 31% of parents rated their child's aesthetic treatment need higher than their child; 17% of parents perceived a definite aesthetic need for treatment whereas their child perceived a low need (p=0.054) (Table 24). Following MTB treatment, 76% of children and parents perceived the same aesthetic treatment need where 69% of both perceived a low aesthetic treatment need. Despite this, 19% of children had a higher perceived need for treatment compared to their parent (p=0.019) (Table 25).

At T1 in the Control group, 48% of parents rated their child's aesthetic treatment need higher than their child; 17% of parents perceived a definite aesthetic treatment need whereas their child perceived a low need (p=0.040) (Table 26). At T2, the level of disagreement was not significant (p=0.262) where 67% of children and parents perceived the same level of aesthetic treatment need; 51% of both perceived a low aesthetic treatment need (Table 27).

Table 24 Level of agreement of Child and Parent Perception of Aesthetic treatment need for MTB group at T1

MTB Group T1				
Self-perception	**Parent perception**			
Frequency	**Low n (%)**	**Moderate n (%)**	**Definite n (%)**	**Total n (%)**
Low n (%)	12 (29%)	5 (12%)	7 (17%)	24 (57%)
Moderate n (%)	2 (5%)	5 (12%)	1 (2%)	8 (19%)
Definite n (%)	2 (5%)	6 (14%)	2 (5%)	10 (24%)
Total n (%)	16 (38%)	16 (38%)	10 (24%)	42 (100%)

55% disagreement = P value 0.054 -The p value is the "disagreement" between parent and child; Orange – Agreement between parent and child; Light Orange – Difference of one point; White – Difference of two points, Blue – Totals. Aesthetic treatment need rated by IOTN-AC: Low need, AC 1-4, Moderate need 5-7, Definite need 8-10

Table 25 Level of agreement of Child and Parent Perception of Aesthetic treatment need for MTB group at T2

MTB Group T2				
Self-perception	**Parent perception**			
Frequency	**Low n (%)**	**Moderate n (%)**	**Definite n (%)**	**Total n (%)**
Low n (%)	29 (69%)	0	2 (5%)	0
Moderate n (%)	8 (19%)	3 (7%)	0	11 (26%)
Definite n (%)	0	0	0	31 (74%)
Total n (%)	37 (88%)	3 (7%)	2 (5%)	42 (100%)

33% disagreement = P value 0.019 - The p value is the "disagreement" between parent and child; Orange – Agreement between parent and child; Light Orange – Difference of one point; White – Difference of two points, Blue – Totals. Aesthetic treatment need rated by IOTN-AC: Low need, AC 1-4, Moderate need 5-7, Definite need 8-10

Table 26 Level of agreement of Child and Parent Perception of Aesthetic treatment need for Control group at T1

Control Group T1				
Self-perception	**Parent perception**			
Frequency	**Low n (%)**	**Moderate n (%)**	**Definite n (%)**	**Total n (%)**
Low n (%)	12 (34%)	7 (20%)	6 (17%)	25 (71%)
Moderate n (%)	1 (3%)	1 (3%)	4 (11%)	6 (18%)
Definite n (%)	2 (6%)	1 (3%)	1 (2%)	4 (11%)
Total n (%)	15 (43%)	9 (28%)	11 (31%)	35 (100%)

60% disagreement = P value 0.040 - The p value is the "disagreement" between parent and child; Orange – Agreement between parent and child; Light Orange – Difference of one point; White – Difference of two points, Blue – Totals. Aesthetic treatment need rated by IOTN-AC: Low, AC 1-4, Moderate, 5-7, Definite, 8-10

Table 27 Level of agreement of Child and Parent Perception of Aesthetic treatment need for Control group at T2

Control Group T2				
Self-perception	**Parent perception**			
Frequency	**Low n (%)**	**Moderate n (%)**	**Definite n (%)**	**Total n (%)**
Low n (%)	18 (51%)	5 (14%)	1 (3%)	24(69%)
Moderate n (%)	1 (3%)	2 (6%)	3 (9%)	6 (17%)
Definite n (%)	2 (6%)	1 (3%)	2 (6%)	5 (14%)
Total n (%)	21 (60%)	8 (23%)	6(17%)	35 (100%)

37% disagreement = P value 0.262 - The p value is the "disagreement" between parent and child; Orange – Agreement between parent and child; Light Orange – Difference of one point; White – Difference of two points, Blue – Totals Aesthetic treatment need rated by IOTN-AC: Low need, AC 1-4, Moderate need 5-7, Definite need 8-10

5.3.6 3D Facial soft tissue changes between MTB and Control Groups at T2

5.3.6.1 Error study for the reliability of soft tissue landmarking.

The intra-observer reproducibility was acceptable at ($p>0.05$). This was tested by randomly re-marking 10% of the images and comparing the x, y, z co-ordinate data to the originals. On average, the landmark identification error was 0.602 mm.

5.3.7 3D soft tissue linear changes in MTB and Control groups at T1 to T2

From T1 to T2 in the upper face, there was a statistically significant difference in the change between the MTB and Control groups at left endocanthion ($p=0.009$), subnasale ($p=0.004$) and the left alar curvature ($p=0.002$). Over the same time period, in the lower face, there was a statistically significant difference in the mean soft tissue change at Pogonion between the MTB group (4.26 SD 1.64mm) and the Control group (3.29 SD 1.95mm); $p=0.011$. Age ($p=0.739$), gender ($p=0.0619$), overjet ($p=0.547$) and time between T1 and T2 ($p=0.489$) did not affect these changes (Table 28).

5.3.8 Association between lower soft tissue landmark changes and child OHRQoL, Self-esteem, IOTN-AC

No correlation was found between landmarks and OHRQoL, self-esteem, self-perception of aesthetic treatment need in the child ($p >0.05$) (Table 29).

Table 28 3D soft tissue linear changes from T1 to T2 for the facial landmarks

Landmark	MTB Group	Control Group	T1-T2
Upper face	Mean (mm) (SD)	Mean (mm) (SD)	P-value
Glabella	1.66 (1.33)	1.25 (0.73)	0.346
Nasion	1.30 (1.02)	1.26 (0.81)	0.834
Exocanthion (R)	1.66 (0.80)	1.73 (0.86)	0.893
Mid Pupil (R)	1.63 (0.63)	1.45 (0.70)	0.0144
Orbitale (R)	1.64 (0.75)	1.57 (0.80)	0.597
Endocantion (R)	1.33 (0.69)	1.20 (0.47)	0.378
Endocantion (L)	1.61 (0.71)	1.13 (0.51)	0.009
Mid Pupil (L)	1.85 (0.89)	1.63 (0.74)	0.115
Orbitale (L)	2.01 (0.97)	1.85 (0.87)	0.103
Exocantion (L)	2.01 (0.91)	1.82 (0.93)	0.087
Pronasale	1.71 (0.88)	1.90 (0.84)	0.109
Subnasale	1.86 (1.05)	1.85 (0.67)	0.004
Alar Curvature (R)	2.29 (1.17)	2.17 (0.96)	0.706
Alar Curvature (L)	2.68 (1.15)	2.22 (0.98)	0.002
Alare (R)	2.25 (1.16)	2.23 (0.98)	0.988
Alare (L)	2.40 (1.01)	2.51 (1.10)	0.127
Lower face			
Chellion (R)	3.32 (1.48)	3.25 (1.34)	0.716
Christa Philtri (R)	2.71 (1.54)	2.43 (1.14)	0.986
Labiale Superiorus	2.74 (1.72)	2.56 (1.46)	0.609
Christa Philtri (L)	2.94 (1.63)	2.66 (1.30)	0.8246
Chellion (L)	3.46 (1.80)	3.69 (1.58)	0.421
Labiale inferius	3.91 (1.72)	3.21 (1.56)	0.378
Lower Lip (R)	3.60 (1.53)	3.40 (1.65)	0.911
Lower lip (L)	3.61 (1.71)	3.22 (1.70)	0.811
Sublabiale	4.04 (1.73)	3.28 (1.72)	0.154
Pogonion	4.26 (1.64)	3.29 (1.95)	0.011

Table 29 Association between lower soft tissue landmark changes and child OHRQoL, Self-esteem, IOTN-AC

Lower face	OHRQoL	Self-Esteem	IOTN-AC
Chellion (R)	0.245	0.5545	0.562
Christa Philtri (R)	0.899	0.989	0.186
Labiale Superiorus	0.941	0.718	0.139
Christa Philtri (L)	0.6548	0.818	0.186
Chellion (L)	0.6825	0.149	0.473
Labiale inferius	0.6330	0.253	0.423
Lower Lip (R)	0.7549	0.072	0.536
Lower lip (L)	0.485	0.094	0.726
Sublabiale	0.893	0.108	0.249
Pogonion	0.661	0.357	0.671

CHAPTER SIX

DISCUSSION

6 Discussion

6.1 Study design

This was a prospective observational cohort study measuring several psychosocial outcomes and 3D soft tissue facial changes in children with II/M before and after MTB treatment compared to children with II/1M awaiting treatment who served as controls. The family QoL, the parent's perception of both their child's OHRQoL and aesthetic treatment need was also evaluated before and after treatment/recall and compared between groups. The comparison between the child and parent in their perception of the child's OHRQoL and aesthetic treatment need was also measured in both groups at both time points. No study appears to have compared all these outcomes in children with II/1M.

6.1.1 Sample size and characteristics

The final sample comprised of 42 subjects (20 males; 22 females) who completed MTB treatment and 35 subjects (15 males; 20 females) were recalled in the Control group. These numbers in both groups met our sample size requirements for assessment of OHRQoL (Johal et al., 2007) and 3D soft tissue facial changes (Morris et al., 1998). There is a slight gender imbalance with both groups favouring females due to a greater dropout rate among males in the MTB group while in the Control group, the gender imbalance was present from the outset with more female subjects (26) compared to males (21). This imbalance differs to Johal et al. (2007) where there were 15 males and 15 females in the II/1M group and a greater number of males (18) to females (12) in the control group. It is comparable, however, to similar prospective MTB studies in children with II/1M where there was a greater number of females compared to males (Al-Jumah et al., 2018; Campbell et al., 2020).

The dropout rate of 30% was similar to other studies with MTB treatment where 20% to 50% failed to complete treatment (Caldwell and Cook., 1999; O'Brien et al., 2003b; Thiruvenkatachari et al., 2010; Campbell et al., 2020). Age was not a significant factor in non-completion which contrasts with Banks et al. (2004) who observed younger patients, less than 12.3 years, were more likely to comply. Gender also had no influence on MTB compliance similar to the findings of other studies (O'Brien et al., 2003b; Banks et al., 2004; Salloum et al., 2018).

Among the Control group the dropout rate was 26% which is similar to that recorded by Benson et al., (2015) where 31% were lost to follow-up.

Treatment time ranged from 5-12 months with an average of 8.5 months. This was similar to treatment times reported previously with TBA/MTB treatment which ranged from 6-15 months (Lund & Sandler, 1998; Morris et al., 1998; Mills & McCulloch, 2000; O'Brien et al., 2003b; Salloum et al., 2018; Campbell et al., 2020). Among the Control group, the time between T1 and T2 was 9-13 months which is slightly longer than the 9 month interval in the study by Morris et al., (1998), comparing 3D soft tissue facial changes between TBA and other functional appliances to untreated controls (Morris et al., 1998).

Between T1 and T2, the only baseline characteristic that was significantly different between the groups was overjet. This reduced in the MTB group (mean 3.1mm) compared to the Control group (mean 8.7mm). The mean reduction in the MTB group was 7.1mm, which was similar to that observed by O'Brien et al., (2003b) with a TBA (6.6mm).

6.1.2 Standardisation protocol

Attempts were made to minimize potential confounders on the treatment outcomes.

These included the following:

- The bite registration technique was standardized by using the white "Projet Bite" gauge for all treatment subjects **(Section 4.1.4)**
- The MTB design and treatment protocol were standardized for all treated subjects **(Section 4.1.5)**
- Questionnaires were self-completed by child and parent separately in rooms adjacent to the clinic
- The 3D scanning procedure was strictly standardized for all subjects **(Section 4.1.16)**
- Landmarking of 3D models was done by the same experienced operator for all subjects.

6.1.3 OHRQoL in children with II/1M before and after MTB treatment

There is limited evidence on OHRQoL in children with II/1M before and after MTB treatment compared to II/1M awaiting treatment. Most studies have been cross-sectional (Johal et al., 2007; Fabian et al.,2018) or did not have an untreated II/1M for comparison

(Al-Jumah et al., 2017; Alzoubi et al., 2017; Khraishi et al., 2019). In our study, the overall OHRQoL at T1 for both groups was poor with no significant differences between the MTB and the Control group (all p-values <0.05). Johal et al. (2007), reported a much poorer mean overall OHRQoL among UK children with untreated II/1M (37.32) compared to that observed at T1 in both groups in our study, MTB (14.2) and Control groups (15.4). A mean overall OHRQoL score of 15.05 was recorded pre-MTB treatment in 11-14 year old Irish children which is comparable to that reported in our study. The mean scores of the four individual domains were also similar to those in our study (Khraishi et al., 2019). That cohort of children differed from our sample as they were recruited from urban areas and had mixed ethnicity compared to our sample which came primarily from rural communities and were all of Caucasian origin.

In our study at T2 in the MTB group, there was a significant improvement in the child's mean overall OHRQoL score (10.2) and in FL, EWB and SWB domains (all p-values <0.05) whereas OS did not change markedly (p=0.187). In the Control group at T2 no significant change was observed (all p values >0.05). This confirms that MTB treatment improved a child's OHRQoL (Alzoubi et al., 2017; Khraishi et al., 2019).

6.1.4 Self-esteem in children with treated and untreated II/1M

The findings from this study were that overall self-esteem was relatively stable in 11-14 year olds with II/1M regardless of orthodontic treatment. While there was a trend for a child's self-esteem to reduce from T1 to T2 in the MTB and Control groups but this was not significant (MTB p=0.0144; Control p=0.056). Our trend is similar to that observed by Benson et al. (2015), where there was a reduction in overall self-esteem among a mixed malocclusion cohort from baseline (T1) to follow-up (T2), regardless of the child's orthodontic status. That study, however, identified a significant reduction in self-esteem in comparison to our study but the follow-up interval was 3 years. The relatively short follow-up interval in our study in comparison may be a possible factor for us observing no change to self-esteem. On the contrary, O'Brien et al. (2003a) reported a significant improvement in the self-esteem of children with II/1M following orthodontic treatment with a TBA with a follow-up interval of 15 months.

6.1.5 Self-perception of aesthetic treatment need in children with II/1M before and after MTB treatment

At T1, a higher percentage of children in the MTB group perceived a moderate-definite aesthetic treatment need compared to the Control group according to IOTN-AC; 46% in the MTB group compared to 29% in the Control group. A prospective study by de Sousa et al. (2016) observed similar ratings where 28% of Brazilian 12-year-old children with II/1M perceived a moderate aesthetic treatment need according to the DAI. While Lima et al. (2010) found a good correlation between IOTN-AC and DAI, a direct comparison cannot be made. A possible reason for the higher rating by children in the MTB group in our study compared to the Control group may be due to a greater dental awareness among the MTB group as they were about to commence treatment after a long waiting period.

At T2 in the MTB group, the child's rating of their aesthetic treatment need significantly improved. At T2, 74% of children perceived a low aesthetic treatment need compared to 57% at T1. This is comparable to a similar prospective study conducted in Irish children with II/1M where 83% perceived a low aesthetic treatment need following MTB treatment (Khraishi et al., 2019). Unfortunately, in that study a pre-treatment record was not available. In the Control group of our study, the perception of aesthetic treatment need remained relatively unchanged (28% at T1 to 31% at T2). This is unsurprising as it is unlikely the aesthetic treatment need changed considerably during this time.

6.1.6 Relationship between self-esteem and OHRQoL

There have been conflicting findings in the literature on the relationship between self-esteem and OHRQoL in children with a malocclusion. It has been reported that self-esteem mediates the impact malocclusion may have on OHRQoL where high self-esteem serves as a protective factor for OHRQoL (Locker., 2007; Agou et al., 2011; Jaeken et al., 2019). Others have found this relationship not to exist (De Baets et al., 2012; Seehra et al., 2013). Our study observed a low-moderate relationship between OHRQoL and self-esteem with high self-esteem being associated with better OHRQoL; this, however, was only significant in both groups cross-sectionally at T1 and was not maintained at T2 suggesting that there is a weak association between these factors. Similarly, Benson et al., (2015) demonstrated a cross-sectional relationship between self-esteem and OHRQoL in a UK cohort but this was not maintained longitudinally so strong conclusions cannot be drawn.

6.1.7 Relationship between self-perception of aesthetic treatment need and OHRQoL

Our observations were that the child's self-perception of aesthetic treatment need appeared to be independent of their OHRQoL score in the MTB and Control groups at both time points. This finding was similar to earlier studies that used CPQ and IOTN-AC where no association was found between OHRQoL or self-perception of aesthetic treatment need. This suggests that they measured different attributes (Kok et al., 2004; Dos Santos et al., 2017). This finding differed to that observed by Agou et al. (2008) who found that a high self-perception of aesthetic treatment need had a negative impact on a child's OHRQoL especially in the EWB and SWB domains.

6.1.8 Relationship between self-perception of aesthetic treatment need and self-esteem

In this study, no relationship was found between self-perception of aesthetic treatment need and self-esteem. This contrasted with Agou et al., (2008) and Dos Santos et al., (2017) who observed that those with a low self-esteem had a high self-perception of aesthetic treatment need even when the malocclusion was mild; whereas those with a high self-esteem perceived a low aesthetic treatment need regardless of the severity of the malocclusion.

6.1.9 Parental perception of their child's OHRQoL in children with treated and untreated II/1M

At T1 in both groups the parents reported their child's OHRQoL to be poor overall and across all four domains. Parents of the MTB group rated their child's overall mean OHRQoL score in the MTB group (46.5) to be significantly worse than parents in the Control group (25.7). A possible reason for this may be that those in the MTB group had been waiting longer for treatment than those in the Control group and so parents may be more sensitive to the possible implication malocclusion can have on their child. The rating by parents in the MTB and Control groups in our study was much higher when compared to parents of children with II/1M in a similar study of Irish children (mean score of 17.35) (Khraishi et al., 2019). The studies were undertaken in different geographical locations with likely differences in socioeconomic backgrounds which may have impacted on OHRQoL (Bernabe et al. 2007).

Following treatment there was a significant improvement in the parent's perception of their child's overall OHRQoL and across the four domains (all p-values <0.0001). Khraishi et al. (2019) also observed a significant improvement in the parent's perception of the child's overall OHRQoL, EWB and SWB (p<0.05) whereas FL and OS domains remained the same. In comparison to the MTB group, the parent perception of the mean overall OHRQoL of the Control group children did not change significantly from T1 (25.7) to T2 (24.5) or across any of the domains (p-values >0.05). This trend mirrors the child's perception of OHRQoL identified in the respective MTB and Control groups. The significant difference at T2 in the mean overall OHRQoL and in the four domains between the MTB and Control groups highlights the significant improvement that MTB treatment had on the parent's perception of their child's OHRQoL (all p-values <0.05)

6.1.10 Family QoL of children with treated and untreated II/1M

This study observed that the overall QoL of the family was adversely affected in those with untreated II/1M (T1 in the MTB group; T1 and T2 in the Control group). This finding mirrors that of Johal et al., (2007) where the families of those with II/1M had a poorer QoL compared to those with no malocclusion (p=0.007). At T1 the impact was significantly worse for parents in the MTB group (mean score 13.6) compared to those in the Control group (mean score 6.9) (p=0.0008). A possible reason may be due to the parents wanting to identify a definite need after waiting for so long for treatment in case not doing so would compromise their child proceeding with treatment. Following treatment, there was a significant reduction in the mean family QoL score from 13.6 to 2.4 (p=0.0001). There are no similar studies to which comparison could be made. Among the Control group there was no significant difference between T1 and T2. An important conclusion from this study is that treatment with II/1M had a positive impact, not only on the child, but also on the overall family QoL.

6.1.11 Comparison between self-perception and parental perception of OHRQoL in children with treated and untreated II/1M

Children with untreated II/1M and their parents reported poor overall OHRQoL as well as in OS, FL, SWB and EWB domains (T1 in the MTB group; T1 and T2 in the Control group). Parents, however, perceived the child's OHRQoL to be worse than the child (all p-values <0.05 apart from OS at T1 in the Control group p=0.143). This discrepancy

between the child and parent's perception of OHRQoL has been previously identified especially with regards to the child's overall OHRQoL, EWB and SWB domains (Jokovic et al., 2004; Zhang et al., 2007; Benson et al., 2010; Al-Jumah., et al., 2017; Khraishi et al., 2019). Similar to our study, Khraishi et al., (2019) observed parents reported poorer overall OHRQoL, EWB and SWB domains compared to their children with II/1M prior to MTB treatment (all p-values <0.05). Findings of that study differed from those of ours as a good level of agreement in FL domain was observed.

Following MTB treatment, we found parents continued to rate the overall OHRQoL, FL, EWB and SWB domains worse than their child with only a comparable score being recorded in the OS domain (p=0.314). Khraishi et al. (2019), however, observed that the level of agreement improved following MTB treatment with children and parents rating the overall OHRQoL and FL, OS and SWB similarly (all p-values >0.05).

6.1.12 Child and parent perception of aesthetic treatment need in treated and untreated II/1M

The observations from our study were that parents were more critical of their child's aesthetic treatment need when II/1M was untreated (T1 in the MTB group and T1 and T2 in the Control group). This corroborates the findings from previous studies but the malocclusion type was not specified in those (Birkeland et al., 1996; Chew and Aw 2002; Hamdan 2004). In contrast, with regard to II/1M, Campbell et al. (2020) found good agreement between child and parent with both groups indicating a high pre-treatment aesthetic need (image 9) compared to a low post-treatment aesthetic treatment need (image 3).

In our study, following MTB treatment 69% of parents and children agreed there was a low aesthetic treatment need; 19% of children, however, rated themselves as having a moderate aesthetic treatment need. The reason for this disagreement between child and parent may be that children had become accustomed to monitoring tooth position and, therefore, more sensitive to residual minor discrepancies. In the Control group, the level of agreement between child and parent perception of aesthetic treatment need remained high and unchanged from T1 to T2 (all p <0.05) reflecting the severity of the malocclusion.

6.1.13 3D landmarking error study

The reproducibility of all the landmarks used in this study have been validated by Farkas (1994) and Hajeer et al. (2002). The intra-observer landmark identification error we observed was 0.602mm. Some previous studies have reported a landmarking error as low as 0.1 mm (Khambay et al., 2008). In that study, however, the landmarking was done and assessed for reproducibility on a plaster model, not on an actual 3D facial image; therefore, the findings cannot be compared to ours. Campbell et al. (2012) have reported an error of 0.57 mm and Salloum et al. (2018) reported an error of 0.562 mm which were similar to our findings.

6.1.14 3D Soft tissue changes in children with treated and untreated II/1M

The changes in position of the upper facial soft tissue landmarks between T1 and T2 were minimal (less than 1 mm). This is unlikely to be related to MTB treatment but could be the result of variability in identifying these soft tissue landmarks (Maal et al.,2011; Karatas and Toy, 2014) or growth of the maxilla and nose (Hajeer et al., 2005).

For both groups, there was a significant change in the soft tissue pogonion between T1 and T2; in the MTB group there was a mean advancement of 4.26 (SD 1.64) mm; ($p= 0.001$) and in the Control group 3.29 (SD 1.95) mm; ($p=0.002$). The results of the MTB group are comparable to Salloum et al. (2018) who assessed 3D soft tissue facial changes following MTB treatment in a similar Irish cohort of children. They reported soft tissue pogonion advanced by a mean of 4.12 (SD 3.03) mm in females and 4.13 (SD 2.13) mm in males although there were no untreated II/1M for comparison. The results differed from our study as we did not find that gender had a significant effect ($p=0.739$). In contrast, Morris et al. (1998) observed no significant changes in soft tissue pogonion from T1 to T2 in a TBA group compared to controls.

While there was statistically greater movement in the MTB group compared to the Control group, this difference was not clinically significant as a change greater than 2mm at soft tissue pogonion is deemed to be required (Cozza et al., 2006; Salloum et al., 2018). Gender ($p=0.0619$), overjet ($p=0.547$) and duration between T1 and T2 ($p=0.489$) did not affect these changes.

No correlation was found between movement in 3D soft tissue facial landmarks and OHRQoL, self-esteem, self-perception of aesthetic treatment need in the child ($p > 0.05$). There are no studies to which we can compare these findings.

6.1.15 Impact of COVID-19 pandemic on QoL measures in children

Significant life events can influence OHRQoL (Rodd et al., 2011) so it is important to consider the possible implication of COVID-19 pandemic and the ensuing lockdown period had on children. As OHRQoL is impacted by a person's environment (Locker and Allen, 2007), it is plausible that the restrictions imposed including social distancing, closure of schools and reduced interaction with peers had an influence on a child's OHRQoL (Knorst et al., 2021). There are concerns about how this has impacted a child psychosocial well-being but at present it is unknown (Caffo et al., 2020; Di Renzo et al., 2020; Dziedzic and Wojtyczka, 2020). A study conducted in Brazil on 10-15 year olds' observed a reduction in their perception of oral health problems; the overall OHRQoL and domain scores of CPQ were significantly lower during the COVID-19 pandemic (Knorst et al., 2021). In our study there was no change in the Control group's OHRQoL or their self-esteem from T1 to T2; it would appear, therefore, that the COVID-19 pandemic had no noticeable impact on children's psychological well-being in the short term. Further follow up, however, would be required for a more definite conclusion.

6.1.16 Implications for practice

II/1M has a significant impact on both the child and family OHRQoL. Being aware of how the parent perceives the child's OHRQoL and aesthetic treatment need may give some insight to the likely support and encouragement a child may receive at home. This is an important factor in their child's compliance and overall success of orthodontic treatment (El-Huni et al., 2019). MTB treatment has significant benefits for the child and the family in terms of OHRQoL and reduction in aesthetic treatment need. Within the limitations of this study, no impact was observed on self-esteem or 3D soft tissue facial changes.

6.2 Strengths of this study

- This was a prospective longitudinal cohort study comparing MTB treatment for II/1M with untreated II/1M children awaiting treatment who served as controls.
- All patients were of the same Caucasian ethnic origin.
- Treatment protocol, MTB design, bite registration technique, data collection and 3D imaging were standardized.
- Standardized and validated questionnaires were used.
- A non-invasive validated 3D camera system was used to monitor facial soft tissue changes following MTB treatment and in controls.
- OHRQoL, self-esteem and aesthetic treatment need were assessed in children with II/1M and in controls.
- The parent perception of child OHRQoL, their perception of child aesthetic treatment need and family OHRQoL were also assessed in MTB treated and control groups

6.3 Limitations of this study

- Children and parents were from one geographical area and a variety of socioeconomic backgrounds so access to dental care may be impacted which could affect OHRQoL and self-esteem.
- A dropout rate of 30% and 26% in the treatment and control groups respectively may contribute to response bias.
- The small sample size for assessment of change in self-esteem limited the outcome of this variable.
- CPQ and P-CPQ may not be sensitive enough to detect changes in malocclusion.

6.4 Further research

- The outcome measures recorded here should be re-recorded at the completion of comprehensive orthodontic treatment in both groups.
- The same outcome measures could be employed in pre- and post-treatment assessment of children with other malocclusions types compared to a control group.

CHAPTER SEVEN

CONCLUSIONS

7 Conclusions

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

Aim 1: To evaluate the impact Modified Twin Block (MTB) treatment has on oral health related quality of life (OHRQoL), self-esteem, self-perception of aesthetic treatment need and 3D soft tissue facial changes in children with Class II division 1 malocclusion (II/1M) compared to children with II/1M awaiting treatment who served as controls.

Conclusions:

- MTB treatment significantly improved the OHRQoL and self-perception of aesthetic treatment need in children with II/1M but had no significant impact on self-esteem or 3D soft tissue facial changes compared to controls.

Null Hypothesis:

- There is no difference in OHRQoL, self-esteem, self-perception of aesthetic treatment need and 3D soft tissue facial changes in children with II/1M following MTB treatment or awaiting treatment.

This null hypothesis is **accepted for self-esteem and 3D soft tissue facial changes** but is **rejected for OHRQoL and self-perception of aesthetic treatment need.**

Aim 2: To assess the effect MTB treatment has on family QoL and on both the parent's perception of their child's OHRQoL and aesthetic treatment need compared to controls.

Conclusion:

- MTB treatment significantly improved the family QoL and both the parent's perception of their child's OHRQoL and aesthetic treatment need compared to controls.

Null Hypothesis:

- MTB treatment has no effect on family QoL or on both the parent's perception of the child's OHRQoL and aesthetic treatment need compared to controls.

This null hypothesis is **rejected.**

Aim 3: To assess the level of agreement of child OHRQoL and perception of aesthetic treatment need by child and parent between groups.

Conclusion:

- In children following MTB treatment or awaiting treatment, poor agreement existed between the child and parent perception of OHRQoL and aesthetic treatment need.

Null hypothesis:

- There is no difference in the level of agreement of child's OHRQoL and perception of aesthetic treatment need by child and parent between groups.

This null hypothesis is **rejected.**

CHAPTER EIGHT

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8 References

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CHAPTER NINE

APPENDICES

9 Appendices

Appendix 1 Details of search strategy by database

Database	Search Strategy
Medline	● (Class II division 1 Malocclusion) AND (psycho-social or psychosocial or bullying) OR (articulation or misarticulation or speech) or (aesthetics) ● (Class II division 1 malocclusion) and (aetiology) ● (Twin block or twin-block or twinblock) AND (facial change or profile change or soft tissue change or three-dimensional effect$ or 3D effect$) OR (treatment effect$ or treatment outcome) ● (Facial expressions) AND (Reproducibility) ● (Facial growth) and (children and adolescents) or (11-14-year-olds) and (class II skeletal or class II division 1 malocclusion) ● (OHRQOL) AND (functional appliance treatment or twin block or twinblock or twinblock) OR (class II division 1 Malocclusion) OR (prominent incisors) AND (children or adolescents or 11-14-year-olds) AND (impact) AND (quality of life) OR (Oral health related quality of life) OR (CPQ 11-14) OR (P-CPQ) AND (orthodontic treatment) or (orthodontics) ● (Self-Esteem) AND (functional appliance treatment or twin block or twin-block or twinblock) OR (class II division 1 malocclusion) OR (prominent incisors) AND (children or adolescents or 11-14 year olds) AND (untreated II/1Malocclusion) AND (impact) ● (Self-esteem) and (children or adolescents) and (malocclusion) or (oral health related quality of life) or (orthodontic treatment) or (functional appliance) ● (IOTN-AC or aesthetic component of IOTN) AND (Parental perception) OR (child perception) AND (comparison) AND (Class II division 1 Malocclusion) or (increased overjet) or (prominent incisors) ● (Aesthetic treatment need) AND (Class II division 1 malocclusion) or (increased overjet) or (prominent incisors) AND (parent) AND (child) AND (comparison)

	● (Three-dimensional imaging) or (3D) or (Stereophotogrammetry) AND (Orthodontics) AND (twin block or twin-block or twinblock) ● (COVID-19) and (OHRQoL) or (orthodontics) or (orthodontic treatment) and (children) or (Coronavirus) and (OHRQoL) or (oral health) or (orthodontics)
Pubmed	**Same as for Medline**
Embase	**Same as for Medline**
Google Scholar	Twin Block, class II division 1 Malocclusion in children and adolescents, Untreated class II division 1 Malocclusion, Soft tissue facial changes, Aesthetic treatment need and class II division 1 malocclusion, increased overjet and aesthetic treatment need, Treatment need and class II division 1 malocclusion, OHRQoL and orthodontics and class II division 1 Malocclusion, OHRQoL and prominent incisors, Bullying and malocclusion, Bullying and class II division 1 Malocclusion, Self-Esteem and class II division 1 malocclusion, Three-dimensional imaging, Stereophotogrammetry, COVID-19 and orthodontics, COVID-19 and orthodontic treatment, COVID-19 and OHRQoL in children, coronavirus and oral health, coronavirus and orthodontic treatment

Appendix 2 Ethical approval letter 1

COISTE EITICE UM THAIGHDE CLINICIÚIL

Clinical Research Ethics Committee of the Cork Teaching Hospitals

Tel: +353-21-4901901
Email: crec@ucc.ie

University College Cork
Lancaster Hall
6 Little Hanover Street
Cork
Ireland

CREC Review Reference Number: ECM 4 (d) 12/02/19

Date: 25th January 2019

Professor Declan Millett
Cork University Dental School and Hospital
Wilton
Cork

Study Title: Children and adolescents with modified twin block for class II division 1 malocclusion compared to controls: quantitative and qualitative analyses.

Approval is granted to carry out the above study at:

Cork University Dental School and Hospital.

The following documents have been approved:

Document	Approved	Version	Date
Cover Letter	Yes		20th December 2018
Application Form	Yes		20th December 2018
CV for Chief Investigator	Yes		
Evidence of Insurance			
Study Protocol	Yes		
Data Collection Sheet			
Participant Information Leaflets	Yes		Version 1 December 2018
Assent/Consent Forms	Yes		Version 1 December 2018
Study Questionnaire/Survey	Not included		Submit prior to commencement
Interview Guide	N/A		

We note that the co-investigator(s) involved in this project will be:

Name	Occupation
Niamh Kelly	Postgraduate Student

Full approval is now granted to carry out the above study.

The date of this letter is the date of authorization of the study.

Please keep a copy of this signed approval letter in your study master file for audit purposes.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter)
2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study

3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.

4. Notify CREC of discontinuation of the study

5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely

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

Appendix 3 Ethical approval letter 2

COISTE EITICE UM THAIGHDE CLINICIÚIL

Clinical Research Ethics Committee of the Cork Teaching Hospitals

Tel: +353-21-4901901
Email: crec@ucc.ie

University College Cork
Lancaster Hall
6 Little Hanover Street
Cork
Ireland

REC Review Reference Number: ECM 4 (d) 12/02/19
& ECM 3 (i) 10/11/2020 re-application

Date: 29th October 2020

Professor Declan Millett
Cork University Dental School and Hospital
Wilton
Cork

Study Title: Children and adolescents with modified twin block for class II division 1 malocclusion compared to controls: quantitative and qualitative analyses.

Approval is granted to carry out the above study at:

Cork University Dental School and Hospital.

The following documents have been approved:

Document	Approved	Version	Date
Cover Letter	Yes		21st October 2020
Application Form	Yes		12th October 2020
CV for Chief Investigator	Yes		
Evidence of Insurance	Yes (CIS)		
Patient Assent Form Treatment Group	Yes	1	December 2018. ***Remove header "Oct 2020 Version 1" prior to use as this document has not been amended***
Patient Assent Form Control Group	Yes	2	22nd October 2020: ***Remove footer "Version 1 Dec 2018" prior to use as this document has been amended***
Parent Consent Form Treatment Group	Yes		***Change header "Version 1 October 2020" to "Version 1 December 2018" prior to use as this document has not been amended***
Parent Consent Form Control Group	Yes		Change header ***"Version 1 October 2020" to "Version 1 December 2018" prior to use as this document has not been amended***
Parent Information Sheet Control Group	Yes	2	22nd October 2020. ***Remove footer "Version 1 Dec 2018" prior to use***
Parent Information. Leaflet Treatment Group	Yes	1	December 2018

Study Protocol	Yes	1	***Remove header "October 2020" prior to use as this document has not been amended***
Study Questionnaires	Yes.		

We note that the co-investigator(s) involved in this project will be:

Name	Occupation
Dr Caroline O'Dwyer	Postgraduate Student.

Full approval is now granted to re-open this study. Please note that only data from participants who consented prior to 25th January 2020 and who were consented by either the Chief Investigator or by Niamh Kelly (approved co-investigator) may be used in the study analysis.

The date of this letter is the date of authorization of this re-application.

Please keep a copy of this signed approval letter in your study master file for audit purposes.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter). ***Please note this date as the CREC will not issue reminders.***
2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study
3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.
4. Notify CREC of discontinuation of the study
5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely



Professor David Kerins
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals