Three-Dimensional Outcomes of Twin-Block Appliance Treatment and the Influence of the Postured Wax Bite

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TABLE OF CONTENTS

LIST OF TABLES

CHAPTER TWO

CHAPTER FIVE

LIST OF FIGURES

CHAPTER FOUR

CHAPTER FIVE

ABSTRACT

Aims

1. To identify the 3D soft tissue volumetric and linear landmark changes following treatment with the Twin-Block Appliance TBA.
2. To estimate the TBA treatment outcome on the soft tissue facial profile volumetric and linear landmark changes from the Postured Wax Bite (PWB).
3. To identify if there is any association between certain soft tissue landmark variables and successful treatment outcome of the TBA as measured by the reduction in overjet.
4. To assess the effects of TBA treatment on facial expressions at rest, natural smile and maximal smile.

Materials and Methods

Forty-seven Caucasian subjects (18 females, 29 males), with Class II division 1 malocclusion and an overjet ≥ 6 mm, were recruited. 3D stereophotogrammetry was used to capture 3D images of each subject, pre-treatment (T1) at rest, natural smile and maximum smile and with the PWB in place (T2). 3D images were also recorded at the end of treatment (T3; overjet 1-3 mm and/or Class I incisor relationship) at rest, natural smile and maximum smile. All images had 25 landmarks digitally placed, by one operator. Landmarking identification error was calculated. The soft tissue volumetric and linear changes (T1-T2 and T1-T3) as well as the correlation between facial parameters and successful treatment, as measured by overjet reduction, were calculated.

Results

The mean soft tissue volumetric change of the overall sample from T1 to T3 was 22.24 ± 16.73 cm^3.

Soft tissue profile linear changes from T1-T3 for lower facial landmarks were all significant (4-5 mm; $p<0.001$), except for labiale superius. All upper facial landmark changes were insignificant and similar for females and males.

From T1-T3, the mean soft tissue volumetric change of the total sample was 60% of the change produced by the PWB (T1 to T2). From T1 to T3, the soft tissue pogonion moved forward by 49% of the movement from T1 to T2.

Correlations were weak for all 3D facial parameters and successful overjet reduction.

For the lower landmarks, there were significant changes in both genders for each facial expression (T1-T3), except for maximal smile in males.

Limitations

It was not possible to account for changes due to growth because there was no control group.

Conclusions

1. TBA treatment, in growing subjects, increased the lower facial soft tissue volume and caused forward movement of the lower soft tissue facial profile landmarks.
2. The PWB can be used to estimate the treatment outcome of the TBA on soft tissue profile changes.
3. No association was found between any soft tissue landmark variable and successful overjet reduction.

4. TBA treatment had no effect on the upper facial landmarks for each facial expression but it changed the lower facial expressions significantly except for maximal smile in males.

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DECLARATION

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

E. Salloum

CHAPTER ONE

INTRODUCTION

1. Introduction

Class II division 1 malocclusion, with prominent upper incisor teeth and increased overjet, is associated with poor profile aesthetics (O'Brien et al., 2009), bullying (Seehra, 2013), and an increased risk of incisor trauma (Petti, 2015).

Growth modification treatment, using Functional Appliances (FAs), specifically the Twin-Block appliance (TBA), is the most common orthodontic treatment for Class II division 1 malocclusion in growing patients (Chadwick et al., 1998). Several studies have assessed the skeletal and dentoalveolar effects of FAs (Illing et al., 1998; Jena et al., 2006; Saikoski 2014), but there is insufficient information with regard to their effects on the soft tissue and facial profile (Flores-Mir and Major, 2006a; Baysal and Uysal, 2013).

Obtaining high quality evidence regarding soft tissue facial profile changes produced by FA treatment is important, as lay perception of successful outcome is influenced by the improvement of facial aesthetics and soft tissue appearance (O’Brien et al., 2009, Satterzadeh et al., 2010).

The effects of FAs have been extensively investigated using two-dimensional (2D) lateral cephalometry (Tumer and Gultan, 1999; Sidlauskas, 2005). The face, however, is a three-dimensional (3D) structure; therefore, an accurate assessment can only be performed using 3D evaluation (Hajeer et al., 2004). The application of 3D technology in the dental field continues to evolve and its clinical application has been proven to be both accurate and reliable (Benington et al., 2010).

The effect of Twin Block appliance (TBA) treatment on soft tissue volumetric and linear landmark changes has not been evaluated. The influence of the PWB on estimating the treatment outcome of the TBA has also not been assessed.

It would also appear that the effect of FAs on facial expressions has not been reported before. There is evidence to show that orthodontic treatment may alter the facial morphology by changing the soft tissue contours (Kau et al., 2006), and may, therefore, influence facial expression post-treatment.

CHAPTER TWO

LITERATURE REVIEW

2. Literature review

2.1 Search Strategy

An electronic database search was conducted from Jan 1st 1960 to Jan 1st 2015 for literature published in the English language only. The search strategy for each data base is summarized in **Table 1**.

Table 1

The Electronic data base search strategy used in the study

Database	Search Strategy
Medline	• (Twin block or twin-block or twinblocks) AND [(prediction of outcome or outcome prediction) OR (estimation of treatment outcome) OR (treatment effect$ or treatment outcome) OR (facial change or profile change or soft tissue change or three-dimensional effect$ or 3D effect$) OR (Functional wax bite or bite registration)} • (Facial expressions AND (Reproducibility) • (Three-dimensional imaging or 3D or Stereophotogrammetry) AND (Orthodontics)
PubMed	Same as Medline
Embase	Same as Medline
Google Scholar	Twin Block, Prediction of outcome, functional wax bite, Three-dimensional imaging, Stereophotogrammetry, Soft tissue profile changes, Facial expressions

Cochrane Library	Same as Google Scholar

2.2 Overview

Since this project is using a specific type of FA which is the TBA, the literature review will briefly discuss FAs, their classifications, types and mode of action. The TBA will be discussed in more detail with regard to different designs, effectiveness and bite registration techniques. Treatment prediction of outcome will be discussed for both FAs, in general, and the TBA, specifically. Then, a summary of 3D imaging in orthodontics will be presented, followed by a review of studies on facial expressions, evaluated by 3D methodology.

2.3 The FAs

2.3.1 Background

Historically, the use of removable orthodontic appliances including FAs (also known as myofunctional appliances) was very common among European orthodontists, especially from 1925 to 1965 as fixed appliance systems were unknown in Europe (Proffit et al., 2006). The first ever FA was the Monobloc which was developed by Robin in the early 1900s. Then the Activator appliance was developed by the Norwegian orthodontist, Andresen, in 1920 and it was the first FA to be widely accepted. In the 1960s-1970s there was a major increase in the use of FAs among North American orthodontists. This was the result of the influence of Faculty members with European backgrounds, and the emergence of animal studies that showed significant mandibular growth and skeletal change when the mandible was held in a postured position (Proffit et al., 2006).

FAs have been classified into various categories for better understanding of their applications. Yet, there is no single universally accepted classification (Ireland et al., 2003). Vig et al. (1986) classified FAs based on their component parts:

- Passive tooth-borne
- Active tooth-borne
- Tissue-borne
- Hybrid.

Graber et al. (1984) classified FAs based on the degree of soft tissue stretch they induce when in place:

- Myotonic: forces that move teeth are generated from the elastic recoil within the stretched tissues
- Myodynamic: forces that move teeth are generated from the stimulation of the masticatory muscles as a result of wearing the FA.

FAs can also be classified as fixed, or removable or whether they are used to treat Class II or Class III malocclusion (Ireland et al., 2003; Mitchell, 2013).

2.3.2 Mode of action

All FAs utilize the forces generated by the orofacial soft tissues in order to move teeth. The soft tissue stretch, generated by posturing the lower jaw away from the rest position, is believed to cause tooth movement and facial growth modification (Mills, 1991). This is based on the concept of 'bite jumping' that was first introduced by Norman Kingsley in North America (Kingsley, 1880). However, there is still considerable controversy surrounding the mode of action of FAs (Aelbers and Dermaut, 1996). According to the lateral pterygoid hypothesis, the postural and functional activities of the superior and inferior heads of the lateral pterygoid muscle increase after the insertion of a FA. This muscle hyperactivity augments condylar growth (Mills and McCulloch, 2000). Several animal studies have supported the actual increase in mandibular length (McNamara Jr, 1973; Xiong et al., 2004).

On the other hand, there are opponents to the muscular hyperactivity and lateral pterygoid theories. Yamin-Lacouture et al. (1997) have tested this hypothesis on non-human primates using inserted electromyographic (EMG) electrodes and found that FAs are associated with a decrease in the postural activity of the masseter, digastric as well as the superior and inferior heads of the lateral pterygoid muscles.

Seven systematic reviews have been published evaluating the mode of action of FAs (Chen et al., 2002; Cozza et al., 2006; Flores-Mir and Major, 2006b; Marsico et al., 2011; Koretsi et al., 2014; Perinetti et al., 2015). Three have focused only on dentoalveolar and skeletal effects (Chen et al., 2002; Cozza et al., 2006; Marsico et al., 2011), two included evaluation of soft tissue as well as dentoskeletal effects (Koretsi et al., 2014; Perinetti et al., 2015) and one focused only on soft tissue effects (Flores-Mir and Major, 2006b). Their findings are summarized in **Table 2**. Some of these reviews have included the TBA in conjunction with other FAs. Studies specifically on the TBA only will be discussed in **Section 2.4**.

The systematic review by Chen et al. (2002) covered the literature from 1966 to 1999 and identified 17 RCTs of which six were selected for final analysis. Only dentoalveolar changes were reported. One study included in this systematic review used the TBA (Illing et al., 1998), and the remaining five used the Bass, Bionator and Frankel appliances. There was a considerable amount of methodological variation and inconsistencies in measuring treatment outcome among the selected studies and there was no detailed quality assessment reported.

Table 2

The systematic reviews published evaluating the mode of action of FAs

Authors	Conclusions
Chen et al. (2002)	• Many inconsistencies in measuring treatment outcome variables are present • No definitive answers about FAs efficacy
Cozza et al. (2006)	• None of 4 RCTs included reported clinically significant supplementary growth of mandible • Two-thirds of total sample from 22 studies reported clinically significant supplementary elongation in mandibular length
Flores-Mir and Major (2006b)	• Significant amount of controversy regarding soft tissue changes with FAs • All statistically significant changes of soft tissues produced by FAs were of questionable clinical significance • 3D quantification required to overcome current limitations in understanding soft tissue changes
Flores-Mir et al. (2006)	• Fixed functional appliances produce some significant statistical changes in soft tissue profile; magnitude of changes may not be perceived as clinically significant
Marsico et al. (2011)	• Statistically significant skeletal effects of FAs, but questionable clinical significance
Koretsi et al. (2014)	• In short term, FAs are effective, although effects are mainly dentoalveolar rather than skeletal

(Perinetti et al., 2015)	• Treatment with fixed FAs has effective skeletal effect when performed during the pubertal growth spurt in addition to dental effects

The Cozza et al. (2006) systematic review searched the literature from 1966 to 2005. They reported on dentoalveolar changes only from 22 selected articles for final analysis. These include four RCTs, two prospective CCTs and 16 retrospective CCTs. Quality analyses of these studies showed that, the methodological soundness was medium to high in six studies, medium in 13 studies, and low in three studies. Six studies included in this review have used the TBA (Illing et al., 1998; Tumer and Gultan, 1999; Toth and McNamara, 1999; Mills and McCulloch, 2000; Baccetti et al., 2000; O'Brien et al., 2003a). In this systematic review, there was a lot of variation in terms of the type of FAs, wear protocols, age of treatment groups (early vs late) and control groups (contemporary versus historical). They have also included retrospective and non-randomized trials.

The Flores-Mir and Major (2006b) systematic review evaluated, through lateral cephalometric radiographs, the facial soft tissue changes after Bionator and activator FAs treatment. They reviewed the literature from 1966 to 2006 and from 30 studies only 11 were selected for final analyses. However, the overall level of evidence from the selected reports was low and all the studies included were cephalometric 2D studies. The limitations of this evaluation method will be highlighted later in **Section 2.6**.

Flores-Mir et al. (2006) combined soft tissue changes with fixed FAs. Only five studies were included for final analyses, and they reported on the Herbst and Jasper jumper appliances. The level of evidence for the included studies was low; therefore, the conclusions of this systematic review should be interpreted with caution. The authors also highlighted the need of 3D studies to quantify soft tissue changes to overcome the limited understanding in this field.

The systematic review and meta-analyses by Marsico et al. (2011) reviewed the literature to September 2009. They reported on dentoskeletal changes only and selected four RCTs for final analyses. This was based on the Cochrane guidelines for assessing the quality of trials included. All RCTs reported on the anatomic condylion with only one RCT reported on the TBA (O'Brien et al., 2003a); three reported on the Activator, Harvold, Frankel and the Bionator appliances. They excluded studies reported on articulare or studies that considered angular measurements because they do not evaluate effective mandibular growth. They also identified the great variability between the studies in terms of measuring outcomes, type of cephalometric analysis and reference points.

The meta-analysis by Koretsi et al. (2014) appraised the literature up to October 2013 and included 17 studies for final analyses, seven RCTs and 10 prospective CCTs. As only trials that reported on cephalometric angular measurements were included, several good quality trials were excluded. Interestingly, of the seven included RCTs, five were judged as being of high risk of bias, one was considered as being unclear and one at low risk of bias.

The most recent systematic review and meta-analysis by Perinetti et al. (2015) evaluated the action of fixed FAs only. This included 12 controlled studies (prospective and retrospective), eight of which were on pubertal patients and four were on post-pubertal patients. Only one study was of high quality, six of medium, and four of medium to high quality. This was the first review to use the growth phase as the main selection criterion, which allowed a direct comparison between pubertal and post-pubertal patients. This review had the following limitations: inclusion of retrospective studies, inclusion of studies with an historical control sample, difference in fixed FA treatment lengths, difference in cephalometric magnification between the studies and pooling of slightly different parameters expressing the mandibular length.

Although there is plenty of high quality evidence regarding the topic of FA treatment of Class II malocclusion, the methodology of the RCTs conducted is far from perfect; hence the conclusions of these RCTs and the systematic reviews based on them should be dealt with critically. These possible flaws were highlighted in a personal view point article by Meikle (2005) and these are:

- It is not clear what is being measured, as so many variables among and in between these RCTs are present, such as: compliance, magnitude and timing of growth, the skill of the clinician and the appliance ability in altering the pattern of maxillary and/or mandibular growth.
- The validity of mandibular growth measurements in the reported RCTs is questionable since it was undertaken on lateral head films. Cephalometric measurements and analysis techniques are always associated with a variety of errors; in addition they do not take into consideration the condylar growth and growth rotations described by Bjork. For example, the Pancherz analysis used in several RCTs tends to underestimate mandibular growth as a result of treatment.
- There is a well-documented variability and unpredictability in the pattern of dentofacial growth between individuals. Focusing on the mean and average values in RCTs tends to obscure the variability of an individual response which is very important in real clinical practice. That is why many orthodontists are

sceptical about the RCTs findings as in many cases they do not reflect their clinical experience.

2.4 The TBA

This project assessed the TBA in a prospective clinical trial. Therefore, this part of the literature review will discuss the TBA in more detail in terms of history, mode of action, different designs and bite registration techniques.

2.4.1 Background

The TBA was first introduced by Dr William Clark. It was developed from the Pierre Robin mono-block and the double plate of Schwarz (Clark, 1982). It consists of upper and lower bite blocks interlocking causing a functional mandibular posturing. Although it is mainly used to correct Class II division 1 malocclusion, a reversed TBA design may be used for treatment of Class III malocclusion (Clark, 1982).

In the UK, a survey conducted by Chadwick et al. (1998), showed that the TBA is the most commonly used appliance to treat Class II division 1 malocclusion in growing patients. Significant improvement in the patient's face was noticed when the appliance was worn full time (Clark, 1988). Its unique design allowed full time wear including eating, leading to it being regarded as the most 'patient friendly' of all the functional appliances (Clark, 2010).

Another reason for the popularity of the TBA is the available evidence showing that the TBA is more effective in modifying dentofacial growth and overjet reduction than headgear and other passive FAs such as the Andresen activator and its variants (Meikle, 2005). The treatment success rate with the TBA has been reported to be high; 100% (Toth and McNamara, 1999; Mills and McCulloch, 2000), 93% (Chintakanon et al., 2000), 80-90% (Illing et al., 1998; Harradine and Gale, 2000; Banks et al., 2004a) and 66% (O'Brien et al., 2003b).

2.4.2 Mode of action

A clinical study by Chintakanon et al. (2000) investigated the function of protrusive muscles, using a non-invasive approach, to test whether these muscles were responsible for mandibular repositioning after treatment with the TBA. Their findings did not support the lateral pterygoid hypothesis mentioned previously. There was also no evidence to support the increased mandibular protrusive function after treatment with the TBA, which was in agreement with the findings of Yamin-Lacouture et al. (1997).

In general, the TBA corrects Class II division 1 malocclusion by means of dentoskeletal and soft tissues changes. Those effects were reported in several studies which are summarized in **Tables 3 and 4**.

Although the studies given in **Tables 3 and 4** are ranked high on the hierarchy of evidence, there are several limitations in their design:

- A wide variation in the methodology, study design and reporting on the same topic (type of appliances, designs, wear protocols, duration of treatment, defining successful outcomes, cephalometric analysis and landmarking)
- The retrospective nature of many

- The concentration on 2D cephalometric outcomes
- The inclusion of very young (early) treatment groups
- The use of historical control samples in some studies for ethical reasons
- Lack of consensus on what is considered a clinically significant change.

The meta-analysis by Ehsani et al. (2014) was the only systematic review published to evaluate dentoskeletal effects of the TBA exclusively. In this review only 4 skeletal variables (SNA, SNB, Co-Gn and LAFH) and 2 dental variables (UI-ANSPNS and Li-GoGn) presented data that could be combined in a meta-analysis and all the reported effects were in the short- term. The authors could not report on soft tissue changes because the data were not adequate to be combined in a meta-analysis.

Table 3

The controlled studies and systematic reviews published on skeletal and dental effects of the TBA

Authors & year	Study design	Mean age at start of treatment (SD)	Control (All matched for age and sex)	Skeletal effects	Dental effects
Illing et al. (1998)	P, L, CCT	11.5 (1.5)	Contemporary sample from a waiting list	• Significant ↑in ML (Ar-Gn) by 2.2 mm in 9 months • ↑ SNB by 1◦ • Forward movement in Pogonion • Significant ↑in LAFH by 3 mm in 9 months	• ↓OJ by 6.4 mm • Retroclination of UI by 7.2◦ • Proclination of LI by 3 mm relative to A-Pog line
Lund and Sandler (1998)	P, CCT	12.4 (NR)	Contemporary sample from a waiting list	• Significant ↑in ML (Ar-Pog) by 2.3 mm per year • ↑ SNB angle by 1.5◦ • ↑in the LAFH by 1.5 mm	• ↓in the OJ of 7.5 mm • Retroclination of UI by 10.8◦ • Prolination of LI by 7.9◦ • Mesial movement in LM • No distal movement in UM • Slight extrusion of UM

Tumer and Gultan (1999)	R, L, CCT	11.5 (NR)	Contemporary sample from a waiting list	• ↓SNA and Co-ANS values • ↑ MPA and gonial angle values • ↓OB	• ↓OJ • Distal movement of UM • Mesial movement of LM • Retrolination of UI • Proclination of LI
Toth and McNamara (1999)	R, L, CCT	10.4 (NR)	Michigan Growth Study	• ↑ML (Co-Gn) by 3 mm in 16 months • ↑SNB by 1.3◦ • ↓Wits appraisal by 4 mm • ↑MPA by 2.1◦ • Significant ↑ in LAFH by 2 mm • Significant ↑in LPFH by 2 mm	• ↓OJ by 3.3 mm • Retroclination of UI by 4.3◦ • Proclination of LI by 2.8◦ • Distal movement of UM with no mesial movement of LM • Extrusion of LM with no change in the eruption of UM
Mills and McCulloch (2000)	R, L, CCT	9.1 (NR)	Burlington Growth Study	• ↑ ML (Co-Gn) 4.2 mm in 14 months • 2/3rd of the ML ↑ is due to ↑in ramus height and 1/3rd due to ↑ mandibular body length • ↑ SNB by 2.2◦ • Statistically significant ↓SNA	• ↓OJ by 5.9 mm • Retroclination of UI by 2.5◦ • Proclination of LI by 3.8◦ • Distal movement of UM and mesial movement of LM • Extrusion of LM

				• Significant ↑ LAFH and LPFH • Clinically small ↑in gonial angle (Ar-Go-Gn) and saddle angle (N-S-Ar)	• Inhibited eruption of UM
Trenouth (2000)	P, CCT		Generated from published normative data	• Statistically significant ↓ ANB • Statistically significant ↑SNA	• Statistically significant ↓OJ • ↓ angulation of UI
Baccetti et al. (2000)	R, L, CCT	Early group: 9.9 (11months) Late group: 12.9 (14 months)	Michigan Growth Study	• Significant ↑total ML (Co-Pog) in both early (4.8 mm) and late treatment groups (1.9 mm) per year. • ↑ ML (Co-Pog) by 1.66 mm per year in the late treatment group • ↑ ramus height (Co-Go) by 2.7 mm per year in the late treatment group • No ↑ in ML and ramus height was found in the early treatment group	• ↓OJ by 4.6 and 5.8 mm (early and late groups respectively). • No significant change in UI position • Proclination of LI by 1.4 and 2.2 mm per year in the early and late treatment groups respectively. • Distal movement of UM and mesial movement of LM.

O'Brien et al. (2003a)	RCT, L	9.7 (0.98)	Contemporary sample from a Waiting list	• Statistically significant ↑ in mandibular base (Po-OLp) by 1mm in 15 months • Statistically significant restriction of maxillary base length • Overall skeletal change is clinically insignificant • Significant ↑ in gonial angle (Ar-Goi-Me) and this was larger in the late treatment group	• ↓OJ by 6.9 mm • Retroclination of UI by 3mm • Proclination of LI by 2 mm
Sidlauskas (2005)	R, CCT	10.2 (NR)	Contemporary sample from a Waiting list	• Significant ↑ ML (Ar-Pog) 2.4 mm per year • Significant ↑ in (Ar-B) distance by 2.9 mm per year • ↑ SNB angle by 1.3◦ • Statistically significant ↓ in SNA	• ↓OJ by 5 mm • Retroclination of UI by 9.1◦ • Proclination of LI by 2.6◦

				• Statistically significant restriction of the maxillary base length • Significant ↑LAFH by 1.8 mm in 12 months	
Jena et al. (2006)	P, CCT	11.4 (0.90)	Contemporary sample from a Waiting list	• Significant ↑total mandibular growth by 1.65 mm in 12.7 months	• ↓OJ of 6.1 mm • Retroclination of UI by 1.8 mm • Proclination of LI by 1.8 mm • Mesial movement of LM with restricted forward movement of UM
Siara-Olds et al. (2010)	P, L, CCT	10.11	Michigan and Denver growth study	• ↑SNB by 0.9◦ per year • ↑ML by 1.5 mm per year • Anterior displacement of Pogonion • ↓ANB by 0.6◦ per year	• Significant change in the occlusal plane • Significant ↓OJ, Wits appraisal, and overbite • Significant flaring of LI

Brunharo et al. (2011)	RCT	9.6 (10 months)	Contemporary sample from a Waiting list	• Significant ↑total ML (Co-Gn) by 2.4 mm • Significant ↑maxillary length (Co-A) by 2.37 mm • No change in ANB	• ↓OJ • Retroclination of UI • Proclination of LI
Saikoski et al. (2014)	P, CCT	11.7 (1.64)	Contemporary sample from a Waiting list	• ↑ML (Co-Gn) • Significant improvement in ANB	• ↓OJ by 5mm • Retroclination and protrusion of UI • Proclination and protrusion of LI
Ehsani et al. (2014)	Systematic review and meta-analysis			• ↓SNA by 0.7◦ • ↑SNB by 1.2◦ • ↑ML (Co-Gn) by 2.9 mm • ↑LAFH by 2.1 mm	• ↓UI inclination by 9.2◦ • ↑ LI inclination by 3.9◦

P: Prospective, R: Retrospective, L: Longitudinal, NR: not reported, LAFH: Lower Anterior Face Height, U1: Upper Incisors, LI: Lower Incisors, LM: Lower Molars, UM: Upper Molars, LPFH: Lower Posterior Face Height, ML: Mandibular Length, OJ: overjet, OB: overbite, MPA: Mandibular Plane Angle

Table 4

Studies and systematic reviews published on soft tissues effects of the TBA

Authors & year	Study design	Mean age in years of treatment group (SD)	Control (matched for age and sex)	Soft tissue changes
Morris et al. (1998)	P, controlled and randomised to 3 treatment groups (TBA, Bass, Bionator), 2D & 3D evaluation	11.5 (1.5)	Contemporary sample taken from waiting list	• Lower lip protrusion by 3-4 mm • Upper lip position remained unchanged • Increase in lower lip length up to 4 mm • Increase soft tissue lower and total face height
McDonagh et al. (2001)	P, cohort randomised to 2 treatment groups (TBA and Bass), 2D and 3D evaluations	11.7 (1.8)	No control	• Forward movement chin by 1-3 mm • Increase LFH
Sharma and Lee (2005)	P, cohort randomised to 2 treatment groups (TBA and	10-14 (NR)	No control	• 3.2 mm increase in the vertical face height • 4 mm forward movement of soft tissue pogonion

	mini-TBA), 2D and 3D evaluations			
Luo and Fang (2005)	P, CCT, 3D evaluation	11-12 (NR)	Contemporary sample taken from waiting list	• No significant change in facial angle • No significant change in nose position • No significant change in lower lip • No significant change in soft tissue menton • More retruded position of labrale superius relative to aesthetic line (-1.9 mm)
Flores-Mir and Major (2006a)	Systematic review			nges in facial angle, nose, lower lip and soft ue menton are not of clinically significant and evaluation studies are highly recommended
Quintão et al. (2006)	P, CCT, 2D evaluation	9.5 (0.8)	Contemporary sample taken from waiting list	• Significant upper lip retraction • Anterior displacement of soft tissue pogonion • Flattening of the facial profile
Lee et al. (2007)	P, Randomised to 2 treatment groups, 2D and 3D evaluations	10-14	No control	• 4 mm increase in the LFH • 3-4 mm forward movement of soft tissue pogonion

Varlık et al. (2008)	RCT, 2D evaluation	11.9 (0.2)	Contemporary sample taken from waiting list	• Significant forward movement of soft tissue pogonion and sulcus inferioris • Forward movement of mandibular soft tissue landmarks by 3.5-4.5 mm • Overall soft tissue profile improvements
Baysal and Uysal (2013)	RCT, 2D evaluation	13 (1.3)	Contemporary sample taken from waiting list	• Increase in mentolabial ange • Decrease in H angle (formed between soft tissue nasion, soft tissue pogonion and labrale superioris)

NR: Not Reported; LFH: Lower Facial Height; P: Prospective; CCT: Controlled Clinical Trial; RCT: Randomised Clinical Trial

The systematic review by Flores-Mir and Major (2006a) only included studies with control groups in their final analysis (Morris et al., 1998; Luo and Fang, 2005). Although the two studies which were not included (Singh, 2002; Singh and Clark, 2003) found significant soft tissue profile improvements after TBA treatment, their findings should be interpreted with caution; the lack of a control will overestimate the TBA treatment effects as no distinction can be drawn between the TBA effects and normal growth changes. Subsequent controlled studies published on the same topic after this systematic review all showed significant improvement in soft tissue profile after TBA treatment (Quintão et al., 2006; Varlık et al., 2008; Baysal and Uysal, 2013), but they had the following short-comings:

- The sample in the Quintão et al. (2006) study had both treatment and control groups in their pre-pubertal growth period
- The treatment group and control group in the Varlık et al. (2008) study were not matched for age, and the post-treatment observation period was short
- The study of Baysal and Uysal (2013) had overcome the short-comings of the two previous studies by having both treatment and control groups around the pubertal growth period, but the post-treatment observation period was still short.

From the previous discussion, it can be concluded that the dentoskeletal mode of action of TBA is well established in the literature. However, the evidence is still fluctuating between supporting and rejecting the clinical significance of any soft tissue changes with the TBA **(Table 4)**.

2.4.3 Designs of the TBA for Class II division 1 treatment

The original TBA described by Clark (1982) had a slightly different design than the one commonly used nowadays. The upper appliance had two 0.7 mm Adams' clasps, each one usually spanning two buccal teeth. These Adams' clasps incorporated a spring coil tube to apply extra-oral traction. The upper block also incorporated a midline expansion device and a labial bow extending from the mesial of the upper first permanent molars. A lingual bow occasionally was incorporated to the upper block design when controlling upper incisor angulation, as required. In the mixed dentition, Clark (1982) suggested to use 0.7 mm 'C' clasps on the lateral incisors in addition to the Adams' claps on the first permanent molars.

In the lower appliance, depending on what teeth had erupted, Clark (1982) suggested interdental clasps spanning two teeth at the incisor and premolar region. A reversed U-loop was used lingual to the lower incisors to allow inter-maxillary traction. A Concorde face-bow was fitted to the coil spring tube on the upper appliance. This tube has a midline labial hook of 1.5 mm wire for application of inter-maxillary traction. The articulation between the upper and lower appliance was achieved by inter-locking of the bite blocks at a 45 degree angle; later this was changed to 70 degrees to maintain a better postured position. The inter-occlusal separation in the premolar region was 4-6 mm (Clark, 1982; Clark, 2010).

The TBA was subjected to various design modifications in order to minimise the dentoalveolar effects and enhance skeletal changes. The modifications described are as follow:

- **TBA without a labial bow:** although the labial bow was incorporated in the TBA original design by Clark, later he suggested that the labial bow should not be used because the retroclination of the maxillary incisors reduced the potential skeletal changes (Clark and Baker, 1995). A recent randomised controlled clinical trial compared two designs of TBA with and without a labial bow. This showed that the labial bow has no influence on skeletal or dentoalveolar changes or on the amount and rate of overjet reduction (Yaqoob et al., 2012). Therefore, many clinicians have omitted this component from the contemporary TBA design.
- **TBA with Southend clasps:** Trenouth (1989) introduced the concept of incorporating two Southend clasps, one on the upper incisors and one on the lower incisors. Subsequently, Trenouth omitted the maxillary labial bow and in a RCT he compared two designs of the TBA with or without Southend clasps (Trenouth and Desmond, 2012). The findings showed more skeletal correction and less tipping of the teeth when Southend clasps were used on the maxillary and mandibular incisors.
- **TBA with upper incisor torqueing spurs:** Harradine and Gale (2000) compared two designs of the TBA, one with an upper labial bow and one with upper incisor torqueing spurs; they concluded that using torqueing spurs substantially reduced upper incisor retroclination and extrusion with slightly more favourable lower jaw growth.
- **TBA in conjunction with headgear traction:** Parkin et al. (2001) have found that headgear addition has effectively controlled the maxillary growth in the vertical and sagittal dimensions and resulted in more skeletal Class II correction.
- **Mini TBA:** In order to avoid some of the undesirable effects of the TBA such as lower incisor proclination, increase in facial height and limited mandibular

growth, a modified version of the TBA, named the ''mini-block'' appliance, was developed by Gill and Lee (2005). This appliance used a posterior bite block of reduced vertical height, included the option of incremental advancement of the mandible and incorporated upper incisors torqueing springs. However, a prospective clinical trial has shown that progressive mandibular advancement was not associated with greater mandibular skeletal change (Gill and Lee, 2005).

- **TBA combined with fixed appliances:** As part of the evolution of the functional orthopaedic appliances, Clark (2011) developed a protocol to integrate functional appliance therapy with the fixed appliance at any stage of treatment by bonding pre-formed blocks directly to the teeth. This approach should eliminate any problem of patient compliance.
- **TBA modified for Class II division 2 malocclusion:** in two case reports, Dyer et al. (2001) introduced a modification of the TBA for Class II division 2 malocclusion cases. Two designs were described; with anterior screw section or with anterior double cantilever spring, to provide active labial segment proclination, which eliminated the need of pre-functional phase of treatment.

2.4.4 Techniques for bite registration

Taking a PWB for the TBA fabrication is of great importance, as it will directly affect the effectiveness and the accuracy of the appliance (Shah and Sandler, 2009). In this section various bite registration techniques will be reviewed.

Clark (1988) suggested that the amount of posture depends on the ease with which the patient can posture forward. This usually should reduce the overjet by 5-7 mm on the initial activation with 3-5 mm inter-occlusal clearance at the premolar region. Bite registration should also address any midline discrepancy caused by functional displacement. More recently, Clark (2010) advocated the use of the “Projet Bite” gauge to an edge-to-edge incisal position. Depending on how deep the bite is; two “Projet Bite” options are available. For deep bite cases, the blue “Projet Bite” with 2 mm incisal clearance and 5-6 mm clearance in the pre-molar area is advised, whereas in cases with reduced overbite, the white project bite with 4 mm incisal-clearance and 5 mm clearance at the premolar region should be used. Keeping the incisal clearance to a maximum of 5 mm is very important for patient comfort and good compliance. Thin blocks, which lead to minimal incisal and premolar clearance, are also incorrect as these allow the patient to retract the mandible to its rest position and result in reducing the efficiency of the appliance.

Shah and Sandler (2009) have stated that the ideal wax bite should provide at least 7-8 mm clearance in the premolar region, as this will encourage the patient to bite in the desired postured position. However, in Clark’s opinion this will be uncomfortable for the patient and compliance might be affected (Clark, 2010).

Some clinicians have advocated the concept of activating the bite in small stages rather than taking the bite to the incisal edge-to-edge position in a single activation. Reasons given to justify this include: improved compliance with less tension applied on the muscles, improved speaking, improved patient general comfort and maintenance of the appliance in a correct position during sleeping. Banks et al. (2004b) disproved previous claims when they investigated the effect of incremental versus maximum bite advancement on treatment effectiveness using the TBA and found no difference between either.

2.5 The prediction of treatment outcome with FAs

One of the aims of this project is to quantify the volumetric facial profile changes produced by the PWB, to assess its ability to estimate the TBA treatment outcome on soft tissue profile. Several previous studies attempted to predict the outcome of growth modification with FAs. This section will highlight this topic in more detail, starting off with FAs in general and then in relation to the TBA, specifically.

In total, seven FAs studies and five TBA studies have tried to predict treatment outcome. All used dental and skeletal landmarks to assist in predicting treatment outcomes. Following an extensive literature review on the topic, one study was found on Obstructive Sleep Apnoea (OSA) (Vanderveken et al., 2011) which aimed to predict treatment outcome by using a wax bite taken in the maximal protruded position of the mandible. This used a special registration fork, similar to the wax bite taken during bite registration for the TBA. The wax bite was inserted again in the patient's mouth during the ''drug induced sleep endoscopy procedure'' to allow the investigation of the upper airway collapse at least for 5 consecutive minutes; images and a video were then recorded. If the upper airway collapse was completely resolved using the bite simulation approach, the patient was considered to be suitable for mandibular repositioning appliance treatment. This method was found to be very reliable and reproducible in predicting the outcome of OSA.

2.5.1 Studies of FAs

Patient compliance (Bishara and Ziaja, 1989) and the presence of active growth (Hagg and Taranger, 1982; McNamara Jr et al., 1982) have been the most commonly reported factors to predict treatment outcome with FAs. However, clinical experience showed that even when compliance and growth were not an issue, there was a wide individual variation when treating similar malocclusions in terms of treatment success (Vargervik and Harvold, 1985). Ultimately this was explained by the possible differences in certain morphological features between patients (Bondevik, 1991).

All studies of FAs, to identify morphological features that could affect and predict treatment success, were 2D cephalometric and they are summarized in **Table 5**. There was a considerable amount of variation in the methodology among all these studies and, therefore, Barton and Cook (1997) have highlighted the need for further investigations.

Ahn et al. (2001) aimed to predict successful treatment outcome of the Bionator appliance. This was the only FA study to look at soft tissue predictor landmarks. Their sample comprised of 40 patients divided equally into two groups; ‘good treatment result’ and ‘poor treatment result’ based on Angle Class I molar relationship, overbite, overjet, the relation of the lips to Rickett’s aesthetic line and the mount of relapse 2 to 5 years after treatment.

Table 5

Studies that assessed the prediction of outcome of FAs other than the TBA

Authors & year	Appliance used	Conclusions
Parkhouse (1969)	Andresen	Improvements in SNB are doubled when ANB is initially large (mean of 7.81)
Tulley (1972)	Activator	Presence of AOB will lead to unsuccessful outcome
Ahlgren and Laurin (1976)	Activator	Treatment outcome cannot be predicted from skeletal features
Pancherz (1979)	Activator	Presence of AOB will lead to unsuccessful outcome regardless the value of MMPA
Charron (1989)	Activator	Successful treatment was related to increased initial OB and mandibular ramus length
Barton and Cook (1997) (Review)	Different FAs	Best outcome when OJ of up to 11 mm, increased OB, active growth and good compliance
Ahn et al. (2001)	Bionator	Good outcome was related to normal ANB, retrusive LI and retrusive lower lip

AOB: Anterior Open Bite, LI: lower Incisors, OB: overbite, OJ: overjet

2.5.2 Studies of TBA

All studies that have reported on prediction of treatment outcome with the TBA were based on cephalometric 2D evaluation except for one (Al-Rahbi, 2014) which was based on 3D laser scanning. Only two TBA studies looked at soft tissue predictor landmarks (Patel et al., 2002; Al-Rahbi, 2014); the others assessed dentoskeletal variables only. The findings of all these studies are summarized in **Table 6** with a brief commentary on each one of them.

Table 6

Studies that have assessed the prediction of outcome with the TBA

Authors	Study design	Treatment success predictors	Comments
Caldwell and Cook (1999)	Prospective cephalometric (2D) study	• Deep OB • Small SNB angle	• Considered treatment successful of OJ ↓ by 50% or 6 mm in 6 months • High dropout rate of 49% (sample bias issue)
Patel et al. (2002)	Retrospective cephalometric (2D) study	• Short mandible • Short ramus height • Reduced ALFH & PLFH • Short cranial base • Retruded soft tissue pogonion	• 72 subjects with Class II division 1 • Analysed face height, antero-posterior, horizontal plane, mandibular, dentoalveolar and soft tissue variables • Change in the ANB was used to determine successful treatment
Franchi and Baccetti (2006)	Prospective cephalometirc (2D) study	• Co-Go-Me angle of smaller than 125	• 51 subjects had FA treatment followed immediately by fixed treatment

			• Measured total mandibular length as discriminator for successful treatment outcome • No effect of the mandibular position on treatment outcome (in disagreement with Caldwell and Cook (1999) and Patel et al. (2002)
Fleming et al. (2012)	Retrospective cohort cephalometirc (2D) study	• Increased initial OJ	• 131 subjects treated with the TBA only • Outcome measured: OJ reduction, changes in mandibular length, anter-posterior changes in mandibular position • Retrospective evaluation could overestimate TBA effectiveness
Al-Rahbi (2014)	Prospective laser scanning (3D) study	• Increased initial OJ • Retrusive and superior positioned chin point	• 64 subjects scanned pre-treatment and 6-9 months into treatment • Control group from Avon Longitudinal Study of Parents and Children

OB: overbite, OJ: overjet

2.6 Three Dimensional imaging in Orthodontics

The vast majority of FAs and TBAs studies have used 2D cephalometric assessment. In this project, the evaluation of treatment change was based solely on 3D stereophotogrammetry using the DI3D surface capturing system. This section will give a brief background of 2D and 3D imaging in orthodontics; 3D imaging methods for soft tissue structures including stereophotogrammetry and the DI3D system will be discussed in more detail.

2.6.1 Background

Craniofacial anthropometry techniques have been widely used for profile assessment, treatment planning, identifying clinical features, quantifying treatment outcomes, and in assessing longitudinal changes (Farkas and Deutsch, 1996). These direct measures are easy to do, cheap, reliable and extensive normative databases exist for comparison and reference (Farkas, 1994; Wong et al., 2008). Nevertheless, they have some limitations (Wong et al., 2008) such as:

- They require training on live subjects
- Performing measurements is time-consuming
- Good patient compliance is necessary as subjects need to remain still while taking the measurements.

Since the introduction of radiographic cephalometry by Broadbent and Hofrath in 1931, the use of traditional anthropologic methods receded and lateral cephalograms became the method of choice for facial and soft tissue profile assessments (Bourne et al., 2001). Clinical experience with 2D cephalometry identified several shortcomings in the use of this method for soft tissue profile assessment (Hillesund et al., 1978; Illing et al., 1998; McDonagh et al., 2001; Bourne et al., 2001; Adams et al., 2004; Incrapera et al., 2010). These include:

- Ethical issues associated with radiation exposure
- Inaccuracies associated with magnification and head positioning
- The unrealistic 2-dimensional representation of a 3-dimensional structure
- Problems in landmark identification
- Variation in lip position during exposure which affects lip thickness evaluation.

2.6.2 2D imaging

The use of sophisticated digital cameras and 2D photography offers quick and easy capture of facial images, permanent storage and the ability to repeat measurements, all in the absence of ionising radiation exposure (de Menezes et al., 2009). Although 2D photography has offered additional advantages over 2D cephalometry, it remains a two-dimensional representation of a 3D object and accuracy is affected by projection, distortion and pose (Ghoddousi et al., 2007; Wong et al., 2008)

2.6.3 3D imaging

In the last two decades 3D imaging has developed to overcome the limitations of 2D imaging. Soon after its marketing, 3D imaging technology was applied to various aspects of orthodontics (Hajeer et al., 2004). It is now used in the assessment of facial deformities and the outcome of surgical or/and orthodontic intervention because it allows the clinician to manipulate the 3D models in any direction which gives valuable and comprehensive information about the soft tissues, without the need for patient recall. Moreover, treatment outcome can be assessed by comparing before and after treatment 3D models and analysing landmark displacement. 3D imaging is also used as a communication tool for ‘Tele-orthodontics’. It has become a promising application in the dental inter-disciplinary team work, as it provides the ability to share the patient 3D records over distance between colleagues which provides much more real-time accurate information for treatment planning. Hajeer et al. (2002) and Hajeer et al. (2004) classified 3D imaging techniques as radiographic-based, visual-based and other methods. These are summarized in **Tables 7-9**.

Table 7

A summary of the radiographic based imaging methods reported in the literature

Radiographic based methods	Drawbacks and limitations
3D cephalometry: Coordinates data from two biorthogonal head films such as lateral and antero-posterior radiographs (Savara, 1965; Grayson et al., 1988)	• Radiation exposure • Poor definition of soft tissue • Time-consuming procedure • Difficulties locating same landmarks on 2 different radiographs • Poor soft tissue contour assessment
Morphoanalysis: Involves taking 3D records using photographs, radiographs and study casts	• Time-consuming • Expensive equipment • Not practical for routine use
3D CT scanning: More common in medical field	• High radiation dosage • Poor facial soft tissue resolution due to slice spacing • Image distortion due to artefacts produced by intra oral metal objects
Cone beam CT: Less radiation scatter with maintained ability to produce high quality 3D models of skeletal and soft tissues. Smaller and less expensive than conventional CT (Mah et al., 2003)	• Unable to map-out muscle structure and attachments • Unable to produce colour and skin texture of scanned object

Stereolithography: Organic model is produced based on CT scans (Bill et al., 1995; Ayoub et al., 1996)	• Experience with technique required • Expensive • High radiation exposure • Inadequate soft tissue production
3D laser scanning: Active stereoscopic scanning method via directional light source and detector to produce x-, y-, and z-coordinates. Classified to single point scanners and slit scanners. Or fixed and portable (Kau and Richmond, 2010). Validated and shown to be reliable Kau et al. (2005).	• Invasive in comparison to other methods • Slow • Distortion if subject not still during the scanning process • Safety concerns due to exposing the eyes to laser beam • No capturing of soft tissue texture • Difficulty in landmark identification

Table 8

A summary of Vision based 3D imaging methods reported in the literature

Vision based methods	Drawbacks and limitations
Moire topography: Uses grid projections during exposure to give standardized contour lines of face (Leivesley, 1983; Kawai et al., 1990). 3D information delivered based on contour fringes and fringe intervals. Fringes are difficult to capture on surface with sharp features. Results usually better on smoothly contoured surfaces.	• Fringes difficult to capture on surface with sharp features • Results better on smoothly contoured surfaces • Variations in head position can produce significant changes in fringe pattern
Structured light technique: Based on the use of a digital camera to capture a photographic image and an illuminating light that illuminates face several times with random patterns of light. Illuminated points in captured image compared to position on the light projection plane to form 3D model of imaged object (Nguyen et al., 2000; Tuncay, 2001)	• Increased capture time • Inability to capture ear to ear facial model

3D ultrasonography: Reflection picture delivered and transformed into digital information. Specific contact probe required to generate a 3D database as ultrasonography waves do not visualize bone or pass through air. No 3D image produced as system only gives 3D coordinates of selected landmarks. (Hell, 1995).	• Time-consuming • Skilful operator and co-operative patients required • Head movements or contact with soft tissue during data collection produces errors
3D facial morphometry: 2 infrared cameras, hardware for recognition of markers and software for 3D rebuilding of landmarks coordinates. Landmark located on face covered with 2 mm hemispheric reflective markers. Infrared stroboscope used to light up the reflective markers. To capture whole face, two acquisition sessions required. Subject image captured by two charged coupled cameras and real time hardware required to recognise markers and software for 3D reconstruction (Ferrario et al., 1996)	• Not true imaging system • Placing landmarks on face time and labour consuming • Reproducibility of landmarks questionable • Changes in facial expression between acquisition sessions increased chances of error • Not possible to show natural soft tissue appearance of face • Cannot be used as 3D treatment planning and communication tool.
Stereophotogrammetry: Technique used in this project. **Section 2.6.3.1**	

Table 9

Other 3D imaging techniques reported in the literature

Other methods	Limitations
Magnetic Resonance Imaging (MRI) (Hamada et al., 2000; Gray et al., 2000; Papadopoulos et al., 2002) • Powerful 3D imaging method • Considered non-invasive method for producing images with high tissue contrast • Mainly used for advanced TMJ analysis of the TMJ, maxillary sinus evaluation, surgical planning of tumour resection and planning of orthognathic cases	• High cost • Interference of magnetic field with metal objects (implants, cardiac pacemakers, artificial valves, stents, prosthesis and orthodontic appliances)
3D ultra-sound (Papadopoulos et al., 2002) • Used to visualize soft tissues and organs such as: salivary glands, tongue, and nose • Cheap, safe, and less time-consuming in comparison to MRI and CT scans	• Distorted images due to artefacts • Limited application in orthodontics

2.6.3.1 Stereophotogrammetry 3D imaging technique

It is defined as “the science or art of obtaining reliable measurements by means of photographs” (American Society of Photogrammetry, 1966). It was first used in 1944 and was applied by Thalmann-Degan who recorded facial changes as a result of orthodontic treatment (Burke and Beard, 1967). Stereophotogrammetry is based on digital cameras, in addition to algorithms that analyse the digital images taken to produce a 3D model. It offers all the features of 3D imaging discussed previously, in the absence of ionizing radiation and great scanning accuracy. Stereophotogrammetry has also been widely applied in the medical field to capture 3D information other than from the facial region with a great level of accuracy. For example, stereophotogrammetry has been assessed for accuracy and reproducibility in breast imaging. It was shown that stereophotogrammetry plays an important role in breast morphology assessment and offered several advantages over other more invasive and expensive 3D imaging methods (Catherwood et al., 2011). Several stereophotogrammetry systems have evolved over the years; these are summarized in **Table 10**.

Table 10

The different stereophotogrammetry systems reported in the literature

Stereophotogrammetry system	System details
C3D system (Hajeer et al., 2002; Ayoub et al., 2003; Hajeer et al., 2004)	• Two synchronized semi-metric cameras mounted on a frame 50 cm apart and positioned in a convergent way with 15° angle. • Computer technology processes complex algorithms to convert simple photographic images into 3D models. • Two digital cameras configured as stereopair and textured illumination used to provide very quick capture of 30 milliseconds. • Third coloured camera positioned centrally and appended with each stereopair to capture the patient's natural skin surface appearance and then "drape" skin texture over the constructed 3D model. • Accuracy validated and reported to be within 0.5 mm.
Vectra 3D dual module (See et al., 2008; Sawyer et al., 2009a)	• Modular 3D image capturing system. • Two pods, each with 3 cameras (two black-and-white cameras and 1 colour) and on each pod illuminating projector attached. • Requires calibration each day before capturing images. • Data analysis and 3D facial model construction done by specialized software (VAM).

3dMDface (Aldridge et al., 2005; Kau et al., 2006; Kau et al., 2007; Talbert et al., 2014)	• Combines structured light and stereophotogrammetry. • Three cameras placed on each side of subject, two infrared, and one coloured. • Highly repeatable 3D images and precise data acquiring. • Random light projected onto object, and image is captured simultaneously by cameras configured at optimum angles. • Images show full face, ear to ear and under chin. • At highest resolution, process takes 1.5 ms. • Advantageous for taking images in young children. • Accuracy is 1.5% of total observed variance.
DI3D surface capturing system	• System used in this project • Discussed in more details. **Section 2.6.3.2**

2.6.3.2 The DI3D system

It uses fixed standard digital cameras and a synchronised normal photographic flash illumination system to capture simultaneously multiple stereo-pairs of images of a subject. Sophisticated software is used to process the stereo-pairs of images in order to automatically produce a dense range map image. The map images and the photographic coloured images are then merged together to form a high definition 3 dimensional (3D) surface image allowing natural skin texture on the 3D models to be shown in a fraction of a second.

The DI3D differs from other 3D imaging systems in that it does not require any pattern projection or laser scanning exposure. The procedure is rapid and immediately gives high resolution 3D models with true photographic quality. The system is designed specifically to capture 3D surface images of the human face (ear to ear view) using four 10 megapixel cameras. Customised DI3D systems are available for capturing larger and more complex volumes using up to 32 cameras to provide a resolution of 21 megapixels. The DI3Dcapture is the software that is used to integrate image capturing and 3D processing into one easy to use application. Using the live on-screen multiple-preview allows the operator to ensure that the subject is accurately positioned and framed so the 3D image can be captured with a single click of a button. The software has many features to make data management easy and efficient. The DI3D viewing software, the DI3Dview, allows the 3D images to be viewed in high definition so that every detail of the face is clearly displayed. The viewing software allows more than one 3D image to be opened and viewed simultaneously which will allow direct comparisons between different 3D models and improve efficiency and communication. The DI3D was technically validated for accuracy and reliability with an acceptable range of error of 0.2 mm (Khambay et al., 2008; Winder et al., 2008).

2.7 Facial expression

The effect of FAs treatment on facial expressions and facial expression reproducibility has not been reported previously in the orthodontic literature. In this project, only the changes of facial expression at rest, natural smile and maximal smile will be evaluated from before to after TBA treatment.

Studying facial expressions have benefited from the advancements in 3D imaging. Traditionally conventional photographs were used to study facial expressions with the disadvantage of assessing a 3D object by 2D means, giving no account to the antero-posterior changes (Ackerman et al., 1998). Direct measurements on patients have been used to allow 3D assessment, for example Burres (1985) studied facial expressions on 30 patients with integrated electromyography. In this technique, subjects were required to hold each expression for 30 seconds, which may have led to loss of accuracy due to fatigue.

Other investigations have used video recording as a method to assess facial expressions. Wood et al. (1994) analysed the variability in two facial expressions from day to day using a video microscope. A very well conducted study by Johnston et al. (2003), overcame the methodological limitations of previous investigations. They used stereophotogrammetry imaging technology and looked at five facial expressions in the lower half of the face. Their findings showed high inter-session reproducibility and minimal variation in expression reproducibility between sessions. Interestingly, female subjects showed significantly more accurate reproduction of maximal smile;

however, this did not reach statistical significance. Their hierarchy of facial expression reproducibility showed the rest position to be significantly more reproducible than natural smile, maximal smile, cheek puff and lip purse.

In a recent study, Sawyer et al. (2009b) evaluated the reproducibility of nine facial expressions in normal white subjects using stereophotogrammetry. Subjects were asked to perform maximal or widest facial expressions in response to spoken and visual cues provided in the following order: resting facial position, raised eyebrows, close eyes as in sleep, close eyes as tight as possible, smile as wide as possible with lips open, purse the lips, lower teeth showing by platysma muscle contraction and blow out the cheeks. Twenty-five landmarks were positioned on the facial scans as described by Farkas (1994). The 3D images were captured three times in three different sessions: the initial capture, 15 minutes after the initial capture and 1 month after the initial capture

The results showed high reproducibility of facial expressions within a 10 to 20 minute period. In a period of one month apart, there were some significant differences in the reproducibility of facial expression but the authors considered it as clinically insignificant. In agreement with the findings of Johnston et al. (2003), the male subjects showed less reproducibility of facial expressions in comparison to females. The authors also found stereophotogrammetry technology to be very promising and useful in evaluating facial motion and expressions.

CHAPTER THREE

AIMS AND NULL HYPOTHESIS

3. Aims and null hypotheses

3.1 Aims

1. To identify the 3D soft tissue volumetric and linear landmark changes following treatment with the TBA
2. To estimate the TBA treatment outcome on the soft tissue facial profile volumetric and linear landmark changes from the PWB
3. To identify if there is any association between certain soft tissue landmark variables and successful treatment outcome of the TBA as measured by the reduction in overjet
4. To assess the effects of TBA treatment on facial expressions at rest, natural smile and maximal smile.

3.2 Null hypotheses

1. The TBA treatment has no effect on the 3D soft tissue volumetric and linear landmark changes.
2. The PWB has no effect on the soft tissue volumetric and linear landmark changes and it cannot be used to estimate the TBA treatment outcome on the soft tissue profile.
3. There is no association between any soft tissue landmark variable and successful overjet reduction following treatment with the TBA.
4. Treatment with the TBA has no effect on the facial expressions at rest, natural smile and maximal smile.

CHAPTER FOUR

PATICIPANTS AND METHODS

4. Participants and Methods

4.1 Study Design

A 3D prospective cohort study was carried out in the Postgraduate Orthodontic Unit at Cork University Dental School & Hospital, Ireland. Ethical approval was obtained from the Clinical Research Ethics Committee of Cork Teaching Hospitals, University College Cork. **(Appendix A)**

4.2 Sample

The anticipated number of subjects for this study was 46 subjects (23 boys, 23 girls), based on the sample size reported in previous studies with similar design **(Section 6.2)** to detect a clinically meaningful difference in soft tissue change of 1 mm at $p < 0.05$.

The Inclusion criteria for treatment were the following:

- Patients with Class II division 1 malocclusion
- Overjet $\geq$ 6 mm
- Growing patients > 9 and <15 years
- Patients treated with the TBA
- Patients with high or low Frankfort/Mandibular planes angle.

Patients were excluded from the study if any of the following was present:

- Poor oral hygiene
- No active growth
- Craniofacial anomaly or metabolic disorder
- Poor compliance.

4.3 Data Collection

Each patient gave informed consent for impressions and 3D images **(Appendix B)**. The following data were collected at baseline (T1): patient name, gender, date of birth, hospital number, initial overjet and treatment start date. This was followed by 3D facial scans taken at T2 with the PWB in place and with the teeth in occlusion without the TBA in three different positions: rest, natural smile and maximum smile.

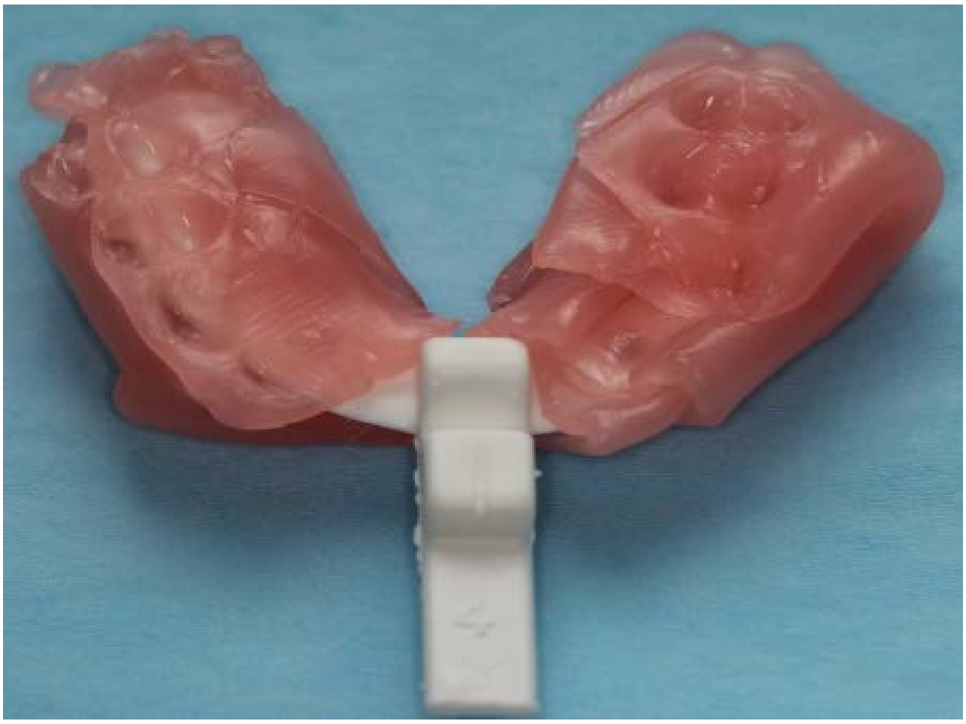
The PWB was recorded with the patient postured to an edge to edge position. When this was not achievable, the registration was recorded to the maximum comfortable protrusion. All PWB records were taken using a 4 mm white "Projet Bite" gauge (Orthocare, (UK) Limited, **Figure 1**), with a softened wax wafer adapted to fit over the gauge **(Figure 2)**. After checking the registration, the PWB was sent to the laboratory with alginate impressions of the upper and lower dental arches. A written instruction sheet was attached detailing the design of the TBA.

Figure 1

A 4 mm "Projet Bite" that was used in the study to take a wax-bite registration

Figure 2

The softened wax wafer adapted to fit over the "Projet Bite" gauge



The TBA design was a modification from the original described by Clark. Adams' clasps were used on all first permanent molars and first premolars, and a Southend clasp on the lower permanent central incisors. A midline expansion screw was always used and Z springs were used when needed mainly to provide labial movement of upper lateral incisors **(Figure 3)**. Before taking the initial 3D facial scans, the TBA was checked to ensure it was made according to the prescription and the excess wax and plastic material on the sides of the "Projet Bite" were trimmed to avoid soft tissue distortion during 3D imaging **(Figure 4)**.

Figure 3

The TBA design that was standardized for all the subjects and used in the study

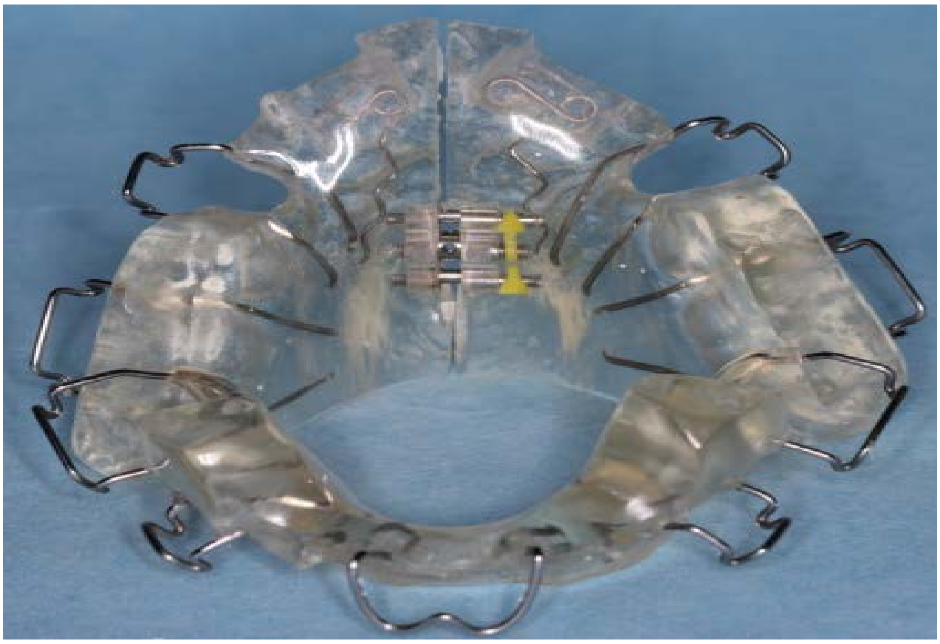
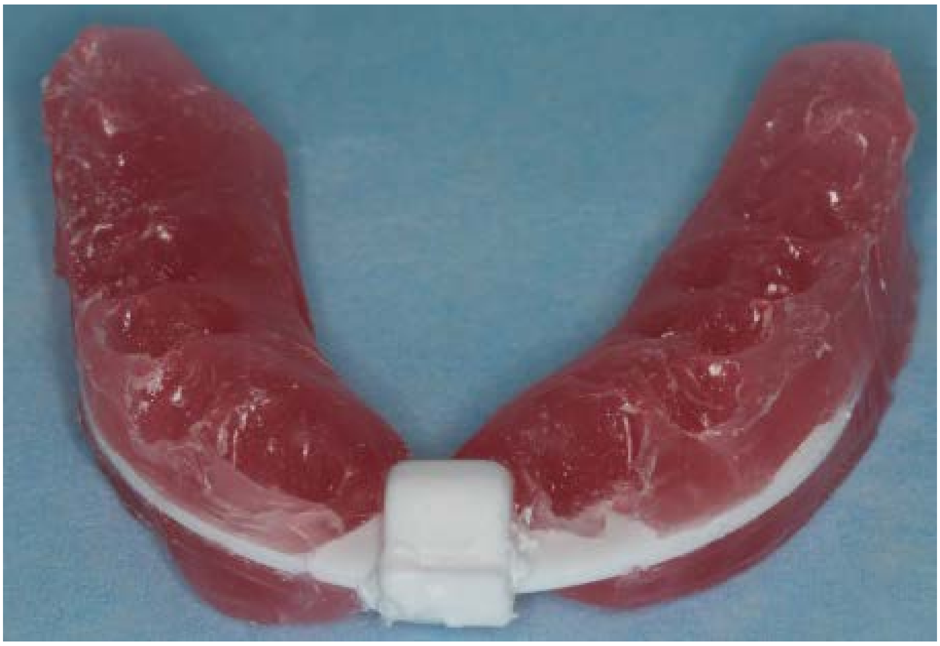


Figure 4

The PWB used during 3D facial scans showing excess wax and plastic trimmed



End of treatment records were taken at T3 when the subject achieved an overjet of 1-3 mm and/or Class I incisor relationship according to the British Standard Institute (BSI). The following data were then collected: overjet, incisor classification, and three dimensional facial scans at rest, natural smile and maximum smile positions with the TBA removed.

Each subject at the time of fitting the TBA was given detailed instructions regarding appliance wear and oral hygiene instructions as follows:

- Full time wear including eating
- Avoid hard chewy or sticky foods and fizzy drinks
- Remove the appliance for contact sport and swimming
- Clean the appliance thoroughly after eating
- Contact the clinic if there are any problems.

4.4 The DI3D imaging system

4.4.1 Equipment and facility

The DI3D imaging system is designed specifically to capture high definition 3D surface images of the human face. It uses four 10 megapixel cameras to produce 3D facial surface images with highly detailed 20 megapixel texture maps. In the Postgraduate Orthodontic Unit at Cork Dental School and Hospital, a stereophotogrametric 3D imaging room is available **(Figure 5)**.

Figure 5

The imaging room where all 3D images were taken

4.4.2 The Hardware

Hardware components are the following **(Figure 6)**:

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

Figure 6

The hardware components of the DI3D stereophotogrammetry system used in the study: (a) the flash; (b) the supporting stand and (c) the cameras

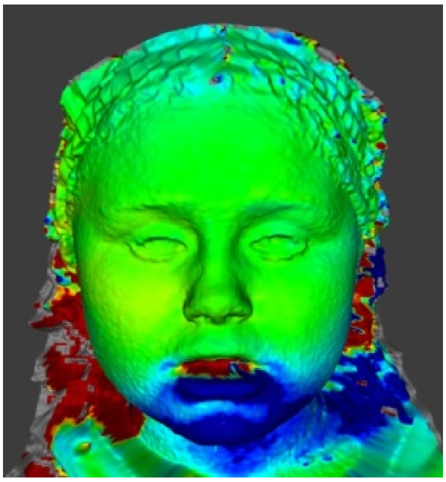
(a) (b) (c)

4.4.3 The Software

DI3Dcapture™ software allows for a simple, fast and efficient workflow and is backed up by DI3Dview™'s powerful suite of analysis and content creation tools **(Figure 7)**.

Figure 7

The DI3D View software showing volumetric changes in soft tissues position on a 3D model

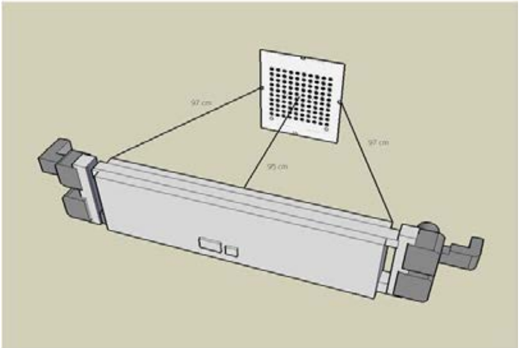


4.4.4 Calibration

Cameras were calibrated to ensure consistency and accuracy of all the images captured. Six images were captured to accurately orient the cameras to each other. When the target object is of known dimensions, the calibration process is done automatically. A matt white sheet of card with matt black spheres, located at known dimensions and distances was used for calibration **(Figure 8)**. As the cameras were held on a rigid supporting stand, their orientation was not changed. The calibration process was done at the beginning of every week. Recalibration was only required if the cameras orientation had been changed or settings such as focus and aperture had been adjusted.

Figure 8

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



4.4.5 Scanning protocol

All 3D images were taken by one experienced operator with subjects seated in the centre of the DI3D system camera structure with any makeup removed, hair tied back with a hair band when necessary, the head in the natural position and teeth in occlusion. Subjects were familiarised with the scanning procedure. Then, they were asked to look straight into the mirror and into their own eyes and to remain completely still during the whole scanning procedure.

For all subjects, images were taken in three positions, before and at the end of treatment: the rest position, smiling, and maximal smiling positions. To ensure reproducibility and reliability between images at different time points, all scans were performed based on the technique described by Zachrisson (1998). For rest position, all subjects were asked to:

- Say Mississippi
- Swallow and say “N”

For natural smile, the subjects were asked to smile and say “cheese”. For maximum smile subjects were asked to show “the biggest smile they can make”.

3D models were created by the computer software 1-2 minutes after the scanning procedure. The images were viewed and checked to ensure they were of the required standard while the subject was in the imaging room. In the absence of errors, the images were named and saved in the appropriate study file.

4.4.6 Landmarks

A single operator landmarked all the 3D models taken before and after treatment. Ten percent of images were re-landmarked one month after the initial landmarking by the same operator to check for error and reliability. The facial landmarks used were the ones suggested by Farkas (1994) and Sawyer et al. (2009b). All points and their definitions are given below and shown in **Figure 9**.

1. Glabella (g): the most prominent midline point between eyebrows.
2. Nasion (n): the point in the midline of both nasal root and nasofrontal suture.
3. Right exocanthion (exR): the outer most point on the commissure of the eye fissure on the right.
4. Mid pupil right (mpR): the centre point of the right pupil.
5. Orbitale right (oR): the lowest point on the lower margin of the right orbit.

6. Endocanthion right (enR): the inner most point on the commissure of the eye fissure on the right.
7. Endocathion left (enL): the inner most point on the commissure of the eye fissure on the left.
8. Mid pupil left (mpL): the centre point of the left pupil.
9. Orbitale left: (oL) the lowest point on the lower margin of the left orbit.
10. Exocanthion left (exL): the outer most point on the commissure of the eye fissure on the left.
11. Pronasale (prn): the most protruded point of the apex nasi identified in the lateral view of the rest position of the head.
12. Subnasale (sn): the midpoint of the angle where the lower nasal septum and the lips meet (the base of Columella).
13. Alar curvature right (acR): the most lateral point in the curved base line of the right ala.
14. Alar curvature left (acL): the most lateral point in the curved base line of the left ala.
15. Alare right (aR): the marking level at the midportion of the right alae.
16. Alare left (aL): the marking level at the midportion of the left alae.
17. Cheilion right (chR): the outermost point of the right lip commissure.
18. Christa philltri right (cphR): point on the right elevated margin of the philtrum just above the vermillion line.
19. Labiale superius (Ls): the midpoint on the upper vermilion border.
20. Christa philltri left (cphL): point on the left elevated margin of the philtrum just above the vermillion line.
21. Cheilion left (chL): the outermost point of the left lip commissure.

22. Labiale inferius (li): the lower border of the lower lip.

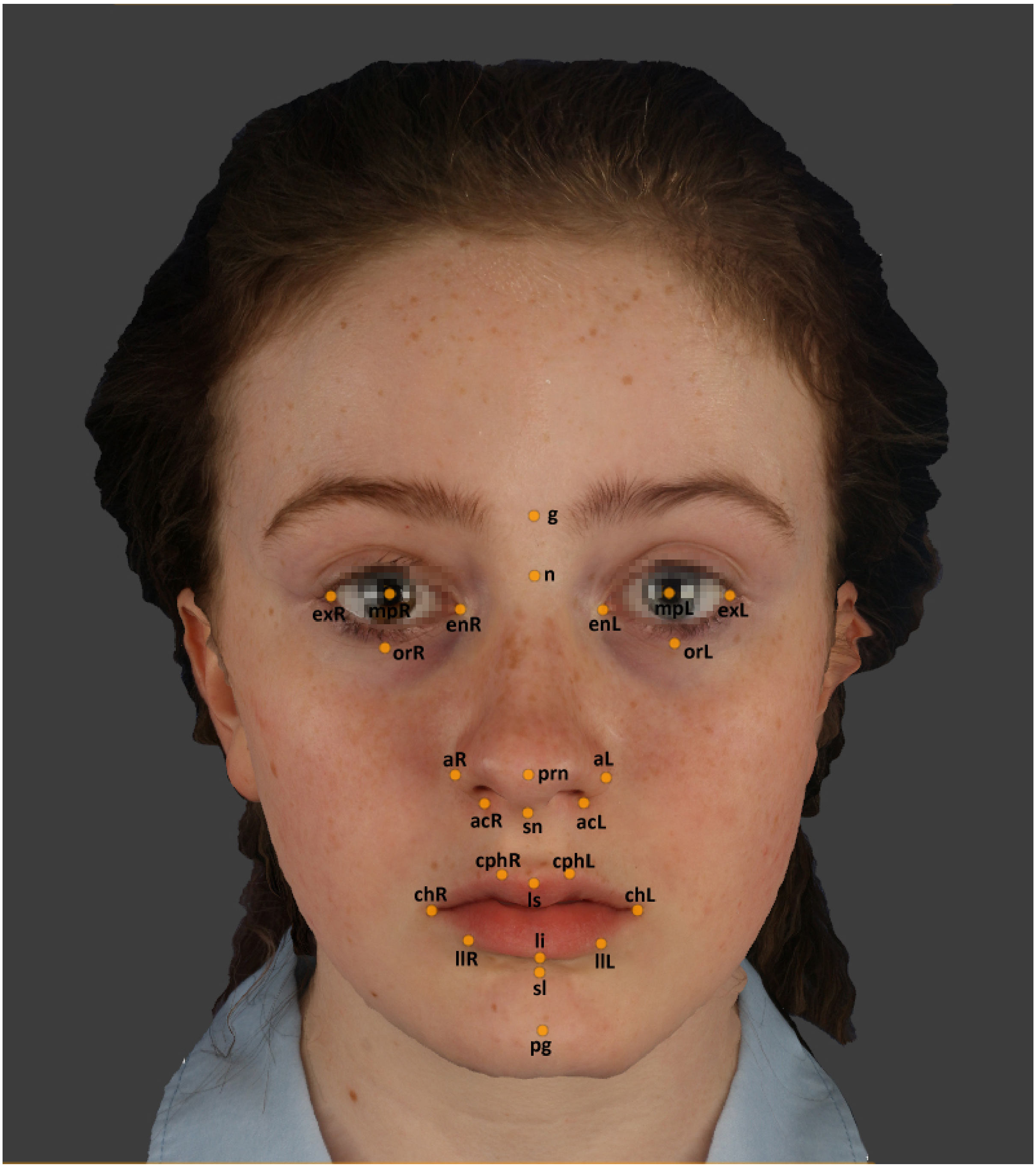
23. Lower lip right (llR): located midway between cheilion right and labiale inferius.

24. Lower lip left (llL): located midway between cheilion left and labiale inferius.

25. Sublabiale (sl): the lower border of the lower lip or the upper border of the chin.

Figure 9

3D image of a patient included in the study showing the landmarks used.



4.5 Statistical analysis

All parameters were compared and analysed using linear mixed effect models. Gender and time-point were included as fixed effects. The interaction between these was also included. Age and length of treatment were included as covariates. The patient was included as a random effect. A variance components covariance matrix was applied. The adequacies of the models were assessed using residual analyses and transformations were applied if required. Correlations were evaluated using Pearson's correlation coefficient. The level of significance was 5%. Analyses were performed in SAS® (Version 9.4).

CHAPTER FIVE

RESULTS

5. Results

In this chapter, the timeline of the initial sample recruitment and the characteristics of the final sample will be given first, followed by the results of the landmarking error study and the findings of the 3D analyses.

5.1 Initial recruitment

All patients who were prescribed a TBA after December 2012 were recruited to the study. The data collection process continued up until September 2014. All TBAs were fitted within 1-2 weeks of the impressions and the PWB being taken. Patients who required TBA replacement or re-activation were re-scanned and kept in the study as long as the overjet at the time of repair or replacement was over 6 mm. A total of 58 patients with a mean age of 13.19 ± 1.26 years were fitted with the TBA. These comprised 33 males (mean age 13.25 ±1.35 years) and 25 females (mean age 13.11 ± 1.16 years).

5.2 Final sample

Eleven patients (19%) did not complete the TBA treatment. Data on 47 subjects (18 females and 29 males) who completed the study were analysed at T3. The characteristics of the final sample are summarized in **Table 11**. There were no differences between the female and male treatment groups in terms of the following variables:

- Pre-treatment overjet ($p=0.5464$)
- Pre-treatment age ($p=0.5243$)

- Length of treatment (p=0.5202).

Table 11

Final sample characteristics of subjects who completed TBA treatment

	n		T1 (mm)	T3 (mm)	Age at T1 (years)	Length of treatment (weeks)
Total	47	Mean	9.91	2.67	13.38	42.69
		SD	2.22	1.17	1.22	16.74
Male	29	Mean	9.76	2.52	13.45	43.97
		SD	2.23	1.06	1.30	17.72
Female	18	Mean	10.17	2.94	13.26	40.72
		SD	2.26	1.34	1.08	14.23

5.3 Error study for the reliability of soft tissue landmarking

The intra-observer reproducibility was acceptable ($p > 0.05$). This was tested by randomly re-landmarking 10% of the images and comparing the x, y, z co-ordinate data to the originals. On average, the landmark identification error was 0.562 mm.

5.4 Results of 3D analyses

5.4.1 Facial profile volumetric and landmark changes

5.4.1.1 Volumetric changes

3D soft tissue volumetric changes from T1 to T2 and from T1 to T3 with the supporting statistical analyses are given in **Tables 12 and 13** respectively. The mean soft tissue volumetric change of the overall sample from T1 to T2 (37.12±15.24 cm^3) and from T1 to T3 (22.24±16.73) was statistically significant ($p < 0.0001$). From T1 to T2, the volumetric change for females (34.46 ± 14.35 cm^3) was marginally less than for males (38.78 ± 15.79 cm^3). From T1 to T3 the mean volumetric soft tissue changes in females (13.35 ± 13.88 cm^3) were 48% less than in males (27.75 ± 16.13 cm^3); $p=0.0114$.

Table 12

3D Soft tissue volumetric changes from T1 to T2 and from T1 to T3 for the final sample

	T1-T2						T1-T3						
	n	Mean	Median	SD	min	max	n	Mean	Median	SD	min	max	P-value
Gender													
F	18	34.46	35.02	14.35	3.03	54.37	18	13.35	10.43	13.88	-14.02	43.41	
M	29	38.78	39.86	15.79	3.92	71.42	29	27.75	25.35	16.13	6.08	75.78	
Total	47	37.12	35.24	15.24	3.03	71.42	47	22.24	18.79	16.73	-14.02	75.78	<0.0001

Table 13

Type 3 tests of fixed effects for 3D volumetric changes for the final sample

Effect	Num DF	Den DF	F Value	Pr > F
Gender	1	45	6.97	0.0114
Age	1	45	0.13	0.7225
Length_Tx	1	45	0.98	0.3282
Time	1	45	25.68	<.0001
Time*Gender	1	45	2.53	0.1189

5.4.1.2 Soft tissue linear landmark changes from T1 to T3

3D soft tissue linear changes from T1 to T3 for the upper and lower facial landmarks are summarized in **Table 14**. All upper facial landmark linear changes were insignificant ($p > 0.05$) and similar for females and males.

Soft tissue profile linear changes for lower facial landmarks were all significant ($p < 0.0001$) except for labiale superius ($p = 0.825$) with no difference between female and male subjects. **Table 15** summarizes the changes in the lower soft tissue profile points namely labiale superius, labiale inferius, sublabiale and pogonion The supporting statistical analyses are given in **Table 16**.

The mean overall linear change in labiale superius position from T1 to T3 (2.19 ± 1.54 mm) was not significant ($p = 0.8259$) and was similar for females (2.28 ± 1.16 mm) and males (2.13 ± 1.75 mm).

For the remaining lower facial profile points, the mean linear change from T1 to T3 was in the range of 4-5 mm for both females and males in the order of sublabiale > labiale inferius > pogonion in terms of the magnitude of change **(Table 15)**.

Table 14

3D soft tissue linear changes from T1 to T3 for the upper and lower facial landmarks in the final sample who completed TBA treatment

Landmark		T1-T3				P-value
		Female		Male		
		Mean (mm)	SD	Mean (mm)	SD	
Upper face	Glabella	0.39	0.16	0.51	0.34	>0.05
	Nasion	0.53	0.26	0.47	0.35	>0.05
	Right exocanthion	1.20	1.02	1.13	0.83	>0.05
	Mid Pupil Right	0.73	0.60	0.83	0.68	>0.05
	Orbitale Right	0.84	0.66	0.98	0.60	>0.05
	Endocantion Right	0.57	0.36	0.66	0.51	>0.05
	Endocantion Left	0.65	0.39	0.78	0.55	>0.05
	Mid Pupil Left	0.69	0.43	0.83	0.50	>0.05
	Orbitale Left	0.95	0.69	0.92	0.58	>0.05
	Exocantion Left	1.02	0.76	1.12	0.72	>0.05
	Pronasale	0.82	0.44	0.97	0.57	>0.05
	Subnasale	1.56	1.14	1.90	1.47	>0.05
	Alar Curvature Right	1.21	1.03	1.24	0.83	>0.05
	Alar Curvature Left	1.35	0.93	1.11	0.77	>0.05
	Alare Right	1.81	1.78	1.71	1.10	>0.05

	Alare Left	2.48	2.26	2.27	2.38	>0.05
Lower face	**Chellion Right**	3.10	1.81	2.64	1.73	<0.05
	Christa Philtri Right	2.30	1.18	2.01	1.67	<0.05
	Labiale Superiorus	2.28	1.16	2.13	1.75	>0.05
	Christa Philtri Left	2.26	1.18	1.97	1.70	<0.05
	Chellion Left	2.73	1.65	2.48	1.86	<0.05
	Labiale inferius	4.33	2.39	4.13	2.06	<0.05
	Lower Lip Right	2.61	2.25	3.13	1.60	<0.05
	Lower Lip Left	3.56	2.23	3.43	1.84	<0.05
	Sublabiale	4.73	2.55	9.74	3.51	<0.05
	Pogonion	4.12	3.03	4.13	2.14	<0.05

Table 15

Summary statistics of the lower facial profile landmarks by gender and overall from T1 to T3 in the final sample that completed TBA treatment

		T1-T2			T1-T3		
Landmark	**Gender**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**
Labiale superius	F	18	1.94	1.49	18	2.28	1.16
	M	29	2.44	1.92	29	2.13	1.75
	Overall	47	1.90	1.77	47	2.19	1.54
Labiale inferius	F	18	9.14	2.82	18	4.33	2.39
	M	29	9.43	2.78	29	4.13	2.06
	Overall	47	9.32	2.77	47	4.20	2.17
Sublabiale	F	18	9.89	2.71	18	4.73	2.55
	M	29	9.74	3.51	29	5.04	2.33
	Overall	47	9.80	3.20	47	4.92	2.39
Pogonion	F	18	8.15	3.29	18	4.12	3.03
	M	29	8.67	3.19	29	4.13	2.14
	Overall	47	8.47	3.01	47	4.13	2.48

Table 16

Lower facial profile landmarks with test of fixed effects for each point

Effect for each landmark	Num DF	Den DF	F Value	P Value
Labiale superius				
Gender	1	45	0.06	0.8136
Age	1	45	0.07	0.7873
Length of Treatment	1	45	2.05	0.1596
Time	1	45	0.05	0.8259
Time*Gender	1	45	1.84	0.1814
Labiale inferius				
Gender	1	45	0.01	0.9320
Age	1	45	0.02	0.8822
Length of Treatment	1	45	0.00	0.9545
Time	1	45	127.91	<.0001
Time*Gender	1	45	0.13	0.7164
Sublabiale				
Gender	1	45	0.01	0.9068
Age	1	45	0.52	0.4745
Length of Treatment	1	45	0.75	0.3910
Time	1	45	149.21	<.0001
Time*Gender	1	45	0.83	0.3685

Pogonion				
Gender	1	45	0.21	0.6517
Age	1	45	0.15	0.7002
Length of Treatment	1	45	0.54	0.4673
Time	1	45	104.75	<.0001
Time*Gender	1	45	0.05	0.8274

5.4.2 Estimation of treatment outcome from the PWB

5.4.2.1 Consideration of volumetric changes

For the total sample, the mean soft tissue volumetric change from T1 to T2 (37.12 ± 15.24 cm^3) was 14.88 cm^3 greater than the mean soft tissue volumetric change from T1 to T3 (22.24 ± 16.13 cm^3). From T1 to T3, the mean soft tissue volumetric change of the total sample was 60% of the change produced by the PWB from T1 to T2. For females this was 39%, and for males 71.5%, as shown in **Table 12**. **Figure 10** shows the mean soft tissue volumetric changes in the total sample. Those for females and males are illustrated in **Figure 11 and Figure 12** respectively.

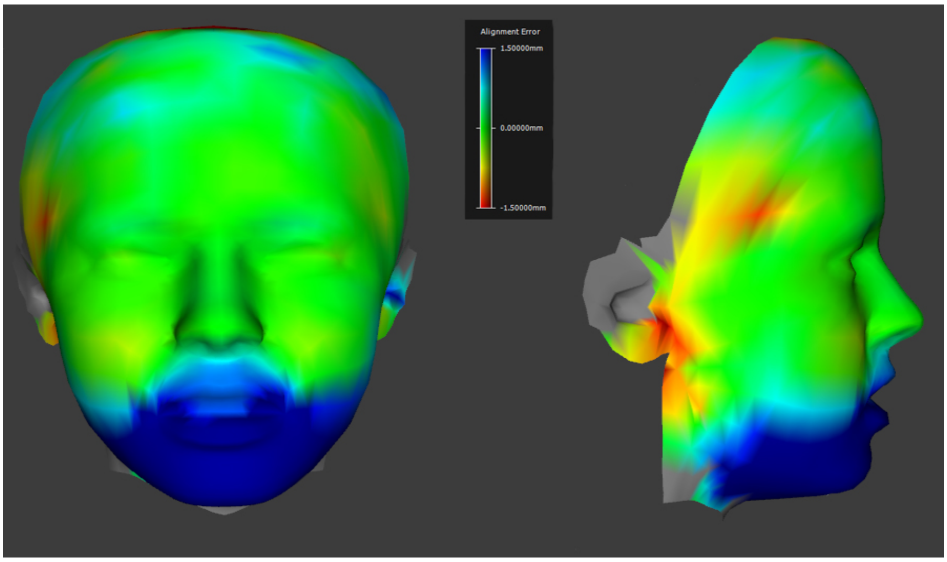
5.4.2.2 Consideration of the linear changes in soft tissue pogonion

For the total sample, the mean forward movement of soft tissue pogonion from T1 to T2 (8.47 ± 3.01 mm) was 4.34 mm greater than that observed from T1 to T3 (4.13 ± 2.48 mm). From T1 to T3, the soft tissue pogonion moved forward by 49% of the movement from T1 to T2 produced by the PWB. For females, this was 50% and for males 48%, as shown in **Table 15**. **Figure 13** shows the mean forward movement of soft tissue pogonion in 3D for the total sample; that for females and males is illustrated in **Figure 14 and Figure 15** respectively.

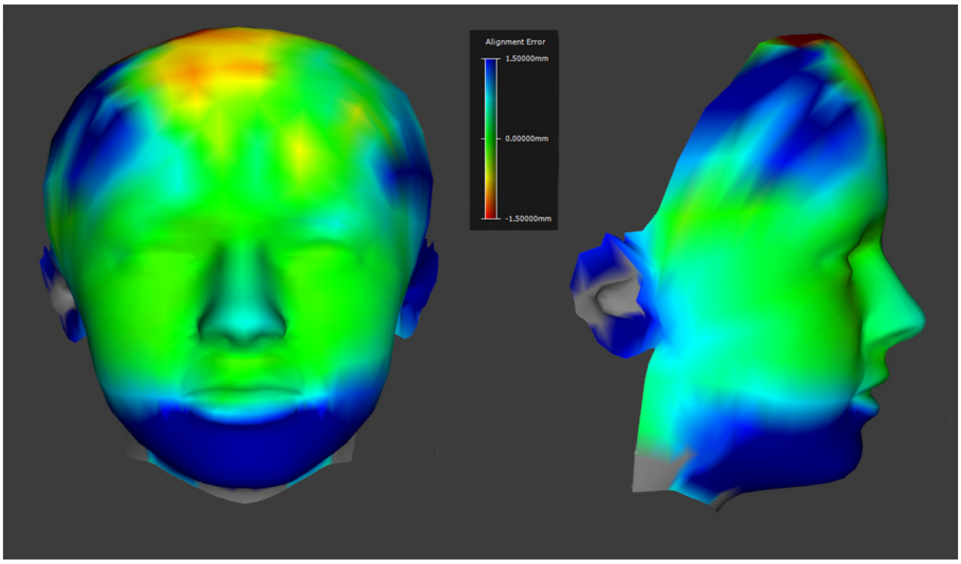
Figure 10

The mean 3D volumetric changes in the overall sample that completed TBA treatment shown in frontal and profile views: (a) T1-T2 and (b) T1-T3

(a)



(b)

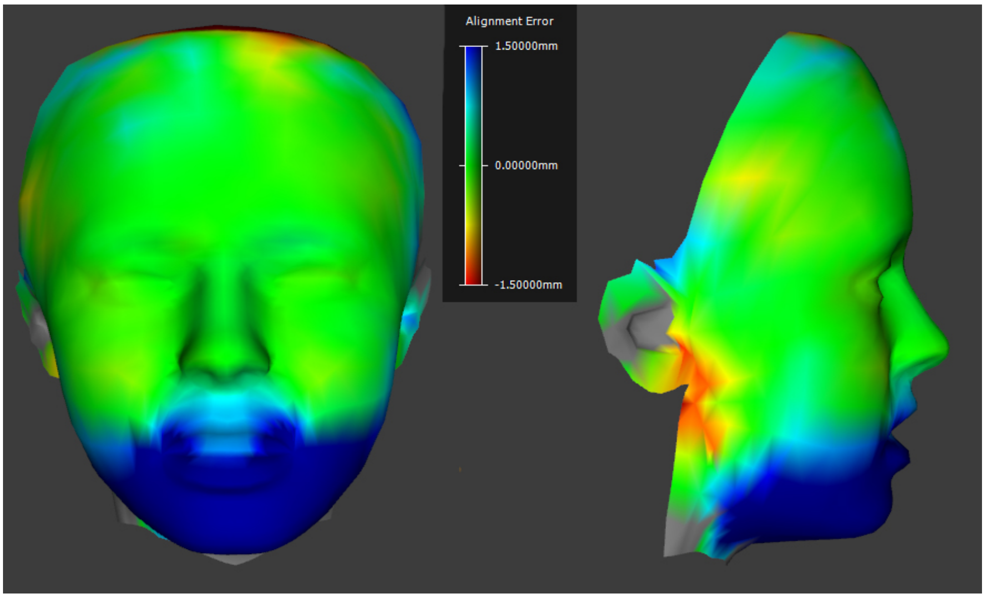


Key- Blue: changes > 1.5 cm^3; green: no changes; red: changes in opposite direction to blue changes

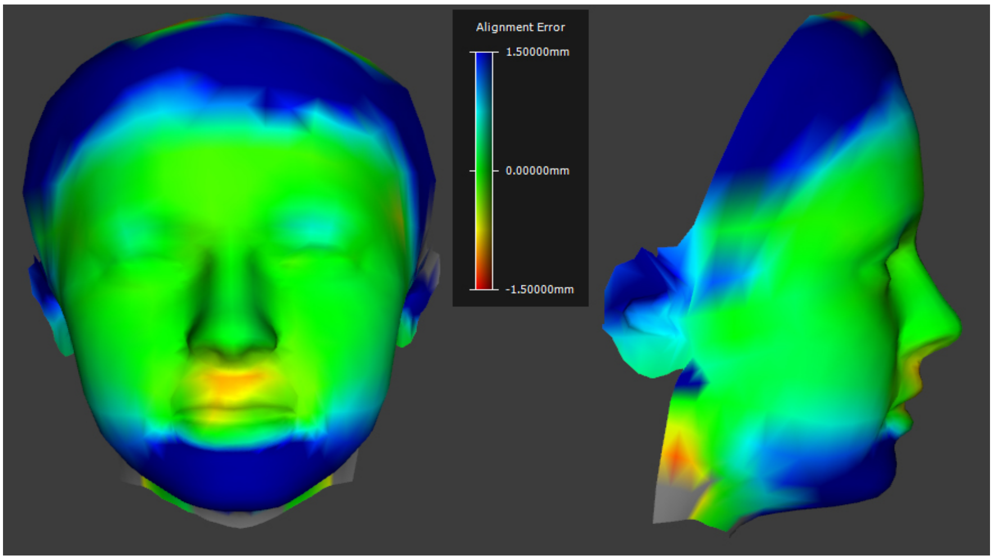
Figure 11

The mean 3D volumetric changes in females who completed TBA treatment shown in frontal and profile views: (a) T1-T2 and (b) T1-T3

(a)



(b)

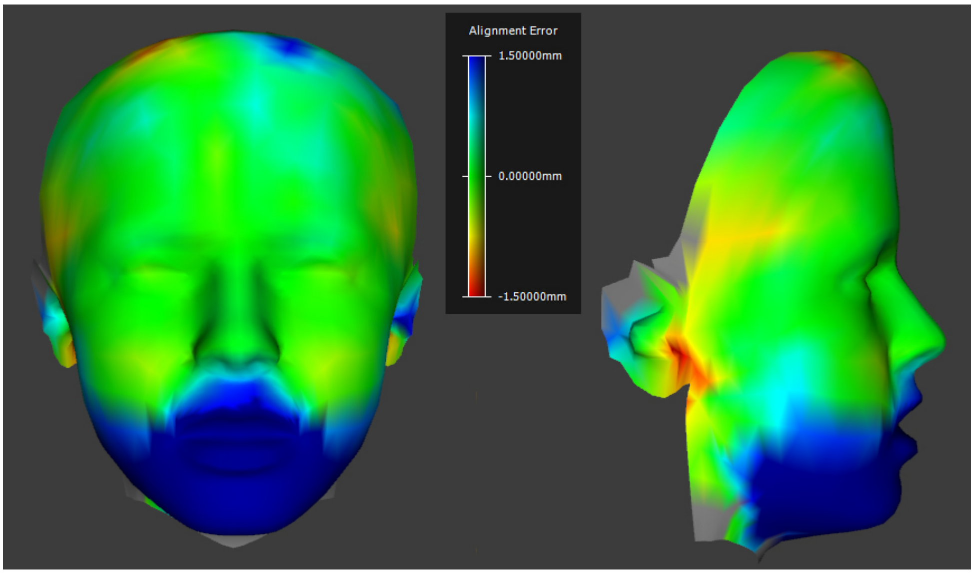


Key- Blue: changes > 1.5 cm^3; green: no changes; red: changes in opposite direction to blue changes

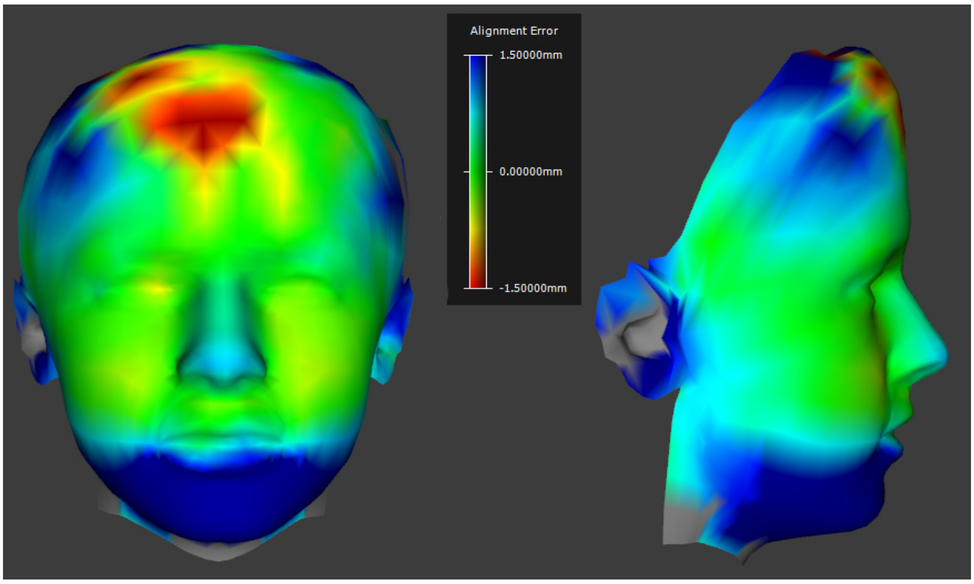
Figure 12

The mean 3D volumetric changes in males who completed TBA treatment shown fontal and profile views: (a) T1-T2 and (b) T1-T3

(a)



(b)

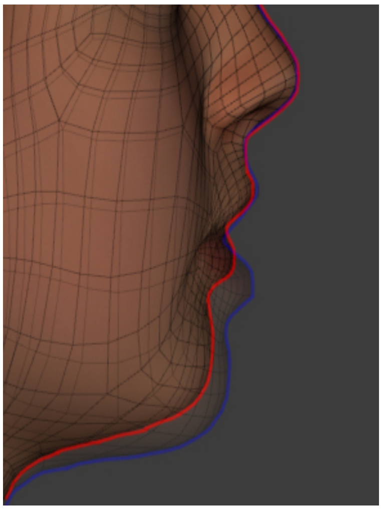


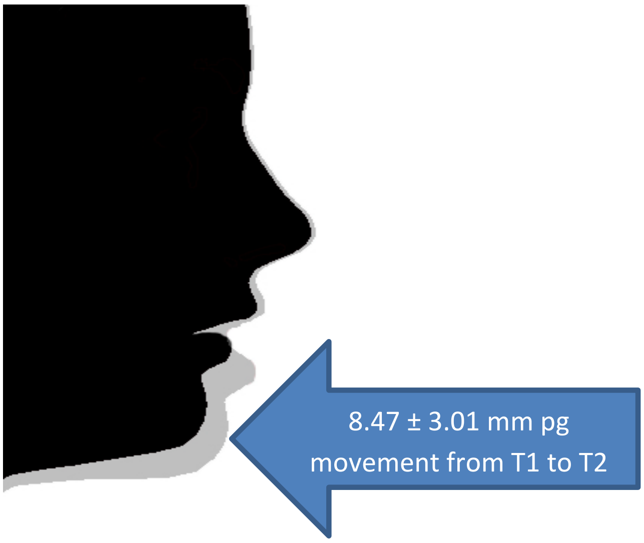
Key- Blue: changes > 1.5 cm^3; green: no changes; red: changes in opposite direction to blue changes

Figure 13

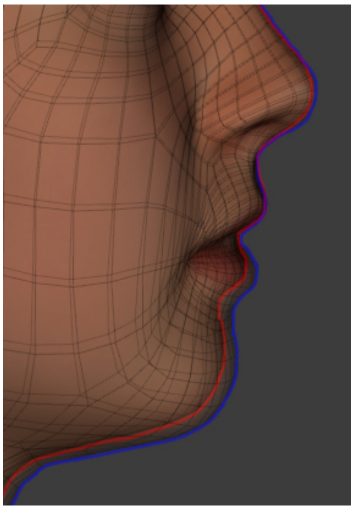
3D Soft tissue profile and silhouette representation of the 3D face showing the mean soft tissue changes in the lower facial profile landmarks and the advancement of soft tissue pogonion in the total sample that completed TBA treatment: (a) T1-T2, (b) T1-T3

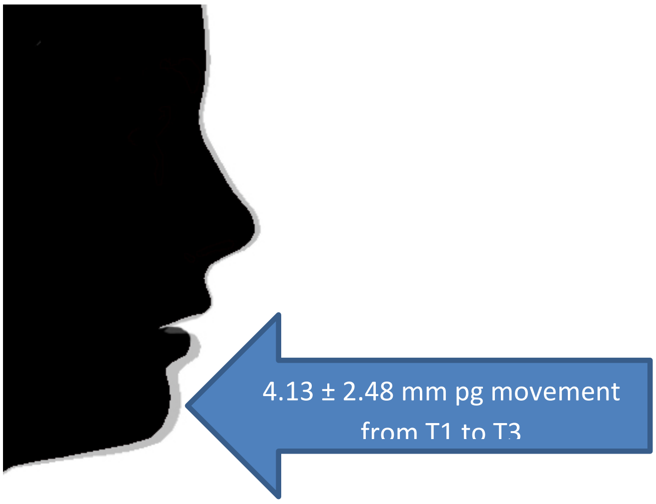
(a)





(b)





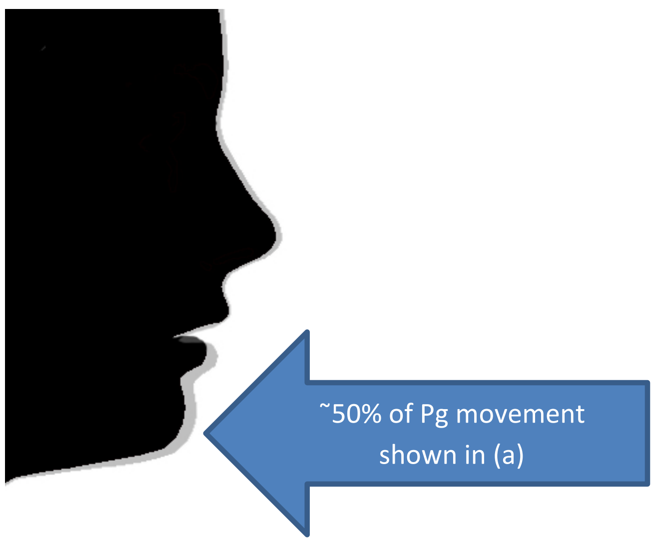
Key- Red: T1; blue: T2 (a) or T3 (b); Black face = T1; grey shadow = T2 (a) or T3 (b); pg = pogonion;

Figure 14

Soft tissue profile silhouette representation of the 3D face showing mean soft tissue changes in the lower facial profile landmarks and the advancement of soft tissue pogonion in females who completed TBA treatment: (a) T1-T2 and (b) T1-T3

(a)

(b)



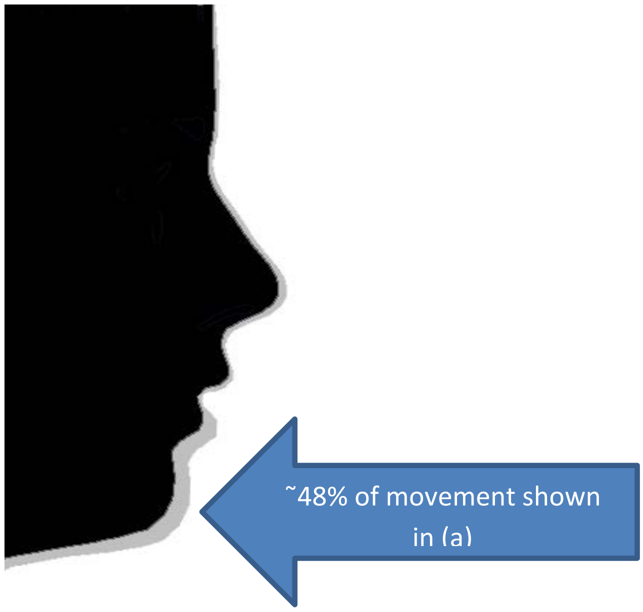
Key- Black face = T1; grey shadow = T2 (a) or T3 (b); pg = pogonion

Figure 15

Soft tissue profile silhouette of the 3D face showing mean soft tissue changes in the lower facial profile landmarks and the advancement of soft tissue pogonion in males who completed TBA treatment (a) T1-T2 and (b) T1-T3

(a)

(b)



Key- Black face = T1; grey shadow = T2 (a) or T3 (b); pg = pogonion

5.4.3 The association of 3D facial parameters with successful TBA treatment as measured by reduction in the overjet

This was evaluated by studying the correlation between the facial parameters given in **Table 17** with the overjet reduction from T1 to T3 and the amount of overjet at T3. Correlation was weak for all the soft tissue parameters studied. The correlation of lower soft tissue facial profile landmarks with the overjet difference from T1 to T3 was analysed for females and males and presented in **Table 18**. All correlations were weak for all the landmarks studied showing that successful TBA treatment outcome as measured by the overjet reduction cannot be reliably associated with any facial or lower soft tissue profile parameter.

5.4.4 Facial expression changes after treatment with the TBA (T1-T3)

5.4.4.1 At rest

For both male and female subjects, the facial expressions at rest were stable for all upper landmarks except for subnasale, alare left and alare right. In contrast, all lower landmarks showed significant changes from T1 to T3 **(Table 19)**. These changes were not significantly different for females and males (p-values > 0.05).

5.4.4.2 At natural smile

For females, all upper landmarks were stable, except for subnasale and all lower landmarks showed significant changes. For males, all upper landmarks were also stable; all lower landmarks showed significant changes except for sublabiale and pogonion **(Table 20)**.

5.4.3.3 At maximal smile

In females, all upper landmarks were stable except for subnasale, alare right and alare left which showed some changes. For the lower landmarks, four points were stable (labiale superius, christa philtre left, labiale inferius and pogonion) and all others showed significant changes. In males, all upper and lower landmarks were stable and did not change significantly **(Table 21)**.

Table 17

The correlation between different facial parameters with overjet difference from T1 to T3 and overjet at T3

Correlation with overjet difference	Correlation
Eyes distance	0.02010
Nose width	-0.05736
Total face height	-0.10635
Lower face height	-0.06975
Mid face height	0.11934
Mid face angle	0.04875
Face convexity	0.07848
Nose prominence	-0.00764
Philtrum depth	-0.17230
Correlation with overjet at T3	
Eyes distance	0.05544
Nose width	0.07334
Total face height	-0.19967
Lower face height	-0.09501
Mid face height	-0.11328
Mid face angle	0.17572
Face convexity	0.04166
Nose prominence	-0.03829
Philtrum depth	-0.15535

Table 18

Correlation of lower soft tissue facial profile landmarks with the overjet difference from T1 to T3

	Male	Female
Labiale superius	0.24934	0.32699
Labiale inferius	0.18086	-0.00957
Subabiale	0.46014	-0.13784
Pogonion	0.00039	-0.16611

Table 19

3D landmarks changes from T1-T3 for the rest position in subjects who completed TBA treatment

	Landmark	T1-T3				
		Female		**Male**		
		Mean (mm)	**SD**	**Mean (mm)**	**SD**	**P Value**
Upper face	Glabella	0.39	0.16	0.51	0.34	0.3512
	Nasion	0.53	0.26	0.47	0.35	0.6879
	Exocantion Right	1.20	1.02	1.13	0.83	0.0993
	Mid Pupil Right	0.73	0.60	0.83	0.68	0.9953
	Orbitale Right	0.84	0.66	0.98	0.60	0.3896
	Endocantion Right	0.57	0.36	0.66	0.51	0.4788
	Endocantion Left	0.65	0.39	0.78	0.55	0.7914
	Mid Pupil Left	0.69	0.43	0.83	0.50	0.9375
	Orbitale Left	0.95	0.69	0.92	0.58	0.7586
	Exocantion Left	1.02	0.76	1.12	0.72	0.8357
	Pronasale	0.82	0.44	0.97	0.57	0.7031
	Subnasale	1.56	1.14	1.90	1.47	0.7827
	Alar Curvature Right	1.21	1.03	1.24	0.83	0.2830
	Alar Curvature Left	1.35	0.93	1.11	0.77	0.3819
	Alare Right	1.81	1.78	1.71	1.10	0.9707
	Alare Left	2.48	2.26	2.27	2.38	0.5326

Lower face	Chellion Right	3.10	1.81	2.64	1.73	0.5551
	Christa Philtri Right	2.30	1.18	2.01	1.67	0.8214
	Labiale Superiorus	2.28	1.16	2.13	1.75	0.8144
	Christa Philtri Left	2.26	1.18	1.97	1.70	0.6631
	Chellion Left	2.73	1.65	2.48	1.86	0.6226
	Labiale inferius	4.33	2.39	4.13	2.06	0.9320
	Lower Lip Right	2.61	2.25	3.13	1.60	0.5594
	Lower Lip Left	3.56	2.23	3.43	1.84	0.8859
	Sublabiale	4.73	2.55	9.74	3.51	0.9068
	Pogonion	4.12	3.03	4.13	2.14	0.6517

Table 20

3D landmark changes from T1 to T3 for natural smile in subjects who completed TBA treatment

	Landmark Smile	T1				T3				
		Female		**Male**		**Female**		**Male**		
		Mean (mm)	**SD**	**Mean (mm)**	**SD**	**Mean (mm)**	**SD**	**Mean (mm)**	**SD**	**P Value**
Upper face	Glabella	0.36	0.16	0.44	0.30	0.39	0.16	0.51	0.34	0.3512
	Nasion	0.33	0.20	0.34	0.27	0.36	0.18	0.44	0.29	0.9957
	Exocantion Right	1.61	1.56	1.71	1.12	2.19	1.55	2.20	1.42	0.6791
	Mid Pupil Right	0.84	0.82	0.79	0.50	0.79	0.82	1.24	1.07	0.2046
	Orbitale Right	0.83	0.84	0.77	0.53	1.36	1.00	1.02	0.89	0.7795
	Endocantion Right	0.71	0.48	0.83	0.53	1.16	0.96	1.15	1.14	0.8805
	Endocantion Left	0.68	0.52	0.84	0.53	0.88	0.58	1.20	0.90	0.2724

	Mid Pupil Left	0.81	0.54	1.06	0.87	0.83	0.62	1.24	0.89	**0.0900**
	Orbitale Left	0.64	0.36	0.78	0.49	1.29	0.89	0.93	0.89	0.2780
	Exocantion Left	1.21	0.74	1.59	1.38	1.74	1.52	2.12	1.28	0.1718
	Pronasale	0.75	0.66	1.43	0.78	1.07	0.47	2.09	1.18	**0.0002**
	Subnasale	1.32	1.21	3.41	2.15	3.88	2.34	4.52	2.12	**0.0103**
	Alar Curvature Right	1.25	1.23	2.89	2.04	1.94	1.46	3.15	2.33	**0.0049**
	Alar Curvature Left	1.17	0.94	2.60	1.94	2.71	1.08	3.15	2.95	**0.0153**
	Alare Right	1.51	0.94	2.86	1.60	2.52	1.89	3.21	1.79	**0.0203**
	Alare Left	3.07	3.06	3.51	2.87	2.81	2.61	3.96	2.61	0.1321
Lower face	Chellion Right	5.85	2.64	14.34	4.97	14.70	2.92	18.28	3.74	**<.0001**
	Christa Philtri Right	2.33	1.98	6.54	2.67	6.21	1.77	8.32	2.03	**<.0001**
	Labiale Superiorus	2.08	1.71	6.40	2.54	6.19	1.55	8.24	2.23	**<.0001**
	Christa Philtri Left	2.47	2.38	6.42	2.71	6.47	1.33	8.75	2.70	**<.0001**
	Chellion Left	6.09	2.86	14.11	4.97	14.50	3.21	18.96	3.60	**<.0001**

	Labiale inferius	8.64	2.78	6.84	2.60	6.58	2.43	8.16	3.15	0.6719
	Lower Lip Right	7.36	2.37	12.24	4.66	11.29	3.80	15.65	4.09	**<.0001**
	Lower Lip Left	7.26	2.67	11.72	4.93	11.91	3.65	15.54	4.03	**0.0004**
	Sublabiale	9.42	2.78	5.32	2.39	5.15	1.95	6.33	3.14	**0.0246**
	Pogonion	7.82	2.88	4.94	2.44	3.96	2.82	5.99	2.98	0.7772

Table 21

3D landmark changes from T1 to T3 for the maximal smile in subjects who completed TBA treatment

	Landmark Max Smile	T1				T3				
		Female		**Male**		**Female**		**Male**		
		Mean (mm)	**SD**	**Mean (mm)**	**SD**	**Mean (mm)**	**SD**	**Mean (mm)**	**SD**	**P Value**
Upper face	Glabella	0.54	0.19	0.83	0.91	0.90	1.48	0.83	0.57	0.4687
	Nasion	0.55	0.18	0.97	1.27	0.79	1.00	0.72	0.52	0.3627
	Exocantion Right	2.32	1.40	2.16	1.38	2.55	1.30	2.65	1.65	0.7564
	Mid Pupil Right	1.04	0.78	1.52	0.98	1.57	1.35	1.66	1.10	0.0811
	Orbitale Right	1.05	0.52	1.40	1.12	1.56	1.40	1.51	1.13	0.3832
	Endocantion Right	1.25	0.56	1.22	0.70	1.63	1.08	1.35	1.12	0.1227
	Endocantion Left	1.07	0.67	1.17	0.89	1.28	0.75	1.53	0.99	0.7878

	Mid Pupil Left	1.19	0.67	1.54	1.17	1.52	1.12	1.61	1.13	0.7598
	Orbitale Left	1.89	3.74	1.32	1.21	1.43	0.91	1.41	1.09	0.6951
	Exocantion Left	2.48	3.70	2.00	1.26	2.01	0.99	2.53	1.48	0.5814
	Pronasale	1.17	0.53	1.78	1.15	1.52	1.41	2.16	1.22	0.0202
	Subnasale	2.81	1.86	3.80	2.38	4.43	3.01	4.50	2.54	0.2963
	Alar Curvature Right	2.18	1.35	2.90	1.81	2.11	1.59	2.76	1.81	0.1631
	Alar Curvature Left	1.93	1.28	2.84	1.72	2.32	1.13	2.97	2.43	0.1644
	Alare Right	2.63	1.75	3.73	1.85	4.41	3.93	3.30	1.53	0.2200
	Alare Left	5.45	4.13	4.51	2.75	3.66	2.72	4.08	2.38	0.9173
Lower face	Chellion Right	12.42	4.91	17.44	4.16	15.34	3.45	17.48	4.85	**0.0018**
	Christa Philtri Right	5.50	1.92	7.94	2.08	6.58	1.92	7.95	2.58	**0.0004**
	Labiale Superiorus	5.60	2.08	7.95	2.10	6.54	1.95	7.76	2.28	**0.0008**
	Christa Philtri Left	5.91	2.36	8.13	2.34	6.86	2.31	8.28	2.75	**0.0052**
	Chellion Left	12.69	4.33	17.50	2.99	14.71	3.60	17.03	4.62	**0.0005**

	Labiale inferius	6.52	3.63	8.53	2.80	6.56	2.48	8.26	3.18	**0.0158**
	Lower Lip Right	10.13	3.86	15.03	4.79	11.47	2.98	15.26	4.61	**<.0001**
	Lower Lip Left	10.28	3.01	14.44	2.92	11.26	3.08	14.46	4.88	**0.0002**
	Sublabiale	4.24	2.48	5.96	3.07	5.50	2.08	6.09	3.48	0.1762
	Pogonion	4.32	2.46	5.53	2.88	4.71	2.11	5.95	3.74	0.1393

CHAPTER SIX

DISCUSSION

6. Discussion

This would appear to be the first study to report the soft tissue 3D volumetric changes following the TBA treatment; it is also the first study to estimate treatment outcome of the TBA on the soft tissue profile using the PWB, and the first study to report on changes of facial expression following TBA treatment. The association between soft tissue parameters and successful treatment with the TBA as well as linear soft tissue landmark changes following TBA treatment have all been reported previously in the orthodontic literature. This chapter will discuss the study design and its findings in more detail.

6.1 Study design

This was a prospective observational cohort study assessing the effects of the PWB and the TBA on volumetric and linear soft tissue profile changes. The method of evaluation was by 3D imaging, using the DI3D stereophotogrammetry system. Previous prospective 3D cohort studies, similar to our study design, were undertaken by Morris et al. (1998), McDonagh et al. (2001), Sharma and Lee (2005) and Lee et al. (2007). However, they differed from our study in the following aspects: they randomised subjects into more than one FA treatment group (one group at least included TBA); they used a 2D evaluation method (lateral cephalometry) in addition to 3D evaluation; their reported findings were only for the total sample (not gender specific) and the study by Morris et al. (1998) compared treatment groups with untreated controls.

6.2 Sample size and characteristics

The sample size was firstly estimated based on the following:

- Previous prospective studies on prediction of treatment outcome of the TBA (Caldwell and Cook, 1999; Franchi and Baccetti, 2006; Al-Rahbi, 2014) and studies that have reported on 3D facial profile changes (Morris et al., 1998; McDonagh et al., 2001; Sharma and Lee, 2005; Lee et al., 2007).
- Reported dropouts due to poor compliance with TBA therapy, and this was in the range of 20% (Banks et al., 2004a) up to 34% (O'Brien et al., 2003b).
- $p < 0.05$, this was in order to detect a clinically meaningful change of 1 mm in any point's position as by Johnston et al. (2003), Gwilliam et al. (2006) and Titiz et al. (2012)

The sample size of studies mentioned in **Section 6.1** ranged from 20-70 subjects. Our final sample was 47 subjects which is exactly the same as the sample size in the study by Morris et al. (1998). Our final sample comprised of 18 females and 29 males. The reason for this gender imbalance is that during the initial sample recruitment, we had less female subjects (25) in comparison to males (33), and the dropout rate was more among female (7) than male subjects (4).

The dropout rate in this study (19%) was within the range of the previously reported dropout rates associated with the TBA (O'Brien et al., 2003b; Banks et al., 2004a). Eleven patients were lost due to:

- Poor compliance (3 patients)
- Unfavourable growth (4 patients)
- Change of treatment plan (2 patients)
- Failure to attend (2 patients).

The analysis of our final sample characteristics showed no difference between the female and male treatment groups in terms of age at the start of treatment, initial overjet and length of treatment. This was very important as it shows that, the effects of gender difference on growth (age) and other variables (overjet and length of treatment) were not significant and allowed the results for male and female subjects to be combined.

6.3 Standardisation protocol

Attempts were made to minimize potential confounders on the treatment outcome. This included the following:

- The bite registration technique was standardised by using the white "Projet Bite" gauge for all treatment subjects **(Section 4.3)**
- The TBA design and treatment protocol were standardised for all subjects **(Section 4.3)**
- The 3D scanning procedure was strictly standardised for all subjects **(Section 4.4.5)**
- Landmarking 3D models and data analyses were done by the same experienced operator for all the subjects.

6.4 Landmarking error study

The reproducibility of all the previous landmarks used in this study have been validated in studies by Farkas (1994) and Hajeer et al. (2002). The intra-observer landmark identification error we observed was 0.562 mm. It has been reported previously that the intra-observer reproducibility in landmarking 3D facial scans can improve with frequency (Gwilliam et al., 2006).

Some previous studies have reported a landmarking error as low as 0.1 mm (Khambay et al., 2008). However in that study the landmarking was done and assessed for reproducibility on a plaster model, not on an actual 3D facial image; therefore, the findings cannot be compared to ours. Campbell et al. (2012) have reported an error of 0.57 mm which was similar to our findings.

6.5 The 3D analyses

The statistical analyses of the data for each aim of this study, took account of all the potential confounders such as the age, gender and length of treatment. This is important as it was previously shown by Weeden et al. (2001) that the magnitude of soft tissue and facial expression changes between females and males is different. Later, Johnston et al. (2003) showed that reproducibility of facial expressions was also different between genders.

6.5.1 Soft tissue volumetric and landmark changes

The findings of this study showed an increase in the volumetric and linear forward movement of soft tissue landmarks mainly in the lower facial region produced by the PWB and to a lesser extent post-TBA treatment. Although previous studies (Morris et al., 1998; McDonagh et al., 2001; Sharma and Lee, 2005; Lee et al., 2007) have all used colour mapping to make comparisons, they only reported on linear changes. Our results showed a significant increase in the lower face soft tissue volume (37.12 ±

15.24 cm^3) and in the forward displacement of soft tissue pogonion for females (4.12 ± 3.03 mm) and males (4.13 ± 2.14 mm). This forward movement of soft tissue pogonion was similar to the forward movement reported by Morris et al. (1998), McDonagh et al. (2001), Sharma and Lee (2005) and Lee et al. (2007) which ranged around 3-4 mm.

6.5.2 The estimation of the TBA treatment on the soft tissue profile outcome using the PWB

The soft tissue volumetric and linear advancement effects of the PWB were more than those produced by the end of TBA treatment **(Sections 5.4.1.1 and 5.4.1.2)**. The clinical application of this finding may be to use the PWB as a guide, to estimate the treatment outcome of the TBA on the soft tissue profile. This could be done clinically by showing the patient and the parent the facial profile while the PWB is in place, then explaining to them that the expected change in soft tissue profile after TBA treatment should be around 70% in males or 40% in females of that produced by the PWB; the expected final position of the soft tissue chin should be around 4 mm behind its position observed with the PWB. Another possible way of illustrating this is to use computer software such as Dolphin® to simulate the predicted changes. Digital simulation will give the patient and the parent a more real time representation of the expected changes with the TBA which could be useful during the informed consent process.

There are no previous volumetric data available from the orthodontic literature to allow comparison with our findings. They are, however, In broad agreement with the findings of Vanderveken et al. (2011) who aimed to predict the treatment outcome of

OSA using a postured wax bite; we found that the PWB could also be used to estimate TBA treatment outcome on the soft tissue profile **(Section 2.5)**.

6.5.3 Soft tissue landmark variables associated with successful TBA treatment outcome

The findings of this study did not show a correlation between soft tissue variables and successful treatment outcome as measured by the reduction in overjet. This was in disagreement with the findings of Patel et al. (2002) and Al-Rahbi (2014) who both reported that a retrusive soft tissue pogonion is associated with more skeletal change and successful treatment as measured by the reduction in ANB and overjet reduction respectively.

The reason for our findings being different to previous studies may be due to:

- Subjects in both of those studies were treated with the TBA to a pre-set length of time (around 9 months); treatment was stopped at that stage regardless of a full overjet reduction and then data were analysed. In our study, treatment was continued until a normal overjet was achieved in all subjects; therefore, it is much less likely to find a correlation between certain soft tissue variables and successful overjet reduction.
- During our analyses the 3D data which involves three planes of space (x, y, z co-ordinates), were compared to 2D data in the horizontal plane (overjet reduction). Comparison of change in the x-co-ordinate data only with the overjet change may have yielded a different result.

6.5.4 Facial expression changes

The assessment of changes in facial expressions from before to after TBA treatment has not been reported previously in the orthodontic literature. In our study, this was assessed for the upper and lower facial landmarks. The TBA is not expected to alter upper facial expression landmarks because its mode of action is mainly directed toward the lower facial region. If any changes of facial expression for the upper facial region were observed, they would be most likely related to growth. Our findings showed that TBA treatment had no effect on any of the upper facial landmarks at rest, natural smile and maximal smile. In contrast, all the lower landmarks showed significant changes for all facial expressions in both genders; this was with the exception of maximal smile in male subjects where no significant changes were observed. The changes in the lower facial expressions might have occured as a result of the forward displacement of the mandible following growth and TBA treatment, and the subsequent changes in soft tissues associated with these. The reason for not finding any facial expression changes at maximal smile for male subjects, maybe due to, the different soft tissue tonicity and maturation in males in comparison to females (Weeden et al., 2001).

Facial expression changes were measured by comparing soft tissue landmark changes from T1 to T3 for each facial expression. For a change to be considered significant the difference in points position from T1 to T3 must be > 1.5 mm (Johnston et al., 2003; Gwilliam et al., 2006; Titiz et al., 2012).

6.6 Strengths of the study

- It is a prospective 3D study that investigated several new aspects in relation to TBA treatment.

- The study used non-invasive 3D technology which has been validated for accuracy.
- The sample size was considered adequate and within the range of previously reported studies with a similar design.
- All patients were of the same ethnic background (all Caucasians) and the treatment protocol, TBA design, bite registration technique and 3D imaging were standardized.
- An error study was performed to check for intra-operator reliability and accuracy during landmarking.
- All the findings were reported for the total sample as well as for each gender.

6.7 Weaknesses of the study

- It was not possible to account for changes due to growth because there was no control group.
- The TBA was prescribed to patients based on the chronological age only. Perhaps the pubertal growth spurt in some patients did not coincide with the chronological age which might have affected the amount of soft tissue change in those patients.

6.8 Future research

The ideal study should be conducted with a similar design, but adding a control group to account for changes induced by natural growth. The reproducibility of facial expressions before and after TBA treatment could also be assessed by taking 3D images at two time points, 10-15 minutes apart, before and after TBA treatment.

Future studies can also use different types of functional appliances or have more than one treatment groups to compare and contrast the effects of different FAs on soft tissue changes.

A 3D comparison of TBA treatment outcome using different types of bite registration techniques could also be conducted such as; project bite versus traditional use of thick wax wafer or single advancement technique versus incremental advancement.

CHAPTER SEVEN

CONCLUSIONS

7. Conclusions

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

Aim 1: To identify 3D soft tissue volumetric and linear landmark changes following treatment with the TBA

Conclusions

- TBA treatment, in growing subjects, increased the lower facial soft tissue volume and this increase was slightly more for males.
- TBA treatment, in growing patients, caused forward movement of the lower soft tissue facial profile landmarks (labiale inferius, sublabiale and pogonion) and this was similar for females and males.

Null hypothesis 1: The TBA treatment has no effect on the 3D soft tissue volumetric and linear landmark changes.

The null hypothesis is rejected.

Aim 2: To estimate the TBA treatment outcome on the soft tissue volumetric and linear landmark changes from the Postured Wax Bite (PWB).

Conclusions:

- The estimated mean volumetric change in the soft tissues following a TBA treatment was 60% of the mean volumetric change produced by the PWB (for females ~ 40% and for males ~ 70%).

- The estimated change, for the lower facial profile (the chin and the lower lip), following a TBA treatment was 4 mm behind the change produced by the PWB (similar for females and males).
- The PWB is an easy, cheap and non-invasive tool that can be used to estimate TBA treatment outcome on the soft tissues.

Null hypothesis 2: The PWB has no effect on the soft tissue volumetric and linear landmark changes and it cannot be used to estimate the TBA treatment outcome on the soft tissue profile.

The null hypothesis is rejected.

Aim 3: To identify if there is any association between certain soft tissue landmark variables and successful treatment outcome of the TBA as measured by the reduction in overjet.

Conclusion:

- No association was found between any soft tissue landmark variable and successful overjet reduction after treatment with the TBA.

Null hypothesis 3: There is no association between any soft tissue landmark variable and successful overjet reduction following treatment with the TBA

The null hypothesis is accepted

Aim 4: To assess the effects of TBA treatment on facial expressions at rest, natural smile and maximal smile.

Conclusions

- TBA treatment had no effect on the upper facial landmarks for each facial expression.
- TBA treatment changed the facial expressions for the lower landmarks except for maximum smile in males.

Null hypothesis 4: Treatment with the TBA has no effect on the facial expressions at rest, natural smile and maximal smile

The null hypothesis is accepted for the upper landmarks and rejected for the lower landmarks except for maximum smile in males.

CHAPTER EIGHT

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CHAPTER NINE

APPENDICES

9. Appendices

9.1 Appendix A

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Tel: + 353-21-490 1901
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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

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

20th December 2012

Our ref: ECM 4 (ss) 09/01/13

Professor Declan Millett
Professor of Orthodontics
Cork University Dental College
Wilton
Cork

Re: The effect of functional appliance therapy on the reproducibility of facial expressions.

Dear Professor Millett

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

- Cork University Dental Hospital.

The following documents have been approved:

- Application Form
- Study Protocol Version 1 dated December 2012
- Patient Information Leaflet Version 1 dated December 2012
- Parent Information Sheet Version 1 dated December 2012
- Consent Form Version 1 dated December 2012 (Remove Version 1 dated 21th November 2012 from bottom of the consent form prior to use).

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

- Niamh Kelly, Dr Siobhan McMorrow, Dr Inam Heulfe, Dr Lamis Koshak and Dr Erfan Salloum.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

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

9.2 Appendix B

CONSENT BY SUBJECT FOR PARTICIPATION IN RESEARCH PROTOCOL

Section A

Protocol Number:_______________ Patient Name:____________

Title of Protocol: The effect of functional appliance therapy on reproducibility of facial expressions.

Doctor(s) Directing Research: Prof. D. Millett Phone: 021 4901139

You are being asked to participate in a research study. The doctors at University College Cork study the nature of disease and attempt to develop improved methods of diagnosis and treatment. In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

Section B

I. NATURE AND DURATION OF PROCEDURE(S):

You are about to start orthodontic treatment to fix your prominent upper front teeth. This is a common problem in growing children. Special braces made from wire and plastic have been shown to work very well at correcting prominent upper front teeth. These braces are made especially for each patient by taking mould's of your teeth and a special bite.

In this study we want to know if the facial expressions that you make before you received your brace change while you have your brace and after you have finished with your brace. To do this we will take special pictures called three-dimensional (3D) images. 3D pictures allow us to see and examine your face on a computer screen from all directions. These pictures allow us to measure your face very accurately and show the effects of treatment on your face and teeth. Each time we take 3D pictures of your face, a camera will be used to take pictures of your face doing the following things:

- At rest
- Making a natural smile
- Making a maximal smile

We will tell you what we want you to do before we take each of the pictures. It will take about 15 minutes each time you get 3D pictures done.

Only those directly involved in the study will have access to your details. All your information will be confidential. At the end of the study we hope to publish our findings in a scientific journal. Your name will never be shown in any report or publication.

II. POTENTIAL RISKS AND BENEFITS:

There are no risks associated with having your 3D pictures taken. The information we collect during the study will help us understand the change in your face and change in your thoughts about yourself. This will allow us to better plan orthodontic treatment in the future.

III. POSSIBLE ALTERNATIVES:

Treatment may still proceed if you decide not to take part. It is your choice to take part in this study or not. You can withdraw at any time without giving a reason.

Section C AGREEMENT TO CONSENT

The research project and the treatment procedures associated with it have been fully explained to me. All experimental procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I understand that the sponsors and investigators have such insurance as is required by law in the event of injury resulting from this research.

I, the undersigned, hereby consent to participate as a subject in the above described project conducted at the Cork Teaching Hospitals. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the doctor(s) listed above. If I have further queries concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall, 6 Little Hanover Street, Cork.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

Doctor: ______________________ ____________________________________

Signature of Subject

Witness: ______________________ ____________________________________

Signature of Parent or Guardian

Date: _____________ Time:__________AM

(Circle) PM