THE 3D MAXILLARY ORIENTATION DEVICE (3DMOD) - A NOVEL DEVICE FOR MEASURING POST-SURGICAL THREE-DIMENSIONAL MAXILLARY CHANGES

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DEDICATION

I dedicate this MSc to my parents, my husband, beautiful daughter and uncle for their endless support and love. They have always believed in me and without their constant prayers, guidance, and patience I would not be where I am today.

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ABSTRACT

Objectives: To assess the validity and reproducibility of the 3D Maxillary Orientation Device to assess the simulated post-surgical 3D changes of the maxilla using an in vivo model.

Methodology: A 3D maxillary orientation device (3DMOD) was developed based on a modified Fox's occlusal plane guide. Equidistant points were marked on the extra-oral arms of the 3DMOD creating nine landmarks for data analysis. Reproducibility of 3DMOD insertion and removal was assessed by placing the 3DMOD onto the maxillary dentition of five volunteers and taking extra-oral facial 3D stereophotogrammetry images (Di4D SNAP system) at one-week intervals (T_1 and T_2). To measure the post-surgical changes of the maxilla, the 3DMOD was secured to the maxillary dentition of an in vivo skull model. The position of the 3DMOD changed a known amount using modified Lego® blocks attached to the 3DMOD, to simulate various maxillary movements. Baseline images of the 3DMOD were taken with 0mm displacement and again with the 3DMOD advanced and vertically impacted by 3mm, 6mm and 9mm. Additionally a left and right cant and 3mm advancement with posterior differential impaction were simulated. Images were re-taken one-week later (T_1 and T_2). Following baseline and simulated maxillary movement, the changes of the landmarks in the x, y and z direction were determined using Di3D viewing software for data analysis.

Results: For 3DMOD insertion on replacement the mean differences in the x, y and z direction were all significantly less than 0.5mm. The difference between the simulated maxillary movements (advancement and impaction) and the 3DMOD derived measurements were all statistically significantly 0.5mm or less. The device

was reproducible, none of the mean differences between T_1 and T_2 were significantly greater than 0.5mm (95% CI range 0.0mm and 1.1mm).

Conclusion: The 3DMOD, coupled with stereophotogrammetry, is an acceptable method to measure 3D simulated maxillary movements. Further studies are needed to assess the validity and reproducibly of using the 3DMOD in patients undergoing maxillary osteotomies.

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LITERATURE REVIEW

1.1 INTRODUCTION

Orthognathic surgery is a commonly carried out elective procedure indicated predominantly for the treatment of patients with visible facial asymmetry. This includes individuals with severe malocclusions that are beyond the scope of orthodontic treatment alone or those associated with syndromes (Royal College of Surgeons, 2013). Orthognathic surgery has been described as the "splitting of the maxilla and or mandible, mobilising the jaws with changes in either of the anteroposterior, transverse and vertical directions and fixating the jaws in the new position". (Hammoudeh and Lypka, 2014). Surgery is performed with the aim of achieving a more harmonious relationship between both jaws, improving aesthetics and function.

At present, the pathway to orthognathic treatment usually includes a referral to an Orthodontic Consultant from the General Dental or Medical Practitioner. This often leads to a series of appointments in a multi-disciplinary setting with the Consultant Orthodontist and Oral and Maxillofacial surgeons. Prior to considering orthognathic surgery, a detailed assessment should be undertaken including relevant history, detailed clinical assessment and special investigations (Bell, 1992; Khechoyan, 2013). Special investigations can take the form of articulated study models; full face and intra oral photographs and any radiographic images, will usually include a pre-treatment panoramic radiograph alongside a lateral cephalometric radiograph. This information is usually uploaded onto digital software for virtual prediction planning. This planning software is usually limited to two-dimensions. Treatment of more complex facial deformities may need further diagnostic investigations; including but are not limited to Magnetic Resonance Imaging (MRI), Computerised Tomography

(CT) and Cone Beam Computerised Tomography (CBCT) (Bell, 1992). These imaging modalities are useful as they provide detail of hard and soft tissues in three-dimensions.

The three fundamental stages to treatment planning should consider planning the amount of soft tissue changes needed, the extent of skeletal jaw movement and the level of pre surgical orthodontic treatment needed to restore a balanced facial profile and achieve optimal hard tissue relationships (Ayoub *et al*., 2014). The patient then undergoes pre-surgical orthodontics that primarily aims to reach an ideal occlusion post-surgery. In addition to this the teeth should be placed over the basal bone (Khechoyan, 2013; Bell, 1992), and will often involve removing the dento-alveolar compensatory movements that have taken place. Following this the orthognathic procedure may involve maxillary and, or mandibular jaw surgery.

1.2 SURGICAL PROCEDURE - LE FORT I MAXILLARY OSTEOTOMY

The Le Fort I osteotomy is named after the fracture patterns originally described by Rene Le Fort in 1901 (Buchanan and Hyman, 2013). The Le Fort I fracture extends from the nasal septum along the root apices in the maxilla through to the pterygomaxillary junction. They also identify the main indications for a Le Fort I as the correction of midface hypoplasia and vertical maxillary excess.

Additional authors have also identified the following as indications for Le Fort I osteotomies; for the correction of maxillary hypoplasia and retrognathic maxilla; the correction of occlusal canting by impacting the longer side or down grafting the shorter side or a combination of both; correction of an anterior open bite usually

achieved by a posterior differential impaction; correction of a narrow maxilla and or dental arch and finally correction of a prominent anterior maxillary segment with or without extractions (Ayoub *et al*., 2014; Posnick, 2014). Once disarticulated the maxilla can be moved in three planes of space with six degrees of freedom; superiorly, inferiorly, anterior, posteriorly (in segments) and rotated around the three axes.

A full thickness incision involving mucosa, muscle and periosteum is made from the upper right first molar to the upper left first molar. A full thickness mucoperiosteal flap is then elevated from the pterygomaxillary suture to the pyriform aperture bilaterally. The anterior floor of the nose is exposed by carefully elevating the mucoperiosteum along the piriform rim and lateral nasal wall. Following this the infraorbital nerves are identified and protected (Urata *et al*., 2014; Ayoub *et al*., 2014; Posnick, 2014). The maxilla is then cut approximately 8mm above the root apices of the maxillary teeth, separated from the floor of the nose and the maxillary septum and subsequently dis-impacted or down fractured. The occlusal repositioning wafer is then inserted between the maxillary and mandibular teeth and the maxilla is placed in the pre-planned position according to the occlusal relationship. This wafer is secured with temporary intermaxillary fixation. Following this the vertical height of the maxilla can then be adjusted in relation to the external reference points, for example soft tissue nasion. Once the desired movements to the maxilla are made, the maxilla is fixed into its final position with titanium plates and screws usually in the maxillary buttress area and the pyriform aperture. Closure may involve cinching suture to the alar base to reduce the undesired widening of the alar base followed by closure of the mucoperiostal flap with resorbable sutures.

Segmental osteotomies may be performed for the correction of a narrow maxilla, maxillary prognathism or vertical maxillary excess. This usually involves the maxilla being segmented in 2, 3 or 4 pieces. The segmented portion is then individually mobilised and fixated. Correction of transverse discrepancies is usually corrected with two-piece segmental osteotomy whereby the right and left parasagittal palatal cuts are made and the maxilla is then extended laterally and fixated. This is preferred over a mid-sagittal cut to prevent perforation of bone and mucosa (Perciccante, 2012).

A multi-segmental osteotomy is indicated when the maxilla is required to expand in the transverse plane as well anteroposteriorly and vertically for the correction of, for example an anterior open bite with a narrow posterior maxilla. The maxilla can be posteriorly impacted to level the maxillary occlusal plane and subsequent auto rotate the mandible to correct an anterior open bite (Posnick, 2014; Bailey *et al*., 1997; Ayoub *et al*., 2014; Perciccante, 2012).

1.3 SURGICAL PREDICTION PLANNING

1.3.1 Photocephalometeric planning

The aim of orthognathic surgery is to either improve or maintain the patient's facial soft tissue appearance. However, surgery does not move the soft tissues directly but moves the underlying skeletal tissue. The final position of the skeletal bone is determined by the occlusion. The dental and skeletal movements can be predicted with a high level of accuracy as they are directly connected and move in general in a 1:1 ratio. The overlying facial soft tissue response is much more variable and therefore harder to predict. The conventional methods of planning surgery involve

model surgery to plan and simulate the occlusion and skeletal position; as well as photocephalometeric planning to plan and simulate the overlying profile soft tissue changes. It is important to ensure the photocephalometric prediction and model surgeries are synchronous to ensure the planned surgical steps are accurate and achieve the desired soft tissue facial appearance and occlusion.

During surgical planning, the surgeons and orthodontists will carry out in depth cephalometric analysis, tracings and predictions combined with the clinical assessment. This is to determine the level of horizontal, vertical and transverse changes required for the maxilla and / or mandible to achieve the desired soft tissue facial and dental result. There have been numerous methods to predict the amount of hard and soft tissue changes. Historically, these include hand tracing of cephalograms, first introduced by Cohen in 1965. Later enhanced with the superimposition of photographs over a cephalogram to visualise the changes (Henderson, 1974). This method relied on sectioning the photograph to be superimposed over the cephalogram along the planned osteotomy lines and moving the hard and soft tissues to within an acceptable limit. It was not until the 1980-90's where modifications to cephalometric tracings became recognised as an important step in aiding the model surgery stages of planning for orthognathic surgery (Fish and Epker 1980, Walters and Walters, 1986; Turpin, 1990).

Although used for decades and currently the preferred method of planning in the United Kingdom, cephalometeric planning is not without problems; these include errors in tracing, questionable reproducibility and is time consuming (Harradine and Bernie, 1985; Kolokitha and Topouzelis, 2011). Moving forwards, computerised

digital methods of prediction planning replaced hand-tracing methods in the hope to overcome many of these deficiencies (Harradine and Birnie, 1985; Talwar and Chemaly, 2008). Computerised software was designed to predict the hard and soft tissue movements by combining both cephalometric radiographs with clinical photographs to give the added benefit of better visualisation of estimated outcomes (Carter *et al*.,1996). This also meant better communication aids for treatment planning but also more realistic visual aids for patients to use in during the consent process (Gossett *et al*., 2005; Eckhardt and Cunningham, 2004; Sarver, 1998).

Computerised prediction tracing involves combining landmarks and outlines of hard and soft tissue identified on the cephalometric radiograph with the patients photograph to create a composite image. Prediction programmes use this composite image alongside mathematical algorithm, to calculate the soft tissue movements produced by the underlying hard tissue movements. This then produces a final profile image based on the planned hard tissue movements. Provided the superimposition is as accurate as possible, the final profile image should give a reasonably realistic image of the expected outcome. However, there are specific landmarks that have reported inconsistencies in accurately predicting the outcome, namely the upper and lower lip soft tissues (Kaipatur and Flores-Mir, 2009; Gimenez *et al*., 2013). These inconsistencies can be clinically significant particularly when performing a Le Fort I osteotomy where movement of the maxilla may cause widening of the alar base, nose tip elevation and change in the nasolabial angle. Despite the obvious potentials for error the use of such software, can provide a better visual representation of the change expected both in the soft and hard tissues once the planned movements are made (Naini, 2011).

In order for accurate superimposition the soft tissue outline must be identical on both the photograph and cephalometric radiograph. Differences can lead to errors due to inaccurate superimposition, landmarking and geometric errors. All of which can create image distortion, and ultimately an unrealistic estimate of the anticipated outcome. It is also interesting to note that two-dimensional computerised prediction methods are also poor at recording facial asymmetries. This questions the usefulness of the technique given a significant number of Class II and Class III skeletal malocclusions can have associated mandibular asymmetries. Being able to plan and correct this during combined treatment is essential. (Harrell *et al*., 2002; Stokbro *et al*., 2016; Hammoudeh *et al*., 2015). Recognising the deficiencies in digital planning the introduction of three-dimensional planning has since overcome many of the faults associated with its predecessors.

1.3.2 Model surgery planning

The aims of model surgery are to:

1. Ensure the planned surgery is clinically appropriate, realistic and feasible.
2. To fabricate the occlusal repositioning wafer which will act as a guide perioperatively for surgeons when repositioning the jaws (Naini and Gill, 2017).

This procedure relies on close liaison between the surgeons, orthodontists and laboratory technicians for the fabrication of an accurate occlusal repositioning wafer. This acts as a guide for surgeons to use intraoperatively to guide the maxillary and mandibular teeth into the new occlusion following the surgical split of the jaws (Ayoub *et al*., 2014).

Ayoub *et al*. (2014) simplifies the stages involved in model surgery which broadly involve:

1. Clinical examination of the patient intra orally and extra orally
2. Taking master impressions of high standard including all teeth in occlusion to create accurate study models
3. Recording the jaw registration (ideally in natural head position)
4. Face bow recording
5. Articulating the study models ideally using a semi-adjustable articulator and using the patients facebow registration
6. Marking of the casts for antero-posterior, vertical movements and marking datum lines
7. Repositioning of the casts using reference points marked on the casts
8. Formation of occlusal repositioning wafer.

With many techniques sensitive stages involved in model surgery, there is potential for introducing systematic errors and subsequent production of inaccurate occlusal repositioning wafers which can influence the surgical movements achieved.

Historically facebow registration was undertaken for the construction of complete dentures and therefore may not be a valid technique for orthognathic planning. For model planning to be clinically valid the maxilla needs to be orientated correctly in 3D space. Current methods of articulating study models using conventional facebow registration may not accurately replicate the orientation of the patients' teeth and jaws (Barbenel *et al*., 2010). The majority of articulators mount study models assuming that the Frankfort plane and the base of the upper horizontal arm of the

articulator are parallel (Walker *et al*., 2008). The angle between the maxillary occlusal plane on the dental model and the horizontal base of the semi-adjustable articulator arm (which is thought to represent the Frankfort plane) is different to that between the patients' true maxillary occlusal plane and horizontal plane angle. This means that the model orientation which will be used to plan the surgery is different to the actual patient, therefore there will be an error in the outcome. Planned forward and downward maxillary movement produced less actual advancement and more inferior displacement. On the contrary, planned forward and upward movement of the maxilla produced more actual advancement of the maxilla but only 50% of the planned impaction (Barbenel *et al*., 2010). This has been further supported by many other studies such as Ellis *et al*. (1992) who firstly considered the Frankfort plane to be horizontal and found that vertical maxillary impaction could also create additional vertical and horizontal movements if the maxillary occlusal plane angle relative to the Frankfort plane was miscalculated. O'Malley and Milosovic (2000) also found that difference between the maxillary occlusal and Frankfort plane angle could change the upper incisor angulation making the incisors appear more proclined or retroclined (O'Malley and Milosovic, 2000).

Accurate post-surgical repositioning of the maxilla relative to the skull base relies on firstly correctly recording the pre-operative position of the maxilla. This relies on correctly mounting the study models on an articulator in an accurate and reproducible manner. Traditionally, a face bow registration is undertaken to relate the maxillary arch to the axis of the condylar hinge in three planes of space on a semi adjustable articulator (Hohl, 1978; Marko, 1986). The facebow uses an arbitrary horizontal plane based on two posterior points around the condylar region and an anterior point.

The horizontal plane is similar to the Frankfort Horizontal Plane. The vertical position of the anterior point will affect the steepness of the horizontal plane. The facebow is then transferred to the articulator, using the upper arm as the horizontal reference line. Evidence suggests that study models mounted on traditional semi-adjustable articulators / facebow systems do not replicate the patients occlusal plane angle accurately (O'Malley and Milosevic, 2000; Bailey and Nowlin, 1984; Ferrario *et al*., 2002; Ellis *et al*., 1992). In addition, patients with marked facial disharmony may not have a habitual head position where Frankfort Plane is horizontal. To overcome this Walker et al. (2008), introduced a new "sprit level facebow" system which recorded the maxillary occlusal plane inclination relative to Natural Head Position (NHP). As well as the facebow system a new orthognathic articulator has been developed which can be adjusted to maintain the correct maxillary cast orientation relative to NHP (Walker *et al*., 2008).

One study compared the differences in the actual and predicted movements of maxillary osteotomies using occlusal repositioning wafers made from study models mounted on a traditional semi-adjustable articulator system and those made from the newly developed orthognathic articulator system described above. The results showed that the wafers constructed using the traditional articulator had systematic prediction errors of up to 5mm. however the improved orthognathic articulator produced much small errors of less than 2mm, which are more clinically acceptable (Paul *et al*., 2012). In addition, errors in locating the centre of rotation of the condyle, and rotation of the mandible, could result in clinically significant malpositioning of the maxilla during maxillary impactions with mandibular autorotation (Turvey, 1982).

Although a prediction planning has been used for many years, the accuracy to predict and simulate the surgical movements is questionable with the potential for errors to be introduced at multiple stages in the process. These could include the production of inaccurate study models from errors in tray selection, impression material and sequence of pouring to form accurate study models (Ceyhan *et al*., 2003), facebow registration (Gateno *et al*., 2001; Walker *et al*., 2008) and transfer of the facebow to the articulator (Sharifi *et al*, 2008). Over the years, there has been a shift towards using digital software to predict and plan the surgical movements required, in an attempt to reduce the time constraints and errors associated with the traditional methods of prediction planning and thus allowing better analysis of the planned hard and soft tissue changes (Proffit and White, 2011; Hammoudeh *et al*., 2015 and Tran *et al*., 2018).

1.4 CURRENT METHODS OF ASSESSING 3D FACIAL CHANGES

The past few decades have seen a revolution in the development of three-dimensional (3D) imaging systems based on radiography, laser and optical scanning within the field of dentistry and orthodontics. Along with this there has been a shift in the treatment objectives of orthognathic surgery from simply improving occlusal discrepancies to achieving a more balanced and improved facial aesthetics (Bennington *et al*., 2010).

Having undertaken detailed planning and elective surgery it is important, from a quality assurance perspective, to establish a means of quantitatively assessing that the planned surgical movements have been achieved. Currently, this is primarily through the superimposition of pre- and post-surgical lateral cephalograms and / or

changes in anthropometric values based on pre- and post-surgical profile photographs (Vittert *et al*., 2018). The current methods used for surgical planning and treatment give limited information regarding 3D changes. Given that skeletal and soft tissue facial differences often display discrepancies in more than one plane; both planning and outcome assessment of the 3D skeletal and / or 3D soft tissue changes produced as a result of the surgery should be carried out in three-dimensions.

Current methods to capture and assess 3D imaging of the hard and soft tissues facial structures can be divided into volumetric and surface techniques.

Volumetric imaging techniques

- Cone Beam Computed Tomography (CBCT)
- Magnetic Resonance imaging (MRI)

Surface Imaging techniques

- Laser scanning
- Structured Light Technique
- Moiré Topography
- Stereophotogrammetry

1.4.1 Volumetric imaging techniques

1.4.1.1 Cone Beam CT scanning (CBCT)

CBCT were first introduced in the field of angiography as a means to produce higher quality images with less radiation than the conventional CT scans. Conventional CT scans were associated with high radiation doses, scatter and high costs of the equipment (Scarfe and Farman, 2009).

During CBCT scanning a divergent or cone shaped source of ionising radiation is directed through the object onto an x-ray detector on the opposite side. The x-ray source and detector rotate about a fulcrum point fixed that is located within the centre of the object. This creates a series of 2D projection images that can be reconstructed into 3D volumetric images using a previously developed algorithm (Feldkamp *et al*., 1984).

CBCT scans can concurrently provide an image of the hard tissues and overlying soft tissue and could produce reconstructed 3D images (Ayoub *et al*., 2014). Although the radiation exposure is reduced compared to conventional CT scans, it is still higher than conventional plane films. The radiation exposure with CBCT scans can be considered anything between 5 and 74 times higher than that of a single plane film. Based on a panoramic radiograph, a CBCT scan is the equivalent of upto 48 days background radiation (Naina, 2017; Ludlow *et al*., 2015; Scarfe and Farman, 2008). Therefore, the use of CBCT must be justified and the frequency of exposures reduced. CBCT allows a more detailed and accurate view of the hard and soft tissue structures and can serve as a viable method of assessing the outcome of orthognathic surgery if the post-surgical scan is compared to the pre-operative CBCT scan. However this involves additional radiation exposures to patients and associated risk factors.

1.4.1.1.1 Risks of radiation - deterministic and stochastic effects of radiation

The main issues identified with the use of CBCT include (Kamburoglu, 2015).

- Image noise - resulting in loss of surface detail due to lower mA used typically between 3-5mA; increasing the dose will decrease the amount of noise.

- Movement artefacts - The patient should ideally be sat upright and not supine, with the head in natural head position avoiding the use of chin cups or head straps to prevent soft tissue distortion (Ayoub *et al*., 2014). However this may lead to loss of stabilising of the head and movement and image distortion.
- Image scatter – due to interference from metallic intra oral restorations.
- Beam hardening – as a result of lower energy photons being absorbed quicker than the higher energy photons, resulting in an exit beam made up of higher energy photons.
- Potential high cost of equipment.
- Non-textured / photorealistic 3D image.

Using a CBCT scan to capture the facial skeleton and soft tissue is not without its risks, as well as being time consuming and expensive. However, it can be effective in assessing soft and hard tissues surgical changes in a pre-orthognathic and post-orthognathic surgical patient.

1.4.1.2 Magnetic Resonance Imaging (MRI)

MRI is form of 3D imaging which uses non-ionising electromagnetic radiation. It works by aligning the proton in a hydrogen nucleus which are in abundance in fat and water, when a magnetic field is applied. Additional energy is added to the protons by radio waves and causes them to resonate. When the radio waves are stopped the photons release an energy signature which corresponds to a specific tissue type. This can be converted into numerical 2D data that is then processed into a 3D image (Shah, 2018). It is considered the gold standard for imaging of the temporomandibular joint (TMJ) (Van Dijke, 1997).

It provides good soft tissue resolution detail of internal structures such as the position and morphology of the TMJ articular disc, the presence of joint effusion, adhesions, and perforations. It does not require repositioning of the patient and can safely be used in patients who may be allergic to contrast agents used during CT scanning. However, the main disadvantage of MRI is that it is expensive, access to the MRI units may not be readily available and they can create significant image artefacts due to the presence of metallic objects, such as orthodontic brackets (Karatas and Toy, 2014). In the context of orthognathic surgery, MRI fails to adequately capture the air / soft tissue boundary in detail which limits its use during orthognathic planning (Hajeer *et al*., 2004).

1.4.2 Surface imaging techniques

1.4.2.1 Laser Scanning

Laser scanning can be used as a method to capture the facial structures. An Image is captured through the reflection of a laser beam from the object surface to a laser detector. The changes in morphological structures and distances within the object are interpreted using computer software to generate an image. It has been considered a less invasive and simple and reliable method to capture the face (Karatas and Toy, 2014; Kau *et al*., 2007; Kovacs *et al*., 2006).

Laser scanning can be a time-consuming process in which there is a high risk of image distortion due to patients moving during the scanning process. Initially, there were concerns regarding the safety of use regarding eye damage, however the newer generation of laser scanners are eye-safe and allow quicker scanning times and less artefacts (Komazaki *et al*., 2011; Eberle, 2014). Laser scanning has also

been criticised of its inability to record soft tissue surface texture which can result in difficulty in identifying landmarks and unrealistic appearance due to lack of detail to skin colour and texture (Karatas and Toy, 2014; Baumrind, 1991; Khambay *et al*., 2008). Again, this is now possible with the newer generation of scanner.

1.4.2.2 Structured Light scanning technique

This is another technique reported to capture 3D images of the face. It produces an image through the use of illuminated points or patterns projected onto the object. When the illuminated points fall onto the surface of the object they create distortions relative the changes in texture and curvature of the object. The positioning of cameras at predetermined distances captures the illuminated image and translate this into a 3D image from converted coordinates (Valkenberg and McIvor, 1998).

1.4.2.3 Moiré Topography

Moiré topography has been used as a method to analyse the human body surface and anatomy (Takasaki, 1970). This technique involved the use of camera, light source and a optic grid. The images are formed from the variations of clear and dark lines formed by the light source passing through the optic grid. The dark lines are termed ‘moiré fringes’. The method is a stereophotogrammetrical technique that essentially creates a 2D image which is converted into 3D information based on the contouring of fringes and fringe intervals.

This technique can be considered a type of structure light technique and its main uses have been for the detection of scoliosis and deformities of the spine (Yeras *et al*., 2003). However, the principle of analysing the symmetry of the fringe patterns, produced between two sides of the body, has been applied to the diagnosis of facial

asymmetries and deformities (Kanazawa, 1978). This technique has the advantage of being relatively cost effective, minimally invasive with no radiation exposure and is relatively simple to use. However, with the analysis involves visual inspection this can be subjective due to fatigue for assessors undertaking multiple analyses. It has also been reported that non-continuous surfaces may generate broken fringes thus making interpretation more challenging (Porto *et al*., 2010). A recent study compared the accuracy of surface data recording of the mid face region using Moire profilometry and digital stereophotogrammetry and found no statistically significant differences in the mean measurement errors between the two methods (Artopoulos *et al*., 2014).

1.4.2.4 Stereophotogrammetry

Stereophotogrammetry is one of the oldest 3D surface imaging methods available. It utilises the principles of triangulation to calculate 3D coordinates of points on an object by measurements made on pairs of photographs captured simultaneously from different positions and angles (Burke and Beard, 1967: Ayoub *et al*., 1998). The use of higher resolution digital cameras and advanced computer software has allowed the process to become more precise and effective (Ayoub *et al*., 2003). Three-dimensional stereophotogrammetry relies on the imaging programme matching corresponding points on the paired images. The computer programme then interprets the data and uses a series of complex algorithms to produce a 3D image capable of showing photorealistic image including surface skin texture and colour reproduction to a high resolution (Weinberg *et al*., 2004).

Several studies have indicated a high level of precision and accuracy of stereophotogrammetry (Ayoub *et al*., 2003; Weinberg *et al*., 2004; Winder *et al*., 2008 Wong *et al*., 2008; Aldridge *et al*., 2005; Kau *et al*., 2005; Khambay *et al*., 2008; Heike *et al*., 2009). When comparing its performance to previously validated techniques such as the 3D contact ultrasonic measuring system, it has shown the average error between measurements being less than 0.6mm (Gwilliam *et al*., 2006). Additionally, its safety, minimal invasiveness, no radiation exposure, high speed of capture and reliability of data make it a particularly useful device for image capture of younger patients (Farkas, 1996; Heike *et al*., 2010). Additionally, the decreasing costs of stereophotogrammetry also make it more popular in the clinical and research settings (Honrado *et al*., 2004).

1.5 NATURAL HEAD POSITION AND ITS ROLE IN ORTHOGNATHIC SURGICAL PLANNING

1.5.1 Historic reference points used for cephalometric studies and orthognathic surgical planning

Although 3D prediction planning is thought to eliminate many of the errors associated with its predecessor, it is not without fault. It is important that even when planning in 3D, the head is in a reproducible and acceptable position as failure to do this can result in inaccuracies. Changes in the head orientation can create image distortion and potential inaccuracies when constructing the occlusal repositioning wafer with the potential to affect clinical outcomes (Heike *et al*., 2010).

Natural head position (NHP) is a concept that has been dated as far back as the 14th century by famous artists such as Leonardo Da Vinci who saw the benefit of this posture in being able to create more accurate and realistic replications of the human

head (Cooke and Wei, 1988). It has been used in cephalometric analysis to study craniofacial morphology and facial forms. It has also found its use in orthodontic treatment and orthognathic surgical planning (Meiyappan *et al*., 2015).

A new radiographic technique, the cephalogram, was developed to help standardise the method of recording craniofacial structures to help understand and study craniofacial growth within orthodontics (Broadbent, 1931; Hofrath, 1931). To understand and compare growth changes it is important to establish reference planes and standardise methods of measurement to compare longitudinal changes more accurately. The most used reference lies in cephalometric studies was the Frankfort plane and Sella-Nasion line. The 'Frankfort plane' (also known as the auriculo-orbital plane), was described as a plane extending from upper periphery of the 'external auricular canals and the lowest point of the left orbit'.

Studies have shown identification of these commonly used reference lines may vary over time, and thus may not represent accurate reference lines when carrying out cephalometric or comparative analyses. When comparing linear and angular intra-observer measurement errors in recording the Sella-Nasion line, a 2^{o} error in angular measurements, 2.5mm linear vertical measurement error and 3.5mm linear horizontal measurement error was recorded (Pancherz and Hansen, 1984). In addition, the large interindividual variability in the inclination of the Frankfort Plane and Sella-nasion line in NHP was considered unreliable as a basis for cephalometric analysis; standard deviation of 5.2^{o} for Sella-Nasion and 4.6^{o} for Frankfort Plane (Lundstrom and Lundstrom, 1995). Although the Frankfurt horizontal plane and Sella-Nasion varied amongst individuals, it did not change significantly over time in

the same individual with angular changes over the 9year period being within 1º (Young *et al*., 2014).

Variations in the location of intra-cranial landmarks such as those mentioned above, can confound cephalometric interpretation (Thurow, 1977). Differences between cephalometric and clinical findings can be particularly challenging for orthognathic surgery, where significant changes can be made and thus the correct diagnosis of facial asymmetry / disharmony becomes crucial in treatment planning (Björk's study, 1951). The inclination of such reference lines in relation to an extra-cranial vertical or horizontal reference may change depending on head position. This variable can lead to misdiagnosis of facial disharmony a crucial aspect to identify particularly during orthognathic surgical planning (Verma *et al*., 2012). Thus, obtaining a standardized orientation of the head, such as the Natural Head Position (NHP), should be a more valid method for cephalometric analysis and surgical planning in patients undergoing orthognathic surgery.

1.5.2 The use of natural head position

There are two generally acceptable methods of orientating the head during a clinical examination; either Frankfort plane horizontal (FPH) or Natural Head Position (NHP). FPH has its origins stemming from a standardised method of orienting dry skulls for anthropometric measurements (Garson, 1885). Natural head position has been defined as the most balanced natural position of the head when a person views an object at their eye level (Morrees and Kean, 1958). It is also defined as a standardised and reproducible orientation of the head in space when the individual is focusing at a point in distance at eye level (Verma *et al*., 2012). The assumption was

that Frankfort plane horizontal was similar to head orientation in a living human (NHP) and therefore the two were inter-changeable. This may be true for orthodontic patients but has been shown not to be the case for orthognathic patients (Profitt, 2011). In addition, the angle between FHP and NHP can vary between skeletal patterns, as well as between the same patient pre- and postoperative orthognathic patients (Hernández-Alfaro *et al*., 2021). As a result of these discrepancies NHP should be used as the true horizontal plane when planning for orthognathic surgery, not FPH (Hernández-Alfaro *et al*., 2021; Jiang *et al*., 2007). NHP has been investigated longitudinally, in women between the ages 20-70, and was found not to vary significantly over a period of 15 years (Tallgreen and Solow, 1981).

Once NHP has been achieved there are generally two methods of recording head position either using a true vertical or true horizontal reference line. The first is by using a gravity determined plumb line (Vig, *et al*., 1980), the second using a spirit level device (Showfety *et al*., 1983). The later method involved getting the patient in NHP and then securing a spirit level to their temporal region in the true horizontal position. This meant that manoeuvring the patient in the cephalostat with the spirit level bubble horizontal would mean their head was in the NHP recorded clinically. This limited the need for unnecessary radiation exposure and minimal interference when taking the cephalogram radiograph. This method of pre-recording NHP is termed ‘Registered natural head position’ (Jiang *et al*., 2007). This study looked at the differenced in registered and estimated NHP.

When positioning patients in the cephalostat care needs to be taken when using the ear rods. Some studies have found no significant difference in the reproducibility

(Cooke and Wei, 1988). However other studies have found that using ear rods can affect the orientation of the condyle within the fossae and this may inadvertently deviate the patient's orientation away from NHP (Bister *et al*., 2002). This is significant for surgical planning, especially in individuals with facial asymmetry and prominent maxillary occlusal cants who have been shown to have asymmetric external acoustic meatuses (Choi, 2015). It is important to identify this and re-orientate the patient back to NHP prior to record taking (Verma *et al*., 2012).

1.5.3 Natural Head Position and 3D orientation

In many centres around the world three-dimensional (3D) surface imaging has become a routine method of capturing facial images to allow anthropometric assessment of the craniofacial complex. This generally involves capturing a 3D facial image of the patient in a standardised orientation, i.e., NHP. The image can then be manipulated around the three principal axis or planes; rotation around the x-axis is "pitch", rotation around the y-axis is "yaw" and rotation around the z-axis is "roll".

Unlike conventional 2D photographs, the orientation of the reloaded 3D image is dependent on the orientation of the 3D planes created during the calibration of the image. This means the image is no longer representative of the patient in NHP, once the image has been saved and reloaded (Zhu *et al.,* 2018). To re-orientate the face to the correct NHP orientation, created at the time of image capture, additional methods are required; in their absence the image will not be in NHP. These include stereophotogrammetry with a reference board (Hsung *et al*., 2014), Clinical photographs and facial markings along laser lines (Bobek *et al*., 2015), Clinical photographs and pose from orthography and scaling with iterations (POSIT)

algorithm (Kim *et al*., 2014), Digital Orientation Sensing (DOS) (Liu *et al*., 2015) and Handheld Camera measuring system and Laser scanning (Pavlovcic *et al*., 2013).

An alternative option is to try and re-orient the facial image based on clinical experience by asking clinicians to “estimate” the patients NHP based on their clinical judgement. A recent study investigated the differences in registered NHP and estimated NHP in three dimensions of pre surgical class III orthognathic patients (Zhu *et al*., 2018). When estimating NHP clinicians tended to position the head with the chin tipped more posterior which could reduce the severity of the skeletal discrepancy. There was a moderate level of intra-rater reliability for roll, yaw and pitch, indicating that clinicians could estimate NHP (Jakobsone *et al*., 2020; Weber *et al*., 2013).

1.6 CURRENT METHODS OF ASSESSING CHANGES IN HARD TISSUES FOLLOWING ORTHOGNATHIC SURGERY

Historically the technique for assessing skeletal change following orthognathic surgery has been based on the following stages: superimposition of the pre- and post-operative cephalogram, ideally of equal magnification, and construction of a co-ordinate system. Normally the base of the skull is chosen for superimposition, as it is a stable structure that does not change as a result of orthognathic surgery and is common on both cephalograms. Any changes in the position of the maxilla or mandible are then measured as linear and angular changes along an x and y-axis. The y-axis is often based on a true vertical line / chain present when the cephalogram is taken with the patient in NHP. The x-axis is then constructed as a line perpendicular to the true vertical. An alternative method relies on generating a

horizontal line based on the SN line + 7º and then dropping a line perpendicular to this passing through Sella. Either of these co-ordinate systems allows measurement of changes of skeletal components in the anterior-posterior direction and vertical directions only. It is worth noting that any rotational / transverse changes cannot be measured but may influence the AP and vertical measurements. This method is still the predominate method of analysis when using 2D planning.

The introduction of 3D imaging, CBCT scanning, has allowed capture of the entire 3D maxilla and mandible. However, to date, most methods of measuring skeletal change as a result of surgery are still based on the changes in linear distance between corresponding reference points on the pre and post–operative image relative to the x, y, and z planes. As with cephalograms these measurements are taken following superimposition of the two 3D images. For 3D images superimposition is performed using surface registration or volume-based registration of the cranial bases. New methods of analysis attempt to represent the changes in maxillary or mandibular position in “three-dimensional language” and describe changes in terms of pitch, roll and yaw. Imagine three lines running through an airplane and intersecting at right angles at the airplane’s centre of gravity, then rotation around the front-to-back axis is called roll, rotation around the side-to-side axis is called pitch and rotation around the vertical axis is called yaw.

The maxilla is a rigid body, and the occlusal surface can be simplified to form a triangle based on marking three points on the maxillary dentition; two posteriorly and one anteriorly. The same points were chosen on both the pre and post op images following superimposition. This produced two nearly identical triangles, which are in

different locations in 3D space. The two triangles were then aligned using only rotation and translation based on the Procrustes superimposition algorithm to produce a rotation and translation matrix. This was then represented as changes in pitch, roll and yaw.

1.7 SUMMARY

Orthognathic surgery is an elective procedure undertaken predominantly for the treatment of patients with visible facial differences, with the aim of improving aesthetics and function. As an elective procedure there is ample time to plan and rehearse the surgical procedure. The interaction between the hard skeletal and dental tissues with the overlying soft tissue is complex and requires planning. Peri operatively, once disarticulated, the maxilla can be moved in three planes of space with six degrees of freedom: superiorly, inferiorly, anterior, posteriorly (in segments) together with rotation around the three principal axes. This freedom of movement allows complex changes to be undertaken but requires careful pre-operative planning.

Conventional planning utilises a combination of two dimensional (2D) photocephalometeric planning and model surgery. The assumption is that these records together provide a clinically valid representation of the patients mid and lower facial anatomy, allowing a platform for “virtual surgical planning”. The human face is a three-dimensional object and planning using 2D radiographs and profile photographs inevitably results in loss of valuable spatial information, for example the transverse dimension. In addition, it has been shown that a facebow recording does not correctly record the orientation of the maxillary occlusal plane and maxilla to the

patient's physiological natural head position. This again introduces another potential source of error. Technological advances, for example three dimensional imaging (3D), have enabled the true 3D nature of the head and face to be captured. This allows construction of a valid digital patient based on combining CBCT scans, dental scans and photorealistic soft tissue facial scans. This eliminates the need for face bow recordings and reduces a potential source of error. However, for clinical validity, assessment and planning needs to begin with the patient in natural head position; this then needs to be transferred to the digital environment for digital planning and production of a physical 3D printed wafer.

For clinical quality assurance it is important to validate the peri-operative skeletal changes against the planned surgical changes in three-dimensions. To date this is only possible of taking a second CBCT post operatively that can be compared to the planned result. In the United Kingdom the additional second post-operative CBCT scan is generally no taken routinely as there is thought to be little clinical indication to do so. It is thought the risks of the additional radiation exposure outway the potential benefits of the scan.

This means that as a clinical team it is not possible to determine whether the surgical plan was executed as planned for bimaxillary procedures. If the intermediate wafer places the maxilla in the incorrect position, then by default the final wafer will produce the final occlusion but also place the mandible in the incorrect position. At present this is carried out using lateral cephalograms which are unable to record changes in the transverse dimension. In addition, any changes in the transverse dimension, for example rotation, will influence the anterior-posterior measurements.

CHAPTER 2

AIMS AND NULL HYPOTHESIS

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2.1 AIMS

The aims of the present study were to determine whether it is possible to develop a device to record the 3D changes of the maxilla following simulated surgery.

2.1.1 Primary outcome measure

The primary outcome measure was the difference in distances in the x, y and z directions between the simulated maxillary movement and the movements determined by the newly developed device.

2.2 NULL HYPOTHESIS

The difference in distance distances, in the x, y and z directions, between the simulated maxillary movement and the movements determined by the newly developed device were not statistically significantly ($p < 0.05$) 0.5mm or greater, as this would be deemed to be clinically significant.

CHAPTER 3

MATERIALS & METHODS

3.1 STUDY DESIGN

This is a proof of concept study, designed to quantify the magnitude and direction of maxillary movement following orthognathic surgery using 3D stereophotogrammetry imaging.

Part I of the study designed an intra-oral device to measure the 3D maxillary changes following surgery.

Part II of the study assessed the validity and reproducibility of placement of the intra-oral device designed in Part I.

Part III of the study aimed to assess the simulated post-surgical 3D changes of the maxilla using an in vivo model.

Part IV of the study was to validate the method in a small group of patients undergoing maxillary surgery. This was however not possible to conduct due to the COVID-19 pandemic.

3.2 PART I – DESIGNING THE INTRA-ORAL DEVICE

3.2.1 Development of the "3D Maxillary Orientation Device (3DMOD)"

The device consisted of a rigid plastic bite fork (Fox's plane guide), used traditionally to record the orientation and level of the maxillary occlusal plane, during full upper denture construction. The bite fork was sectioned into three pieces; the central bite fork and the two left and right orientation arms. The outer arms of the bite fork were secured to the central bite fork portion, so they sat closer to the right and left outer surfaces of the cheek. An upright "L-shaped" plastic strip was secured to each arch

and centre portion of the modified plane guide. A black and white specked paper strip was glued onto the surface of each of the plastic uprights with three equidistant points marked in red on each strip. In total 9 landmarks were identified created around the periphery of the modified guide plane. This produced a rigid device, named the “3D Maxillary Orientation Device (3DMOD)”, for securing extra-oral markers around the periphery of the maxilla secured to the dentition (Figure 3.1, Figure 3.2).

3.3 PART II - VALIDITY AND REPRODUCIBILITY OF PLACEMENT OF THE INTRA-ORAL DEVICE

3.3.1 Di4D SNAP imaging system

The imaging system consisted of 3 camera banks positioned in a rigid rig secured to a tripod. One camera bank was located in the middle of the rig facing directly forward, whilst the other 2 camera banks were positioned to the right and left side of the rig. All six cameras were orientated to view the same 3D volume. Each camera bank consisted of a pair of colour high-resolution (24.1M pixels) digital cameras (250D Cannon). In addition, there were 2 studio lights (Esprit Digital DX1000, Bowens, Essex, UK) placed either side of the camera system and designed to flash simultaneously when capturing the image. The resolution of the cameras was 3504 pixels × 2336 pixels, with a focal length of 50 mm. It took 1ms to capture an image of the face with the 3D imaging system.

3.3.2 System calibration

Prior to facial image capture the Di4D SNAP system required calibration according to the manufactures instructions. This process was necessary to determine the relative

Figure 3.1 Image of constructed 3DMOD, ready to insert onto volunteer maxillary dentition.

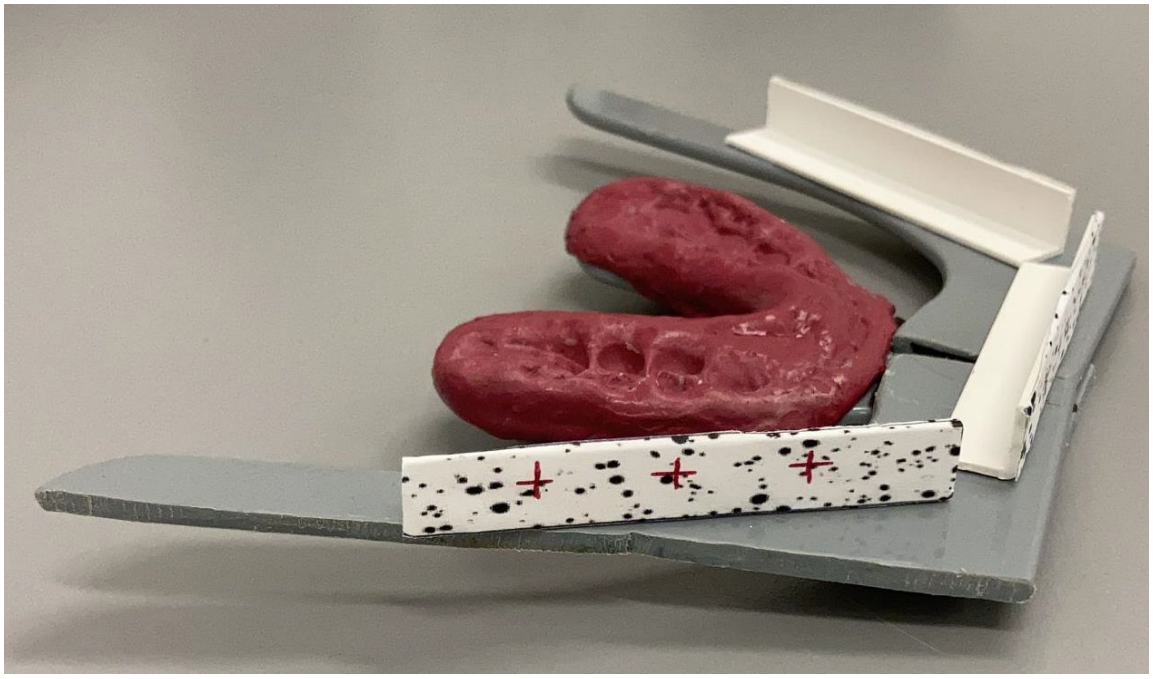


Figure 3.2 3DMOD showing speckled paper application and red cross-hair landmarks.

positions of each camera to one another within each bank but also to determine the relative positions of the camera banks to one another. These are termed the "extrinsic" parameters; in addition, the "intrinsic" parameters of the cameras also need to be determined e.g., lens distortion. The calibration process involved taking a minimum of 6 images of the calibration target in 6 different orientations. The calibrations target was a series of dots whose centres were of a known distance apart. Using the principle of "triangulation" it was possible to determine depth i.e., the 3rd dimension. The calibration file was saved and linked to any subject images taken that day. This information could then be used to re-construct a 3D image from the 2D images taken of the subject.

3.3.3 Image capture

Following calibration, the subject was seated directly in front, at a distance of 130cm, from the Di4D SNAP system, in front of a blue background. The camera system was adjusted for height until the subject was in the correct position in all six cameras, again according to the manufactures instructions. Following image capture and calibration attachment the final 3D image was saved as a Wavefront (.OBJ) file. Each file was 2-3MB in size.

3.3.4 Validity and reproducibility of placement of the intra-oral device

To determine whether the 3DMOD could be accurately repositioned on separate occasions i.e., pre and post-surgery, for each volunteer, Triad® Transheet Pink wax (Dentsply Sirona Prosthetics, York, U.S.A.) was softened and secured to the upper surface of the 3DMOD bite fork surface. The fork was then placed in the volunteer's mouth and orientated so the dentition was centrally positioned relative to the bite fork

and the front surface of the 3DMOD was parallel to the inter-pupillary line. The wax was allowed to harden and the 3DMOD device removed.

Before image capture a surgical cap was used to expose the volunteer's forehead and keep any stray hair away from the forehead. The 3DMOD was then inserted onto the maxillary dentition of each volunteer. Each volunteer was then asked to sit facing the Di4D SNAP system with their head in Natural Head Position (NHP). This was obtained utilising the oscillating head technique as described by Sollow and Tallgreen (1971). The 3DMOD used earlier was then re-inserted into the volunteer's mouth which they stabilised with their thumbs using light pressure. Each volunteer was imaged twice, with a one-week intervals (T_1 and T_2), and each image saved as an .OBJ file. (Figure 3.3 and Figure 3.4).

3.4 ANALYSIS

For each volunteer their T_1 and T_2 images were loaded into Di3DView software which allowed viewing, manipulation, superimposition and landmarking of the 3D image

3.4.1 Image superimposition

This process involved aligning the T_1 and T_2 images of the same patient firstly using manual rigid registration followed by ICP alignment. For rigid registration, 3 corresponding landmarks were chosen on each image and the software aligned the two images based solely on the landmarks. For ICP alignment the forehead was selected on the T_1 image, and the software aligned the two images based on the vertices within the selected region (patch). The ICP alignment superimposed the T_1 and T_2 images to the "best-fit" based on the forehead patch. Once the two images were

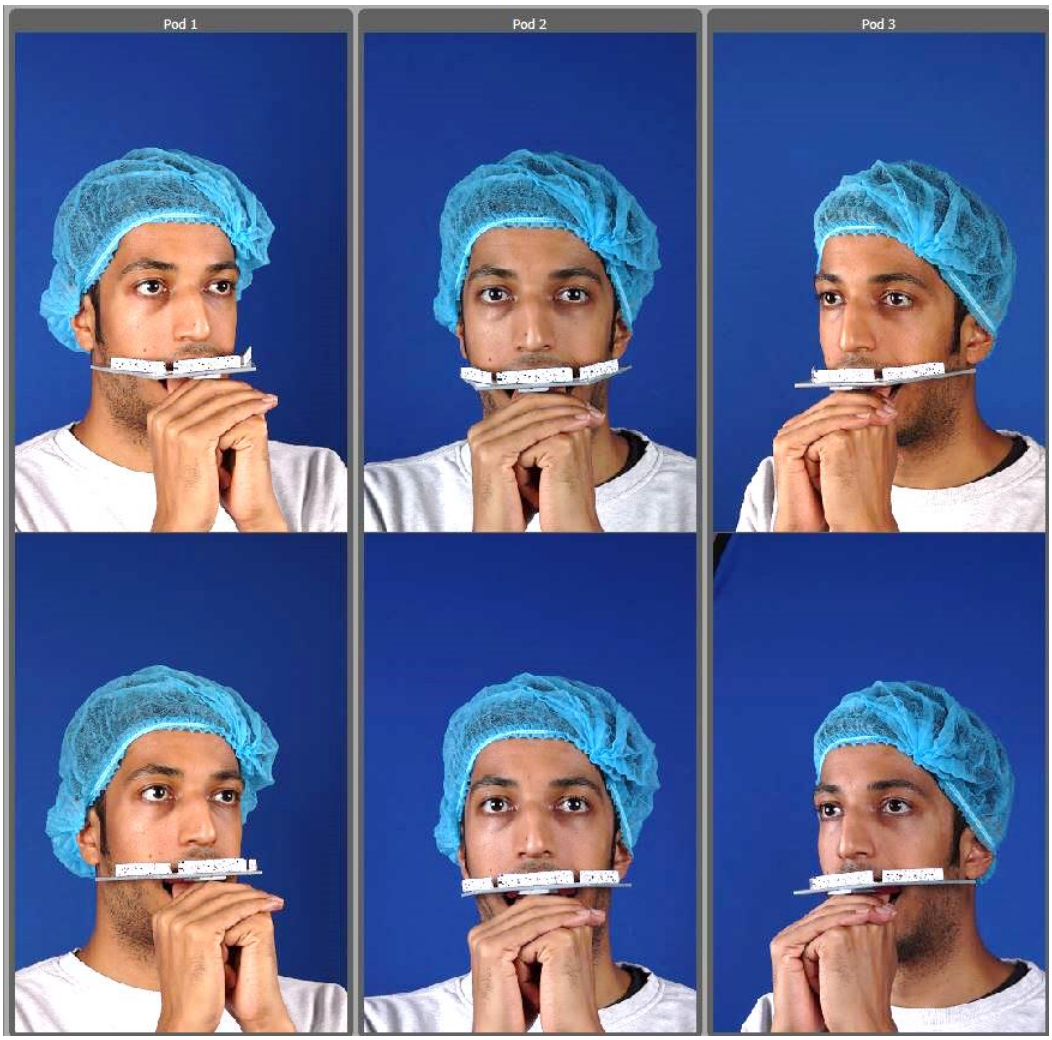


Figure 3.3 Six images simultaneously captured of volunteer with 3DMOD in situ using the Di4D SNAP software.

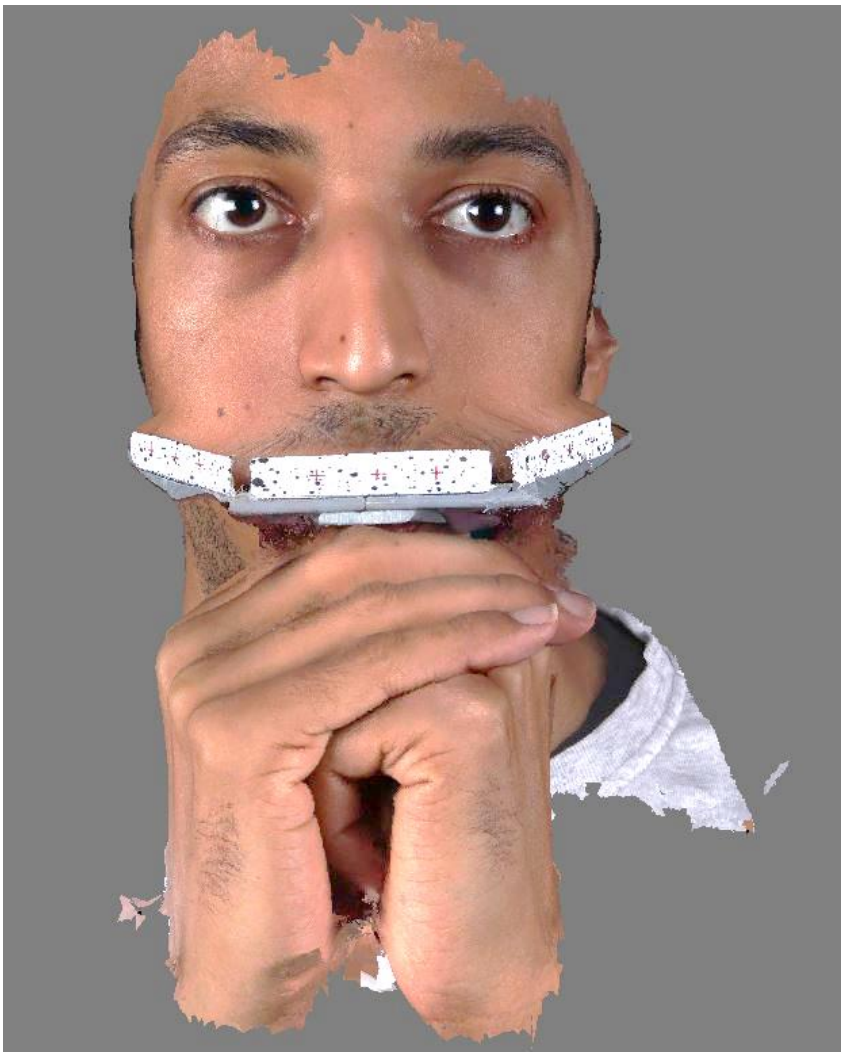


Figure 3.4 3D image reproduced of volunteer with 3DMOD in situ using the Di3DView software.

superimposed the 3DMOD should be in the same place relative to the forehead for the same volunteer at T_1 and T_2.

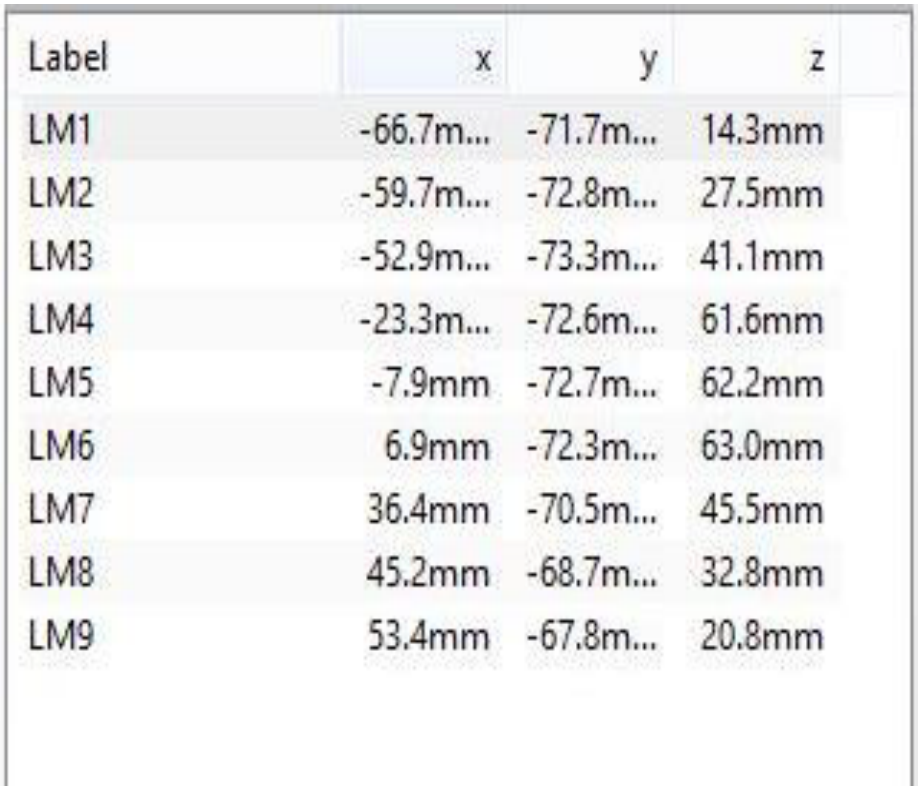
The 9 landmarks on the 3DMOD device were identified and selected on the T_1 and T_2 images. The x, y and z co-ordinates of each landmark were saved in .dilm format and imported into EXCEL for analysis. The Euclidian distance between the 9 landmark pairs as well as differences in the x, y and z direction were determined (Figure 3.5).

3.5 PART III - VALIDITY AND REPRODUCIBILITY OF THE 3DMOD IN ASSESSING THE SIMULATED 3D CHANGES OF THE MAXILLA USING AN IN VIVO MODEL.

The aim of this part of the study was to carry out a Le Fort I osteotomy on a plastic skull. To perform a pre-determined maxillary movement and assess whether the 3DMOD could determine the changes. However, it soon became apparent that moving the osteotomised maxilla a pre-determined amount would not be possible. To overcome this, the maxilla was not moved but instead the 3DMOD secured to the occlusal surface of the maxilla, was moved a known amount which was used to indirectly move the maxilla.

3.5.1 Construction of an in vivo head model

A plastic skull (A-246 skull on a tripod 4-piece, Cranstein Scientific GmbH, Erkelenz, Germany), with the mandible removed, was used to represent the upper skeletal hard tissue of a human skull in the in vivo model, (Figure 3.6).



Label	x	y	z
LM1	-66.7m...	-71.7m...	14.3mm
LM2	-59.7m...	-72.8m...	27.5mm
LM3	-52.9m...	-73.3m...	41.1mm
LM4	-23.3m...	-72.6m...	61.6mm
LM5	-7.9mm	-72.7m...	62.2mm
LM6	6.9mm	-72.3m...	63.0mm
LM7	36.4mm	-70.5m...	45.5mm
LM8	45.2mm	-68.7m...	32.8mm
LM9	53.4mm	-67.8m...	20.8mm

Figure 3.5 x, y and z landmarks values recorded using Di3DView software.

Figure 3.6 A-246 skull on a tripod 4-piece, Cranstein Scientific GmbH, Erkelenz, Germany. Available at: A-246 skull on a tripod 4-piece, Cranstein Scientific GmbH, Erkelenz, Germany.

A modified plastic mask was required on top of the skull to represent the soft tissue / air boundary. The original plastic mask was glossy white and would not be suitable for stereophotogrammetry capture as it lacked texture. To create a textured surface, pieces of newspaper were soaked in a water-based adhesive and layered over the white plastic mask to produce a papier-mâché mask, (Figure 3.7). This not only provided a random texture pattern for correspondence detecting between images but also improved the rigidity of the plastic mask. The papier-mâché face was then secured, in the correct anatomical position, to the plastic skull with an interim spacer of heavy body impression silicon (PRESIDENT The Original putties, Coltène / Whaledent Ltd, West Sussex, United Kingdom), which represented the muscle, fat and facia layer. The orbits were filled also with heavy body impression material silicone.

The midsagittal plane was marked on the papier-mâché face using glabella, nasion, nasal tip, maxillary dental centreline and pogonion. The midsagittal plane was also marked on the skull head using the glabella, nasion and nasal vomer and maxillary dental midline suture. Following this the lower portion of the papier-mâché face was sectioned at the level of the maxillary dentition to separate it from the remainder of the face. The lower portion was kept for later use. The skull was orientated on the tripod so that the Frankfort Plane (profile) and infra-orbital rims (frontal) were horizontal and a round bubble spirit level was permanently secured to the top of the skull, so the bubble rested in the centreline of the bullseye. This setup was a substitute for natural head position in a live subject.

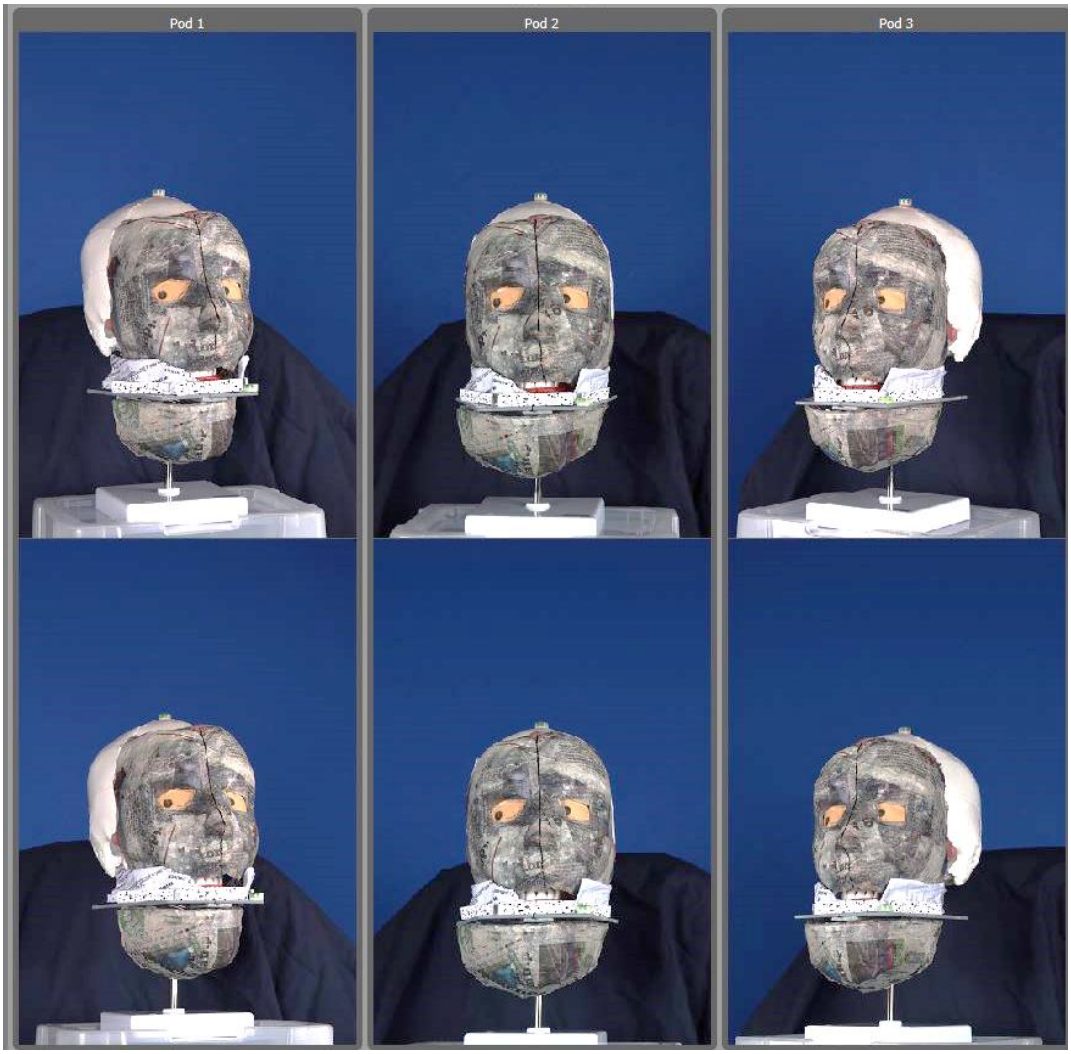


Figure 3.7 Invivo skull model with midsagittal plane outlined. Papier-mâché face secured to skull with a heavy body silicone spacer filling. Spirit levels placed on dorsal surface of skull head and 3DMOD to ensure skull mounted parallel to Frankfort plane with no rotations.

3.5.2 Mounting of the 3DMOD to the in vivo model - creating a flat and parallel maxillary occlusal plane

The skull was positioned to ensure the bubble rested in the centreline of the bulls' eye of the spirit level. An acrylic circular disc was mounted and secured to the occlusal surface of the maxillary dentition by heating multiple layers of pink hard setting wax (Triad® ROSA Transheet Pink). A wax knife was used to seal the wax to the maxillary dentition and remove any excess. A circular spirit level was placed on the acrylic disc to ensure the disc was parallel to the Frankfort plan and correctly positioned horizontally. This represented a flat and level maxillary plane in the pre surgical position.

3.5.3 Modification of the 3DMOD for the in vivo maxillary dentition

Two Lego® pieces (8 studs) of equal height and length (length 64mm x width 8mm x height 3.2mm) were secured, parallel to one another, at a fixed distance of 45cm apart using acrylic adhesive, to the inner semi-circular arms of the 3DMOD device. Two "tile" Lego® pieces were placed ontop of the Lego® pieces previously secured to the 3DMOD. Using a marker pen the midsagittal point was marked on the 3DMOD (Figure 3.8).

The 3DMOD and Lego® pieces were secured to the acrylic disc using adhesive. To ensure there was no rotation of the 3DMOD, the midsagittal plane marked on the 3DMOD was lined up with the mid sagittal plane marked on the in vivo skull. In addition, the 3DMOD was positioned anterior-posterior to ensure it was as close as possible to the in vivo skull model and maxillary dentition. Once the adhesive had set, the Lego® pieces could be separated and the 3DMOD could be easily detached

Figure 3.8 3DMOD with Lego® pieces secured parallel for the in vivo skull

from the acrylic disc (maxillary occlusal plane).

The circular projections on the inside of the tile Lego© pieces were removed leaving behind a hollow Lego® block. This allowed free sliding of the 3DMOD relative to the acrylic disc, which was constrained to only allow anterior-posterior movement guided by the sides of the Lego tile piece. The Lego® pieces on both the acrylic disc and 3DMOD were marked using a fine tip black permanent marker pen at 3mm, 6mm and 9mm using a metal measuring caliper.

The papier-mâché mask portion that represented the soft tissue overlying the mandible was secured to the bottom of the 3DMOD using adhesive tape. The 3DMOD mounted to the plastic skull was now complete and ready for image capture. The position of the skull with the 3DMOD mounted with the spirit level in the centre of the bulls' eye spirit level was considered to be the baseline position (T_1), and represented the pre-surgical position of the maxilla.

3.5.4 Baseline Di4D SNAP imaging of the in vivo skull

The skull was mounted on its tripod and placed at the correct height and distance from the camera system. Prior to image capture, the skulls orientation was adjusted to ensure the bubble was in the centre of the circular spirit level. As previously discussed, this would mean the 3DMOD was also horizontal. This was to be the standardised position of the skull for every maxillary movement recorded. A baseline image of the skull with the 3DMOD device with 0mm displacement was taken using the Di4D SNAP imaging capture system, T_1 (Figure 3.9).

Figure 3.9 3D Baseline image of Skull and 3DMOD at 0mm using Di3DView Software

3.5.5 Simulated horizontal maxillary advancement

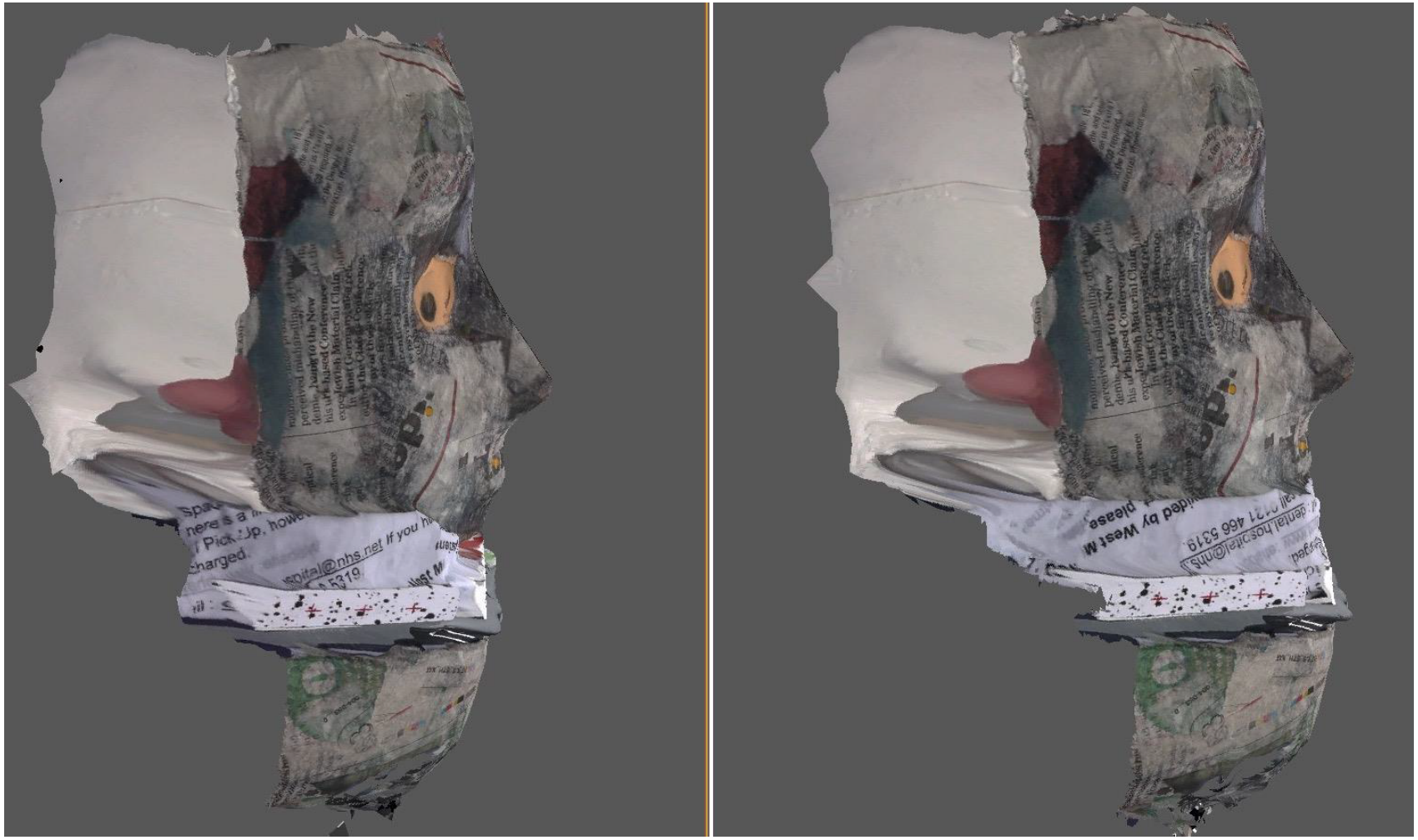
The 3DMOD was advanced 3mm horizontally by sliding the Lego® blocks along each other using the points previously marked on the Lego® blocks. A new Di4D SNAP image (H_3mm) was taken and saved in .OBJ format. This procedure was repeated for 6mm (H_6mm) and 9mm (H_9mm) 3DMOD forward movements; each simulating a 3mm, 6mm and 9mm maxillary advancement. .A Di4D SNAP image was captured at each movement and saved (3.10).

3.5.6 Simulated vertical maxillary impaction

The 3DMOD was replaced in its original baseline position and three additional Lego® block were inserted between the two Lego® pieces on the 3DMOD. A new baseline Di4D SNAP image was taken. To simulate a 3mm vertical maxillary impaction (V_3mm) one Lego® piece was removed and a new Di4D SNAP image was taken. Following this, an second Lego® block was removed from between the right and left Lego® blocks, simulating a 6mm vertical maxillary impaction (V_6mm).Finally the third Lego® piece was removed to simulate a 9mm vertical maxillary impaction (V_9mm), each time a new Di4D SNAP image was taken and saved as an OBJ file.

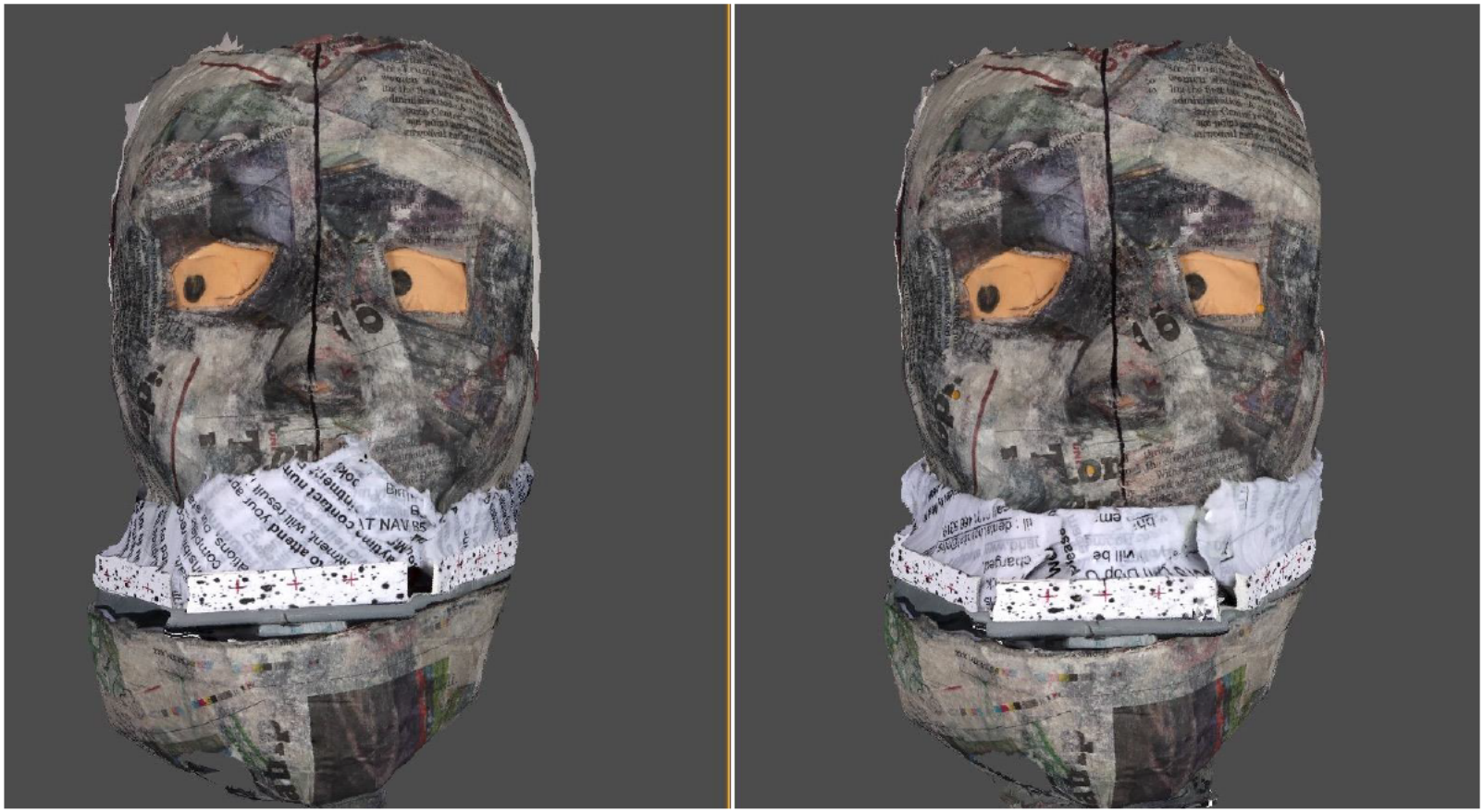
3.5.7 Right and left maxillary cant simulation

The 3DMOD was replaced in its original baseline position. One additional Lego® block was added to the right Lego® block on the 3DMOD and a new Di4D image was taken (RD_3mm). This was removed and one additional Lego® block was added on the left side only and a new Di4D image was taken (LD_3mm). Images RD_3mm and LD-3mm represented a right and left maxillary differential down graft of 3mm respectively (Figure 3.11).



Base line image (0mm) 9mm simulated maxillary advancement.

Figure 3.10 Right sided view of in vivo skull with 9mm simulated maxillary advancement.



3mm cant down on right

Base line image

Figure 3.11 Di3D view of the in vivo skull simulating a right sided 3mm cant.

3.5.8 Simulated maxillary posterior impaction and advancement

The 3DMOD was replaced in its original baseline position. To simulated posterior differential maxillary impaction a Lego® block was added to the right and left sides of the Lego blocks bases but only posteriorly and a new baseline image taken. The additional Lego piece was removed to simulate a maxillary posterior differential impaction of 3mm (PI_3mm) and a new Di4D SNAP image taken.

All simulated maxillary movements were repeated a further time at a one-week interval to allow a total of two complete series of images for comparison for each maxillary movement (T_1 and T_2).

3.6 DATA EXTRACTION

This process involved aligning the baseline image, with no movement of the 3DMOD (0mm maxillary change), to each of the images where movement of the 3DMOD has occurred.

3.6.1 Principal plane alignment of baseline image

Each pair of images (baseline and 3DMOD movement) were loaded into Di3DView software. Before superimposition could be carried out the baseline image needed to be orientated correctly in space, using the principal planes alignment function. The midsagittal plane of the skull was re-oriented to match the mid-sagittal principal plane. The Frankfort horizontal plane was re-orientated, so it was parallel to the horizontal principal plane and finally the coronal plane was adjusted. This image was then saved and used as the baseline when superimposing with the maxillary simulated images (Figure 3.12).

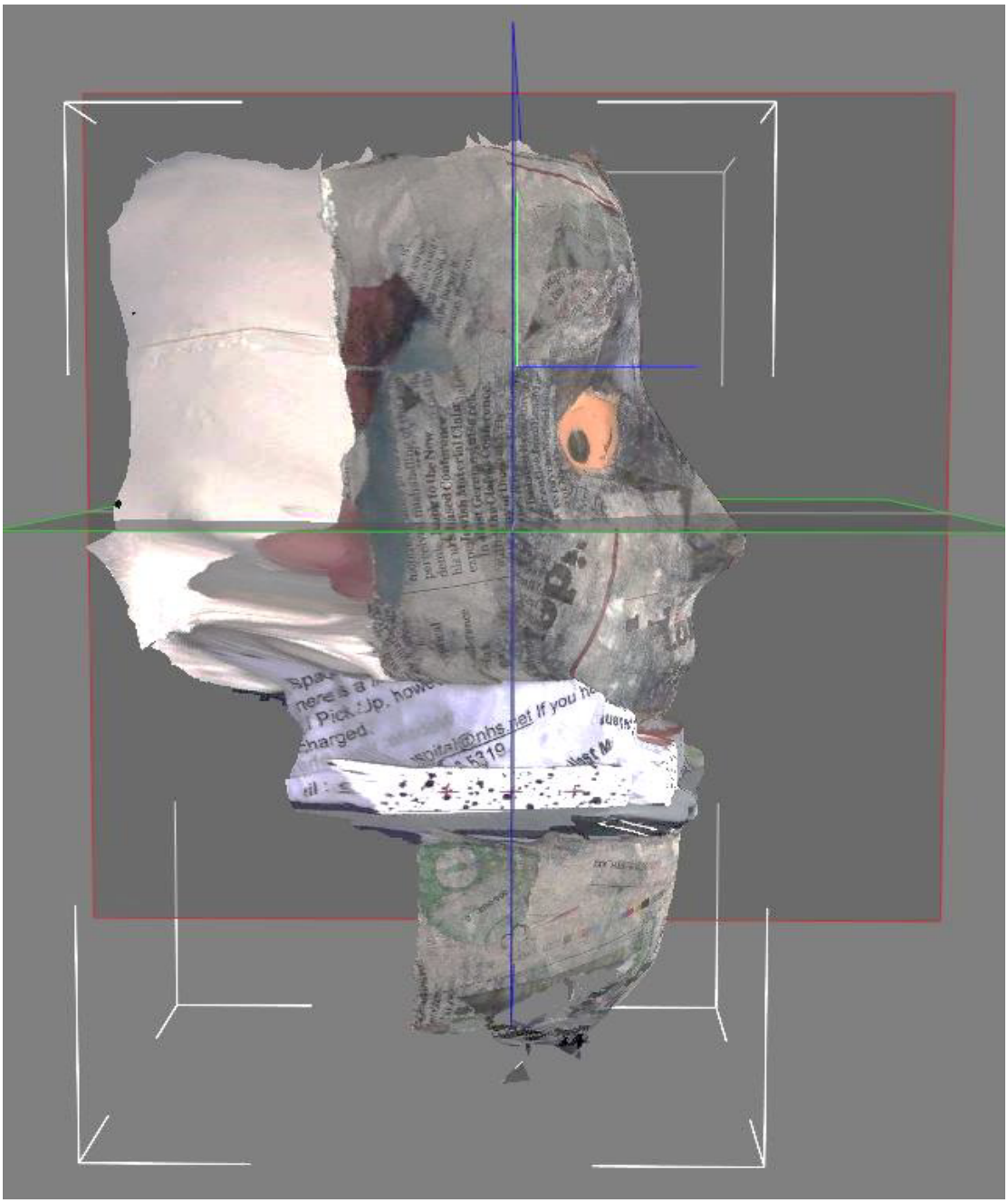


Figure 3.12 Principal plane alignment on the 3D image of the Skull in preparation for superimposition showing Frankfort plane parallel to the horizontal principal plane.

3.6.2 Image superimposition

The 3DMOD movement image was superimposed onto the baseline image using manual rigid registration followed by ICP alignment. For rigid registration, 3 corresponding landmarks were chosen on each image and the software aligned the two images based solely on the landmarks. For ICP alignment the forehead was selected on the baseline image and the software aligned the two images based on the vertices within the selected region (patch). The ICP alignment superimposed the baseline and 3DMOD movement to the “best-fit” based on the forehead patch. Once the two images were superimposed the difference in position of the 3DMOD represented the simulated maxillary movement.

The 9 landmarks on the 3DMOD device were identified and selected on the baseline and 3DMOD movement images. The x, y and z co-ordinates of each landmark were saved in “dilm” format and imported into EXCEL for analysis. The Euclidian distance between the 9 landmark pairs as well as differences in the x, y and z direction were determined.

3.7 PART IV VALIDATION OF THE 3DMOD IN A SMALL GROUP OF PATIENTS UNDERGOING MAXILLARY SURGERY.

This proof of concept study was originally planned to be undertaken in a small group of orthognathic patients. However, due to COVID-19 restrictions this was not possible.

Part IV of this study was designed to be trialled on orthognathic patients. Patients that required a Le Fort I maxilla movement would have a custom made 3DMOD

constructed. Once constructed and seated onto the maxillary dentition, an image using the Di4D SNAP system would be taken of the patient, pre and post-surgery. Following this, the images would be aligned and superimposed on Di3D software, and the landmarks recorded.

Once both images are correctly aligned, the landmarks would be recorded and the x, y and z coordinates would be recorded for the pre and post-surgical image. The differences in the x, y and z coordinates would be measured to record the distance and direction the maxilla has moved in three planes of space. Thus, allowing the orthodontist and surgeon to assess what movement has been made and whether this movement has correlated to the predicted maxillary movement. Consequently, eliminating the need to use CBCT radiation for 3-Dimensional imaging of the maxilla.

3.7.1 Construction of the 3DMOD for the surgical patient

The 3DMOD would be constructed as outlined in Part I of the study, 'Development of the 3DMOD'. A circular spirit level would be secured to the top flat surface of the 3DMOD.

3.7.2 Recording the maxillary occlusal plane in Natural Head Position (NHP)

NHP is thought to be a standardised and reproducible position of the head in space, independent of intracranial reference points that are subject to biological variation. The patient would be positioned in NHP, using the Sollow and Tallgreen oscillating head technique (1971). Whilst in NHP the 3DMOD would be secured to the maxillary dentition using Triad® Transheet Pink wax (Dentsply Sirona Prosthetics, York, U.S.A.), and oriented so the bubble was centred into the middle of the bulls' eye.

This would mean that the orientation of the 3DMOD would be parallel to true horizontal.

3.7.3 Recording an image of the 3DMOD using the Di4D SNAP system

Pre-surgery the 3DMOD would be inserted to fit the maxillary dentition. The patient would then be asked to sit in NHP and checking that the bubble in the spirit level was centred in the bulls' eye thus ensuring NHP was achieved. Once positioned correctly the patient would be asked to hold the 3DMOD in place and a 3D image would be taken. Post-surgery and when intra-oral access can be gained a second image would be recorded again with the original pre-surgery 3DMOD in situ.

The pre-surgery image would then be uploaded on the DiView software and based on the 3DMOD the image would be realigned to the "Principal planes". The front of the 3DMOD would allow correct roll and yaw position, the lateral arms of the 3DMOD would allow for correct pitch. This process would re-establish NHP in 3D space and allow the correct measurements.

The post-surgery image would then be superimposed on the forehead. Once successfully superimposed the 9 landmarks would be recorded for the pre and post-surgical images. The differences between the landmarks would determine the distance and direction of maxillary movement taken place, thus eliminating the need for CBCT radiation 3D imaging of the maxilla.

CHAPTER 4

RESULTS

4.1 PART I – DESIGNING THE INTRA-ORAL DEVICE

4.1.1 Development of the "3D Maxillary Orientation Device (3DMOD)"

Figure 3.1 shows the final 3D Maxillary Orientation Device (3DMOD). The device provides a method of assessing intra-oral maxillary movement by measuring extra-oral landmark movement.

4.2 PART II - VALIDITY AND REPRODUCIBILITY OF PLACEMENT OF THE INTRA-ORAL DEVICE

4.2.1 Validity and reproducibility of placement of the intra-oral device

The magnitude of the reproducibility error in the x-direction was 0.4 ± 0.1 mm (95% CI 0.3 to 0.5 mm), in the y-direction 0.2 ± 0.3 mm (95% CI -0.1 to 0.5 mm) and in the z-direction 0.1 ± 0.1 mm (0.0 to 0.1 mm), Table 4.1. Following a one sample t-test, with a hypothesised mean of 0.5 mm, in all directions the mean difference was significantly less than 0.5 mm.

4.3 PART III - VALIDITY AND REPRODUCIBILITY OF THE 3DMOD IN ASSESSING THE SIMULATED 3D CHANGES OF THE MAXILLA USING AN IN VIVO MODEL

4.3.1 Simulated horizontal maxillary advancement

Table 4.2 shows that the simulated maxillary advancement mean (SD) movements recorded by the 3DMOD at T_1 and T_2. Maxillary advancement is represented by changes in the z-direction whilst impaction changes are seen as changes in the y-direction. The 3DMOD was able to measure maxillary advancement. The 3DMOD recorded mean changes of 3.0 ± 0.3 mm, 5.9 ± 0.5 mm, 8.7 ± 0.2 mm respectively, for each of the three simulated maxillary advancements, 3 mm, 6 mm and 9 mm. The

Table 4.1 Mean differences in x, y and z co-ordinates for the 9 landmarks between two 3DMOD insertions

	x		y		z	
Landmark	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
4	0.5	0.4	-0.2	0.3	0.0	0.7
5	0.5	0.3	-0.1	0.2	0.1	0.8
6	0.4	0.4	-0.2	0.3	0.0	0.5
7	0.4	0.2	0.2	0.4	0.0	0.6
8	0.4	0.3	0.1	0.4	0.1	0.4
9	0.4	0.3	0.2	0.6	0.0	0.7
10	0.3	0.2	0.7	0.3	0.2	0.8
11	0.3	0.4	0.5	0.1	0.1	0.7
12	0.4	0.4	0.6	0.2	0.0	0.8
Overall	**0.4**	**0.1**	**0.2**	**0.3**	**0.1**	**0.1**

Table 4.2 Simulated mean (SD) maxillary advancement movements recorded by the 3DMOD in the x, y and z directions at T_1 and T_2.

	T_1							T_2						Average					
	x		y		z			x		y		z		x		y		z	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)		Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Advancement																			
3mm	0.4	0.1	-0.2	0.4	2.8	0.2		0.4	0.2	-0.3	0.4	3.2	0.4	0.4	0.2	-0.3	0.4	3.0	0.3
6mm	-0.8	0.2	-0.4	0.4	5.6	0.5		0.0	0.3	-0.3	0.7	6.1	0.4	-0.4	0.3	-0.4	0.6	5.9	0.5
9mm	0.3	0.3	-0.2	0.3	8.5	0.2		0.8	0.1	0.5	0.2	8.8	0.1	0.6	0.2	0.2	0.3	8.7	0.2

mean difference between all the simulated movement and the movement recorded by the 3DMOD, for maxillary advancements was 0.2 ± 0.3 mm. Following a one sample *t*-test with a hypothesised mean of 0.5 mm, these differences were statistically significantly less than 0.5 mm (p = 0.001), the 95% confidence interval for the difference was 0.2 mm to 0.3 mm.

The reproducibility of the method is shown in Table 4.3, which shows the mean absolute difference, between T_1 and T_2, using the 3DMOD to determine the magnitude of maxillary advancement. The absolute mean differences in the x-direction ranged from 0.1 ± 0.1 mm to 0.8 ± 0.4 mm, in the y-direction from 0.4 ± 0.2 mm to 0.8 ± 0.4 mm and the z-direction from 0.3 ± 0.1 mm to 0.6 ± 0.5 mm. Following the result of a one sample t-test, with a hypothesised mean of 0.5 mm, none of the absolute difference were significantly greater than 0.5 mm. However, most upper limits of the 95% confidence intervals for the mean absolute difference were above 0.5 mm and closer to 1.0 mm.

4.3.2 Simulated vertical maxillary impaction

For maxillary impactions there was a general trend for the 3DMOD to slightly overestimate the simulated maxillary impaction for 3 mm, 6 mm and 9 mm. The 3DMOD recorded mean changes of -3.2 ± 0.1 mm, -6.5 ± 0.2 mm, -9.9 ± 0.3 mm respectively. The negative value indicates a superior movement of the maxilla i.e., an impaction, Table 4.4. The mean difference between all the simulated movements and the movements recorded by the 3DMOD, for maxillary impactions was 0.5 ± 0.3 mm. Following a one sample *t*-test with a hypothesised mean of 0.5mm, these differences

Table 4.3 Mean absolute difference, between T_1 and T_2, using the 3DMOD (Advancement)

	X direction						Y direction						Z direction				
	Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value
			Lower	Upper					Lower	Upper					Lower	Upper	
3mm	0.1	0.1	0.0	0.2	0.001†		0.4	0.2	0.2	0.6	0.357		0.5	0.3	0.2	0.7	0.681
6mm	0.8	0.4	0.5	1.1	0.074		0.6	0.6	0.2	1.1	0.554		0.6	0.5	0.3	1.0	0.411
9mm	0.5	0.3	0.2	0.7	0.836		0.8	0.4	0.4	1.1	0.115		0.3	0.2	0.2	0.5	0.033†

One sample t-test hypothesized mean of 0.5mm.

† Statistically significantly less than 0.5mm

Table 4.4 Simulated mean (SD) maxillary impaction movements recorded by the 3DMOD in the x, y and z directions at T_1 and T_2.

	T_1							T_2							Average					
	x		y		z			x		y		z			x		y		z	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)		Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)		Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Impaction																				
3mm	0.0	0.1	-3.3	0.1	-0.6	0.2		0.1	0.2	-3.1	0.1	-0.3	0.1		0.1	0.2	-3.2	0.1	-0.5	0.2
6mm	0.0	0.2	-6.4	0.3	-0.5	0.1		0.0	0.2	-6.5	0.1	0.0	0.2		0.0	0.2	-6.5	0.2	-0.3	0.2
9mm	-0.1	0.2	-9.6	0.2	-0.6	0.2		-0.7	0.4	-10.1	0.3	-0.1	0.2		-0.4	0.3	-9.9	0.3	-0.4	0.2

were not statistically significantly different to 0.5mm (p = 0.974), the 95% confidence interval for the difference was 0.4 mm to 0.6 mm.

The reproducibility of the method is shown in Table 4.5, which shows the mean absolute difference, between T_1 and T_2, using the 3DMOD to determine the magnitude of maxillary impaction. The absolute mean differences in the x-direction ranged from 0.2 ± 0.1 mm to 0.7 ± 0.4 mm, in the y-direction from 0.3 ± 0.1 mm to 0.5 ± 0.3 mm and the z-direction from 0.3 ± 0.2 mm to 0.5 ± 0.3 mm. Following the result of a one sample t-test, with a hypothesised mean of 0.5 mm, none of the absolute difference were significantly greater than 0.5 mm. However, the majority of upper limits of the 95% confidence intervals for the mean absolute difference were above 0.5 mm but this time less than 1.0 mm.

4.3.3 Right and left maxillary cant simulation

Table 4.6 shows that the simulated maxillary canting (SD) movements recorded by the 3DMOD at T_1 and T_2. Maxillary canting is represented by changes in the y-direction with the point of rotation being around the opposite molar. This means that one side of the 3DMOD will be displaced superiorly (+ve values); with a left downside cant, landmarks 4, 5, 6 will move up. The other side of the 3DMOD will move inferiorly (-ve) i.e., landmarks 8 to 12. As landmarks 7, 8 and 9 are on the front of the 3DMOD, their displacement will progressively increase. The displacement of landmarks 10, 11 and 12 should all be approximately equal and greater than 3mm, for landmarks 4-6 the displacements of the landmarks will all again be approximately equal but less than 3mm. The landmark that is in the same plane as the line of the

buccal segments will represent the vertical maxillary changes of the teeth i.e. molars, this is landmark 9.

Table 4.5 Mean absolute difference, between T_1 and T_2, using the 3DMOD (Impaction)

	X direction						Y direction						Z direction				
	Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value
			Lower	Upper					Lower	Upper					Lower	Upper	
3mm	0.2	0.1	0.1	0.3	0.001†		0.3	0.1	0.1	0.4	0.001†		0.3	0.2	0.1	0.5	0.047†
6mm	0.2	0.1	0.1	0.2	0.001†		0.3	0.2	0.1	0.5	0.021†		0.5	0.3	0.3	0.7	0.616
9mm	0.7	0.4	0.4	0.9	0.236		0.5	0.3	0.3	0.7	0.907		0.5	0.3	0.3	0.7	0.819

One sample t-test hypothesized mean of 0.5mm.

† Statistically significantly less than 0.5mm

Table 4.6 Simulated mean (SD) maxillary left side down cant movements recorded by the 3DMOD in the x, y and z directions at T_1 and T_2. Red – landmarks moving inferiorly, Blue – landmarks moving superiorly

	T_1				T_2		
Landmark	x	y	z		x	y	z
4	0.3	2.5	0.0		0.4	2.5	-0.1
5	0.2	2.0	0.1		0.4	1.9	0.2
6	0.3	1.2	-0.1		0.4	1.1	0.0
7	0.0	-0.9	0.0		0.5	-0.9	0.0
8	0.4	-2.2	0.1		0.3	-1.8	-0.1
9	0.4	-3.4	0.0		0.2	-2.6	-0.1
10	0.7	-5.2	0.5		0.6	-5.1	-0.1
11	0.5	-5.7	1.2		0.8	-5.4	-0.6
12	0.7	-6.2	1.4		0.6	-6.0	-0.3

Following a right downside cant, landmarks 10, 11 and 12 will move up. The other side of the 3DMOD will move inferiorly (-ve) i.e., landmarks 4 to 8. The magnitude of displacements of landmarks 4-6 will all be approximately equal, but greater than 3mm. The magnitude of displacements of landmarks 10, 11 and 12 will all be approximately equal, but less than 3mm. Again, the landmark that is in the same plane as the line of the buccal segments will represent the vertical maxillary changes of the teeth i.e., molars, this is landmark 7, Table 4.7.

Following the result of a one sample t-test, with a hypnotised mean of 0.5 mm, none of the mean absolute difference were significantly greater than 0.5 mm. However, the upper limits of the 95% confidence intervals for the mean absolute difference ranged between 0.0 mm and 1.1 mm, Table 4.8

4.3.4 Simulated maxillary posterior impaction and advancement

Table 4.9 shows the simulated maxillary posterior impaction and advancement movements recorded by the 3DMOD at T_1 and T_2. A 3mm maxillary posterior impaction and simultaneous 3mm advancement is represented by changes in the y-direction (vertical) and z-direction (advancement), with the point of rotation being around the upper incisor edge. As the position of the landmarks 7, 8 and 9 are anterior to the incisal edge, they will move inferiorly (-ve), whilst landmarks 4, 5, 6 and 10, 11 and 12 will move superiorly (+ve), progressively increasing from anterior to posterior landmarks. In addition, the superior movement of landmarks 4 & 12, 5 & 11 and 6 and 10 should be similar, as they are on the lateral arms of the 3DMOD. There will be minimal changes in the x-direction, as there should be no horizontal change in the 3DMOD. Table 4.9 shows that landmarks 4 and 12, which were at the

Table 4.7 Simulated mean (SD) maxillary right side down cant movements recorded by the 3DMOD in the x, y and z directions at T_1 and T_2.

Red – landmarks moving inferiorly, Blue – landmarks moving superiorly

	T_1				T_2				Average (T_1 & T_2)		
Landmark	x	y	z		x	y	z		x	y	z
4	0.0	-6.2	-0.6		0.6	-6.3	-0.6		0.3	-6.3	-0.6
5	0.0	-5.7	-0.6		0.2	-5.6	-0.3		0.1	-5.7	-0.5
6	-0.1	-5.2	-0.9		0.3	-5.0	-0.5		0.1	-5.1	-0.7
7	0.0	-3.3	-0.6		0.2	-3.1	-0.2		0.1	-3.2	-0.4
8	-0.1	-2.4	-0.4		-0.2	-1.7	-0.3		-0.2	-2.1	-0.4
9	0.0	-1.0	-0.5		-0.1	-0.7	-0.2		-0.1	-0.9	-0.4
10	0.0	1.5	0.1		-0.8	1.8	0.7		-0.4	1.7	0.4
11	-0.1	1.9	0.8		0.4	2.0	-1.0		0.2	2.0	-0.1
12	0.5	2.5	0.7		-0.5	2.6	0.1		0.0	2.6	0.4

Table 4.8 Mean absolute difference, between T_1 and T_2, using the 3DMOD (3mm canting)

	X direction						Y direction						Z direction				
	Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value
			Lower	Upper					Lower	Upper					Lower	Upper	
Canting																	
3mm up on right	0.4	0.3	0.2	0.7	0.550		0.2	0.2	0.1	0.4	0.003†		0.5	0.5	0.1	0.9	0.998
3mm up on left	0.2	0.1	0.1	0.3	0.001†		0.2	0.3	0.0	0.4	0.011†		0.5	0.7	0.0	1.1	0.928

One sample t-test hypothesized mean of 0.5mm.

† Statistically significantly less than 0.5mm

Table 4.9 Simulated mean (SD) 3mm maxillary impaction and 3mm advancement recorded by the 3DMOD in the x, y and z directions at T_1 and T_2.

Red – landmarks moving superficially at level of upper 6's., Blue – landmarks moving anteriorly

	T_1				T_2		
Landmark	x	y	z		x	y	z
4	0.2	-2.2	2.0		0.0	-2.1	1.7
5	-0.2	-1.2	2.0		0.2	-0.9	2.2
6	-0.3	0.5	1.7		-0.2	0.5	1.7
7	0.0	2.9	2.3		-0.2	2.4	2.0
8	0.6	2.8	2.2		0.3	2.7	1.9
9	0.1	3.4	1.8		0.6	2.9	1.9
10	0.1	0.8	2.2		0.4	0.6	1.7
11	0.2	-0.5	1.9		0.3	-0.7	1.9
12	0.2	-2.0	2.2		0.2	-2.2	2.2

same level as he first permanent molars, showed a vertical change (posterior impaction) of 2.1mm and 2.2mm respectively, with minimal changes in the x-direction. As the 3DMOD is a rigid body all the landmarks should move anteriorly by 3mm. Table 4.9 shows that the change in AP position (x-direction) of the 3DMOD was from 1.7mm to 2.2mm

Following the result of a one sample t-test, with a hypnotised mean of 0.5 mm, none of the mean absolute difference, in the x, y and z direction, were significantly greater than 0.5 mm. However, the upper limits of the 95% confidence intervals for the mean absolute difference ranged between 0.0 mm and 1.0 mm, Table 4.10.

Table 4.10 Mean absolute difference, between T_1 and T_2, using the 3DMOD (3mm posterior impaction and 3mm advancement)

	X direction						Y direction						Z direction				
	Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value		Mean	SD	95% CI for absolute mean difference		p value
			Lower	Upper					Lower	Upper					Lower	Upper	
Bi-directional movement																	
3mm posterior impaction + 3mm advancement	0.3	0.3	0.1	0.6	0.184		0.3	0.2	0.1	0.4	0.007†		0.5	0.6	0.0	1.0	0.916

One sample t-test hypothesized mean of 0.5mm.

† Statistically significantly less than 0.5mm

CHAPTER 5

DISCUSSION

5.1 DISCUSSION

At present, in the United Kingdom, there is no consonance whether three-dimensional orthognathic surgery planning improves the clinical outcome of orthognathic surgery. The main reluctance for the routine use of 3D planning by surgeons is the additional radiation exposure associated with 3D cone beam CT scans over lateral cephalograms. In addition, the cost of the equipment and software also hinders routine clinical use; let alone the additional time taken to plan the case.

Cone beam CT scans can capture both the hard and soft tissues simultaneously, the main disadvantage of using this imaging modality is that for the purposes of assessing surgical outcomes each orthognathic patient requires two large field of view CBCT images: one pre-operatively and the second post-operatively. In the UK this is felt not be justified given the significantly high level of radiation exposure (Naina 2017; Ludlow *et al*., 2015; Scarfe and Farman 2008). However, technological advances have resulted in reduced radiation doses being used, which can only be beneficial.

At present, to assess skeletal change, the pre and post lateral cephalograms are superimposed on the anterior cranial base, de Coster's line, which is thought to be relatively stable due to minimal change after the age of seven (De Coster; 1953). The same principle of using the anterior cranial base is used to superimpose per and post CBCT scans. This is however not necessary as an equivalent level of accuracy can be obtained by using the zygomatic arches on a CBCT scan (Nada *et al.,* 2011; Lin *et al.,* 2015). It is not necessary to have an extended field of view scan including the anterior cranial base. Instead, a reduced field of view can be used, which terminates

at the superior limit of the zygomatic arches. This reduction in scanning volume size will reduce the radiation exposure but still allow superimposition of the pre and post operative images on stable structures i.e. the zygomas, instead of the anterior cranial base. Moving away from historical superimposition techniques and the reduced radiation exposure will hopefully eventually encourage orthognathic teams to consider taking pre and post orthognathic CBCT scans.

The reluctance to take routine CBCT scans for conventional orthognathic surgery planning and post-surgery means it is impossible to quantify the accuracy of the planned maxillary surgical movement in three-dimensions. The assumption, at present, is that the planned surgical movements have been correctly executed peri-operatively. Currently within the majority of UK hospitals, clinicians will routinely take a post operative two-dimensional image using a lateral cephalogram and clinical photographs to assess the outcome of surgery (Vittert *et al*., 2018). As a result, current clinical practice fails to accurately quantify the amount of maxillary or mandibular movement in three dimensions, achieved during surgery. Given the shortcomings of using 2D images to determine 3D movements and the lack of acceptance of 3D planning in the UK an alternative method of quantifying 3D maxillary movement, without the use of ionising radiation is required. Therefore, the aim of this proof of concept study was to quantify the magnitude and direction of simulated maxillary movement using 3D stereophotogrammetry. It may seem counterintuitive to use stereophotogrammetry as it captures only the air / soft tissue boundary and not any skeletal or dental tissue. Stereophotogrammetry was chosen as it captured the facial surface with colour texture in milliseconds reducing

movement artefacts and inaccuracies. Therefore, a specifically designed device was required to indirectly measure maxillary skeletal movement in three planes of space.

The 3DMOD was designed as a means of measuring the maxillary movement during simulated surgery. The device needed to record the movement of the maxilla using extra-oral measurements captured using stereophotogrammetry. This was achieved by assuming the maxilla and the dentition moved as a single unit i.e. as a one piece maxilla. The device required an intra-oral component, which could be secured to the dentition and underlying maxilla, with extra-oral projections to enable the movement of the maxilla to be captured by the stereophotogrammetry system. A modified Fox's Plane Guide was the starting point for the device. Previous studies, based on CBCT scans, have used three points on the maxillary dentition to form a triangle and then determined the movement of the maxilla by determining the change in position of the triangle, based on the concept of "rigid body transformation". Rigid body transformation is where an object i.e. the pre-operative maxilla, is modelled as a set of points i.e. a triangle, in Euclidean space. The change in position of the original triangle from the pre-operative position to the post-operative position can be calculated such that the Euclidean distances between the points of the triangle are preserved. This same principle was extended to the landmarks located on the extra-oral arms of the 3DMOD. The 9 extra-oral landmarks located on the periphery 3DMOD when secured with to the maxilla, will behave as a single unit and will undergo a rigid body transformation. The extra-oral movement of the guide plane mirrors the movement of the maxilla it is attached too.

Ideally to test this proof of concept the 3D maxillary movements recorded by the 3DMOD would be compared to the actual 3D changes in a group of patients. The actual maxillary changes would be determined by firstly superimposing the pre and post-operative CBCT scans of the same individual on the anterior cranial base. Then, secondly, placing landmarks on the maxilla itself, or maxillary dentition, and calculating the changes of the landmarks between the pre and post operative images in the x, y and z-direction. In the present study this was not possible for two main reasons; firstly, it is not routine practise to take pre and post-operative CBCT images for orthognathic patients in the UK, hence the need for the research. Secondly as a result of the COVID19 pandemic all elective surgery in the UK was halted. This meant very few orthognathic surgery patients underwent surgery, potentially delaying the research project.

The solution was to create a physical simulation model to determine the accuracy of the 3DMOD in determining 3D maxillary movement, in this case a plastic skull. One option was to section the maxilla from the plastic skull base, simulating a Le Fort I osteotomy, and move it into a known new position and determine whether the 3DMOD recorded the same maxillary movements. The problem with this technique it is difficult to precisely measure the true movement of the maxilla once it is detached from the base of the plastic skull. Keeping the maxilla attached to the base of the skull but physically moving the 3DMOD a known amount overcame this problem. In the real clinical situation, the 3DMOD would move the same amount as the maxilla it was attached to via the dentition. Simulating a maxillary advancement by advancing the 3DMOD alone allowed greater precision of movement using Lego pieces, which were parallel, and of known height. To facilitate this the occlusal surface of the

maxillary dentition was replaced with a flat surface which allowed even and stable adhesion of the Lego pieces.

Clinically, orthognathic surgery planning should start with the head in natural position. This is not possible using a plastic skull and so the plastic skull was oriented, so the Frankfurt plane was horizontal, with the orbital rims parallel to the horizontal and no rotational error. This orientation also ensured that the movement of the maxilla would be measured digitally in reference to the correct planes and co-ordinate system. The Frankfort plane was parallel to the X-Z plane (axial plane), the orbital rims were parallel to the axial plane and the mid-sagittal plane (Y-Z plane) was perpendicular X-Z plane passing through nasion. In other words, the planes used to position the plastic skull, and determine the direction of maxillary movement were replicated in the digital environment.

As part of the process of quantifying maxillary change using CBCT scans the first step is to superimpose the pre and post images on the anterior cranial base. Any change in maxillary position is then due to the surgery. In the present study as there was no image of the anterior cranial base so the soft tissue forehead and nasal bridge region were used for superimposition. If two 3D facial images of the 3DMOD are taken of the same individual in situ and superimposed on the forehead the 9 landmarks on the 3DMOD will line up with one another. Applying this principle but moving the 3DMOD forward by 3mm will mean all of 9 landmarks will move forward by 3mm. As a result, following superimposition of the pre and post facial images, if the 3DMOD moves forward 3mm then this would mean the maxilla had moved forward 3mm i.e. a 3mm maxillary advancement.

Clinical use of the 3DMOD would involve taking a pre-operative 3D facial image of the patient with their 3DMOD in situ whilst in Natural Head Position (NHP) (Sollow and Tallgreen, 1971). Then following the maxillary osteotomy, and when intra-oral access can be gained, a post-operative 3D facial image of the patient with their pre-operative 3DMOD in place would be taken. This means that the 3DMOD would be inserted on two separate occasions. The 3DMOD would need to be removed and inserted with minimal error to ensure that maxillary change was measured and not errors in seating the 3DMOD on two separate occasions. In this study there was less than 0.5mm difference in the x, y and z direction in landmark registration when the 3DMOD was inserted at two different time intervals. This error is clinically acceptable and will be a combination of several sources of error including capture error of the system, superimposition error and landmark identification error. A single individual wearing upper & lower fixed appliances was included in the group and the error associated with 3DMOD placement was of a similar magnitude to the non-fixed appliance group. Given that patients undergoing orthognathic surgery will be wearing fixed appliance; this suggests that the fixed appliance does not interfere with 3DMOD placement reproducibility.

For uni-directional maxillary movements (advancement and impaction) the results showed that the mean differences between the simulated maxillary movement and the 3DMOD measurement were significantly less or equal to 0.5mm. The results suggest that the 3DMOD is clinically valid to measure simulated maxillary advancement and impaction. The measurements were also reproduceable for the sample tested. It is worth noting that the upper limit of the 95% confidence intervals for the mean absolute differences for simulated maxillary advancements were upto

1.1 mm. Given this is difference is greater than the 0.5mm threshold of clinical significance, the reproducibility of simulated maxillary movement recorded by the 3DMOD may be upto 1.1mm in the larger population. Bearing in mind this includes image capture error, image superimposition and landmark identification error. These simple maxillary advancement and impaction measurements could also be measured on a lateral cephalogram as they are single vector movements. However, if there was any additional movement i.e. rotation in the transverse plan, then these measurements based on two-dimensional images would be inaccurate.

More complex movement such as cants cannot be measured from a lateral cephalogram and would need a posterior- anterior cephalogram. However, these are not routinely taken and are difficult to analysis given the superimposition of numerous skeletal and dental structures. The 3DMOD was able to accuracy measure the change in cant or “roll” which was simulated. However, the analysis is not straightforward since there is an axis of rotation around which the maxilla rotates. For simulated surgery this was along the length of the Lego spacer which was in turn parallel too along the length of the opposite occlusal surface. Given that some of the 9 landmarks were rotating upwards and some downwards, the point of rotation could easily be determined. For a left down cant the 3DMOD would rotate around the z-axis passing through landmarks 7 and for a right down cant the 3DMOD would rotate around the z-axis passing through landmarks 9. For routine orthognathic cases this is representative of a clinical situation where a maxillary cant is being surgically corrected. This means that for the 3DMOD to be used in this manner it may not be possible to use a pre-landmarked device but some of the landmarks would need to be placed specifically on the device at pre-defined points of rotation as the maxillary

width would vary between individuals. The reproducibility of assessing maxillary canting was less than 0.5mm which again suggests that the 3DMOD is clinically valid. However, the upper 95% confidence interval for the mean absolute differences in simulated maxillary canting and those recorded by the 3DMOD may be upto 1.1mm in the larger population. Again, this may be clinically valid given all the systematic sources of bias.

The most complex simulated maxillary procedure was the posterior maxillary impaction and simultaneous advancement. Again, this involves a point of rotation for the posterior impaction around the plane of the upper incisor tip and translation of the entire 3DMOD. Again, results would suggest that the 3DMOD is clinically valid and reportable at measuring this type of movement. There are two aspects which need to be borne in mind when placing the landmarks on the 3DMOD. The first is that the axis for rotation of the maxilla surgically when carrying out a posterior impaction is the incisor edge, therefore landmarks 6 and 9 need to be in the right position on the 3DMOD to recreate this axis. Secondly the molar that is being used to measure the amount of impaction needs the landmark (4 and 12) to lie adjacent to them on the 3DMOD. This highlights the need to customise landmark placement on the 3DMOD rather than generic or random placement.

No previous studies have investigated the accuracy of measuring 3D maxillary changes not based on a CBCT scan. Previous studies have however developed new digital tools to measure maxillary changes based on pre and post-operative CBCT scans. The authors have reported on the validation of the digital tools; however, they have assessed the planned surgical movements and the post-surgical position of the

skeletal and dental tissues. The problem with this is that the studies are assuming that the planned surgical movements have been carried out at the time of surgery. A situation could arise were the actual maxillary change is under achieved whilst the digital tool underestimates the maxillary movement. The end result would be that the tool was valid, but it was not measuring the actual surgical change, as it had not been achieved. The ideal would have been to carry out a similar as the present study using simulated known surgical maxillary movements.

This study has several limitations as it is in vitro study based on simulated maxillary movements rather than on actual orthognathic patients. As previously discussed, to conduct this study on patients would require full NHS ethical approval, as it is not routine practice to take pre and post CBCT scans of patients. Other options would be to work with teams; generally, out of the UK, who do take pre and post CBCT scans as a matter of routine. Prior to COVID19 this was the plan. Another major limitation of the study and the 3DMOD is that only one-piece maxillary movements can be assessed; this is because the 3DMOD would not fit post-surgically in following a segmental maxillary osteotomy. Fortunately, in the UK the need for segmental maxillary osteotomies is uncommon due to the skeletal aetiology of the malocclusion. In addition, mandibular movements cannot be directly assessed using the 3DMOD. However, using the final occlusion it would be possible to indirectly measure mandibular change relating back to the maxilla.

CHAPTER 6

CONCLUSIONS

6.1 CONCLUSIONS

This study showed that the 3D Maxillary Orientation Device (3DMOD) can measure simulated three-dimensional changes, in the x, y and z direction, of the maxilla. The device has been validated, in a simulated clinical environment, and can measure maxillary anterior-posterior changes and vertical changes to within an error of 0.5mm or less. In addition, the 3DMOD can measure changes in maxillary cant. The device can be inserted and removed reproducibly i.e. in a simulated pre-operative and post-operative simulation. The 3DMOD is only usable for one-piece maxillary osteotomies and not following a segmental maxillary osteotomy. In the present sample, and under the present conditions, the 3DMOD produces reproducible measurements, within an error of around 0.5mm. Based on the 95% confidence intervals this error could go upto 1.1mm.

The null hypothesis was accepted as the difference between the simulated maxillary movement and the movements determined by the newly developed 3DMOD were not statistically significantly ($p < 0.05$) 0.5mm or greater, as this would be deemed clinically significant.

The 3DMOD, coupled with stereophotogrammetry, is an acceptable method to measure 3D simulated maxillary movements. Further studies are needed to assess the validity and reproducibly of using the 3DMOD in patients undergoing maxillary osteotomies.

CHAPTER 7

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7.1 REFERENCES

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CHAPTER 8

APPENDICES

8.1. CONSENT FORM

UNIVERSITY OF BIRMINGHAM | SCHOOL OF DENTISTRY

Version 2 / 23rd August 2018

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM
Title of project: Recording your top jaw position
Name of Researcher: Professor Balvinder Khambay

Please initial box

1. I confirm I have read and understand the information sheet dated 23rd August 2018 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to Withdrawmy data within 12 weeks of participation without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the above study. ☐

4. I understand that data from this study may be used in future research. ☐

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Name of Patient	Date	Signature
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Name of Person taking consent	Date	Signature

8.2. PARTICIPANT INFORMATION SHEET

UNIVERSITY OF BIRMINGHAM | SCHOOL OF DENTISTRY

The title of the research project
Recording your top jaw position

Invitation paragraph
You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us / me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

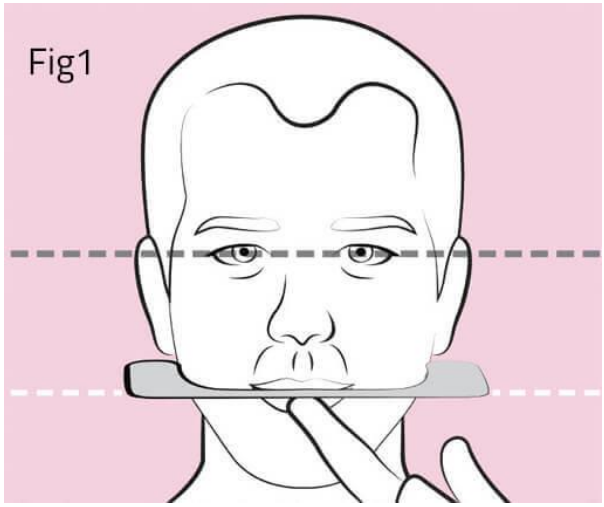
What is the purpose of the project?
To see if it is possible to determine how much the upper jaw has moved as a result of "simulated" surgery. Obviously you have not had surgery to your top jaw but we can simulate surgery to your top jaw but making modifications to a device that will record the position of your top jaw. The device sits in side your mouth and we can move it and take a 3D image of your face with the device in different positions – simulating the surgery.

Why have I been chosen?
We are looking for 5 volunteers between the ages of 18 and 50.

What do I have to do and what will happen to me if I take part?
You will be asked to attend the Birmingham Dental Hospital & School for a period of approximately 30 minutes on two separate occasions.

At **Visit 1** we will

1. Take molds of your teeth
2. Take a picture of your face – using a 3D camera system
3. Place a device in your mouth to record the position of your upper teeth and jaw and take a 3D photograph of your face.



At **Visit 2** (4 weeks later) we will

1. Place the device back into your mouth with 10 different spaces in place and take a 3D picture with each of the spacers in place.

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form). If you wish to withdraw you can do so without it affecting any benefits that you are entitled to in any way. You do not have to give a reason. You can withdraw at any time but your data cannot be withdrawn after 12 weeks of completion of the study.

We may use your data from this study for future research projects.

Will my taking part in this project be kept confidential and what will happen to the results of the research project?
Yes. Only the researchers involved will know you have taken part. The images generated will not be used in publications unless you have specifically consented. They may however be used in presentations to fellow researchers who are also interested in this technology. Your facial images will not be shown, only the results of the study.

What will happen to the results of the study?
The main findings will be written up and submitted to an appropriate scientific journal; again your facial images will not appear in the journal unless formal approval has been obtained.

Contact for further information

If you have any further queries please do not hesitate to contact any of the researchers involved via the email addresses supplied above.

Professor Balvinder Khambay
Tel
Email:

This study has been reviewed and given a favourable opinion by University of Birmingham, Research Ethics Committee