THE VALIDITY OF 3dMD VULTUS IN PREDICTING SOFT TISSUE MORPHOLOGY FOLLOWING ORTHOGNATHIC SURGERY.

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ABSTRACT

Objectives: To determine the validity of 3dMD Vultus in predicting soft tissue morphology following orthognathic surgery.

Methods: Thirteen patients with a skeletal discrepancy that required surgical correction limited to a Le Fort I surgical advancement osteotomy were included within the study. These patients had previously undergone a CBCT scan immediately before surgery (T_1) and 6 months after surgery (T_2).

To permit validation, hard and soft tissues were linked for each time point and the hard tissues superimposed on the cranial vault and base. Using 3dMD Vultus virtual surgery was carried out to position the mandible and maxilla at T_1 to the post-surgical position at T_2. The resulting 3D soft tissue prediction mesh was then compared to the actual soft tissue mesh at T_2 by segmenting both meshes at distinct anatomically areas of the face. The absolute distance between meshes for each region was then calculated using a custom developed computer program.

Results: A one sample t-test showed the distances between the predicted soft tissue and the actual soft tissue at T_2 were within 3mm for all areas ($p<0.05$).

Conclusions: The ability of 3dMD Vultus to construct three-dimensional soft tissue predictions following Le Fort I advancements was clinically acceptable in all regions of the face.

DEDICATION

I dedicate this project to my parents and wife for their hard work, love, and support during my efforts to become an orthodontist. They have sacrificed much and have never ceased to encourage and support me. I am extremely grateful for their love and patience.

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1.1 Introduction

When a patient attends with a dentofacial deformity that is beyond the limits of correction by orthodontics alone, a combination of orthodontics and orthognathic surgery may provide the only feasible treatment option that will result in an acceptable occlusion and facial balance.

Conventional orthognathic surgery aims to correct antero-posterior, vertical and transverse discrepancies of the jaws and to produce a more balanced and aesthetic facial appearance. The surgery itself does not only change the skeletal relations of the facial structures, but also the contour of the overlying soft tissues.

Modern day orthognathic procedures can be used to manage conditions other than facial deformities, such as the treatment of obstructive sleep apnoea: a recent systematic review and meta analysis concluded that maxillo-mandibular advancements are a safe and highly effective treatment for obstructive sleep apnoea. (Holty *et al.,* 2010). Orthognathic surgical approaches have also been described to reach centrally placed cranial base tumours (Myoken *et al.,* 2000; Liu *et al.,* 2008).

1.2 Patient motivation for seeking orthognathic surgery

The motivating factors that impel patients with facial deformities or severe malocclusions to seek treatment have been investigated comprehensively, with a desire for aesthetic improvement, being cited as the primary reason for patients to seek orthognathic surgery in numerous studies (Finlay *et al.,* 1995; Phillips *et al.,* 1997; Rivera *et al.,* 2000; Kiekens *et al.,* 2005; Williams *et al.,* 2005).

Rivera *et al*. (2000) investigated patient rationale for undergoing orthognathic surgery and found that improvement in physical appearance was a motivating factor given by 71% of patients from a sample of 143, whilst improvement in function was a reason given by only 47% of the sample. These results are very similar to Williams *et al*. (2005) who found that from a sample of 326 orthognathic patients 222 (68%) stated they underwent surgery to “improve their looks”, whilst only 175 (54%) stated it was to improve function and their ability to eat.

The desire for functional improvements has also been stated to be an important consideration for many patients (Auerbach *et al.,* 1984; Flanary *et al.,* 1985; Nurminen *et al.,* 1999; Modhig *et al.,* 2006; Proothi *et al.,* 2010).

Most recently Proothi *et al.* (2010) analysed patients who had undergone orthognathic surgery at the New York Center for Orthognathic & Maxillofacial Surgery. The most common reason for patients opting for surgical intervention in this sample was for correction of a functional impairment and not for an improvement in facial aesthetics. Although 76% of the 501 subjects stated that they felt that their appearance was affected negatively, of these only 15% stated it was their primary motivation for undergoing surgical intervention, with 37% of the sample specifying that their malocclusion and the corresponding functional deficiency was their main motivation for pursuing surgical management.

These studies on motivating factors for patients opting for orthognathic surgery suggest patients present with aesthetic, functional and psychosocial concerns, and it is the proportional significance of these factors that varies. Different social, psychological and cultural pressures in populations studied may explain the differences found in different studies (Macgregor, 1981; Jensen, 1978; Auerbach *et al.,* 1984; Kiyak, 2000; Frazao *et al.,* 2006; Esperão *et al.,* 2010).

The motivating factors for patients pursuing orthognathic surgery have been described as either external or internal (Edgerton and Knorr, 1971). This classification analyses the reasoning behind patients seeking orthognathic surgery and whether the patient has inner deep dissatisfaction about themselves, or an external factor has influenced them to seek surgical correction.

External motivating factors described include having irrational views and ideas about one's appearance, the need to please others and the belief that one’s career or social ambitions are being impeded by their physical appearance. External motivations also include pressure from others, such as family members or partners, to seek treatment and require a change in the patient’s personal circumstances rather than surgery to resolve the patient’s anxiety, as the fixation on the belief that appearance is affected has an underlying psychological source (Cunningham *et al.,*1995).

Internal motivation is usually a more compelling form of motivation and includes long established inner feelings about deficiencies in appearance. Internal motivating factors generally have a primary physical source and individuals driven by internal motivations are identified as making more suitable candidates for surgery (Ostler and Kiyak, 1991; Cunningham *et al.,* 1995).

Ryan *et al*. (2012) on investigating patient motives for orthognathic surgery concluded that, rather than having distinct categories, the source of motivation was a spectrum, with purely externally motivated patients at one end and those who were purely internally motivated at the other. The authors found that most patients interviewed were somewhere in between with characteristics not only confined to one group, suggesting that the two traditional categories form a continuum, rather than being distinct and separate factors.

Dentofacial deformities can affect an individual's self-esteem and awareness especially in relation to the development of self-image (Shalhoub, 1994). The psychosocial impact of any dentofacial deformity can be of more significance to an individual than the related physical concerns, and an individual's entire life can be enhanced as a result of improving their facial appearance (Proffit and White, 1990).

1.2.1 Motivations at Presentation

It has been established that whereas children and adolescent patients often seek orthodontic treatment following a joint or sole parental decision (Story, 1966), adult patients tend to be self-motivated in seeking treatment (McKiernan *et al.,* 1992). Despite these differences, children, adolescents and adult patients all present with similar motivational factors when attending new patient clinics, with a desire for improved appearance and function being the primary motivating factor to seek treatment (Pabari *et al.,* 2011; Story, 1966; Sheats *et al.,* 1998).

1.2.2 Facial Aesthetics

The effect that dentofacial deformities have on self-esteem and self-image for patients has been studied by numerous researchers who have found that the reaction of other people to an individual with a facial deformity has a significant effect on that individual's self-image (Schonfeld, 1966; Macgregor, 1970; Edgerton and Knorr, 1971; Macgregor,1971).

Not unexpectedly other studies have demonstrated that patients with a facial deformity are deemed to have a lower facial attractiveness compared to "normal" population controls, with facial attractiveness improving after orthognathic surgery (Garvill *et al.,* 1992; Chung *et al.,* 2013). Numerous authors have found facial appearance to have a significant influence on social behaviour in modern day society (Dion *et al.,* 1972; Faure *et al.,* 2002). The problems that a patient with a facial deformity may experience were investigated by Garvill *et al.* (1992). This study found that 63% of patients who had undergone orthognathic surgery thought that their facial appearance had previously created significant problems and adversely affected their personal life; a recurring theme was for participants to avoid social gatherings.

The notion that physically attractive people have an advantage over those considered to be less attractive has also been studied abundantly with the evidence suggesting that individuals with lower facial attractiveness are deemed to be less successful, less sociable and less happy than attractive individuals (Dion *et al.,* 1972; Eagly *et al.,* 1991; Watkins and Johnston, 2000).

These studies support the premise that facial appearance influences assumptions about an individual's character. Sinko *et al*. (2012) found that patients with a dentofacial deformity who underwent surgery were considered more attractive, pleasant, intelligent, good natured and confident when their pre and post operative photos were compared. This study suggests that stereotyped views exist of patients with dentofacial deformities which may be perceived by patients in their daily lives.

1.2.3 The Severity of Facial Deformity

Other research has looked for a correlation between the severity of a deformity and a patient's motivation for seeking orthognathic surgery and orthodontic treatment; with no conclusive link between these being found (Wilmott *et al.,* 1993; Bailey *et al.,* 2001; Chew *et al.,* 2006). However patients with more severe facial deformities tend to show a significantly higher prevalence of emotional instability and anxiety (Wilmott *et al.,* 1993), resulting in orthognathic patients with severe facial deformities being more prone to depression, psychological suffering and adverse psychological reactions when confronted with social gatherings (Kovalenko 2012). It has also been noted that patients with facial deformities demonstrate higher levels of psychological stress, when encountering common social situations (Rumsey and Harcourt, 2004). Despite these studies the evidence to suggest that those individuals with greater facial deformities would be more likely to seek orthognathic treatment does not exist.

In conclusion, over the last few decades, as society has become more accepting of surgical procedures to improve facial deformities, orthognathic surgery has gained widespread acceptance along with a significant increase in its demand by patients.

The mainstay motivation for the majority of patients to pursue surgical correction of facial deformities is to improve facial appearance with an expectation that their quality of life will also be improved.

1.3 Body Dysmorphic Disorder

Body Dysmporphic Disorder (BDD) was first described in 1886 by Morselli (Fava, 1992) as dysmorphophobia. It is defined as a psychiatric disease with disproportionate concerns regarding appearance for which patients seek medical intervention (Vulink *et al.,* 2008). Patients with this condition firmly believe that they have a deformity and if any barriers are put in their way to achieving surgery many of them seek another healthcare professional for treatment (Phillips *et al.,* 1993).

BDD is characterised by an excessive fixation of a perceived bodily defect that is either unrecognisable to others or very minor in nature. To be categorized as BDD this debilitating preoccupation must cause significant distress and/or impairment in an individual's daily life and not be accounted for by any other mental disorder. It is often said to impair work, social or personal functioning (Veale *et al.*, 1996). The incidence of BDD in orthognathic patient samples has been found to be between 7.5% (Hepburn and Cunningham, 2006) and 10% (Vulink *et al.,* 2008), compared to a 2% incidence in the general population (Wilson *et al.,* 2004). BDD has a higher prevalence in women than in men (Phillips *et al.,* 1993; Thomas, 1995; Phillips *et al.,* 2005; Rief *et al.,* 2006).

1.3.1 Outcomes of surgery on patients with BDD

Patients with body dysmorphic disorder are rarely satisfied with the results of the surgery (Hepburn and Cunningham, 2006): it is therefore important to recognize this group of patients and to refer them for appropriate management and to avoid unnecessary treatment. (Phillips *et al.,* 1993; Veale *et al.,* 1996). To recognise Body Dysmorphic Disorder, clinicians need to explore a patient's expectations of surgery before commencing combined treatment (Nurminen *et al.,* 1999).

A survey of American surgeons highlighted the extent of the problem that arises when BDD patients are dissatisfied with outcomes: ten percent of respondents had received threats of both violence and legal action and a further 2% reporting that they had been physically threatened (Sarver *et al.,* 2002). Surgeons have even been murdered by unsatisfied patients who have symptoms consistent with of BDD, highlighting the disturbed psychological frame of mind that these patients can present with (Crerand *et al.,* 2006).

1.4 Quality of life measures in orthognathic surgery

The term 'quality of life' has been defined by The World Health Organisation as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHO, 1997). Medical interest in quality of life measures has been inspired by success in extending life expectancies coupled with the understanding that people want to live with an acceptable quality of life and "not just exist" (Cunningham *et al.,* 1996).

There are numerous quality of life measures available for orthognathic patients, however, a condition specific quality of life questionnaire for patients with dentofacial deformity has been available since 1998 - The Orthognathic Quality of Life Questionnaire (OQLQ) (Cunningham *et al.,* 2000). Several studies have concluded it provides suitable measures for patients undergoing orthognathic surgery (Lee *et al.,* 2007; Lee *et al.,* 2008; Choi *et al.,* 2010) and it remains the most widely used quality of life measurement tool used by investigators in the orthognathic surgery setting.

1.4.1 Effects of orthognathic surgery on the Quality of Life for patients

Orthodontists and maxillofacial surgeons who work in an orthognathic setting can provide anecdotal evidence of the improvement in psychological and social wellbeing that combined orthodontic and orthognathic treatment can bring to patients with dentofacial deformities. However, modern health care funding requires a more robust level of evidence, particularly for extensive and costly interventions that have well documented risks, such as orthognathic surgery.

Numerous studies have concluded that patients with dentofacial deformities experience psychosocial benefits following orthognathic surgery, including improved self-confidence and social adjustment (Kiyak, 1986; Hunt *et al.,* 2001), and a notable increase in quality of life indices beyond the initial surgery period (Hatch *et al.,* 1998; Modhig *et al.,* 2006; Lee *et al.,* 2008; Al-Ahmed, 2009).

Other studies have failed to establish a conclusive link between orthognathic surgery and improved quality of life measure outcomes. This may have possibly been be due to patients concentrating on specific aspects of their appearance that they wished to improve rather than adopting a holistic approach to assess the overall benefits (Cunningham *et al.,* 1996).

The accepted notion in orthognathic surgery is that patients accept short term risks and discomfort in return for long term improvements in the quality of their lives. It is for this reason that quality of life analyses are usually carried out several months after surgery. Studies that have analysed the quality of life effects on the immediate post operative period report an expected initial reduction in quality of life markers and indices (O'Young and McPeek, 1987; Lee *et al.,* 2008; Esperao *et al.,* 2010).

A systematic review by Hunt *et al*. (2001) established that after orthognathic surgery, the majority of patients report psychological improvements which include improvements in self-esteem, self-confidence and perception of body image (i.e. improved facial attractiveness after surgery). This is coupled with desirable changes in personality, social functioning, emotional stability, as well as positive life changes such as better employment prospects. However, a wide variation in study designs and an absence of uniformity in measuring the resultant psychosocial changes has made it difficult to quantify the resultant psychosocial benefits (Hunt *et al.,* 2001).

1.5 The need for orthognathic surgery prediction planning

Orthodontic and orthognathic prediction planning is a method of simulating the proposed orthodontic tooth movements and surgical jaw movements in a way that predicts the proposed hard tissue changes and concomitant alteration in the soft tissue profile.

1.5.1 Value of prediction planning to the clinician

Meticulous and accurate treatment planning is an essential component of orthognathic surgery if optimum functional and aesthetic results are to be obtained (Eckhardt and Cunningham, 2004). A comprehensive understanding of the soft tissue response to skeletal movement is crucial for accurate treatment planning. This assists the orthognathic team to plan for optimal surgical movements that optimise facial appearance allowing the orthodontist to plan dentoalveolar movements that will result in a functional occlusion that supports the facial profile.

The use of surgical predictions also allows clinicians to assess what other treatment options are viable, with different proposed treatment options being able to be carried out in a virtual environment and the suitability of the plan assessed (Loh *et al.,* 2012).

Analysis of treatment predictions can improve clinical communication between the orthodontist, surgeon and patient and also improve clinical decision making while enhancing patient understanding of the proposed treatment outcomes (Grubb *et al.,* 1996; Kaplan and Lundsgaarde 1996; Sarver,1998).

1.5.2 Value to the patient

The prediction of facial appearance prior to surgery can be useful to educate patients regarding the aesthetic effects of treatment on the facial profile along with managing patient expectations to avoid post-surgical dissatisfaction.

In a randomised clinical trial of patients who requested a treatment consultation with an orthodontist due to a perceived facial deformity, patients that were assigned to a group that was shown a treatment “simulation” rated the treatment prediction as the most valuable part of the consultation (Phillips *et al.,* 1995).

Preparing patient expectations is an important component of orthognathic surgery as it has been demonstrated that patients who have either a neutral or a negative expectation regarding the outcome of orthognathic surgery tend to have more psychological distress after surgery, whilst those with more positive treatment expectations tend to diminish or overlook unfavourable symptoms (Phillips *et al.,* 2001). The above findings have also been demonstrated by Ryan *et al*. (2012), concluding that one of the key determinants of satisfaction post orthognathic surgery is the patient's expectations beforehand (Ryan, 2012).

Phillips *et al.* (1995) found that when patients viewed 2D surgical predictions preoperatively, 89% felt that the predicted images were realistic and that the desired results of surgery were achieved (Phillips *et al.,* 1995). This was followed by Sarver *et al.* (1998), who reviewed the medico-legal implications of video imaging on patient expectations when used for orthognathic surgery and demonstrated that patients had a positive attitude toward the imaging process.

The concern that a patient's expectations might become too great if shown a pre surgical prediction does not appear to be supported by any study to date (Sarver *et al.,* 1998).

It has also been demonstrated that patients who have viewed 2D computer generated image predictions carried out prior to surgery, have more realistic expectations as to the achievable treatment outcome and therefore the chances of dissatisfaction are considerably reduced compared to those patients that have had no visualisation of the potential surgical result (Sinclair *et al.,* 1995).

These 2D computer generated predictions have thus far acted to give patients a reasonable preliminary view of the surgical outcome along with serving as an important communication tool between the orthodontist and surgeon (Gossett *et al.,* 2005). It has however been questioned whether showing computer generated predictions of possible post-surgical results to patients raises the possibility of litigation if a patient feels the outcome is dissimilar from the prediction (Chavez *et al.,* 1997; Koch *et al.,* 1998; Sarver *et al.,* 1998; Loh *et al.,* 2001). Pospisil (1987) advocated that clinicians do not attach significance to these tracings to such an extent that they are shown to the patient, until their accuracy has been proven.

1.5.3 Clinically noticeable differences between predictions and actual results

A systematic review that evaluated the accuracy of various computer prediction programs at predicting soft tissue changes after orthognathic surgery using 2D prediction software demonstrated that in general these software systems showed accurate prediction results (<2 mm) when compared with the actual soft tissue profile post-surgery (Kaipatur and Flores-Mir, 2009). Jones *et al*. (2007) demonstrated that a 3mm change in facial soft tissue profile is required before it is noticed by laypeople or a specialist panel.

Whether the accuracy of surgical predictions can be improved with the advent of three dimensional surgical planning software systems remains to be seen.

If surgical predictions are shown to patients, it is current practice to make the patient aware that this may not be the exact result achieved post operatively due to individual variations and responses arising from orthognathic surgical intervention.

1.6 Methods of prediction planning in orthognathic surgery

1.6.1 Model Planning

Maxillofacial technicians provide essential laboratory support for surgical prediction planning and the fabrication of occlusal wafers / splints to guide the surgical correction of dentofacial deformities.

Following a comprehensive clinical examination supported by an in depth evaluation of a lateral cephalogram, the orthognathic team agree on the necessary horizontal, vertical and transverse skeletal movements which are communicated to the maxillofacial technician. The required movements are subsequently mimicked using model surgery to produce surgical wafer(s) which are used to reposition the maxilla and/or mandible during orthognathic surgery.

The ability of model surgery to simulate the actual surgical movements accurately is dependent on several factors, all of which can introduce errors into the process. The positioning of dental models mounted on articulators using face bow may not accurately reproduce the orientation of the patients' dentition and jaw bases (Berbenel *et al.,* 2010). Not only can errors occur registering the maxillary complex on the articulator in the same relationship as the maxilla exists to the temporomandibular joint in the patient (Gateno *et al.,* 2001), but the process of facebow transfer itself has been shown to further introduce inaccuracies in study model orientation (Sharifi *et al.,* 2008).

There is abundant evidence of inaccuracies in orthognathic planning when using model surgery and the development of three dimensional technologies has provided the potential to overcome some of these inaccuracies. Several reports on how using CAD/CAM (Computer Assisted Design/Computer Assisted Manufacturing) technology can obviate the need for model surgery: with surgical wafers and splints being constructed directly from three dimensional surgical simulations (Metzger *et al.,* 2008; Schendel and Jacobson, 2009; Swennen *et al.,* 2009; Quevedo *et al.,* 2011; Centenero and Hernández-Alfaro, 2012).

The Lockwood key-spacer system (Lockwood, 1974) and the Eastman model surgery technique (Anwar and Harris, 1990) are variants of model surgery and are currently the most widely used techniques for orthognathic surgical planning within the United Kingdom (Bamber *et al.,* 2001).

The Lockwood key-spacer planning method incorporates spacers which are constructed from plaster though modifications using acrylic have been suggested (Peretta and Caruso, 1983). The resultant model segments are held together with elastic bands and spacers, which during handling and fabrication of occlusal registrations can become difficult to control. The Lockwood technique has the theoretical advantage of being able to demonstrate undesired transverse shifts of the maxillary model as it has trimmed parallel sides. It also does not require a second set of mounted models for the final post-surgical relationship (Bamber *et al.,* 2001).

The Eastman model surgery technique (Anwar and Harris, 1990) requires four horizontal and seven vertical reference lines to be drawn onto casts to register the preoperative position of the mandibular and maxillary sections. When all the reference lines have been drawn, measurements between the vertical and horizontal lines are recorded onto the cast and the plaster mounting is then sectioned at the osteotomy sites. The resulting sections are then repositioned in the planned postoperative position using modelling wax. Once the required position is achieved sticky wax is used to secure the sections firmly in place.

Bamber *et al.* (2001) investigated the accuracy of these two techniques and found neither to be completely accurate. However, the Eastman technique resulted in smaller errors in the transverse and vertical planes and a significantly smaller error in the anteroposterior plane when compared to the Lockwood key-spacer system.

1.6.2 Cephalometric prediction planning methods

Cephalometric prediction planning for orthognathic surgery is a method of predicting hard tissue movements to be carried out at surgery and also attempts to estimate the post-surgical profile of the patient.

A number of methods have been devised to plan surgical movements. These include:

- Freehand alterations of tracing of cephalometric radiographs (McNeil *et al.,* 1972)
- Combined cephalometric tracings and photographs (Henderson, 1974)
- Computerised prediction (Harradine and Birnie, 1985)

1.6.3 Free hand alteration of tracings of cephalometric radiographs

Using cephalometric radiographs to assist in predicting the soft and hard tissue relationship post-surgery was however first described by McNeil *et al*. (1972). Fish and Epker (1980), Bell *et al*. (1980) and Moshiri *et al*. (1982) later recommended the modification of tracings from lateral skull radiographs as a means of orthognathic prediction to supplement model surgery.

The procedure for this technique is as follows:

1. Establish a provisional post treatment dental relationship using dental casts.
2. The prescribed tooth movements are simulated with a diagnostic set up prior to repositioning the casts within an articulator to the desired occlusion.
3. Separately an overlay tracing is made on the cephalometric radiograph of the hard tissues which will be unaffected by the surgery along with the soft tissue profile which likewise will be unaffected.
4. This overlay tracing is sectioned allowing the surgical movements predicted to be simulated on the tracing, to reproduce the planned occlusion. Molar and incisor relationships on the repositioned casts serve as a guide for correct overlay positioning. The new skeletal relationships are then traced on the overlay in a different colour.
5. The prediction planning is completed by adding the soft tissue profile outlines.
6. This prediction process is undertaken several times until best compromise between ideal tooth position and jaw position is achieved.

This method of surgical prediction is valuable in orthognathic planning but it suffers from some disadvantages. Firstly it is extremely time consuming if carried out accurately and carefully; the available data on soft tissue changes to hard tissue movement is limited and a degree of subjective skill is required to utilise them as part of free hand prediction tracing (Fish and Epker, 1980).

1.6.4 Combined cephalometric tracings and photographs

In an effort to produce a more realistic prediction, Henderson advocated combining the cephalometric radiograph with a photograph of the patient which is in a 1:1 ratio to the lateral cephalogram (Henderson, 1974). This is a much simpler method than the overlay tracing technique.

The procedure for this technique involved:

1. A tracing is made of the relevant hard tissue structures from the cephalometric radiograph.
2. The photograph is sectioned along the planned osteotomy sites
3. The soft tissues are then moved according to the accepted ratios of hard to soft tissue movements.

A much simpler and quicker technique of cutting round and repositioning segments of a tracing only was described by Cohen (1965), but as with sectional photographs, this method doesn't take into account the differential soft tissue movement within each cut section (Harradine and Birnie, 1985).

It is well known that the suggested ratios of the soft to hard tissue movement published in the literature can vary significantly between individual patients (Freihofer, 1977). It is therefore reasonable to assume that inaccuracies will be inevitable when using these mean values.

Furthermore, photographs of the face have their limitations (Robertson, 1976; Moss *et al.,* 1994): small variations in camera angulations can give the impression of improving or worsening the facial profile. This error can be minimised by taking standardised profile and frontal facial views (Robertson, 1976; Ras *et al.,* 1996). However, even when standardising conventional photography problems still remain. In the frontal standardised full face view, the nose is closest to the camera and appears larger, while the ears which are further away appear smaller resulting in inaccuracies when using these images for measurements (Miller, 2007).

1.6.5 Computerised prediction

Early computer software programs were developed to simulate surgical manipulation of the skeletal tissue and by utilising linear ratios, to predict the soft tissue changes following orthognathic surgery (Walters and Walters, 1986; Laney and Kuhn, 1990; Turpin, 1990). These soft tissue to hard tissue changes have been derived primarily from cohort studies of orthognathic surgery patients (Hunt and Rudge, 1974; McCollum *et al.,* 2009).

Quick Ceph (Quick Ceph Systems, San Diego, USA) was the first orthognathic surgical prediction software program to be made commercially available. Harradine & Birnie (1985) described a computer program which would subsequently be called Consultants Orthodontic Group Software Orthognathic Prediction Analysis (COGSoft) (British Orthodontic Society, London, UK) and which has been under development since 1982. The program wasn't commercially available until 1988 and was subsequently released in a Microsoft Windows format as OPAL™ (Orthognathic Prediction Analysis).

These computerised prediction software systems were introduced to overcome short comings of the available hand prediction techniques described previously, which were deemed to be time consuming and lacking in accuracy because of human error involved in model planning, tracings, distortion in radiographic images and photographic angulation errors (Harradine and Birnie 1985; Pospisil, 1987; Talwar and Chemaly, 2008).

However the programs require time, practice, and patience to use and learn the different functions which the novice user may find challenging (Kusnoto, 2007).

Many current prediction software programs were developed by academic institutions for research purposes, and then evolved into commercially available software prediction packages specifically for orthognathic surgery (Bryan and Hunt, 1993). The accuracy of the soft tissue prediction by many of these programs has been tested with varying results reported.

Early computer prediction methods used only lateral cephalogram tracings without requiring soft tissue profile photos and it was noted that the predictions from these programs mostly portrayed the upper labial region to be more anterior than the actual result and the lower labial region to be more posterior than the actual outcome (Eales *et al.,* 1994; Konstianto *et al.,* 1994).

Carter *et al.* (1996), used photographs linked to cephalometric tracings in an attempt to achieve a more accurate prediction of the overlying soft tissue in the Orthodontic Treatment Planner software program (Pacific Coast Software Inc., USA). The results however were no different from other studies, with significant differences still present in the upper and lower labial areas (Gerbo *et al.,* 1997; Sameshima *et al.,*1997; Upton *et al.,* 1997; Mobarak *et al.,* 2001; Koh *et al.,* 2004; Jones *et al.,* 2007; Donatsky *et al.,* 2009). Although it was found that the addition of a profile photo to assess the resultant soft tissue certainly improved the ability to assess the aesthetic result of the planned surgery (Carter *et al.*, 1996).

Some programs incorporate different ratios for the soft tissue response for different facial forms (Dolphin Imaging™, Dolphin Imaging Inc., California, USA) but despite the differences between the numerous available programs, the prediction of changes to the outline of the upper and lower lip seem to be the most difficult areas to predict accurately (Konstiantos *et al.,* 1994; Chunmaneechote *et al.,* 1999; Kaipatur and Flores-Mir., 2009; Gimenez *et al.,* 2013).

The stated reasons for the inconsistency between prediction tracings and the actual post operative profile for the labial regions are due to different lip tone, length, posture and mass of the lips along with individual variations in response to surgery (Quast *et al.,*1983; Stella *et al.,* 1989; Sameshima *et al.,*1997; Kazandjian *et al.,*1999).

Kaipatur and Flores-Mir (2009) and Magro-Filho *et al*. (2010) have demonstrated very little overall differences in the predictive accuracy of the main orthognathic prediction software programs available on the market.

The methods of 2D prediction discussed above have been criticised for the prediction of the surgical correction of facial asymmetry because the programs they do not record and therefore can not report on the third transverse dimension (Shafi *et al.,* 2013).

1.7 Current knowledge of soft tissue response following surgery

1.7.1 Limitations of cephalometric orthognathic surgery planning

One of the main shortcomings of 2D orthognathic computer planning is that the predicted soft tissue changes are based on cohort studies on hard to soft tissue changes. The original studies devised to examine these ratios are open to criticism as they were derived from non homogenous groups.

Moreover, only horizontal and vertical profile changes can be determined in 2D (Kaipatur and Flores-Mir, 2009). Patients are unaccustomed to viewing themselves in profile and it is therefore difficult for them to visualise profile changes in their facial appearance following surgery (Pospisil, 1987).

1.7.2 Predicting soft tissue outcome with maxillary and mandibular surgery.

The prediction of soft tissue changes associated with maxillary surgery has been found to not be as accurate as those for the mandible (Hunt and Rudge, 1974; Friede *et al.,* 1987; Magro-Filho *et al.,* 2010). Chew *et al*. (2008) who found that while a linear relationship existed between soft and hard tissue movement post surgery for mandibular movements this wasn't the case for maxillary movements, which demonstrated a non linear response following orthognathic surgery.

With maxillary advancements, due to the minimal contact between the upper incisors and lip there is initially modest soft tissue movement for a corresponding hard tissue movement. Continuation of the advancement results in an increase in the amount of soft tissue movement which is now in direct contact with the dentition. Further advancement still, stretches the lip which results in resistance and a consequent decrease in the ratio of hard to soft tissue movement (Smith *et al.,* 2004).

Cephalometric prediction software program developers have used linear ratios for soft tissue to hard tissue changes with the assumption that the soft tissue response is a predetermined amount of the overall skeletal movement. However, the use of linear ratios for both maxillary and mandibular soft tissue response to surgery is not a true reflection of the actual changes that take place (Chew *et al.,* 2008).

Dento Facial Planner (DFP, Dento Facial Software Inc., Canada) is unique in orthognathic surgical planning software programs, as it uses algorithms which account for the nonlinear response of the soft tissue change following surgery (Smith *et al.,* 2004).

1.8 Surgical Accuracy of Planned Movements

The ability to predict a patient's final profile following orthognathic surgery relies partly on the ability of the surgeon to accurately undertake the planned skeletal movements (Jacobson and Sarver, 2002). A study by Bryan and Hunt (1993) investigated the accuracy with which the maxilla and mandible were repositioned during orthognathic surgery and found that whilst there was varying degrees of variation between patients, no statistically significant difference could be established between the original required surgical movement and the surgical result. These findings were supported by Jacobson (2002), who found 80% of the surgical movements fell within 2 mm of the prediction and Ong *et al.* (2001) who found that 97% of maxillary movements in the vertical dimension, 90% of maxillary movements in the horizontal dimension and 87% of movements which involved a change in both dimensions were accurate within 2mm.

Pospisil (1987) investigated the accuracy of 2D prediction tracings and found that 60% of patients analysed showed inaccuracies between the prediction tracing and postoperative tracings which were greater than 1mm. No distinction between surgical inaccuracy and post operative relapse was made in this study.

It is generally accepted that even if both the orthognathic prediction and the actual surgery are identical the soft tissue profile will often differ between the two. This is most likely due to a number of factors including variations in soft tissue thickness, elasticity and muscle tone (Subtelny, 1959; Eckhardt and Cunningham, 2004).

1.9 Current methods of three dimensional hard and soft tissue imaging

The use of 3-dimensional (3D) imaging of the face and skull has steadily increased in orthodontics and maxillofacial surgery over the last 3 decades as a result of the development of sophisticated three dimensional imaging technologies (Blais, 2004). These new imaging modalities can record the facial form in three dimensions using non invasive techniques.

Soft tissue imaging methods may be classified as follows (Hajeer *et al.,* 2004).

1. Photogrammetry and stereophotogrammetry.
2. Lasers – fixed and portable units.
3. Structured light.
4. Moiré topography

These technologies will be discussed in turn.

1.9.1 Photogrammetry

Photogrammetry is the technique of measuring objects from standardized photographs. Early methods of facial photogrammetry utilised procedures developed by cartographers for constructing maps and surveying the environment, this was carried out clinically by reflecting contours with set distances onto the face, which were subsequently recorded as ‘contour mappings’ (Burke and Beard, 1967). It was often laborious and costly to record facial morphology using this method and hence the technique was rarely used (Bjorn *et al.,* 1953; Berkowitz *et al.,* 1977).

Stereophotogrammetry is a technological advancement of the photogrammtery technique and uses two or more cameras configured as a stereo pair to obtain a 3D image of facial morphology (Heike *et al.,* 2010). The early attempts at stereophotogrammetry were technically demanding and relatively crude as they again required the construction of facial contour maps (Burke and Beard, 1967). Advances in this field now generate 3D images from compact devices capable of producing fast high resolution images in colour (Weinberg al., 2004).

Modern computerised stereophotogrammetry is based on the acquisition of two stereoscopic views; the algorithm identifies common points from each of these two images and then uses the concept of multiple point geometric triangulation to determine the surface coordinates of the target object (Kusnoto and Evans, 2002). As 3D stereophotogrammetry relies on the software program being able to match corresponding points from separate images, it is essential that the acquired images should be of high quality to enable areas and points from each image to be identified and coordinated with one another (Winder *et al.,* 2008).

Following this computer software synchronises the data, and using complex algorithms generates a 3D image. To accurately express surface information in 3D, the subject's face must be converted into a series of coordinates. These coordinates represent the visible geometry of the patient's face in the resultant 3D image (Lane and Harrell, 2008).

Over the past two decades stereophotogrammetry has undergone considerable developments with the introduction of high resolution digital cameras allowing even the finest of skin detail to be recorded (Wong *et al.,* 2008). Stereophotogrammetry has also developed into a safe, non invasive and highly accurate image capture technique that can capture 3D images in extremely fast capture times (<1ms), eliminating movement artefacts often seen with other 3D imaging modalities which have longer capture times (Lane and Harrell, 2008; Heike, 2009).

Due to its ease of use, automated stereophotogrammetry has become the preferred facial surface imaging modality in craniofacial and dentofacial settings (Mutsvangwa and Douglas, 2010). These systems can serve as an extremely valuable tool for surgeons, providing a 3D image of the patient's facial morphology, without the patient being exposed to radiation, while simultaneously being archived for future analysis (Aldridge *et al.,* 2005; Heike *et al.,* 2010).

1.9.2 Lasers

Prior to the refinement of stereophotogrammetry systems over the last decade, 3D laser scanning was considered to be the optimum method of recording the face in 3D. Laser technology utilises optical principles and essentially is a stereoscopic technique in which the distance and morphology of the object is calculated by computer software using a laser source and CCD detector (Kusnoto and Evans, 2002; Kau *et al.,* 2007).

There are two primary classifications of laser devices for image acquisition in 3D. These are categorised according to the source of the beam and are either single point and slit / stripe scanners. Although single point laser scanners result in higher resolution and accuracy than slit / stripe scanners, due to the time required scanning the subject, a slit / stripe scanner is the more suitable option for capturing facial morphology (Blais, 2004). Depending on the set up slit / stripe scanners incrementally scan the subject in either a horizontal or vertical direction.

Using laser scanners as a means of data capture of the soft tissues has had a number of limitations. The capturing of a full 3D image is slow and routinely results in image artefacts caused by movement of the subject or a change in facial expression, reducing the accuracy of the recorded image (Kovacs *et al.,* 2006). In addition, the final image produced lacks the photorealistic appearance and the characteristic texture and colour of the skin surface (Khambay *et al.,* 2008).

Even though laser scanning has fallen behind stereophotogrammetry as the preferred method of 3D imaging of the face, the systems used have continued to improve. Scanning times have reduced from a typical 1-15 minutes to less than 3 seconds, which is less demanding for patients, and also produces higher quality images free from artefacts (Komazaki *et al.,* 2011; Djordjevic *et al.,* 2012). Concerns however persist that laser scanning isn't suitable for use in a paediatric population due to the relatively long scanning time, resulting in distortion of captured images (Al-Omari *et al.,* 2005; Devlin *et al.,* 2007).

An example of a modern laser scanner used in the dentofacial setting is the Konica Minolta Vivid series 900 (Kau *et al.,* 2005; Fourie *et al.,* 2011). Using this device, the subject to be scanned is positioned to allow optimum simultaneous bilateral imaging and a laser beam is reflected onto the subjects face. This laser light is then swept across the area to be recorded by a mirror which is rotated by a precise galvanometer. The reflected light from the face is recorded by a CCD detector, and using triangulation converted into distance information. The same CCD sensor is used to obtain a colour image of the subject when the laser light is not emitted. The distance between the object and the detector and source is calculated by geometric principles and the data translated into simple x, y and z coordinates. The contour of the recorded surface is derived from the shape of the image of each reflected scan line (Minolta Vivid Series 910 manual, Osaka, Japan). Although these scanners are available individually, they are most commonly used as a stereo pair in order to be able to fully record the more lateral areas when imaging the face in a single capture avoiding any positional changes of the subject that may result in higher registration errors (Kau *et al.,* 2005a; Kau *et al.,* 2005b). Despite this stereo set up, an error in the computerised registration of left and right scans still exists and has been found by to be approximately 0.13 ± 0.18 mm (Kau *et al.,* 2004).

3D laser scanning is simple, easy to use and non invasive to the patient with the technique providing an efficient, valid and reproducible method of recording a subject's face (Kau *et al.,* 2005b; Kau *et al.,* 2007).

With the introduction of "eye safe" FDA approved Class I lasers, laser scanning technology now offers the ability to record 3D images of the face with a subject's eyes being open (Kau *et al.,* 2005). Many of the newest models of laser scanners are ‘eye safe’, which is essential for facial scanning, particularly with infants and children (Fang *et al.,* 2008).

1.9.3 Structured light and Moiré topography

The structured light technique is another means used for capturing 3D information. Using this technique, a known pattern of ‘structured’ light, such as squares, circles or more commonly parallel stripes is projected onto the target surface. (Koninckx and Van Gool, 2006). When the light patterns illuminate the surface being imaged, they distort and bend with the contours of the subject’s facial morphology. A system of cameras at a known distance and angulation to one another captures the reflected pattern and subsequently translates the data into 3D coordinates, creating a three dimensional model (Valkenberg and McIvor, 1998; Hsieh, 2001).

Moiré topography is considered to be a variation of the structured light technique. It is a contour - mapping technique that involves projecting different light patterns / grids onto a surface and then creating a topograph from the interference patterns. Despite being routinely recorded as a monocular 2D image, it is said to deliver 3D information based on the contour fringes and fringe intervals (Takasaki, 1970).

Moiré topography can be an efficient tool for the evaluation of facial deformities. It is possible to quantify subtle changes which are just perceptible to the eye (Kawai *et al.,* 1990). It is however accepted that better results are obtained on smoothly contoured objects (Moore *et al.,* 1979). When using this technique to image the face, great care is needed in positioning the head, as a small change in head position can produce a large change in the resultant fringe pattern (Kanazawa and Kamiishi, 1978; Hajeer *et al.,* 2004).

1.9.4 Conventional Computed Tomography (CT)

The work of a British engineer - Sir Godfrey Hounsfield, resulted in a paradigm shift in medical radiology with the invention of X-ray computed tomography (CT). The word 'tomography' is derived from the Greek words 'tomos' meaning 'to slice' and 'graph' meaning 'image' and has been be translated as "the picture of a cut" (du Boulay, 2000).

Computed tomography uses an X-ray radiation source to image the patient and acquires a series of individual images known as image slices. During a CT scan, the individual lays flat on a table, which is passed through the centre of a large x-ray machine (Hounsfield, 1973).

The image data is generated using an X-ray source that rotates around the subject and positioned directly opposite the source are X-ray sensors. This results in the 'images' being captured as slices with subsequent slices being 'stacked' to obtain a final complete 3D image, allowing the generation of cross sectional x-ray images. The mathematical basis for achieving such cross sectional views is known as image reconstruction (Robb, 1982).

Although x-ray sources, acquisition geometries, and detectors have evolved, the basic principle behind CT scanning remains unchanged. This gradual evolution has occurred through five generations of the system up to the present day (Kohl, 2005).

Great technological advances have occurred in CT scanning since its introduction to the medical profession. The original processing time for a full CT scan required up to 9 hours of computer time, but as computer processor speeds have increased and software is refined, processing the large amount of data arriving from the scan has reduced to minutes (Baumrind, 2011; Dawson, 2011). Other advances have included scanners with multiple x-ray emitters and multiple sensors, further reducing the time required for full body scans and the presence of motion artefacts (Mettler *et al.,* 2000).

1.9.5 Cone beam computed tomography (CBCT)

Cone beam Computed Tomography (CBCT) was designed to deal with the problems of conventional CT scanning devices such as the relatively high radiation dose imparted to the patient, the cost of the equipment and the large size of the equipment that required to be accommodated (Farman and Scarfe, 2009).

With CBCT imaging, the radiation source consists of a divergent pyramidal or cone shaped x-ray beam that is centred on a detector which rotates around the subject being imaged, producing a series of 2D images which are subsequently collated into a 3D image (Scarfe and Farman, 2008). CBCTs produce a more focused beam and much less radiation scatter compared with the conventional CT resulting in higher quality images (Sukovic, 2003; Kau *et al.,* 2009).

CBCT technology uses a rectangular or round 2D x-ray detector, which allows a single rotation (180º or 360º) of the x-ray source to generate a scan of the entire region of interest (Farman and Scarfe, 2009). The resulting data can then be viewed as secondary reconstructed images in the three spatial planes (axial, sagittal, and coronal).

The main advantage of CBCT is that the radiation dosage is considerably less than conventional CT scanning: it has been reported that the total radiation is approximately 20% of conventional CTs, 2-7 times panoramic radiolography doses and equivalent to a full mouth periapical radiographic exposure (Mah *et al.,* 2003; Ludlow *et al.,* 2003). In addition, the patient is scanned in the upright position resulting in less distortion of the soft tissues in comparison to conventional CT where the patient is imaged in a supine position (Khambay *et al.,* 2002; Kau *et al.,* 2005).

As with conventional CT, CBCT soft tissue images do not capture colour and the true texture of the skin and thus does not provide photorealistic images (Plooij *et al.,* 2011). A set up describing the simultaneous capture of a 3D photorealistic skin surface of the face on the untextured skin image of the CBCT Scan has recently been described (Naudi *et al.,* 2013)

Amongst the first clinical applications of CBCT were angiography, single photon emission computerised tomography (SPECT) and image guided radiotherapy (Robb, 1982; De Vos *et al.,* 2009). Dedicated CBCT scanners for the oral and maxillofacial region weren't pioneered until the 1990's (Arai *et al.,* 1999; Mozzo *et al.,* 1998).

1.9.6 Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging (MRI) has traditionally been used as a technique for 2D imaging of body structures and is better suited for examining soft tissue rather than hard tissue where other imaging modalities perform better (Weekes *et al.,* 1985).

An MRI scanner consists of a large cylinder shaped electromagnet, equipped with coils along with transmitters and receivers of radio waves. The patient to be scanned lies on a motorised table which enters the cylinder and a powerful magnetic field is generated together with radio wave pulses. This causes polarization of the hydrogen atoms within the tissues: their subsequent depolarization emits radiation which is detected by receiver coils (Berger, 2002; Kau *et al.,* 2011). The subsequent 2D data collected can be generated into 3D images for analysis.

MRI can be used to analyse the soft tissues around the temporomandibular joint (Hamada *et al.,* 2000), preoperative planning of tumour resections (Grevers *et al.,* 1991) and maxillary sinus evaluation (Gray *et al.,* 2003). MRI images have also been combined with CT scans for surgical treatment planning (Grevers *et al.,* 1991; Moroder *et al.,* 2013). Whist MRI is safe procedure, the financial cost of the equipment is high (Papadopoulos *et al.,* 2002). MRI also fails to provide natural photographic facial appearance or skin texture (Hajeer *et al.,* 2004).

1.10 Registration of 3D Images

To allow 3D planning and to evaluate the 3D effects of orthognathic surgery, pre and postoperative 3D images of the patient's face can be matched. In medical imaging, this matching procedure is referred to as registration (Maal *et al.,* 2008).

The term 'registration' has been defined as "determining the spatial alignment between images of the same or different subjects, acquired with the same or different modalities" (Hill *et al.,* 2001). As a result, information from images is displayed in the same coordinate frame to enhance the diagnostic value of the image data (Klabbers *et al.,* 2002). This is particularly helpful when considering imaging of the head and neck as there currently isn't one ideal imaging modality that will suitably obtain all the required hard and soft tissue data together without any issues in one or the other (Heiland *et al.,* 2004). CBCT has been used extensively in investigating the effects of orthognathic surgery but has the disadvantage of lacking photorealistic texture on the soft tissue along with the presence of artefacts (Swennen *et al.,* 2009). A stereophotogrammetric image can be taken along with the CBCT and subsequently fused to the soft tissue of the CBCT, resulting in the production of a patient specific anatomic reconstruction (Schendel and Lane, 2009). However as discussed above there is a registration error that is introduced with this method.

Extensive research has been carried out over the last two decades on the computer based registration of medical images provided by the different 3D imaging modalities, resulting in a large number of algorithms dedicated to this task.

When building a three dimensional model of a patient prior to orthognathic surgery, the 3D prediction software requires the hard tissues and overlying soft tissues to be “linked” in some way if they have been taken by different imaging modalities e.g. a CBCT scan and a stereophotogrammetric image. Capturing them independently and trying to relate them back to one another without any error has so far been unattainable (Khambay *et al.,* 2002; Ayoub *et al.,* 2007; Jayaratne *et al.,* 2012). This is owing to the fact that the face is used as a reference structure and is an animate object, therefore subtle variations in muscle tone, facial expression, and head posture will result in the two different imaging modalities not sharing the same reference (Maal *et al.,* 2010).

It has been demonstrated that where both soft tissue and hard tissue 3D imaging is taken simultaneously albeit with different 3D imaging modalities it results in a more accurate registration, however a small error still remains between the registered images (Naudi *et al.,* 2013).

1.10.1 Rigid and non-rigid registration

Traditionally, image registration has been classified as being “rigid” or “non-rigid”. A large amount of the earlier work in image registration for medical purposes, was based on registering 3D brain scan images of the same subject acquired with different imaging methods, such as MRI and CT (Englmeier *et al.,* 1994). These early registration methods primarily used rigid registration algorithms, which assume that between image acquisitions, the anatomical structures of interest have not distorted due to image acquisition or biological change (Pelizzari *et al.,* 1989). Rigid registration methods by their nature are linear transformations based on algorithms which do not alter the target image to achieve a complete registration (Hill *et al.,* 1991).

While this was appropriate for the brain, which has a relatively constant shape and size when imaged within short time periods between scans; it clearly isn't the case for other organs, including the skin (Crum *et al.,* 2004).

Non-rigid registration, also known as elastic registration, assumes that distortion of the subject has taken place between image acquisitions, which is most commonly due to biological changes in the subject such as the loss or gain of adipose tissue. This method of registration works on the premise that matching between structures of two images can not be achieved without some localized "stretching" of the images (Rohr *et al.,* 2001). Unlike rigid registrations, where the distances between all points remains constant before and after the registration, non rigid registration involves more complex algorithms and computations such as localised stretching and scaling to match the two images: this approach may however subsequently generate inaccurate deformations of the image being registered (Menon *et al.,* 2010).

1.10.2 Voxel based and feature based registration

For accurate registration of images it is important to distinguish between voxel based and feature based registration methods. Voxel based registration directly uses the scanned data and registers according to voxel values whereas feature based registration uses areas / points extracted from the images, such as curves, surfaces and label maps (Maintz and Viergever, 1998). It has been noted that voxel based registration retains the maximum amount of information (Holden *et al.,* 2000). Accurate registration can be an issue, especially when there are large changes between the images (Hartkens *et al.,* 2002).

1.10.3 Advantages of registering 3D images

With the different registration methods, it is possible to superimpose 3D textured soft tissue surface data on data lacking texture and photo realistic qualities i.e. surface data obtained from Cone Beam CT scans. This has many advantages over conventional 2D imaging including the production of highly realistic facial and skeletal images, improved diagnostic value, improved pre-operative planning and improved post-operative evaluation (Maal *et al.,* 2008).

1.11 3D Orthognathic Planning – Mathematical Deformation Models

Attempting three dimensional prediction in the change of the facial soft tissues following orthognathic surgery requires a mathematical model that can imitate the deformation behaviour of the facial soft tissues in response to skeletal repositioning. Various models have been proposed for this function (Mollemans *et al.,* 2007; Schendel and Lane, 2009). These include:

1. The finite element model.
2. The mass spring model.
3. The mass tensor model.

1.11.1 Finite Element Model

The finite element model (FEM) was the first deformation model that was applied to prediction planning for orthognathic surgery and has been applied extensively in numerous research studies that investigate soft tissue morphology following surgery (Schutyser *et al.,* 2000; Chabanas *et al.,* 2003).

FEM has been shown to give an accurate representation when simulating deformations of biological tissues affected by maxillofacial surgery (Keeve *et al.,* 1996). However, the method is not particularly appropriate in surgical planning due to the computational power needed and its high memory usage (Mollemans *et al.,* 2007). For this deformation model to run at a reasonable speed special computers are needed with higher processing capabilities than is envisaged to be available on personal computers for some time (Sarti *et al.,*1999).

1.11.2 Mass Spring Model

To reduce the processing burden an alternative deformation model termed Mass Spring Model (MSM) has been developed (Teschner, 2001; Meehan *et al.,* 2003). In comparison to finite element models it has some important benefits. A considerable advantage of this model is the combination of a large number of ‘elements’, resulting in a better modelling accuracy along with a fast simulation time. A criticism of the

MSM is that it lacks a biomechanical foundation (Mollemans *et al.,* 2007). The 3D prediction software that is being validated with this research (3dMD Vultus, 3dMD, Atlanta, Georgia, USA) is itself based on the Mass Spring Model technique; its research and development team have previously described the software's Mass Spring Model algorithm as having a biomechanical basis without providing any evidence (Schendel and Lane, 2009).

Recently, Schendel *et al*. (2013) reported on the accuracy of the deformation mass springs used in 3dMD Vultus to predict post surgical soft tissue morphology. This study found an average difference of 0.27 mm between the simulated and actual soft tissue points, with the greatest difference found to be 0.6mm at the extremities of the mental fold (Schendel *et al.,* 2013). However the methodology of this study as discussed later is questionable.

1.11.3 Mass Tensor Model

In an attempt to overcome the perceived disadvantage of the mass spring model lacking a biological foundation, Cotin *et al*. (2000) investigated the possibility of a hybrid model that amalgamated both the FEM and MSM, which was later termed the Mass Tensor Model (Cotin *et al.,* 2000)

This deformation model has the simple architecture of the mass spring model but yet retains the biomechanical relevance of the finite element model. Moreover, the processing time is greatly reduced when compared to both the MSM and FEM (Mollemans *et al.,* 2007).

1.11.4 Validation of the different deformation models

Mollemans *et al* (2007) found the mass tensor model to have superior orthognathic planning prediction accuracy. The results demonstrated that the mass tensor model and finite element model predictions achieved the highest accuracy, but the mass tensor model was faster than any of the other model in processing time. The Mass Tensor Model is used in the algorithm of the Maxilim maxillofacial surgical planning program for which Mollemans is a key developer (Medicim, Medical Imaging Computing, Mechelen, Belgium).

Chapter Two

Aims and

Null Hypothesis

2. Aims and Null Hypothesis

2.1 Aim of the study

The aim of the study was to determine the accuracy and validity of 3dMD Vultus in predicting soft tissue morphology following Le Fort I maxillary advancements for correction of Class III skeletal relationships.

2.2 Null Hypothesis

The null hypothesis was that the mean difference between the soft tissue predictions simulated by 3dMD Vultus and the post-surgical soft tissue morphology of the subjects within this study is not different to 3mm, six months after orthognathic surgery at pre-defined anatomical regions of the face.

Chapter Three

Materials and Methods

3. Materials and Methods

3.1 Design of the study

The study was designed to validate the three dimensional (3D) soft tissue predictive ability of 3dMD Vultus, a software programme used for planning the correction of facial deformities. To ensure a homogenous subject population and reduce the number of possible confounding factors, only subjects with a class III malocclusion requiring a Le Fort I maxillary advancement were included in this study.

3.2 Ethical approval and Research and Development approval

Ethical approval was granted from the Proportionate Review Sub-committee of the East Midlands – Nottingham 1 NRES Committee. Reference number: 12/EM/0387 (Appendix 1).

Local NHS Research and Development approval was granted from Birmingham and the Black Country Comprehensive Local Research Network. Reference number: BCHCDent313.107279 (Appendix 2).

3.3 Sample size calculation

The required sample size was calculated to be 13 subjects using Minitab 16.2.4 (Minitab Inc., Coventry, United Kingdom), based on the following parameters:

- Power of 80%
- Significance level of 0.05
- A previous study found that the greatest variability associated with a landmark of interest to be soft tissue point at prognathion, which had a standard deviation of ±3.19 mm (Donatsky *et al.,* 2009).
- Jones *et al.* (2007) demonstrated that a 3mm change in soft tissue position was defined as clinically significant before it was noticed by a lay and expert panel.

A one sample *t*-test was used to test the null hypothesis that the mean absolute difference between the soft tissue mesh generated by 3dMD Vultus and the final soft tissue morphology of the patient, six months post orthognathic surgery is not different to 3mm.

3.4 Subjects

Permission was granted by NHS greater Glasgow and Clyde to access a database of Class III skeletal patients that had undergone a Le Fort I maxillary advancement from the Dentofacial Planning Clinic, Glasgow Dental Hospital and School.

The records of these patients had been used in a previous study investigating the accuracy of another orthognathic planning software called Maxilim (Shafi *et al.,* 2013).

All subjects had undergone orthognathic surgery under the care of one Consultant Oral and Maxillofacial Surgeon at the Southern General Hospital, Glasgow, UK.

3.4.1 Inclusion criteria

- Non syndromic adults
- Caucasian origin
- Class III skeletal relationship
- Correction by maxillary Le Fort I advancement only

3.4.2 Exclusion criteria

- Craniofacial defect or syndrome
- Significant facial asymmetry
- Previous osseous or soft tissue surgery to the facial region
- Bimaxillary surgery or additional procedures indicated i.e. genioplasty
- Distraction osteogenesis

3.5 Materials

Anonymised data received from the Dentofacial Planning Clinic, Glasgow Dental Hospital and School included cone beam computer tomography scans collected at two time intervals:

- T_1 - Pre surgical CBCT taken immediately prior to surgery.
- T_2 - Post surgical CBCT taken six months after orthognathic surgery.

3.5.1 Cone Beam Computer Tomography

Routine CBCT scans of each patient were taken at the Radiology Department, Glasgow Dental Hospital and School. The scans were taken with an Extended Field of View Option (EFOV 22cm) and a 0.4mm voxel size resolution, producing an over all scan time of 40 seconds at 120kV. Each CBCT image was taken by the same operator using the same i-CAT CBCT machine (Imaging Sciences International, Hatfield, PA, USA).

The protocol for the scan was:

- Remove any jewellery and hairpins.
- Use the high head band to support head.
- Teeth in centric occlusion – if there was evidence of over closure, a wax wafer taken in a rest position was used.
- Have the face and lips in repose.

The data files from the CBCT machine were stored in DICOM format (Digital Imaging and Communications in Medicine) on a secure centralised server. Following a request to Greater Glasgow and Clyde National Health Service for Scotland via the academic lead at Glasgow Dental Hospital and School it was agreed that the above data could be released provided all patient identifiable data was removed.

3.6 Method

The methodology followed to assess the validity and accuracy of 3dMD Vultus relied on the following stages.

- Determine the actual hard tissue change from T_1 to T_2.
    - Convert the CBCT images from volumetric data to surface data.
    - Align the 3D images at T_1 and T_2 for each patient on a stable structure.
- Use 3dMD Vultus to move the pre-operative hard tissue from its position at T_1 to T_2.
- Generate a soft tissue prediction as a result of the actual hard tissue change.
- Compare the 3dMD Vultus 3D soft tissue prediction to the actual 3D post-surgical soft tissue.

3.6.1 Determining the actual hard tissue change from T_1 to T_2.

Converting the CBCT images from volumetric data to surface data.

To determine the actual hard tissue change it was first necessary to superimpose the pre (T_1) and post surgical (T_2) images on structures not changing as a result of surgery i.e. the anterior cranial base, as surface images rather than volumetric data. For later analysis both the hard and soft tissue surface for each patient were segmented. As the hard and soft tissue at T_1 and T_2 were of the same patient taken at the same point in time, the data shared at each scan shared a common reference and would therefore be automatically aligned to one another by definition i.e. the soft tissue would be aligned to the hard tissue at T_1 as would the soft and hard tissue at T_2.

The pre (T_1) and post surgical (T_2) DICOM files were imported into 3dMD Vultus® 2.2.0 (3dMD, Atlanta, Georgia, USA) installed on a personal laptop computer (HP G6, Intel i5 Core processor) and the 3D soft and hard tissue surfaces were segmented using the default threshold levels in 3dMD Vultus (Figures 3.1-3.4). This process took approximately five minutes to build a pre-surgical and post-surgical 3D hard and soft tissue model for each subject. The surface files produced by this process were saved as STL files.

Figure 3.1 T$_1$ (Pre-surgical) soft tissue constructed from CBCT scan.

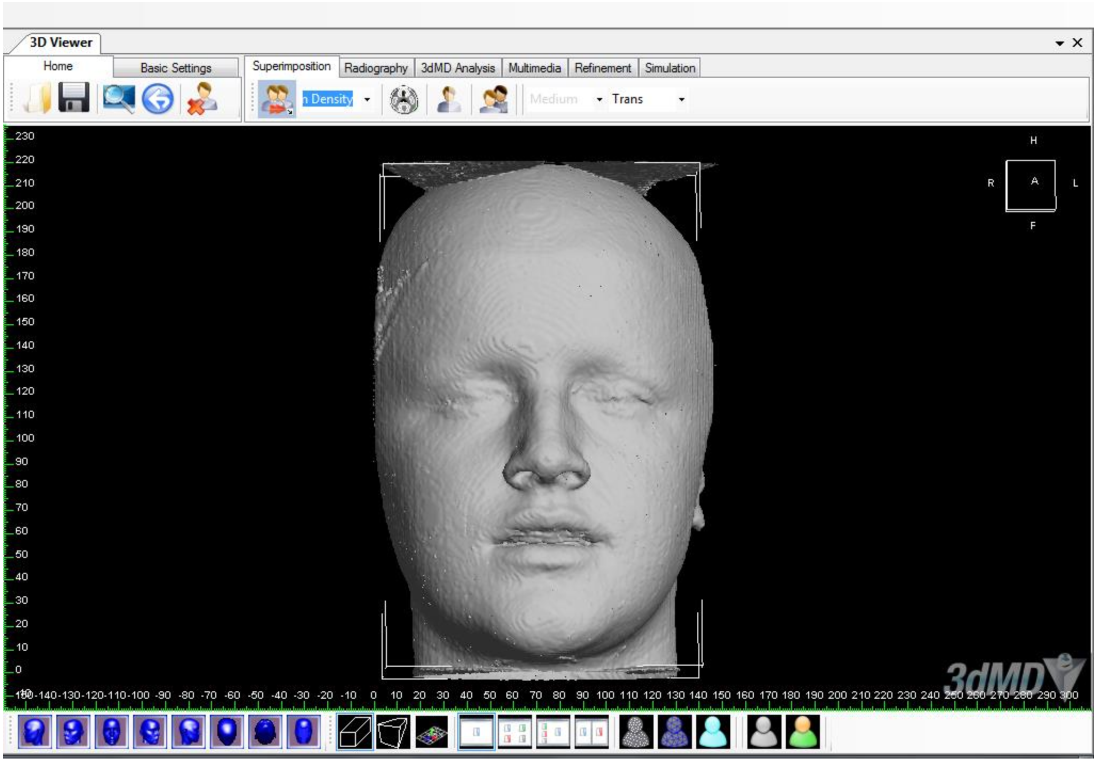


Figure 3.2 T$_1$ (Pre-surgical) hard tissue constructed from CBCT scan.

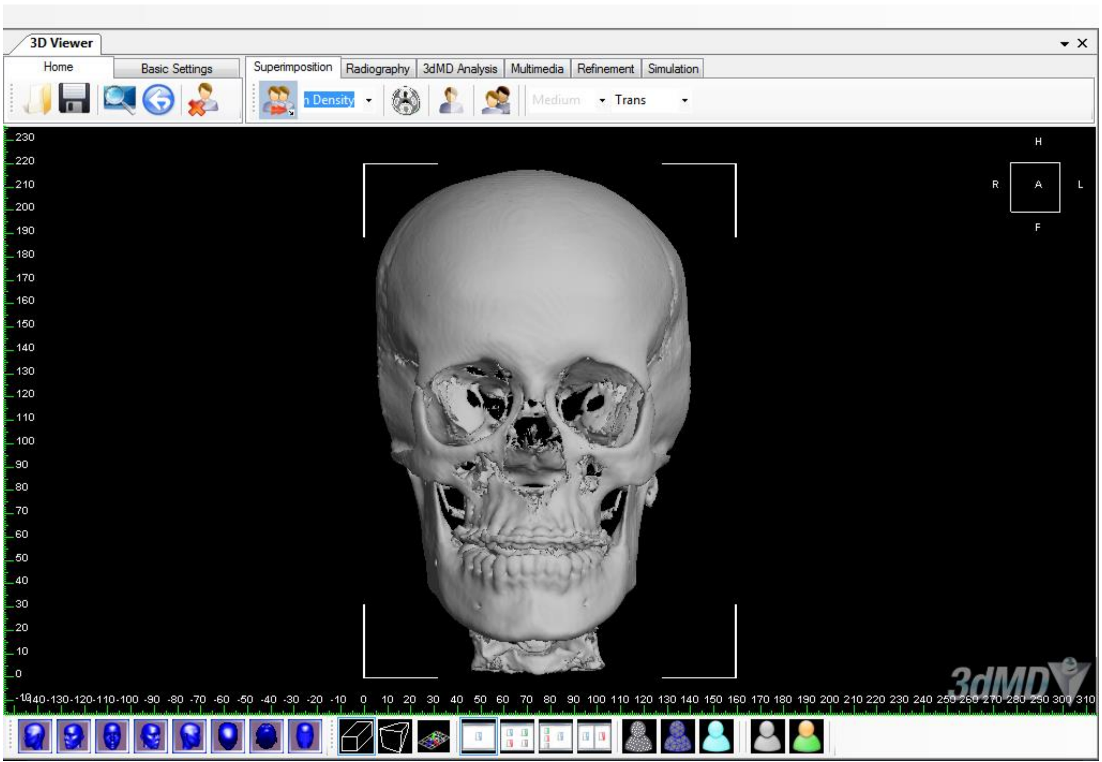


Figure 3.3 T_2 (Post-surgical) soft tissue constructed from CBCT scan.

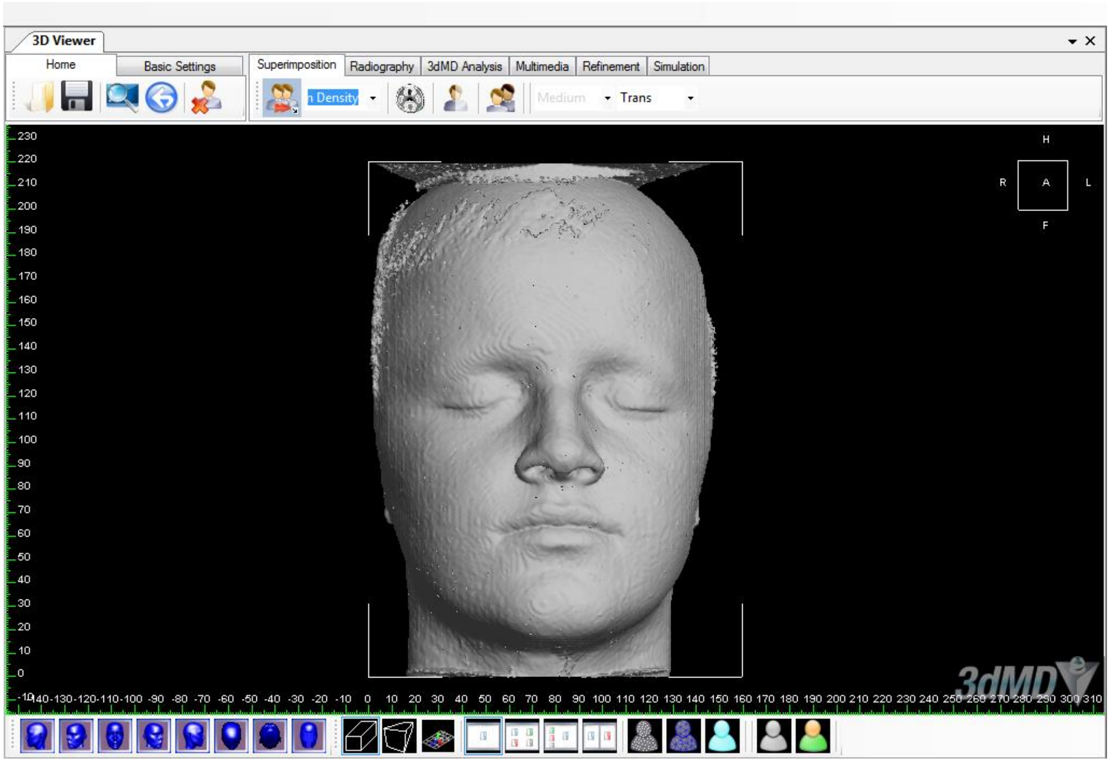
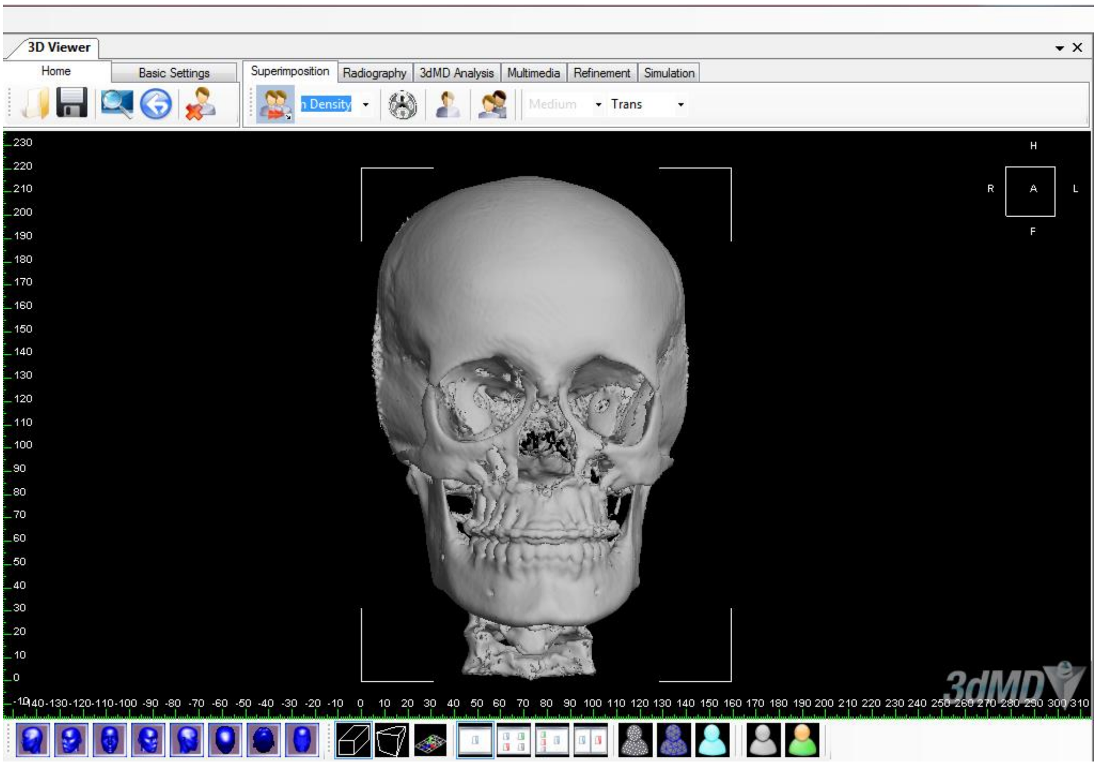


Figure 3.4 T_2 (Post-surgical) hard tissue constructed from CBCT scan.



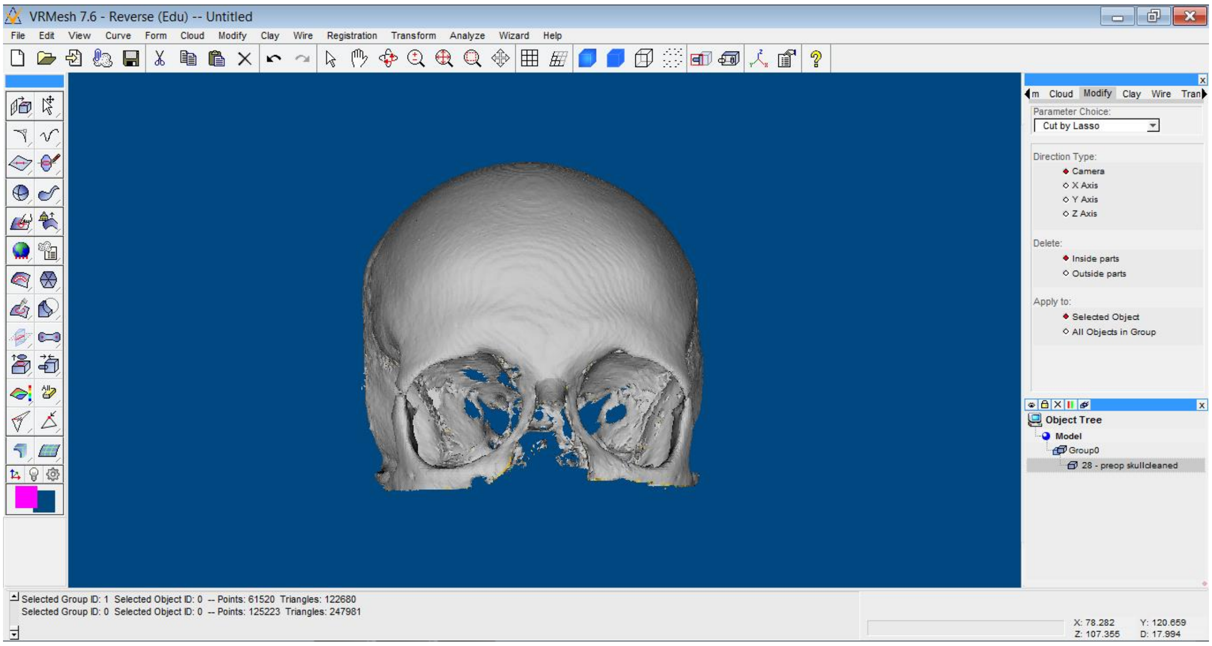
3.6.2 Aligning the 3D images at T_1 and T_2 for each patient on a stable structure

The data obtained from both time points (T_1 and T_2) could not be aligned with each other as at each time point the patient was in a slightly different position in the CBCT machine, and thus required T_1 and T_2 to be registered to one another on the anterior cranial base.

The STL files of the pre-operative and post-operative soft and hard tissues at T_1 and T_2 for each patient were imported into VRMesh Reverse® 7.6 - 3D point cloud and mesh processing software (VirtualGrid, Seattle City, WA, USA) installed on a personal laptop computer (ASUS X52F Intel i5 Core processor).

For each patient the soft tissue meshes were made "invisible" along with the hard tissue mesh at T_2 (actual post-surgical position) in VRMesh. The remaining hard tissue mesh at T_1 was cut to leave areas unaffected by surgery i.e. the forehead and cranial base to produce a "pre surgical hard tissue template", Figure 3.5. Any areas of the mesh that could effect superimposition were also removed, including scatter and incomplete sections.

Figure 3.5 Pre surgical hard tissue template construction.

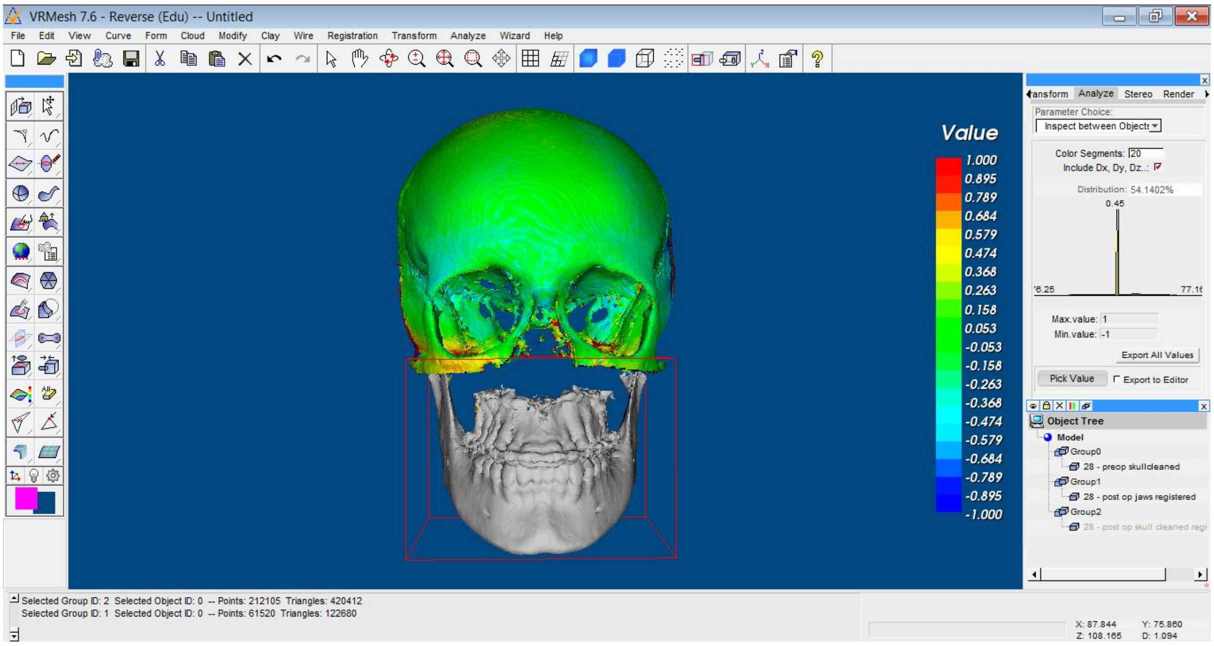


The corresponding post surgical hard tissue surface model was then made visible and superimposed onto the pre-surgical hard tissue template, using rigid registration. This involved selecting four corresponding points on the forehead (left and right zygomatico-frontal sutures and supra-orbital foramen) and a point on the anterior cranial base (crista galli) on both the images and translating and rotating them until they were aligned on the selected landmarks. This was followed by refined mesh registration using the Iterative Closest Point (ICP) alignment method. This process moved both the T_2 soft and hard tissue meshes to the same 3D space as the T_1 soft and hard tissue meshes. The superimposition of the surfaces meshes were checked for accuracy by measuring the distance between the post surgical and the pre-surgical hard tissue template model. The distance between the surfaces was represented as a colour error map. An acceptable tolerance between the meshes was set to ±0.5mm. Following this the soft and hard tissues at T_1 were grouped together.

3.6.3 Registered maxillary and mandibular templates for surgical prediction

The maxilla and mandible of the post surgical hard tissue mesh were isolated and exported from VRMesh as an STL file. This would produce a template to which the pre-surgical maxilla and mandible will be moved to in the next step, Figure 3.6. The previous step had moved the T_2 hard tissue to the T_1 3D space.

Figure 3.6 Final post-surgical position of the maxilla and mandible realigned to the pre surgical frame of reference.



3.6.4 Computer prediction by 3dMD Vultus

The pre-surgery hard tissue (T_1) CBCT DICOM file was then imported into 3dMD Vultus together with the template to which to move the pre-surgical maxilla and mandible previously constructed and virtual surgery was undertaken with a Le Fort 1 osteotomy. 3dMD Vultus allows movements of surgical bony sections in all three planes of space. Using this function, the pre surgical maxillary bony section was moved and matched to the post surgical STL maxillary template.

The superimposition of the meshes was checked for accuracy by exporting the pre surgical maxilla as a STL file together with the post surgical maxillary template, and using the comparison analysis tool in VRMesh. This was repeated until the registration accuracy of the two superimposed meshes could not be improved further; again acceptable tolerance between the meshes was set to ±0.5mm.

The pre surgical mandibular mesh was then matched by autorotation, if it had occurred, to the post surgical mandibular template. The superimposition of the meshes was again checked using the “compare objects” function in VRMesh for accuracy. This assessment included viewing the match of the meshes of the right ramus, left ramus along with the left and right body of the mandible and the chin. Any scatter or differences over the dentition were disregarded with the aim of achieving the best match possible over the bony surfaces. This was repeated until the registration accuracy of the two superimposed meshes could not be improved further; again acceptable tolerance between the meshes was set to ±0.5mm, Figures 3.7 to 3.12.

Once the pre-surgical maxillary and mandibular section were positioned as accurately as possible to the post-surgical position, a new overlying soft tissue prediction model was produced. This soft tissue prediction mesh was then exported as a STL file to be analysed by VRMesh, Figures 3.13 to 3.13.

Figure 3.7 Following osteotomy cuts – mass spring model enabled to allow surgical movements and profile prediction - Profile view.

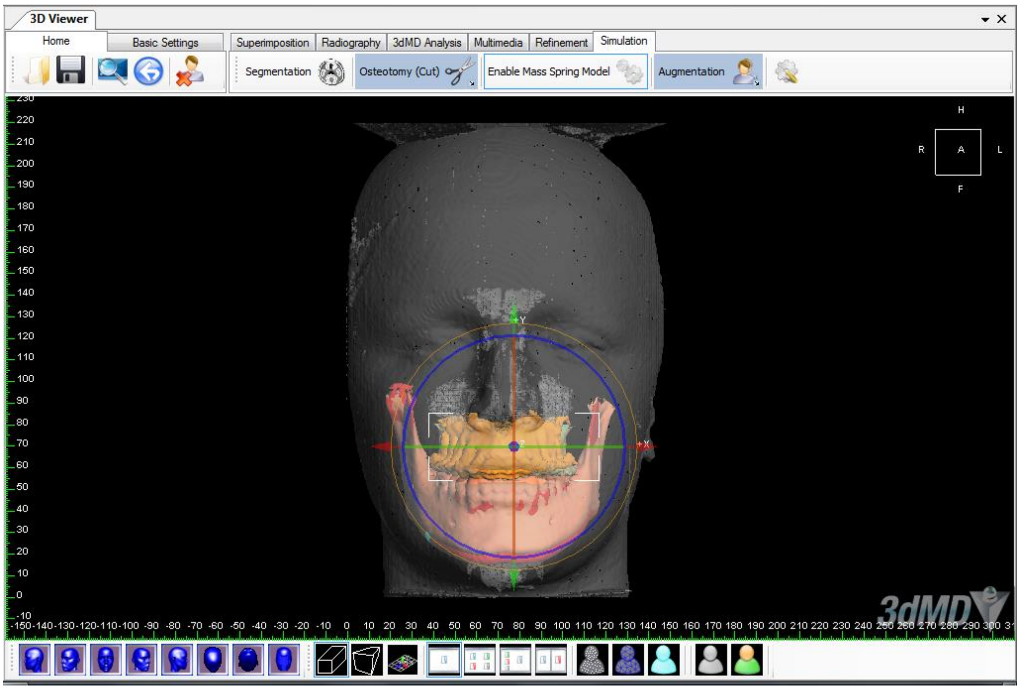


Figure 3.8 Following osteotomy cuts – mass spring model enabled to allow surgical movements and profile prediction - 3/4 view.

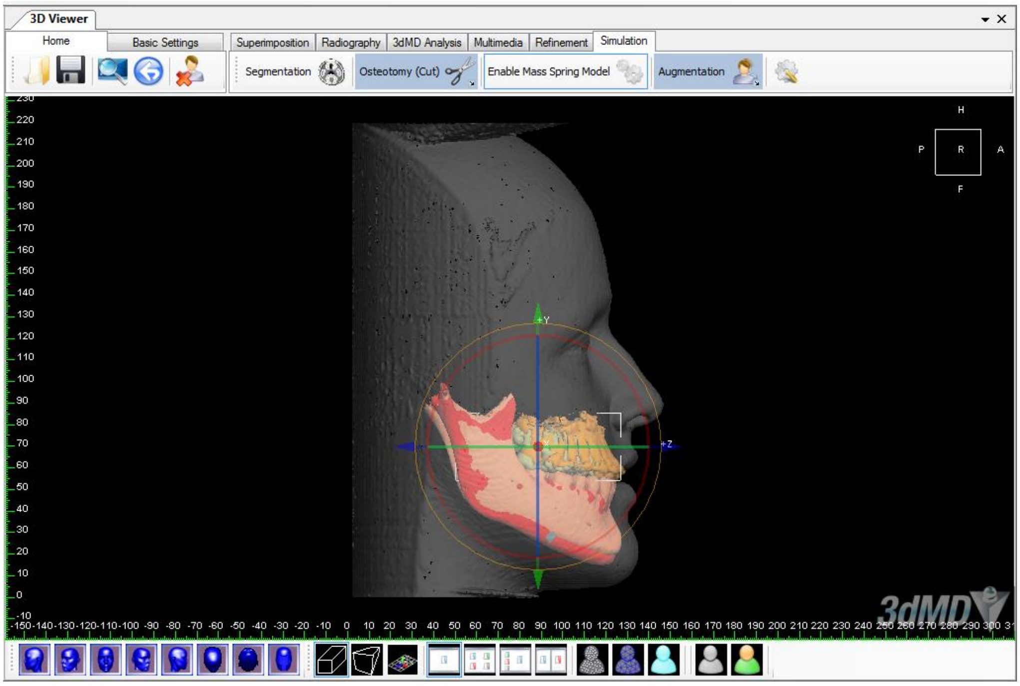


Figure 3.9 Following virtual surgery – matching pre-surgical skeletal position to post-surgical (registered) position – Profile view.

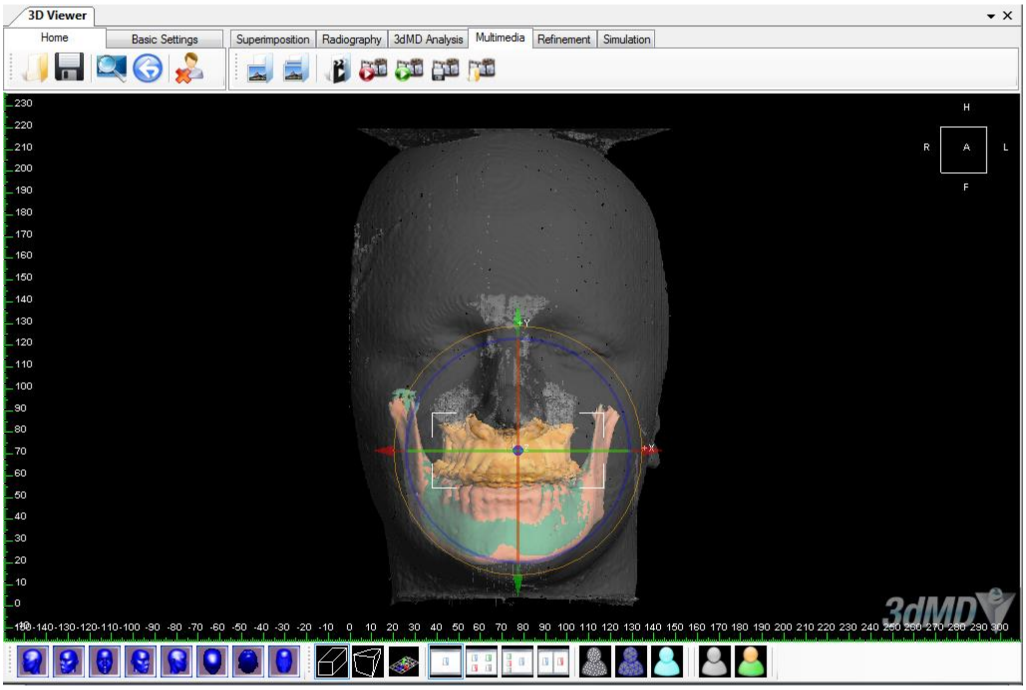


Figure 3.10 Following virtual surgery – matching pre-surgical skeletal position to post-surgical (registered) position – 3/4 view.

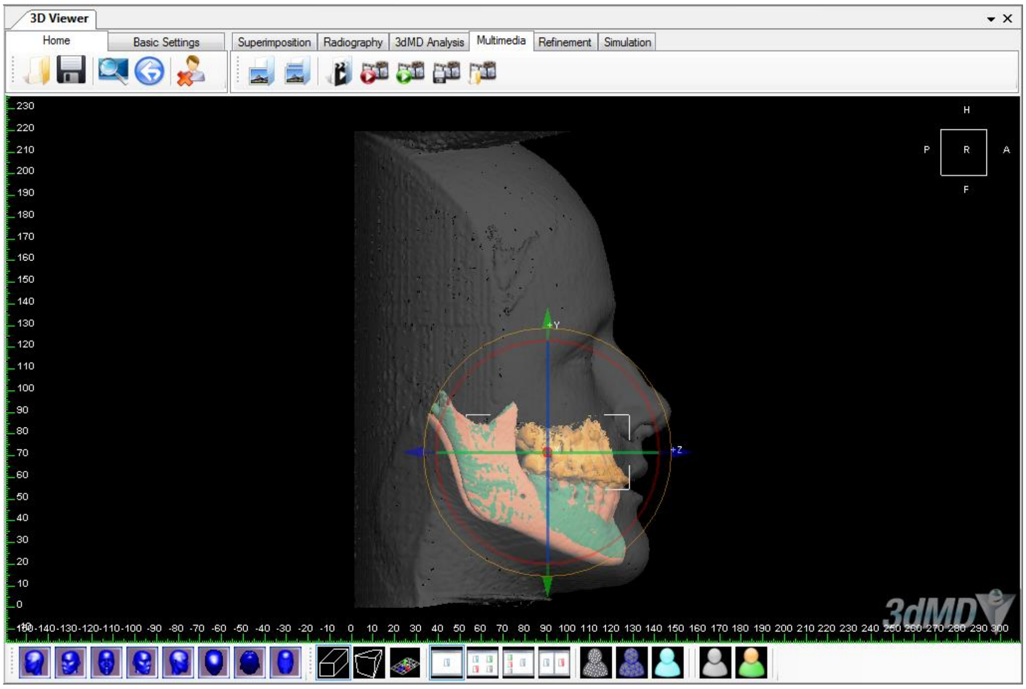


Figure 3.11 Assessment of accuracy of Maxillary repositioning - until positioning could be improved no further.

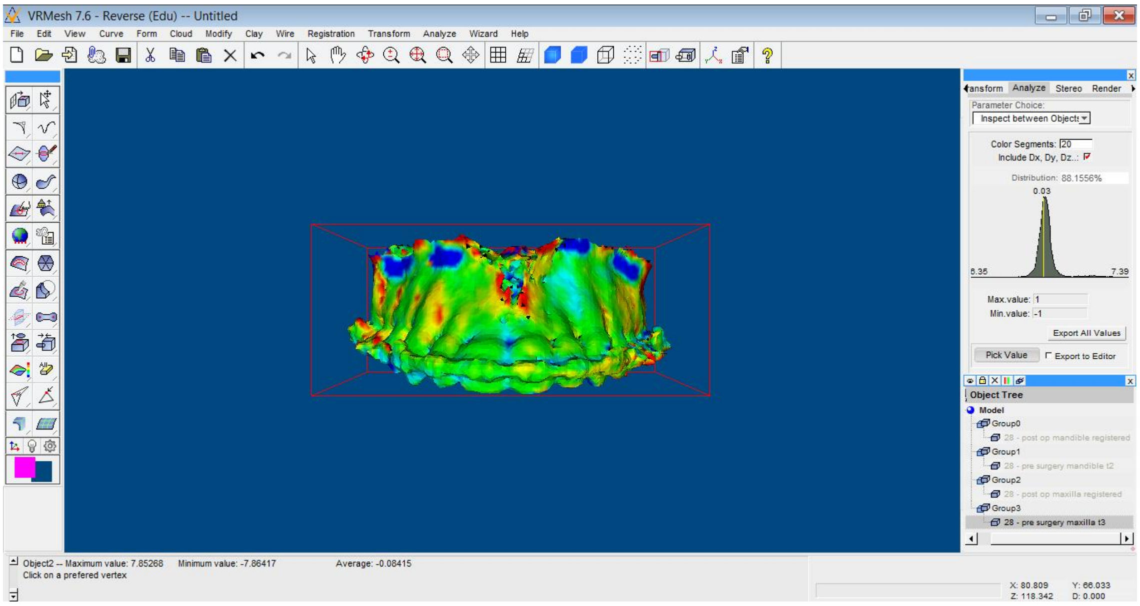


Figure 3.12 Assessment of accuracy of Mandibular repositioning - until positioning could be improved no further.

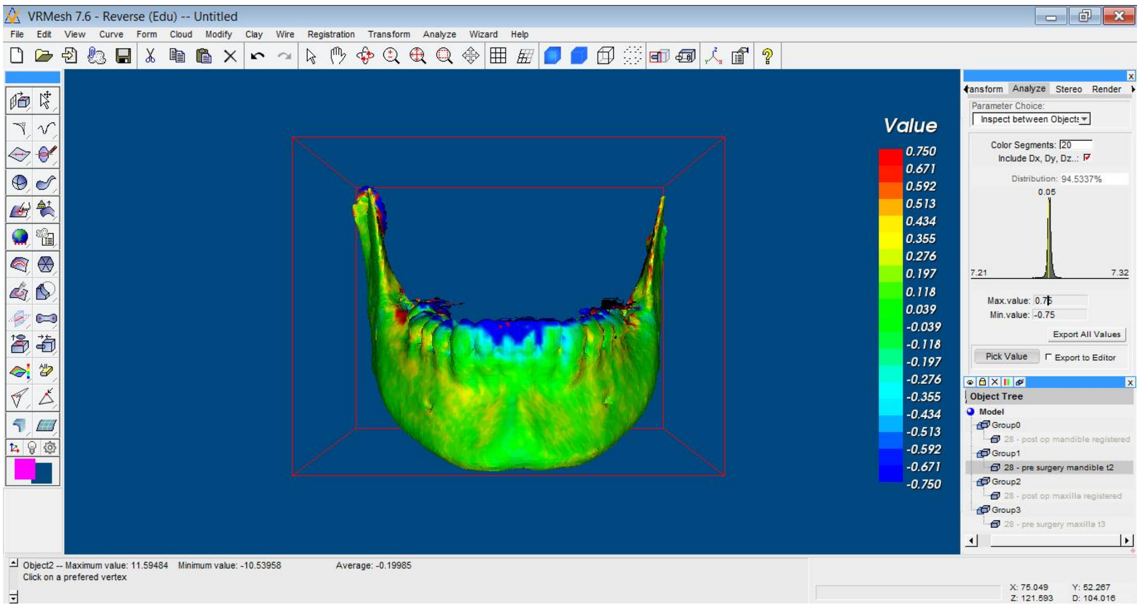


Figure 3.13 Predicted soft tissue as constructed by 3dMD Vultus following virtual surgery.

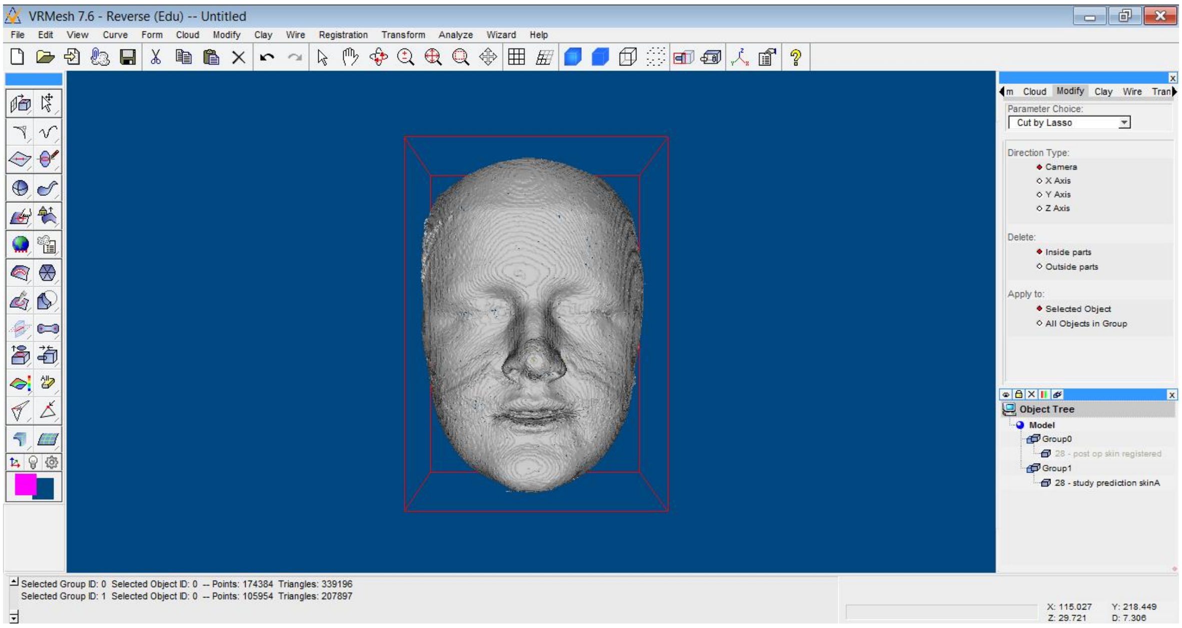
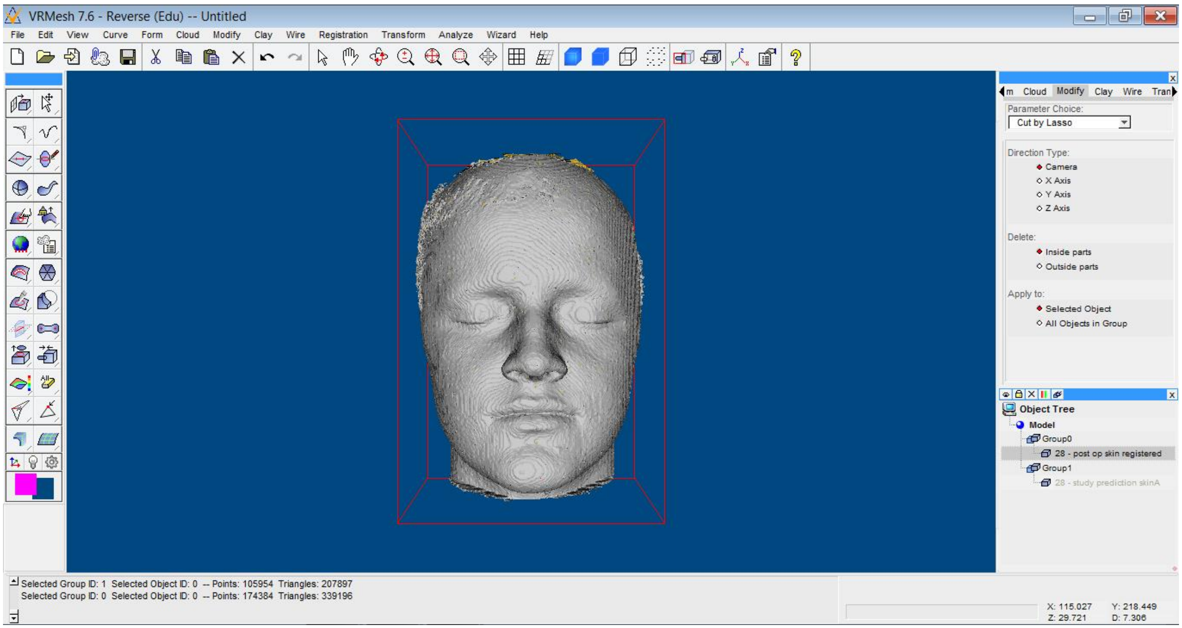


Figure 3.14 Actual soft tissue as thresholded from CBCT by 3dMD Vultus.



3.6.5 Accuracy of 3dMD Vultus soft tissue prediction

After importing the soft tissue prediction mesh generated by 3dMD Vultus, the actual surgical post-op mesh which had been registered in step 3.5.1 was also imported. Using the "compare objects" function, a colour map was generated by VRMesh, which allowed the operator to view the overall predictive accuracy of 3dMD Vultus.

3.6.6 Regional anatomical division of soft tissue prediction

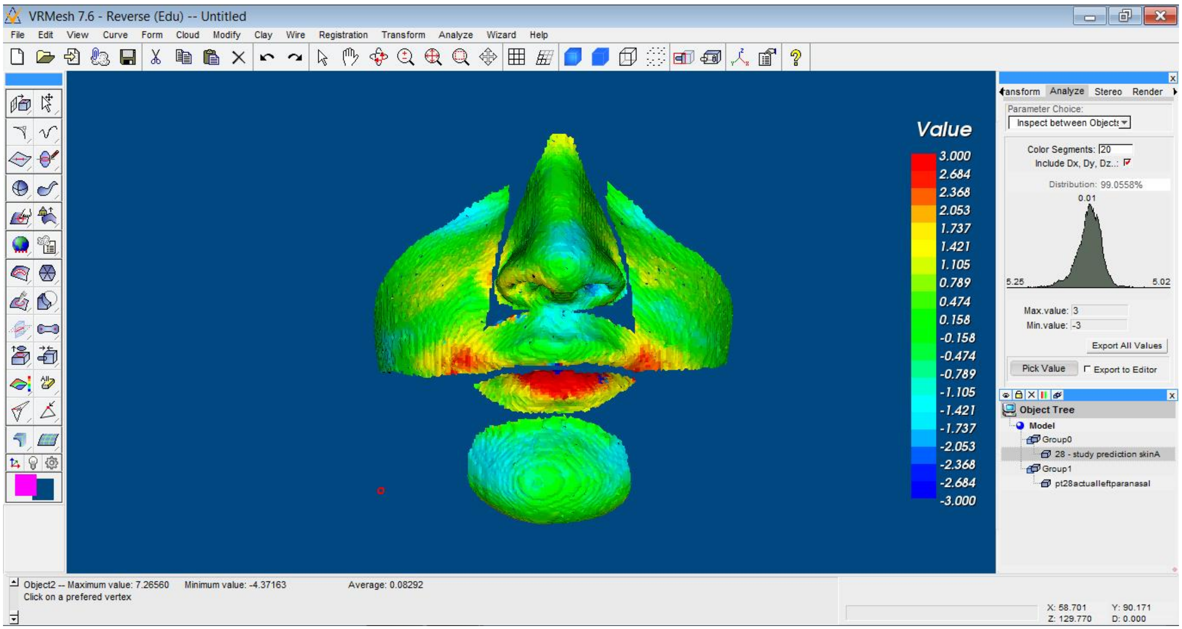
The superimposed 3dMD Vultus soft tissue prediction mesh and the registered actual post-surgical soft tissue mesh were divided into regional anatomical sections in VRMesh. The anatomical regions were the chin, lower lip, upper lip, nose, right nares, left nares, right paranasal and left paranasal areas (Table 3.1). If the prediction was perfect then 100% of the points between the meshes should be 0mm apart from one another. An example of the percentage of points for one patient that were within a tolerance ± 3.0mm is shown in Figure 3.15.

The STL superimposed regions for each patient were exported from VRMesh as VRML files (Virtual Reality Modelling Language) and imported into a custom built software package which calculated the minimum and maximum distances between 90% of the mesh points, the absolute mean and the standard deviation for 90% of the mesh points.

Table 3.1 Anatomical regions of soft tissue used to compare 3dMD soft tissue prediction and actual post surgical soft tissue.

Anatomical Region	Description of soft tissue area
Chin	Sublabiale - $Chelion_R$ (perpendicular at level of Pogonion) - $Chelion_L$ (perpendicular at level of Pogonion) - Gnathion
Lower Lip	$Chelion_R$ - $Chelion_L$ - Stomion – Sublabiale
Upper Lip	Subnasale - $Chelion_R$ - $Chelion_L$ – Stomion
Nose	Nasion - $Maxillofrontale_R$ - Subnasale - Nostril base $point_R$ - Nostril base $point_L$ - $Maxillofrontale_L$
Right Nares	Nostril base $point_R$ - Alare curvature $point_R$
Left Nares	Nostril base $point_L$ - Alare curvature $point_L$
Right Paranasal	$Endocanthion_R$ - $Chelion_R$ - $Gonion_R$
Left Paranasal	$Endocanthion_L$ – $Chelion_L$ – $Gonion_L$

Figure 3.15 Accuracy of 3dMD Vultus predicted soft tissue with the actual post-surgical soft tissue at the predetermined anatomical regions represented as a “colour error map”.



3.7 Error Study

The validity and reproducibility of the method was assessed by an error study. Each patient was assigned a number from one - thirteen. Using on-line software (www.random.org), six patients were randomly selected two weeks later and the whole methodology repeated as previously described (sections 3.5 to 3.5.6).

3.8 Statistical methods and analyses

The measurements in millimetres were analysed using Minitab 16.2.4 (Minitab Inc., Coventry, United Kingdom). Intra-class correlation coefficients (ICC) were used to determine intra-rater agreement for each soft tissue prediction attempt. A one-sample t-test was used to determine if in each anatomical region the mean absolute distance between the actual and predicted surface meshes were not significantly different from 3.0mm (Jones *et al.,* 2007).

Results

4 Results

During this study, 13 anonymous patient sets of CBCT data were analysed and processed with virtual orthognathic surgery developed by 3dMD Vultus surgical planning software. The mean maxillary surgical advancement was 5.5mm ± 2.2mm with minimum vertical and rotational change.

4.1 Error study

The results of the error of the soft tissue methods superimposition are presented:

Table 4.1 Reproducibility of soft tissue prediction surface mesh.

Anatomical Region	**Intra-class correlation coefficient.**
Chin	0.94
Lower Lip	0.98
Upper Lip	0.93
Nose	0.95
Right Nares	0.99
Left Nares	0.99
Right Paranasal	0.87
Left Paranasal	0.99

Table 4.1 shows the ICC ranged from 0.87 to 0.99 for the reproducibility of soft tissue superimposition. Precision and reproducibility in data obtained is important in orthodontics, Sayinsu *et al*. (2007) categorised an ICC of 0.75 or above as good and above 0.9 to be excellent.

4.2 Regional division of soft tissue prediction

Tables 4.2 to 4.9 show regional divisions of soft tissue prediction results for the chin, lower lip, upper lip, nose, right nares, left nares, right paranasal and left paranasal.

4.2.1 Chin

Table 4.2 shows the distances between the 3dMD Vultus predicted soft tissue mesh and the patient's actual soft tissue following maxillary advancement for the region previously defined as the soft tissue chin region.

The mean absolute maximum distance for 90% of the mesh points was 1.45mm ± 0.63mm (range 0.8mm to 2.8mm). The mean absolute distance of these measurements was 0.65mm ± 0.28mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.48mm to 0.81mm.

4.2.2 Lower lip

Table 4.3 shows the distances between the soft tissue prediction and the actual soft tissue result following maxillary surgery in the region of the lower lip.

The mean absolute maximum distance between 90% of the mesh points was 2.36mm ± 1.23mm (range 0.9mm to 5.1mm). The mean absolute distance of these measurements was 1.09mm ± 0.54mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.76mm to 1.42mm.

4.2.3 Upper lip

The distances between the 3dMD Vultus soft tissue prediction and the patient's actual soft tissue following maxillary advancement for the region of the upper lip soft tissue is shown in Table 4.4.

The mean absolute maximum distance between 90% of the mesh points was 2.43mm ± 0.7mm (range 1.2mm to 3.4mm). The mean absolute distance of these measurements was 1.17mm ± 0.49mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.87mm to 1.46mm.

4.2.4 Nose

The distances between the predicted and the patient's actual soft tissue following maxillary advancement for the region previously representing the soft tissue nose is shown in Table 4.5.

The mean absolute maximum distance between 90% of the mesh points was 2.35mm ± 0.86mm (range 1.2mm to 4.3mm). The mean absolute distance of these measurements was 0.73mm ± 0.19mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.62mm to 0.84mm.

4.2.5 Right nares

The distances between the predicted soft tissue and the patient's actual soft tissue following surgery for the region defined as the right nares is shown Table 4.6.

The mean absolute maximum distance for 90% of the mesh points was 2.29mm ± 0.69mm (range 1.1mm to 3.6mm). The mean absolute distance of these measurements was 0.85mm ± 0.29mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.68mm to 1.03mm.

4.2.6 Left nares

Table 4.7 shows the distances between the predicted soft tissue and the patient's actual soft tissue following surgery for the region defined as the left nares.

The mean absolute maximum distance between 90% of the mesh points was 2.17mm ± 0.66mm (range 1.1mm to 3.5mm). The mean absolute distance of these measurements was 0.91 ± 0.34mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.70mm to 1.11mm.

4.2.7 Right paranasal

Table 4.8 shows the distances between the predicted soft tissue and the patient's actual soft tissue following maxillary advancement for the right paranasal region.

The mean absolute maximum distance for 90% of the mesh points was 2.31mm ± 0.78mm (range 1.2mm to 3.9mm). The mean absolute distance of these measurements was 0.98mm ± 0.39mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.75mm to 1.22mm

4.2.8 Left paranasal

Table 4.9 shows the distances between the predicted and the patient's actual soft tissue following maxillary advancement for the left paranasal region.

The mean absolute maximum distance including 90% of the mesh points was 2.27mm ± 0.9mm (range 1mm to 4.7mm). The mean absolute distance of these measurements was 0. 95mm ± 0.32mm.

A one-sample t-test comparing this mean to the hypothesized mean of 3.0mm showed a statistically significant difference, $p<0.001$ (Table 4.10). The 95% confidence interval for this difference ranged from 0.75mm to 1.14mm.

Table 4.2 Regional anatomical division of soft tissue prediction – Chin.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2	0.7	0.6
2	1	0.5	0.3
3	2.3	0.9	0.6
4	0.8	0.4	0.2
5	0.9	0.4	0.2
6	1.2	0.5	0.3
7	2.8	1	0.7
8	1.2	0.5	0.3
9	1.2	0.6	0.3
10	1.7	0.7	0.4
11	1.9	1.3	0.4
12	1.1	0.6	0.3
13	0.8	0.3	0.2

Table 4.3 Regional anatomical division of soft tissue prediction – Lower Lip.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2.7	1.6	0.8
2	2.3	1.2	0.7
3	2.2	1.0	0.6
4	0.9	0.4	0.2
5	1.0	0.5	0.3
6	1.5	0.7	0.4
7	2.6	1.4	0.8
8	2.9	1.3	0.6
9	1.4	0.8	0.4
10	1.3	0.7	0.4
11	4.2	2.4	1.1
12	2.6	1.4	0.7
13	5.1	1.2	1.1

Table 4.4 Regional anatomical division of soft tissue prediction – Upper Lip.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	3.2	2.1	0.7
2	1.2	0.5	0.3
3	3.4	2.0	0.8
4	1.5	0.7	0.4
5	2.0	0.6	0.4
6	2.2	1.2	0.5
7	3.2	1.4	0.9
8	2.1	0.8	0.6
9	3.4	1.4	0.9
10	2.2	1.1	0.6
11	2.2	1.1	0.6
12	2.6	1	0.7
13	2.4	1.3	0.7

Table 4.5 Regional anatomical division of soft tissue prediction – Nose.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2.3	0.7	0.5
2	3.3	0.7	0.8
3	4.3	1.0	1.1
4	1.4	0.5	0.4
5	1.8	0.7	0.5
6	2.9	0.9	0.7
7	2.5	0.8	0.6
8	1.2	0.4	0.3
9	1.4	0.5	0.3
10	2.0	0.7	0.5
11	2.3	0.9	0.6
12	2.4	0.7	0.6
13	2.8	1.0	0.9

Table 4.6 Regional anatomical division of soft tissue prediction – Right Nares.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2.7	0.9	0.7
2	1.7	0.6	0.4
3	3.6	1.0	0.8
4	2.8	0.9	0.8
5	2.1	1.1	0.5
6	2.3	0.8	0.6
7	3.2	0.9	0.8
8	1.1	0.3	0.3
9	2.3	1.0	0.6
10	2.1	0.7	0.6
11	1.4	0.6	0.4
12	2.0	0.8	0.4
13	2.5	1.5	0.9

Table 4.7 Regional anatomical division of soft tissue prediction – Left Nares.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2.2	0.9	0.5
2	1.7	0.6	0.5
3	3.5	1.2	0.7
4	2.5	1.0	0.7
5	1.8	0.7	0.5
6	1.9	0.7	0.5
7	2.3	0.6	0.5
8	1.1	0.4	0.3
9	2.9	1.3	0.8
10	2.0	0.7	0.5
11	2.8	1.6	0.7
12	1.9	1.2	0.5
13	1.7	0.9	0.5

Table 4.8 Regional anatomical division of soft tissue prediction – Right Paranasal.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2.6	1.5	0.6
2	1.9	0.9	0.5
3	1.6	0.8	0.4
4	3.9	1.7	0.9
5	2.1	0.8	0.6
6	2.2	0.7	0.6
7	3.1	1.6	0.9
8	1.2	0.5	0.3
9	3.4	0.9	0.9
10	1.8	0.8	0.4
11	1.7	0.7	0.4
12	2.6	1.2	0.7
13	1.9	0.7	0.5

Table 4.9 Regional anatomical division of soft tissue prediction – Left Paranasal.

Patient	Maximum distance between 90% of mesh overlap (mm)	Mean distance between 90% of mesh overlap (mm)	Standard Deviation
1	2.9	1.5	0.7
2	1.6	0.7	0.4
3	1.9	1	0.5
4	2.4	0.8	0.5
5	1.8	0.7	0.5
6	2.1	0.8	0.6
7	2	1	0.6
8	1	0.4	0.2
9	4.7	1.5	1.3
10	2.1	0.9	0.6
11	1.7	0.9	0.4
12	3	1.3	0.8
13	2.3	0.8	0.6

Table 4.10 A one-sample t-test to determine if in each anatomical region the mean distance between the predicted and actual surface meshes is not different to 3.0mm.

Anatomical Region	Mean distance between 90% of mesh overlap (mm)	Standard Deviation	95% Confidence Interval		P Value
			Lower Limit	Upper Limit	
Chin	0.65	0.28	0.48	0.81	P<0.001
Lower Lip	1.09	0.54	0.76	1.42	P<0.001
Upper Lip	1.17	0.49	0.87	1.46	P<0.001
Nose	0.73	0.19	0.62	0.84	P<0.001
Right Nares	0.85	0.29	0.68	1.03	P<0.001
Left Nares	0.91	0.34	0.70	1.11	P<0.001
Right Paranasal	0.98	0.39	0.75	1.22	P<0.001
Left Paranasal	0.95	0.32	0.75	1.14	P<0.001

Chapter Five

Discussion

5 Discussion

5.1 Accuracy of 3dMD Vultus

The aim of the present study was to determine the accuracy and validity of 3dMD Vultus in predicting the position of the soft tissues in all three dimensions, following Le Fort I osteotomy.

5.2 Subjects

It has been well documented that both the maxillary and mandibular soft tissues respond differently to hard tissue movements following orthognathic surgery with the maxillary soft tissue response being less predictable (Hunt and Rudge, 1974; Friede *et al.,* 1987; Magro-Filho *et al.,* 2010). Given the varied nature of the soft tissue response following maxillary surgery this study set out to obtain a homogenous subject group and thereby reduce the number of possible variables that would influence the outcome.

The subjects recruited all presented with Class III skeletal patterns treated with pre surgical orthodontics and orthognathic surgical correction limited to a Le Fort I maxillary advancement.

The study sample was selected through the use of careful inclusion and exclusion criteria. For example, patients with a history of previous skeletal or soft tissue surgery to their facial soft tissue were excluded as were cleft lip and/or palate patients: in these individuals the response of the soft tissues could potentially have be affected by previous surgery and any scarring that may have occurred.

5.3 Statistical Parameters

The results of a previous study had shown that a 3mm change in the position of the facial soft tissue was necessary before it was detected by laypeople and by an expert panel (Jones *et al.,* 2007). The assumption was therefore made that if the difference between the 3dMD Vultus soft tissue prediction and the patients actual post-surgery soft tissue position was less than 3mm it would not be clinically significant for the purpose of this study.

A one-sample *t*-test was used to test the null hypothesis that the mean difference between the 3D soft tissue predicted by 3dMD Vultus and the actual post-surgical 3D soft tissue mesh of the patient was not different to 3mm.

From the current literature, he greatest variability associated with a landmark of interest was found to have a standard deviation of ±3.19 mm, this was related to the horizontal position of soft tissue gnathion (Donatsky *et al.,* 2009). Setting a significance level of 0.05 and a power of 80%, resulted in a minimum sample size of 12 subjects in order to detect a 3mm change. A sample of thirteen patients was therefore recruited to this study to ensure detection of a clinical significance if one existed.

5.4 Methodology

5.4.1 Use of CBCT Imaging

Cone Beam CT images capture the hard and soft tissue in all three planes of space simultaneously. However, CBCT does not always accurately capture the dental structures. Any metallic material such as amalgam restorations or fixed appliances produce artefacts in the field of view and thus reduce the diagnostic value of the scan if it interferes with an area of interest, these are commonly known as “streak artefacts”. CBCT images show the hard tissue surfaces well and are therefore excellent for displaying changes in hard tissue. The soft tissue acquisition is however not ideal, lacking texture and colour.

5.4.2 Registering 3D images

Software programs designed for registering 3D stereophotogrammetric images and CBCT images have built-in functions for superimposition of mesh models using either operator selected landmarks or surface based areas on the soft tissue. A problem arises however as soft tissue structures are not stable enough to serve as accurate references for superimposition (Cevidanes *et al.,* 2010).

This causes difficulty in accurately registering 3D soft tissue stereophotogrammetric images to CBCT soft tissue mages (Khambay *et al.,* 2002). Stereophotogrammetric images and CBCT images obtained independently one after the other, show registration errors which are reasonably large in the regions lateral to the neck, mouth and around the eyes, with approximately 90% of the total registration error located in these anatomical areas (Maal *et al.,* 2008). A way of overcoming these problems is to have the simultaneous acquisition of CBCT and 3D photographs, which has been experimentally shown to reduce the registration error but unfortunately not eliminate it entirely (Naudi *et al.,* 2013).

Until CBCT and 3D photographs can be acquired simultaneously, the use of fiducial markers for both CBCT and 3D stereophotogrammetric image acquisition has been advocated to decrease errors in registrations, however, these markers can not control for soft tissue distortions caused by different facial expressions and positioning during the image acquisition (Cevidanes *et al.,* 2010). Fiducial markers have been defined as external points used in 3D images and subsequently used for registration (Maurer *et al.,* 1997).

As the superimposition of CBCT scans and stereophotogrammetry can introduce another source of error, for the purpose of this study only the CBCT scan was used and no soft tissue image superimposition was attempted. This methodology was employed by Cevidanes *et al.* (2005) who found that the superimposition of pre and post operative CBCT models of orthognathic surgery patients is a valid and reproducible technique, ideally suited to examining treatment outcomes.

5.4.3 Positioning the patient

There is currently no standardised patient position used for CBCT and 3D stereophotogrammetric acquisition. During CBCT scanning, the patients' head is commonly held in a fixed position with either a strap on the forehead or a chin support.

However close analysis of the soft tissue outline indicates that the chin support distorts the tissues around the chin, and should be avoided. Likewise the forehead strap if possible should also not be used when looking to record fine soft tissue changes (Cevidanes *et al.,* 2010).

5.4.4 Clinical Limitations

For this research there was a significant amount of time spent collating, processing and verifying data which would undoubtedly make this whole process unsuitable for routine clinical use.

It has been suggested that imaging technicians with a maxillofacial background could be trained to carry out the process of virtual surgery on prescription from a surgeon and/or orthodontist in an analogous manner as to how model surgery is carried out currently or trained technicians could be used for some of the stages prior to planning (Paul Thomas, Dolphin Imaging).

We have certainly entered an extremely fascinating time in orthognathic surgical planning with huge advances in technology driven by many research teams around the globe. To date several authors have reported techniques in which CAD/CAM technology obviates the need for model surgery completely: instead surgical splints are constructed from the three dimensional surgery simulations. (Metzger *et al.,* 2008; Schendel & Jacobson, 2009; Swennen *et al.,* 2009; Quevedo *et al.,* 2011; Centenero and Hernández-Alfaro, 2012).

5.4.5 Superimposition on the anterior cranial base and forehead

In order to assess 3D surgical outcomes when comparing pre and post-surgical scans, both data sets have to be registered using reference landmarks and stable structures.

In 2D cephalometrics it has been found that the anterior cranial base shows very minimal change after seven years of age when the spheno-ethmoidal synchrondosis fuses, providing a stable reference for superimpositions (de Coster, 1951). Landmark location in 2D can be difficult; however locating landmarks in 3D is considerably more demanding.

Superimposition should not rely solely on landmark identification or best fit procedures on structures as these may have changed between image acquisitions (Shafi 2013). More stable structures such as, superimposition of the hard tissues on the anterior cranial base and vault are more appropriate and were selected for this study. A key advantage of the superimposition method used in this study is that registration process does not depend on the accuracy of a single user placed landmark but relies on the complex topography of the surface.

5.5 Results

Currently in the literature there are four similar studies assessing the validity of a 3D orthognathic surgical planning software systems, two of which were published very recently.

Bianchi *et al*. (2010) and Marchetti *et al*. (2011), from the same research team based at the Oral and Maxillofacial Surgery Unit of S. Orsola Malpighi University Hospital (Bologna, Italy) validated the accuracy of SurgiCase CMF Pro 1.2 (Materialise, Leuven, Belgium). Each study was based on a series of 10 consecutive patients and assessed the validity of the resultant soft tissue prediction (Bianchi *et al.,* 2010; Marchetti *et al.,* 2011).

As in the present study, both of these studies used the absolute mean error as a measure of the superimposition of the meshes. This was undertaken as the superimposition assessment outcome of comparing the meshes could have both positive and negative values. Hence the statistical mean of these results would cancel each other out. Other similarities in the method include the use of superimposition on the forehead for the hard and soft tissue between the actual and virtual prediction results. There was however no discussion regarding the error of the method in the predicted surgical movements. Furthermore, both studies used imaging equipment which imaged the patient in a supine position. This would have affected the soft tissue drape of the patients (Khambay *et al.,* 2002; Kau, *et al.,* 2005), any effect this may have had was unfortunately not discussed. Another major difference was that unlike the homogenous cohort used within this study, the surgical procedures were bimaxillary, with some subjects undergoing an adjunctive genioplasty and others having planned vertical changes, thus involving a more heterogeneous sample in terms of surgery carried out..

For these studies comparisons were made for the whole of the soft tissues of the face, and not regional anatomical areas. This method of analysis does not highlight areas of specific concern in prediction but produces an overall global error which may distort the results. Accepting these dissimilarities, the average absolute error of soft tissue prediction accuracy for Bianchi *et al.* (2010) was 0.94 mm (range 0.63 to 1.40mm), and for Marchetti *et al.* (2011) was 0.75mm (range 0.5mm to 1.15mm).

If the results for the present study are accumulated, the average absolute error would be 0.92mm (range 0.3mm to 2.4mm), although these are comparable results, the present study did not inspect the soft tissue predictive abilities at regions of the face that were deemed out with key anatomical areas and if any change had occurred in those areas, it was likely to be very minimal as these areas such as the forehead should not be affected directly by the surgical procedure. Had these areas been included the overall accuracy of 3dMD Vultus in predicting soft tissue morphology would possibly have been higher with the smaller differences in these regions reducing the larger differences in other regions by simply cancelling out larger root mean square values by a series of smaller root mean square numbers.

Both previous studies also discuss that the simulation resulted in particular regions of the face that showed large errors, specifically the tip of the chin and the lips (Bianchi *et al.,* 2010; Marchetti *et al.,* 2011). This was not found to be the case in this current study.

Most recently Schendel *et al.* (2013) assessed the accuracy of 3dMD Vultus (3dMD, Atlanta, Georgia, USA) using a heterogeneous sample consisting of 23 subjects who had undergone a range of orthognathic procedures. They investigated the precision of predicting the soft tissue surface at different soft tissue cephalometric landmarks. Unlike the present study whereby distinct anatomical areas were compared, this study considered the difference at 28 distinct soft tissue points (of which 8 should not have been affected by any orthognathic surgical procedure), along with the overall mesh differences.

Schendel et al. found an average difference of 0.27 mm between the simulated and actual soft tissue surface meshes, which indicates a very high predictive ability. The results for the soft tissue surface landmarks were all given independently with the largest errors being associated to the commissure areas (0.9mm -1.10mm), which in the present study would equate to the upper and lower lip regions. Interestingly these were the only regions for which the present study demonstrated a discrepancy between 90% of the mesh points to be over 1mm. This is therefore in agreement in both studies.

Two major limitations of the above study were that firstly it did not assess accuracy of moving pre-op hard tissue to the actual achieved post-op position. If there was any error in this step it would have had a certain implication on the soft tissue accuracy, either for the better or worse. Secondly, similar Bianchi *et al*. (2010) and Marchetti *et al*. (2011) the authors opted to compare the overall mesh differences without removing the relatively large surfaces not affected by surgery: this would certainly bias the final figure of the overall difference between the meshes. It would have been more appropriate to carry this out removing the areas not affected by surgery, such as the forehead.

Most recently, Shafi *et al.* (2013) independently verified the validity and accuracy of Maxilim (Medicim, Medical Imaging Computing, Mechelen, Belgium). The methodology employed and the subjects involved in the study by Shafi *et al*. (2013) were identical to that of this study. Shafi et al. found an average absolute error of 0.97 mm (range 0.26 to 2.73mm), which when compared to the average absolute error of the present study at 0.92mm (range 0.3mm to 2.4mm), indicate very similar results at first glance. However on further inspection it becomes apparent that all the points located in the mid-facial axis were predicted more accurately by this study and those areas that were more lateral, were predicted better by Maxilim. This highlights why simply using the average absolute error over the whole of the face may mask results as it may compensate for badly predicted areas by those predicted better.

The reasons for the differing results are due to several independent variables, some of which have been introduced by the methodology of the studies themselves as discussed above and others by the software programme being analysed.

For the above orthognathic surgery planning programmes, each developer has opted to use a different algorithm for surgical simulation and this has certainly contributed to the differences in accuracy between each study. The results of the current study in comparison to Shafi *et al*. (2013) suggests that areas located in the mid-facial axis are predicted more accurately by the Mass Spring Model and those areas that were more lateral are predicted better by the Mass Tensor Model. Whether our computer software colleagues can advance orthognathic surgery planning further by combining different algorithms within the one planning programme remains to be seen.

Chapter Six

Conclusions

6 Conclusions

6.1 Aim of the study:

This research was conducted to evaluate the clinical validity and accuracy of an “off the shelf” computerised 3D orthognathic planning program (3dMDvultus). The study examined the programs ability to clinically predict the soft tissue facial morphology after orthognathic surgery using a study sample limited to a Le Fort I maxillary advancement.

The null hypothesis tested was that the average difference in absolute distance between the 3dMDvultus predicted facial surface and the actual 3D facial surface of this group of patients, at eight different selected regions of the face, were not different to 3mm; as this would be considered clinically significant.

6.2 Conclusion

The distances between the predicted surface morphology and the actual facial morphology of the eight regions of the face which were examined, were all statistically significantly less than 3mm ($p<0.001$), demonstrating that 3dMDvultus produces clinically acceptable three-dimensional soft tissue predictions for patients undergoing Le Fort I advancement osteotomies.

Chapter Seven

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Chapter Eight

Appendices

8.1 REC Ethical Approval Documentation

8.2 Research and Development Approval Documentation