On Treatment Outcomes Of Protraction Headgear In Pre-Pubertal Patients

A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy

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Preface

This thesis is prepared in the 'publishable style'. Chapter 1 presents the literature review together with the objectives and hypotheses for the study. Chapter 2 outlines the Materials and Methodology for the following chapters. Chapters 3 through 5 present the clinical outcomes of the interventions, the Compliance rate effect on treatment outcomes and finally Patients related outcomes of the treatment provided. Finally, Chapter 6 closes this thesis with an overarching discussion and conclusion for this research.

Abstract

There is a consensus in the dental literature supporting the notion that facemask therapy, in general, can induce dentoalveolar, rather than skeletal effects. Alternative Rapid Maxillary Expansion and Constriction (Alt-RAMEC), was introduced by Eric Liou, with reports of potential skeletal changes. These preliminary reports on the Alt-RAMEC effect deserve thorough clinical investigation in a randomised clinical trial.

In this dissertation, we conducted a randomised clinical study to test the skeletal effect of facemask therapy using the Alt-RAMEC approach in two different prepubertal groups; Group I (17 patients) with a tooth-borne rapid maxillary expander (RME) attached to a facemask and Group II (17 patients), with a skeletally anchored rapid maxillary expander attached to the facemask. In both groups, the facemask contained a sensor which was concealed in the facemask forehead pad that assessed the compliance, as hours of wear, during treatment. We also explored the clinical outcomes between the two groups and the relation between the compliance rate and clinical outcomes. Lastly, The research measured patients' oral-health-related quality of life and the cost-effectiveness of the two treatment arms of the study.

Comparison of each group to its baseline (T0-T1) showed a significant mean difference of 2.10 degrees for SNA in Group I. A significant mean difference of ANB was 3.9 degrees (P=0.001) for Group I and 3.1 degrees for Group II (P=0.001). Wits appraisal showed a significant mean difference (T0-T1) for Group I 4.7 degrees (0.001) and Group II 3.2 degrees (0.002). Overjet showed a significant mean difference of 5.4 mm for Group I (P<0.001) and 4.5 mm for Group II (P<0.001). Lower incisors to the mandibular plane showed a significant mean difference of -4 degrees for Group I (P=0.0023) and Group II =-6.1 (P=0.005). Nasolabial angle showed a significant mean difference of 13 degrees in Group I (P=0.028).

Group I patients wore the facemask for 7.87 ± 2.88 hours per day and Group II patients wore the facemask for 6.98±2.68 hours per day. Patients' quality of life tended to show the same

trends in both groups. Group I showed a worsening in quality of life in Group I (T0-T1) with a mean difference of 10 (P=0.013) and Group II 10 (P=0.054). Similarly, Group I showed worsening in the physical limitation domain (T0-T1) 10 (P<0.001), (T0-T2) 7 (P=0.002), (T0-T3) 7 (P=0.022), (T0-T4) 5 (P=0.022), (T0-T5) 6 (P=0.003) and (T0-T7) 6 (P=0.006). Global Domain of Group I showed significant differences (T0-T8) and (T0-T9) 25 and 26, respectively (P=0.017 and 0.005). ICER (incremental cost-effectiveness ratio) showed higher costs for Group II.

In conclusion, Alt-RAMEC approach in both groups resulted in the same or comparable skeletal and dentoalveolar outcomes. Furthermore, although the compliance rate was far less than instructed by the clinician, the short hours of wear resulted in beneficial skeletal changes. Quality of life in both groups showed similar trends.

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List of Abbreviations

Abbreviations	*Descriptor*
ANS	Anterior Nasal Spine
PNS	Posterior Nasal Spine
RANK	Receptor activator of nuclear factor kappa-B l
RANKL	Receptor activator of nuclear factor-kappa-B ligand
RME	Rapid Maxillary expander
Alt-RAMEC	Alternative Rapid Expansion and Constrictions Cycles
FM	Facemask
SNB	The angle between Sella, Nasion and A point
SNA	The angle between Sella, Nasion, B point
Co-GoI	Condylon and Gonial intersection
Co-Pg	Condylon - Pogonion
Ar-Go-Me	Condylon-gonion-Menton
OJ	Overjet
GTRV	Growth treatment response vector
CS	Cervical Stage
CVM	Cervical Vertebrae Maturation
OHRQoL	Oral Health-Related Quality of Life
QoL	Quality of Life
Point A	Most anterior in the depth of concavity between anterior nasal spine and alveolus
Point B	The deepest point in the curvature of the mandibular alveolar bone
DMFT	Decayed Missing Filled Tooth
G	Gram
C°	Celsius
UR6, UL6	Upper Right and Left first molar
URE, ULE	Upper Right and Left deciduous second molar
ICC	Inter Class Coefficient
IQR	Interquartile Range
SD	Standard Deviation
CV	Coefficient Variant
ANOVA	Analysis of variance
CPQ	Child Perception Questionnaire
ICER	Incremental Cost-Effectiveness Ratio
COHQoL	Child Oral Health Quality of Life

Introduction:

A Class III skeletal relation is considered to be a deviation from the norm due to an imbalance in the size or position of the maxilla and mandible. This malocclusion was first described by Bourdet in the 18th century, who also demonstrated that the malocclusion worsens with growth (1). Later in the 19th century, Delabarre introduced the concept of reduced overbite or underbite or edge to edge as a feature of Class III malocclusion. Angle in 1900 described Class III malocclusion as when 'the lower teeth occlude mesial to the normal width of one bicuspid or even more in extreme case' (2–4).

In 1802, Fox was particularly interested in the use of an expansion arch and a chin cup for maxillary orthopaedics. Angle, in 1915, pioneered opening the median palatal suture with a split plate. Case, in 1930, showed remarkable foresight in distinguishing between "dental malposition" and "dentofacial imperfections," comparable in modern terminology to dentoalveolar and skeletal. He stressed facial aesthetics in contrast to Angle's dependence on occlusion. He said, "The occlusion or malocclusion of the buccal teeth does not indicate the real position of the dentures in relation to facial outlines." (5).

Managing orthodontic problems in growing children with skeletal Class III malocclusion is problematic, mainly because of the unpredictable nature and unfavourable growth pattern in patients' malocclusion patterns. Mild cases may be treated by dentoalveolar compensation however, young patients with more severe Class III malocclusion must be treated with orthopaedic appliances, with the hope that growth does not exceed the limits of this type of treatment. Mid-term follow up showed a success rate of 62.7% -100% of treated patients (6). However the long term outcome is still unclear and in case of treatment failure , it leaves orthodontist with one choice for ideal treatment outcomes, that is, orthognathic surgery. Maxillary anteroposterior deficiency is the commonest aetiological factor in a Class III skeletal

base relationship, occurring in 56% of cases. Mandibular prognathism the cause in 19% of cases and a combination of both in 25% of cases (6-8). The downward and forward growth of the maxilla and treatment modalities, aimed at influencing mild to moderate Class III skeletal base inconsistencies, has shifted to a maxillary protraction therapy.

The facemask is classified as an orthopaedic appliance. This was introduced in the 1960s by Delaire to treat patients with cleft palate patients (6). Delaire's approach involves applying traction to the maxillary sutures, while reciprocally pushing on the mandible and the forehead through the anchorage provided by the facial mask. Modifications have been made to the Delaire facemask, such as the design of the Petit facemask by Henry Petit (7) (Figure 1). The facemask per se is made of three components: the facemask frame, elastics, and an intraoral appliance. The elastics are attached to the facemask to pull the maxilla forward. The point of application of force in the intraoral appliance is placed near the maxillary centre of resistance to generate the maximum skeletal effect.

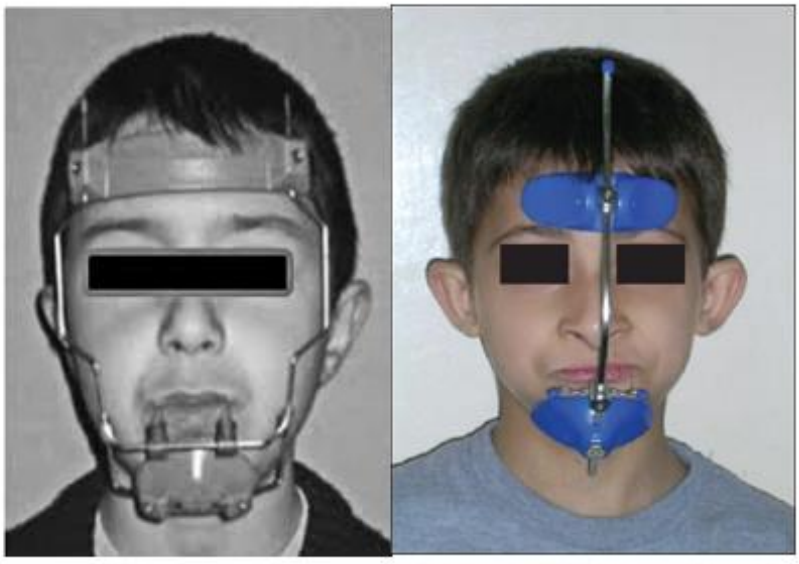

Figure 1: Delaire facemask (Left) and Petit facemask (Right). Images obtained (www.orthocosmos.com)

The effectiveness of maxillary orthopaedic guidance in Class III treatment has received relatively little attention and the evidence remains equivocal. Literature reviews reveal few long-term studies that deal with the effect of treatment produced by extra-oral orthopaedic protraction (8–11). Further research is needed in this area to draw conclusions that contribute valid data to the scientific community (12). Furthermore, most of the systematic reviews linking the effectiveness of facemask therapy and hours of wear are based on the patient's subjective reports, thereby having to assume that they are truly reporting accurate data. This approach of course lacks the scientific vigour expected and therefore severely curtails the conclusions of these reviews. However, new digital advancements, such as compliance sensors, may lend themselves to more accurate and objective data collection. It is therefore interesting to look at the clinical effect of facemask and alternating RME (Alt-RAMEC) therapy in the presence of an accurate digital reporting device that would eliminate misleading self-reports of patient compliance.

Chapter 1

Literature Review

Literature Review:

Class III malocclusion may be defined as follows (1) :

1) Class III individuals tend to have a small cranial base, which places the glenoid fossa in a more anterior position. The open bite type tends to have a large gonial angle and the maxillary plane tipped upward (ANS up and PNS down) and vice versa for deep bite patients.
2) British Standard Institute (1982): The lower incisor edge lies anterior to the cingulum plateau of the upper incisors (13).
3) Class III molars relationship is defined by Angle as " having the lower first molar mesially positioned relative to the upper molar (mesio-occlusion)" (1).

Class III malocclusion prevalence among Americans was less than 1-2% (1). The differences in data are attributed to different ethnic groups and a selection bias can be created when only patients seeking treatment are reported, without taking into consideration those not seeking treatment. The prevalence in European Americans and African Americans was estimated at 0.7% and 0.6-1.2%, respectively (14).

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Aetiology:

Skeletal Factors

Class III malocclusion has a complex aetiology. San born found that 42.2% of Class III cases had actual mandibular protrusion with a normal maxilla, on the other hand, 33% showed maxillary retrusion with normal mandibular position anteroposteriorly. Nine and a half per cent of both jaws were within the normal range anteroposteriorly and 9.5% exhibited a prognathic mandible and retruded maxilla (2).

A study of lateral cephalograms of 144 children with Class III malocclusions. He concluded that malocclusion is attributed to 56% of maxillary retrusion and 19% of mandibular prognathism or 25% of a mixture of both (15). He classified Class III malocclusion into different categories according to maxillary skeletal position, maxillary position, mandibular position, and mandibular skeletal position (15).

Furthermore, the question of whether the maxilla or mandible is the source of the problem was also investigated by Guyer et al. They compared Class III patients with Class I patients and found that the posterior cranial base length (B-Sa) was significantly longer in Class III patients. Furthermore, both genders in Class III groups showed a retrusive maxilla. The effective length of Class III maxillae (Co-A) was shorter than in the Class I group and the mandible in the Class III group (Co-Gn) showed prognathism on average of 3-6 mm. The vertical component of Class III patients should also be taken into consideration. Class III cases showed higher maxillary mandibular plane angles and increased lower facial heights in addition to a more obtuse and anteriorly positioned gonial angle. The dentoalveolar component showed proclination of the maxillary incisors and retroclination of the mandibular incisors (15). Ellis et al. studied 302 adult males' and females' lateral cephalometric radiographs. All patients received presurgical orthodontic treatment, all tracings were digitized to measure the horizontal and vertical components of facial structure. He concluded that 30% had a combination of retruded maxilla

and prognathic mandible, 19% had a retruded maxilla and normal mandible in the sagittal plane and 14% had a normal maxilla anteroposteriorly with a normal mandible (16). These data should be interpreted with caution as only one unblinded clinician performed the tracings. There was no report of intra-operator or inter-operator errors either. This may have led to bias in the collection of data.

Genetic and hereditary combinations may play a role in the development of maxillary transverse deficiencies. Whether malocclusion is heritable was studied and the conclusion was that occlusal pattern is acquired rather than inherited while craniometric variables such as (asymmetry, size disharmonies anteroposteriorly, vertical and transverse, TMD, and inter or intra arch problems) tend to be heritable (17). Harrison and Johnson also found that craniometric variable values spike between the age of 4 and 20 years with a correlation of 0.43, on the other hand, the dental base variables decline to zero correlation as age increases (17). Mental symphysis, lateral surface of the ramus, and frontal curvature of the mandible are genetically determined while the antegonial notch is environmentally determined. In simpler words, the authors concluded that the anterior-posterior direction of mandible growth is mainly under genetic control while the vertical growth of the mandible is mainly environmental (18). Sometimes, as a consequence of cleft palate repair, the patient develops a Class III skeletal base relation because of scar tissue retarding the growth of the maxilla (1).

There is considerable evidence for a genetic component, with several examples of familial aggregation. The classic example is the Hapsburg royal family (19), the facial characteristics were prognathic mandible, protruding lower lip, and increased nasal dorsal hump (Figure 2) and this is evident in several of the royal family portraits. Most Class III patients who require orthognathic surgery have a first-degree relative with a similar problem. Litton et al. studied the families of 51 individuals with severe Class III malocclusion; the results showed one-third of Class III groups had a parent with the same overall features. One-sixth had an affected

brother or sister (20). The racial prevalence is also variable. The reports of prevalence of Class III individuals in Chinese and Koreans range from 9.0 to 19.0 percent (21,22).

Many genome-wide association studies have been carried out, however, due to the polygenic nature of the trait, racial variation and phenotypic heterogeneity, replication across studies is poor, with very few variants explaining the variation across the studies (23).

Recent studies have reported that genes that encode specific growth factors or other signalling molecules are involved in condylar growth under mechanical strain (24). These genes include Indian Hedgehog Homolog (IHH), Parathyroid-Hormone Like Hormone (PTHLH), Insulin-Like Growth Factor-1 (IGF-1) and Vascular Endothelial Growth Factor (VEGF). Variations in their levels of expression may play an important role in the aetiology of Class III malocclusion (24).

Figure 2:This portrait of Charles II of Spain depicts his "Hapsburg jaw". Image obtained from (www.spainsnews.com)

All this evidence emphasises that the aetiology of Class III malocclusions is complex due to involvement of the cranial base, maxillary and mandibular bones to varying degrees. Our incomplete understanding of the genetic and environmental factors causing this malocclusion

further obscures the picture. Further in-depth investigation will help unfold the hidden facts that directly and indirectly affect Class III development.

Growth

Facial growth studies are divided into longitudinal, or cross-sectional studies of untreated Class III malocclusions. Unfortunately, most growth studies looked at untreated individuals with Class I or II malocclusions, while Class III malocclusion was barely examined. This may be because the prevalence of Class III malocclusion is very low, or because clinicians intervene to treat this malocclusion at a very young age. Thus, accurate epidemiological data is not available.

A study used data from untreated children from the Bolton-Brush Growth Study and Burlington Growth Study at the University of Toronto. In children between the age of 6 and 12 years, maxillary anteroposterior growth increased by 1 mm/year, the mandible grew just under 3 mm/year and the lower facial height increased by 1 mm/year. In conclusion, the mandible showed more anteroposterior growth in comparison to the maxilla (25–27).

Many studies showed similar trends, but it is worth mentioning that most of these studies exhibited shortcomings, such as a short period of observation, small sample size, poor gender matching, lack of consideration of skeletal maturation, or pubertal growth spurt (27).

A study looked at Class III malocclusion in Japan. Serial cephalometric x-rays were taken from 7 to 10 years of age for a female group. The conclusion was that mandibular protrusion is associated with a normal size maxilla but that it is posteriorly positioned. The growth pattern of both prognathic mandible and retrognathic maxilla was similar to that of a normal, prepubertal growing face. In addition, in Class III cases with a large mandible, the growth pattern is similar to the normal mandible growing pattern. In other words, the problem is not the growth pattern but the oversized mandible. The large size of the mandible was established at a very young age (28). Further studies supported mandibular prognathism in Class III being due to the establishment of a large mandible at a young age, prior to the pubertal growth spurt.

A study examined Class III malocclusion and the associated aetiological features. This

involved 495 lateral cephalometric radiographs of Caucasian patients (210 controls and 285 Class III cases). Evaluation was made between the control group and Class III children in each of the eight subgroups. The conclusion was that Class III children showed changes in facial morphology in all facial dimensions upon comparison with their control group. The saddle angle was acute, the maxilla retrusive anteroposteriorly, while the mandible was longer and more prominent in Class III patients. This is partially due to a forward position of the mandibular articulation with the cranium (29). The study group showed proclination of upper incisors as a form of compensation, however, the lower incisors were still in a forward position in the study and control groups. In the Class III group, growth remained active and exhibited more vertical growth, whereas females' faces seemed to have horizontal development (29). Baccetti et al. found similar features when they looked at 22 untreated Class III patients. They used the Cervical Vertebral Maturation System (CVM) to assess growth completion toward stages CS5-6 (30). The researchers concluded that Class III malocclusion is an early life problem. Furthermore, it is not a self-limiting problem that resolves with growth; Class III malocclusion becomes more pronounced in the pubertal growth spurt and worsens until the completion of growth. (30).

Growth Prediction

Growth prediction can be divided into three components: direction, timing and the amount of growth achieved (1). The direction of mandibular growth can be estimated depending on what type of grower the patient is, for instance forward rotator or a backward rotator can affect the prognosis of Class III (1). The peak of mandibular growth is associated with the pubertal growth spurt, where the mandible will show robust growth (31). Prediction of Class III malocclusion growth patterns would greatly aid case selection and improve the prognosis for treatment. Many methods have been advocated to predict growth; Johnston suggested using the "forecast grid"(32). The concept is based on evaluating a mean value for each lateral cephalometric anatomical point change over time. This method was a simple and easy way to predict growth (32). However as this is only based on average changes, the more extreme growth patterns cannot be forecast with any reasonable accuracy (33).

Research has concentrated on cephalometric characteristics to predict future growth patterns. Björk and Skieller were the first to describe growth rotations of the jaws. Growth rotations determine the direction of growth of the jaws. Rotation of the mandible can result from its hinge relationship with the cranium (34). The critical factor appears to be the proportionality of vertical development between the condyle-fossa area on one side and the maxillary sutural and alveolar process on the molar region on the other. When vertical growth in the condyle-fossa region exceeds vertical growth in the molar area, there is a forward rotation of the mandible and when vertical growth in the condyle-fossa area is less than vertical growth in the molar area, there is a backward rotation. Class III cases with reverse overjet and low mandibular plane angle demonstrated a backward rotation of the mandible during treatment to correct the incisor relationship. However, the majority showed relapse, with a forward rotation, post-treatment (35)

Baccetti et al. concluded that orthopaedic therapy of Class III malocclusion might be unfavourable in the long term when a patient's pre-treatment cephalometric records show a long mandibular ramus (ie, increased posterior facial height), an acute cranial base angle, and a steep mandibular plane angle. The outcome of interceptive orthopaedic treatment for each new patient with Class III malocclusion can be anticipated with a probability error of 16.7%, in other words, 83.3% accuracy (36). Similarly, another paper compared successfully and unsuccessfully treated cases and found four variables to be important in predicting successful treatment outcomes:

1) Position of the condyle with relation to the cranial base.
2) Ramal length (Co-Goi).
3) Mandibular length (Co-Pg).
4) Gonial angle (Ar-Goi-Me).

The gonial angle was larger in the unsuccessful treatment Class III group. The probability of successful treatment was associated with an increase of Co-GD and Co-Goi and a decrease of Co-Pg and Ar-Goi-Me. The equation used in this study predicted the accuracy of successful treatment of Class III cases 95.5% of the time and failure 70% of the time (37).

Growth treatment response vector (GTRV) analysis was proposed, to predict whether early treatment of Class III with protraction headgear in the mixed dentition stage would need a second phase of orthodontic treatment, or even surgical intervention in the future (38). The concept of this method is to take a series of lateral cephalometric radiographs a few years apart and use the GTRV analysis to predict future mandibular growth.

Following the end of facemask therapy, the patients are followed for 3-4 years. Subsequently, at the early permanent dentition stage, GTRV analysis would be initiated, to establish whether the result favours a camouflage or a surgical procedure when the growth ends (Ngan, 2005).

The horizontal growth changes of the maxilla and mandible between the post-treatment and follow-up radiographs are determined through the change in position of A-point and B-point on the post-treatment radiograph. The GTRV is worked out using the ratio:

GTRV= Horizontal growth changes of the maxilla ⁄horizontal growth changes of the mandible.

Mild to moderate Class III cases with a GRTV ratio of 0.33-0.88 can be camouflaged by facemask therapy and those with a ratio below 0.38 should have orthognathic surgery (38).

In conclusion, Class III growth prediction is possible, albeit with a considerable margin of inaccuracy. This should be taken into consideration before commencing any treatment. Because of the unpredictability and long-term nature of mandibular growth, patients should be aware that even if the initial treatment is successful, the patient will be influenced by future growth and should understand that another phase of orthodontic treatment may be required, either to camouflage any resultant relapse or orthognathic surgery in case of severe horizontal growth.

Cervical Skeletal Maturation Indicator

The morphological changes of cervical vertebrae may be used to estimate skeletal maturation stages. This method may be utilised to determine the timing of the pubertal growth spurt and estimate peak growth (39). The hand-wrist radiograph is considered to be the most standardised method of skeletal maturity through staging the carpal bones ossification sequence (39). However, the hand-wrist method is not regarded favourably in Europe because of the high radiation dose delivered however, it is still being used in Australia and East Asia(40). Some

authors advocated the use of chronological and dental age as a guide toward the circum-pubertal phase (41). However, dental eruption is controlled by gender, nutrition, ethnicity and socioeconomic status and is not reliable. Dental calcification shows no correlation with skeletal development (41,42). Chronological age is not well correlated with the growth spurt (33). Peak growth velocity in standing height is considered to be the most valid representation of skeletal growth, but many authors have pointed out that it tends to give little information about the remaining growth or cessation of growth (39). The use of a growth chart for detection of the growth spurt shows high reliability as a biological marker (43). The practical limitation of this method would be the need to repeat measurements at regular intervals for (example every 3 months) to build an individual curve of growth velocity (43). The cervical vertebral skeletal maturation indicator (CS) was proposed by Lamparski in 1972 as a part of his unpublished thesis, it was discussed in detail in the craniofacial growth series (44). However, Lamparski's method was adapted from Bick et al. who introduced the idea of maturity through cervical vertebrae (45). The method was progressively refined until finally Baccetti and co-workers introduced the Cervical Vertebral Maturation (CVM) system in 2007 (46). The CVM system is divided into 6 stages (CS1, CS2, CS3, CS4, CS5, and CS6) as shown in Figure 3. The CVM stages, as described by Baccetti and co-workers, are shown in Table 1:

Stage	Description
CS1	when the inferior borders of vertebral bodies C2 to C4 are flat
CS2	when the concavity at the lower border of C2 is evident and both C3 and C4 are trapezoidal with flat lower borders
CS3	very clear concavity at the lower borders of C2 and C3 with the inferior border of C4 flat still. Sometimes the C3 and C4 will be visualized as rectangular horizontal shapes and at this stage, the maximum growth is expected
CS4	a stage where the lower borders of C2, C3, C4 show a concavity in addition C3 and C4 are still rectangular horizontals in shape. During CS4 the growth is still expected to be at its peak.
CS5	C3 and C4 are showing lower borders concavities and one of the bodies' shapes is square at least and if not square at least one of them rectangular horizontal
CS6	CS6 stage is when C3 and C4 are rectangular vertical shape however, this stage is very challenging which might dictate to measure the posterior and inferior border of the vertebrae bodies

Table 1: Cervical Vertebral Maturation Stages (CVM) as described by Baccetti (2005)

CS1 phase is the ideal time to treat with a facemask and rapid maxillary expansion (RME) (30). Mid-facial growth adaptation takes place during this period since the sutures are still patent. In addition, more skeletal effects can result in comparison to dentoalveolar effects (41). The 3rd to 4th cervical vertebra bodies are trapezoidal during the CS1 stage (41). CS2 stage is considered as a preliminary stage, as the maximum growth of the mandible occurs one year after this stage (41). A reader should keep in mind that the stages are not discrete, but

continuous. For E.g. the terms late CS3 or early CS4 are synonymous (41). During CS4 the growth is still expected to be at its peak.

CS6 stage is a very challenging stage that may require measurement of the posterior and inferior borders of the vertebral bodies, (41). In general, for vertebrae C3 and C4, the posterior border will be longer than the lower border (Figure 3).

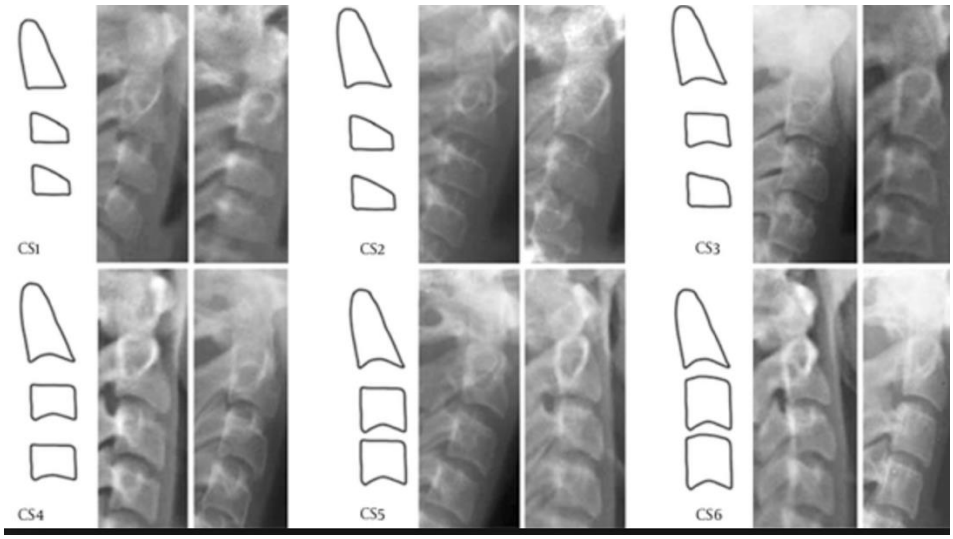

Figure 3: The Cervical Vertebrae Maturation (CS) stages show the progressive alteration in vertebral morphology with age from CS1-CS6.(43)

The CVM is not universally accepted, with doubts as to its reproducibility and accuracy and its ability to predict the growth spurt. Many studies investigating CVM show serious methodological errors and better studies are needed (39). A large proportion of papers showed methodological errors such as failure to report blinding, randomisation or sample size calculations, and repeated use of the same cohort between studies and authors (39,47). Cross-sectional studies are not considered ideal evidence as inter-individual variation is so wide; therefore longitudinal studies are preferable. Studies have found the inter and intra-examiner reliability to be low, in particular, classification of C3 and C4 morphology (47). To eliminate

the methodological shortcomings of previously published studies, Gabriel and co-workers studied 30 randomly selected patients (15 boys and 15 girls) and concluded that the inter-examiner agreement for CVM staging was below 50% for practising orthodontists. For one of the three examiners, staging accuracy was 62 %, with a range of 60 % to 42 % for the other 2 clinicians (47,48). It has also been pointed out that, in some papers, the authors themselves are among the assessors. This creates a bias, as these authors have an experience level in CVM assessment superior to other team members (39). Furthermore, the authors reported reproducibility with the Pearson correlation coefficient, where a more stringent test may have been more appropriate (47). On the other hand, a recent systematic review concluded that the CVM system is a reliable method to replace a hand-wrist radiograph in predicting the pubertal growth spurt (49). A study was conducted in Spain on 958 patients to predict their skeletal maturation via the use of the CVM staging method. The authors concluded that the CVM method is reliable in estimating skeletal growth (50).

Perinetti and co-workers found that proper training for visual assessment of the CVM stages results in good reliability and reproducibility (43). Similar findings were reached by a team at the University of Liverpool. Rainey et al. looked at the reliability of the CVM method. The conclusion was that inter and intra-examiners readings of CVM are repeatable and reliable (51). Care is necessary during interpretation as the cervical vertebra readings do not always follow the rules. It is essential also to take other developmental factors such as stature, chronological age and stages of dental development (52).

Orthopaedic Appliances

For many years, many authors proposed different modalities to treat Class III malocclusions. Intraoral appliances have been used, such as the Frankel III appliance, a functional appliance that claims to promote the growth of the maxilla and restrict the growth of the mandible. The Reverse Twin Block appliance is a variation of the appliance used to treat Class II skeletal malocclusions, modified by inverting the inclined bite planes. This will theoretically restrict mandibular growth and promote maxillary advancement. The effect of such appliances tends to be dentoalveolar, with proclination of upper incisors and retroclination of lower incisors (53). A chin cup is an orthopaedic appliance that was used extensively in the 1950s, designed to restrain forward mandibular growth. However, evidence shows that the benefit of such an appliance is minimal (54). A study by Stensland et al. reported on a group of 51 children treated with a chin cup. They found that 43 children responded in a good way to the treatment while eight responded poorly. The group that responded poorly had particular morphological characteristics such as a shorter cranial base, more prominent chin and more advanced position of the mandible. After 2 years of treatment, they concluded that the size of the anterior cranial base, jaw angle, and size of the inter-incisor angle all played a role in the prognosis of the treatment (55). A similar study found that the chin cup is a good treatment option for patients with Class III malocclusion but as the patient grows, the treatment changes will fade away. The milder the case the better the prognosis (54). A study concluded that the chin cup is preferred for patients with mandibular prognathism while the facemask is the treatment of choice among patients with maxillary deficiency (56,57).

The facemask is a removable extra-oral orthopaedic appliance that is attached to an intraoral appliance via elastics in the canine or molar regions. An upper pad rests on the patient's forehead and a lower pad on the patient's chin. The effects of the facemask are protraction of the maxilla and the maxillary dentoalveolar complex. It is recommended for low-angle patients

as it tends to rotate the mandible downward and backwards and may cause an anterior open bite (58). The facemask can aid in protraction of the maxilla when the cause of skeletal Class III is maxillary retrusion or a combination of maxillary dentoalveolar retrusion and mandibular prognathism (59–61). Both the chin and the forehead act as anchorage for protraction (1). Recently, facemask therapy has been incorporated with mini-implants as a skeletal anchorage, to help overcome proclination of the upper incisors and reduce the retroclination of the lower incisors (5,62,63).

A longitudinal study was carried out on 28 growing children with Class III malocclusions, treated with a protracting facemask and RME (64). Williams et al. performed a longitudinal study to evaluate the effect of facemask appliances. The results showed that the maxilla moved 1.54mm forward and the SNA improved by 0.87 degrees (64). The maxillary teeth are proclined and the lower mandibular incisors are retroclined, in addition to downward and backward rotation of the mandible. The long-term results supported the use of facemask and RME to correct Class III malocclusion (64). A similar study investigated the effect of the facemask and RME on 21 patients at different time intervals, with the conclusion that the maxilla moved anteriorly by 3.34mm and SNA improved by 2.35 degrees in addition to maxillary counter-clockwise rotation (65). The ANB improved by 3.66 degrees and the mandible moved backward and downward with a mild decrease in SNB (-1.32 degrees) (65).

The facemask aids in a downward and forward movement of the maxilla, which will correct maxillary vertical and sagittal deficiencies. It will also rotate the mandible backward and downward which will help in correcting Class III patients (1). It was advocated that the effect of the protraction facemask is enhanced by the addition of RME, which allows the separation of the mid-palatal and circum-maxillary sutures, thus helping to overcome mandibular prognathism (66). Using RME in conjunction with a facemask helped in forward, vertical and lateral movements in comparison to a facemask without RME. Gautam et al also concluded

that using RME with a facemask will give a greater skeletal effect (67). On the other hand, other studies have found no differences between facemask groups treated with or without expanders (62,68).

A study, carried out in China, looked at Class III patients who received facemask treatment versus an observation control group. This was based on cephalometric radiographs taken pre and post-treatment and 2 years post-retention (69). The 20 patients' ages were approximately 8.5±2 years. The results showed that the maxilla moved anteriorly, on average, by 2mm and molar relationships ended up as Class II in some patients. During the post-retention phase, the palatal plane tipped back to its pre-treatment status. During the follow-up period, it was concluded that Class III corrections were stable after 2 years of treatment (69). Another study found that the maxilla moved forward; SNA increased by 2.1degrees and point A moved forward when a facemask was used with RME for approximately 11 months in a group of Class III female patients. The maxilla moved forward with counter-clockwise rotation since the PNS rotated to an inferior position in comparison to ANS. The mandible also rotated clockwise as the lower facial height was increased (70). A landmark systematic review by Kim et al. concluded that treatment of Class III should be performed at a younger age, approximately 9 years. In patients 10 years or older, there is a tendency to have a less skeletal effect and more dentoalveolar effect (8). Early treatment will allow for greater skeletal effects and more stable results. Simpler treatment will be required when passing to the fixed appliance stage, resulting in less iatrogenic damage, and improved patient compliance (1).

Baccetti et al. concluded that there were no differences between a group treated with the protraction facemask and RME versus a control group. The study group was divided into early and late groups: Group I: 7 years ±7 months and group II: 10 years ±12 months. The study found no differences between the late and control groups but did find significant forward positioning of the maxilla and upward tilting of the maxillary plane in the early treatment

group, while the control and later treatment groups showed more downward rotation of the maxilla. Both intervention groups showed minor changes in mandibular protrusion and major changes in the vertical relationship in comparison to the control group (71). It was recommended that the treatment of Class III patients should take place at the age of 8 years, in order to harness significant skeletal effects (58). Unfortunately, the study failed to report any measurement of compliance.

Another study compared a protraction facemask group with an untreated control Class III group. A lateral cephalogram was taken at three-time points (T1 = before treatment, T2 = after treatment, and T3 = after the fixed appliance treatment). The researchers found that after facemask and expansion treatment a forward maxillary movement of approximately 1.8mm occurred in comparison to the control group. Mandibular prognathism was reduced in the sagittal plane as assessed by the Eastman and the Wits analysis (57). During follow-up, the patients in the control group showed a forward mandibular and maxillary movement, but no effect was seen in the treatment group. In general, early treatment with a protraction facemask and RME showed less relapse and led to the long-term stability of up to 75% of the total sample size (57). Similarly, a study was conducted by Masucci et al. to test the effect of a Class III protraction facemask and expansion group with a Class III untreated group. Cephalometric radiographs were taken at different time intervals (T1 = before, T2 = after the facemask, T3 = fixed appliance), with long-term follow-up of both groups. The results showed that ANB improved due to maxillary advancement, with a reduction of mandibular prognathism in the treated group (72).

Macdonald et al. found cephalometric differences among treated Class III patients versus two control groups of Class I and untreated Class III patients. They reported that the maxilla moved forward in the treatment group and during the post-treatment phase. The maxilla grew similarly to the untreated Class III, but less than the Class I patients. The mandible grew similarly

between the study and the control groups. Furthermore, an inter-control comparison showed that in untreated Class IIIs, point A moved forward less, in comparison to the Class I control group. Due to these differences, the use of Class I malocclusion as a control is not recommended, as this will lead to underestimation of treatment effects and overestimation of post-treatment changes (73). Mandall et al. came to similar conclusions, in that that the facemask can improve the maxilla-mandibular relationship and that over-correction is important to ensure that the relapse is reduced to a minimum (74)

A Korean study investigated the effect of protraction headgear with three different skeletal maturation groups. Patients were divided into pre-pubertal, pubertal and post-pubertal stages. It was found that there was no difference in maxillary advancement between pre-pubertal and pubertal stages but there was less advancement in post-pubertal stage patients. In the post-pubertal stage group, dentoalveolar compensation was higher than the other two groups post-treatment. The authors concluded that biological age must be taken into consideration when protraction headgear is going to be used (75).

Facemask therapy shows very promising results if the clinician takes the variables mentioned into account in order to perform appropriate case selection

The Direction of Forces and Magnitudes:

Protraction headgear is usually attached to metal hooks buccal to upper first molar sites, to be as close to the centre of rotation of the maxilla as possible. This has raised the question of whether the attachment site can play a role in controlling the vertical dimension of the face. Backward mandibular rotation may lead to an increase in the lower facial height in Class III patients (1). Ishii et al. reported that if traction were applied to the first molar area, the maxilla would rotate upwards and forwards but if the traction point was at the first premolar site a backward rotation might occur. They concluded that, if the skeletal discrepancy between both

jaws is extreme, then anterior traction at the first molar site should be selected. If the patient is at risk of developing an anterior open bite, then traction should be applied to the first premolar site (28). Alcan et al. stated that forces must be oriented parallel to the Frankfort Horizontal Plane to avoid using the mandible as an anchor (76). The force vector parallel to the occlusal plane will result in the distribution of stress over the maxillofacial sutures, which may lead to a favourable counter-clockwise rotation and forward movement of the naso-maxillary complex (77). Evidence by Keles and coworkers. showed that the direction of force affects the rotation of the maxilla (78). For instance, if the point of force application is anteriorly positioned, it tends to create a clockwise rotation, while a posterior point of force application tends to generate an anticlockwise rotation.

There is a wide variation in the magnitude of force used. Low forces, below 300g per side, were recommended by Berger et al. and by Suda et al. (79,80) Berger et al., stated that the maxilla moved 1.6 degrees (S.D= ±0.4) registered through SNA while Suda et al. showed that the maxilla moved forward 1.24 degrees. Both studies showed a proclination of 2.2 degrees of the upper incisors (S.D= ±0.4). Low forces resulted in maxillary protraction, although not significant to the degree that it would be used in everyday practice (61). Medium forces of 300g and 400g per side were tested by many authors. A study illustrated the use of 380g per side with palatal expansion, the patients were asked to wear the appliance 12 -14 hours per day. The facemask resulted in maxillary advancement, with an increase in SNA of 1.36 degrees, maxillary tooth proclination of 3.4 degrees (S.D= ±7.8) and mandibular incisor retroclination of -5.2 degrees (S.D=±5.6) (69,81). Baccetti, 1998, conducted a study where he used 400g per side, with patients who were assessed according to the stage of their dentition (early or late mixed dentition). Patients were instructed to wear the facemask 14 hours a day and the results demonstrated that, in the early mixed dentition group, the maxillary advancement was 3.58mm (S.D ±2.26) in addition to maxillary dentition proclination of 4.1mm (S.D ±2.4) and lower

incisor retroclination of -1.13mm (S.D ±1.24) In the late mixed dentition, the maxilla advanced by 1mm (S.D ±0.9), much less than the results obtained from the early mixed dentition group and the maxillary teeth proclined 1.98mm (S.D ±0.9) (82). This article illustrated that late mixed dentition treatment tends to show less improvement, but it is wise to keep in mind that these articles did not offer any readings in degrees. This makes it hard to establish precise and reliable comparisons with other evidence (61).

The application of medium forces tends to result in a considerable advancement of the maxilla but more maxillary incisor proclination. It is worth bearing in mind that these studies showed a wide variation in study design, i.e. different methodologies, treatment duration, daily hours of wear, and appliance design. This makes valid comparisons difficult.

High forces of 500g per side and higher were discussed by Tanne and Sakuda in 1991, they looked at the effect of facemask therapy on the craniofacial complex and the resultant morphological skeletal changes (83). The study concluded that the direction and the point of force application must be substantial to induce efficient maxillary growth and forward movement. (61,84). Another study looked at applying forces in different directions, using a facemask appliance, on 20 patients with a mean age of 8 years, who had undergone RME in addition to 16 hours of facemask wear. Two groups were assigned, Group 1 had the force applied at a 30-degree angle below the occlusal plane, and in Group 2 the force was applied 2cm above the maxillary occlusal plane (78). The results showed that the maxilla moved forward based on an increase in SNA of 3.11 degrees (S.D ±1.05) with proclination of upper incisors by 3.6 degrees (S.D ±4.06) in Group 1, while Group 2 showed an increase in SNA of 3.09 degrees (S.D ±1.7) and proclination of upper incisors of 8 degrees (S.D ±3.77) (78). Thus, we can conclude that forces near the maxillary centre of resistance cause more skeletal effects and less dental effects (61). It is worth mentioning that the differences in these studies between

groups might be statistically significant, but clinically they seem to be comparable, not to say, indistinguishable.

The general line of facemask studies indicates that if the facemask and RME are worn, a forward maxillary translation with downward rotation in the same direction of elastic traction will take place, leading to an improvement of a Class III malocclusion. The problems faced by this treatment modality are compliance, that is, wearing the facemask for the required number of hours and undesirable dentoalveolar movement. The optimal amount of force can vary but in general, may be between 180g to 800g per side. The line of force should be 20 -30 degrees below and parallel to the occlusal plane and wearing time may vary between 10 to 24 hours. Table 2 summarises the range of angles and forces advocated.

Author	**Direction to the occlusal plane In degrees**	**Magnitude of force**	**Time (hours)**	**Mean Difference of (SNA degrees) (Mean/SD)**	**Mean Difference of Dental effect (palatal plane/ SN plane in degrees (Mean/SD) or mm**	**Study Design**
Suda et al,.2000 (79)	30	180-250 g	10	1.6 (0.4)	2.2 (0.5)	Cohort
Ngan et al,.1998 (69)	30	380 g	12-14	1.4 (3.4)	3.4 (9.0)	Cohort
Franchi et al. 2000 (71)	Parallel to the occlusal plane	400 g	14	Maxilla:3.58mm Mandible: 1mm	Upper:4.14 (2.4) mm Lower:1.51 (0.9) mm	Cohort
Vaughn et al,.2005 (62)	15-30	300-500 g	24	3.02 (0.68)	1.27 (1.94)	Cohort
Tortop et al. 2000(68)	20	300 g	16	3 (0.4)	1.5 (1.4)	Cohort
Ngan et al,.1996 (81)	30	380 g	12	1.4(3.4)	3.4 (9.0)	Cohort
Ge et al 2012(85)	30	250-400g	14-24	2.44 (0.88)	-0.3	RCT

Ngan et al 2015 (86)	30	400 g	24	2.22(1.44)	1.7(3.57)	Cohort
Zhang et al. 2017 (87)	30	400-500 g	14	3.1	1.5	Case Report
Sar et al. 2011(88)	30	400 g	16	2.53 (1.24)	- 0.83 (3.95	Cohort

Table 2: Angles relative to the occlusal plane (in degrees) and forces used (in grammes) with the resulting skeletal effects (in millimetres) in various facemask studies.

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Skeletal Anchorage

The preponderance of evidence suggests that the facemask can produce proclination of the upper incisors, mesial tipping of upper molars, retroclination of lower incisors as well as downward and backward mandibular rotation (1). Many researchers have investigated the use of skeletal anchorage devices, such as mini-screws, to enhance skeletal effects and reduce the dentoalveolar effect as much as possible. The use of mini-screws allows direct transmission of forces to bone and permits the maximum skeletal effect. This may reduce dentoalveolar side effects, such as mandibular downward-backwards rotation through prevention of molar extrusion, as well as providing skeletal anchorage to allow maxillary protraction. Recently, Cevidanes et al. proposed a treatment modality for patients with Class III skeletal bases. The authors selected 21 Caucasian patients at CVM stages CS1 and CS2 with a mean age of 11±1.8 years. In the study group, four Bollard mini-plates only were inserted in the sub-zygomatic area and the right and left mandibular incisor-canine areas versus RME/FM control group. The mini-plates were activated and left unloaded for 3 weeks after the surgery to allow healing and gain compliance. At 3 weeks 150 grams of force Class III elastic traction per each side was applied, increased to 200 grams after 1 month. Clinicians asked the patients to change the

elastics at least once a day and wear them full-time (89). A Cone Beam Computed Tomogram (CBCT) was taken at T1 (baseline) and T2 (after one year) to construct 3D lateral cephalometry for analysis. The results were outstanding. A forward maxilla movement of 3mm was obtained at Orbitale and 2 mm at the pterygomaxillary suture in the study group, compared to the FM/RME group. In addition, the increase in mandibular length was significantly less in the study group in comparison to the control. The mean overjet was 3.8mm and the soft tissue profile showed significant improvement in comparison to controls, however, no significant changes in maxillary anterior teeth inclination was seen. (Cevidanes et al., 2010). It was concluded that the use of mini-plates results in more maxillary forward movement, by ¼ premolar width, approximately 2-3mm, than the FM/RME group. (89). A follow-up study was conducted by Nguyen et al. using 3D lateral skull radiograph analysis to assess the maxillary changes in detail. The study was made up of 25 treated Class III patients (13 females, 12 males) but no controls. They found that the maxilla moved 3.7mm anteriorly and the maxillary incisors advanced by 4.3mm. In addition, the left and right zygoma showed a mean advancement of 3.6mm and 3.7mm respectively. It was concluded that all circum-maxillary sutures were modified and opened which allowed the forward translation of the maxilla at a young age (92). Another study compared the facemask effect with skeletal anchorage using mini-plate treatment against a control group. The authors concluded that using a facemask and mini-plates resulted in more skeletal effect, in comparison to purely dental anchorage (93). The dilemma of treating the patient at a young age or waiting until the appropriate age is reached to perform osteotomy should be considered. We aim to perform interceptive orthodontics at a young age due to the advantage of open sutures where the maxilla, in theory, is more responsive to anterior traction. Despite that, the uncertainty of the extent of growth should always be considered in treatment planning for Class III cases. Skeletal anchorage tends to be a promising mode of treating Class III malocclusion such as hybrid HYRAX (94), however, there are drawbacks,

such as perforation of the mucosa, gingival inflammation, restriction of tooth movements if the mini-screws are placed between roots, swelling, pain, and transient difficulty in brushing (95,96).

Expansion

The prevalence of transverse maxillary deficiency in patients seeking orthodontic care may reach 23.3% within the primary dentition population (97). Hypoplasia of the maxilla can be attributed to a multifactorial aetiology such as myo-functional disorders, usually associated with deleterious habits such as thumb sucking. In these cases, the tongue may be in an abnormally low position, which leaves room for the antagonist muscles (buccinators) to apply dominant forces and consequently constrict the maxillary arch. The intramembranous maxillary bone formation may be affected by surrounding muscle activity and individual breathing patterns along with development. Hypoplastic maxillae tend to have crossbite and a narrow arch which will affect the buccal corridor size (98). The most serious consequence of maxillary transverse discrepancy might be the narrowing of the nasal cavity, which increases nasal air resistance and may be an aetiological factor in obstructive sleep apnea syndrome (97). Transverse maxillary deficiency can be addressed using RME. The first reported endeavour at RME was by Emerson Angell in 1860, who attempted to expand the maxillary arch to gain space over a period of two weeks, on a girl at age of 14.5 years.

The success of RME is dependent on the stage of maturation of the mid-palatal suture. Maxillary median suture maturation was classified by Melsen through a cadaver histological study. Melsen divided maxillary mid palatal suture maturation into three stages; the first stage is from 0-8 years old (Infantile stage), the second stage from 8 –10 years old (Juvenile stage), and the third stage from 10 –13 years (Adult stage) (99). The theory put forwards was that, in the Infantile stage, the suture is patent and easily responsive to expansion. In the later stages,

the median suture tends to show further interdigitation, thus higher forces are needed to open the suture.

Nanda found that the forces of the rapid maxillary expander modify the circum-maxillary sutures of young Rhesus monkeys (100). Similarly, Baccetti et al. advised using maxillary orthopaedic appliances at Cervical Stage 1 (CS1) till Cervical Stage 3 (CS3), since at this stage the circum-maxillary sutures are patent and responsive to forces (30). Another recent method was introduced by Angelieri et al., based on bone density, to assess the level of midpalatal suture maturity. The authors classified the midpalatal suture as (A) where the midpalatal suture is wide and patent, (B) more interdigitated, (C) tends to appear as two lines along the suture, (D) the line is dense and starts to fade away due to high density and (E) completely disappeared (101). This method can be a game-changer, since we shift from using chronological age, based on a cadaver study by Melsen, to a more relative way of classification, based on CBCT and bone density. This might allow better judgement of the type of expansion possible, based on individual needs.

Hass showed that maxillary expansion is associated with a forward downward movement of the maxilla (66). Protraction headgear should be used after 7-10 days of maxillary expansion to ensure smoother forward translation (62,66). Similarly, a Korean study found that RME with a facemask caused 2mm forward advancement of the maxilla, in comparison to 0.2mm advancement in a control group which used protraction headgear without RME. The maxilla rotated downward and forward, which led to reducing the mandibular plane angle in comparison to the control group (21). On the other hand, other papers stated that there are no differences between facemask groups treated with or without expanders (62,68).

A new form of therapy consisting of Alternate Rapid Maxillary Expansion and Constriction (Alt-RAMEC) was proposed. The rationale of the expansion-constriction cycles is to disarticulate the circum-maxillary sutures thus stimulating forward maxillary translation with

facemask therapy without overexpansion of the maxilla (102). The original experiment on Alt-RAMEC was performed on cats, the RME appliance was fitted intraorally and expansion-constriction cycles were performed for 5 weeks. The cats were sacrificed and skulls harvested. The effect of the Alt-RAMEC was evaluated by passing a 0.5 mm periodontal probe through the maxillary sutures. If the probe did not pass, this indicated that sutures were still interdigitated and not responsive to expansion. It was concluded that this approach resulted in widening the circum-maxillary sutures which, in theory, might aid the further forward movement of the maxilla (103). Subjecting the craniofacial sutures to repeated alternating forces will create an environment similar to sutural growth during development. The compression cycle puts the bone under pressure and activates the osteoclasts through the RANK- RANKL-OPG pathway. This will reduce the sutural interdigitation. The expansion cycle will further separate the bones and allow for more efficient maxillary protraction. Under tension from the facemask, the osteoblasts will deposit bone in the sutures as a form of sutural distraction osteogenesis (103). Liou et al. proposed this method in cleft palate patients where the alternative expansion-constriction pattern resulted in the further translation of maxilla in cleft patients (102). A study used a facemask to protract the maxilla, comparing one-week expansion versus the expansion and constriction cycle. The results showed that the anterior part of the maxilla (Point A) moved twice as much forward in the expansion–constriction group compared to the control group (104). Alt-RAMEC was tested in Germany, on 17 patients with Class III malocclusion. The maxilla translated forward in response to expansion-constriction cycles. Unfortunately, the standard deviations of SNA were not given in this paper, making the results difficult to evaluate (105). A recent systematic review investigated the effect of Alt-RAMEC and it was concluded that this method is effective to translate the maxilla. However, it is believed that Alt-RAMEC is effective in translating the maxilla yet high-quality evidence is needed, Pithon and co-workers found in a systematic review that many articles had high bias

and only a few met selection criteria(12). In conclusion, available data indicates that expansion affects the forward translation of the maxilla, but there is still no clear-cut evidence of whether the Alt-RAMEC approach is the best method to overcome low advancement rates. Clinical studies are required to answer this question.

Wearing Time Compliance

The number of hours of recommended wear varies widely, based on patients' self-reported compliance rate. Wearing the facemask for less than 11 hours was discussed by Suda et al., who advocated the wear time to be 10 hours (79). Another researcher (106), found out that wearing time of 10-12 hours for 10 months resulted in maxillary forward movement, for patients in the deciduous dentition stage. Ngan et al. advocated 12 hours per day of facemask wearing, it was noted that the effects were chiefly dentoalveolar with little skeletal effect (69,81). Another study found that patients who used the facemask 14 hours a day for 6-12 months showed a skeletal effect based on forward advancement of A point and fewer dentoalveolar effects, depending on the subjects' age (107). Despite Saadia and Torres using optimal forces for 12-14 hours per day, the skeletal forward movement was minimal. Vaughn et al. found that the use of the facemask for 24 hours per day resulted in SNA changes of 3 degrees with little dental effect (62).

Ten hours or more wearing facemask results in more desirable skeletal effects and less undesirable dentoalveolar effects such as proclination of upper incisors and retroclination of lower incisors. The exact force needed to cause the maximum skeletal effect is uncertain as all studies have different designs, and use different genders, ages, the direction of forces, and points of application. Thus, this area needs further investigation

Compliance, in health sciences, has been defined as “the extent to which a person’s behaviour coincides with medical or health advice” (108). Due to criticism that the term compliance refers to one aspect and neglects other aspects, it became unpopular and the alternative term “adherence” was introduced. Adherence is defined as “the extent to which a person’s behaviour such as taking medication, following a diet, and/or executing lifestyle changes, corresponds with recommendations the person has agreed upon with a healthcare provider’’ (109). Nevertheless, both terms are now used interchangeably (110).

Patient compliance with treatment cannot be predicted since it has a multifactorial dimension. The main factors controlling treatment adherence are gender, age, psychosocial and socioeconomics (111,112). Thus, it is very difficult to assume which patient will be ideal for orthodontic treatment, where compliance is the essence. Authors have proposed models to predict orthodontic adherence. Bos and co-workers developed a comprehensive model that aims to find the link between patients' compliance with treatment and the role of the orthodontist. Gender, age and personality are unchanged pillars that the clinician has no control over, while the adaptable or changeable factors are pain and physical discomfort (113). If environmental factors, such as treatment time reduction, communication with the patient, behaviour modelling, positive cognitive appraisal and changing beliefs or ideas are taken into consideration, this can improve compliance to orthodontic treatment (114).

It has been documented that the recommended approach results in good treatment compliance outcomes are verbal positive praise and patient education (115). In addition, active educational programs can increase patient compliance (116), and motivation, and cognitive behavioural therapy can be beneficial methods to increase compliance. For instance, cognitive behavioural therapy increased the wear of sleep apnea devices by 3 hours/day in the first month of treatment (117).

Leventhal's common-sense model (CSM) provides a framework for behavioural, and cognitive processes that explain individuals' management of ongoing health threats. CSM is used to understand the relationship between peoples' responses and illness or disease (118). Illness perception influences the outcome and the presence of an action plan can either help in adherence to treatment or vice versa (118). In short, the illness is comprised of personal experience and perception of information. This can be applied to orthodontic treatment where information can be gathered from multiple sources and patients can put together a strategy of how to adapt and comply with treatment. It includes 5 main cognitive domains: 1) identity (label and symptoms), 2) timeline, 3) consequences, 4) cause, and 5) perceived controllability or curability (119). For instance, if a Class III patient is aware of the consequences of failure of treatment, the patient will adopt a routine to wear the orthodontic appliance.

The self-regulation and control theory model is based on objective feedback and observes patient compliance. This model results in patients being more aware and motivated to change their attitude toward the treatment (111,120,121).

The success of orthodontic treatment is proportional to the patient's compliance with the treatment protocol or instructions given by the clinician. Many authors have tried over the years to assess the real compliance rates of patients undergoing orthodontic treatment but the technology available at the time was primitive to arrive at definite conclusions.

Many methods have been used to record compliance rates, such as asking the patient to keep a log of hours an appliance was worn. The obvious disadvantage here is that the patient might not be completely honest about their compliance and objective measurements are required. A study reported the use of a micro-sensor to assess compliance with removable headgear appliances. The sensor was bulky and primitive but proved to be a good way to assess the compliance rate (122).

The performance of compliance sensors has improved considerably with the advancement of technology. One such sensor, the TheraMon sensor (Handelsagentur Gschladt, Hargelsberg, Austria) records the temperature of the oral environment at 15-minute intervals. Temperatures were recorded between 33ºC and 38.50ºC as wear-time. The manufacturing company reports that the sensitivity of the temperature sensor makes it very difficult for patients to fake or manipulate compliance as the software can register any abnormal temperature fluctuations as "doubtful" activity (123). The microsensors convey data through a radio frequency identification reader (RFIR). TheraMon microsensors are small and light 0.40±0.01g, with a length of 13±0.1mm, a width of 9.0±0.1mm and a height of 4.3±0.1mm. They are designed to capture data for 100 consecutive days. The temperature data recorded by the sensor is transferred electronically to the TheraMon station and converted into wearing time by the TheraMon software (TheraMon, Software, Version 2.1.0.13; Handelsagentur, Gschladt, Austria). The data recorded can be adjusted for convenience to daily mean wearing hours or every two days wearing hours.

Compliance sensors accurately record time spent wearing the appliance(124). It was concluded that when sensors were used to assess the compliance rates, the subjects wore the removable appliances on average of 7-8 hours per day, similar to that advised by orthodontists (125). A study conducted in Canada to compare three different types of thermo-sensors concluded that, despite minor differences, the thermo-sensors proved to be sufficiently reliable and valid to be used as compliance detectors (126). Compliance was not influenced by the type of appliance but varied according to age, place, and insurance coverage of the treatment (124). A different approach was taken to assess the compliance rate of two different orthodontic appliances (Frankel II and Bionator) versus the Facemask, both groups had a micro-sensor in their appliance and the authors followed them up for 8 months. The authors concluded that the average compliance recorded by the chips was 8.6 ± 2.9 hours, less than the 13 hours

advocated, and showed a range of fluctuation. Younger patients' compliance rate was significantly higher than adolescents. However, insignificant differences in compliance were found between intra- and extra-oral appliances and neither gender, psychological scores, treatment duration, nor awareness of being monitored had any significant effects (127). Similarly, Tsomos et al. found that patients regularly overestimate orthodontic appliance wear, even when the parent and the children were aware of the recording sensors. Age was a significant factor in the compliance rate but on the other hand, gender was an insignificant variable (128). A similar study supported these conclusions, i.e. that patients' self-reported data of removable orthodontic appliance wear are highly overestimated (129).

A Turkish study found that facemask wear is mainly during bedtime and less during the day, in addition to more compliance during the weekend (130). A systematic review found only 11 studies suitable for inclusion in the quantitative analysis. A weighted estimate of objectively assessed compliance levels about stipulated wear time was calculated, with the discrepancy highest in the headgear group (5.81 hours per day, 95% confidence interval), based on 6 studies. The average discrepancy between self-reported and objectively recorded headgear wear was 5.02 hours per day (95% confidence interval). The authors reported that the compliance rate with removable orthodontic appliances was below the prescribed instructions and patients routinely amplify the duration of wear (129). Techniques for refining compliance have evolved but further evaluation in high-level research is required (129).

A study concluded that the variation in the intraoral position of the sensor can cause fluctuations in results. Following placement of a TheraMon sensor in the lower molar buccal area and palatally in the upper molar area, Brieley et al. found that TheraMon reported fewer wearing hours when placed in the palate, while more realistic results were obtained when it is placed in the lower molar buccal area (131). However, this study had shortcomings. It was a pilot study, with a sample size of only 5 patients. Furthermore, the methodology was flawed.

In the rest position, the tongue does not touch the palate. Salivary flow and mucosal friction tend to be higher on the lower buccal side, in comparison to the palate. Therefore, a sensor placed in the palate will record a lower temperature for reasons other than compliance. It would be more accurate to place them in different intraoral positions and apply the same stimulus to the whole oral cavity, such as eating hot and cold. On the other hand, it was reported that extraoral use of TheraMon is accurate (132). In the latter study, they compared readings of TheraMon at different locations (near orbit, in a trouser pocket and at the forehead) The difference between the results was insignificant and all sites measured comparable readings to the actual wearing time (132). It is worth mentioning that this recording method was outdated since it lacked the calibration system and the new Theramon sensors possess new technology to calibrate and isolate any undesirable background fluctuations that might induce reading biases.

One can therefore assume that the TheraMon sensor is a reliable method to assess compliance. This will help orthodontists to understand the dynamics of patient compliance rates, which will, in turn, aid in determining the effect of patient compliance on protraction headgear effects.

The Impact of Malocclusion on Quality of Life:

Recently, the term “quality of life” emerged in the medical, dental, and philosophical literature. It can be observed that in the sixties and seventies, as medical procedures advanced, researchers started including quality-of-life parameters to measure the outcomes beyond the classical treatment protocols. In the nineties, researchers opened a new dimension of debate by trying to relate patients’ happiness and quality of life with a given treatment modality (133).

Oral Health:

In the past three decades' health was defined as the 'absence of illness' but this sentence is not truly valid. However, the notion of "well-being" is not that definition alone, and the World Health Organization (WHO) in 1948, defined health as the following:

"Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity." Moreover, individual oral health is an important part of general health and a crucial factor that impacts an individual quality of life.

More specifically and closer to our area of interest, oral health was defined by WHO in 2013 as "*a state of being free from chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal disease, tooth decay, and tooth loss, and other diseases and disorders that affect the oral cavity".*

Individuals with an increased concern about their facial appearance have a lower quality of life standards and tend to isolate themselves from society and any social interaction. Any disorder resulting in consequences on oral health may have a huge impact on the physical, social, and psychological well-being of a person (134).

Quality of life:

Quality of life is defined as the "perceptions of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" (135). Oral health-related quality of life (OHRQOL) is a multidimensional construct that reflects on people's comfort when eating, sleeping, and engaging in social interaction; their self-esteem; and their satisfaction concerning their oral health (135).

Lately, we observed a transition from traditional clinical dental/medical treatment outcome criteria which focus on diseases only, such as (caries, periodontitis, gingivitis, etc.) to more patient-centred oral health delivery systems, that focus on a person's social, emotional, and

physical experience. In other words, it should address the patient's health complaints and take into consideration the impact of the patient illness on his/her quality of life (136). Oral health-related quality of life assists in making clinical decisions, taking into account patients' desires and emotional and physical needs (137).

Health-related quality of life and theoretical models:

Researchers have tried to elucidate how oral health is related to the quality of life (138) and to understand the relationship between diagnosis and information from clinical examinations, person-centred, self-reported health and health experiences (136). Many authors considered the impact of the disease on an individual's quality of life and tried to formulate theoretical models to explain the interrelation between health and sickness and quality of life. All these models attempted to explain the illness from multi-dimensional aspects; the following models can illustrate these interactions:

Wilson and Cleary model (1995):

Wilson and Cleary presented a conceptual model that is composed of five aspects: physiological factors, symptom status, functional health, general health perceptions and overall quality of life. It was proposed that physiological variables influence symptom status, which in turn influences functional health. The latter health affects general health perceptions that affect ultimately the overall quality of life (139).

Oral Health-Related Quality of Life in children (2011):

The theoretical model proposed by Sischo and Broder combined biological, social, cultural and psychological factors. This model was adapted from the Wilson & Clearly model. It linked

health status and/or clinical variables, functional status, oral-facial appearance, psychological status, OHRQoL and overall QoL. Besides, this model also illustrated the effects of environmental factors, such as education, family income and structure, sociocultural factors and access to care on oral health perception and QOL (136).

Conceptual Framework:

The conceptual framework, described by Locker, (140) is based on the WHO classification of impairment, handicap and disability. It attempts to record the psychosocial and functional consequences of illness (141).

Malocclusion is one of the most common oral disorders and its prevalence is high in most countries (142). The main reasons for malocclusion are a combination of genetic and environmental factors. The shift from a diet consisting of unrefined foods to one of softer processed foods has been reported to be a factor in the increase in the prevalence of malocclusion in modern times compared to prehistoric times (141,143). It is reported that traumatic overbite cases can cause pain leading to a poorer quality of life (144). Increased overjet may have a significant effect on the QOL of an individual, it is reported that individuals with over jets greater than 3 mm were two and half times more at risk of trauma than individuals with normal overjet (145). On the other hand, early treatment can improve the quality of life and self-esteem of the patient, who will have fewer negative social experiences (146).

Malocclusion is the most common oral disorder which can cause negative impacts on social life and self-confidence and may be greatly associated with negative psychological connotations (147). Orthodontic treatment of malocclusion from a purely clinical perspective may therefore not address patients' concerns completely (141). Orthodontic treatment expectations showed to be similar for the patient and parents in most aspects. Ethnicity was shown to significantly affect expectations for the outcome of orthodontic treatment (148).

Studies reported that while the OHRQoL worsened during the treatment process in intervention groups, there was a considerable improvement afterwards (149,150).

A study that used the short form of the Child Perceptions Questionnaire (CPQ11-14) was used to compare the difference in terms of impact on daily quality of life during the treatment period, in two groups of children who received functional appliances and headgear respectively. Subjects in both groups demonstrated lower OHRQOL scores during the treatment phase, in comparison to the control group (151).

Researchers reported conflicting results with regards to the connection between malocclusion or orthodontic treatment needs and oral health-related quality of life. Some reported a strong correlation (152), whilst others found no such relation (153). The previous findings confirm that patients' subjective and objective opinions are the most important variable in this equation, which can sustain or negate any correlation.

Assessment methods for measuring OHRQoL:

There are two broad categories used for the assessment and evaluation of OHRQoL, some being generic measures and others disease-specific. The generic measures can be applied to several disorders/diseases and evaluate the impact on QoL, while the disease-specific measure evaluates disorder impact on the QoL using distinct tools. However, some researchers pointed out that it is not appropriate to use generic measures for the assessment of OHRQoL in people suffering from oral disorders or orofacial syndromes, since these generic tools do not accurately evaluate such problems and as a result, the QoL evaluation will not be sensitive nor accurate (154).

Disease-specific assessment measures have more advantages over generic tools. They were established for specific conditions which enhance the sensitivity of the tool compared to generic instruments (136). However, the disease-specific instruments may focus precisely on

symptoms, so they fail to register some broader domains included in generic instruments (154). Similarly, questionnaires that target children are the Child Oral Health Quality of Life (COHQoL) questionnaire and the Child-Oral Impacts on Daily Performances (Child-OIDP) (155,156). COHQoL is a multidimensional scale that measures oral and orofacial disease and abnormality impact on quality of life. One of the components on COHQoL is CPQ 11-14. It was adopted for simplicity of use and feasibility in a clinical setting (157).

Child Perception Questionnaire (CPQ 11-14)

The CPQ11-14 was devised based on a process defined by Guyatt et al (158). Items were created in two stages. The first, comprised of 46 items, was developed by an evaluation of available oral health and child health status measures. These encompassed four domains: oral symptoms, functional limitations, emotional well-being and social well-being (peer interaction, schooling and leisure activities). Second, the significance and importance of these items were evaluated by an expert board composed of 17 health professionals, who treat children with oral and oro-facial disorders and 33 parents of child patients with these conditions. Based on their answers and remarks, the authors developed 50 items by writing additional items, excluding irrelevant items, and combining items. These were revised further following in-depth interviews with 11 child patients. Items for the final questionnaire were selected using an item impact study (158).

Children from three clinical groups were chosen. This was followed by a face to face interview, for every child that had experienced, in the past three months, any problem described by the questionnaire. The response scoring followed the Likert scale:

- 1= Does not bother me at all.
- 5= Severe bother.

Toward the end of the research, the investigators calculated an impact score by multiplying the percentage of children's positive answers. Items were divided into four health domains according to their scores, and items above the median were chosen for the final CPQ (11-14) survey (155,158).

The final CPQ (11-14) is made of 37 items divided into four health domains as follows:

- Oral symptoms (six items).
- Functional limitations (nine items).
- Emotional wellbeing (nine items).
- Social well-being (thirteen items).

The questionnaire scores were answers on the scale (“never” = 1, “once or twice” = 2, “sometimes” = 3, “often” = 4, “everyday” = 5. The CPQ (11-14) has items to assess global ratings of children’s oral health and to what degree the oral conditions affect overall well-being. The scores of global rating items of oral health range from 1 = “excellent” to 5 = “poor” and for the wellbeing domain 0 = “not at all” and 5 = “very much” for well-being (155).

The reliability and validity of CPQ (11-14) were assessed by the University of Toronto, involving a new sample of 123 children recruited from paediatric dentistry, craniofacial and orthodontic departments.

The CPQ questionnaire was associated with different parameters such as orthodontics, dental anomalies, temporomandibular disorders (TMD), periodontology, restorative dentistry (dental caries, fluorosis, tooth erosion, enamel defects), oral surgery and trauma, and systemic diseases (159). Foster Page et al. tested the validity of CPQ (11-14) on a random 430 children aged between 12-13 years old in New Zealand (160). It was concluded that children with higher dental caries rates and severe malocclusions had higher overall CPQ11-14 scores, and the top

quartile of DMFT scores had higher CPQ11-14 scores overall and higher for each domain of CPQ11-14 (161).

Many authors assessed the impact of malocclusion on the quality of life using CPQ11-14 (155,162,163). They all agreed that the CPQ 11-14 is a valid and reliable tool for orthodontic research, in addition to the presence of malocclusion in growing children, which has had a negative impact on their wellbeing and OHRQoL compared to malocclusion-free children. Finally, it was advised that longitudinal analysis of cohorts with the short version of CPQ 11-14 worded precisely for malocclusion might be more useful for future trials.

A short form of CPQ11-14 was established (157), which enabled the usage of CPQ11-14 in clinical settings and oral health-based surveys. The CPQ11-14 was shortened to 16 and 8 items respectively. The Items Impact Method was used to assess which domain most commonly affects individual health. The short version of CPQ11-14 showed variability among children, however, the mean scores of the short form of CPQ11-14 are higher than the original CPQ11-14 ($P<0.001$) and a strong correlation exists between the short version of CPQ11-14 and the original version (0.81-0.98) ($P<0.001$). Short forms of CPQ11-14 showed a positive correlation with scores of oral health and wellbeing. The relative validity coefficient was 0.81-1.18 and Cronbach's alpha ranges between (0.71-0.83) while the correlation coefficient ranged from (0.71-0.77). It was concluded that the short version of CPQ11-14 is an excellent tool to be used clinically (155). A study was conducted in the UK to evaluate the validity and reliability of CPQ11-14. Eighty-nine children between 11-14 years old were investigated by clinicians. The clinical investigators looked at caries, white spot lesions, gingival abnormalities, and malocclusions. The results showed that Cronbach's alpha for the total scale was 0.81. In addition, the Intra Class Correlation (ICC) of repeated measurements showed a high level of agreement (0.81) (164).

Foster Page and co-workers tested the validity of CPQ (11-14) on a random 430 children aged between 12-13 years old in New Zealand (160). It was concluded that children with higher dental caries rates and severe malocclusions had higher overall CPQ11-14 scores, and the top quartile of DMFT scores had higher CPQ11-14 scores overall and higher for each domain of CPQ11-14 (161).

It was

Cross-cultural reliability was examined by many investigators. It was found that CPQ 11-14 in Portuguese was valid and showed acceptable psychometric properties when it was tested in Brazil (165,166). Furthermore, it was found that Iranian, Chinese, Arabic and Danish forms of CPQ11-14 were considered reliable and valid when psychometric aspects were examined (167–169).

A modification was adopted to enable clinicians to use CPQ for younger age children between 8-10 years old. Reliability of the CPQ 8-10 and CPQ11-14 groups, ranged from 0.67 for oral symptoms to 0.92 for social well-being, and from 0.75 for oral symptoms to 0.90 for emotional well-being, respectively, indicating acceptable to good internal consistency (170-173). It was concluded that CPQ 11-14 and CPQ 8-10 are equivalent in efficiency, reliability, and validity (170,171). However, the Maltese version of CPQ 8-10 is not available and it is worth validating. The original English CPQ 8-10 should be analysed versus the proposed future Maltese CPQ 8-10 and a very good internal consistency should be reached to enable the use of the proposed questionnaire locally.

In conclusion, CPQ 8-10 is a reliable method to assess the quality of life and behaviour which assists researchers to investigate and research with a specific tool that is directed to children of a specific age.

Conclusions and Statement of the Problems

The consensus of clinical experience and research emphasises the notion that the management of Class III malocclusion is considered challenging to treat due to its multifactorial aetiology and varying degrees of severity. Many authors advocate that treatment should start at 8 to 10 years old to obtain the maximum skeletal effect (8,172). Notwithstanding, there is a paucity of evidence demonstrating the impact of patients' compliance rate on treatment outcomes, i.e. dental and skeletal effects. In addition, there is a lack of evidence to support the notion that skeletal anchorage, used in conjunction with protraction headgear, is superior to tooth-borne, protraction headgear. Furthermore, although there is ongoing research into the different aspects of treatment impact on patients' quality of life, to date, no research has looked at the impact of protraction headgear on patients' quality of life, or if the treatment of Class III malocclusion improves patients' quality of life. Although several articles have been published on the management of Class III malocclusions, many questions remain. Specifically, the diverse treatment protocols recommended should be investigated to include clinically recognised and accepted outcomes, as well as their impact on the patient's quality of life. Furthermore, more accurate long-term studies reporting in a standardised manner on treatment protocols are required to allow meaningful comparison.

Aims of the Study

Primary Aim:

Objective quantification of patients' compliance with facemask therapy and associated clinical outcomes in patients treated with a skeletally anchored RME versus a Tooth-borne RME, using the Alt-RAMEC protocol and protraction headgear.

Secondary Aim:

To assess the effectiveness of skeletal and dentoalveolar outcomes of a skeletally anchored RME/Alt-RAMEC protocol versus a Tooth-borne RME/ Alt-RAMEC protocol, using protraction headgear.

Tertiary Aim:

To investigate patient-reported outcomes, specifically oral-health related quality of life and associated economic analysis in patients treated with a skeletally anchored RME versus a Tooth-borne RME, using protraction headgear

Null Hypotheses

In patients treated with skeletally anchored RME versus a Tooth-borne RME, using the Alt-RAMEC protocol and protraction headgear, there are:

- No differences in patients' compliance rates.
- No differences in the skeletal and dental outcomes.
- No differences in patients' reported outcomes.

Chapter 2

Patients And Methods

Ethics and Law

A detailed research protocol was prepared to abide by all the requirements as stated in the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, WMA General Assembly (173).

The protocol was submitted for consideration, guidance and approval to the Faculty of Dental Surgery Research Ethics Committee (FREC) and the Research Ethics Committee at the Ministry for Health. The research was granted ethical approval for the present Single Center RCT (HEC04/19). Copies of the approval letters are found in Appendix I.

The study was registered as a Randomised Clinical Trial (RCT) with ISRCTN (ISRCTN12197405, https://doi.org/10.1186/ISRCTN12197405).

Study sample size, inclusion criteria, recruitment & randomization

Sample size calculation was made initially with the statistician, to estimate the number of patients required to estimate the skeletal and dentoalveolar outcomes as a primary outcome. Unfortunately, the sample size indicated that each group should have 1000 patients. The large number was attributed to the similarity of measurement between tooth-borne and skeletal-borne RME/FM published data in 2018. As a result, the statistician suggested changing the research order, by placing patient compliance (wearing hours per day) as a primary outcome which resulted in 17 patients per group. It is worth mentioning that the sample size is similar to almost 14 published articles mentioned in Wu et al. systematic review (174). The sample size was calculated based on a significance level of $\alpha = 0.05$ and a power of 80% to detect a clinically meaningful difference of 1 degree (±0.97) for the SNA for 12 hours of wear of the facemask (175,176). Sample size calculation was performed using the online calculator (http://powerandsamplesize.com/Calculators/).

Inclusion criteria were as follows:

- Skeletal Class III malocclusion
- Negative Overjet
- No sign of a functional shift
- No history of TMD, congenital deformities or previous orthodontic treatment.
- Young Caucasian, prepubertal patient (8-10.99 years).

Exclusion criteria:

- Previously treated with an orthodontic appliance
- Craniofacial anomalies affecting the growth of the jaws
- Patient with skeletal Class I and II malocclusion.
- Patients with a functional shift.

Patient Recruitment

A senior dental surgery assistant acted as an intermediary and invited every eligible patient together with the parent or guardian to participate in the study (Invitation letters in Appendices II and III). Patients were given information leaflets, a consent form for the parent and an assent form for the child patient (Appendix IV). In case of refusal, the patient was referred to Mater Dei Hospital Orthodontic Department to receive a conventional removable appliance in National Health Service treatment or back to their Private Practitioner as appropriate. Consenting patients were examined by the PI only. Patients were told clearly that they could withdraw at any point and that participation was voluntary.

Randomisation

The study was designed following Consort guidelines (177) (Figure 4). The allocation of study subjects was done using an online randomisation tool (www.randomizer.at). The software generated codes for each patient, to pseudonymise the study, and assign the patients 1:1 into one of two groups: Group I (tooth-borne FM/RME) and Group II (skeletally anchored FM/RME).

The codes were placed into sealed envelopes and handed to the patient via an intermediary nurse. Each patient and guardian were met by an intermediary nurse and the study was explained in detail. Having consented, the patient was asked to open the envelope to determine

which group he/she belonged to. The principal investigator (PI) then planned the appropriate treatment. If the patient or parent objected to their allocated group, the patient was referred to Mater Dei Hospital Orthodontic Department to receive a removable appliance at National Health Service treatment or back to their Private Practitioner as appropriate

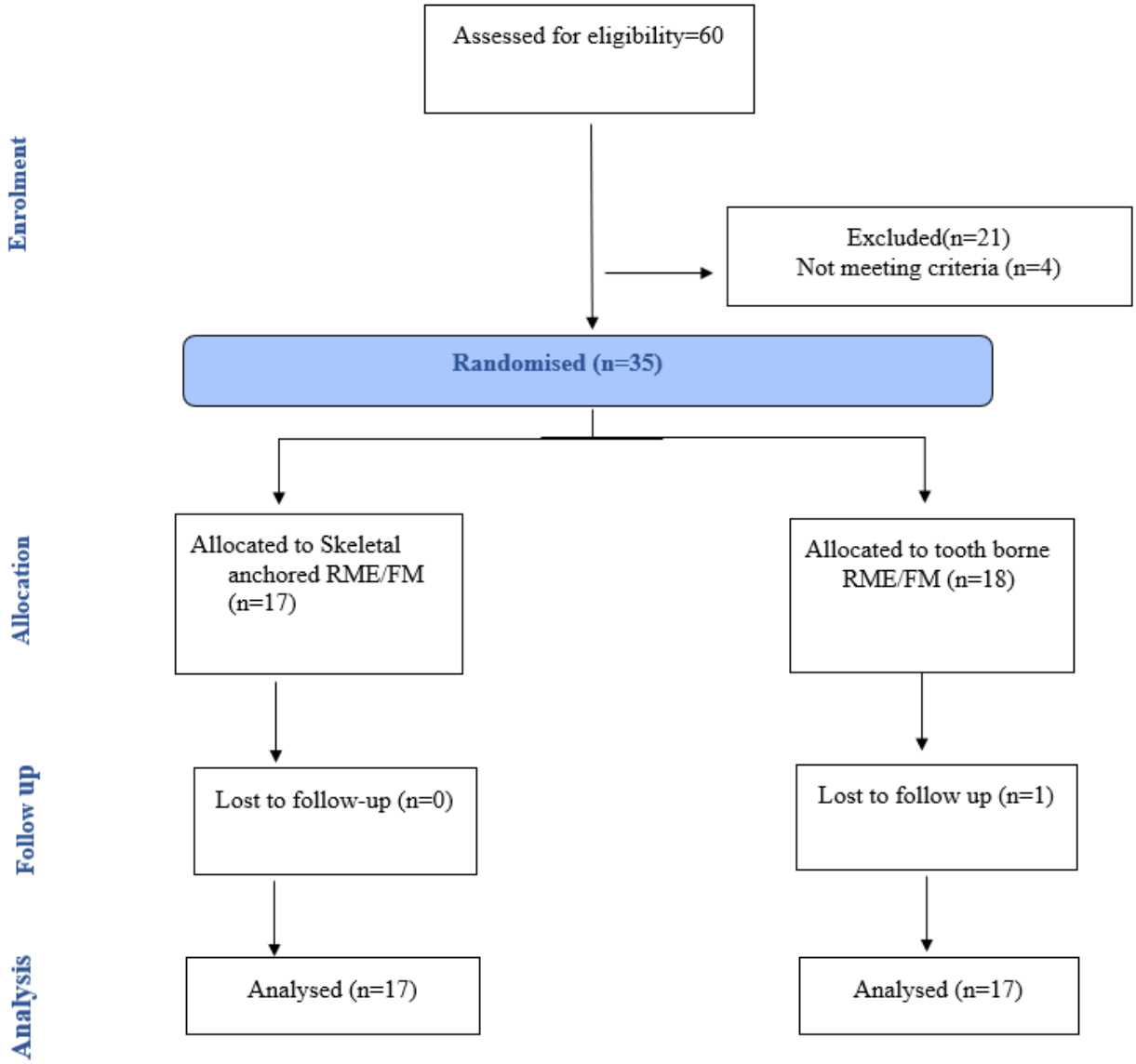

Figure 4: Consort Flow Chart showing the structure of the Prospective Randomised Controlled Trial.

Clinical Intervention

Tooth-borne RME (McNamara design) was fabricated, and bands were placed on UR6, UL6, ULD, and URD with a half band with a palatal coverage on the ULD and URD (Figure 5). The skeletally anchored RME group had two temporary anchorage devices (TAD) 9 mm in length X 2 mm in width, inserted freehand with no surgical guide, paramedian at the third rugae region, as described previously in the literature (178) (Figure 6). The diameter of TADs was chosen to resist the torsional forces once inserted into the palatal bone to avoid fracture. Patients were instructed on how to use the appliance- the RME was opened and closed twice daily (0.2mm per turn) for 7 weeks in both groups.

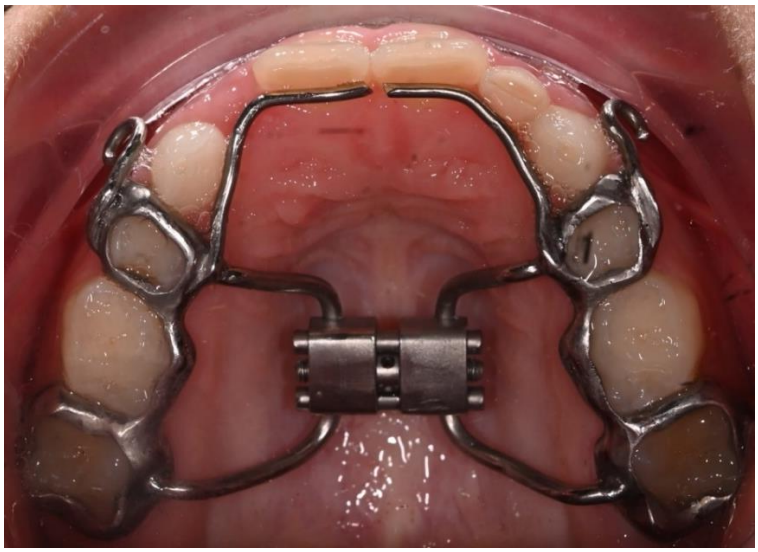

Figure 5: McNamara expander banded on URD ULD and UR6 UL6

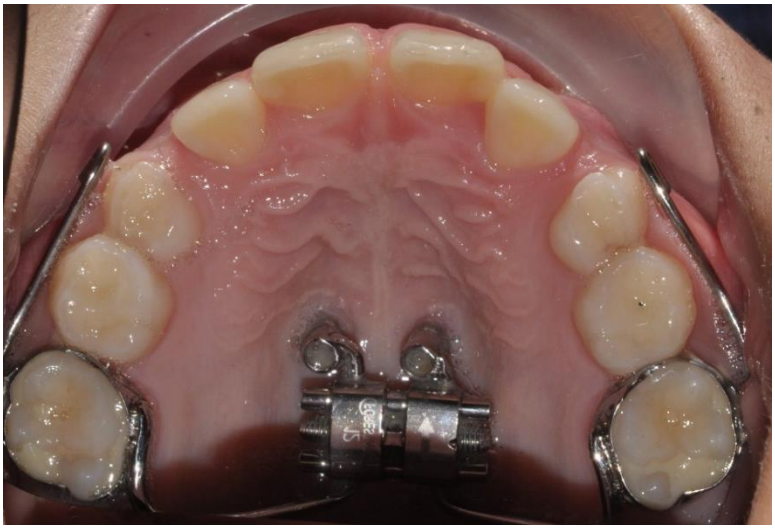

Figure 6: Mini implant PSM 9 X2 mm placed paramedian of midplatal suture.

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In both groups, a Petit facemask (Forestadent, Germany) was used (179). A protraction force of 500g per side, with an anteroinferior force vector of approximately 30 degrees to the occlusal plane, was applied to hooks placed at the canine region on the buccal side of the expanders. The patients were instructed to wear the FM at least 12 -14 hours per day until a 2 mm positive overjet was achieved. The patient was asked to change the extraoral elastics daily.

The lateral cephalometric analysis was a composite of two analyses, the McNamara and Eastman analysis by Mills, to allow a standardised reproducible, scientifically valid approach (180). Both analyses have skeletal sagittal and vertical components in addition to dentoalveolar components. The Dolphin software (Dolphin Imaging and Management Solutions® Version 11.95, USA) was used for digital analysis of the lateral cephalograms. This software has a feature that allows the selection of the required points and planes from the McNamara and Mills analyses, and their subsequent merging in one customised analysis (Appendix VI).

The standardised lateral cephalograms were taken by an experienced radiographer at the treatment planning stage (T0) and the end of the FM treatment (T1) using the same cephalostat (Siemens Nanodor 2, Siemens AG, Munich, Germany). The lateral cephalograms were traced by the (PI), on average 1 lateral cephalometric view day to avoid scoring fatigue. When all tracings were finished, 3 days were left as a washout period and the second round of tracings was done by the PI, in order to estimate the intraexaminer error. This was done at a rate of five lateral cephalometric views per week. In order to ensure blinding, patients' appliances were removed before taking the T1 cephalometric radiograph. Once the lateral cephalogram was taken, the image was cropped to remove any patient details and traced at a later time. A second clinician (RH), a specialist orthodontist experienced in lateral cephalometric tracing, performed tracing on 15 views, selected at random, in order to assess inter-examiner error.

Tracing was performed digitally with Dolphin (Dolphin Imaging and Management Solutions® Version 11.95, USA) (Figure 7). The skeletal and dental reference points were positioned on

the Dolphin tracing screen by the PI and by RH separately and the results were subsequently compared.

Both the PI and RH underwent training in the CS staging method. The training was based on using the Cervical Staging user manual and communicating with Prof. Lorenzo Franchi for guidance (41). Once calibration was complete, the CS staging was scored by examining the lateral cephalogram at T0 and the CVM scores were tabulated. Following a washout period of 2 weeks, all the lateral cephalograms were scored by the PI to assess intra-examiner error. Twenty radiographs were randomly selected and scored by RH to assess inter-examiner error.

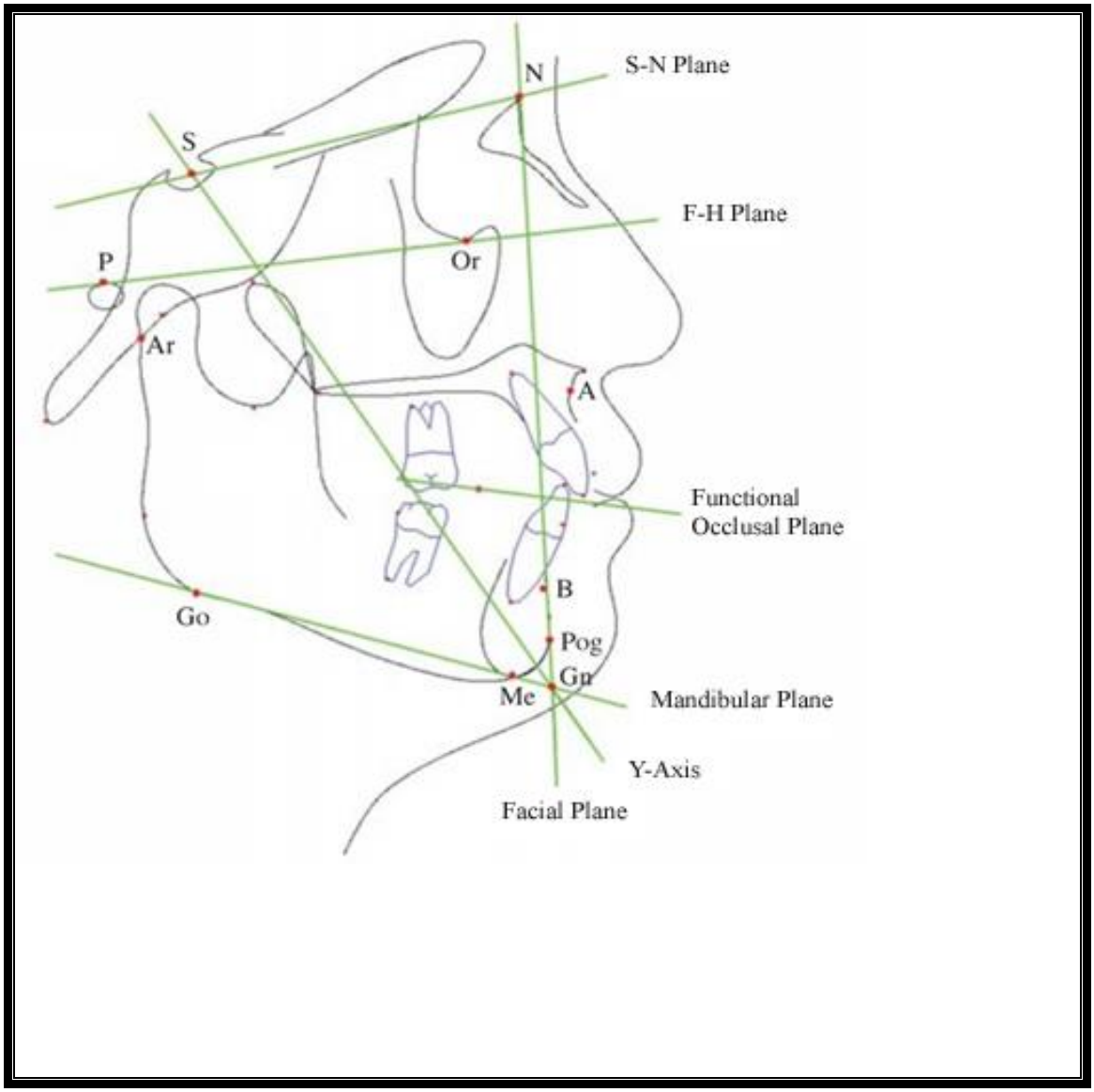

Figure 7: Cephalometric angles and planes used as reference lines and points

Clinical and Laboratory Procedures

Although patients had already agreed to participate in the study, treatment procedures were reviewed again at every visit to ascertain that the child patient and legal guardians were aware of every clinical step. Informed consent was invariably obtained from all patients recruited in both groups.

The skeletally anchored RME group received pre-operative instructions. Topical analgesia was applied (Topix, Benzocaine 20%), followed by 75% of a local analgesic carpule (2% Lidocaine, Epinephrine1:80000, 1 cartridge) in the paramedian region, behind the third palatal rugae. A 5-minute wait allowed full analgesia and two molar bands were placed on the upper left first molar (26) and upper right first molar (16).

A preliminary osteotomy was performed with a pilot drill in the paramedian region behind the third rugae area (181). In some instances the child presented with a very small palate, making it impossible to place the mini-implants in the said position thus, they were placed slightly ahead of the third rugae. Two titanium mini-screws (9 mm X 2mm), (PSM Medical Solutions, Germany) were inserted using a digital, pre-calibrated digital mini implant micromotor system (NSK iSD900, Japan) paramedian to the mid-palatal suture, with a torque of 32 Newton until the implants were fully inserted (182). Due to the ethical committee restrictions, CBCT could not be taken to assess bicortical anchorage(182). Implants caps were placed on the PSM mini implants and a fast-setting silicone putty impression was taken. A mini implant analogue was placed in the mini implant caps, in the silicone impression. The dental assistant disinfected the impression by spraying it with Zeta 7 spray (Zhermack, Switzerland) and then sent it to the laboratory.

Patients assigned to the Tooth-borne RME arm received molar bands on the 16, 26, URD, and ULD and a fast-setting silicone putty impression was taken (Zhermack, Hydrorise putty). A Forestadent Snap Lock expander was used (Dimension 16 & expansion 12) and soldered to the bands.

Insertion of Appliances:

Prior to seating the appliance intraorally, it was inspected for any sharp edges or defects. Intraorally, moisture control was achieved via the use of low-volume suction and cotton wool

rolls. The Dental Surgery Assistant mixed Ketac-Cem (3M ESPE, Gmbh, Seefeld, Germany) and placed it around the inner rim of the bands. In the case of the implant-anchored expander appliance, the abutment head was screwed to ensure full engagement between the implant and the head. Post-operative instructions were given, both verbally and in writing. In particular, patients were given instructions about how to take care of the appliance with an emphasis on cleaning and avoiding any intentional sabotage of the appliance such as dislodging it with the tongue or fingerpicking it.

Provision of Facemask and Measurement of its Utilisation:

The expanders in both groups were attached to a Petit facemask via extraoral elastics. The elastics used initially were (MASEL™) extraoral elastics. The starting force was 220 g per side, then the force was increased to 450 g after the distance from the traction hook arm to the facemask was seen to decrease. The extra-oral elastics were attached to the facemask at 30 degrees below the occlusal plane with a force of 450 g per side. The extraoral forces were measured with a Dillon GL force gauge (Fairmont, MN, USA).

Patients were asked to wear the facemask appliance between 12-14 hours daily and were asked to register their average daily wear as a self-reported method. Furthermore, a thermal sensor was used in the forehead region to record patients' temperature. TheraMon chips (TheraMon Microelectronic System; MC Technology GmbH) were integrated into the facemasks to objectively document the compliance of the patient. A small indentation was made on the underside of the forehead foam pad with a scalpel. The sensor was placed in it and the foam pad was attached to the facemask (Figure 8). The sensor was calibrated as per the manufacturer's description and was set to record a range of temperature between 35-38 C°. The range was set following an online meeting with IT developers at the manufacturing company,

where it was agreed that this range would be the most realistic reflection of the body temperature fluctuations. Patients were given a chart to fill, which contained the date and number of hours worn per day.

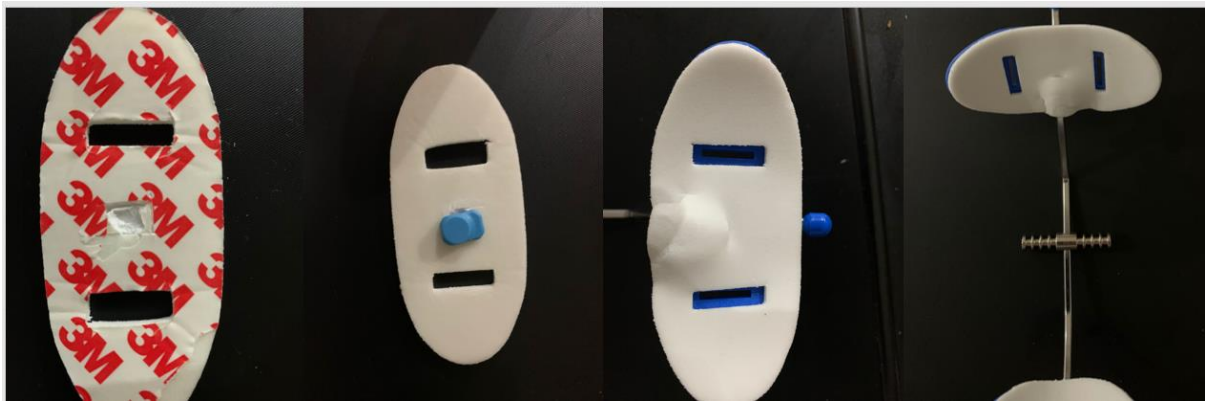

Figure 8: Theramon sensor preparation prior to delivery of facemask to the patient, with blade number 15 a slice of forehead cotton is removed to place the sensor.

Facemasks with sensors were given to Group I (18 FM with tooth-borne RME with Alt-RAMEC) and Group II (17 FM with skeletally anchored RME with Alt-RAMEC). Patients were aware of the presence of the sensor however the principal clinician did not convey the real purpose of the sensor. The patients were told that the sensor function is to balance the forces between the right and left side of the face, as a consequence eliminating the Hawthorne bias effect Patients were followed up for 9 months, and visits were made on monthly basis to download data from the microsensor and to assess wearing behaviour. During the review, the 'patient's sensor was scanned with the TheraMon reader. The data collected from the sensor were transferred to the TheraMon cloud. This enabled the PI to input the data into compliance charts. The data were then exported to an Excel (Microsoft Corporation, USA) worksheet and tabulated for each patient. Patients' names and identities were blinded, based on the code given through the randomisation process. In case any search was needed in the Theramon Cloud, searching by the given code is the standard criterion.

Measurement of the Child Patients' Oral health-related Quality of Life: Since Malta is a bilingual country (Maltese and English) a pilot study was conducted to validate the sensitivity of Maltese CPQ 8-10. The total score can vary from 25 to 125, the higher the score the poorer the quality of life and vice versa. Translation of the CPQ8-10 questionnaire The English CPQ8–10 version (Appendix V) was translated into one of the Maltese languages using the forward-backwards technique for translating (183). Translation from English to the Maltese language was performed by a board of four native-speaking Maltese linguistics. The first translator was a dentist, who previously participated in the translation of the Oral Health Impact Profile (183). The second translator was the pediatric dentist who works with children. The third and fourth translation was performed by Maltese language teachers All translations were edited until an agreement was reached. The Maltese version of the CPQ8-10 was back-translated into the English language by a Maltese linguistic teacher. This translated version was compared to the original questionnaire. CPQ 8-10 was distributed to children and asked to score the Maltese and English versions and report if there are any complicated questions. In the teaching clinic at the University of Malta, 48 children were selected to fill out the questionnaire. Validity was assessed by administering the questionnaires 3 weeks later to 17 participants and asking them to score CPQ 8-10. Once the agreement was reached, both Maltese and English CPQ 8-10 can be used.

The questionnaire has two questions at the beginning to collect demographic data (age, gender). The questionnaire scores answers were on the scale ("never" = 1, "once or twice" = 2, "sometimes" = 3, "often "= 4 and "everyday" = 5). A global score of 125 reflects poor quality of life while a score of 25 reflects a very good quality of life.

On the day of record taking the consent and assent forms were signed, and the intermediary nurse handed both patient and parents a CPQ 8-10 questionnaire form (Appendix V) to fill in

at home. The same form was given to the patients at each orthodontic review, i.e. on a monthly basis. CPQ 8-10 covers the following domains:

Oral complaint (5 items).

Functional limitations (5 items).

Emotional well-being (5 items).

Social well-being (10 items).

Global outcome (25 items).

The questionnaires were handed to an intermediary towards the end of the clinical session ensuring that patients' codes were written on them to tabulate them in an Excel worksheet. Due to the COVID pandemic, the questionnaires were sent to parents via mail and the parents used to send them back. Furthermore, due to the lockdown, all review appointments were performed via telecommunication (teledentistry) for a few months, thus all questionnaires were sent via emails.

Economic Analysis

The clinical costs and associated time costs involved in the management of the patients throughout the study were calculated. The Human Capital Approach was employed to give value to the time that the patient spent in the clinic.

The clinical costs from the initial treatment (consultations, preparation and delivery of orthodontic appliance, and the actual surgery which involved the installation of the mini-implants in group 2 and all the follow-up visits included the cost of orthodontic reviews, maintenance and complications including the respective clinical treatment.

Costs for the Initial Treatment:

The costs for initial treatment were collected and consisted of a global figure initial treatment which included the costs for the orthodontic appliances, and cephalometric imaging mini-implants for group 2 patients. The initial treatment costs also included the professional fees (orthodontist and auxiliary staff in a hospital setting) required to provide the service.

The appliances of Group I were fabricated by the senior dental technician at the University of Malta Dental Laboratory (MZ), while Group II appliances were fabricated by a private laboratory technician (MM) as these are not available in the University of Malta Dental Laboratory.

The total cost of a skeletally anchored rapid maxillary expander appliance with two mini implants is Euros 405 including laboratory fees and mini-implants, while the tooth-borne rapid maxillary expander appliance was Euros 150 including laboratory fees.

The costs included all the scheduled orthodontic treatment visits and unscheduled visits required by the patients for maintenance such as appliance adjustments and repairs and the complications such as the remaking of these appliances when necessary. In addition, the total costs of appliances in each group were calculated based on the initial costs of items and the dental laboratory assembly cost. Emergency appointments were considered to consist of the following: broken traction hook, broken bands, broken solder between expander and bands, poorly fitting appliances, and lack of proper retention. The emergency repairs cost as follows, in Malta, (Table 3):

Emergency type	Costs/ Euros
Broken Traction hooks arms repair	15
Broken appliance in group II	405
Repairs solder in Group I and II	25
New appliance in Group I	150
Cement	1
Impression material	1.0

Table 3: Cost of different types of emergency procedures performed in Group I and II in Euros

Clinical Time Measurement per Visit

The number and nature of visits and associated time for each intervention were recorded with a stopwatch. The clinical time was measured from when the patient entered and left the clinic (including waiting time). Due to the COVID pandemic estimating travel time couldn't be accurate, since the majority of follow-up during the first few months were done via telecommunication (teledentistry). Taking into consideration that the compliance sensor can store data for up to 100+ days and can be collected later on.

A stopwatch (Casio, Japan) was used to measure the time of each consultation, review and emergency appointment. The Dental Surgery Assistant started the time when the patient was seated on the chair and stopped when the patient was finished and the chair was upright. The time was recorded in minutes. The PI noted the type of visit, what was done to the patient and the time consumed per visit.

Financial costs were calculated as summarised in Table 4:

Definitions	Time (min)	Costs (€)
Consultations	Time consumed in consultation for both groups (Orthodontist and nurse fees included)	x 70 € / hours
Facemask		10
Compliance Sensor		6
Bands, impression material and cement		8
Tooth-borne expander appliance		150
Skeletal borne expander with implant fixtures and abutment head		405
Review	Sum of Review times T1 to T9	x 70 € / hours
Emergency	Sum of Emergency times T1 to T9	x 70 € / hours
Total time	Consultation + Review appointments + Emergency time	Consultation + Review + Emergency Cost in Euros
Original price of the appliance		The price of the appliance before delivery and gross cost in Euros
Emergency (repairs)		The costs paid for repair or replacement of broken components or malfunctioning appliances in Euros (see Table 2)
Total Cost of Material		Original costs + Emergency Costs
Total Costs		Total Time + Total Material Costs

Table 4: Financial analysis and simple explanation of the methodology used in cost analysis

Statistical Analysis

The distribution of the variables was analysed by the Shapiro-Wilk test. Parametric or non-parametric tests were utilized accordingly to analyse the bivariate relationship between the dependent and independent variables.

Inter and intra-examiner reliability for both the Cephalometric analysis and the CVM method was assessed via Intra-class Correlation Coefficient (ICC)

Multivariate Regression analysis for outcome changes was performed. The predictors or independent variables were identified through the bi-variate analyses.

Spearman's Correlation Coefficient was used to calculate the association between variables such as skeletal outcomes and compliance. For nonparametric data, the Wilcoxon test was used to compare distributions of cephalometric parameters over time (within subjects) in each group. The Mann-Whitney U test was used to compare cephalometric parameters over time between groups and the Chi-square test to compare the results of two groups.

For parametric data (normal distribution) The two-sample T-test was used to compare inter-group values. Two-way ANOVA was used to analyse the effect of gender on the compliance parameters. Spearman’s correlation coefficient was estimated to assess the non-linear association between daily meantime of wearing and skeletal changes (SNA, ANB, maxilla Na perpendicular).

Multiple Regression Analysis was carried out, using compliance as the dependent or outcome variable versus age, gender, skeletal outcomes and CPQ 8-10 at (T1-T0) and Global scores.

Regarding validation of CPQ 8-10 English to Maltese Cronbach´s alpha coefficient was used to estimate the internal consistency between English and Maltese versions for each domain and global scores of CPQ 8-10.

Test-retest reliability was assessed by computing the intra-class correlation coefficient (ICC) based on a one-way repeated measures analysis of variance, using CPQ 8-10 scores from the repeated administration of the tests.The correlation between English and Maltese domains and global scores CPQ 8-10 was assessed by using Spearsman's Correlation Coefficient. Mann-Whitney U tests were used to compare groups.

The Wilcoxon test was used to measure CPQ 8-10 intergroup differences, and the Mann-Whitney test to measure CPQ 8-10 intragroup and gender differences. Spearman´s coefficient correlation was used to correlate the wearing compliance rate to quality of life. Clinical and time costs were calculated. ICER (incremental cost-effectiveness ratio) is the principal rate of a cost-effectiveness analysis. The ICER represents a measure of how efficiently a type of appliance can produce an additional gain of SNA (maxillary advancement). In other words cost of improvement per degree in SNA.

$$ICER = \frac{Costs\ TAD - Costs\ CON}{Gain\ TAD - Gain\ CON}$$

Since the distribution of economic data was skewed, non-parametric analysis was used. Specifically, the bootstrap sampling method was used to find the variation in the ICER. It consists of extracting random samples from our data and computing ICER for each one of them. We extracted 1,000 samples to obtain summary statistics and confidence intervals for the ICER. This approach avoided the use of the median since the latter precluded calculation of the confidence intervals.

The significance level used in the analysis was set at 5% (α=0.05). All statistical analyses were performed using SPSS software (SPSS Inc., Chicago, IL, USA, version 25.0 for windows).

Chapter 3

Patients' compliance during early Class III facemask treatment using compliance sensor technology.

Introduction

Patient compliance with the wear of removable orthodontic appliances has always been a problem. In the past, clinicians used to depend on patients' subjective reports of wearing time and this approach is not accurate. Many orthodontic studies, including RCTs and systematic reviews, have been published, based on patients' subjective reports of wearing time (61,184). Few orthodontic studies look at the compliance rate when the treatment result is dependent and directly proportional to the reported wearing time. Schafer et al. found that patients exaggerate their reports of wearing time when compared to a real-life scenario. They found that the average wearing time of a removable appliance was 8 hours per day, which was below the recommended wearing time of 15 hours per day (185).

There have been many attempts to invent an accurate and valid device for measuring the time that a patient wears an orthodontic appliance (186). Recently, a device was introduced to objectively assess the compliance of patients wearing orthodontic appliances (TheraMon Microsensor, Handelsagentur Gschladt, Hargelsberg, Austria). TheraMon microchips accurately reported temperature records within a water bath (187,188). The microsensor records the temperature every 15 minutes. The software currently validates compliance by measuring the time patients wore the appliance through temperature. Values between 33.5°C and 38.0°C. would indicate the wearing time for intraoral appliances (128). Every visit the orthodontist can download the data from the microsensor and use specific software provided by the company to decode the data. TheraMon sensors have been placed in many orthodontic appliances such as removable appliances (127,128,189). The TheraMon chip (TheraMon Microelectronic System; MC Technology GmbH, Austria) can be integrated into a facemask to objectively document the compliance of our patients (Figure 8).

Figure 9: TheraMon microelectronic sensor system; MC Technology GmbH

The present study aims to assess patient compliance rate during facemask therapy over 9 months in an attempt to correlate the compliance rate effect with the magnitude of skeletal and dental changes.

Patients and Methods

This Randomised Clinical Trial (RCT) investigated the compliance, as measured by hours of wear, of facemask orthopaedic appliances. The trial consisted of 34 prepubertal patients that were divided randomly into two groups of 17 patients. Patients were asked to wear the facemask appliance between 12-14 hours daily and a thermal sensor (TheraMon Microsensor, Handelsagentur Gschladt, Hargelsberg, Austria). was used in the forehead region to record patients' temperature. The sensor was placed in the forehead pad and calibrated. Patients, guardians and parents were aware of the presence and nature of the sensor. They were asked to record the average wearing time of facemask on daily basis as a subjective form of self-reporting. For further details please refer to Chapter 2.

Results

The parents reported excellent cooperation, with full-time wear as instructed 12-14 hours per day, in other words, a 100% compliance rate. However, the Group I patients wore the facemask for 7.87 ± 2.88 hours per day and Group II wore the facemask for 6.98±2.68 hours per day (Figure 10). The patients were instructed to wear the facemask on average 12-14 hours per day. To facilitate calculations, 10 hours and above was taken as a cut-off for a good compliance rate, 23.5% of the patients in Group I and 11.7% in Group II showed values >= 10 hours per day. Both groups showed insignificant differences in compliance rates (P = 0.356, T-test) (Table 5).

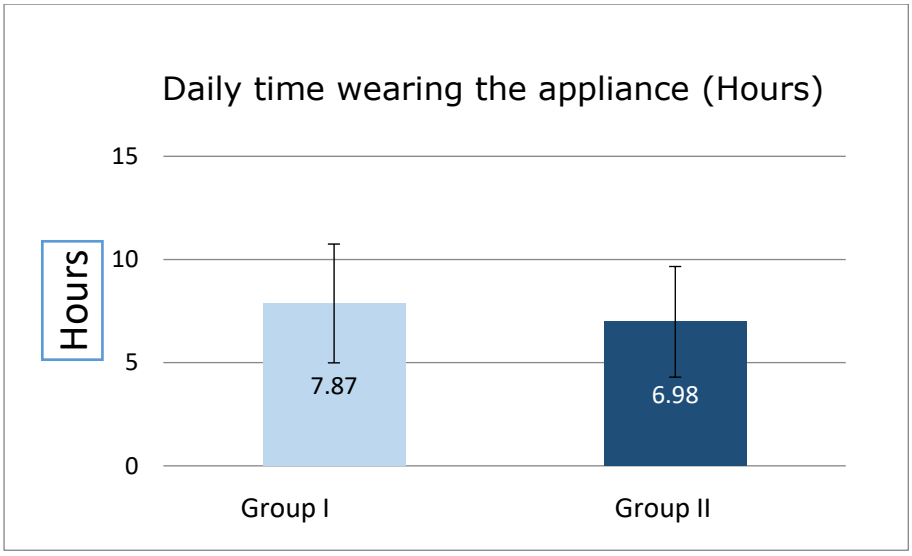

Figure 10: Daily compliance rate in Tooth-borne RME/FM (Group I) and (skeletally anchored RME/FM) (Group II). The average daily wearing time for Group I was 7.87 hours and for Group II 6.98 hours.

Standard Deviation (SD) of hours per day:

The mean of the SD was analysed to assess the variability of hours of wear throughout the follow-up. It is a measurement of subject regularity (worn hours) regardless of the number of compliance hours worn per day. Group I mean value was 3.53 hours and Group II 3.76 hours,

respectively. No significant differences were observed in subject dispersion between groups (P=0.608, T-test) (Table 5).

Coefficient of Variation (CV):

The CV was calculated. In short, CV is a form of reporting SD in percentage or ratio of the standard deviation to the mean, CV = (Standard Deviation / Mean) * 100. Group I and Group II CV was 53.9% and 65.25%, respectively. No statistically significant differences were found between groups (p=0.345, T-test) (Table 5).

		Group I	Group II	Two-way T-Test
Wearing hours per day	Mean	7.87	6.98	P=0.356 (t=0.94)
	SD	2.88	2.68	
SD hours	Mean	3.53	3.76	P=0.608 (t=0.52)
	SD	1.28	1.30	
CV hours	Mean	53.9	65.25	p=0.345 (t=0.96)
	SD	31.67	37.14	

*Table 5: Compliance wear time in Group I (Tooth-borne RME/FM) and Group II (Skeletally anchored RME/FM) in hours. 2-way sample T-test. *p<0.05; **p<0.01; ***p<0.001. t = statistical significance.*

Compliance rate and gender

The whole sample compliance mean was 8.27±3.32 and 7.02 ± 2.45 hours per day for female and male patients. Intra-group, the compliance rate of Group I was 9.57 ± 1.88 and 7.16 ± 2.98 hours per day for females and males, respectively. This difference was especially large within Group I when compared to Group II 7.19 ± 4.02 and 6.86 ± 1.83 hours per day for females and males, respectively. However, insignificant differences were found for the intragroup between genders (p=0.186) and intergroup genders (p=0.309, ANOVA test) (Table 6).

		Group I		Group II		p-value
		Males	Females	Males	Females	
Wearing hours/day	Mean	7.16	9.57	6.86	7.19	0.309 (F=1.07)
	SD	2.98	1.88	1.83	4.02	
SD hours	Mean	3.71	3.12	3.77	3.75	0.563 (F=0.34)
	SD	1.15	1.64	1.06	1.79	
CV hours	Mean	62.49	33.31	58.68	77.29	0.062 (F=3.75)
	SD	32.93	16.71	24.49	54.27	

*Table 6: Compliance Rate by group and Gender: 2-way ANOVA model for comparisons of the mean within-subject CV of hours per day. *p<0.05; **p<0.01; ***p<0.001. F= statistical significance.*

Effect of Compliance on Skeletal changes

Spearman´s correlation coefficient was used to assess correlations between wearing time and skeletal changes.

Maxilla Perpendicular to Na

Table 7 represents changes of Maxilla Perpendicular to N-A at (T1-T0) against the mean number of daily hours wearing the appliance. There was no correlation detected (Spearmans' Correlation Coefficient) in Group I and II (r =0.27, r =-0.006),

SNA angle

Spearman's Correlation Coefficient showed no correlation between the change in SNA angle and the compliance hours in Group I and II (Table 7). Group I and Group II (r=-0.10 and r= -0.07), respectively.

ANB Angle

Spearman's Correlation Coefficient showed no correlation between change in ANB angle and the compliance hours (Table 7). Group I and II (r=-0.09 and r=0.15), respectively. presents a summary of SNA, ANB, and Maxilla Perpendicular to Na correlation to facemask wearing time.

Reference plane/angle		N	Spearman's Correlation Coefficient (r)	p-value
Maxilla Perpendicular to N-A	Total	34	0.21	0.227
	Group I	17	0.27	0.292
	Group II	17	-0.06	0.818
SNA	Total	34	-0.10	0.609
	Group I	17	-0.10	0.693
	Group II	17	-0.07	0.786
ANB	Total	34	0.08	0.558
	Group I	17	-0.09	0.740
	Group II	17	0.15	0.558

Table 7: Maxilla perpendicular to Na, SNA and ANB in correlation to compliance wearing time.

Multivariate Linear Regression analysis

An insignificant relationship was found between compliance rate and age, gender and quality of life at (T1-T0) (Table 8). Similarly, an insignificant relationship exists between compliance and gender, age and CPQ 8-10 global scores (Table 9). It is worth mentioning that more models were performed but all showed no association. These are listed in Appendix VII.

Model	Independent variable	Unstandardised Coefficients		Standardised Coefficients	t	P. Value	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		18.308	5.858		3.25	0.004	6.345	30.270
	Age	-1.155	0.631	-0.328	-1.831	0.077	-2.444	0.134
	Gender	0.747	1.054	0.128	0.709	0.484	-1.405	2.899
	CPQ 8-10 (T1-T0)	-0.041	0.052	-0.136	-0.792	0.435	-.148	0.065

Table 8: Regression analysis of compliance as outcome versus age, gender and CPQ 8-10 (T1-T0)

Model	Independent variable	Unstandardised Coefficients		Standardised Coefficients	t	P. Value	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		16.785	5.962		2.815	0.009	4.592	28.978
	Age	-1.129	0.678	-0.320	-1.665	0.107	-2.515	0.258
	Gender	0.759	1.097	0.130	0.692	0.494	-1.484	3.003
	Global scores CPQ 8-10	0.016	0.052	0.058	0.311	0.758	-0.091	0.123

Table 9: Regression analysis of age, gender, Global scores Qol and Dependent variable hourly compliance per day

In view of the insignificant differences between the groups as regards composition, compliance and outcomes, the groups were merged and analysed as one group. All correlation and regression analyses showed statistically insignificant correlations and associations. The

average FM wear for the combined group was 7.42 ± 2.77 hours per day and 17.6% of the patients showed values equal to or greater than 10 hours per day. The results of the regression analyses and correlation coefficients are given in Appendix VII.

Discussion

Dental and skeletal outcomes and compliance have been studied by many authors. Suda et al. found that, for patients in the deciduous dentition stage, a facemask wearing time of 10-12 hours for 10 months resulted in a maxillary forward movement. This was based on an SNA difference of 4.16 degrees and an upper incisor proclination of 9.3 degrees (79). Ngan et al. advocated 12 hours per day of facemask wearing (69,81). Furthermore, a study found that patients who used the facemask 14 hours a day for 6-12 months showed a skeletal effect based on forward advancement of A point (107). In the light of the previous literature, an attempt to correlate skeletal outcomes to facemask compliance time, SNA, ANB and maxilla perpendicular to Na showed no correlation to compliance time. This RCT found that SNA in Group I improved significantly, with a mean difference (T1-T0) of 2.10 degrees. On the other hand, the SNA in Group II improved toward the end of the treatment, but the difference here was not significant. This is in agreement with the studies that advocated 10 hours of facemask wearing time (79).

The current study showed that the facemask-wearing times in both groups were less than prescribed by the orthodontist, or as reported by the parents, which was (12-14 hours per day). This was despite the patients and parents being aware of the presence and nature of the sensor. The average facemask-wearing time for Group I was 7.87 ± 2.88 hours per day and Group II wore the facemask for 6.98±2.68 hours per day. This agrees with other studies that used Theramon sensors with removable appliances and it was found that patients' compliance time tends to be overestimated. Schott and Ledwig reported that children wore removable appliances

for 9 hours while the prescribed time was 12-15 hours (125). A study compared Twin Block wearing time versus headgear. The headgear was worn, on average, 7 hours per day and the Twin Block group wore it for 9 hours per day (190). Historically, the wearing time reported was 7.6 hours/ day when the instructions were 12-15 hours/day (191). Reports in the literature show that even though patients did not wear the appliances as instructed, the orthopaedic and orthodontic movements took place. This suggests that treatment efficacy can be achieved with less wearing time (189,192). Similarly, this study's results indicate that 76.5% of the children in Group I and 88.3 % in Group II wore the facemask for less than 10 hours. Analysis of the sample as a whole showed a wearing time of 7.42 ± 2.77 hours per day. As a percentage, 82.4 % of the children did not wear their facemasks for more than 10 hours per day. However, despite the poor cooperation, significant dentoalveolar and skeletal changes took place toward the end of the treatment. The contemporary guidelines recommend that the duration of force is based on clinical experience and patients' self-reported compliance rate. Most authors recommend that patients should wear the facemask from 14 to 24 hours per day (82,105,193). In other words, we can claim that wearing a facemask below 10 hours daily can result in favourable maxillary protraction. Our trial found that wearing the appliance between 5 -10 hours daily can be as beneficial as 12 hours and more of facemask wearing. This might be an advantageous point to reduce the burden of long hours wear on the patients and parents. In order to achieve the desired outcome, clinicians may prescribe night-time wear, or fewer hours during the day, as an alternative.

Many studies have shown different outcomes in compliance rates and gender. This could be attributed to the wide range of ages of the populations in the different studies (191,194–197). Children in younger age groups might not demonstrate a significant difference between males and females, on the other hand, studies that recruited older adolescents may unveil significant differences between genders. In general, the younger children of both genders show good

compliance (198,199). In this study, the Coefficient of Variation and the Standard Deviation showed that for females and males in Groups I and II, the wearing hours were comparable and with no significant difference between the genders.

Females tend to wear removable appliances better than males. This may be attributed to the fact that females tend to be more conscious about their appearance than males (146). A simple explanation for this is that females' average maturation is earlier than males, so females of equivalent age are more concerned about personal appearance and desire to improve their overall orthodontic outcome (199). Female compliance rates tend to be better than males due to the internal motivation for compliance, although compliance-related gender differences are small in magnitude and so results have to be interpreted in the light of possible measurement error (200). The results agree with the literature in that, at a young age, patients tend to comply more and gender differences are minimal. However, this has to be interpreted in light of the small sample size. All models of regression analysis failed to find any association between compliance rate and age, gender or QoL at different time points. Merging the two groups into one larger group gave the same results, indicating that differences, if any, are small. The lack of association with age and gender is not surprising as the groups were composed of young children, who, at that age, are incapable of understanding the nature of the malocclusion. It was the parents who sought treatment, not the child. The results of the regression analysis support the CV and SD ratios as regards compliance and gender. However, face mask wearing was surprisingly not associated with the QoL score. This may mean that the facemask might not affect the quality of life as negatively as some clinicians assume.

Facemask-wearing time in prepubertal children can be efficient and sufficient if it is worn below 10 hours. In this study, skeletal outcomes with average wear of 7-8 hours a day were comparable to studies that reported long-wearing hours.

Conclusion

Group I patients wore the facemask 7.87 ± 2.88 hours per day and Group II patients wore the facemask 6.98±2.68 hours per day, with no association between hours of wear and skeletal outcomes Patient's compliance rate was 5-6 hours less than the recommended or the reported wearing time. Despite that, patients still achieved favourable results. None of the variables examined had any association with the outcome. The null hypothesis was accepted.

Chapter 4

Comparison of skeletal and dentoalveolar outcomes in patients treated with skeletally anchored RME versus tooth-borne RME with protraction head gear; utilising the Alt-RAMEC approach.

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Introduction

Class III malocclusion is considered to be among the most challenging orthodontic problems in orthodontics and is characterised by any combination of maxillary retrognathism, mandibular prognathism, retrusive mandibular dentition or protrusive maxillary dentition (15). These characteristics were originally described by Angle and subsequently many authors reported the same findings, reflecting the complexity of Class III cases (15,201). The prevalence was reported to be approximately 1–5% in White populations, while this prevalence was as high as 14% for Asian populations (202–204).

Şar et al. compared the FM effect with skeletal anchorage using mini-plate treatment against controls. The authors concluded that using a FM and mini-plates resulted in a more skeletal effect in comparison to dental anchorage (93). Seiryu et al. found that, during treatment of skeletal Class III malocclusion, FM therapy along with a miniscrew exhibited fewer negative side effects, such as loosening of the mini-screws. It delivered orthopaedic forces more efficiently to the maxillary complex than FM therapy alone (205). FM/anchored mini-implant showed improvement of SNA by 1.18 degrees and ANB by 0.88 degrees (205).

Rapid Maxillary Expansion (RME) has been advocated as a routine part of Class III treatment because it aids in maxillary disarticulation, leading to favourable cellular and morphological changes in the circum-maxillary sutures. This, in turn, may facilitate maxillary protraction (59,206). Facemask (FM) therapy with RME was shown to be a reliable option for treating a growing patient with Class III malocclusion associated with maxillary retrusion (21,207). FM therapy aided in the protraction of the maxilla with counterclockwise rotation and clockwise rotation of the mandible (62,208). Despite the controversy around the use of FM with or without RME, Baik and Sung reported statistically significant forward and downward movement of point A in a FM with a RME group compared to FM without RME (21). A study

comparing the use of Tooth-borne RME /Alt-RAMEC versus no RME reported that the use of FM without RME did not exclusively aid in the correction of Class III malocclusion. The authors speculated that the greater effect seen in the Alt RAMEC group could be due to the circum-maxillary sutures being less disarticulated with RME in comparison to the Alt-RAMEC group (209).

The effectiveness of FM/RME with Alt-RAMEC was reported by Isci et al. They concluded that A point moved 4.13 mm forward in comparison to 2.33 mm movement by the control group (104). Similarly, Kaya et al. investigated the effect of FM attached to skeletal mini plates following Alt-RAMEC protocol and reported 2 mm maxillary forward movement and 0.8 degrees counterclockwise rotation (210). However, Kaya et al. did not have a control group, which made drawing a conclusion challenging.

There has been an increase in interest from scientists over the past few years in FM/RME implant-supported versus Tooth-borne FM/RME. For instance, it was concluded that both treatment modalities showed a comparable improvement in the values of SNA, SNB, ANB and overjet. Nevertheless, both groups showed an insignificant difference between the essential variables (211), suggesting the need for more research in the area.

Indeed, a recent systematic review indicated that evidence for the effectiveness of RME in maxillary protraction is scarce and further long-term follow-up is required to reach concrete conclusions, specifically regarding the Alt-RAMEC approach (208).

Therefore, the present Prospective, Randomised, Controlled Single Center Study (RCT) aimed to test the null hypothesis that there were no differences in skeletal and dentoalveolar changes induced by the facemask skeletally anchored RME and tooth-borne RME groups.

Patients and Methods

Following random allocation, as described in Chapter 2; Group I (tooth-borne RME/FM) had a tooth-borne expander cemented on UR6, UL6, ULD and URD. Group II (skeletally anchored RME/FM) had an expander cemented on teeth 16 and 26, in addition, to being screwed to two (9x2 mm) paramedian implants, free-handed technique. Insertion aimed to achieve bicortical anchorage (182). Patients were asked to perform alternative cycles of constriction and expansion following the fitting of RME. The RME in both groups had a traction hook arm extended anteriorly to the canine region, in theory, this design will minimize any maxillary rotation. Extraoral forces of 400-450 g were used to connect the facemask to the expander and the elastics were attached at 30 degrees to the facemask. The force was measured using a force gauge (Leone Force Guage, Spain). All patients had cephalometric radiographs taken at T0 (baseline) and T1 (end of the treatment).

All patients were followed up for 9 months to assess the skeletal, dentoalveolar and soft tissue changes. The cephalometric radiographs were collected, pseudonymised and traced randomly by the PI, using Dolphin (Dolphin Imaging and Management Solutions® Version 11.95, USA), using a custom-made composite Cephalometric analysis, as described in Chapter 2.

Results

Sample Description and Demographics

The power analysis showed that 17 individuals in each arm were required. Thirty-four Class III patients were recruited and treated using the Alt-RAMEC approach, Group I (Tooth-borne RME/FM) consisted of 17 patients: 12 males and 5 females. Group II (skeletally anchored FM/RME) consisted of 17 patients: 11 males and 6 females. One patient in Group II was lost to follow-up. Patients' age in Group I was 8.2±0.6 years and Group II 8.8±0.8 years. All

patients were primary school students, while the parents showed some variation in their level of education and work fields; 41.2 % finished at the College level, 8.8% at the High School level and 50% at the university level. The parent incomes were divided into two categories based on information obtained from National Statistics Office (NSO) (Appendix II). The low-income scale was Euros 10,000-26000 per annum and the medium-income scale was Euros 27,000-39000. The Chi-Square test showed insignificant differences between the two groups' parent income ($p=0.084$; $p=Chi^2$). (Table 10).

Inter-rater and intra-rater reliability

Cephalometric tracing inter-rater reliability (ICC) was 0.9 which reflects a high agreement between the two raters and intra-rater reliability was 0.88 which reflects high accuracy and reproducibility.

Cervical Staging (CS) inter-rater reliability (ICC) was 0.79 which reflects a very good agreement between the two raters and intra-rater reliability was 0.70 which reflects a very good accuracy and reproducibility.

Item	**Group**		**Number**	**Variable**
Gender	Group I	Male	12	70.6%
		Female	5	29.4%
	Group II	Male	11	64.7%
		Female	6	35.3%
Age Group (Years)/SD	Group I		17	8.2±0.6yrs
	Group II		17	8.8±0.8yrs
Child Education	Group I (Primary government school students)		17	100%
	Group II (Primary government school students)		17	100%
Parent Education	Group I	College	7	41.2%
		High School	1	5.9%
		University	9	52.9%
	Group II	College	7	41.2%
		High School	2	11.8%
		University	8	47.0%
		Low Income	8	47.3%

Parent Income Scale	Group I	Middle Income	8	47.6%
		High Income	1	5.1%
	Group II	Low Income	8	47.5%
		Middle Income	8	47.5%
		High Income	1	5.0%
Cervical Stage (CS)	Group I	Male	12	CS2
		Female	5	CS2
	Group II	Male	11	CS2
		Female	6	CS2

Table 10: Demographic data of the two arms of the study

Cephalometric analysis intra-group:

Skeletal changes.

Group I showed a significant mean difference of 2.10 (0.90 5.20) (T1-T0) _skeletal improvement in SNA for Group 1, P=0.007, but not for Group II. Similarly, ANB showed a significant mean difference of 3.90 (2.40 4.90) (T1-T0) in Group I (P=0.001) and Group II showed a significant mean difference of 3.10 (0.70 -4.20) (T1-T0) (P=0.007) (Table 11).

The Wits appraisal showed a significant mean difference of 4.70 (2.10 5.10) (T1-T0) within Group I, (P=0.001). Group II showed a similar significant mean difference improvement of 3.20 (0.30- 4.40) (T1-T0) (P=0.002).

Dentoalveolar changes

Overjet showed a significant mean difference at (T1-T0) within Group I: 5.40 (4.10 5.70)(P ≤0.001). Similarly, within Group II a significant mean difference at (T1-T0) was 4.50 (2.80 5.70) (P =0.001).

The previous measurements show that both treatment modalities resulted in improvement of the overjet from a negative value to a positive value or in other words normalised the negative overjet. Furthermore, the lower incisor to the mandibular plane (IMPA) showed a significant

mean difference at (T1-T0) of -4.00 degrees (-11.4 0.00) (P=0.023) in Group I and Group II mean difference (T1-T0) -6.10 (-9.00 -0.50) (P=0.005).

Soft tissue analysis shows the nasolabial angle showed a significant mean difference increase of 13.0 (-20.4 3.1) in Group I (P≤0.028). But in Group II the nasolabial angle showed nonsignificant changes. The other tested cephalometric parameters showed some degree of change but did not reach the level of significance (Table 11).

Parameters	Group	T0	T1	Diff. T1-T0	P-value
MAND. SKELETAL (Pg-Na Perp) mm	**Group I**	2.80 (-5.00 5.00)	0.80 (-3.90 1.00)	-2.00 (-9.60 1.10)	0.906 (z=0.12)
	Group II	3.50 (-1.40 6.40)	0.20 (-4.00 2.10)	-3.10 (-6.30 0.00)	0.129 (z=2.18)
Maxilla Skeletal (Co-A point) mm	**Group I**	75.5 (80.0 90.5)	93.8 (90.8 97.4)	8.70 (-9.30 21.1)	0.552 (z=1.0)
	Group II	90.7 (80.5 105.2)	107.5 (100.8 110.1)	10.00 (-4.50 19.8)	0.481 (z=1.80)
MAX. SKELETAL (A-N Perp) mm	**Group I**	-0.30 (-3.90 2.00)	0.20 (-2.30 2.20)	0,75 (-1.40 1.70)	0.449 (z=0.76)
	Group II	0.00 (-3.80 2.30)	1.00 (-4.50 1.30)	1.00 (-1.30 1.25)	0.277 (z=1.09)
MAND. LENGTH (Co-Gn) mm	**Group I**	80.9 (75.0 99.5)	94.8 (93.8 97.4)	3.70 (-9.30 21.1)	0.332 (z=0.97)
	Group II	100.7 (86.5 115.2)	107.5 (101.8 112.1)	3.00 (-4.50 19.8)	0.121 (z=1.55)
SNA (Degrees)	**Group I**	78.8 (77.0 81.6)	80.9 (79.5 82.5)	2.10 (0.90 5.20)	**0.007** (z=2.68)**
	Group II	78.6 (78.0 80.2)	81.0 (79.0 82.0)	2.50 (0.00 3.80)	0.088 (z=1.71)
SNB (Degrees)	**Group I**	79.6 (78.5 81.5)	79.7 (77.8 80.2)	-1.40 (-2.90 1.20)	0.201 (z=1.28)
	Group II	80.6 (79.0 82.6)	81.3 (79.0 81.8)	0.00 (-2.00 1.20)	0.530 (z=0.63)
ANB (Degrees)	**Group I**	-0.50 (-2.80 0.10)	2.50 (1.10 3.80)	3.90 (2.40 4.90)	**0.001** (z=3.24)**
	Group II	-1.40 (-3.30 -0.60)	1.00 (-0.90 2.40)	3.10 (0.70 4.20)	**0.001** (z=2.72)**
PALATAL-MAND. ANGLE (Degrees)	**Group I**	25.5 (24.9 28.1)	26.8 (18.9 28.2)	-0.20 (-4.40 1.90)	0.619 (z=0.50)
	Group II	24.6 (21.3 26.9)	26.3 (24.8 27.2)	0.30 (-0.60 4.80)	0.140 (z=1.48)
LAFH/TAFH	**Group I**	55.0 (53.1 55.7)	53.6 (52.7 55.7)	-0.40 (-1.50 0.90)	0.148 (z=1.45)
	Group II	55.9 (54.3 56.2)	55.6 (54.9 57.1)	0.30 (-0.40 1.00)	0.352 (z=0.93)
WITS	**Group I**	-5.50 (-7.60 -3.20)	-3.30 (-3.90 0.40)	4.70 (2.10 5.10)	**0.001** (z=3.20)**
	Group II	-6.30 (-7.90 -3.90)	-2.80 (-4.50 -0.80)	3.20 (0.30 4.40)	**0.002** (z=3.11)**
OVERJET	**Group I**	-2.00 (-2.40 -0.40)	3.30 (2.10 3.90)	5.40 (4.10 5.70)	**<0.001*** (z=3.63)**
	Group II	-1.30 (-1.80 -0.30)	2.90 (2.50 3.90)	4.50 (2.80 5.70)	**<0.001*** (z=3.52)**
OVERBITE	**Group I**	-0.90 (-1.30 1.40)	0.10 (-1.10 3.10)	1.90 (-1.30 3.30)	0.093 (z=1.68)
	Group II	-0.40 (-1.10 1.40)	0.80 (0.40 2.50)	1.00 (0.00 3.70)	0.062 (z=1.87)
U1-MAXILLARY PLANE	**Group I**	114.1 (112.4 122.5)	119.6 (116.4 122.6)	1.90 (-2.90 7.40)	0.245 (z=1.16)
	Group II	119.5 (108.5 122.8)	119.5 (110.0 127.1)	4.40 (-1.40 5.00)	0.162 (z=1.39)
IMPA	**Group I**	95.6 (89.5 99.7)	88.0 (85.6 96.7)	-4.00 (-11.4 0.00)	**0.023* (z=2.28)**
	Group II	88.9 (85.3 97.1)	86.6 (81.8 91.0)	-6.10 (-9.00 -0.50)	**0.005** (z=2.79)**
INTERINCISAL ANGLE	**Group I**	122.5 (121.2 125.2)	124.9 (121.7 131.5)	2.40 (0.20 4.40)	0.124 (z=1.54)
	Group II	129.9 (119.1 137.4)	129.6 (114.2 134.0)	0.60 (-4.10 4.00)	0.836 (z=0.21)
NASOLABIAL ANGLE	**Group I**	120.2 (113.9 132.9)	124.0 (101.0 124.8)	13.0 (-20.4 3.1)	**0.028* (z=2.20)**
	Group II	109.6 (94.0 124.3)	110.3 (108.9 120.8)	1.00 (-12.9 12.0)	0.717 (z=0.36)

*Table 11:Cephalometric analysis Intragroup at baseline (T0) and the end of treatment (T1). Wilcoxon´s test for comparison within-Groups, *p<0.05; **p<0.01; ***p<0.001. Group I: Tooth-borne RME/FM, Group II:*

skeletally anchored RME/FM. Z value is the statistical significance.

Cephalometric analysis inter-Group (Group I Vs Group II) at baseline (T0).

Baseline (T0) comparison between Group I and II showed a significant difference in mandibular length (Co-Gn), P=0.022, Group II showed a greater length at (T0) 100 mm while Group I was 80.9 mm. Furthermore, there was a significant difference in the Lower Incisors to Mandibular Plane Angle between Group I and II, P=0.038, which showed Group I at 95.3 degrees and Group II at 88.9 degrees (Table 12).

	GROUP	T0	P Value Group I Vs II
MAND. SKELETAL (Pg-Na Perp)	**Group I**	1.80 (-5.00 5.00)	0.231 (z=1.21)
	Group II	3.50 (-1.40 6.40)	
MAX. SKELETAL (A-N Perp)	**Group I**	-0.30 (-3.90 2.00)	0.760 (z=0.33)
	Group II	0.00 (-3.80 2.30)	
Maxilla Skeletal (Co-A point) mm	**Group I**	100.7 (86.5 115.2)	**0..030* (z=2.10)**
	Group II	80.9 (75.0 99.5)	
MAND. Length (Co-Gn).	**Group I**	80.9 (75.0 99.5)	**0.022* (z=2.29)**
	Group II	100.7 (86.5 115.2)	
SNA	**Group I**	78.8 (77.0 81.6)	0.812 (z=0.24)
	Group II	78.6 (78.0 80.2)	
SNB	**Group I**	79.6 (78.5 81.5)	0.274 (z=1.10)
	Group II	80.6 (79.0 82.6)	
ANB	**Group I**	-0.50 (-2.80 0.10)	0.339 (z=0.98)
	Group II	-1.40 (-3.30 -0.60)	
PALATAL-MAND. ANGLE	**Group I**	25.5 (24.9 28.1)	0.433 (z=0.81)
	Group II	24.6 (21.3 26.9)	
WITS	**Group I**	-5.50 (-7.60 -3.20)	0.610 (z=0.53)
	Group II	-6.30 (-7.90 -3.90)	
OVERJET	**Group I**	-2.00 (-2.40 -0.40)	0.150 (z=1.47)
	Group II	-1.30 (-1.80 -0.30)	
OVERBITE	**Group I**	-0.90 (-1.30 1.40)	0.586 (z=0.57)
	Group II	-0.40 (-1.10 1.40)	
U1-MAXILLARY PLANE	**Group I**	114.1 (112.4 122.5)	0.683 (z=0.43)
	Group II	119.5 (108.5 122.8)	
IMPA	**Group I**	95.6 (89.5 99.7)	**0.038* (z=2.09)**
	Group II	88.9 (85.3 97.1)	
INTERINCISAL ANGLE	**Group I**	122.5 (121.2 125.2)	0.322 (z=1.02)
	Group II	129.9 (119.1 137.4)	
NASOLABIAL ANGLE	**Group I**	120.2 (113.9 132.9)	0.099 (z=1.67)

	Group II	109.6 (94.0 124.3)	

*Table 12:Cephalometric parameters at T0 between groups: median (IQR): Results of Mann-Whitney´s test for comparisons between groups. *p<0.05; **p<0.01; ***p<0.001. Group I: Tooth-borne RME/FM, Group II: skeletally anchored RME/FM. Z value is the statistical significance.*

Inter-group comparison (T0) and (T1) of cephalometric parameters showed insignificant changes, in other words, the changes were very close in Group I and Group II (Table 13).

Parameter	Group	T0	T1	Diff. T1-T0	p-value
MAND. SKELETAL (Pg-Na Perp) mm	**Group I**	2.80 (-5.00 5.00)	0.80 (-3.90 1.00)	-2.00 (-9.60 1.10)	1.00 (z=0.02)
	Group II	3.50 (-1.40 6.40)	0.20 (-4.00 2.10)	-3.10 (-6.30 0.00)	
Maxilla Skeletal (Co-A point) mm	**Group I**	75.5 (80.0 90.5)	93.8 (90.8 97.4)	8.70 (-9.30 21.1)	0.683 (z=0.41)
	Group II	90.7 (80.5 105.2)	107.5 (100.8 110.1)	10.00 (-4.50 19.8)	
MAX. SKELETAL (A-N Perp) mm	**Group I**	-0.30 (-3.90 2.00)	0.20 (-2.30 2.20)	0,75 (-1.40 1.70)	0.683 (z=0.09)
	Group II	0.00 (-3.80 2.30)	1.00 (-4.50 1.30)	1.00 (-1.30 1.25)	
MAND. LENGTH (Co-Gn) mm	**Group I**	80.9 (75.0 99.5)	94.8 (93.8 97.4)	3.70 (-9.30 21.1)	0.332 (z=0.97)
	Group II	100.7 (86.5 115.2)	107.5 (101.8 112.1)	3.00 (-4.50 19.8)	
SNA	**Group I**	78.8 (77.0 81.6)	80.9 (79.5 82.5)	2.10 (0.90 5.20)	0.946 (z=0.09)
	Group II	78.6 (78.0 80.2)	81.0 (79.0 82.0)	2.50 (0.00 3.80)	
SNB	**Group I**	79.6 (78.5 81.5)	79.7 (77.8 80.2)	-1.40 (-2.90 1.20)	0.812 (z=0.26)
	Group II	80.6 (79.0 82.6)	81.3 (79.0 81.8)	0.00 (-2.00 1.20)	
ANB	**Group I**	-0.50 (-2.80 0.10)	2.50 (1.10 3.80)	3.90 (2.40 4.90)	0.245 (z=1.19)
	Group II	-1.40 (-3.30 -0.60)	1.00 (-0.90 2.40)	3.10 (0.70 4.20)	
PALATAL-MAND. ANGLE	**Group I**	25.5 (24.9 28.1)	26.8 (18.9 28.2)	-0.20 (-4.40 1.90)	0.160 (z=1.43)
	Group II	24.6 (21.3 26.9)	26.3 (24.8 27.2)	0.30 (-0.60 4.80)	
LAFH/TAFH	**Group I**	55.0 (53.1 55.7)	53.6 (52.7 55.7)	-0.40 (-1.50 0.90)	0.919 (z=0.12)
	Group II	55.9 (54.3 56.2)	55.6 (54.9 57.1)	0.30 (-0.40 1.00)	
WITS	**Group I**	-5.50 (-7.60 -3.20)	-3.30 (-3.90 0.40)	4.70 (2.10 5.10)	0.496 (z=0.69)
	Group II	-6.30 (-7.90 -3.90)	-2.80 (-4.50 -0.80)	3.20 (0.30 4.40)	
OVERJET	**Group I**	-2.00 (-2.40 -0.40)	3.30 (2.10 3.90)	5.40 (4.10 5.70)	0.322 (z=1.00)
	Group II	-1.30 (-1.80 -0.30)	2.90 (2.50 3.90)	4.50 (2.80 5.70)	
OVERBITE	**Group I**	-0.90 (-1.30 1.40)	0.10 (-1.10 3.10)	1.90 (-1.30 3.30)	0.812 (z=0.26)
	Group II	-0.40 (-1.10 1.40)	0.80 (0.40 2.50)	1.00 (0.00 3.70)	
U1-MAXILLARY PLANE	**Group I**	114.1 (112.4 122.5)	119.6 (116.4 122.6)	1.90 (-2.90 7.40)	0.786 (z=0.28)
	Group II	119.5 (108.5 122.8)	119.5 (110.0 127.1)	4.40 (-1.40 5.00)	
IMPA	**Group I**	95.6 (89.5 99.7)	88.0 (85.6 96.7)	-4.00 (-11.4 0.00)	0.973 (z=0.03)
	Group II	88.9 (85.3 97.1)	86.6 (81.8 91.0)	-6.10 (-9.00 -0.50)	
INTERINCISAL ANGLE	**Group I**	122.5 (121.2 125.2)	124.9 (121.7 131.5)	2.40 (0.20 4.40)	0.540 (z=0.64)
	Group II	129.9 (119.1 137.4)	130.1 (114.2 134.0)	0.60 (-4.10 4.00)	
NASOLABIAL ANGLE	**Group I**	120.2 (113.9 132.9)	124.0 (101.0 124.8)	13.0 (-20.4 3.1)	0.067 (z=1.84)
	Group II	109.6 (94.0 124.3)	110.3 (108.9 120.8)	0.00 (-12.9 12.0)	

*Table 13:Cephalometric parameter intergroup at T0 (baseline) and T1 (end of treatment). Mann-Whitney´s test s test for comparisons between groups. *p<0.05; **p<0.01; ***p<0.001. Group I: Tooth-borne RME/FMvGroup II: skeletally anchored RME/FM. Z value is the statistical significance.*

Skeletal changes

Skeletal cephalometric analysis shows insignificant changes in SNA between the groups, in other words, they showed similar close effects (P=0.946) (Figure 11).

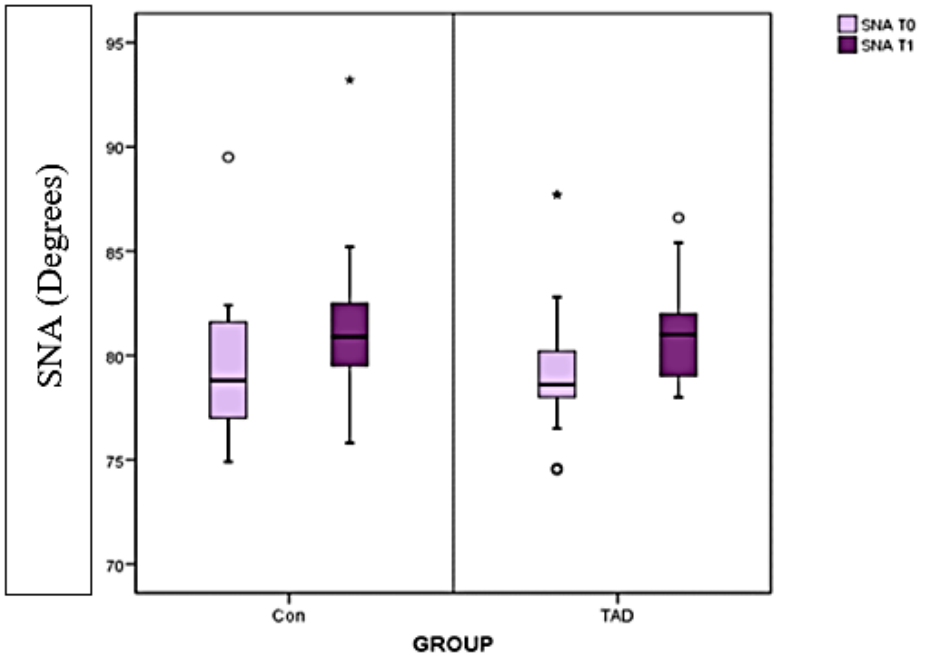

Figure 11: SNA angle intragroup and intergroup comparison. Both groups showed close enough medians at (T0) and (T1)

ANB increased significantly within both groups (P=0.001 and P=0.007, respectively). The magnitude of these changes was similar and insignificant between groups (P=0.245) (Figure 12).

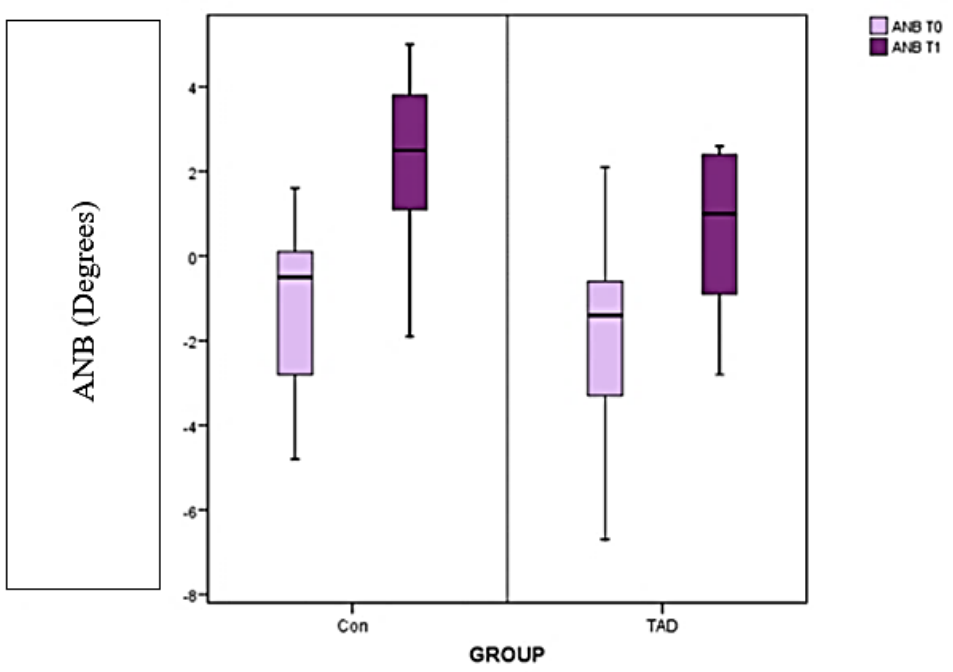

Figure 12: ANB angle intergroup and intergroup T0 and T1. Improvement in median when Group I and II were compared to baseline (T0) however, comparable difference between groups

Wits appraisal showed that the effect of the treatment protocols in both groups was significant (P=0.001 and P=0.002), but statistically insignificant differences between the groups (P=0.496) (Figure 13).

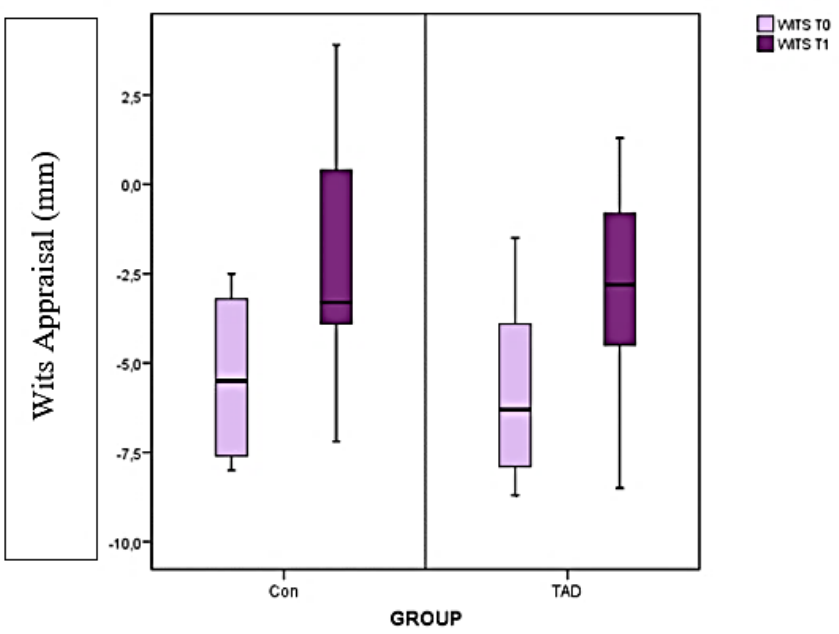

Figure 13: Wits appraisal showed improvement in median and IQR when Group I and II were compared to baseline (T0) however, insignificant comparable difference between groups

Dentoalveolar changes

Dental changes such as the overjet showed a remarkable change in both groups at the end of the treatment (T1). A substantial change was seen in intragroup ($P \leq 0.001$), respectively but an insignificant change in intergroup ($P \leq 0.032$) (Figure14). The nasolabial angle changes between the two groups showed insignificant changes ($P=0.067$) (Figure 15).

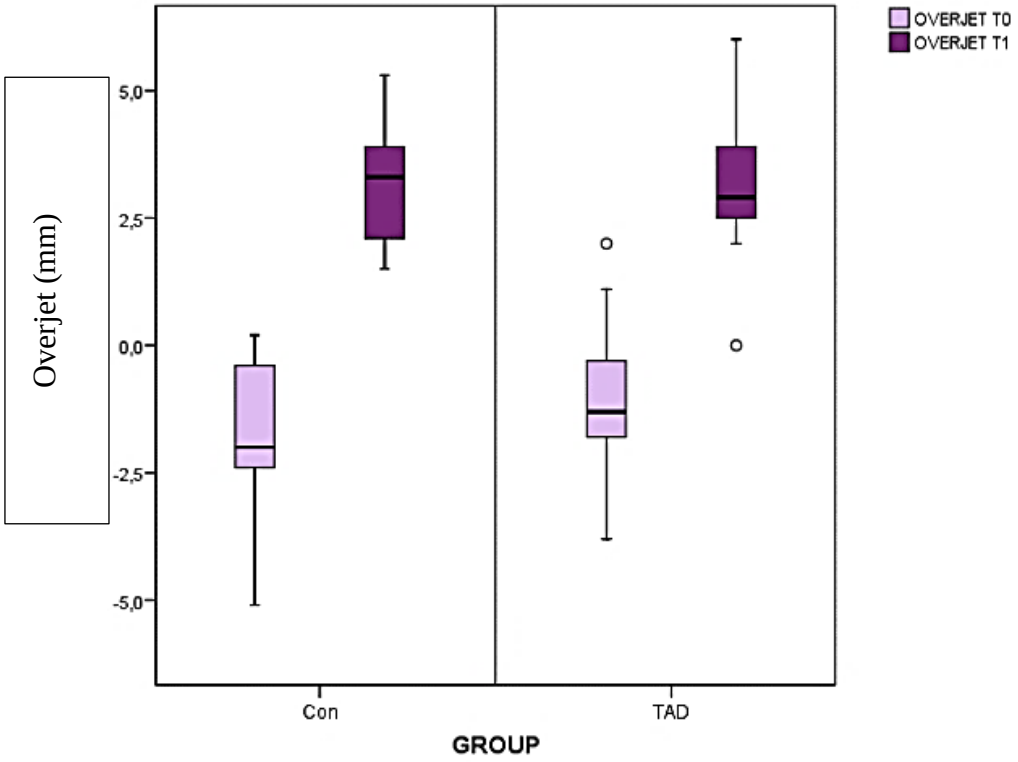

Figure 14: Overjet change T0 and T1. Improvement in the median when Group I and II were compared to baseline (T0) however, comparable difference between groups.

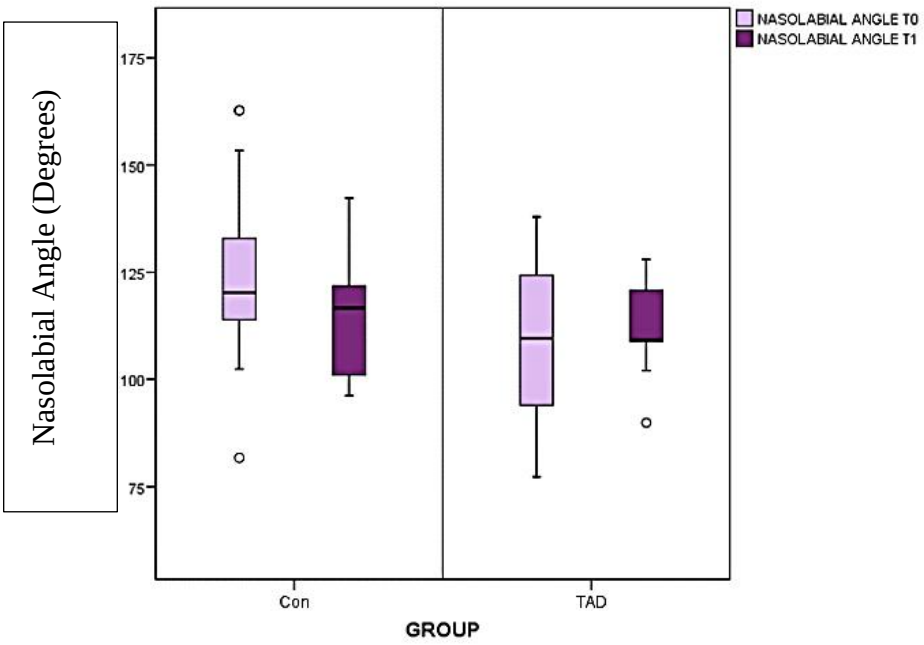

Figure 15: Nasolabial angle showed a mild change in the median when Group I and II were compared to baseline (T0) however, comparable difference between groups.

Regression Analysis

Multivariate linear regression analysis showed a statistically insignificant association between the difference in SNA (T1-T0) and CPQ 8-10 scores at T1-T0, gender, age, and compliance (Table 9) and CPQ 8-10 Global scores (Table 14).

Statistically insignificant associations were found between predictors and differences in SNB (T1-T0) and CPQ 8-10 Global scores, (Tables 15 and 16). Statistically insignificant changes were found between predictors and ANB (T1-T0) and CPQ 8-10 Global scores (Tables 17 and 18). An insignificant relationship was found between dependent (Wits Appraisal) and predictors at (T1-T0) and CPQ 8-10 Global scores (Tables 18 and 19).

Changes in overjet (T1-T0) showed insignificant associations with age, compliance, gender and CPQ 8-10 (T1-T0) (Table 20) and CPQ 8-10 Global scores, (Table 21). It is worth

mentioning that the regression analyses model was created for the whole variables and all resulted in insignificant associations. The full analyses are included in Appendix VII

Model 1	Independent variables	Unstandardised Coefficients		Standardised Coefficients	t	P. Value	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		-2.246	8.430		-0.266	0.792	-19.487	14.996
	AGE	0.757	0.827	0.179	0.915	0.368	-0.935	2.449
	GENDER	-1.383	1.302	-0.198	-1.062	0.297	-4.045	1.280
	Compliance /hours per day	-0.051	0.235	-0.43	-0.219	0.828	-0.531	0.429
	CPQ 8-10 (T1-T0-) scores	-0.028	0.034	-0.150	-0.820	0.419	-0.097	0.042

Table 14: Regression analysis model, The difference SNA (T1-T0) (outcome) and age, gender and CPQ at T1-T0 (independent variables)

Model 2	Independent variables	Unstandarised Coefficients		Standardised Coefficients	t	P. Value	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		-5.519	8.375		-0.659	0.515	-22.674	11.637
	AGE	0.913	0.883	0.216	1.033	0.310	-0.897	2.722
	GENDER	-1.275	1.377	-0.181	-0.926	0.362	-4.095	1.546
	HOURS PER DAY	0.000	0.231	00	0.001	0.999	-0.473	0.474
	CPQ 8-10 Global scores	-0.005	0.065	-0.015	-0.075	0.940	-0.138	0.128

Table 15: Regression analysis model. Difference SNA (T1-T0) (outcome) and age, gender and Global scores CPQ 8-10 (independent variables

Model 1	Independent variables	Unstandardised Coefficients		Standardised Coefficients	t	P. Value	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		-8.489	7.347		-1.156	0.257	-23.515	6.536
	AGE	0.779	0.721	0.211	1.080	0.289	-0.696	2.254
	GENDER	-1.563	1.135	-0.255	-1.378	0.179	-3.883	0.757

	Compliance /hours per day	0.106	0.204	0.101	0.517	0.609	-0.312	0.524
	CPQ 8-T1-T0	0.013	0.030	0.082	0.454	0.653	-0.047	0.074

Table 16: Regression analysis model. The difference in SNB (T1-T0) versus age, gender, compliance and CPQ 8-10 T1-T0

Model 2	**Independent variables**	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**P. Value**	**95% Confidence Interval for B**	
		B	**Std. Error**	**Beta**	**Lower Bound**	**Upper Bound**	**B**	**Std. Error**
		-8.798	7.192		-1.223	0.231	-23.531	5.935
	AGE	0.899	0.759	0.242	1.185	0.246	-0.655	2.453
	GENDER	-1.676	10.182	-0.272	-1.417	0.167	-4.098	0.46
	HOURS PER DAY	0.083	0.199	0.079	0.417	0.680	-0.324	0.489
	CPQ 8-10 global scores	-0.038	0.056	-0.130	-0.687	0.498	-0.153	0.076

Table 17: Regression analysis model. The difference in SNB (T1-T0) versus age, gender, compliance and global scores CPQ 8-10 scores

Model 1	**Independent variables**	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**P. Value**	**95% Confidence Interval for B**	
		B	**Std. Error**	**Beta**	**Lower Bound**	**Upper Bound**	**B**	**Std. Error**
		4.493	7.142		0.629	0.534	-10.115	19.101
	AGE	0.081	0.701	0.024	0.116	0.908	-1.352	1.515
	GENDER	0.177	1.103	0.031	0.160	0.874	-2.079	2.432
	HOURS PER DAY	-0.046	0.199	-0.047	-0.231	0.819	-0.453	0.361
	CPQ 8-10 global scores	-0.037	0.029	-0.246	-1.300	0.204	-0.096	0.021

Table 18: Regression analysis model. The difference in ANB (T1-T0) versus age, gender, compliance and T1-T0 CPQ 8-10 scores

Model 2	**Independent variables**	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**P. Value**	**95% Confidence Interval for B**	
		B	**Std. Error**	**Beta**	**Lower Bound**	**Upper Bound**	**B**	**Std. Error**
		1.252	7.224		0.173	0.864	-13.547	16.051
	AGE	0.169	0.762	0.049	0.222	0.826	-1.391	1.730
	GENDER	0.303	1.188	0.052	0.255	0.801	-2.130	2.736
	HOURS PER DAY	0.026	0.199	0.026	0.130	0.897	-0.383	0.434

	CPQ 8-10 global scores	0.014	0.056	0.051	0.249	0.805	-0.101	0.129

Table 19: Regression analysis model. The difference in ANB (T1-T0) versus age, gender, compliance and Global scores CPQ 8-10 scores

Model 1	**Independent variables**	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**P. Value**	**95% Confidence Interval for B**	
		B	**Std. Error**	**Beta**	**Lower Bound**	**Upper Bound**	**B**	**Std. Error**
		13.270	7.649		1,735	0.093	-2.374	28.914
	AGE	-0.579	0.751	-0.148	-0.771	0.447	-2.114	0.957
	GENDER	-0.329	1.181	-0.051	-0.279	0.782	-2.745	2.086
	HOURS PER DAY	-0.155	0.213	-0.139	-0.726	0.474	-0.590	0.281
	CPQ 8-10 T1-T0 CPQ 8-10	-0.072	0.031	-0.416	-20.333	0.027	-0.135	-0.009

Table 20: Regression analysis model. The difference in Wits Appraisal (Dependent variable) versus age, gender, compliance and T1-T0 CPQ 8-10 scores

Model 2	**Independent variables**	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**P. Value**	**95% Confidence Interval for B**	
		B	**Std. Error**	**Beta**	**Lower Bound**	**Upper Bound**	**B**	**Std. Error**
		6.255	8.037		0.753	0.458	-10.408	22.519
	AGE	-0.301	0.848	-0.078	-0.355	0.725	-2.038	1.0435
	GENDER	0.086	1.321	.013	0.065	0.948	-20.621	2.793
	HOURS PER DAY	-0.030	0.222	-0.027	-0.133	0.895	-0.484	0.425
	CPQ 8-10 global scores	0.021	0.062	0.070	0.344	0.733	-0.106	0.149

Table 21Regression analysis model. The difference in Wits Appraisal (Dependent variable) versus age, gender, compliance and global scores CPQ 8-10 scores.

Model 1	**Independent variables**	**Unstandardized Coefficients**	**Standardized Coefficients**	**t**	**P. Value**	**95% Confidence Interval for B**

		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		4,839	4,692		1.032	0.311	-4.756	14.435
	AGE	0.013	0.463	0.006	0.029	0.977	-0.933	0.960
	GENDER	-0.259	0.739	-0.066	-0.351	0.728	-1.771	1.252
	HOURS PER DAY	0.175	0.127	0.259	1.375	0.180	-0.085	0.434
	CPQ 8-10 CPQ 8-10	-0.046	0.037	-0.223	-1.246	0.223	-0.21	0.029

Table 22:Regression analysis model. The difference in overjet (Dependent variable) versus age, gender, compliance and T1-T0 CPQ 8-10 scores.

Model 2	Independent variables	Unstandardized Coefficients		Standardized Coefficients	t	P. Value	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
		3.051	4.603		0.663	0.513	-6.378	12.480
	AGE	0.050	0.486	0.022	0.102	0.919	-0.945	.044
	GENDER	-0.141	0.757	-0.037	-0.187	0.853	-1.691	1.409
	HOURS PER DAY	0.179	0.127	0.273	1.411	0.169	-0.081	0.440
	CPQ 8-10 Global scores	0.29	0.036	0.156	0.798	0.431	-0.045	0.102

Table 23: Regression analysis model. The difference in overjet (Dependent variable) versus age, gender, compliance and CPQ 8-10 scores global changes

Discussion

This research recruited prepubertal growing children aged (8-10.99) years old. The mean age for Group I was 8.2±0.6 and Group II 8.8 ±0.8 years old. All patients were in CS2 however, it was crucial to use the chronological age with CS2 because of the low reported correlation between Cervical Stage Maturation and chronological age (212). Combining both gives us a better picture that patients are in the prepubertal stage. The ideal method to estimate the maturity level of the children would have been a growth chart, however, it was difficult to perform as it would have been necessary to recruit the children much earlier and follow them

up until puberty in order to estimate the true growth status of the child (213). This was deemed impractical given the time constraints and would only have been applicable in retrospect.

Group I had 12 males (70.6%) and 5 females (29.4%) while Group II had 11 males (64.7%) and 6 females (35.3%). The gender distribution showed that males were almost twice more than females which can be a source of bias, this can be explained that the process of randomisation was not based on stratification but rather just simple randomisation. This was also attributed to the fact that the Class III sample was low and patient recruiting was not an easy task during the pandemic.

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All children were in private primary school (100%) in both groups. It was evident that almost all parents were highly educated, except for 2 parents in both groups, with 16 parents in Group I and 15 parents in Group II having a College education or higher. Parents with a higher level of education would probably be more aware of the malocclusion. This is supported by a report that awareness and intervention of dental problems is a multifactorial process, but one pillar is high-level parent education, which influences awareness of dental problems in a positive manner (214).

Many authors advocate starting treatment as early as possible to produce a more significant response from the protraction facemask (65,77). Kim et al. reported that younger patients had a larger skeletal effect in comparison to older patients (8). At a younger age, the circum-maxillary sutures tend to be wider and more easily displaced (102). Liou and Tsai also suggested that the circum-maxillary sutures were separated and stretched to a greater degree

by Alt-RAMEC compared to RME (102). This was also confirmed by Wang et al. who reported that the Alt-RAMEC procedure opened both the sagittal and coronal circum-maxillary sutures significantly more than did the RME. However, the advancement of the maxilla was surprisingly found to be only 2.0 mm in a recent study using both Alt-RAMEC and miniplate anchorage. The forward displacement of the maxilla is considered the curative measure that allows the clinician to estimate the improvement of Class III skeletal base(209).

The baseline data comparison showed that Group I and II showed a significant difference in mandibular length (Co-Gn), P=0.022, Group II 100 mm while Group I 80.9 mm. McNamara analysis was performed on adults not growing individuals which means the average measurement of 134±6 mm might not be applicable here nor the unit differences (215). Males tend to have larger linear measurements of the mandible in Class III patients (216). Maxillary unit length was significant between Group I and II at T0, this might be attributed to the small sample size.

At baseline (T0) significant difference in lower incisors to the mandibular plane between Group I and II, P=0.038, Group I 95.3 degrees and Group II 88.9 degrees and both groups falls in the average inclination of the lower incisors to the mandibular plane which in return means the significance is only statistical rather clinical.

The current study showed that (SNA) (T0-T1) improved significantly in Group I, by a mean difference of 2.10 degrees (P = 0.007), while Group II showed an insignificant mean difference change (T1-T0) of 2.90 degrees (P=0.088). This finding is consistent with other studies, (217) that reported an improvement in SNA (2 degrees) when patients were treated with Tooth-borne RME/FM. Similarly, it was reported that SNA improved when treated with Tooth-borne RME/FM (2 degrees) (85). Maino et al. reported that skeletally supported RME/FM resulted in an improvement of SNA (2.3 degrees), which is very similar to the improvement in Group II in this study (218). Sousa et al. reported that maxilla advancement

improved and the difference was 3 degrees in the expander mini-implant supported group (211). Similarly to this study, it was reported that skeletally supported RME/FM improved SNA by 2 degrees compared to the control group (63).

This study reported a sagittal skeletal improvement by a positive mean difference change in SNA of 2.10 degrees and a Wits appraisal of 4.7mm in Group I, compared with a change in SNA of 2.5 degrees and a change in Wits of 3.2mm in Group II. In a controlled clinical study, Westwood et al. found increases of 1.6 degrees in SNA and 4.3 mm in the Wits appraisal. This is very comparable to the figures this study has reported in Group I. On the other hand, in this trial, Group II showed a slightly higher change in SNA in comparison to that reported by Westwood and co-authors (57). This indicates that the skeletally anchored RME/FM resulted in more advancement of the maxilla than Tooth-borne RME/FM.

The important debatable point in this context is that skeletally anchored RME and Tooth-borne RME using the Alt-RAMEC method, together with FM treatment, resulted in improvement toward the end of the treatment. However, the improvement was similar for both groups. In other words, the difference between the two methods is not statistically significant. Despite the use of skeletal anchorage, the maxillary advancement was comparable to the Tooth-borne method, taking into consideration the skeletal parameters.

The mandible position in both groups tended to be unchanged or, in other words, the mandibular prominence reduced. Change in SNB was insignificant in both groups, Group I (T1-T0 = -1.40 degrees) and Group II (T1-T0 = 0 degrees), P = 0.205 and 0.530, respectively. This finding is in agreement with Masucci et al., who reported an SNB change of fewer than -0.8 degrees when comparing before and after cephalometric results (193). Similarly, Mandall et al. found that SNB change was 0.2 degrees toward the end of the treatment (219). In theory, a facemask can cause a restrictive force that prevents the forward growth of the mandible, an idea proposed by chin cup advocates (220). However, this theory is not widely accepted as the

current opinion is that genetics is the main driver of mandibular growth and if there are any restrictive forces, they are transitory (221,222). A similar trend was observed for mandibular prominence as measured by Na-Pg perpendicular, both groups showed similar changes and the magnitude of change was minimal and statistically insignificant. It is important to stress that 56% of the Class III malocclusion is caused by retrusion of the maxilla rather than the prominence of the mandible (15). This means that restriction of mandibular growth is unlikely to solve the issue of midface retrusion.

ANB showed a substantial improvement in Group I with a significant mean difference (T1-T0) of 3.90 degrees and Group II of 3.10 degrees, respectively. The reported differences in ANB were insignificant despite the substantial improvement in both groups. Our findings agree with Souza et al. where two groups were recruited, Group I had implant-supported RME/FM and Group II had infra-zygomatic implants and mental symphysis implants with heavy Class III elastics. Both groups reported a statistically insignificant intergroup difference of ANB improvement (T1-T0) of 2.5 degrees but significant intragroup ANB change. (211).

It was reported that Alt-RAMEC/FM treatment resulted in ANB improvement of 4.70 degrees toward the end of the treatment compared with Tooth-borne RME/FM (104). Similarly, the Alt-RAMEC/FM approach resulted in an ANB improvement of 4.0 degrees toward the end of the treatment when T0 compared to T1 (baseline and after FM treatment) as reported by Masucci et al. (193). Another study reported that implant-supported RME/FM resulted in an ANB improvement from -3.6 degrees to 0.77 degrees toward the end of the treatment (85). The improvement in the ANB reflects maxillary advancement which was evident at T0 and T1 (Co-A point) and to a very lesser extent, restriction or reduction of mandibular prominence.

The information given by the differences in ANB, Co-A and SNA along with N-A perpendicular demonstrates unequivocally that, in this study, the Alt-RAMEC/FM approach in tooth-borne and skeletally anchored RME resulted in improvement when compared to baseline.

Nevertheless, a comparison of the two groups reported statistically insignificant differences. This can be attributed to similar facemask-wearing hours and many comparable variables. Perhaps having a larger sample could have resulted in more accurate analysis. Post-hoc calculations based on the results showed that 60 patients per group are required to detect significance.

Placing the facemask traction hook anteriorly, distal to the deciduous canine region, closer to the maxillary centre of resistance, tends to overcome any undesirable maxillary counter-clockwise maxillary rotation. (78). Placing the forces at an angle of 30 degrees below the occlusal plane also helped to control the anticlockwise rotation of the maxillary complex (76). It is also mentioned that placing the traction hook anteriorly 20-30 degrees to the occlusal plane will result in more linear advancement of the maxilla (9). The results of this study are consistent with the literature.

Downward and backward rotation of the mandible was reported in the literature as an undesirable side effect that should be eliminated or controlled (9). However, the effect of mandibular downward and backward rotation is transient and patients tend to normalise to the initial rotation pattern after the treatment (223). The results of this study agree with that of Salazar et al, in that the mandibular-maxillary plane angle remained almost unchanged during the treatment in Groups I and II (T1-T0 = -0.30 degrees) and (T1-T0 = 0.20 degrees), respectively and these minor changes were statistically insignificant, both intergroup and intragroup (P = 0.619 and 0.140), respectively.

Wits appraisal is a supplementary measurement that is used to relate the maxilla to the mandible independent of the cranial base. (224). In this study, the Wits appraisal showed a significant change in each group toward the end of the treatment. Group I Wits appraisal showed a mean difference (T1-T0) of 4.70mm and Group II mean difference of 3.20mm, $P \leq 0.001$ and 0.002, respectively. The comparison between both groups showed insignificant change ($P \leq 0.496$).

Similar trends were reported by Liu et al. following Alt-RAMEC Tooth-borne RME/FM therapy, Wits appraisal showed a difference of 4.0 mm toward the end of the treatment (209). Tooth-borne RME/FM showed a difference of 4.86 mm in Wits appraisal between baseline and the end of treatment (225). The current study findings agree with this. Studies that used skeletally anchored RME/FM also reported similar findings to this research. It was concluded that the Wits appraisal improved through skeletally anchored RME/ FM toward the end of the treatment with a difference between (T1-T0) of -4.83 mm, $P \leq 0.01$ (85). In addition, it was reported that skeletally anchored RME/FM showed an improvement in Wits appraisal toward the end of the treatment with (T1-T0) difference of 4.0 mm, $P \leq 0.001$ (175).

Overjet showed a significant mean difference of 5.4 mm for Group I ($P<0.001$) and 4.5 mm for Group II ($P<0.001$). These findings also came in agreement with many studies (85,175,225). This suggests that the upper incisor angulation has changed in both groups. This resulted in a significant increase of nasolabial angle in Group I only, ($P \leq 0.028$), while Group II showed almost no changes between T0 and T1. This can be attributed to the forward component of the force exerted by the facemask that allowed the teeth to tip forward in the tooth-borne appliances. The mean change in upper incisor angulation (T1-T0) was 1.9 degrees for Group I as opposed to 4.40 degrees for Group II. This suggests that improvement of overjet in the skeletally anchored RME/FM group was through a predominantly skeletal effect, rather than dentoalveolar changes. Despite this finding, the two groups showed insignificant changes when compared.

Kim et al. reported in a systematic review that as a result of facemask pressure on the lower incisors, they tend to retrocline (8). In this study, lower incisor retroclination was statistically significant this may be due to the establishment of a positive overjet, which allowed subsequent dentoalveolar compensation to reduce the reverse overjet and produce a tendency to establish

a Class I incisor relationship. In addition, the skeletal effect was evident with SNA improvement ranging between (0.1-4 degrees and SNB ranging between (-1 to 2 degrees).

The current literature suggests that this topic is still new and evolving. Many published studies show differences in study design, methodology, patient ages and type of appliances. This research shed a light on similar results reported by many authors on the topic despite the different methodologies (106).

The skeletally anchored RME/FM showed greater skeletal effects and lesser dentoalveolar changes. For instance, overjet was improved in Group II with a lesser change of upper incisor inclination or interincisal angle. This implies that the reduction of overjet resulted from the skeletal advancement of the maxilla.

It would be desirable to follow up with the treated patients for at least five years, past puberty, to assess the stability of the outcomes.

Conclusions

1. Skeletal changes in both groups were evident however, comparing each group to its baseline (T0-T1), the results showed SNA with a significant mean difference of 2.10 degrees for Group I. There was an ANB mean difference of 3.9 degrees (P=0.001) for Group I and 3.1 degrees for Group II (P=0.001). The Wits appraisal showed a significant mean difference (T0-T1) for Group I, 4.7 degrees (0.001) and Group II, 3.2 degrees (0.002).
2. Overjet showed a significant mean difference of 5.4 mm for Group I (P<0.001) and 4.5 mm for Group II (P<0.001). Lower incisors to the mandibular plane showed a significant mean difference of -4 degrees for Group I (P=0.0023) and Group II =-6.1

(P=0.005). Nasolabial angle showed a significant mean difference of 13 degrees in Group I (P=0.028).

3. Intergroups comparison showed similar improvements trends and insignificant changes. This indicates that both treatment modalities gave a comparable amount of improvements.
4. Multivariant Linear Regression Analysis showed an insignificant association between skeletal and dentoalveolar outcomes and independent variables (Age, Quality of Life, Gender and Compliance).
5. The Alt-RAMEC approach in Tooth-borne RME/FM and skeletally anchored RME/FM showed similar skeletal and dental effects on prepubertal patients thus, the null hypothesis is accepted.

Chapter 5

Patients' Oral Health-related Quality of Life Outcomes and Economic Analysis

Introduction

Malocclusion is a deviation from the norm and is considered an abnormality in occlusion that requires intervention (226). Untreated malocclusions can affect an individual's quality of life and well-being directly or indirectly (227).

The concept of oral health-related quality of life (OHRQoL) is linked with the impact of the oral condition on a person's daily function, well-being, and overall quality of life (228). Studies on the psychological aspect of malocclusion emphasised the impact of malocclusion and orthodontic treatment on the self-esteem of adolescents (229). Studies of Oral Health-related Quality of Life (OHRQoL) in orthodontics are crucial because they provide information about therapeutic needs and outcomes as well as long-term oral health improvement (230).

It is suggested that patients can provide better-informed consent based on the patient's perception and understanding of the nature of treatment (230). Patients and their guardians/parents have been found to share comparable expectations of orthodontic treatment in most aspects, even though parents tend to have more realistic expectations in their estimated period of treatment at the initial visit. (148).

Studies reported that while the OHRQoL worsened during the treatment process in the treatment group, there was a considerable improvement afterwards (149,150). Johal et al. concluded that the impact of orthodontic treatment on OHRQoL in adults during the first 3 months of treatment with fixed orthodontic therapy had a negative impact on the OHRQoL of the patients, which was followed by an improvement toward the end of the treatment (231). This is expected when a patient receives a new orthodontic appliance, as soon as the patient adapts to the appliance and significant improvements in malocclusion are evident, the quality of life recovers and improve (232). Malocclusion has an impact on a patient's psychological

well-being, it was found that patients' orthodontic treatment enhances the patient's psychological state (229).

Measurement of Oral Health-Related Quality of Life in the Child Patient.

CPQ (8-10) proved to be a reliable valid tool to assess children's perceived quality of life (161). Measuring OHRQoL in children through questionnaires is not an easy task and faces many obstacles ranging for instance from the child's ability to read and their age-related ability to understand the concepts used in the questionnaire (169). The CPQ 8-10 was created to measure the OHRQoL among children between the ages of 8 and 10, (161,233). The CPQ includes four domain subscales of oral symptoms, functional limitations, emotional well-being and social well-being (157). In the literature very little is reported about Class III in growing young children and the impact of treatment on patients' quality of life.

This study aims to study the impact of Group I (Tooth-borne RME/FM) and Group II (Skeletally anchored RME/FM) and patients' related outcomes which cover oral-health-related quality of life and the financial aspects of the treatment.

Patients and Methods

This Randomised Clinical Trial (RCT) investigated the reported outcomes following treatment with two types of expanders and Facemask appliances. Group I: Tooth-borne RME/FM and Group II: Skeletally anchored RME/FM. Both groups were divided randomly into two groups of 17 patients each. The patients' reported outcomes investigated in this chapter are the quality of life and the economics of the treatment. The quality of life was assessed via the Child Perception Questionaire 8-10 (CPQ 8-10). The CPQ 8-10 was administered at different time points T0= baseline (pretreatment), T1= first month,

T2=second month,… till T9 (9 months). The CPQ 8-10 questionnaire was validated from English to Maltese, The English CPQ8–10 version (Appendix V) was translated into one of the Maltese languages using the forward-backwards technique for translating (183). The validation method was discussed in Chapter 2.

Economic Parameters:

As explained previously in Chapter 2, in this study we measured the time and clinical costs from the initial treatment (pre-surgical consultations and actual surgery which involved the installation of the implant fixture in group 2) and all the follow-up visits that included the cost for orthodontic reviews, maintenance and complications including the respective clinical travel and waiting time costs, during the treatment.

Costs for the initial treatment:

The costs for initial treatment were collected and consisted of a global figure for initial treatment which included the costs for both treatment modalities as necessary, the orthodontic rapid expanders, facemask, compliance sensor and mini-implant. The initial treatment costs also included the professional fees (orthodontist and auxiliary staff in a hospital setting) required to provide the service.

Costs for reviews, maintenance and complications:

These costs included all the scheduled visits and unscheduled visits required by the patients for maintenance such as appliance adjustments and repairs and the complications such as the remaking of these appliances when necessary.

Clinical time per visit

A cost-effectiveness analysis was undertaken to identify the least costly alternative since clinical and quality of life outcomes of the two procedures were comparable as reported previously. The time for each intervention was recorded with a stopwatch. The clinical time was measured from when the patient entered and left the clinic (including waiting time).

Results

Internal Consistency of CPQ 8-10 (Maltese version)

Cronbach´s alpha coefficient was used to estimate the questionnaire´s internal consistency on a sample of n=48 children between 8 to 11 years old. Maltese version CPQ 8-10 domains showed high consistency (alpha>0.8).

The overall consistency was very high (alpha=0.915). Thus, it was concluded that the Maltese version of CPQ 8-10 is highly reliable to assess the child's oral health-related quality of life (Table 24).

	Alpha	Interpretation
Oral symptoms	0.822	Good
Functional limitation	0.844	Good
Emotional	0.860	Good
Social	0.950	Excellent
Global	0.915	Excellent

Table 24: Internal reliability of the CPQ scores: Cronbach´s alpha coefficient. Oral symptoms, Emotional and Functional limitation domains showed Good correspondence while Social and global domains showed excellent agreement.

Reliability: Test-retest

Seventeen patients managed to fill out the CPQ questionnaire 3 weeks after the first session. The test-retest reliability was assessed by computing the intra-class correlation coefficient (ICC) based on a one-way repeated measures analysis of variance, using summary CPQ scores from the repeated administration of the tests. Intra-class correlation coefficients were all estimated larger than 0.95, reflecting very high reliability (Table 25).

	CCI	**Confidence Interval (95%)**	**Assessment**
Oral Domain	0.96	0.89 – 0.98	Very good
Functional Domain	0.99	0.98 – 1.00	Very good
Emotional Domain	0.98	0.95 – 0.99	Very good
Social Domain	0.99	0.99 – 1.00	Very good
Global	0.99	0.99 – 1.00	Very good

Table 25: Test-retest reliability of total scores and per domain of CPQ: Intra-class correlation coefficient (CCI)showed a very good agreement.

CPQ scores were stable over time, paired t-test was used to assess any statistical significance. All subdomains and global scores were insignificant (P >0.05) for all mean differences which reflects the stability of scores (Table 26).

	Mean difference	Confidence Interval (95%)	p-value
Oral Domain	0.18	-0.22 – 0.55	0.332 (z=1.56)
Functional Domain	0.18	-0.03 – 0.38	0.083 (z=2.032)
Emotional Domain	0.12	-0.19 – 0.43	0.431 (z=1.3)
Social Domain	-0.12	-0.29 – 0.05	0.163 (z=2.55)
Global	0.35	-0.05 – 0.76	0.083 (z=1.1)

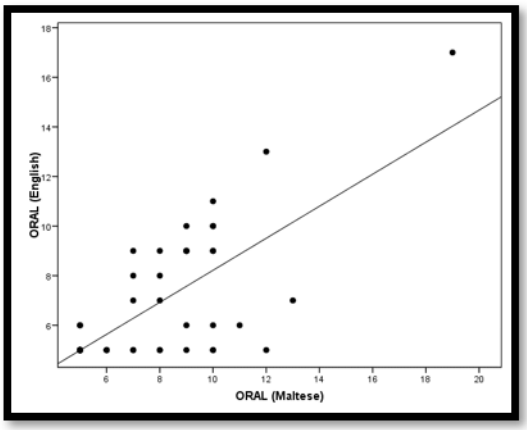
Table 26:Test-retest reliability of total scores and per domain of CPQ. Stability over time: Mean difference time 1 – time 2, 95% CI and p-value from paired t-test.

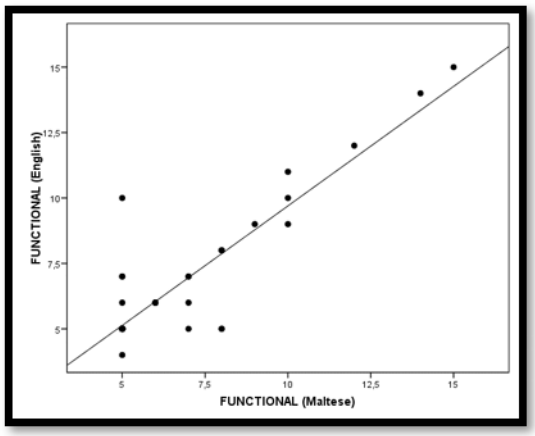
CPQ 8-10 Validity

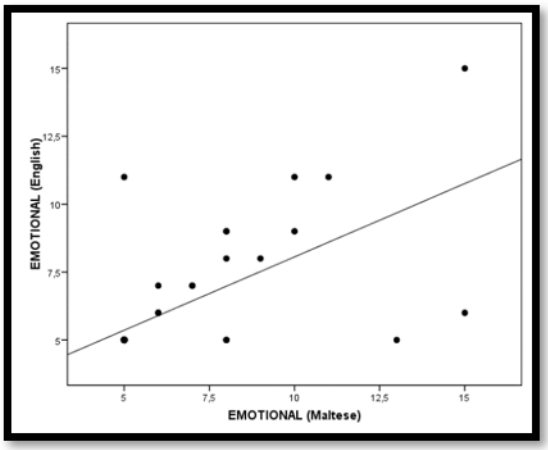
Correlation between English and Maltese scores CPQ 8-10 was assessed. Spearsman's Correlation Coefficient was high (r>0.7) in Figures 18 and 19. Indicating that the Maltese version of CPQ 8-10 is a valid tool and almost identical to the original English CPQ 8-10 (Table 27), Figure 16 and 17.

CPQ 8-10 Domains	r	p-value	Assessment
Oral Domain	0.625	**<0.001*** **	Moderate-high
Functional Domain	0.749	**<0.001*** **	High
Emotional Domain	0.770	**<0.001*** **	High
Social Domain	0.797	**<0.001*** **	High
Global	0.776	**<0.001*** **	High

Table 27: Validity of total scores and per domain of CPQ: Spearman´s correlation coefficient between Maltese and English versions of the questionnaire







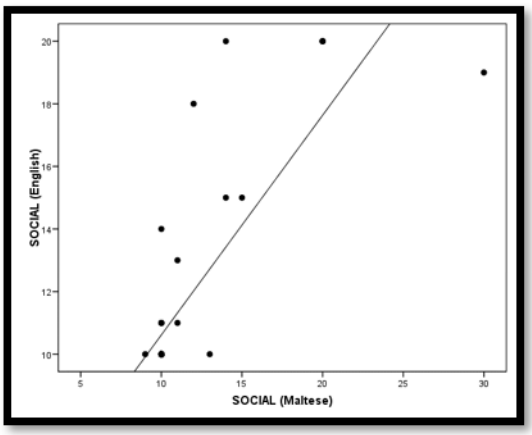


Table 28: CPQ 8-10 4 four domains (Maltese and English) Spearsman's Correlation Coefficient showing a good correlation between the two versions.

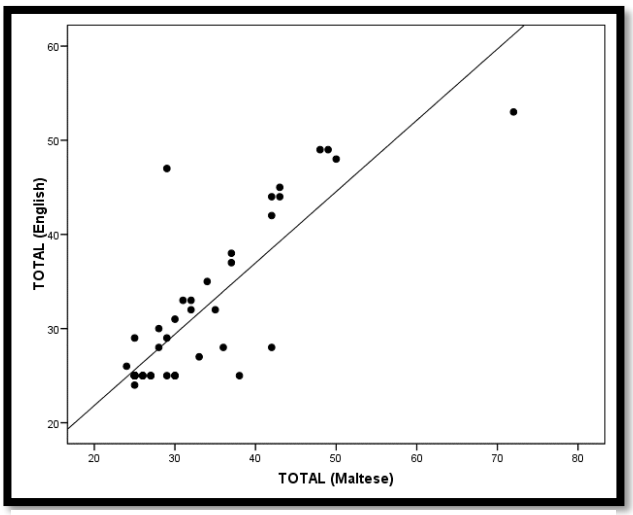


Table 29: global scores of CPQ 8-10 (Maltese and English), Spearsman's Correlation Coefficient showing that the global scores of Maltese and English versions are very close to the projected line which reflects strong correlation

Figure 16 shows four domains of CPQ 8-10. Interestingly oral pain and functional domains worsened immediately after starting treatment. Then, they drop down similar to the pretreatment level (T0). On the other hand, emotional and social well-being keep quite stable throughout the treatment time

The global scores (T0-T9) in Figure 17 showed similar trends and were highly determined for these partial changes.

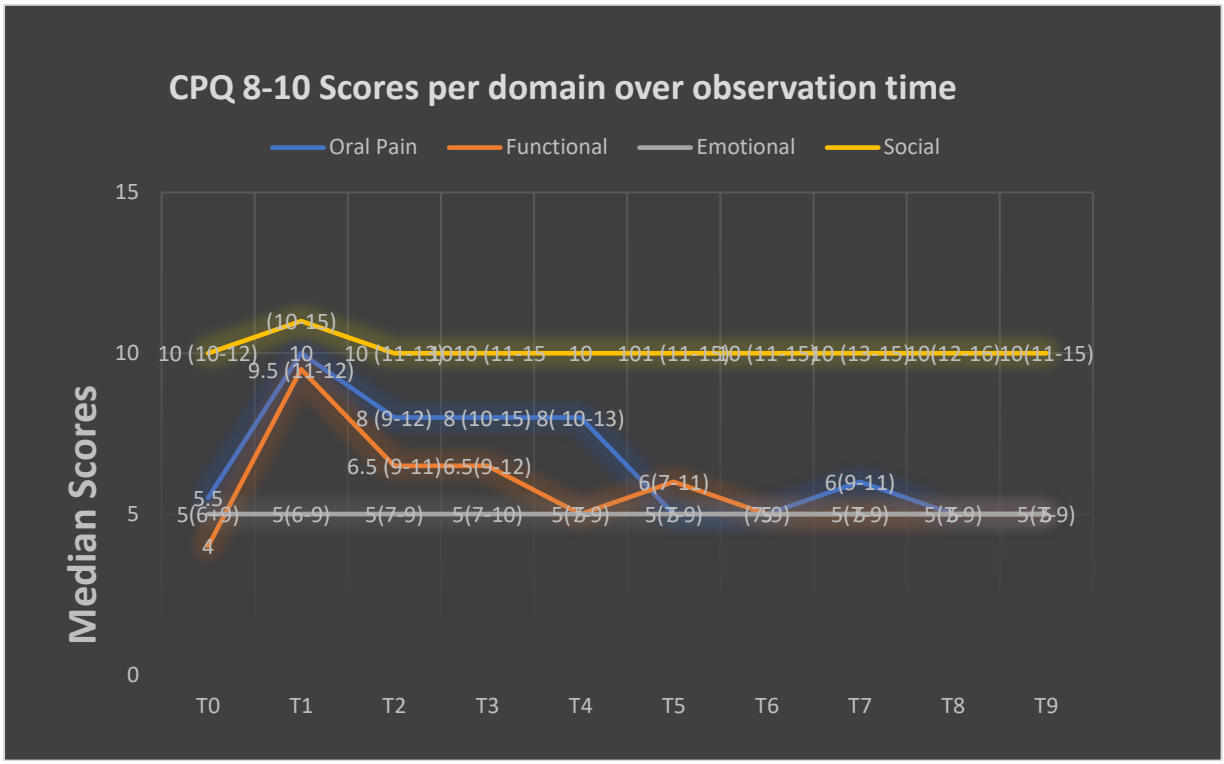


Figure 16: CPQ 8-10 median changes per domain scores between (T0) baseline and (T9) end-of-treatment follow-up time points. Pain and Physical limitation domains are affected (T1-T0) then normalise with time and most other domains tend to stabilise with time. Median and IQR

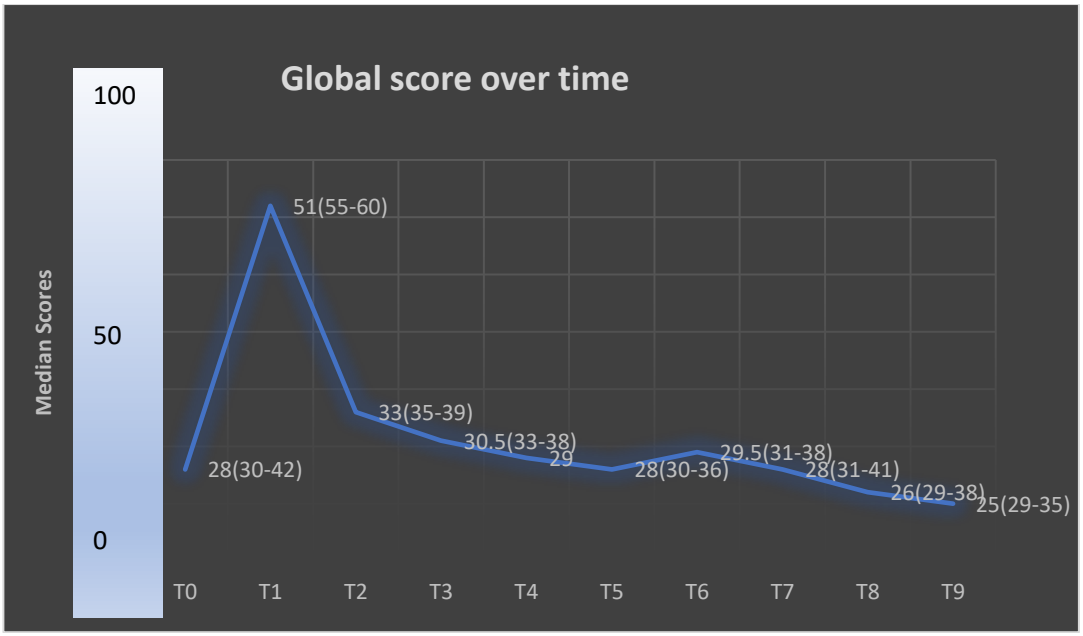


Figure 17: Median changes of global CPQ 8-10 scores between (T0) baseline and (T9) end of treatment follow-up time points showing a spike or worsening in quality of life (T1-T0) then it normalises with time. Median and IQR

Table 28 shows that the functional domains worsened almost throughout the treatment time within Group I and Group II. For the oral pain domain at T1, the CPQ 8-10 score spiked up compared to T0 (baseline), 10(7-12) (P=0.013) and 10(5-12) (P=0.05) for Group I and II, respectively. Through the rest of the time points, insignificant differences were found in comparison to the T0 (baseline) measurement. Remarkably at T4, the Tooth-borne RME patients still experienced a higher level of pain than at baseline 8(7-13) (p=0.038). However, there were insignificant differences found between Groups I and II at all time points (Figure 18 and Table 30).

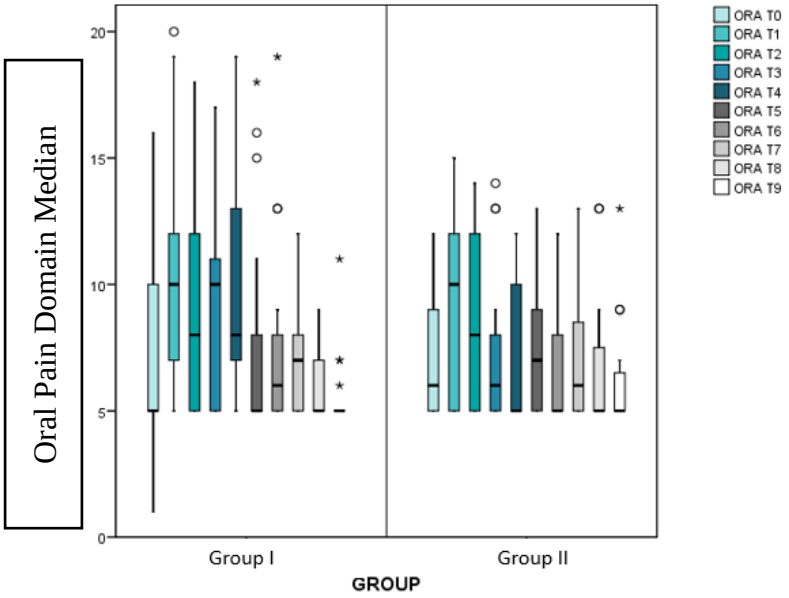


Figure 18:Oral Pain Domain Median and interquartile range (IQR) of pain domain in CPQ 8-10 between Group I (Tooth-borne RME/FM and Group II (Skeletally anchored RME/FM). Both groups showed comparable medians and each group showed improvement toward T9.

The Functional domain showed that Group I and II suffered a significant impact on function compared to T0 (baseline). Intergroup functional limitation domain comparisons showed insignificant differences (Figure 19 and Table 30).

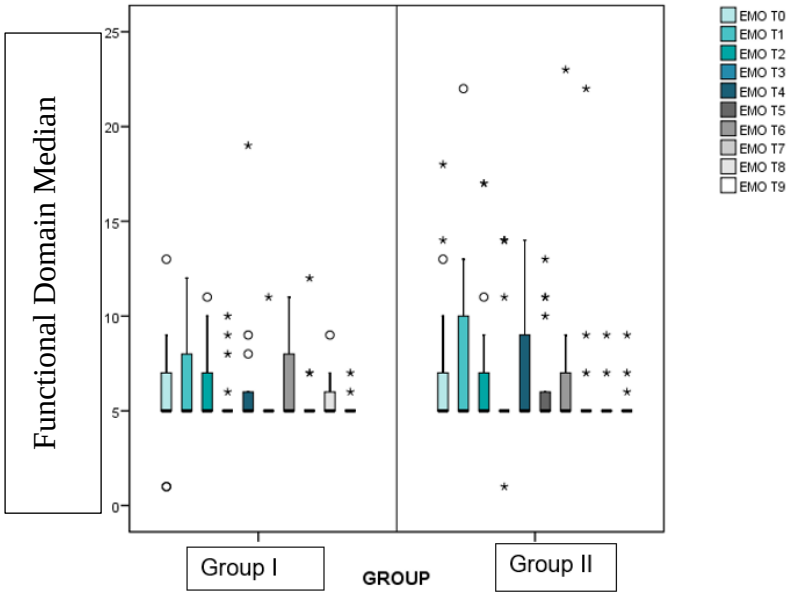


Figure 19: Functional Domain Median and interquartile range (IQR) of pain domain in CPQ 8-10 between Group I (Tooth-borne RME/FM and Group II (skeletally anchored RME/FM). Both groups showed comparable medians and each group showed improvement toward T9.

The social well-being domain showed insignificant differences within and between the two groups (Table 30).

The global score of CPQ 8-10 showed a significant increase in the median at T1 in comparison to T0 in both groups. Group I Median = 53(41-65) (P=0.001) and Group II median = 51 (35-59) (P≤0.002). The total score at T8 Group I showed a significant reduction in median score reflecting an improvement in quality of life median 26 (25-29) (0.017) and at T9 median = 25(25-27) (P=0.005). No significant differences were noticed between groups (Figure 20 and Table 30).

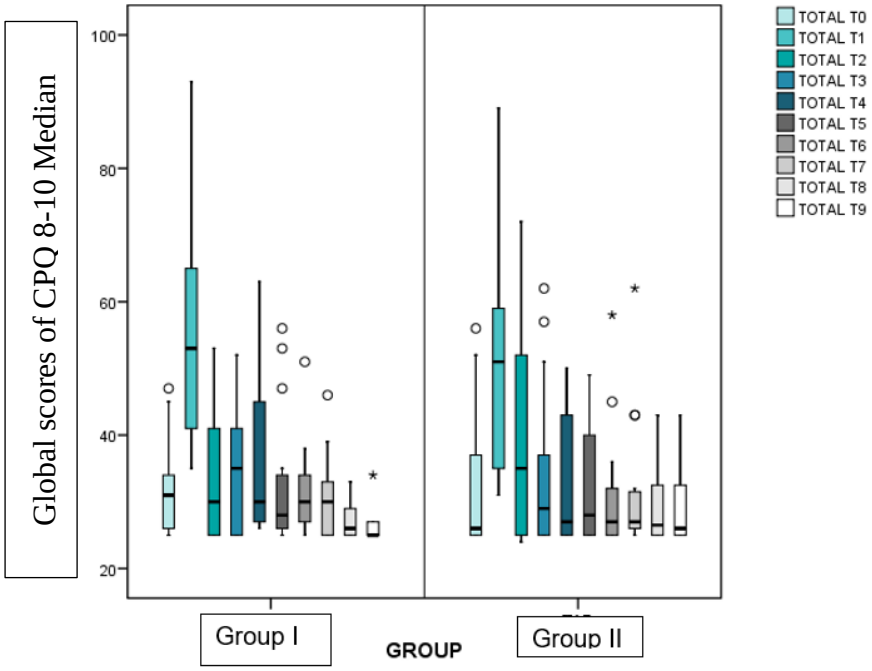


Figure 20:Global scores of CPQ 8-10 Median and interquartile range (IQR) of pain domain in CPQ 8-10 between Group I (Tooth-borne RME/FM and Group II (skeletally anchored RME/FM). Both groups showed improvement in the global scores of qualities of life toward the end

	GROUP	T0	T1	T2	T3	T4	T5	T6	T7	T8	T9
Oral Complaint	**Group I**	5 (5-10)	10 (7-12) **p=0.013 * z=2.48**	8 (5-12) p=0.196 z=1.29	10 (5-11) p=0.119 z=1.56	8 (7-13) **p=0.038 * z=2.08**	5 (5-8) p=0.953 z=0.06	6 (5-8) p=0.777 z=0.28	7 (5-8) p=0.893 z=0.13	5 (5-7) p=0.205 z=1.27	5 (5-5) p=0.058 z=1.90
	Group II	6 (5-9)	**10 (5-12) p=0.054 * z=1.93**	8 (5-12) p=0.307 z=1.02	6 (5-8) p=0.752 z=0.32	5 (5-10) p=1.000 z=0.00	7 (5-9) p=0.538 z=0.62	5 (5-8) p=0.305 z=1.03	6 (5-8.5) p=0.783 z=0.28	5 (5-7.5) p=0.423 z=0.80	5 (5-6.5) p=0.229 z=1.20
	Diff.TI-T0 G1 vs GII		p=0.540 z=0.64	p=0.658 z=0.45	p=0.140 z=1.51	p=0.114 z=1.63	p=0.892 z=0.14	p=0.205 z=1.31	p=0.817 z=0.24	p=0.901 z=0.13	p=0.845 z=0.21
Functional Limitation	**Group I**	4 (4-5)	10 (5-15) **p<0.001 *** z=3.65**	7 (5-11) **p=0.002 ** z=3.07**	7 (5-10) **p=0.002 ** z=3.12**	5 (5-7) **p=0.022 * z=2.28**	6 (5-7) **p=0.003 ** z=2.96**	6 (5-7) **p=0.006 ** z=2.78**	5 (5-5) p=0.064 z=1.85	5 (5-5) **p=0.039 * z=2.07**	5 (5-5) p=0.377 z=0.88
	Group II	4 (4-5)	8 (5-13) **p=0.005 ** z=2.83**	5 (5-16) **p=0.007 ** z=2.71**	5 (5-9) **p=0.020 * z=2.32**	5 (5-10) **p=0.019 * z=2.34**	5 (5-9) **p=0.018 * z=2.37**	5 (5-6) p=0.216 z=1.24	5 (5-7) p=0.134 z=1.50	5 (5-8) **p=0.046 * z=1.99**	5 (5-9) p=0.089 z=1.70
	Diff.TI-T0 G1 vs G2		p=0.518 z=0.67	p=0.760 z=0.32	p=0.205 z=1.31	p=0.760 z=0.33	p=0.245 z=1.19	p=0.274 z=1.15	p=0.606 z=0.57	p=0.444 z=0.90	p=0.110 z=1.80
Emotional Limitation	**Group I**	5 (5-7)	5 (5-8) p=0.229 z=1.20	5 (5-7) p=0.474 z=0.72	5 (5-5) p=1.000 z=0.00	5 (5-6) p=0.687 z=0.40	5 (5-5) p=0.572 z=0.57	5 (5-8) p=0.798 z=0.26	5 (5-5) p=0.720 z=0.36	5 (5-6) p=0.538 z=0.62	5 (5-5) p=0.258 z=1.13
	Group II	5 (5-7)	5 (5-10) p=0.438 z=0.78	5 (5-7) p=0.552 z=0.59	5 (5-5) p=0.917 z=0.11	5 (5-9) p=0.858 z=0.18	5 (5-6) p=0.674 z=0.42	5 (5-7) p=0.905 z=0.12	5 (5-5) p=0.527 z=0.63	5 (5-5) p=0.115 z=1.58	5 (5-5) p=0.075 z=1.78
	Diff.TI-T0 GI vs GII		p=0.892 z=0.16	p=0.946 z=0.09	p=0.946 z=0.09	p=0.892 z=0.14	p=0.496 z=0.77	p=0.734 z=0.38	p=0.763 z=0.35	p=0.736 z=0.37	p=0.817 z=0.25
Social wellbeing	**Group I**	10 (10-11)	12 (10-13) p=0.068 z=1.83	10 (10-10) p=0.075 z=1.78	10 (10-11) p=0.837 z=0.21	10 (10-10) p=0.720 z=0.36	10 (10-12) p=0.783 z=0.28	10 (10-11) p=0.887 z=0.14	11 (10-14) p=0.223 z=1.19	10 (10-10) p=0.066 z=1.84	10 (10-10) p=0.091 z=1.69
	Group II	10 (10-14)	10 (10-12) p=0.483 z=0.70	10 (10-11) p=0.723 z=0.35	10 (10-12) p=0.674 z=0.42	10 (10-14) p=0.570 z=0.57	10 (10-12) p=0.438 z=0.78	10 (10-10) p=0.400 z=0.84	10 (10-11) p=0.292 z=1.05	10 (10-11) p=0.235 z=1.19	10 (10-11) p=0.065 z=1.84
	Diff.TI-T0 GI vs G II		p=0.376 z=0.94	p=0.182 z=1.41	p=0.474 z=0.77	p=0.454 z=0.80	p=0.812 z=0.25	p=0.683 z=0.45	p=0.204 z=1.31	p=0.901 z=0.13	p=0.958 z=0.08
Total Scores	**Group I**	31 (26-34)	53 (41-65) **p<0.001 *** z=3.62**	30 (25-41) p=0.529 z=0.63	35 (25-41) p=0.362 z=0.91	30 (27-45) p=0.201 z=1.28	28 (26-34) p=0.691 z=0.40	30 (27-34) p=0.842 z=0.20	30 (25-33) p=0.629 z=0.48	**26 (25-29) p=0.017 * z=2.39**	**25 (25-27) p=0.005 ** z=2.83**
	Group II	26 (25-37)	51 (35-59) **p=0.002 ** z=3.15**	35 (25-52) p=0.140 z=1.48	29 (25-37) p=0.421 z=0.81	27 (25-43) p=0.346 z=0.94	28 (25-40) p=0.529 z=0.63	27 (25-32) p=0.955 z=0.06	27 (26-31.5) p=0.780 z=0.28	26.5 (25-32.5) p=0.442 z=0.77	26 (25-32) p=0.310 z=1.02
	Diff.TI-T0 GI vs G II		p=0.786 z=0.28	p=0.395 z=0.88	p=0.946 z=0.07	p=0.683 z=0.41	p=0.865 z=0.60	p=0.563 z=0.31	p=0.763 z=0.31	p=0.363 z=0.94	p=0.292 z=1.07

*Table 30:Total and Domain CPQ scores of Quality of Life over time between groups: median (IQR). Wilcoxon´s test for comparisons within-groups in relation to T0. Mann-Whitney test for comparisons between groups. *p<0.05; **p<0.01; ***p<0.001. Z= statistical significance*

Effect of Gender on Quality of Life

In Group II, some significant differences were observed between genders for the time points T0-T8 and T0-T9. The T0-T8 changes for male patients showed similar distributions, whilst females showed a big reduction of the score (improving quality of life). For T0-T9, a similar significant trend was noticed (Table 31). Therefore, in the last months of the follow-up females showed a substantial improvement in their quality of life.

	T0	T1-T0	T2-T0	T3-T0	T4-T0	T5-T0	T6-T0	T7-T0	T8-T0	T9-T0
WHOLE sample	0.445 z=0.81	0.363 z=0.92	0.344 z=0.98	0.690 z=0.43	0.258 z=1.16	0.772 z=0.31	0.403 z=0.87	0.611 z=0.54	0.154 z=1.46	**0.105 z=1.65**
Group I	0.574 z=0.59	0.442 z=0.79	0.879 z=0.21	0.574 z=0.58	0.082 z=1.74	0.234 z=1.22	0.959 z=0.11	0.160 z=1.48	0.879 z=0.21	**0.959 z=0.11**
Group II	**0.122 z=1.65**	**0.660 z=0.46**	**0.149 z=1.46**	**0.216 z=1.27**	**0.884 z=0.15**	**0.098 z=1.67**	**0.350 z=0.96**	**0.635 z=0.54**	0.042* z=2.02	**0.022* z=2.24**

*Table 31: Total score of Quality of Life over time by Gender: Results of Mann-Whitney´s test for comparisons between gender *p<0.05; **p<0.01; ***p<0.001. Z= statistical significance*

The effect of compliance on Quality of Life

No significant correlations were observed within and between the two Groups I and II for all time points (Table 32).

	T1-T0	T2-T0	T3-T0	T4-T0	T5-T0	T6-T0	T7-T0	T8-T0	T9-T0
WHOLE sample	-0.23 t=1.34 p=0.188	-0.11 t=0.63 p=0.556	0.01 t=0.06 p=0.946	-0.17 t=0.98 p=0.351	-0.15 t=0.86 p=0.401	-0.19 t=1.09 p=0.281	-0.09 t=0.51 p=0.632	-0.08 t=0.45 p=0.654	**-0.16 t=0.92 p=0.386**
Group I	-0.20 t=0.79 p=0.450	-0.12 t=0.47 p=0.640	0.22 t=0.87 p=0.401	-0.09 t=0.35 p=0.747	0.01 t=0.04 p=0.984	-0.41 t=1.74 p=0.104	-0.05 t=0.19 p=0.862	-0.18 t=0.71 p=0.500	**-0.24 t=0.96 p=0.358**
Group II	**-0.24 t=0.96 p=0.359**	**0.02 t=0.08 p=0.948**	**-0.09 t=0.35 p=0.742**	**-0.25 t=1.00 p=0.332**	**-0.32 t=1.31 p=0.208**	**0.01 t=0.04 p=0.903**	**-0.16 t=0.63 p=0.552**	**0.13 t=0.51 p=0.627**	**0.12 t=0.47 p=0.671**

*Table 32: Correlation between Changes at Total score and Number of daily hours wearing the appliance. . Group I (Tooth-borne RME/FM) and Group II (Skeletally anchored RME/FM). Spearman´s correlation coefficient and p-value *p<0.05; **p<0.01; ***p<0.001*

Cost and financial analysis

The mean consultation time was significantly longer in Group II compared to Group I ($p<0.001$). The mean difference was 8.8 minutes although this is of minor clinical significance (Table 33). Insignificant differences in time were detected during the reviews ($p=0.322$), and the total time for all reviews (T1-T9) was insignificant in Group I and II ($P=0.062$).

Consultation fees were significantly higher in Group II in comparison to Group I ($P<0.001$) (Table 33). On the other hand, insignificant financial costs differences were detected between groups during review appointments, emergency appointments and total time.

The original appliance price was significantly higher for Group II (Euros 405) since it included two mini-implants in addition to RME/FM in comparison to Group I which had RME/FM ($P<0.001$) (Table 33). The total cost of emergency reviews was significantly higher in Group II (Euros 533.5 ± 187.4) in comparison to Group I (Euros 177.6 ± 57.9) (Table 33).

Taking into consideration the total costs (Total time + Total material costs), Group II showed significantly higher costs of Euros 580.1 ± 202.5 and Group I Euros 213.6 ± 63.1 ($P<0.001$) (Table 33).

Loose band emergency appointments were significantly higher in Group I in comparison to Group II ($P<0.001$). Loose bands emergency appointments ratio in Group I to Group II, 7:0 (Table 34). Broken appliances were significantly higher in Group I in comparison to Group II,

	TIME (min)				COSTS (€)		
	Group I	**Group II**	**p-value**		**Group I**	**Group II**	**p-value**
Consultation	14.8 ± 2.3 15 (14-16)	23.6 ± 6.0 22 (20-25)	**<0.001*** * (z=4.61)**		3.1 ± 0.5 3.1 (2.9-3.3)	4.9 ± 1.2 4.6 (4.2-5.2)	**<0.001*** (z=4.61)**
Review	136.1 ± 10.8 137 (130-140)	142.3 ± 16.5 140 (130-155)	0.322 (z=1.02)		28.4 ± 2.3 28.5 (27.1-29.2)	29.6 ± 3.4 29.2 (27.1-32.3)	0.322 (z=1.02)
Emergency	21.6 ± 29.9 15 (0-20)	57.8 ± 109.0 5 (0-62)	0.838 (z=0.21)		4.5 ± 6.2 3.1 (0-4.2)	12.0 ± 22.7 1.0 (0-12.9)	0.838 (z=0.21)
Total Time	172.5 ± 31.7 165 (155-173)	223.6 ± 108.6 202 (164-243)	0.062 (z=1.86)		35.9 ± 6.6 34.4 (32.3-36.0)	46.6 ± 22.6 42.1 (34.2-50.6)	0.062 (z=1.86)
Original (appliance)					150	405	**<0.001*** (z=5.75)**
Emergency (repairs)					27.6 ± 57.9 15 (10-15)	128.5 ± 187.4 15 (0-190)	0.658 (z=0.48)
Total emergency					177.6 ± 57.9 165 (160-165)	533.5 ± 187.4 420 (405-595)	**<0.001*** (z=5.03)**
Total Costs					213.6 ± 63.1 199.6 (194.2-202.1)	580.1 ± 202.5 464.4 (439.4-637.1	**<0.001*** (z=4.70)**

*Table 33:Time duration and Costs per group: In 1st row mean ± SD; in 2nd-row median (IQR). Results of Mann-Whitney test for comparisons between groups. Group I (Tooth-borne RME/FM) and Group II (Skeletally anchored RME/FM). p-value. =. *p<0.05; **p<0.01; ***p<0.0*

Rates and Type of Emergencies between Groups			
Emergency	**Group I**	**Group II**	**P-Value**
Lose bands (yes/no) [a]	**7**	**0**	**0.018***
Breakage of band (yes/no) [a]	0	6	0.335
Broken Traction hooks arms (yes/no) [b]	8	4	0.151 (Chi=2.06)
Broken Appliance (yes/no) [a]	9	2	**0.014***

*Table 34:Types of emergencies during the whole period time between Group I and II. a=Fisher's exact test used to com and b= Chi2 test. *p<0.05; **p<0.01; ***p<0.001*

Estimating ICER based on SNA gain

ICER was Euros -516.2 (a negative sign means that Group II appliances are more expensive and less efficient gaining extra change in SNA. The mean of ICER was calculated by a bootstrap approach, Euros -247.5 per degree change of SNA. and CI ranges from Euros -4700 to +4200 per degree change in SNA, which mandates caution in interpreting the results (Table 35).

	GROUP		
	Group I	**Group II**	**MEAN DIFFERENCE**
SNA Gain T1-T0 (º)	2.22 ± 2.79	1.51 ± 3.84	-0.71 ± 1.11
TOTAL COST (€)	213.6 ± 63.1	580.1 ± 202.5	366.5 ± 21.2
ICER (TOTAL COST per 1º at SNA gain)	-516.2		
Mean	-247.5		
SD	4,830.9		
95% CI	-4,724.3 4,201.7		

Table 35. Cost-effectiveness analysis based on SNA (º): Mean ± SD for SNA gain and Total cost, Mean ± SE for difference, ICER and statistical uncertainty of the ICER calculated from bootstrapping method on 1,000 samples

Figure 21 represents the cost-effectiveness plane (CE), including ICER and confidence limits

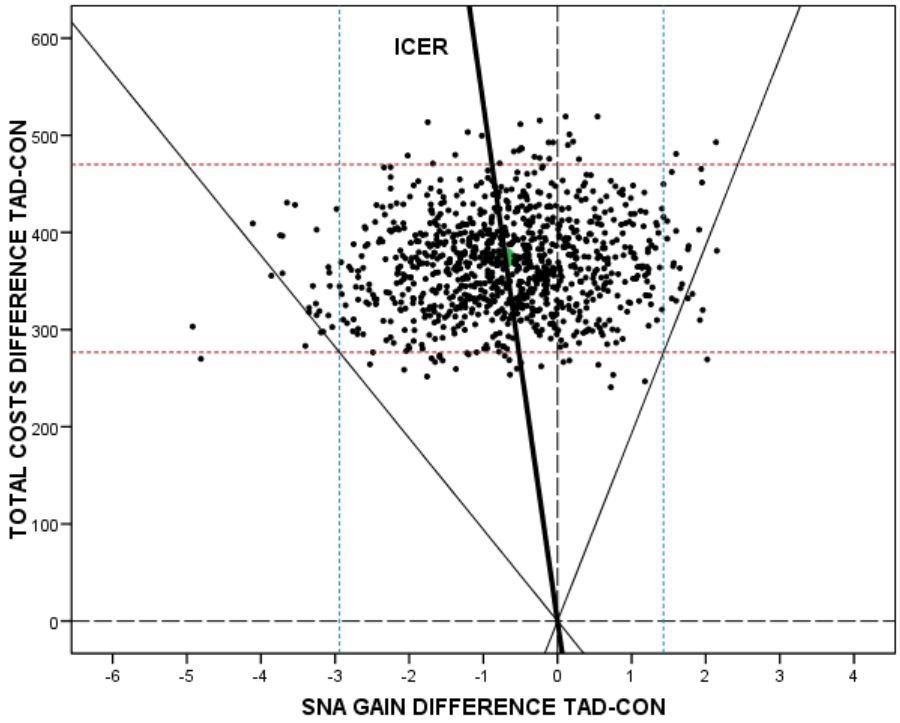


Figure 21: Differences in ICER per SNA degree change. Y axis represents the cost and X axis represents the benefit, the ICER is represented as the green ellipsoid body at the far left of the diagram. The location of ICER represents similar effectiveness and higher costs.

Costs and Quality of Life

Quality of life showed a worsening in oral and functional limitations domains in both groups. The magnitude of worsening in quality of life was the same in both groups. Similarly, it was found that mini-implant-supported appliances used in Group II were more expensive than the Tooth-borne expanders in Group I. Therefore, skeletally anchored devices showed higher costs with similar effects on patients' quality of life compared to Group I.

Table 36 shows no significant correlation between the oral complaint domain and total costs. The effect of the appliances on oral pain was not correlated with the total cost at all time points.

	T1-T0	**T2-T0**	**T3-T0**	**T4-T0**	**T5-T0**	**T6-T0**	**T7-T0**	**T8-T0**	**T9-T0**
WHOLE sample	-0.15 t=0.86 p=0.386	-0.15 t=0.86 p=0.396	-0.28 t=1.65 p=0.109	-0.22 t=1.28 p=0.208	-0.02 t=0.11 p=0.932	-0.28 t=1.65 p=0.111	-0.08 t=0.45 p=0.673	0.01 t=0.06 p=0.964	**0.01** **t=0.06** **p=0.989**
Group I	-0.22 t=0.87 p=0.388	-0.14 t=0.55 p=0.596	-0.16 t=0.64 p=0.536	-0.17 t=0.67 p=0.515	-0.11 t=0.43 p=0.663	-0.18 t=0.71 p=0.485	-0.31 t=1.26 p=0.225	-0.07 t=0.27 p=0.785	**-0.21** **t=0.83** **p=0.423**
Group II	**0.09** **t=0.35** **p=0.741**	**-0.09** **t=0.35** **p=0.719**	**-0.04** **t=0.16** **p=0.879**	**0.26** **t=1.04** **p=0.309**	**0.09** **t=0.35** **p=0.723**	**-0.04** **t=0.16** **p=0.894**	**0.23** **t=0.92** **p=0.398**	**0.10** **t=0.39** **p=0.712**	**0.21** **t=0.83** **p=0.443**

*Table 36: Correlation between Changes at Pain score and Total costs: Spearman´s correlation coefficient and p-value, *p<0.05; **p<0.01; ***p<0.001*

Table 37 shows an insignificant correlation between the functional limitation domain and total costs. The effect of the appliances on functional limitation was not correlated with the total cost. Similarly, the global scores of CPQ 8-10 of both groups showed an insignificant correlation between total costs and CPQ 8-10 total scores of the previous domains Table 38.

	T1-T0	T2-T0	T3-T0	T4-T0	T5-T0	T6-T0	T7-T0	T8-T0	T9-T0
WHOLE sample	-0.19 t=1.09 p=0.272	-0.01 t=0.06 p=0.979	-0.23 t=1.34 p=0.195	-0.08 t=0.45 p=0.662	-0.19 t=1.09 p=0.283	-0.14 t=0.80 p=0.446	0.03 t=0.17 p=0.886	0.06 t=0.34 p=0.744	0.22 t=1.28 p=0.229
Group I	-0.23 t=0.92 p=0.369	0.03 t=0.12 p=0.916	0.03 t=0.12 p=0.921	-0.26 t=1.04 p=0.316	-0.01 t=0.04 p=0.962	0.10 t=0.39 p=0.710	-0.23 t=0.92 p=0.382	-0.14 t=0.55 p=0.594	-0.26 t=1.04 p=0.324
Group II	-0.08 t=0.31 p=0.763	-0.13 t=0.51 p=0.611	-0.22 t=0.87 p=0.392	0.18 t=0.71 p=0.496	0.08 t=0.31 p=0.760	-0.01 t=0.04 p=0.958	0.01 t=0.04 p=0.955	-0.12 t=0.47 p=0.647	0.03 t=0.12 p=0.919

*Table 37: Correlation between Changes at Functional score and Total costs: Spearman´s correlation coefficient and p-value *p<0.05; **p<0.01; ***p<0.001*

	T1-T0	T2-T0	T3-T0	T4-T0	T5-T0	T6-T0	T7-T0	T8-T0	T9-T0
WHOLE sample	-0.15 t=0.86 p=0.392	0.07 t=0.40 p=0.682	0.02 t=0.11 p=0.930	-0.08 t=0.45 p=0.666	0.08 t=0.45 p=0.640	0.10 t=0.57 p=0.558	0.13 t=0.74 p=0.465	0.13 t=0.74 p=0.484	**0.15** **t=0.86** **p=0.420**
Group I	-0.40 t=1.69 p=0.115	-0.23 t=0.92 p=0.384	-0.16 t=0.63 p=0.535	-0.17 t=0.67 p=0.522	0.04 t=0.16 p=0.881	-0.14 t=0.55 p=0.600	-0.15 t=0.59 p=0.605	-0.18 t=0.71 p=0.493	**-0.23** **t=0.92** **p=0.379**
Group II	**0.17** **t=0.67** **p=0.503**	**0.12** **t=0.05** **p=0.645**	**0.09** **t=0.36** **p=0.731**	**0.24** **t=0.96** **p=0.362**	**0.25** **t=1.00** **p=0.338**	**0.24** **t=0.96** **p=0.345**	**0.38** **t=1.59** **p=0.152**	**0.20** **t=0.79** **p=0.456**	**0.25** **t=1.00** **p=0.357**

*Table 38: Correlation between Changes at Global and Total costs: Spearman´s correlation coefficient and p-value.*p<0.05; **p<0.01; ***p<0.001*

Estimating ICER based on QoL per unit change

ICER showed that Group II showed higher costs and less unit change in QoL. For instance, at T9-T0 ICER was at -159.3 € per unit change of QoL. This negative sign means that skeletal-borne RME/FM is a more expensive system and probably does not provide an extra gain of QoL. However, the uncertainty is extreme because of the dispersion of costs and gains in the original samples and the small sample size. The mean ICER calculated from the bootstrapping approach was -65.2 €/unit QoL. Interval 95% CI ranged from -1,201 to 891,9 € per unit. Median (-76.6 €/unit QoL) is a more stable estimation (Table 39).

	GROUP				Estimations from bootstrapping method		
	Group I	**Group II**	**MEAN DIFFERENCE**	**ICER (Total cost per 1 unit at QoL gain)**	**Mean ± SD**	**95% CI**	**Median+IQR**
TOTAL COST (€)	213.6 ± 63.1	580.1 ± 202.5	366.5 ± 21.2				
QoL Gain T1-T0	-22.5 ± 15.6	-18.8 ± 16.5	3.7 ± 2.3	99,1	43.8 ± 539.9	-861.3 782.5	47.5 (50-66)
QoL Gain T2-T0	-2.5 ± 9.0	-5.8 ± 15.1	-3.2 ± 1.8	-114,5	-49.0 ± 758.3	-1027.9 1059.5	-63.2 (10-35)
QoL Gain T3-T0	-2.9 ± 10.8	-1.4 ± 13.6	1.5 ± 1.7	244,3	33.0 ± 799.7	-1033.6 1498.2	58.6 (35-66)
QoL Gain T4-T0	-3.8 ± 11.5	-0.5 ± 12.2	3.4 ± 1.7	107,8	12.0 ± 646.4	-1160.2 723.2	68.0 (26-99)
QoL Gain T5-T0	-0.7 ± 9.4	0.2 ± 9.5	0.8 ± 1.3	458,1	34.4 ± 952.9	-1674.7 1853.1	76.4 (66-90)
QoL Gain T6-T0	0.7 ± 6.7	1.9 ± 13.7	1.2 ± 1.5	305,4	30.0 ± 857.2	-1579.1 1300.4	68.8 (68-100)
QoL Gain T7-T0	1.1 ± 8.9	1.9 ± 14.2	0.4 ± 1.6	916,3	11.2 ± 813.4	-1148.4 1046.8	43.2 (46-61)
QoL Gain T8-T0	4.7 ± 7.3	3.6 ± 13.5	-1.6 ± 1.5	-229,1	-39.9 ± 819.1	-969.5 1195.4	-72.7 (5-35)
QoL Gain T9-T0	5.8 ± 7.2	4.1 ± 12.5	-2.3 ± 1.4	-159,3	-65.2 ± 623.4	-1201.3 891.9	-76.6 (20-50)

Table 39: Cost-effectiveness analysis based on Quality of Life: Mean ± SD for QoL gain and Total cost, Mean ± SE for difference, ICER and statistical uncertainty of the ICER calculated from bootstrapping method on 1,000 samples. Median and IQR

Discussion

The prevalence of malocclusion is considered to be as high as 86.8% in a population (234). Anterior crossbite and posterior crossbite were the highest prevalence of malocclusion among primary dentitions (235). Malocclusion is a deviation from the norm and is considered an abnormality in occlusion that requires intervention (226). Untreated malocclusions can affect an individual's quality of life and well-being directly or indirectly (227).

Children's quality of life was assessed by various tools one of which is the Child Oral Health Quality of Life Questionnaire (COHQoL). However, Jokovic et al. adapted the Child Perception Questionnaire (CPQ) from COHQoL, taking into consideration that CPQ is more tool-specific (155).

CPQ 8-10 and 11-13 is considered to be specific tool that can enable discrimination between different clinical orthodontic treatment need groups (236). This study adapted the original

English language CPQ 8–10 version to the Maltese language and investigated its psychometric properties in Maltese children aged 8–10 years.

The back-and-forth translated version (CPQ-M8–10) was very similar to the original. It was concluded that all of the questions could be used in the Maltese context. CPQ-M8–10 scores were reliable and valid in the general population. Pilot study results showed that the reliability assessment agreed with findings from previous studies. For the evaluation of test-retest reliability, the time interval between the distributions of the questionnaires was restricted to 3 weeks in the current study, which was in comparison with previous research that used a time interval of 2 to 3 weeks (155,170). The test-retest reliability showed stability in responses to the Maltese version of the CPQ8–10. It is worth noticing that Test-retest was stable over some time (Global and domains), reflecting the high reliability of Maltese CPQ 8-10.

The ICC for the total scale was 0.95, indicating very good reproducibility. Barbosa et al., 2009 reported ICC was close to (0.96) which is almost identical to our findings (170). On the other hand, in the original research, the ICC for the overall scale was lower than 0.90 (155). The internal consistency, Cronbach's alpha was high for the total score (0.915). Within the Domains, the scores ranged between 0.82 for oral symptoms, functional limitation 0.84, emotional limitation 0.86 and 0.95 for social wellbeing illustrating adequate internal reliability (reliability of 0.5 or above is considered acceptable) (237,238).

The internal consistency results were close to almost identical to the original English version ($\alpha > 0.80$) (155) and similarly, it was reported in the Brazilian version of CPQ 8-10 ($\alpha = 0.88$) (170), and the Danish version ($\alpha = 0.87$) (169). A high correlation between the English version to Maltese CPQ 8-10, Spearsman's Correlation Coefficient was high ($r>0.7$, $P\leq0.001$)

for all domains and global scores, which indicates a high level of validity of Maltese CPQ 8-10.

It was found that patients who received orthodontic treatment demonstrated a worsening in quality of life at the beginning of the treatment but tend to improve toward the end of the treatment (239). In particular pain, levels spiked up in the first 24 hours and then showed normalisation. Similarly, this research showed a similar trend in Group I, oral complaint domain score was high at the beginning of the treatment, which indicates a significant worsening in patients' QoL which tended to improve afterwards.

Chen et al. concluded that patients' oral health-related quality of life was better after treatment than before or during it. They followed 250 patients who received fixed orthodontic appliances (240). Similar to this study, this RCT reported insignificant levels of improvement in quality of life in all CPQ 8-10 domains, but an improvement trend could be seen. Gender differences and OHRQoL have been documented, with QoL scores being better among males than among female patients across all age groups in adolescence (241). Finnish men with increased overjet reported higher social disability and psychological disability (242). Several studies have also concluded that males had more positive experiences of OHRQoL than females, especially in emotional and social well-being (241,243). On the contrary, our RCT showed that males and females showed comparable trends in all domains except toward the end of the treatment at T8 and T9 ($P=0.042$ and 0.022), respectively, where young girls showed a significant improvement in quality of life in comparison to young boys.

Dentofacial attractiveness is important for males and females. It is established that females are more sensitive to negative or reduced overjet (Class III) and more accepting of increased overjet (Class II) (244,245). A decrease in overjet in females was reflected in poor OHRQoL (high scores of OHIP) while males showed higher functional limitation with negative overjet (244,245). However, this was not the case here, with males and females showing more or less

the same scores in all domains except a functional limitation. This explanation may be that the Class III malocclusion was not perceived as an aesthetic problem at T0 while the use of expander and facemask caused a functional limitation, but improved toward the end of the treatment, possibly due to adaptation. The perception of aesthetics in children as young as 8 years old was not explored, since the literature studied older children. Thus, the perception of dental aesthetics at a very young age in a healthy individual is not established. That might explain why the quality of life was good at baseline. For instance, CPQ 8-10 scores were low for the oral complaint, functional limitation and emotional well-being domains. One can notice insignificant higher scores of social well-being domains for both groups at baseline, this might be an unconscious awareness of the malocclusion and fear of their peers' acceptance. Similarly, results were found in children 4 to 6 years with cleft and lip palate. Social acceptance was a burden on parents and children (246). In addition, dental aesthetics and peer image in children 10-14 years were perceived similarly to adults, however in the latter study, the children's ages were higher than this study cohort (247) and therefore might not be directly comparable. It is very important to state that during this trial, patients' awareness of the problem was not present, rather the parent's concern was the driver of the treatment. In turn, the parent's concern was solely generated from consultations with orthodontists who directed them to wait until the end of growth, i.e.18 years of age for boys and 16 years for girls with the proviso that should the Class III malocclusion deteriorate, then the sole treatment option would be orthognathic surgery. Although the parents' concern was understandable, it was not concerned with the malocclusion itself, but rather the prospect of a future surgery required to correct it.

The psychological aspect of OHRQoL was stable almost during the whole treatment time. Moreover, both groups showed similar and comparable results. This is similar to Farzanegan et al.'s study that emotional well-being and psychological well-being were stable during the treatment period (248). The finding is in full agreement with our study however, the same study

showed that, before initiating treatment and at the initial stages of treatment, the OHRQoL was worsened by malocclusion. This is in contrast to our findings. This research shows that throughout treatment the effect of Class III malocclusion on psychological wellbeing was almost stable and comparable to pretreatment baseline time points. The main difference again is that our sample was composed of very young children who might not have developed a proper awareness of malocclusion. It is difficult to compare with the literature, as most of the reported data are for older children, 11-14 years old (249)

The costs of orthodontic treatment were calculated based on accurate documentation of each appointment and the time consumed during that appointment. Clinical performance is crucial at the patient, national and practice levels. It is essential to deliver a high level of care but at the lowest possible unit cost (250). Cost-effectiveness is one way to assess the treatment input and outcome from an economical point of view. Cost-effectiveness can give an indicator of the efficiency of orthodontic treatment (250).

Consultation time was significantly longer in Group II in comparison to Group I, this can be attributed to the nature of the treatment that requires placing of 2 mini-implant which will take some time to explain, and to gain the patients' and guardians/parents' acceptance of the treatment option. This is in agreement with Rittersma et al.'s recommendation that surgical dental intervention should be divided into 2 parts; information about the intervention and simplified technical terms in the first part and explaining the advantages and disadvantages with risk/benefit outcomes in the second part (251). As a result, the cost of consultation for Group II was significantly higher than for Group I. The cost of appliances was significantly high in Group II, Euros 405, as two mini-implants are included in the prices. In addition, Group II showed significantly higher emergency costs of Euros 533.5 while Group I showed Euros

177.6. Total costs for Group II were significantly higher; Euros 580 while Group I showed Euros 213.6.

Within the limitations of the large confidence interval per degree change observed in this study, the incremental cost-effectiveness ratios indicated that treatment for Group II was higher in costs with a less efficient advancement of the maxilla when compared to Group I. similarly Group I was a better option than Group II to reflect the change per unit of QoL, however, the limitations of the large confidence interval per unit change observed.

It is crucial to remember that skeletal and dentoalveolar outcomes for Mini-implant supported expander and facemask group appeared to be comparable to the Tooth-borne expander and facemask group. On the other hand, the mini-implant-supported hyrax is promoted as a life-saving surgery-free transverse corrector. Studies stated that a mini-implant-supported expander can produce true sagittal expansion (97,252). A non-surgical implant-supported expander can help improve the airway (97). Thus, we cannot negate the efficiency of this appliance solely because it is expensive and requires higher maintenance. For instance, it is worth investigating the cost-effectiveness of correcting transverse malocclusion with a non-surgical approach in comparison to the surgical maxillary expansion approach. It is worth remembering that the SNA differences were about (0.8 Degrees) between Group I and II, which is very small clinically. Bhatia et al.,1985 stated that some data might be statistically different but clinically insignificant (253).

The total costs in association with the quality of life global scores and domains were insignificant, which indicates that both groups showed similar trends, regardless of the costs. However, Group I appliances were cheaper than Group II. Emergency ratios were higher in Group I: Group II (7:0). A simple explanation is that the forces are acting on the upper first

molars in Group I which led to the dislodgement of the appliance. On the other hand, Group II had two mini-implants that acted as extra anchorage to resist and distribute forces.

The breakage rate was higher in Group I versus Group II (9:2), which can be attributed to the fact that the appliances for Group I and II were manufactured by different technicians in different laboratories under different (NHS vs Private) schemes. Patients' care the appliance may also be a factor. Similarly, it was found that diet can play a role in fixed appliance breakages (254). Both appliances and techniques have the same impact on patients' OHRQoL however, the total costs of Tooth-borne design of RME/FM were cheaper than mini-implant supported RME/FM. This makes it a more favourable appliance to treat Class III than skeletally anchored RME/FM.

Conclusion

1. Patients' quality of life tended to show the same trends in Groups I and II.
2. Multivariant Linear Regression Analysis showed an insignificant association between Compliance versus age, gender, and Quality of Life.
3. Validation of CPQ 8-10 English to Maltese showed that Maltese version valid and reliable as the English version.
4. Intragroup comparison of CPQ 8-10 scores, Group I showed a worsening in quality of life in Group I (T0-T1) with a mean difference of 10 (P=0.013) and Group II 10 (P=0.054). Similarly, Group I showed worsening in the physical limitation domain (T0-T1) 10 (P<0.001), (T0-T2) 7 (P=0.002), (T0-T3) 7 (P=0.022), (T0-T4) 5 (P=0.022), (T0-T5) 6 (P=0.003) and (T0-T7) 6 (P=0.006). Global Domain of Group I showed

significant differences (T0-T8) and (T0-T9) 25 and 26, respectively (P=0.017 and 0.005).

5. Intergroup comparison showed that Group I and Group II had insignificant differences and comparable trends the majority of the time.
6. Cost-effectiveness evaluation showed Group II treatment was more expensive with comparable outcomes to Group I.
7. Tooth-borne RME/FM is clinically cheaper and both modalities resulted in a similar impact on OHRQoL. The null hypothesis for this study was accepted. Furthermore, the Maltese CPQ 8-10 is considered as sensitive as the English version.

Chapter 6

Discussion, Limitations of The Study, Recommendations and Conclusion

Discussion

This randomised control trial explored the impact of the Alt-RAMEC approach in two groups, Group I, (18 patients) receiving (Tooth-borne RME/FM) and Group II (17 patients) treated with skeletally anchored RME/FM. All the patients were followed up for 9 months with the exception of one patient who was lost from Group I at timepoint 3months due to the development of leukaemia. The follow-up was on a monthly basis to record patients' quality of life and compliance rate. OHRQoL was measured via the use of CPQ 8-10, which was distributed to patients every month. The compliance rate was measured via the use of a compliance sensor in the facemask forehead pad.

This RCT has shown that Group I (Alt-RAMEC Tooth-borne RME/FM) had more advancement of SNA in comparison to Group II (Alt-RAMEC skeletally anchored RME/FM). However, the other skeletal and dentoalveolar parameters were insignificant.

For instance, SNA position improved in Groups I and II toward the end of the treatment 2.10 degrees) and (2.50 degrees), respectively. This finding is consistent with other studies, (217) that reported improvement in SNA (2 degrees) when patients were treated with Tooth-borne RME/FM. similarly, it was reported that SNA improved when treated with Tooth-borne RME/FM (1 degrees) (85). On the other hand, mini-implant-supported RME/FM reported similar trends, Maino et al. reported that skeletally anchored RME/FM resulted in improvement of SNA (2.3 degrees) which is very similar to the improvement in Group II in this study (218).

Similarly, Maxilla Perpendicular to N-A measurements showed improvements in both groups however, the improvement rates were insignificant between the two groups. Subsequently, one can conclude that both appliances yielded a similar comparable effect. It is essential when looking at the values to look at the difference between the maxilla and mandible (ANB) which was significant in both groups, moreover, both groups showed similar comparable changes.

ANB showed a substantial improvement in Group I with a difference at (T0-T1) of 3.90 degrees and Group II of 3.10 degrees, respectively. Our findings are in agreement with Souza et al. where two groups were recruited, Group I had implant-supported RME/FM and Group II had infra-zygomatic implants and mental symphysis implants with heavy Class III elastics Both groups reported an ANB improvement at (T1-T0) of 2.5 degrees (211). The results of Nienkemper et al. are also similar. The skeletally anchored RME group showed significant changes when compared to baseline, though there is a substantial difference in the study design, in that there was no control group. (105).

This reflects that both groups gave the same outcome, meaning that either treatment modality will result in a similar improvement in the sagittal plane. Tracing errors are a major issue in the interpretation of the Lateral Cephalometric view. The error of identification, error of magnification and error of anatomical point definition are all issues, therefore a small difference of 0.80 degrees should be analysed with caution (255). 3D views would have reduced these errors. However, due to radiation protection and ethical considerations, this RCT was based on Lateral Cephalometric views rather than CBCT. Another dilemma is whether we got a dentoalveolar effect or skeletal effect and the cephalometric view is not accurate in that matter, ideally, a CBCT heat map (finite element analysis) can show the real effect per region. The current study showed that the facemask-wearing time in both groups was less than the prescribed 12-14 hours per day. The average facemask-wearing time for Group I was 7.87 ± 2.88 hours per day and Group II wore the facemask for 6.98±2.68 hours per day. This agrees with other studies that used Theramon sensors with removable appliances and it was found that patients' compliance time tends to be overestimated. Schott and Ledwig reported that children wore removable appliances for 9 hours while the prescribed time was 12-15 hours (125).

The contemporary guidelines recommending the duration of force are based on clinical experience and patients' self-reported compliance rates. Most authors recommend that patients should wear the facemask from 14 to 24 hours per day (82,105,193). Linking the compliance rate to the skeletal changes showed that on average 7 hours of facemask wearing can result in a significant change of ANB. This might be an advantageous point to reduce the burden of long hours worn on the patients or parents, to achieve the desired outcome. Clinicians instead may prescribe night-time wear, or a few hours during the day, as an alternative.

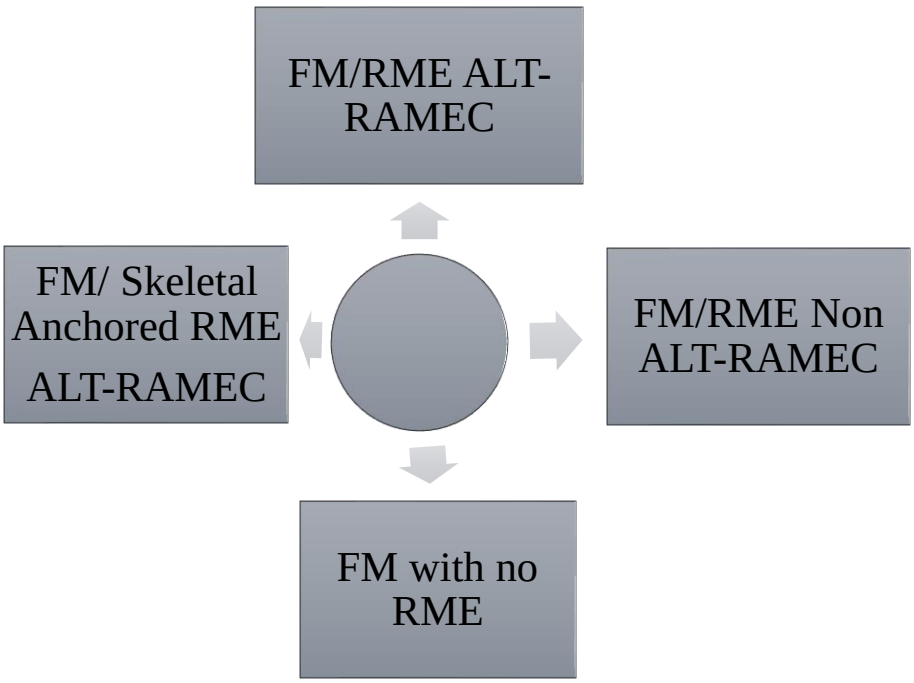
The general costs of the appliances showed that Tooth-borne RME/FM therapy was significantly cheaper than mini-implant-supported RME/FM. It was interesting to see that the emergency visit rates were higher in Group I vs Group II, this could be simply explained as patients' care, awareness of treatment and responsibility. However, the most important factor, in my opinion, was the laboratory technique. Silver solder was used in the construction of the Tooth-borne RME. This, in many instances, resulted in overheating the adjacent band and as a result, weakened them. On the other hand, Group II was manufactured in a private laboratory using a laser welder, a far more accurate technique that did not affect the band material.

OHRQoL showed significant worsening in physical and oral limitation domains, which is understandable, as the young patients had expanders in their mouth and a facemask worn for 7 hours on average for 9 months. However, the other domains showed comparable improvements or stable patterns. An explanation may be that both treatments were similar, except for the implant insertion appointment which might result in slight discomfort at T1. Gender and quality of life were not associated, which was a surprise, since many other studies revealed that young adolescents tend to show gender differences in relation to their quality of life. A simple

proposal here would be that the children were very young and couldn't appreciate the nature of the treatment. In addition, their young age might eliminate the gender differences.

Limitations of the Study and Recommendations for improvements

1. Larger sample size would have resulted in an improvement of the study design, however, due to the low prevalence rate of Class III in population and taking into consideration that Malta is a small island, long-term recruitment would be ideal. Post-hoc sample size analysis using the trial outcomes to generate the exact sample size will be needed in the future, to improve sample size calculation.
2. A multicenter RCT will be helpful in order to overcome the problem of low numbers and recruit more arms to assess the effects of variation in the protocol. Such an approach can provide data about skeletal and dentoalveolar outcomes among groups.



3. CBCT would have been ideal to create finite element analysis which can provide us with a heat map of major differences. Furthermore, CBCT can be useful in segmentation, allowing the clinician to assess dentoalveolar movement and skeletal changes.
4. Follow-up at least for 2 years, to assess the stability of the treatment outcomes toward the end of growth.
5. Differences in laboratory techniques for the two arms of the study may have produced a bias in the rate of complications observed.
6. A larger sample size would have been beneficial to address potential shortcomings of CPQ 8-10 validation. In addition, some aspects should have been taken into consideration, such as the severity of Class III at the beginning of the trial and the socioeconomic background of participants and parents.

Conclusions:

The investigation attempted to examine all aspects associated with tooth-borne RME/FM and skeletal anchored RME/FM appliances. The RCT faced a lot of obstacles since 2019, represented by the pandemic and the closure of hospitals and dental clinics.

This trial showed that dentoalveolar and skeletal outcomes between Group I and II were insignificant and comparable. This throws light on the question of whether skeletally anchored RME/FM can result in superior results presented by many non-randomised control studies. The compliance rate was similar. Group I and II wore their FM for 7.87 hours and 6.98 hours respectively. The FM wearing time was less than the instructed time by the clinician. However, patients still had favourable dentoalveolar and skeletal results. Patients'quality of life showed similar trends in Group I and II. Pain domain and physical limitation were the variables most affected during the treatment. Cost is a factor

that should be considered when treating young patients and this RCT suggests that Tooth-borne RME/FM with Alt-RAMEC might be a cost-effective option, particularly if care is used in its construction.

Pandemic effect on the randomised clinical trial and the ideal study design

On the 19th of December 2019, the University Research Ethics Committee gave its approval to the study. Four months after that, Italy was hit by the Covid-19 pandemic and Malta started to take protective measures including airport shutdown, COVID testing hubs, mandatory mask wearing and closure of schools and universities.

The Faculty was supportive. A mobile dental unit was on campus and this was made available to me to see patients and fit appliances. After a few months COVID-19 cases spiked in Malta, hospitals were overwhelmed and the mobile dental unit was shut down. At that point, we shifted to teledentistry to follow up on patients, in addition to liaising with parents to send them elastics, scan the sensor or manage any sort of emergencies. This was done for approximately 5-6 months and helped us to follow up with the patients, but at the same time, I was unable to take progress records such as images or impressions or make accurate measurements of the reverse overjet improvement with time.

The ideal study design would have been to recruit a large sample size to allow the elimination of outliers and maximize the effect. Even though our study sample size is not considered low in comparison to other studies, a larger sample size would have been more effective. In addition, having control groups would have added more value to our findings, such as having a group with a Facemask and no RME.

In an ideal situation, a customised cephalometric analysis with customised points would have been ideal. However, the supervisor at the time, Prof. Lorenzo Franchi, advised against this, as this would require a pilot study to ensure the points are valid and reproducible. This would not have been possible under pandemic conditions.

It would have been ideal to superimpose the before-treatment casts and after-treatment casts digitally, in order to more accurately assess 3D dentoalveolar movements. Furthermore,

using CBCT to visualize the skeletal and dentoalveolar movement with heat maps would have helped enormously.

Thus, the study was based on cephalometric analysis composites rather than a custom-made analysis. Furthermore, it would have been ideal to validate the CPQ 8-10 English to Maltese with a larger sample size which will add a higher significant level to the findings.
Economic analysis in the ideal situation would have been calculated differently. For instance, parent hourly income should have been calculated in addition to the travel time and waiting in the waiting room before consultation or review or emergencies. In some instances, patients would have attended the clinics with grandparents (pensioners) or non-working mothers and in both cases, the hourly wages should have been taken into consideration.
Finally, this trial was conducted in difficult times and the principal investigator attempted all possible ways to make this project move forward despite pitfalls.

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Appendix I

KUMITAT
DWAR L-ETIKA FIS-SAĦĦA

Direttorat ta' l-Informazzjoni fuq is-Saħħa u Riċerka
95, Telgħet Guardmangia ,
Pieta' PTA 1313
Malta

Our Ref: HEC04/19
Your Ref

HEALTH
ETHICS COMMITTEE

Directorate for Health Information & Research
95, Guardamangia Hill,
Pieta' PTA 1313
Malta

Tel: (+356) 25599000
Email: hec@gov.mt

Date: 29/11/2019

Dr Emad Eddin Alzoubi

University of Malta
Msida, Tal-Qroqq MSD2080

Dear Dr Emad Eddin Alzoubi,

The Health Ethics Committee has recently reviewed your application for ethical approval for the project outlined below. Your proposal is deemed to be ethically sound. It is also deemed to be in line with the General Data Protection Regulation and MCCAA.

Approval Number	HEC
Project Title	On Treatment outcomes of protraction headgear in prepubertal patients.
Approval Date	19th November 2019
HEC Decision	Approved

The approval is conditional to the following conditions:

a. Conduct of the project is to strictly adhere to the proposal submitted and granted ethics approval, including any amendments made to the proposal as required by the HEC.
b. Any amendment from the proposed study protocol should be submitted to the HEC (email:hec@gov.mt) for approval.
c. Any serious unexpected adverse events that occur during the study should be notified to the HEC within 3 working days of the event.
d. A short progress report is to be provided for every 12 months period of the study from the date of approval.
e. Advise in writing is to be submitted to the HEC on completion or discontinuation of the project; if discontinued, kindly supply reason.

Please note that, the conduct of the trial is subject to assessment, without prior notification, by the Licensing Authority.

Kind regards,

Profs. Neville Calleja
Secretary- Health Ethics Committee

MINISTERU TAS-SAĦĦA – MINISTRY FOR HEALTH

Appendix II

Oana Nemes <oana.nemes@um.edu.mt>
to me

Dear Dr Alzoubi

I am willing to act as an intermediary for the study titled "CBCT As a Diagnostic Aid for Impacted Maxillary Canines: A Panel Survey".
I will approach the candidates and explain the study for them independently.

Oana Nemes
Dental Surgery Assistant

Għażiż Sinjur/Sinjura .....

Jien jisimni Dr Emad Eddin Alzoubi. Jiena Ortodontista speċjalista (Reġistrazzjoni tal-Kunsill Mediku numru: 358), naħdem l-Universita' ta' Malta. Ser inkun qed naħdem fuq riċerka intitolata: Fuq trattament qabel l-iżvilupp ta' pazjenti bi Protraction head gear u riżultati relatati.

Dan l-istudju ser jevalwa l-effett ta' projbizzjoni ta' maskra fuq wiċċ il-pazjent u jekk hemmx titjib sinifikanti li jista jintlaħaq. Barra minn hekk ser jevalwa l-konformita' tal-pazjent mal-istruzzjonijiet li jiġu mogħtija mid-dentist. Dan ukoll ser jinvestiga l-impatt ta tip ta' trattament fuq il-kwalita' ta ħajja tal-pazjenti waqt it-trattament u l-perjodu miżmum.

Il-parteċipazzjoni f'din ir-riċerka hija volontarja u tinvolovi wkoll mili ta kwestjonarju dwar il-kwalita ta' ħajja waqt it-trattament Ortodontiku.
L-istudju ser isir bejn Jannar 2019 u Ġunju 2022.

Tislijiet

Dr Emad Eddin Mohamed Alzoubi
Assistant Għalliem tal-Orthodontic
Ortodontist Speċjalizzat

Dear Sir/Madam……..

My name is Dr.Emad Eddin Alzoubi. I am a specialist Orthodontist (Medical council registration number: 358), working at University of Malta. I will be carrying a research titled: **" On Treatment Outcomes Of Protraction Headgear In pre-Pubertal Patients".**

The study will be assessing the effect of protraction facemask on patient profile and if any significant improvement can be reached. In addition, assessing the patients' compliance to instructions given by the dentist. Furthermore, the research will investigate the impact of this type of treatment on patients' quality of life during the treatment and the retention periods

Participation in this research is on a voluntary basis and involves filling in questionnaire regarding their quality of life during orthodontic treatment.

The study will take place between January 2019 and June 2022.

Kind regards

Dr.Emad Eddin Mohamad Alzoubi

Assistant Lecturer of Orthodontic

Specialist orthodontic

Appendix III

What about tooth brushing?

You should remove the Facemask to brush your teeth. It is important that you brush your teeth for at least 3 minutes, twice a day. If possible, carry a brush with you for use after lunch. To further protect the teeth use an alcohol-free fluoride mouth rinse daily at a different time to when you brush your teeth. Avoid eating or rinsing for 20 minutes after use.
Avoid sugary diet/drinks and poor teeth cleaning ; otherwise the appliance will lead to permanent damage to your teeth.

Can I eat with the headgear on?

No. It will not be possible for you to eat and drink with the protraction headgear in place. You will need to remove it for meal times. Upon finishing eating brush your teeth and wear the protraction headgear again.

How often do I need an appointment?

You will need regular appointments (about every 4-5 weeks) to review the progress of your protraction headgear, and evaluate your compliance with orthodontist instructions.

Do I still need to see my regular orthodontist?

Yes. It will be important for you to have check-ups with your regular orthodontist throughout the treatment; so that your teeth can be checked for decay or any adverse side effect.

What should I do if there is any problem with the protraction headgear?

If you have any problems with the headgear, contact your orthodontist as soon as is reasonably possible to arrange an appointment. Do not wait for your next routine appointment as such action might reduce the effect of the protraction headgear effect.

What should I do if there is any problem with the protraction headgear?

Contact your orthodontist as soon as is reasonably possible to arrange an appointment. Do not wait for your next routine appointment; as the problem may slow your treatment, or cause damage to your teeth.

- The more you wear the protraction headgear the faster the treatment will be.
- Follow the instructions from your orthodontist for putting on and removing the protraction headgear.
- Contact your orthodontist as soon as reasonably possible in case of breakage.
- Brush your teeth for 7 minutes at least twice each day.
- Please bring your headgear with you to every visit.
- The day time telephone number you should contact if you have a problem with your protection headgear is:

  25454809

Patient information leaflet

PROTRACTION HEADGEAR

Xi nghidu dwar il-ħasil tas-snien?

Trid tneħħi il-krema tad-tindif tal-wiċċ qabel taħsel snienek. Huwa mportanti li taħsel snienek għal tlett minuti, darbtejn kuljum. Jekk possibli ħu l-ixkupilja miegħek biex taħsel snienek wara l-ikel ta' nofs inhar. Biex tkompli tipproteġi s-snien uża l-ilma tat-tlaħlieħ tal-ħalq mingħajr alkoħol kuljum wara kull ħasla tas-snien. Evita li tiekol jew tixrob għal 20 minuta wara li tuża l-ilma tat-tlaħlieħ.
Evita xorb tad-dieta u l-ħasil tas-snien ta fuq fuq; inkella l-magna tagħmel ħsara permanenti lis-snien.

Nista niekol bil- *headgear* fuqi?

Le. Ma Tkunx tista tiekol u tixrob bil-magna fuqek. Jeħtieġ li tneħħieha kull darba biex tiekol. Meta tlesti aħsel snienek u erġa ilbisha..

Kemm il-darba għandi bżonn appuntament?

Għandek bżonn appuntamenti regolari (bejn 4 – 5 ġimgħat) biex tara l-progress li qed tagħmillek il-*protraction headgear* u tevalwa l-progress tiegħek u kif ukoll taqbel mal-istruzzjonijiet tal-ortodontist.

Għandi bżonn nara l-ortodontist iktar regolari?

Iva. Huwa mportanti li tiċċekkja regolarment mal-Ortodontist matul it-trattament tiegħek; biex is-snien tiegħek jiġu iċċekkjati għat-thassir jew ħsara oħra.

X'għandi nagħmel jekk ikolli problemi bil- *protraction headgear*?

Jekk ikollok xi problema bil-*headgear*, ikkuntattja lil Ortodontist tiegħek biex tirranġa appuntament. Toqgħodx tistenna għal appuntament li jmissek għax dan jista jfisser li jonqos l-effett tal- *protraction headgear* fuqek.

X'irrid nagħmel jekk ikolli problema bil- *protraction headgear*?

Ikkuntattja lil Ortodontist minnufih biex tirranġa appuntament. Tistenniex l-appuntament li jmiss għax tista tnaqqas ir-ritmu tat-trattament; jew tikkawża ħsara lis-snien.

- Iktar ma tilbes il-*protraction headgear* iktar jaħdem malajr it-trattament.
- Imxi mal-istruzzjonijiet li jagħtik l-Ortodontist biex tilbes u tinża l-apparat.
- Ikkuntattja l-Ortodontist jekk l-apparat jinkiser.
- Aħsel snienek għal 7 minuti mill-inqas darbtejn kull jum.
- Ġib l-apparat ma kull appuntament li jkollok.
- In-numru ta' matul il-ġurnata li inti trid iċċempel jekk ikollok xi problema bl-apparat huwa:

25454809

Fuljett ta informazzjoni għal-pazjent

PROTRACTION HEADGEAR

NATIONAL STATISTICS OFFICE • MALTA

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Main > News Releases > View by Unit > Unit C1 > Living Conditions and Culture Statistics > Statistics on Income and Living Conditions

Contact Information:

Communication and Dissemination
2599 7219
nso@gov.mt

Statistics on Income and Living Conditions

2021

EU-SILC 2020: Material Deprivation and Monetary Poverty	NR221/2021	NR221/2021
EU-SILC 2020: Main Dwellings	NR187/2021	NR187/2021
EU-SILC 2020: Salient Indicators	NR175/2021	NR175/2021
EU-SILC 2020: Estimates of Material Deprivation and Housing Problems	NR075/2021	NR075/2021

2020

EU-SILC 2019: Material Deprivation and Monetary Poverty	NR202/2020	NR202/2020
EU-SILC 2019: Main Dwellings	NR166/2020	NR166/2020
EU-SILC 2019: Salient Indicators	NR135/2020	NR135/2020
EU-SILC 2019: Estimates of Material Deprivation and Housing Problems	NR043/2020	NR043/2020

2019

EU-SILC 2018: Main Dwellings	NR143/2019	NR143/2019
EU-SILC 2018: Salient Indicators	NR128/2019	NR128/2019
EU-SILC 2018: Estimates of Material Deprivation and Housing Problems	NR036/2019	NR036/2019

Appendix IV

CONSENT FORM

I have been asked to consent to allow my child to participate in a research study entitled:

"On Treatment Outcomes Of Protraction Headgear In pre-Pubertal Patients".

The purpose and details of the study have been explained to me and any difficulties which I raised have been adequately clarified.
I give my consent to the Principal Investigator to make the appropriate observations/ tests / take the necessary samples. I am aware of the inconveniences which this will cause.
I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from this study in which my child is participating may be reported or published. However, my child shall not be personally identified in any way, either individually or collectively, without my expressed written permission.

I understand I am under no obligation to allow my child to participate in this study and am doing so voluntarily.

I may withdraw my child from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to my child.
I understand that any complications and/or adverse effects which may arise during or as a consequence of the study will be recorded and any treatment which this may entail will be given within university of Malta.
I am/I am not receiving any remuneration for participating in this study.

In case of queries during the study I may contact
Dr. Emad Eddin Mohamad
Telephone :99385673
Email: Emad.alzoubi@um.edu.mt

Signature of parent (mother/father) _____
Name of parent (mother/father) *(in block letters)*
Name of child *(in block letters)*

Signature of Chief Investigator/Investigator _____
Name of Chief Investigator/Investigator *Emad Eddin Mohamad Alzoubi*
Id. No.: _____

DATE: _____

FORMOLA TA' KUNSENS

Ġejt mistoqsija biex nagħti kunsens biex nipparteċipa fi studju ta 'riċerka intitolat:

' Trattament fuq adoloxxenti żgħar b'tagħmir ta' *Protraction head gear* u riżultati relatati'

L-iskop u d-dettalji ta' dan l-istudju ġie spjegat lili u kull diffikulta li kelli ġiet iċċarata.

Nagħti l-kunsens tiegħi lil investigatur prinċipali biex jagħmel osservazzjonijiet/testijiet xierqa. Jiena konxju tal-inkonvenjent li dan jista jikkawża.

Jiena nifhem li r-riżultati ta' dan l-istudji jistgħu jintużaw għal skopijiet mediċi jew xjentifiċi u r-riżultat li joħroġ minn dan l-istudju jiġi rraportat u ppublikat. Madankollu, jiena qatt mhu ser niġi identifikat b'xi mod , la individwalment u lanqas kollettivament mingħajr permess tiegħi bil-miktub.

Jiena nifhem li ma għandi l-ebda obligazzjoni nipparteċipa f'dan l-istudju u qed nagħmel dan volontarjament. Nista nieqaf minn dan l-istudju f'kull ħin mingħajr ma nagħti raġuni. Dan mhux ser jinfluwenza bl-ebda mod l-attenzjoni u l-kura u kif ukoll t-trattament li normali nieħu.

Jiena nifhem li l-komplikazzjonijiet jew effetti diversi li jistgħu jinqalgħu waqt jew b'konsegwenza ta l-istudju jiġi rreġistrat u kull trattament li jkun hemm bżonn jiġi mogħti lili mill-Universita' ta' Malta.

Jiena qed/ Jiena mhux qed nirċievi l-ebda remunerazzjoni talli qed nipparteċipa f'dan l-istudju.

Jekk ikolli xi mistoqsijiet waqt l-istudju nista nikkuntattja lil

Dr Emad Eddin Mohammed

Telephone: 99385673

E-mail: emad.alzoubi@um.edu.mt

Firma tal-pazjent b'eta ta' 12 il-sena jew ikbar

- Numru tal-Identita' tal-Pazjent: .....
- Numru tal-Identita' ta' min qed jieħu ħsieb il-pazjent:.....
- Firma tal-investigatur ewlieni/ tabib

  .....
- Isem tal-investigatur ewlieni/ tabib

  .....
- Data:

  .....

CONSENT FORM

I have been asked to consent to allow my child to participate in a research study entitled:

"On Treatment Outcomes Of Protraction Headgear In pre-Pubertal Patients".

The purpose and details of the study have been explained to me and any difficulties which I raised have been adequately clarified.
I give my consent to the Principal Investigator to make the appropriate observations/ tests / take the necessary samples. I am aware of the inconveniences which this will cause.
I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from this study in which my child is participating may be reported or published. However, my child shall not be personally identified in any way, either individually or collectively, without my expressed written permission.

I understand I am under no obligation to allow my child to participate in this study and am doing so voluntarily.

I may withdraw my child from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to my child.
I understand that any complications and/or adverse effects which may arise during or as a consequence of the study will be recorded and any treatment which this may entail will be given within university of Malta.
I am/I am not receiving any remuneration for participating in this study.

In case of queries during the study I may contact
Dr. Emad Eddin Mohamad
Telephone :99385673
Email: Emad.alzoubi@um.edu.mt

Signature of parent (mother/father) _____
Name of parent (mother/father) *(in block letters)*
Name of child *(in block letters)*

Signature of Chief Investigator/Investigator _____
Name of Chief Investigator/Investigator *Emad Eddin Mohamad Alzoubi*
Id. No.: _____

DATE: _____

Appendix V

Maltese Version of CPQ 8-10

Kwestjonarju fuq kif jahsbuha t-tfal minn 8 sa 10 snin (CPG 8-10)

Mistoqsijiet dwar is-sahha tal halq fit-tfal

Ahna qed naghmlu dan l-istudju biex nifhmu ahjar fuq dak li jista' jigri lit-tfal minhabba s-snien u l-halq.

Jekk joghgbok ftakar:

- Tiktibx ismek fuq dan l-kwestjonarju
- Dan mhux ezami u m'hemmx mistoqsijiet hziena jew tajjbin.
- Irrispondi bl-onesta' kollha
- Titkellimx ma haddiehor waqt li tkun qed tirrispondi l mistoqsijiet
- M'hemm hadd li taf inti li se jara t-twegibiet tieghek
- Aqra kull mistoqsija bil galbu u ahseb fuq dak li gralek dawn l-ahhar erba' gimghat
- Qabel twigeb, staqsi lilek innifsek u ghid 'Qed jigrli hekk minhabba snieni jew halqi?'
- Ghamel X fil-kaxxa hdejn ir-risposta li hija tajba ghalik

Jum/Xahar/Sena __ /__ /__

L-ewwelnett, ftit mistoqsijiet fuqek innifsek

Id-data tal-lum:

Inti tifel jew tifla? :

Status iehor:

Kemm ghandek zmien?: _____

Issa ftit mistoqsijiet dwar snienek u halqek

Kemm –il darba kellek:

1. Ugigh fis-snien jew fil-halq, f'dawn l-ahhar erba' gimghat

Qatt
Darba jew darbtejn
Ta' spiss
Kuljum jew kwazi kuljum
Ma fhimtx din il-mistoqsija

2. Pustumetti f'halqek f'dawn l-ahhar erba' xhur?

Qatt

Darba jew darbtejn

Ta' spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

3. Ugigh fi snienek meta tixrob jew tiekol ikel kiesah, f'dawn l-ahhar erba' gimghat?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

4. Jehillek l-ikel fis-snien, f’dawn l-ahhar erba’ gimghat?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

5. Riha tinten f’halqek, f’dawn l-ahhar erba’ gimghat?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

F’dawn l-ahhar erba’ gimghat, kemm –il darba:

6. Kellek bzonn aktar hin minn haddiehor biex tiekol minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

7. Sibt diffikulta biex tigdem jew tomghod ikel bhal tuffieh, ‘corn’ jew laham minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

8. Sibt diffikulta biex tiekol ikel li thobb minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

9. Sibt diffikulta biex tghid certu kliem minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

10. Ma stajtx torqod bil-lejl minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

Ftit mistoqsijiet fuq dak li thoss
F’dawn l-ahhar erba’ gimghat, kemm – il darba

11. Kont thossok imdejjaq minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

12. Kont thossok frustrat minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

13. Sthajt minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

14. Inkwetajt fuq dak li haseb haddiehor fuq snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

15. Inkwetajt li m’intix daqshekk attrajenti daqs l-ohrajn minhabba snienk jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

Mistoqsijiet dwar l-iskola tieghek

F’dawn l-ahhar erba’ gimghat, kemm il –darba

16. Ma mortx skola minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

17. Batejt biex taghmel ‘homework’ minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

18. Sibtha difficli biex toqghod attent l-iskola minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

19. Ma ridtx titkellem jew taqra b’vuci gholja fil-klassi minhabba snienek jew haqlek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

Mistoqsijiet dwar kif iggib ruhek ma’ l-ohrajn

Nies

F’ dawn l-ahhar erba’ gimghat, kemm il- darba:

20. Ippruvajt ma titbissimx jew ma tidhaqx minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

21. Ma ridtx titkellem ma’ tfal ohra minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

22. Ma ridtx toqghod ma’ tfal ohra minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

23. Zammejt milli tiehu sehem f’ attivitajiet bhal sports jew clubs minhabba snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

24. Tfal ohra inkewk jew ghajruk fuq snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

25. Tfal ohra staqsewk fuq snienek jew halqek?

Qatt

Darba jew darbtejn

Ta’ spiss

Kuljum jew kwazi kuljum

Ma fhimtx din il-mistoqsija

The English Version of CPQ 8 -10

CHILD ORAL HEALTH QUESTIONNAIRE Subject Number:

We are doing this study to understand better things that may happen to children because of their teeth and mouth.

Please Remember:

• Don’t write your name on the questionnaire.

• This is not a test and there are no right or wrong answers.

• Answer as honestly as you can.

• Don’t talk to anyone about the questions when you are answering them.

• No one you know will see your answers.

• Read each question carefully and think about the things that have happened to you in the past 4 weeks.

• Before you answer, ask yourself: “Does this happen to me because of my teeth or mouth?”

• Put an in the box beside the answer that is best for you.

DAY MONTH YEAR ____/____/____

FIRST,A FEW QUESTIONS ABOUT YOU

Today’s date:

Are you a boy or a girl?

Boy

Girl

How old are you? _____

NOW A FEW QUESTIONS ABOUT YOUR TEETH AND MOUTH

How often have you had:

1. Pain in your teeth or mouth in the past 4 weeks?

Never

Once or twice

Sometimes

Often

Every day or almost every day

2. Sore spots in your mouth in the past 4 weeks?
3. Pain in your teeth when you drink cold drinks or eat foods in the past 4 weeks?
4. Food stuck in your teeth in the past 4 weeks?
5. Bad breath in the past 4 weeks?

In the past 4 weeks, how often have you:

6. Needed longer time than others to eat your meal because of your teeth or mouth?

7. Had a hard time biting or chewing food like apples, corn on the cob or steak because of your teeth or mouth?"

8. Had trouble eating foods you would like to eat because of your teeth or mouth?

9. Had trouble saying some words because of your teeth or mouth?

10. Had a problem sleeping at night because of

your teeth or mouth?

SOME QUESTIONS ABOUT YOUR FEELINGS

In the past 4 weeks, how often have you:

11. Been upset because of your teeth or mouth?

12. Felt frustrated because of your teeth or mouth?

13. Been shy because of your teeth or mouth?

14. Been concerned what other people think about your teeth or mouth?

15. Worried that you are not as good-looking

as others because of your teeth or mouth?

QUESTIONS ABOUT YOUR SCHOOL

In the past 4 weeks, how often have you:

16. Missed school because of your teeth or mouth?

17. Had a hard time doing your homework

because of your teeth or mouth?

18. Had a hard time paying attention in school because of your teeth or mouth?

19. Not wanted to speak or read out loud in class because of your teeth or mouth?

QUESTIONS ABOUT YOU BEING WITH OTHER

PEOPLE

In the past 4 weeks, how often have you:

20. Tried not to smile or laugh when with other children because of your teeth or mouth?

21. Not wanted to talk to other children because of your teeth or mouth?

22. Not wanted to be with other children because of your teeth or mouth?

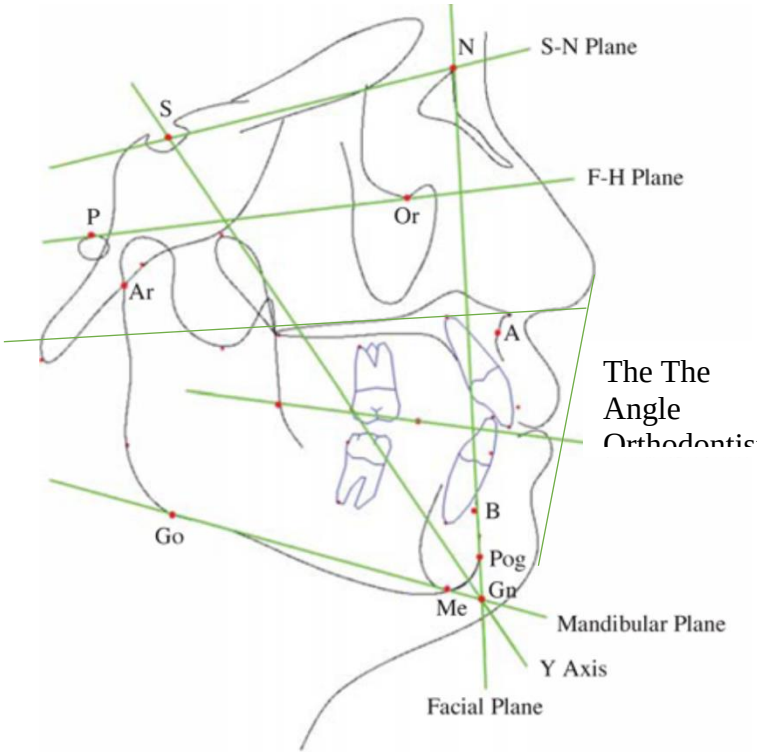
23. Stayed away from activities like sports and clubs because of your teeth or mouth?

24. Other children teased you or called you names because of your teeth or mouth?

25. Other children asked you questions about your teeth or mouth?

Appendix VI

Variables	**Degrees**	**Distance in Mm**
Maxilla to Na perpendicular		3mm
SNA	82±3 º	
SNB	87±3 º	
ANB	2±2 º	
Wits analysis	Male AO-BO= -1 Female AO-BO= 0	
Vertical skeletal relationship	**Angle**	**Distance in Mm**
Mandibular-Maxillary plane angle	27±5 º	
Interdental relationship	135 º±9	
Overjet		2-3 mm
Molar relationship		
Dentoalveolar relationship		
U1 -Mx plane	109º±10	
L1-MPAº	93º±6	



The The Angle Orthodontist

Variables	Definition
Nasion(Na point)	The anterior point of the intersection between the nasal and frontal bones
Pogonion (Pog)	The most anterior point on the contour of the chin
S point	The midpoint of the cavity of sella turcica
U1	Most facial aspect of Upper incisor in incisal edge
L1	Most facial aspect of lower incisor in incisal edge
Gonion (Go)	The midpoint of the contour connecting the ramus and mandibular body
Gnathion (Gn)	The center of the inferior point on the mandibular symphysis
Anterior nasal spine (ANS)	The tip of the anterior nasal spine
A point	Innermost point on the contour of the premaxilla
Menton (Me)	The most inferior point on the mandibular symphysis
Condylon (Co)	The upper midpoint of the mandibular condyle
B point	Innermost point on the contour of the mandible
Pterygomaxillary fissure (PTM)	The point at the base of the fissure where the anterior and posterior walls meet

Variables	**Degrees**	**Distance in Mm**
Point A- Nasion perpendicular		3mm
Maxillary unit length (Co-Point A)		Distance from Condylion to A point
Mandibular unit length Co-Gnathion		Distance from Condylion to Gnathion
Pogonion-Nasion perpendicular: relating Mandible-cranial base		Distance from Pog-Nasion at puberty. In mixed dentition= 6-8mm posterior to Nasion, more forward due to growth. In adult female= 0-4 mm behind Nasion perpendicular line. In adult male= 2±2 mm behind or forward
Gonial angle	128±7º	
Vertical skeletal relationship	**Angle**	**Distance in Mm**
Ans-Me		Midfacial length 85mm LFH should be 60-62 mm. Midfacial length 94 mm LFH should be 66-68mm

		Midfacial length 100 mm= LFH should be 70-74mm
Mandibular-Maxillary plane angle	27±5 º	
Inter dental relationship	135±10 º	
Overjet		2-3 mm
Molar relationship		
Dentoalveolar relationship		
U1 -SNº	109±6º	
L1-MPAº	87º	
E line : Dr. Ricketts felt that to have a pleasing facial profile, in the average Caucasian face, the lower lip would be 2 mm behind the line, and the upper lip 4 mm behind the line, with variations being normal for patients of different ethnic backgrounds, but with some commonalities applying to all patients	0-4	

Appendix VII

Regression analysis for outcome Complicance (low/high)

Multiple logistic regression models will be conducted for ***predictors: gender, age and total CPQ score at T0 (initial QoL)***:

		B	S.E.	Wald	df	Sig.	OR	95,0% C.I.for EXP(B)	
		Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
Step 1(1)	**AGE**	-1,419	1,095	1,679	1	,195	,242	,028	2,070
	GENDER	,321	1,016	,100	1	,752	1,379	,188	10,105
	TOTALT1-T0	-,012	,052	,050	1	,823	,989	,893	1,094
	Constant	10,400	9,278	1,257	1	,262	32872,324		

1,00 Variable(s) entered on step 1: AGE, GENDER, TOTALT0.

Multiple logistic regression models will be conducted for ***predictors: gender, age and total CPQ score at Global (the worst time-point of QoL)***:

		B	S.E.	Wald	df	Sig.	OR	95,0% C.I.for EXP(B)	
		Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
Step 1(1)	**AGE**	-1,485	1,098	1,831	1	,176	,226	,026	1,947
	GENDER	-,122	1,148	,011	1	,915	,885	,093	8,399
	CPQ T9-T0	-,058	,042	1,972	1	,160	,943	,869	1,023
	Constant	13,565	9,533	2,025	1	,155	778291,251		

1,00 Variable(s) entered on step 1: AGE, GENDER, TOTALT1.

No factor showed significant association with probability of a low (or high) compliance. See p-values (Sig.) >0.05.

Multiple logistic regression models will be conducted for ***predictors: gender, age and total CPQ score T9-T0 change (changes at QoL)***:

Variables in the Equation

	B	S.E.	Wald	df	Sig.	OR	95,0% C.I.for EXP(B)	
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper

Step 1(1)	**AGE**		-1,444	1,109	1,697	1	,193	,236	,027	2,(
	GENDER		,190	1,025	,034	1	,853	1,209	,162	9,(
	CPQ GLOBAL	**8-10**	-,005	,052	,011	1	,916	,995	,899	1,1
	Constant		10,290	9,186	1,255	1	,263	29445,049		

1,00 Variable(s) entered on step 1: AGE, GENDER, CPQ 8-10 GLOBAL.

No factor showed significant association with probability of a low (or high) compliance. See p-values (Sig.) >0.05.

Regression analysis for outcome Wearing time (mean number of hours per day)

Multiple linear regression models will be conducted for ***predictors: gender, age and total CPQ score at T0 (initial QoL)***:

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	18,308	5,858		3,125	,004	6,345	30,270
	AGE	-1,155	,631	-,328	-1,831	,077	-2,444	,134
	GENDER	,747	1,054	,128	,709	,484	-1,405	2,899
	CPQ 8-10 (T1-T0)	-,041	,052	-,136	-,792	,435	-,148	,065

1,00 Dependent Variable: HOURS PER DAY

Age showed a weak association with the wearing time (p=0.077). One additional year at age involved less compliance (-1.15 hours per day). The younger the child, the longer wearing time per day was.

Multiple linear regression models will be conducted for ***predictors: gender, age and total CPQ score at T1 (the worst time-point of QoL)***:

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	19,404	5,522		3,514	,001	8,126	30,681
	AGE	-1,166	,608	-,331	-1,918	,065	-2,407	,075
	GENDER	,512	1,009	,088	,507	,616	-1,549	2,572
	CPQ 8-10 (T9-T0)	-,043	,025	-,276	-1,699	,100	-,094	,009

1,00 Dependent Variable: HOURS PER DAY

A similar conclusion was obtained from this model (using QoL at T1 instead of at T0).
Multiple linear regression models will be conducted for ***predictors: gender, age and total CPQ score T9-T0 change (changes at QoL)***:

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	16,785	5,962		2,815	,009	4,592	28,978
	AGE	-1,129	,678	-,320	-1,665	,107	-2,515	,258

	GENDER		,759	1,097	,130	,692	,494	-1,484	3,003
	CPQ GLOBAL	**8-10**	,016	,052	,058	,311	,758	-,091	,123

1,00 Dependent Variable: HOURS PER DAY

Regression analysis for outcome Changes at skeletal and dental parameters T1-T0 (final-baseline).

For each parameter, three linear regression models will be performed.

Dependent variables: Changes T1-T0 at parameter

Predictors: Gender, age, wearing time and …

- Model 1: CPQ total score at T1-T0
- Model 2: CPQ total score at T9-t0
- Model 3: Changes at CPQ total score

3.9.1 Changes at mandibular skeletal

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-7,196	22,529		-,319	,752	-53,274	38,881
	AGE	,707	2,223	,065	,318	,753	-3,840	5,253
	GENDER	-1,468	3,550	-,081	-,413	,682	-8,728	5,792
	HOURS PER DAY	,422	,610	,136	,692	,495	-,825	1,669
	CPQ 8-10 (T1-T0)	-,137	,176	-,145	-,779	,442	-,498	,223

1,00 Dependent Variable: DIF.MANSKELETAL

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-15,287	22,937		-,666	,510	-62,197	31,623
	AGE	,975	2,251	,089	,433	,668	-3,629	5,579
	GENDER	-1,886	3,542	-,104	-,533	,598	-9,131	5,358
	HOURS PER DAY	,520	,638	,167	,815	,422	-,785	1,825
	CPQ 8-10 (T9-T0)	,015	,092	,030	,159	,875	-,174	,203

1,00 Dependent Variable: DIF.MANSKELETAL

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-5,218	21,991		-,237	,814	-50,265	39,828
	AGE	,036	2,319	,003	,016	,988	-4,715	4,788
	GENDER	-1,502	3,615	-,082	-,415	,681	-8,908	5,904
	HOURS PER DAY	,473	,607	,152	,779	,443	-,771	1,716
	CPQ 8-10 GLOBAL	,196	,171	,225	1,148	,261	-,154	,546

1,00 Dependent Variable: DIF.MANSKELETAL

There were not significant factors influencing on changes at parameter.

Changes at maxillary skeletal

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-1,014	14,688		-,069	,945	-31,054	29,027
	AGE	,208	1,449	,029	,144	,887	-2,756	3,172
	GENDER	-2,483	2,314	-,206	-1,073	,292	-7,216	2,251
	HOURS PER DAY	,326	,398	,158	,821	,419	-,487	1,140
	CPQ 8-10 (T1-T0)	-,079	,115	-,127	-,691	,495	-,314	,156

1,00 Dependent Variable: DIF.MAXSKELETAL

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-2,611	14,890		-,175	,862	-33,065	27,844
	AGE	,253	1,461	,035	,173	,864	-2,736	3,242
	GENDER	-2,769	2,300	-,230	-1,204	,238	-7,472	1,934
	HOURS PER DAY	,319	,414	,155	,769	,448	-,529	1,166
	CPQ 8-10 (T9-T0)	-,023	,060	-,072	-,381	,706	-,145	,100

1,00 Dependent Variable: DIF.MAXSKELETAL

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-,289	14,437		-,020	,984	-29,861	29,283
	AGE	-,134	1,523	-,018	-,088	,930	-3,253	2,985
	GENDER	-2,455	2,373	-,203	-1,034	,310	-7,317	2,406
	HOURS PER DAY	,352	,398	,170	,883	,385	-,465	1,168
	CPQ 8-10 GLOBAL	,109	,112	,188	,972	,339	-,121	,339

1,00 Dependent Variable: DIF.MAXSKELETAL

There were not significant factors influencing on changes at parameter.

Changes at mandibular length

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-75,795	54,151		-1,400	,172	-186,547	34,957
	AGE	9,007	5,343	,329	1,686	,103	-1,921	19,935
	GENDER	11,770	8,532	,260	1,379	,178	-5,681	29,221
	HOURS PER DAY	,851	1,466	,110	,581	,566	-2,147	3,850
	CPQ 8-10 (T1-T0)	-,188	,424	-,080	-,445	,660	-1,055	,678

1,00 Dependent Variable: DIF.MANLENGTH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-61,467	53,658		-1,146	,261	-171,209	48,275
	AGE	8,467	5,266	,310	1,608	,119	-2,304	19,237
	GENDER	10,828	8,287	,239	1,307	,202	-6,120	27,776
	HOURS PER DAY	,457	1,493	,059	,306	,762	-2,597	3,511
	CPQ 8-10 (T9-T0)	-,238	,216	-,198	-1,103	,279	-,680	,203

1,00 Dependent Variable: DIF.MANLENGTH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-84,638	53,913		-1,570	,128	-195,074	25,798
	AGE	9,269	5,687	,338	1,630	,114	-2,380	20,917
	GENDER	10,956	8,864	,240	1,236	,227	-7,201	29,112
	HOURS PER DAY	,960	1,488	,123	,645	,524	-2,088	4,008
	CPQ 8-10 GLOBAL	-,011	,419	-,005	-,026	,979	-,869	,847

1,00 Dependent Variable: DIF.MANLENGTH

There were not significant factors influencing on changes at parameter.

Changes at SNA

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-6,522	8,426		-,774	,445	-23,755	10,710
	AGE	,905	,831	,214	1,089	,285	-,795	2,605
	GENDER	-1,445	1,328	-,206	-1,088	,285	-4,160	1,270
	HOURS PER DAY	,021	,228	,018	,094	,926	-,445	,488
	CPQ 8-10 (T1-T0)	,032	,066	,087	,482	,633	-,103	,167

1,00 Dependent Variable: DIF.SNA

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-2,246	8,430		-,266	,792	-19,487	14,996
	AGE	,757	,827	,179	,915	,368	-,935	2,449
	GENDER	-1,383	1,302	-,198	-1,062	,297	-4,045	1,280
	HOURS PER DAY	-,051	,235	-,043	-,219	,828	-,531	,429
	CPQ 8-10 (T9-T0)	-,028	,034	-,150	-,820	,419	-,097	,042

1,00 Dependent Variable: DIF.SNA

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-5,519	8,375		-,659	,515	-22,674	11,637
	AGE	,913	,883	,216	1,033	,310	-,897	2,722
	GENDER	-1,275	1,377	-,181	-,926	,362	-4,095	1,546
	HOURS PER DAY	,000	,231	,000	,001	,999	-,473	,474
	CPQ 8-10 GLOBAL	-,005	,065	-,015	-,075	,940	-,138	,128

1,00 Dependent Variable: DIF.SNA

There were not significant factors influencing on changes at parameter.

Changes at SNB

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-10,103	7,171		-1,409	,170	-24,769	4,563
	AGE	,828	,708	,224	1,170	,252	-,620	2,275
	GENDER	-1,776	1,130	-,290	-1,572	,127	-4,087	,535
	HOURS PER DAY	,108	,194	,103	,558	,581	-,289	,505
	CPQ 8-10 (T1-T0)	,061	,056	,190	1,081	,289	-,054	,175

1,00 Dependent Variable: DIF.SNB

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-8,489	7,347		-1,156	,257	-23,515	6,536
	AGE	,779	,721	,211	1,080	,289	-,696	2,254
	GENDER	-1,563	1,135	-,255	-1,378	,179	-3,883	,757
	HOURS PER DAY	,106	,204	,101	,517	,609	-,312	,524
	CPQ 8-10 (T9-T0)	,013	,030	,082	,454	,653	-,047	,074

1,00 Dependent Variable: DIF.SNB

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-8,798	7,192		-1,223	,231	-23,531	5,935
	AGE	,899	,759	,242	1,185	,246	-,655	2,453
	GENDER	-1,676	1,182	-,272	-1,417	,167	-4,098	,746
	HOURS PER DAY	,083	,199	,079	,417	,680	-,324	,489
	CPQ 8-10 GLOBAL	-,038	,056	-,130	-,687	,498	-,153	,076

1,00 Dependent Variable: DIF.SNB

There were not significant factors influencing on changes at parameter.

Changes at ANB

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	1,065	7,288		,146	,885	-13,840	15,971
	AGE	,204	,719	,059	,284	,778	-1,266	1,675
	GENDER	,246	1,148	,043	,214	,832	-2,102	2,595
	HOURS PER DAY	,028	,197	,029	,142	,888	-,376	,432
	CPQ 8-10 (T1-T0)	-,005	,057	-,017	-,091	,928	-,122	,111

1,00 Dependent Variable: DIF.ANB

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	4,493	7,142		,629	,534	-10,115	19,101
	AGE	,081	,701	,024	,116	,908	-1,352	1,515
	GENDER	,177	1,103	,031	,160	,874	-2,079	2,432
	HOURS PER DAY	-,046	,199	-,047	-,231	,819	-,453	,361
	CPQ 8-10 (T9-T0)	-,037	,029	-,246	-1,300	,204	-,096	,021

1,00 Dependent Variable: DIF.ANB

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	1,252	7,224		,173	,864	-13,547	16,051
	AGE	,169	,762	,049	,222	,826	-1,391	1,730
	GENDER	,303	1,188	,052	,255	,801	-2,130	2,736
	HOURS PER DAY	,026	,199	,026	,130	,897	-,383	,434
	CPQ 8-10 GLOBAL	,014	,056	,051	,249	,805	-,101	,129

1,00 Dependent Variable: DIF.ANB

There were not significant factors influencing on changes at parameter.

Changes at SN-Maxillary plane

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	7,156	9,651		,742	,464	-12,582	26,894
	AGE	-,760	,952	-,163	-,798	,431	-2,707	1,188
	GENDER	,029	1,521	,004	,019	,985	-3,081	3,139
	HOURS PER DAY	-,007	,261	-,005	-,026	,979	-,541	,528
	CPQ 8-10 (T1-T0)	-,053	,075	-,132	-,704	,487	-,208	,101

1,00 Dependent Variable: DIF.SN_MAXPLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	4,966	9,809		,506	,617	-15,097	25,028
	AGE	-,690	,963	-,148	-,716	,480	-2,658	1,279
	GENDER	-,147	1,515	-,019	-,097	,923	-3,245	2,951
	HOURS PER DAY	,012	,273	,009	,042	,966	-,547	,570
	CPQ 8-10 (T9-T0)	-,004	,039	-,019	-,098	,923	-,085	,077

1,00 Dependent Variable: DIF.SN_MAXPLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	7,212	9,528		,757	,455	-12,305	26,730
	AGE	-,947	1,005	-,203	-,942	,354	-3,006	1,112
	GENDER	-,046	1,566	-,006	-,029	,977	-3,254	3,163
	HOURS PER DAY	,016	,263	,012	,061	,951	-,523	,555
	CPQ 8-10 GLOBAL	,058	,074	,155	,778	,443	-,094	,209

1,00 Dependent Variable: DIF.SN_MAXPLANE

There were not significant factors influencing on changes at parameter.

Changes at Palatal-Mandibular angle

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-5,154	16,867		-,306	,762	-39,650	29,343
	AGE	,339	1,664	,041	,204	,840	-3,065	3,742
	GENDER	2,807	2,658	,205	1,056	,300	-2,628	8,243
	HOURS PER DAY	,366	,457	,156	,802	,429	-,567	1,300
	CPQ 8-10 (T1-T0)	,002	,132	,002	,013	,990	-,268	,271

1,00 Dependent Variable: DIF.PALATAL_MANANGLE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-13,962	16,484		-,847	,404	-47,675	19,751
	AGE	,654	1,618	,079	,404	,689	-2,655	3,962
	GENDER	2,941	2,546	,214	1,155	,257	-2,265	8,148
	HOURS PER DAY	,551	,459	,234	1,200	,240	-,388	1,489
	CPQ 8-10 (T9-T0)	,090	,066	,248	1,361	,184	-,045	,226

1,00 Dependent Variable: DIF.PALATAL_MANANGLE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-5,813	16,727		-,348	,731	-40,078	28,452
	AGE	,409	1,764	,049	,232	,818	-3,205	4,023
	GENDER	2,687	2,750	,195	,977	,337	-2,946	8,320
	HOURS PER DAY	,373	,462	,158	,809	,425	-,572	1,319
	CPQ 8-10 GLOBAL	-,024	,130	-,036	-,183	,856	-,290	,242

1,00 Dependent Variable: DIF.PALATAL_MANANGLE

There were not significant factors influencing on changes at parameter.

Changes at LAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-40,199	21,188		-1,897	,068	-83,532	3,135
	AGE	4,308	2,091	,394	2,061	,048*	,033	8,584
	GENDER	3,933	3,338	,217	1,178	,248	-2,895	10,761
	HOURS PER DAY	,794	,574	,255	1,384	,177	-,379	1,967
	CPQ 8-10 (T1-T0)	-,010	,166	-,011	-,061	,952	-,349	,329

1,00 Dependent Variable: DIF.LAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-34,514	21,162		-1,631	,114	-77,796	8,767
	AGE	4,104	2,077	,375	1,976	,058	-,144	8,351
	GENDER	3,812	3,268	,210	1,166	,253	-2,872	10,496
	HOURS PER DAY	,670	,589	,216	1,138	,264	-,534	1,875
	CPQ 8-10 (T9-T0)	-,063	,085	-,130	-,736	,468	-,237	,111

1,00 Dependent Variable: DIF.LAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-43,829	20,728		-2,114	,044	-86,289	-1,368
	AGE	4,629	2,186	,424	2,117	,43*	,150	9,107
	GENDER	3,164	3,408	,175	,928	,361	-3,817	10,144
	HOURS PER DAY	,847	,572	,274	1,480	,150	-,325	2,019
	CPQ 8-10 GLOBAL	-,117	,161	-,135	-,727	,473	-,447	,213

1,00 Dependent Variable: DIF.LAFH

Changes at UAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-24,537	19,072		-1,287	,208	-63,544	14,470
	AGE	2,989	1,882	,309	1,588	,123	-,860	6,837
	GENDER	4,280	3,005	,267	1,424	,165	-1,866	10,427
	HOURS PER DAY	,457	,516	,166	,886	,383	-,599	1,513
	CPQ 8-10 (T1-T0)	-,090	,149	-,107	-,601	,552	-,395	,215

1,00 Dependent Variable: DIF.UAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-24,122	19,216		-1,255	,219	-63,423	15,178
	AGE	2,960	1,886	,306	1,570	,127	-,897	6,817
	GENDER	3,925	2,968	,244	1,322	,196	-2,145	9,994
	HOURS PER DAY	,403	,535	,146	,753	,457	-,691	1,496
	CPQ 8-10 (T9-T0)	-,048	,077	-,113	-,625	,537	-,206	,110

1,00 Dependent Variable: DIF.UAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-28,977	19,010		-1,524	,139	-67,918	9,964
	AGE	3,133	2,005	,323	1,563	,129	-,974	7,240
	GENDER	3,764	3,125	,234	1,204	,239	-2,638	10,166
	HOURS PER DAY	,518	,525	,188	,987	,332	-,557	1,593
	CPQ 8-10 GLOBAL	-,020	,148	-,026	-,133	,895	-,322	,283

1,00 Dependent Variable: DIF.UAFH

There were not significant factors influencing on changes at parameter.

Changes at LAFH/TAFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-6,968	3,663		-1,902	,067	-14,459	,523
	AGE	,534	,361	,279	1,477	,150	-,205	1,273
	GENDER	-,645	,577	-,203	-1,118	,273	-1,826	,535
	HOURS PER DAY	,152	,099	,280	1,534	,136	-,051	,355
	CPQ 8-10 (T1-T0)	,047	,029	,284	1,644	,111	-,011	,106

1,00 Dependent Variable: DIF.LAFH_TAFHPCT

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-4,476	3,859		-1,160	,256	-12,368	3,417
	AGE	,452	,379	,236	1,193	,242	-,323	1,226
	GENDER	-,498	,596	-,157	-,835	,410	-1,717	,721
	HOURS PER DAY	,124	,107	,229	1,158	,256	-,095	,344
	CPQ 8-10 (T9-T0)	-,002	,016	-,026	-,139	,891	-,034	,030

1,00 Dependent Variable: DIF.LAFH_TAFHPCT

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-6,320	3,593		-1,759	,090	-13,680	1,041
	AGE	,622	,379	,324	1,642	,112	-,154	1,399
	GENDER	-,723	,591	-,227	-1,224	,231	-1,933	,487
	HOURS PER DAY	,143	,099	,262	1,439	,161	-,060	,346
	CPQ 8-10 GLOBAL	-,049	,028	-,320	-1,749	,091	-,106	,008

1,00 Dependent Variable: DIF.LAFH_TAFHPCT

There were not significant factors influencing on changes at parameter.

Changes at LPFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-31,222	21,218		-1,471	,152	-74,618	12,174
	AGE	2,605	2,094	,248	1,244	,223	-1,677	6,887
	GENDER	-,898	3,343	-,052	-,269	,790	-7,736	5,939
	HOURS PER DAY	,644	,574	,216	1,121	,272	-,531	1,818
	CPQ 8-10 (T1-T0)	,152	,166	,168	,915	,368	-,188	,491

1,00 Dependent Variable: DIF.LPFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-13,183	21,108		-,625	,537	-56,354	29,988
	AGE	1,983	2,072	,189	,957	,346	-2,253	6,220
	GENDER	-,567	3,260	-,033	-,174	,863	-7,234	6,100
	HOURS PER DAY	,346	,587	,116	,589	,560	-,855	1,547
	CPQ 8-10 (T9-T0)	-,109	,085	-,235	-1,278	,211	-,282	,065

1,00 Dependent Variable: DIF.LPFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-29,373	20,643		-1,423	,166	-71,658	12,913
	AGE	2,903	2,177	,278	1,333	,193	-1,557	7,364
	GENDER	-1,535	3,394	-,088	-,452	,655	-8,487	5,417
	HOURS PER DAY	,640	,570	,216	1,124	,271	-,527	1,808
	CPQ 8-10 GLOBAL	-,192	,160	-,231	-1,196	,242	-,520	,137

1,00 Dependent Variable: DIF.LPFH

There were not significant factors influencing on changes at parameter.

Changes at UPFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-28,536	16,642		-1,715	,097	-62,572	5,501
	AGE	3,203	1,642	,376	1,951	,061	-,155	6,562
	GENDER	3,539	2,622	,250	1,350	,188	-1,824	8,902
	HOURS PER DAY	,491	,451	,203	1,090	,285	-,430	1,413
	CPQ 8-10 (T1-T0)	,007	,130	,009	,050	,960	-,260	,273

1,00 Dependent Variable: DIF.UPFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-23,876	16,652		-1,434	,162	-57,934	10,181
	AGE	3,038	1,634	,356	1,859	,073	-,305	6,380
	GENDER	3,497	2,572	,247	1,360	,184	-1,763	8,757
	HOURS PER DAY	,397	,463	,164	,858	,398	-,550	1,345
	CPQ 8-10 (T9-T0)	-,044	,067	-,118	-,658	,516	-,181	,093

1,00 Dependent Variable: DIF.UPFH

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-32,190	16,300		-1,975	,058	-65,579	1,198
	AGE	3,593	1,719	,420	2,090	**,46**	,072	7,115
	GENDER	3,127	2,680	,220	1,167	,253	-2,363	8,616
	HOURS PER DAY	,513	,450	,211	1,141	,264	-,408	1,435
	CPQ 8-10 GLOBAL	-,109	,127	-,161	-,863	,395	-,369	,150

1,00 Dependent Variable: DIF.UPFH

Changes at Wits

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	8,174	8,213		,995	,328	-8,623	24,972
	AGE	-,391	,810	-,100	-,482	,633	-2,048	1,267
	GENDER	-,097	1,294	-,015	-,075	,941	-2,743	2,550
	HOURS PER DAY	-,028	,222	-,025	-,124	,902	-,482	,427
	CPQ 8-10 (T1-T0)	-,041	,064	-,120	-,635	,530	-,172	,091

1,00 Dependent Variable: DIF.WITS

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	13,270	7,649		1,735	,093	-2,374	28,914
	AGE	-,579	,751	-,148	-,771	,447	-2,114	,957
	GENDER	-,329	1,181	-,051	-,279	,782	-2,745	2,086
	HOURS PER DAY	-,155	,213	-,139	-,726	,474	-,590	,281
	CPQ 8-10 (T9-T0)	-,072	,031	-,416	-2,333	,027	-,135	-,009

1,00 Dependent Variable: DIF.WITS

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	6,055	8,037		,753	,458	-10,408	22,519
	AGE	-,301	,848	-,078	-,355	,725	-2,038	1,435
	GENDER	,086	1,321	,013	,065	,948	-2,621	2,793
	HOURS PER DAY	-,030	,222	-,027	-,133	,895	-,484	,425
	CPQ 8-10 GLOBAL	,021	,062	,070	,344	,733	-,106	,149

1,00 Dependent Variable: DIF.WITS

There were not significant factors influencing on changes at parameter.

Changes at Overjet

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	4,839	4,692		1,032	,311	-4,756	14,435
	AGE	,013	,463	,006	,029	,977	-,933	,960
	GENDER	-,259	,739	-,066	-,351	,728	-1,771	1,252
	HOURS PER DAY	,175	,127	,259	1,375	,180	-,085	,434
	CPQ 8-10 (T1-T0)	-,046	,037	-,223	-1,246	,223	-,121	,029

1,00 Dependent Variable: DIF.OVERJET

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	4,807	4,745		1,013	,319	-4,898	14,512
	AGE	,008	,466	,003	,017	,987	-,945	,960
	GENDER	-,437	,733	-,111	-,597	,555	-1,936	1,062
	HOURS PER DAY	,152	,132	,225	1,150	,259	-,118	,422
	CPQ 8-10 (T9-T0)	-,022	,019	-,212	-1,160	,256	-,061	,017

1,00 Dependent Variable: DIF.OVERJET

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	3,051	4,603		,663	,513	-6,378	12,480
	AGE	,050	,486	,022	,102	,919	-,945	1,044
	GENDER	-,141	,757	-,037	-,187	,853	-1,691	1,409
	HOURS PER DAY	,179	,127	,273	1,411	,169	-,081	,440
	CPQ 8-10 GLOBAL	,029	,036	,156	,798	,431	-,045	,102

1,00 Dependent Variable: DIF.OVERJET

There were not significant factors influencing on changes at parameter.

Changes at Overbite

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	6,009	7,003		,858	,398	-8,314	20,332
	AGE	-,590	,691	-,174	-,854	,400	-2,004	,823
	GENDER	,392	1,103	,070	,355	,725	-1,865	2,649
	HOURS PER DAY	-,094	,190	-,097	-,493	,626	-,481	,294
	CPQ 8-10 (T1-T0)	,020	,055	,068	,365	,718	-,092	,132

1,00 Dependent Variable: DIF.OVERBITE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	8,292	7,049		1,176	,249	-6,125	22,708
	AGE	-,669	,692	-,197	-,967	,342	-2,084	,746
	GENDER	,437	1,089	,078	,402	,691	-1,789	2,664
	HOURS PER DAY	-,131	,196	-,136	-,667	,510	-,532	,270
	CPQ 8-10 (T9-T0)	-,013	,028	-,089	-,471	,641	-,071	,045

1,00 Dependent Variable: DIF.OVERBITE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	4,625	6,775		,683	,500	-9,252	18,503
	AGE	-,376	,715	-,112	-,526	,603	-1,839	1,088
	GENDER	,493	1,114	,088	,443	,661	-1,788	2,775
	HOURS PER DAY	-,109	,187	-,114	-,583	,565	-,492	,274
	CPQ 8-10 GLOBAL	-,042	,053	-,158	-,799	,431	-,150	,066

1,00 Dependent Variable: DIF.OVERBITE

There were not significant factors influencing on changes at parameter.

Changes at U1-maxillary plane

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-6,542	15,472		-,423	,676	-38,187	25,102
	AGE	1,165	1,527	,147	,763	,451	-1,957	4,288
	GENDER	1,729	2,438	,132	,709	,484	-3,257	6,715
	HOURS PER DAY	,568	,419	,252	1,356	,186	-,289	1,424
	CPQ 8-10 (T1-T0)	-,172	,121	-,252	-1,424	,165	-,420	,075

1,00 Dependent Variable: DIF.U1_MAXPLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-8,053	15,812		-,509	,614	-40,391	24,286
	AGE	1,194	1,552	,151	,769	,448	-1,980	4,367
	GENDER	1,078	2,442	,082	,442	,662	-3,916	6,073
	HOURS PER DAY	,511	,440	,227	1,161	,255	-,389	1,411
	CPQ 8-10 (T9-T0)	-,069	,064	-,199	-1,091	,284	-,199	,061

1,00 Dependent Variable: DIF.U1_MAXPLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-8,944	15,271		-,586	,563	-40,224	22,336
	AGE	,843	1,611	,106	,523	,605	-2,456	4,142
	GENDER	1,964	2,511	,149	,782	,441	-3,179	7,107
	HOURS PER DAY	,605	,422	,268	1,436	,162	-,258	1,469
	CPQ 8-10 GLOBAL	,174	,119	,276	1,469	,153	-,069	,417

1,00 Dependent Variable: DIF.U1_MAXPLANE

There were not significant factors influencing on changes at parameter.

Changes at IMPA

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	7,764	21,810		,356	,724	-36,843	52,371
	AGE	-,859	2,152	-,081	-,399	,693	-5,261	3,542
	GENDER	,608	3,437	,034	,177	,861	-6,420	7,637
	HOURS PER DAY	-,826	,590	-,273	-1,398	,173	-2,033	,382
	CPQ 8-10 (T1-T0)	-,005	,171	-,005	-,028	,978	-,354	,344

1,00 Dependent Variable: DIF.IMPA

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	17,463	21,487		,813	,423	-26,484	61,409
	AGE	-1,206	2,109	-,113	-,572	,572	-5,519	3,107
	GENDER	,450	3,318	,025	,136	,893	-6,337	7,237
	HOURS PER DAY	-1,030	,598	-,340	-1,722	,096	-2,253	,193
	CPQ 8-10 (T9-T0)	-,101	,086	-,215	-1,166	,253	-,278	,076

1,00 Dependent Variable: DIF.IMPA

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	9,440	21,601		,437	,665	-34,807	53,686
	AGE	-1,052	2,278	-,098	-,462	,648	-5,719	3,615
	GENDER	,532	3,551	,030	,150	,882	-6,743	7,806
	HOURS PER DAY	-,817	,596	-,269	-1,370	,182	-2,038	,405
	CPQ 8-10 GLOBAL	,032	,168	,037	,188	,852	-,312	,375

1,00 Dependent Variable: DIF.IMPA

There were not significant factors influencing on changes at parameter.

Changes at Interincisal angle

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	4,434	17,083		,260	,797	-30,505	39,373
	AGE	-,825	1,686	-,093	-,489	,628	-4,272	2,623
	GENDER	-5,534	2,692	-,377	-2,056	,9	-11,039	-,028
	HOURS PER DAY	-,007	,462	-,003	-,015	,988	-,953	,939
	CPQ 8-10 (T1-T0)	,198	,134	,259	1,479	,150	-,076	,471

1,00 Dependent Variable: DIF.INTERINCISALANGLE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	5,099	17,364		,294	,771	-30,414	40,613
	AGE	-,819	1,704	-,093	-,481	,634	-4,304	2,666
	GENDER	-4,772	2,682	-,326	-1,780	,086	-10,257	,712
	HOURS PER DAY	,080	,483	,032	,167	,869	-,908	1,069
	CPQ 8-10 (T9-T0)	,090	,070	,232	1,294	,206	-,052	,233

1,00 Dependent Variable: DIF.INTERINCISALANGLE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	6,219	16,854		,369	,715	-28,305	40,742
	AGE	-,348	1,778	-,039	-,196	,846	-3,990	3,293
	GENDER	-5,642	2,771	-,382	-2,036	,051	-11,317	,034
	HOURS PER DAY	-,063	,465	-,025	-,135	,894	-1,016	,890
	CPQ 8-10 GLOBAL	-,206	,131	-,292	-1,573	,127	-,474	,062

1,00 Dependent Variable: DIF.INTERINCISALANGLE

Male patients achieved a higher gain at angle:

Changes at L1 protrusion

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-5,839	5,096		-1,146	,261	-16,260	4,583
	AGE	,285	,503	,106	,567	,575	-,743	1,313
	GENDER	1,879	,803	,420	2,341	,**26**	,237	3,521
	HOURS PER DAY	-,091	,138	-,119	-,660	,515	-,373	,191
	CPQ 8-10 (T1-T0)	,035	,040	,150	,878	,387	-,047	,116

1,00 Dependent Variable: DIF.L1PROTRUSION

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-5,441	5,169		-1,053	,301	-16,013	5,130
	AGE	,276	,507	,102	,544	,590	-,761	1,314
	GENDER	2,010	,798	,449	2,518	**.18**	,377	3,642
	HOURS PER DAY	-,081	,144	-,106	-,566	,576	-,376	,213
	CPQ 8-10 (T9-T0)	,013	,021	,111	,633	,532	-,029	,056

1,00 Dependent Variable: DIF.L1PROTRUSION

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-4,610	5,076		-,908	,371	-15,007	5,787
	AGE	,274	,535	,102	,511	,613	-,823	1,370
	GENDER	1,844	,834	,415	2,209	**,36**	,134	3,553
	HOURS PER DAY	-,099	,140	-,130	-,703	,488	-,386	,188
	CPQ 8-10 GLOBAL	-,020	,039	-,096	-,515	,611	-,101	,060

1,00 Dependent Variable: DIF.L1PROTRUSION

Male patients achieved a higher reduction at this distance.

Changes at L1-facial plane

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-2,403	6,567		-,366	,717	-15,835	11,029
	AGE	,187	,648	,058	,289	,775	-1,138	1,512
	GENDER	1,535	1,035	,285	1,484	,149	-,581	3,652
	HOURS PER DAY	-,169	,178	-,183	-,950	,350	-,532	,195
	CPQ 8-10 (T1-T0)	-,006	,051	-,023	-,125	,902	-,111	,099

1,00 Dependent Variable: DIF.L1_FACIALPLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-1,559	6,600		-,236	,815	-15,057	11,939
	AGE	,156	,648	,048	,241	,811	-1,169	1,481
	GENDER	1,498	1,019	,278	1,470	,152	-,586	3,583
	HOURS PER DAY	-,190	,184	-,205	-1,033	,310	-,565	,186
	CPQ 8-10 (T9-T0)	-,012	,027	-,082	-,441	,662	-,066	,043

1,00 Dependent Variable: DIF.L1_FACIALPLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-1,855	6,494		-,286	,777	-15,158	11,448
	AGE	,111	,685	,034	,161	,873	-1,293	1,514
	GENDER	1,607	1,068	,296	1,505	,143	-,580	3,794
	HOURS PER DAY	-,171	,179	-,185	-,954	,348	-,538	,196
	CPQ 8-10 GLOBAL	,024	,050	,091	,466	,645	-,080	,127

1,00 Dependent Variable: DIF.L1_FACIALPLANE

There were not significant factors influencing on changes at parameter.

Changes at Upper lip to E plane

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	25,854	7,529		3,434	,002	10,456	41,252
	AGE	-2,154	,743	-,514	-2,900	**,7**	-3,674	-,635
	GENDER	,560	1,186	,081	,472	,640	-1,866	2,986
	HOURS PER DAY	-,452	,204	-,380	-2,220	**,34**	-,869	-,036
	CPQ 8-10 (T1-T0)	-,054	,059	-,148	-,913	,369	-,174	,067

1,00 Dependent Variable: DIF.UPPERLIPTOE_PLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	21,713	7,664		2,833	,008	6,039	37,387
	AGE	-2,014	,752	-,480	-2,678	**,12**	-3,553	-,476
	GENDER	,410	1,184	,059	,347	,731	-2,010	2,831
	HOURS PER DAY	-,394	,213	-,331	-1,847	,075	-,830	,042
	CPQ 8-10 (T9-T0)	,016	,031	,085	,507	,616	-,047	,079

1,00 Dependent Variable: DIF.UPPERLIPTOE_PLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	26,742	7,283		3,672	,001	11,823	41,661
	AGE	-2,428	,768	-,577	-3,161	**,4**	-4,002	-,855
	GENDER	,559	1,197	,080	,467	,644	-1,894	3,012
	HOURS PER DAY	-,433	,201	-,363	-2,156	**,40**	-,845	-,022
	CPQ 8-10 GLOBAL	,080	,057	,239	1,412	,169	-,036	,196

1,00 Dependent Variable: DIF.UPPERLIPTOE_PLANE

Changes at Lower lip to E plane

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	11,768	9,101		1,293	,206	-6,845	30,381
	AGE	-1,240	,898	-,276	-1,380	,178	-3,076	,597
	GENDER	-,072	1,434	-,010	-,050	,960	-3,005	2,861
	HOURS PER DAY	,044	,246	,035	,180	,858	-,459	,548
	CPQ 8-10 (T1-T0)	-,026	,071	-,068	-,370	,714	-,172	,119

1,00 Dependent Variable: DIF.LOWERLIPTOE_PLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	10,807	9,194		1,175	,249	-7,997	29,611
	AGE	-1,209	,902	-,269	-1,340	,191	-3,055	,636
	GENDER	-,161	1,420	-,022	-,114	,910	-3,065	2,743
	HOURS PER DAY	,051	,256	,040	,199	,844	-,472	,574
	CPQ 8-10 (T9-T0)	-,003	,037	-,016	-,087	,932	-,079	,072

1,00 Dependent Variable: DIF.LOWERLIPTOE_PLANE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	12,632	8,962		1,410	,170	-5,725	30,989
	AGE	-1,418	,945	-,314	-1,500	,145	-3,354	,519
	GENDER	-,044	1,473	-,006	-,030	,976	-3,062	2,974
	HOURS PER DAY	,052	,247	,041	,212	,834	-,454	,559
	CPQ 8-10 GLOBAL	,050	,070	,138	,712	,482	-,093	,192

1,00 Dependent Variable: DIF.LOWERLIPTOE_PLANE

There were not significant factors influencing on changes at parameter.

Changes at Nasolabial angle

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-43,339	58,317		-,743	,463	-162,609	75,932
	AGE	3,350	5,754	,119	,582	,565	-8,419	15,118
	GENDER	-5,689	9,189	-,122	-,619	,541	-24,482	13,104
	HOURS PER DAY	1,190	1,579	,149	,754	,457	-2,039	4,419
	CPQ 8-10 (T1-T0)	,170	,456	,070	,372	,712	-,763	1,103

1,00 Dependent Variable: DIF.NASOLABIALANGLE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-53,022	58,324		-,909	,371	-172,307	66,264
	AGE	3,721	5,724	,132	,650	,521	-7,986	15,428
	GENDER	-4,887	9,007	-,105	-,543	,592	-23,309	13,535
	HOURS PER DAY	1,478	1,623	,185	,911	,370	-1,841	4,798
	CPQ 8-10 (T9-T0)	,182	,235	,147	,775	,445	-,298	,662

1,00 Dependent Variable: DIF.NASOLABIALANGLE

Coefficients(1)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta	Lower Bound	Upper Bound	B	Std. Error
1	(Constant)	-51,947	53,997		-,962	,344	-162,554	58,660
	AGE	4,925	5,695	,187	,865	,395	-6,742	16,591
	GENDER	-2,388	8,877	-,055	-,269	,790	-20,572	15,797
	HOURS PER DAY	,890	1,490	,119	,597	,555	-2,163	3,943
	CPQ 8-10 GLOBAL	-,108	,419	-,052	-,258	,799	-,967	,751

1,00 Dependent Variable: DIF.NASOLABIALANGLE