A STUDY TO COMPARE THE ACCURACY OF VOLUME MEASUREMENT BETWEEN A COMMERCIALLY AVAILABLE 3D FACIAL IMAGING SYSTEM (DI4D SNAP) AND AN "APP" BASED SYSTEM (BELLUS3D).

by

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ABSTRACT

AIM

The aim of the study is to compare the accuracy of volume measurement between a commercially available 3D facial imaging system (Di4D SNAP) and an "App" based system (Bellus3D).

STUDY DESIGN: Single centre, prospective trial.

MATERIALS & METHODS

Thirty-three volunteers comprising of staff and students at Birmingham Dental Hospital and School were recruited. Volunteers had to meet the inclusion and exclusion criteria, no recent dental or medical interventions and no known craniofacial conditions. Baseline 3D facial images at rest were taken using Di4D SNAP and Bellus3D. 2cm^3 polyvinylsiloxane putty simulated volume explants were added to the chin, upper lip and right and left paranasal regions and the volunteers re-imaged using Di4D SNAP and Bellus3D. Following facial image capture, the simulated volume images were superimposed on the baseline images and the volume difference in the chin, lip, right and left paranasal regions were measured, using the Tetrahedral Construction Method (TCM), and compared to the gold standard known volume of the putty (2cm^3). In addition, the accuracy of using TCM and a Coons patch, to measure volume, was assessed using only the Di4D SNAP facial images.

RESULTS

Overall, the mean percentage error for Bellus3D was an over estimation of 10.4% (95% CI 2.5 to 18.2%). Overall, the mean percentage error for Di4D SNAP was an underestimation of 1.6% (95% CI -4.4 to 1.1%). The median volume difference between Bellus3D and Di4D SNAP was statistically significantly different ($p<0.05$) in all areas except the left paranasal region. When comparing the Coons patch and TCM for volume measurement, overall as a percentage, the Coons patch overestimated the mean volume by 9.4% (95% CI 5.0 to 13.6%). Whilst the TCM algorithm underestimated the mean volume by 1.6% (95% CI -4.4 to 1.1%).

CONCLUSIONS

Across the 4 regions investigated there was close to a 10% error in mean volume measurement using Bellus3D and a 2% error using Di4D SNAP. This was a statistically significant difference ($p<0.05$) based on the actual volume differences. The results of the present study would suggest that Bellus3D captures simulated volume changes of the left side of the face with greater accuracy than the right side of the face. Based on the Di4D SNAP images, across the 4 regions investigated, there was close to a 10% error in mean volume measurement using Coons patch and a 2% error using TCM.

LIST OF FIGURES

LIST OF TABLES

Contents

CHAPTER 1

LITERATURE REVIEW

1.1 INTRODUCTION

Prior to commencing orthodontic treatment, records are collected to document the current health and position of the patient's dentition as well as their soft tissue facial appearance. These are essential for treatment planning, as well as for medico-legal reasons. Orthodontic records have historically included radiographs, study models and intra- and extra-oral two-dimensional (2D) photographs. As technology has advanced, three-dimensional (3D) imaging has allowed facial capture of a volume or surface that can be viewed from different perspectives. From a diagnostic perspective, volumetric 3D imaging, for example CBCT and MRI scans, provide a vast amount of information that was previously unavailable. These methods of imaging are generally expensive and not routinely available in all clinical settings. They also, in the case of CT or CBCT, rely on additional radiation exposure and are therefore used in specific clinical situations, for example impacted teeth, where the benefit outweighs the risk (Alqerban *et al.*, 2014). Surface 3D imaging, on the other hand, is less expensive and captures the objects surface in detail and also has a role in medical and dental imaging. For example surface imaging is used for capturing the dentition using intra-oral scanners and during breast reconstructive surgery (Chae *et al.*, 2016).

1.2 Clinical indications for volume measurements

1.2.1 Orthodontics

Orthodontics as a speciality is involved in the precise diagnosis of craniofacial "normals" and abnormality. Traditionally, clinical records are two-dimensional (2D) in nature i.e. lateral cephalometric radiographs and 2D facial photographs, and can only capture the facial profile and provide no volumetric data. As a result, few studies have assessed the volumetric facial changes associated with orthodontic treatment. The technical advances and increased patient awareness of facial aesthetics has meant the clinician needs to be more aware of the potential soft tissue volumetric changes associated with orthodontic treatment. In a recent study, based on a volume transformation within the areas of the cheeks using modified 3D image, decreased cheek volumes were associated with lower aesthetic scores and were perceived with increased ageing. Interestingly, increased cheek volume also received lower aesthetic scores; suggesting there may be an "ideal" aesthetic cheek volume (Feng *et al.*, 2019). The study highlights the importance of cheek volume on perceived facial aesthetics and the appearance of premature ageing.

Three-dimensional (3D) scanning has been shown to be a reliable tool to analyse the circumoral region for treatment planning and assessing orthodontic outcomes (Zogheib *et al.,* 2018). Orthodontics commonly deals with the growing patient and many appliances have been designed and used to "modify" growth of the maxilla and mandible. Interestingly few studies have investigated the facial soft tissue volumetric changes following growth modification treatment. In a recent study comparing the facial soft tissue changes after Twinblock mono-block and Herbst treatment, an increase in soft tissue volume in the mandibular region was reported (Güler and Malkoç, 2020). The general lack of reporting of changes in facial soft tissue volume following growth modification treatment has been previously highlighted as deficiency, which can readily addressed using current technology (Flores-Mir and Major, 2006).

1.2.2 Orthognathic surgery

Three-dimensional volumetric and surface image capture has been used to assess the changes following orthognathic surgery. The main reported volumetric changes following surgery have focused on pharyngeal airway changes based on CBCT (Grauer *et al.*, 2009). When three-dimensional facial surface changes have been reported, they are predominantly based on changes in two-dimensional linear and angular measurements, historically derived from lateral cephalometric radiograph analysis. There are a limited number of studies reporting the facial volumetric changes following orthognathic surgery (Ferrario *et al.*, 1999; Sforza *et al.*, 2007; Oh *et al.*, 2013). Following class III correction, with bimaxillary surgery, there was a reduction in lower third facial volume and surprisingly middle third facial volume (maxillary volume). It was suggested that the reduction in maxillary volume as a result of the maxillary impaction was greater than the increase in volume resulting from the maxillary advancement resulting in a net reduction in the middle facial third volume. Compared to a non-treated cohort the upper lip volume was significantly greater following surgery and subsequent post-surgical orthodontic treatment (Ferrario *et al.*, 1999; Sforza *et al.*, 2007; Oh *et al.*, 2013).

Three-dimensional imaging has been used to assess facial soft tissue swelling extent and resolution following orthognathic surgery. Van Der Vlis *et al.* (2014) carried out a study to assess changes in soft tissue swelling using serial stereophotogrammetry images and showed 50% of post-surgical swelling reduced in the first three weeks, with less swelling in patients with a lower BMI (Van Der Vlis *et al.*, 2014). These findings can form the basis of communication and managing expectations of patients undergoing orthognathic surgery. An understanding of soft tissue volumetric changes is useful for diagnosis and treatment planning of orthognathic surgery (Ryckman *et al.*, 2010). Progression in this area may allow the development of more predictive methods for orthognathic treatment planning (Nkenke *et al.*, 2003).

1.2.3 Assessing growth and ageing

Changes in facial volume are a well-accepted consequence of ageing (Shue *et al.,* 2018). Non-invasive sequential 3D imaging over time provides a method to monitor facial ageing and a deeper understanding of the facial changes that take place over time (Camp *et al*., 2011). 3D scanning can also be used to assess facial growth and can be particularly useful in patients who require growth cessation before treatment can be provided, for example class III camouflage orthodontic cases, in which mandibular growth needs to be completed before treatment can be provided (Ferrario *et al.*, 1998). Monitoring of growth and ageing can be carried out using 2D photographs; however 3D imaging provides a more accurate and detailed view, with the added ability of overlaying images to detect small changes.

1.2.4 Oral & Maxillofacial procedures

Cleft lip and palate surgery is concerned with restoring both form and function to the naso-labial region. There are several methods of outcome assessment regarding naso-labial aesthetics, these include the Asher-McDade system (Asher-Mcdade *et al.*, 1991), the V.L.S (vermilion, lip, scar) classification (Assuncao, 1992), Cranio-facial proportion indices (Farkas and Munro, 1987), the aesthetic index (Johnson and Sandy, 2003) and the cleft lip evaluation profile (CLEP) index (Ohannessian *et al*., 2011). These all rely on conventional 2D photographs. However given the 3D nature of the naso-labial complex and the reduction in anterior projection of the lip and nasal tip, nasal volumetric changes are more clinically useful and have been reported using 3D stereophotogrammetry (Mancini *et al.*, 2021).

Oral surgery procedures, such as third molar removal, commonly cause post-operative swelling. 3D surface scanning has been shown to be a reliable method of assessment for this purpose (Harrison *et al.*, 2004; Brüllmann *et al.*, 2014). The degree of swelling has been quantified as differences in volumes based on 3D surface scans using stereophotogrammetry (Rana *et al.*, 2013).

Following oral and facial cancer resection the residual defects are often managed with musculocutaneous flaps. These flaps are not only required to close defects but also to restore volume in some of the most aesthetically demanding areas of the face. At present CT scanning has been used to assess the muscle and fat volume transferred into the head and neck region (Yamaguchi *et al.*, 2012). Although the use of flaps is relatively routine in the United Kingdom, few studies have assessed the long-term muscle and fat and overall volume changes.

1.2.5 Cosmetic Procedures

Non-surgical procedures to harmonise facial appearance by altering volume have become increasing popular. A common technique is the use of Botulinum toxin injection into the masseter muscles to reduce the volume of the muscle and in turn give the face a slenderer appearance; this treatment is particularly useful for patient's suffering from masseter hypertrophy. Three-dimensional volumetric measurements allows the efficacy of this procedure to be measured and would also allows the long term volumetric changes to monitored (Chang *et al.*, 2019). Cosmetic fillers to add volume to lips, cheeks, jaw line and for non-surgical rhinoplasty are also becoming increasing popular. Previous studies have reported on the apparent changes in facial volume with different types of filler using 3D stereophotogrammetry (Downie *et al.*, 2009). The use of 3D volumetric measurement, using stereophotogrammetry, allows this to be assessed and in turn provides the clinician with the volume of filler required for the desired outcome.

3D stereophotogrammetry has also be used to quantitatively assess the outcome of facial rejuvenation following laser treatment, small volume changes to scars, wrinkles, facial rejuvenation surgery and face-lifts (Machado *et al.*, 2021). Facial fat grafts are now commonly used in conjunction with face lifts to replace fat which has been lost as a result of ageing atrophy (Marten and Elyassnia, 2018). Changes in volume, in particular loss in volume, are common cause of the appearance of ageing and hence restoring this volume can help to reverse and reduce the signs of ageing. In addition, providing plastic surgeons with an objective way to analyse their results, especially in relation to the volume of fat injection required. Currently credible methods of evaluation are lacking (Shue *et al.,* 2018). 3D facial volume measurements allow the evaluation of current techniques to restore volume and their long term effectiveness, this is an integral part of developing procedures and obtaining informed consent from patients (Mailey *et al.*, 2016; Cohen *et al.*, 2020).

1.2.6 Monitoring pathology and disease

Soft tissue and bone pathology, such as cysts and tumors, can cause expansion and volume changes of the face. Diagnosis and assessment usually involves volumetric assessment using CT or CBCT. Treatment is commonly surgical with enucleation or reduction in the size of the lesion using marsupialisation. For soft tissues lesions the imaging of choice is initially plain film radiology to rule out bone involvement and then MRI, CT and/or ultrasound (Church *et al.,* 2017). The use of CT has declined as the popularity of MRI has increased as it is considered the most sensitive and specific imaging technique for the evaluation of soft tissue masses (Church *et al.,* 2017).

1.3 CURRENT THREE-DIMENSIONAL VOLUMETRIC CAPTURING MODALITIES

1.3.1 Computerised Tomography (CT)

Computerised axial tomography (CT) is a medical imaging technique that uses multiple x-ray measurements from different angles to generate an image via computerised reconstruction (Erten and Yılmaz, 2018). CT scans are widely used in medicine and dentistry for their diagnostic value. CT scanners can be divided into two main forms, based on the shape of the x-ray source: fan and cone beam. When taking an image with a fan CT machine the patient is positioned horizontally on a table and passes through a circular x-ray source, which is simultaneously revolving around the table. As the x-ray source rotates around the patient it generates a fan shaped beam of x-rays through the patient. A detector, which is positioned opposite the generator, then registers the exiting x-ray beam and converts this into an image. In this manner, multiple sections of the patient's body are scanned in turn and a final 3D image is produced, as these consecutive axial slices are "stacked" on top of one another. These images can then be rendered into a 3D surface image to create a 3D model that can be viewed from any angle.

1.3.2 Cone Beam Computerised Tomography (CBCT)

A Cone Beam CT machine is made up of a rotating x-ray source and x-ray detector. During imaging the subject is placed between the source and the detector, whilst the centre of the region of interest becomes the fulcrum of rotation. A cone shaped source of ionizing radiation is directed through the subject onto the x-ray detector on the opposite side. The main advantage of CBCT over conventional CT is the reduced radiation dose to the patient. Both type of CT scanners are able to produce a 3D volumetric image which can be manipulated in many planes.

The applications of CBCT in the field of dentistry and orthodontics have increased since its introduction. CBCT scans are justified when conventional radiographic assessment does not provide sufficient information for planning and execution of the treatment. In orthodontics CBCT is commonly used to assess:

- The position of impacted teeth or supernumeraries (Erten and Yılmaz, 2018).
- Root morphology – including root resorption or ankylosis which would not be diagnosed by conventional radiography (Abdelkarim, 2019).
- Crown / root morphology of fused or geminated teeth.
- Planning of treatment mechanics (Abdelkarim, 2019).
- Planning of multi-disciplinary care, especially where the CBCT could be used to aid the patient's surgical management (Venkatesh and Elluru, 2017).
- Planning of orthognathic treatment and construction of surgical wafers (Venkatesh and Elluru, 2017).

However, due to the increased exposure to ionising radiation compared with conventional radiographs, detailed clinical assessment is needed to determine whether the CBCT is clinically necessary and justifiable so as to reduce exposure to the patient as much as possible.

1.3.3 Magnetic Resonance Imaging

Unlike CT scanners, MRI machines have the benefit of not utilising ionising radiation. Instead, they use magnetic fields and radiowaves to generate images. The cells of the human body contain hydrogen atoms and are made up of hydrogen protons which spin on their axis. When the body is placed in a strong magnetic field, such as an MRI machine, the hydrogen proton axes line up, creating a “magnetic vector”. When the cells are then exposed to radiowaves, the magnetic vector becomes deflected. Once the radio waves are stopped, the magnetic vector returns to its original state which causes a signal to be emitted in the form of a radiowaves which is picked up by receptors present in the machine. The signal is then numerated and processed by a computer into sectional images. The rate at which the magnetic vector returns to its resting state is different for different tissues, as is the intensity of the radiowaves signal produced and emitted. This produces the contrast that allows different tissues to be imaged in detail.

In medicine, MRI scans allow 3D visualisation of internal structure and are useful for the detection of pathology. The problems with MRI scanning are that pacemakers, metal valves, metal joints can move when subjected to the magnetic field. In addition there is distortion of the image around metallic objects (Berger, 2002). In the field of dentistry, MRI is particularly useful to visualise the TMJ. However, the use of MRI in dentistry is limited because a patient with metallic dental restorations within the image field would produce scatter of the radiowaves and produce images of very low diagnostic value. Similarly, the metals used in orthodontic appliances would produce scatter if imaged and hence this is not the imaging technique of choice in orthodontics or orthognathic surgery (Karatas and Toy, 2014).

1.4 CURRENT THREE-DIMENSIONAL SURFACE CAPTURING MODALITIES

1.4.1 3D Structured light scanners

Structured light techniques involve illuminating an object with a pattern of light (dots, strips or grids) and as the light makes contact with the object it becomes distorted. A camera positioned at a different angle to the light source is used to capture the image of the object with the light pattern over laid. The difference between the light position on the projection and the source of the image is calculated and 3D co-ordinates are produced. These are then used to construct a 3D image. Essentially, a superficial three-dimensional image of an object is produced but it provides no information on the internal anatomy.

The quality of the final image is improved when the object is illuminated by numerous light patterns. However, this increases the capture time which can lead to problems with positioning reliability that directly affects the quality and accuracy of the image produced (Karatas and Toy, 2014). When structured light is used to produce an accurate image of the face from ear to ear, more than one image is required, or the object needs to be rotated. The movement of the subject and increased capture time of a live subject, who may find it difficult to remain static, can introduce error (Karatas and Toy, 2014) (Tzou *et al.*, 2014).

1.4.2 Stereophotogrammetry

Stereophotogrammetry is a non-invasive 3D imaging technique used to produce a 3D image of an object. It works by utilising at least two cameras set up at different angles to the subject (Karatas and Toy, 2014). There are three different types of stereophotogrammetry: active, passive and hybrid.

Active stereophotogrammetry is similar to structured light scanning and projects a speckled light pattern onto the surface of the object during image capture. A stereopair of cameras, at different angles, are used to capture the speckled pattern and underlying object. Generally, the specked pattern is infrared and so does not appear on the final textured image. The speckled infrared and conventional images are captured simultaneously. Following calibration, the "depth" of 2D speckled points is calculated using the images captured using the infrared cameras. This depth information, using the principle of "triangulation" is then used to reconstruct the 2D image captured by the conventional cameras to create a photo-realistic 3D textured image of the object.

Passive stereophotogrammetry is similar to active stereophotogrammetry but does not use the specked pattern. Passive stereophotogrammetry utilises conventional high-resolution camera pairs at different angles to capture images of the subject. Without the speckled light pattern, the system relies on high quality images that use corresponding points on the surface texture to aid the processing and location of corresponding points i.e. hair follicles or skin surface imperfections. Finally, hybrid stereophotogrammetry combines both the active and passive to produce high-quality 3D surface imaging.

1.4.3 Laser Scanners

Laser scanners, used to capture the face, project a laser line onto the surface of interest whilst two sensor cameras continuously record the changing distance and shape of the laser line in three dimensions (x, y and z) as it moves across the object. This allows the scanners to triangulate the distance of the surface and produce a point cloud with known x, y and z co-ordinates.

Alternative systems are "time-of-flight lasers" which work by combining controlled movement of a laser line and distance measurements. Multiple scanning mirrors are adjusted to direct the lasers line and control the scanning motion. The time for the laser line to travel from the scanner to the object and back is measured using a laser range-finder. As the speed of light is known, the distance between the scanner and the object can then be calculated using a simple formula. The accuracy of this method is dependent on the accuracy of the time measurement (Karatas and Toy, 2014). As a single scan is unlikely to capture sufficient data to produce the entire model, multiple scans are brought together into a common reference system to produce a final 3D facial image.

A previous problem associated with laser scanning of the face was that the patient would need to close their eyes due to the risk of exposure to the laser beam (Karatas and Toy, 2014). Closing of the eyes will change the resting position of the soft tissues around the patient's eyes, not giving an accurate reflection of the soft tissues in the area. As the eyes and interpupillary distance/lines are important reference points, this affects the diagnostic value of images acquired by laser scanning. The newer generation of laser scanners have overcome this problem and are now eye-safe.

1.5 3D PORTABLE SCANNING SYSTEMS

The availability of hand-held portable 3D scanners has given rise to further options and opportunities for clinicians to capture the face. Portal scanners offer flexibility with regards to ease of use at a fraction of the price of larger commercial units. Portable scanners can be further divided into desktop scanners, handheld scanners, and smartphone 3D scanners. Some are able to scan objects, others human body parts and some are able to do both. For the purpose of capture of the human face the handheld and smartphone 3D scanners are of particular interest for routine clinical use. The options available are extensive and the field is continuously growing and therefore it is beyond the scope of this review to cover all available systems. Below is an overview of a few of the available products which have been used for facial capture.

1.5.1 FastSCAN™

The FastSCAN handheld laser scanner is based on laser scanning technology. It is able to scan organic objects and objects not made up of ferrous metals. FastSCAN is made up of two symmetrically arranged cameras around a central laser and an electromagnetic tracker. It allows the operator to produce a 3D digital imaging by holding the scanner and pointing it at the object and swiping over it several times. The scanner has been used to measure postoperative facial volume change after extraction of third molars. The volume error was $1.8 \pm 1.2cm^3$ during clinical use and $0.8 \pm 0.2cm^3$ in vitro (Harrison *et al.*, 2004).

1.5.2 Bellus3D

Bellus3D is a software application that either uses its own proprietary camera system or uses the existing technology incorporated into the later iPhone and iPad camera systems. The proprietary camera system, supplied by Bellus3D is attached to a non-Apple Tablet or phone using the Android based operating system. Unlike some other portable scanners, Bellus3D is designed only to capture the face and cannot be used to scan other objects. When based on an Apple device the Bellus3D app functions by combining two state of the art proprietary technologies used in the facial recognition security system incorporated in the device - Depthshape™ and Photoshape™. Depthshape™ technology uses an infrared structured-light depth camera with 0.4mm resolution and submillimeter accuracy, whilst Photoshape™ uses the mobile device's camera resolution to capture facial details. An external LED light source can be added to improve lighting for facial capture. A recent study showed that compared to the other scanners tested, EinScan Pro, EinScan Pro 2X Plus using Shining Software and Planmeca ProMax 3D Mid, the iPhone X with Bellus3D software application software showed the lowest accuracy in depth measurement (Amornvit and Sanohkan, 2019). A further study measuring the accuracy of Bellus3D to an Industrial scanner (GOM Atos Q 3D 12 M) showed that the scanning accuracy was dependent on the region of the face; the middle of the face was more accurate than the sides (Revilla-León *et al.*, 2021). Currently there are no available studies testing the accuracy of volume measurements using Bellus3D.

1.5.3 Vectra H1 handheld 3D scanner

The Vectra H1 handheld 3D Imaging system uses 3 images captured by the device to produce a 3D image. The H1 handheld scanner has been compared to a traditional tripod 3D capturing device and manual method using handheld callipers for recording anthropometric measurements (Kim *et al.*, 2018). The results showed that the handheld device and conventional 3D tripod device were more accurate and reliable than the manual method of callipers for all landmarks except Ch-Ch linear distance. When compared to 3dMD, differences in registration of the nostrils, eyelids and mouth were noted and upper bound error of 0.44mm and 0.4mm reported (White *et al.*, 2020). However, there are no available studies assessing volume measurement.

1.5.4 Fuel3D Scanify

Fuel3D Scanify can be used to scan non-reflective highly textured objects including natural materials such as wood and skin. The scanner is unable to capture translucent objects as the light passes through them, or shiny object where the light reflects. The scanner is made up of three LED guide lights, three Xenon flashes and two 3.5-megapixel RGB, one in the centre and one in the bottom-centre. It uses photogrammetry algorithms to distil depth information from multiple photos all taken within a second.

A study evaluated the accuracy of the low budget portable 3D stereophotogrammetry (Fuel3D Scanify) system for scanning the challenging nasal region. The study compared scans of the nasal region using Scanify with impressions taken and converted to plaster models, which were then scanned with 3Shape D500. Landmarks were analysed on generated STL (Standard Tessallation Language Files) and 3D best-fit analysis of both models were performed. The results demonstrated very high to excellent intra-class correlation coefficients for most landmarks. The lowest was found for the columella length and left nostril. The study concluded that Fuel3D Scanify had comparable accuracy for clinical use (Ritschl *et al.*, 2018). As this study compared direct scans to scans of plaster models possible errors may have been introduced during the impression taking process, the casting process and lastly the scanning process of the casts. Had the authors compared the scans taken with Fuel3D Scanify to direct stereophotogrammetry scans taken with a validated system the results may be more reliable. In addition, no studies assessing volume measurement were identified.

1.5.5 iSENSE Scanner

The iSENSE scanner is a small device which attaches to the rear camera of an iPhone or iPad. It is a structured light scanner that emits a pattern of infrared light on to the subject; the light is then reflected back to the camera which then finds the shape of the object. It is able to scan a variety of objects as long as they are stationary including human beings. Previous studies have compared the circumferential knee measurement of subjects using manual measurement, a high-level scanner (EVA scanner) and the iSense handheld scanner. The study reported that the low-cost scanner overestimates the geometry of the leg by a mean bias of 13mm (0.88%) in a relatively consistent way (SE = 0.13%) in comparison with the high-level scanner (EVA) that over-estimated by 2.5mm (Dessery and Pallari, 2018)

1.6 CURRENT METHODS OF MEASURING VOLUME

1.6.1 Definition

Volume is a measure of quantity in the three dimensions within an enclosed space. The volume of a container is often considered the volume of its contents rather than a volume of the space it displaces. When the space is uniform or regular, simple measurements can be used to calculate volume; for example, the volume of a cube is calculated as height x width x length. For a sphere which is a perfectly round geometric three-dimensional object with every point on its surface equidistant from its centre, the volume (V), is calculated by its radius (r) and using the formula, $V = \frac{4}{3}\pi r^3$. If the object is not uniformly shaped but can be split into uniform three-dimensional shapes the volume can be calculated using the summation of the volume of the individual shapes. However, when the shape of the object is irregular the volume cannot be determined by simple mathematics.

1.6.2 Volume measurements based on direct clinical measurements

1.6.2.1 Water displacement

Archimedes, the Greek mathematician and inventor, was the first to describe the water displacement method of volume measurement. The Archimedes Principle states that any object completely or partially immersed in a liquid, is buoyed up with a force that is equal to the weight of the fluid that the object displaces. This method can be used to measure the volume of irregular objects, for example when object X is placed in a cylinder of water of volume A, the volume changes to volume B. The volume of object X is calculated in the difference between volume B and volume A, i.e. (volume of object = volume B - volume A).

The accuracy of water displacement has been measured in several previous studies and have been used to measure the volume of different body parts, including lower limbs (Stranden, 1981), breasts (Henseler *et al.*, 2012) and hands (Hargens *et al*., 2014). A high correlation between the water displacement method and surface measurement for measuring volume has previously been reported (Stranden, 1981). In all these studies the water displacement technique has been used to determine the "gold standard" volume for comparative testing. There are however potential problems associated with the accuracy and reliability of the water displacement method. Surface tension is created at the "air / water surface boundary" which causes an inwardly directed force and a tendency for the water surface to contract. It also causes the water to adhere to the surface of the container and to the surface of the object which results in reduced measurement accuracy. Methods to reduce these effects have been investigated further and it has been reported that the addition of 6% ethanol to the water was thought to reduce surface tension, adhesion and air bubble formation. This in turn improved the accuracy and reproducibility of hand volumetry (Hargens *et al.*, 2014). Other than issues associated with accuracy, the water displacement technique has been found to be time consuming, cumbersome and also not suitable for patients in the initial postoperative period. In addition it is not associated with a pleasant patient experience (Kaulesar Sukul *et al.*, 1993). Immersing the body part in water can be technically difficult in particular isolating the body area of interest. It may be easier for extremities such as the foot but areas of the torso or the face will be particularly difficult. As keeping the head or face immersed long enough to take measurement would be challenging. Also it may also involve suspending the head upside down into water in order to fully immerse the entire head evenly, this would be technically difficult and an unpleasant experience for the patient. Regardless of the practical difficulties water displacement has been considered the gold standard in volume measurement of irregularly shaped objects.

1.6.2.2 Thermoplastic casting

Another method of measuring volume is thermoplastic casting. Fast-setting plaster or a thermoplastic sheet is applied onto the surface area of interest, and this creates a negative mould of the area. The negative moulds' volume is then measured using sand or water. This method has been used to measure breast volume. Problems associated with this technique include soft tissue compression whilst placing the thermoplastic casting which can affect volume measurement. Also the material is inflexible and so moulding onto more complex surfaces can be difficult and boundaries can become unclear (Chae *et al.*, 2016). This technique would be difficult to use on the face. The technique has been found to have poor accuracy for breast volume measurements (Edsander-Nord, Wickman and Jurell, 1996).

A study by Kovacs (2007) compared the breast volume measurement using 3D laser scanning, MRI, anthropomorphic measurements and thermoplastic casting for 6 patients. Although they found a general correlation between all for volumes; their results show a deviation of 7.97% of the measured volume value for thermoplastic casting. They attributed the errors to tissue compression, inaccuracies with casting due to the rigid material, exclusion of breast volume measurement near the chest wall and assumption of a flat chest wall, rather than curved, resulting in a reduced volume measurements (Kovacs *et al.*, 2007).

1.6.2.3 Anthropomorphic measurement

A volume is calculated from a mathematical formula. The formula is derived from predefined end-to-end measurements taken directly from the patient or indirectly using imaging (Chae *et al.*, 2016). Anthropomorphic methods have been used in breast volume measurements. Individual measurements are taken on the subjects and then predefined geometrical shapes are imposed on the breast form and this is used to calculate the breast volume. However, as the predetermined geometric shape will not completely correspond to the individual anatomy of the subjects' breast there is scope for over or under estimation of the breast volume. Anthropomorphic measurements showed the lowest precision compared to 3D laser scanner, nuclear magnetic resonance imaging (MRI), and thermoplastic castings (Kovacs *et al.*, 2007).

1.6.3 Volume measurements based on 3D volumetric images

1.6.3.1 Cone Beam CT Scanning

Numerous studies have shown CBCT to be an accurate and reliable method for measurement of volume in the craniofacial region (Adisen *et al.*, 2015). To measure volume on a CT and MRI the Cavalieri principal is often used. It involves taking parallel sections of an object of equal thickness and calculating the volume (V) using the formula $V = t \times A$. Where t is the section thickness and A is the total sectional area of consecutive sections. The Cavalieri principle, a stereological method, is an effective method in volumetric measurements of biological structures. The Cavalieri principle provides numerical values expressing precise and unbiased quantitative measurements. In this principle, sections of an object that are parallel and of equal thickness are taken, and the volume of the object is calculated by the total number of section areas and thickness of the section. CT, MRI or ultrasonography section imaging studies have compared physical volume calculation based on the Archimedean principle with CBCT images using the Cavalieri principle and found them to similar (Kayipmaz *et al.*, 2011). The disadvantage of this method is the need to take a CBCT scan with the additional radiation exposure or access to an MRI machine. This method, even though possible, would not be of routine clinical use.

1.6.3.2 Magnetic resonance imaging (MRI)

MRI is seen as an attractive option for volumetric assessment of organs due to the absence of radiation and ability to assess internal organs. The volume of, for example, a tumour can be quickly estimated by multiplying the distance between sections *t* by its total cross-sectional area, however this would assume that the object is of a uniform shape. With the advancement and availability of computer software for quantitative analysis in cross-sectional imaging, the entire tumour, regardless of its shape, can be identified and traced as a region of interest on each imaging slice. This second method considers the irregularities in shape and border. The total volume of the irregular shape can then be calculated to a higher degree of accuracy; however, this method is more time consuming. One such study compared the MRI derived volume and the physical volume calculation, determined by dividing weight by density, of a series of phantom eyes and orbit. The study showed good correlation between the MRI volume measurements and the physical volumes (Chau, Fung and Yap, 2005). Again, MRI scanning to asses changes in the facial region is not practically possible in routine clinical practice.

1.6.4 Volume measurements based on 3D surface images

To measure volume using a 3D facial surface image a closed or "water tight" image is necessary. Stereophotogrammetry captures only the air / soft tissue boundary similar to that seem in a "physical costume mask"; this means the image is not closed and therefore volume cannot be directly measured. To overcome this there are several options, all of which include creating a “back wall” and sealing off the surface area into a volume. Different algorithms have been described to measure volume:

1. Backplane construction: a back plane parallel to the xy-plane and perpendicular to the z-axis is used to close off a patch and then the volume difference between the two is calculated by subtracting one from the other (Hajeer *et al.*, 2005).
2. Triangular mesh method: A closed triangular mesh between the two corresponding surface areas of particular interest is created and volume measured (Liu and Zheng, 2021).
3. Tetrahedron Method: triangular meshes are projected to the origin point (x=0, y=0, z=0) to construct a tetrahedron and then volume of the tetrahedron is calculated (Hajeer *et al.*, 2005).
4. Projection method: each triangle is projected to an arbitrary plane and the volume between each triangle and that plane is calculated (Hajeer *et al.*, 2005).
5. The use of a Coons patch (Henseler *et al.*, 2012).

1.6.4.1 Three-dimensional reconstruction

Following a 3D scan, the raw data is converted into point clouds (or ventricles) from the surface of the object. The ventricles are then connected via an algorithm to a manifold surface called a mesh; this is called the meshing process. The mesh is then stored as a series of component and is refined further. The next stage involves mapping texture onto the image. This is done by mapping each of

3D co-ordinates onto a corresponding 2D parametric (UV) unit plane and a 2D texture is mapped across the surface of the 3D model.

1.7 STUDIES VALIDATING 3D SYSTEMS MEASURING FACIAL VOLUME

Previous studies have assessed the validity of measuring changes in volume based on 3D facial scans (Brüllmann *et al.*, 2014; Harrison *et al.,* 2004; Hajeer *et al.*, 2005). The 'back-plane construction' method (BPCM) projects each image onto an arbitrary plane; this plane is parallel to the xy-plane and perpendicular to the z-axis. With each image sealed off the volume can be calculated. The volume difference is difference between these two volumes. The projection method either calculates the volume of a shape by projecting each triangle in the mesh back to the origin point to construct a tetrahedron (tetrahedron formation method - TFM) or by projecting each triangle back to an arbitrary plane (projection method - PM). For the TFM method the volume of each tetrahedron can be calculated whilst for the PM method the volume between each triangle and that plane is calculated.

Based on known volumes of polyvinylsiloxane explants, the actual volumes of which were determined by the water displacement technique, the three different methods of volume measurement were investigated using an invitro plastic head (Hajeer *et al.*, 2005). The mean difference between the water displacement method and the TFM method was $0.071cm^3$ which was not statistically significant. Both the differences for the projection method (PM) ($0.463cm^3$) and for the BPCM method ($0.442cm^3$) were statistically significant. On a human subject with polyvinylsiloxane explants, the mean difference in measured volumes increased to $0.314cm^3$ for the TFM, 1.399cm^3 for the PM, and 1.646cm^3 for the BPCM; only the error for TFM was not statistically significant.

The simplest method of creating a back wall is to superimpose the pre and post-intervention images over one another and use the pre-intervention image to form the back wall. Brüllmann *et al*. (2014) assessed facial volume following third molar removal. The study aimed to a test the prototype contact-free structured light scanner (Vitroscan-3D v.3, Vitro Laser Solutions, Minden, Germany) for its ability to measure postoperative facial swellings. A control group of 20 participants was used to test the accuracy of the scanner regarding volumetric measurements. A water balloon of known volume between 10ml to 30ml was placed in the buccal corridor of the volunteer's mouth and scans taken pre- and post-placement. Following rigid registration, based on a minimum of 4 stable corresponding landmarks, and fine registration using the iterative closest point (ICP) algorithm, the volume difference between the two images was calculated and compared to the known volume of the balloon. The results showed a median difference between the real and measured volumes of 0.67 cm^3. The standard deviation (SD) was 1.83 cm^3, the maximum difference was +3.46 cm^3, and the minimum difference was −4.96 cm^3. The use of the intra-oral water balloon is potentially a problem, as the full extra-oral volume of the balloon may not have been expressed intra-orally. For instance, this would depend on the elasticity of the overlying cheek tissue. This may explain the wide range of values reported. It may have been more suitable to place a known volume extra orally in the region of interest so that the accuracy of the scanner could be assessed with less bias.

The in vitro accuracy of the FastSCAN (Polhemus Inc., Colchester, VT, USA) handheld scanner for volume measurement has been investigated using known volumes of material placed extra orally (Harrison *et al.*, 2004; Edgar *et al.*, 2008)). A known volume of Blu-Tack® (12.3 ± 0.1cm^3) (Bostik Findley, Thomastown, Vic., Australia Pty. Ltd.) was attached to the right mandibular angle and submandibular regions of a mannequin head. Scans were taken pre and post addition of Blu-Tack® and the difference in volume calculated. The mean volume for the right side with the additional Blu-Tack® was 12.5 ± 0.5 cm^3. The same region on the left side was scanned twice without the addition of Blu-Tack® and used to assess scanning error; this was calculated as 0.8 ± 0.2 cm^3 (Harrison *et al.*, 2004). This confirms an acceptable level of accuracy in vitro. However, the in vivo part of the study, measuring the error associated with subject positioning, indicated the magnitude of the error caused by variations in position, ranged from 0.0 to 7.6 cm^3. There was obviously much larger range of error in volume measurement associated with live subjects. Interestingly a similar outcome was reported in a study using the same scanner to measure volume changes in arms in a control group as well as in a burns group. The study reported the accuracy of the scanning system compared poorly with water displacement measures in the burn clinical environment (Edgar *et al.*, 2008).

Generally, for measuring changes in facial volume related to an intervention, the baseline pre-interventional image and post-intervention image are used. However, during breast surgery, measuring and comparing breast volume between the left and right sides of the same patient is important, as the use of a baseline image may not be appropriate or possible. A reported technique for breast volume measurements has been the use a “Coons patch”. The Coons patch allows the measurement of a discreet volume based on a single image. The patch is a surface patch used in computer graphics to smoothly join other surfaces together and constructs a back wall i.e. the chest based on four point, joining surfaces together as an extension of the existing curves / shapes. The patch is formed mathematically by an algorithm and can be used for comparative clinical analysis of breast size where absolute volume measurements are not required (Henseler *et al.*, 2012).

1.8 SUMMARY

Traditional three-dimensional imaging such as CT and MRI have an integral role in the diagnosis and management of disease and pathology (Church et al., 2017). Beyond pathology the use of 3D volume measurement has important applications in the more aesthetically driven fields of medicine such orthodontics, oral & maxillofacial surgery, plastic surgery and dermatology.

From a diagnostic perspective, volumetric 3D imaging provides additional information that was previously unavailable using traditional two dimensional images such as photographs and plain film radiographs. As patients become more aesthetically aware and driven, planning and communication should offer an opportunity to address all the concerns of the patient and offer an indication of the soft-tissue volume changes following the recommended treatment options. Although studies have started to assess the soft tissue changes following orthodontic treatment such as the Twinblock and Herbst appliances (Güler and Malkoç, 2020). The general deficiency in reporting soft tissue volume changes has been identified and can be addressed using current technology (Flores-Mir and Major, 2006).

The options for 3D volume analysis can be broadly split into 3D volumetric imaging and 3D surface imaging. The uses of CBCT in orthodontics are vast and a common use is to locate impacted teeth and supernumeraries (Erten and Yılmaz, 2018). This addition three dimensional visualisation however is associated with additional radiation exposure. Although CBCT has been accepted to have a lower radiation dose than conventional CT this must be carefully evaluated against the perceived benefits to the patient. Currently routine CBCT and CT imaging is not considered normal practice or justifiable to plan or evaluate the volume changes following orthodontic or orthognathic procedures due to the radiation exposure encountered. In these circumstances 3D surface imagining systems provides a radiation free alternative.

3D surface imaging techniques include stereophotogrammetry, 3D structured light scanners and laser scanners. There are a limited number of studies reporting the facial volumetric changes following orthognathic surgery using 3D surface imaging (Ferrario *et al.*, 1999; Sforza *et al.*, 2007; Oh *et al.*, 2013). The systems used are large and costly and although a hospital setting may be able to accommodate for the space requirement and financial output, this is unlikely to be the case in primary care settings which limits the clinical applicability of these systems. Whilst several more affordable and portable imaging systems have come into the market the reliability and accuracy of many of these systems is yet to be determined. One such system, the FastSCAN portable scanner, has been investigated and although it was shown to be accurate during in vitro testing, during in vivo testing a larger range of error was reported (Harrison *et al.*, 2004).

When investigating the accuracy of volume measurement and validating systems for volume measurement the addition of a stimulated volume using materials such as Blu-Tack® and polyvinylsiloxane have been used (Harrison *et al.*, 2004; Hajeer *et al.*, 2005). In many of these volume studies the water displacement technique has been used to determine the "gold standard" volume for comparative testing (Stranden, 1981). Generally, for measuring changes in facial volume related to an intervention, the baseline pre-interventional image and post-intervention image are superimposed and the volume difference is calculated. Several algorithms such as the black plane method, triangulation method, tetrahedron method, projection method and Coon's patch can be used to measure the volume difference (Hajeer *et al.*, 2005; Henseler *et al.*, 2012; Liu and Zheng, 2021).

Software applications that either use its own small proprietary camera system or existing technology incorporated into the later iPhone and iPad camera systems are able to produce 3D facial images in a convenient and cost effective manner. A robust study assessing their accuracy compared to a more conventional stereophotogrammetry device for volume change would address the need for an evidence based, portable and cost effective system that can be implemented into a variety of clinical settings for volume measurement.

CHAPTER 2

AIMS & NULL HYPOTHESIS

2.1 AIMS

The aim of this study was to compare the accuracy of volume measurement between a commercially available professional 3D facial imaging system (Di4D SNAP) and an "App" based system (Bellus3D).

Primary outcome measure

1. The difference in volume, in cm^3, measured by Bellus3D and Di4D SNAP.

Secondary outcome measure

1. The difference in volume, in cm^3, measured using a Coons patch and Tetrahedral Construction Method (TCM) and Di4D SNAP.

2.2 NULL HYPOTHESIS

There is no statistical difference ($p > 0.05$) in volume, in cm^3, measured by Bellus3D and Di4D SNAP against a 'gold standard volume".

1. There is no statistical difference ($p > 0.05$) in volume, in cm^3, measured using a Coons patch and Tetrahedral Construction Method (TCM) and Di4D SNAP.

CHAPTER 3

MATERIALS & METHODS

3.1 STUDY DESIGN

The study was designed to validate an "App" Tablet based 3D facial imaging system and a commercially available 3D facial imaging system for the measurement of facial volume. The study was designed to be conducted on volunteers with simulated volume difference to reduce bias and allow validation of the Tablet based system prior to use on patients.

3.2 ETHICAL APPROVAL

Ethical approval was granted by the Science, Technology, Engineering and Mathematics Ethical Review Committee, the University of Birmingham (ERN_19-0165).

3.3 SAMPLE SIZE

The sample size of the present study was based on a similar study by Hajeer *et al.* (2005) which validated a new imaging system for volume measurement based on 30 scans of a dummy head and one individual (Hajeer *et al.*, 2005).

3.4 SUBJECTS

Subjects participating in this study were volunteers consisting of clinical and non-clinical staff and students at the Birmingham Dental Hospital and School.

3.4.1 Inclusion criteria

- Male or Female
- Aged between 20 to 50

- Clean shaven
- Non-syndromic adults

3.4.2 Exclusion criteria

- High risk Covid-19 category
- Craniofacial defect or conditions
- Facial hair
- Undergoing orthodontic treatment
- Significant facial asymmetry
- Mobility associated medical conditions which make staying stationary difficult
- Received dental treatment or facial cosmetic procedures in the past month

3.5 MATERIALS

3.5.1 DI4D SNAP

The Di4D SNAP imaging system was developed by Dimensional Imaging Ltd (Dimensional Imaging Ltd., Glasgow, Scotland). Di4D SNAP 6200 is a passive stereophotogrammetry system that uses six 24-megapixel digital cameras to capture 3D facial images in 1ms. The system consists of several components including 3 vertical banks of 2 Cannon cameras (250D). The vertical banks of cameras and two commercial white light studio flashes (Esprit digit DX1000, Bownes, Essex, UK) were connected to a personal desktop computer to synchronise all the cameras and flashes, Figure 3.1. Calibration was required prior to image capture and was carried out according to the manufacturer's instructions. Calibration determined the relative positions of the cameras to each other i.e. the external parameters, as well their internal parameters, camera settings.

Figure 3.1 Di4D SNAP camera system 6200

To calibrate the system a calibration target, supplied with the system, was used. The target was a board with rows and columns of white dots with their centres 2cm apart. The calibration processes involved capturing the calibration target in 6 different positions. The calibration software analysed the dots on the board and using the principle of triangulation, the depth dimension was determined. This information was stored as file (.dcb), this was then attached to the subject image file when it was captured and used to reconstruct the final 3D facial image.

3.5.2 Bellus3D Face camera pro (Model FCPO1)

Bellus3D Face Camera Pro (#1300 Campbell, CA 95008) is a "bolt-on" dual structured light mobile 3D camera for high-resolution face scanning. Bellus3D used an infrared structured-light depth camera which scans upto 0.4mm resolution and measures 500,000 3D points on the face. Bellus3D Face Camera Pro combines a high-resolution front-facing camera to capture fine face detail and reconstructs 3D facial shape using an infrared structured-light depth camera. Bellus3D has a working range of 25cm to 60cm, has a scan time of 15-25 seconds and can be attached to Android and Windows devices. For this study the Bellus3D Face Camera Pro was attached to a Huawei Media Pad T3 (Huawei UK, Berkshire, UK) and the Bellus3D Face Camera Pro Application (Face Camera Pro for Android (Service) Release: 2.1.1) was downloaded and utilised to produce the 3D facial images, Figure 3.2. Once captured the images were saved in Wavefront Object format (.OBJ) and transferred to a personal desktop computer.

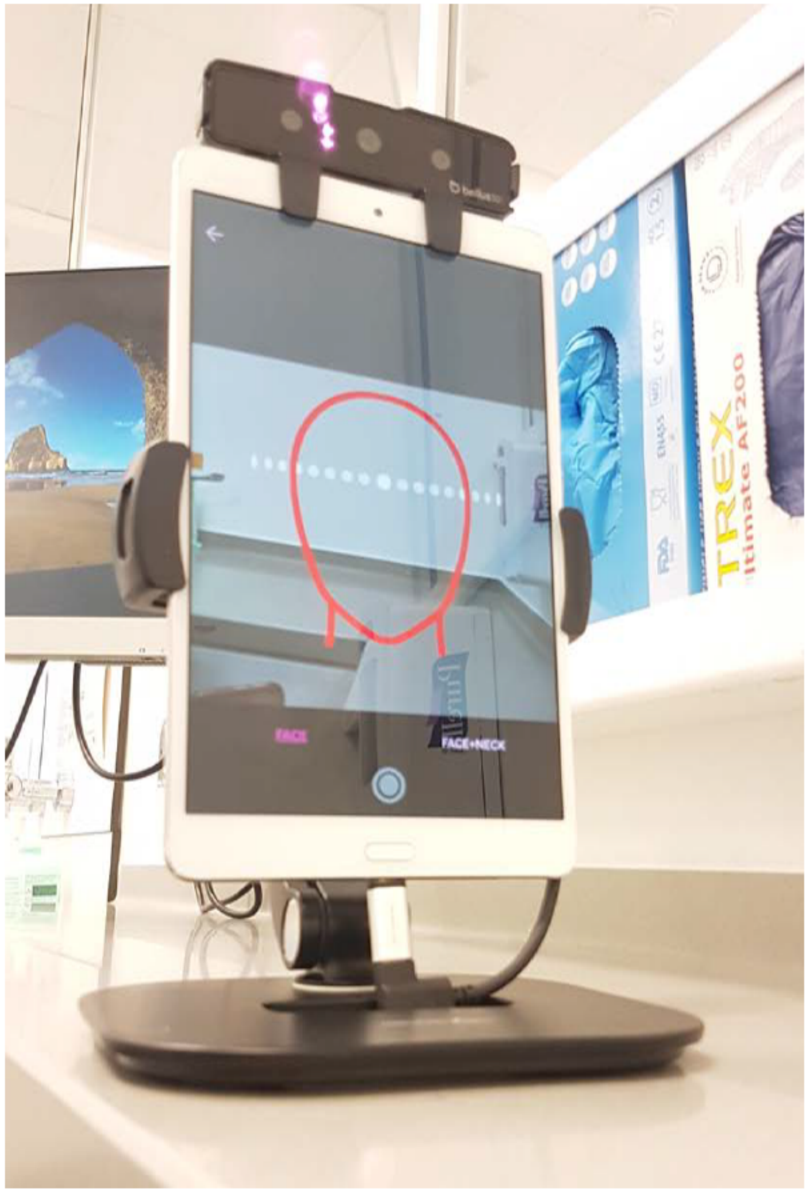

Figure 3.2 Bellus3D camera attached to a Huawei tablet. The participant positions their face within the red ring. When the participant is in the correct position for image capture, the ring will turn green.

3.6 METHODS

3.6.1 Development and validation of a "gold standard" volume (Explant)

Heavy body polyvinylsiloxane impression material base and catalyst paste was mixed in a 1:1 ratio according to manufactures instructions (PRESIDENT The Original putties, Coltène / Whaledent Ltd, West Sussex, United Kingdom). The impression material was then loaded into a measuring scoop with a known volume of 2.0ml / 2.0cm^3 (Ultraspec, Newton, UK), any excess impression material protruding over the top of the scoop was removed with a sharp knife making sure no voids were present, Figure 3.3. Before the impression material had set it was removed from the scoop and was rolled into a cylinder. A graduated measuring cylinder (BRAND® SILBERBRAND, Merck Life Science UK Limited, Dorset, UK) with a maximum measurable volume of 10 cm^3 was secured to a flat horizontal surface and filled with distilled water until the bottom of the water meniscus was level with the 5cm^3 mark, Figure 3.3. The impression material was gently lowered into the measuring cylinder making sure it was not binding to the sides of the cylinder and that it was totally immersed under the water. The new level of the water meniscus was measured and the increase in volume recorded in cm^3 in an EXCEL spread sheet (Microsoft Office, Microsoft, USA). Following disposal of the impression material and water the entire procedure was repeated 10 times on the first occasion (T_1) and again one week later (T_2); in total 20 repeated measurements were made.

3.6.2 In vitro methodology

A mannequin head was positioned on a rotating plate that allowed it to be rotated 180°. To simulate the clinical situation the mannequin head was captured with the Bellus3D attached to the

Figure 3.3 Left: Measuring spoon used to measure 2cm^3 of putty - simulated volume (explant) of known volume.

Right: 0.5ml gradient measuring cylinder used for the water displacement technique to validate the gold standard volume of putty.

Huawei Tablet on a stationary stand. The mannequin head was positioned in the centre of the rotating plate. The plate was then rotated following the cues from the Bellus3D app to capture an ear-to-ear image of the mannequin head. A baseline image of the mannequin head was captured using Bellus3D and saved as a .OBJ file. A second baseline image of the mannequin head was captured using Di4D SNAP, positioning the mannequin head on a height adjustable chair ensuring that the head was within the correct field of view, and again saved as a .OBJ file.

Heavy body polyvinylsiloxane impression material base and catalyst paste was then mixed in a 1:1 ratio. The impression material was then loaded into a measuring scoop with a known volume of 2.0cm^3, any excess impression material protruding over the top of the scoop was removed with a sharp knife making sure no voids were present. The material was then removed from the scoop before it had set and rolled into a ball, the base was flattened using the palm of the hand. The polyvinylsiloxane explant was then added to chin of the mannequin head. The explant was adapted to the mannequin head to create a dome shape with the edges adapted to the plastic surface to avoid any undercuts. Two images of the head were then captured, one using Bellus3D and the other using Di4D SNAP. The above process was then repeated with a polyvinylsiloxane explant added to the upper lip region, and right and left paranasal regions.

3.6.3 Image capture technique

3.6.3.1 Protocol for Di4D SNAP capture

Prior to imaging with the Di4D SNAP, volunteers were asked to remove any facial jewellery and piercings. The volunteers were asked to tie back their hair out of their face and then a hair net was placed over the head up to the hair line. The volunteer was then asked to sit on a height adjustable chair in front of a blue screen facing the centre of the Di4D SNAP system. Each volunteer was positioned in the ideal field of view, correctly positioned on all 6 cameras. The participant was directed to stay stationary with face and lips relaxed and their teeth in occlusion.

3.6.3.2 Protocol for Bellus3D

Prior to imaging using Bellus3D, the volunteer was prepared in a similar manner to imaging with Di4D SNAP. Bellus3D was attached to the Huawei Tablet and placed on top of a high table. The participant was asked to sit on a height adjustable chair. The height of the chair was adjusted until the volunteer's face was in the correct position. An additional ring flash white light source was positioned to illuminate the participants' face. Once the individual was positioned correctly, they moved their head from centre to right (capturing the left side of the face), back to centre, centre to left (capturing the right side of the face) and back to centre. Bellus3D verbally instructed the individual to carry out the movement until the capture was complete. The participant rehearsed the required movement before the final image was captured.

3.6.4 Protocol for image capture with the simulated volume in situ

Baseline images of each participant were captured using Di4D SNAP and Bellus3D without the addition of a polyvinylsiloxane explant using the method described above, Figure 3.4. Heavy body polyvinylsiloxane impression material base and catalyst paste was then mixed in a 1:1 ratio. The impression material was then loaded into a measuring scoop, any excess impression material protruding over the top of the scoop was removed with a sharp knife making sure no voids were

Figure 3.4 Baseline images of a participant prior to addition of the putty explant using Bellus3D (right) and Di4D SNAP (left).

present. The material was then removed from the scoop before it had set and rolled into a ball, the base was flattened using the palm of the hand. The polyvinylsiloxane explant was then added to chin, upper lip, right and left paranasal regions of the volunteer's face. The edges of the putty were adapted onto the skin, creating a dome shape without any undercuts, Figure 3.5. The participant was asked to stay stationary and avoid speaking after the explants were placed. Prior to capturing the image, the position of all the explants were checked for close adapted to the skin, with the absence of undercuts. An image was taken with Di4D SNAP and with Bellus3D with all 4 explants *in situ* using the method described earlier. In this way each individual had two images taken with Bellus3D and the same two images with Di4D SNAP. In total 132 facial images were taken.

3.6.5 Calculation of volume difference

3.6.5.1 Based on TCM

For each subject the Bellus3D baseline image and the image with the four explants in situ were exported from the Huawei Tablet to Di3D View software. Before volume measurements could be carried out, the images needed to be superimposed.

The images were superimposed using the following method:

1) *Manual alignment* – the same three distinct landmarks in a triangular arrangement were identified on both images. For example, distinct facial marks or easily identifiable stable landmarks such as the inner canthus of the eyes, Figure 3.6 and Figure 3.7.
2) *Fine alignment* – An area on the forehead was selected and the ICP algorithm used to further align the two images using the 'best fit', Figure 3.8 and Figure 3.9.

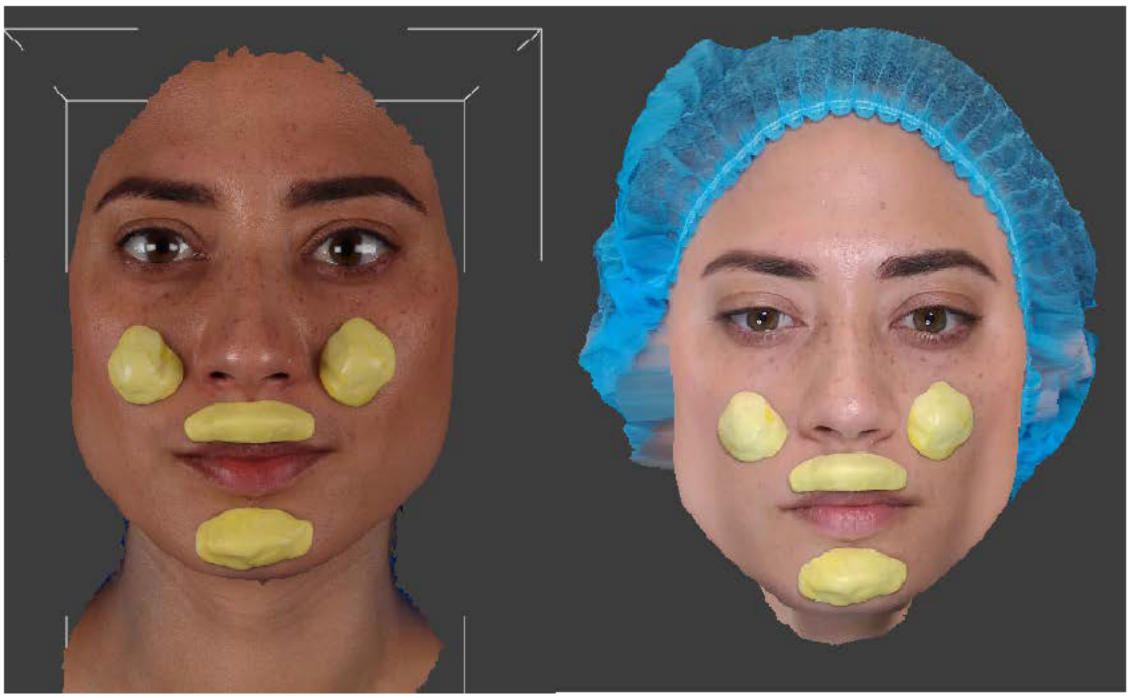

Figure 3.5 Participant images with simulated volume (explants) in situ using Bellus3D (right) and Di4D SNAP (left).

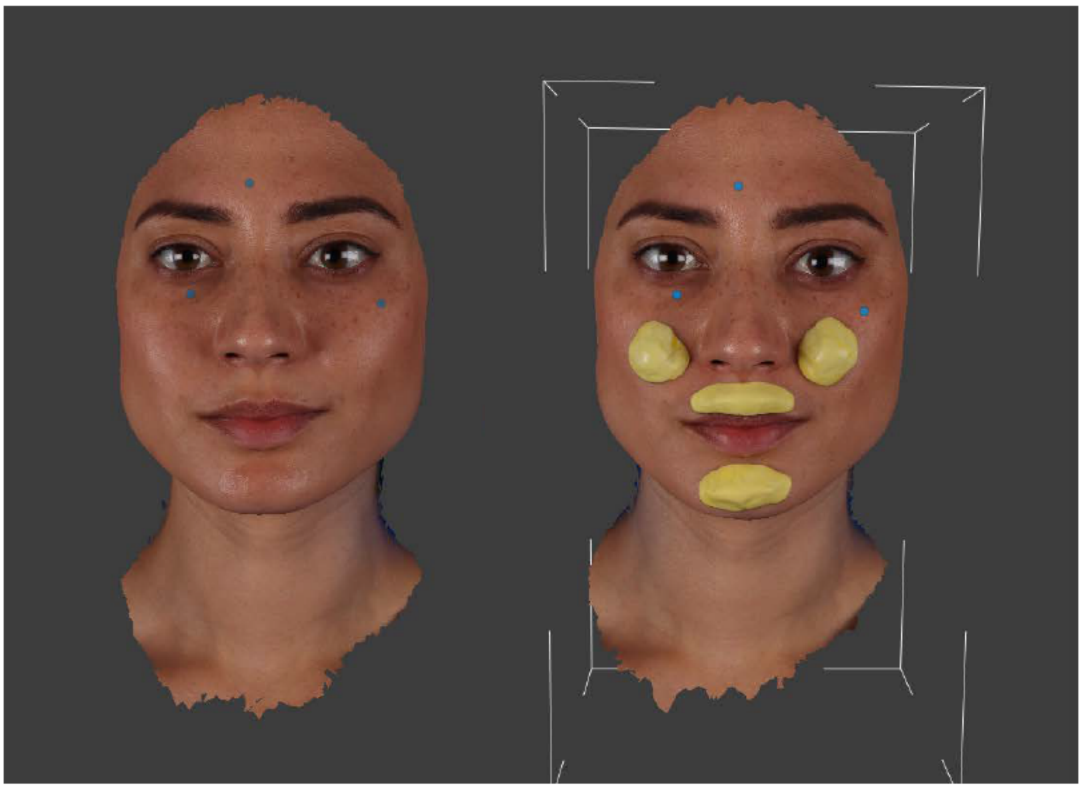

Figure 3.6 Manual alignment: First stage of superimposition, three landmarks are chosen on the baseline and simulated volume putty images. Di4D images shown in above example.

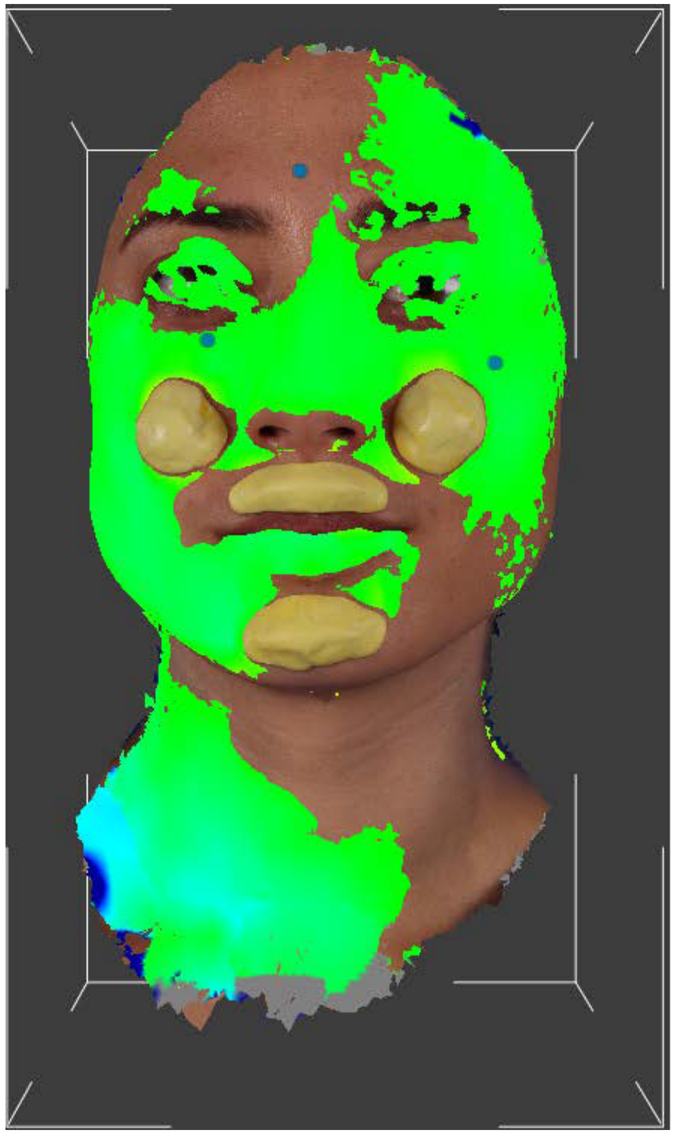

Figure 3.7 Di4D SNAP image superimposition following manual alignment.

Figure 3.8 ICP alignment: Second stage of superimposition. A stable patch such as the forehead is selected and used to superimpose the images.

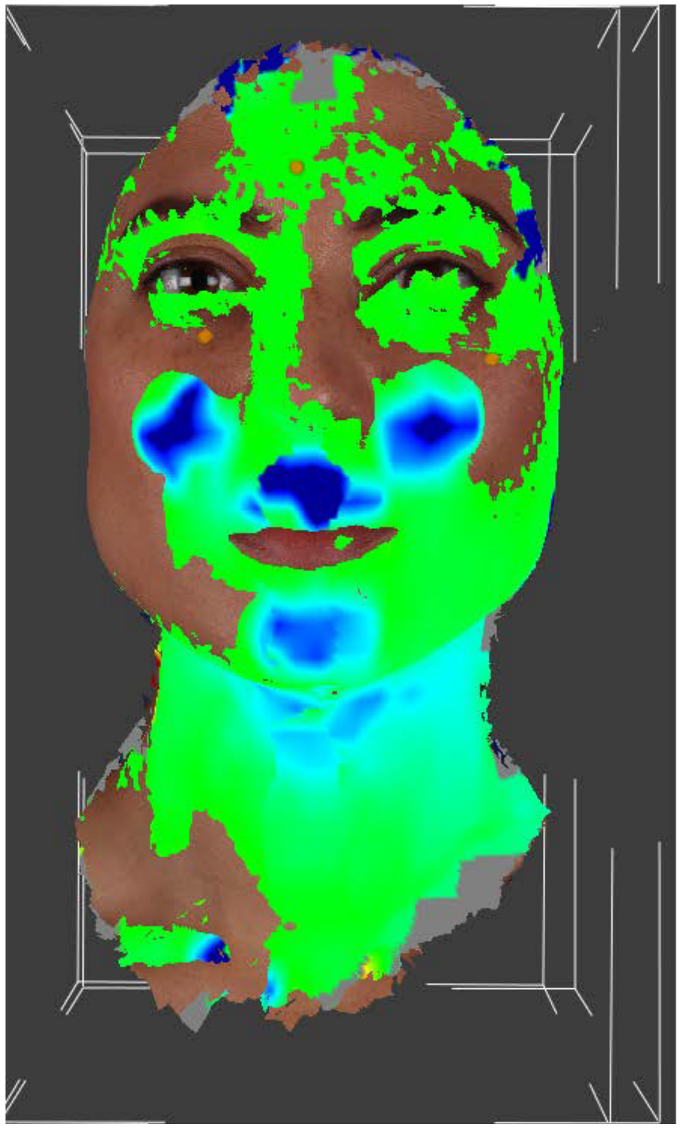

Figure 3.9 Di4D SNAP baseline and simulated volume images superimposed following ICP alignment.

Following superimposition of the images the volume was calculated using the TCM algorithm by identifying, selecting and tracing the boundary of each explant (chin / upper lip / right and left paranasal), in turn, Figure 3.10. The volume enclosed between the two images was then calculated and recorded in cm^3 in an EXCEL spread sheet (Microsoft Office, Microsoft, USA). The same procedure was repeated for each individual as well as for their Di4D SNAP images.

3.6.5.2 Based on a Coons patch

For each subject **only the Di4D SNAP images** with the four explants in situ was exported from the Huawei Tablet to 3dMD Patient software (3dMD Limited, Brentford, London). This time no superimposition was required as there was only a single image. The volume was calculated by identifying 4 points around the boundary of each explant (chin / upper lip / right and left paranasal region). The volume was then calculated and recorded in cm^3 in an EXCEL spread sheet (Microsoft Office, Microsoft, USA).

3.7 INTRA-OPERATOR ERROR

3.7.1 Validity of the methodology

To assess the reliability of the methodology, five subjects were taken at random and their Di4D SNAP and Bellus3D baseline images and images with simulated volumes in place were superimposed as previously described. The volumes were remeasured at T_1 and T_2.

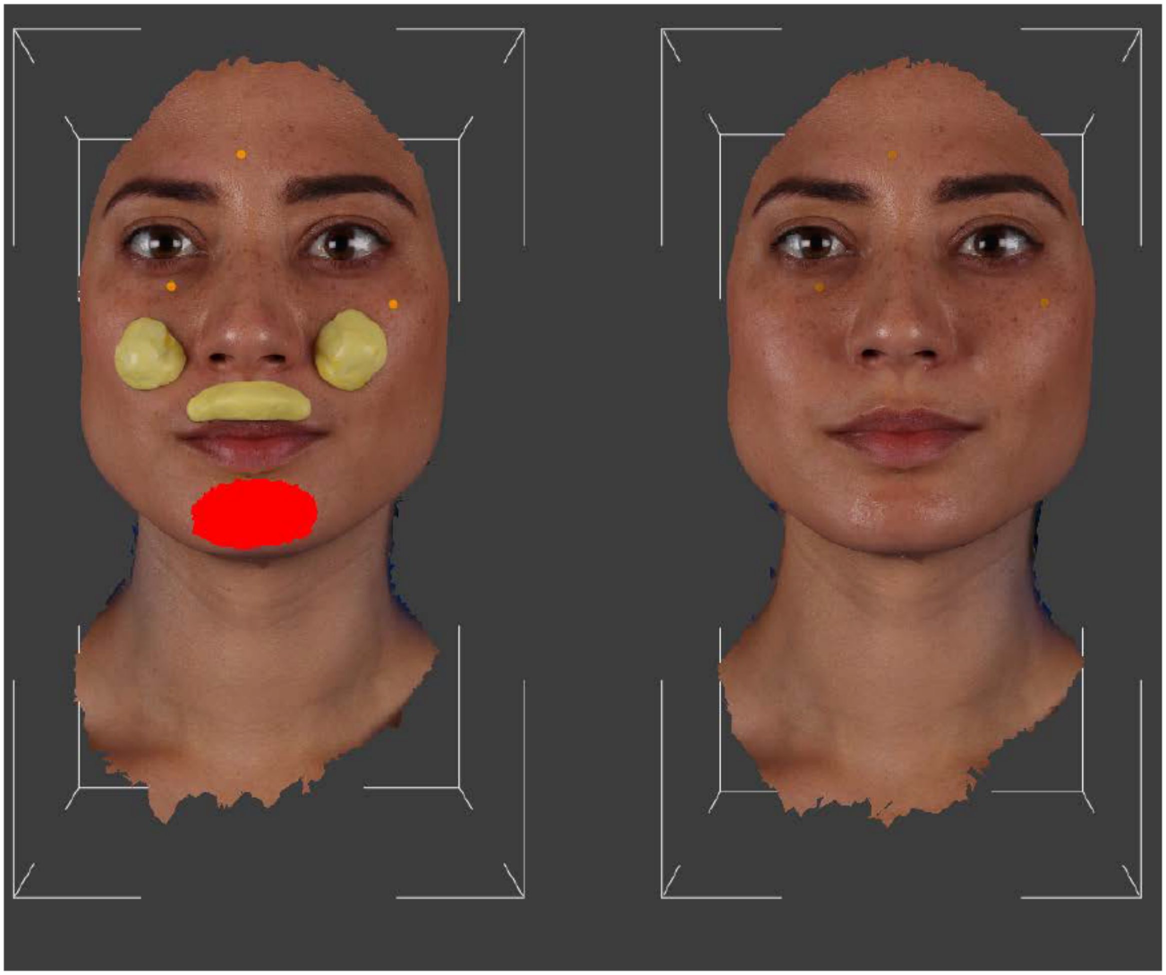

Figure 3.10 Volume measurement using TCM algorithm on Di4D SNAP image. A close border around each putty explant is selected and the volumes measured individually.

CHAPTER 4

RESULTS

4.1 VALIDATION OF A "GOLD STANDARD" VOLUME (EXPLANT)

The water displacement technique consistently measured the heavy body polyvinylsiloxane impression material volume as 2cm^3 based on the measuring scoop with a known volume of 2.0ml / 2.0cm^3.

4.2 COMPARISON OF DI4D SNAP & BELLUS3D

4.2.1 In vitro assessment

The in vitro volume measurements calculated using Bellus3D and Di4D SNAP are shown in Table 4.1. For both the 2cm^3 and the 4 cm^3, Bellus3D overestimated the volumes (mean = 2.12cm^3 and 4.43 cm^3 respectively). Expressed as a percentage the mean percentage error between the actual and measured volume increased from 5.7% to 10.7% from 2cm^3 to 4cm^3. The 95% confidence interval error for the difference in mean percentage error in volume was larger and wider for Bellus3D.

For Di4D SNAP the actual measurement in volume was 2.00cm^3 and 3.91cm^3 for the 2cm^3 and 4cm^3 volumes respectively. Di4D SNAP showed a tendency to underestimate the volume -0.1% for the 2cm^3 volume and -2.2% for the 4cm^3 volume. In contrast to Bellus3D, the 95% confidence interval error for the difference in mean percentage error in volume using Di4D SNAP was small and narrow.

Table 4.1 The in vitro volume measurements calculated using Bellus3D and Di4D SNAP for a known volume of 2cm3 and 4 cm^3

	Measured volume (cm^3)		Mean % error	95% CI for the mean % error	
	Mean	SD		Lower	Upper
Overall error ($2cm^3$)					
Bellus3D	2.12	0.14	5.75	2.76	8.74
Di4D SNAP	2.00	0.07	-0.10	-1.6	1.4
Overall error ($4cm^3$)					
Bellus3D	4.43	0.29	10.69	7.53	13.8
Di4D SNAP	3.91	0.15	-2.24	-3.85	-0.63

4.3 Reproducibility of the methodology (error study)

Five subjects were taken at random and their Di4D SNAP baseline image and image with simulated volumes in place were superimposed as previously described. The volumes were remeasured at T_1 and T_2. No systematic errors were observed, and all coefficients of reliability were above 90%. The mean overall measurement error was -0.2 ± 0.4cm^3 for Di4D SNAP and -0.1 ± 0.4cm^3 for Bellus3D, Table 4.2.

4.4 IN VIVO ASSESSMENT

4.4.1 Subjects

For the in vivo part of this study 33 volunteers were recruited in total, 19 females and 14 males.

4.4.2 Left paranasal region simulated volume

The mean volume measurements for the simulated volume on the left paranasal region were 2.2 ± 0.9cm^3 using Bellus3D and 2.0 ± 0.3 cm^3 using Di4D SNAP. The median values were similar to the mean values, but the interquartile range was much wider using Bellus3D, as was the maximum value (5.5 cm^3), Table 4.3. As a percentage Bellus3D overestimated the mean volume by 5.9% (95% CI -5.0 to 16.8%). Whilst Di4D SNAP underestimated the mean volume by 2.2% (95% CI -8.2 to 3.8%), Table 4.4.

The data was not normally distributed following a Kolmogorov-Smirnov test. The median volume difference between the two imaging systems for the left paranasal region was 0.2cm^3 (95% CI for

Table 4.2 Reproducibility of the methodology (error study) for five subjects taken at random, including image superimposition and volume measurement.

Region	Di4D SNAP		Bellus3D	
	Mean difference between T_1 and T_2 (cm^3)	SD (cm^3)	Mean difference between T_1 and T_2 (cm^3)	SD (cm^3)
Left paranasal	-0.2	0.5	-0.1	0.3
Right paranasal	-0.1	0.2	-0.1	0.2
Lip	-0.3	0.4	-0.1	0.5
Chin	-0.1	0.4	-0.1	0.5
Overall	**-0.2**	**0.4**	**-0.1**	**0.4**

Table 4.3 The volume measurements for the simulated volume using Bellus3D and Di4D SNAP for the upper lip, chin, left and right paranasal regions.

	Mean (cm^3)	SD (cm^3)	Minimum (cm^3)	Median (cm^3)	Maximum (cm^3)	IQR (cm^3)
Left paranasal region						
Bellus3D	2.2	0.9	0.8	2.2	5.5	0.7
Di4D SNAP	2.0	0.3	1.1	2.0	2.8	0.2
Right paranasal region						
Bellus3D	2.1	0.4	1.2	2.2	3.1	0.5
Di4D SNAP	1.9	0.3	1.3	1.9	2.5	0.2
Upper lip						
Bellus3D	2.6	0.5	1.6	2.6	3.3	0.7
Di4D SNAP	2.0	0.2	1.1	2.0	2.7	0.2
Chin						
Bellus3D	2.5	0.5	1.2	2.5	3.6	0.7
Di4D SNAP	2.0	0.4	1.0	1.9	2.6	0.4

Table 4.4 Difference in volume between the known volume of $2cm^3$ and each facial region as a percentage error. A positive value indicates the system overestimates the volume, whilst a negative value indicates an under estimate in volume.

	Mean % error	95% CI for the mean % error	
		Lower	Upper
Left paranasal region			
Bellus3D	5.88	-5.02	16.78
Di4D SNAP	-2.18	-8.17	3.81
Right paranasal region			
Bellus3D	6.17	-0.95	13.28
Di4D SNAP	-4.82	-9.77	0.13
Upper lip			
Bellus3D	20.98	3.31	38.66
Di4D SNAP	1.02	-3.33	5.36
Chin			
Bellus3D	8.40	-15.10	31.80
Di4D SNAP	-0.55	-7.35	6.26
OVERALL			
Bellus3D	**10.35**	**2.54**	**18.16**
Di4D SNAP	**-1.63**	**-4.37**	**1.11**

median difference of -0.1 to 0.4 cm^3). Following a Mann-Whitney test this difference was not statistically significant (p = 0.099), Table 4.5.

4.4.3 Right paranasal region simulated volume

For the right paranasal region, the mean volume measurements for the simulated volume were 2.1 ± 0.4 cm^3 using Bellus3D and 1.9 ± 0.3 cm^3 using Di4D SNAP, Table 4.3. As with the left simulated volume, the median values were similar to the mean values, but the interquartile range was much larger using Bellus3D, as was the maximum value (3.1cm^3), but both values were smaller than for the left simulated volume. Similar to the left paranasal region Bellus3D overestimated the mean volume by 6.2% (95% CI -1.0 to 13.3%). Whilst Di4D SNAP underestimated the mean volume by 4.8% (95% CI -9.8 to 0.1%), Table 4.4.

A Mann-Whitney U test was run to determine if there was a median difference in volume measurements between Bellus3D and Di4D SNAP. The median difference in volume between the two systems was statistically significant (p = 0.017) with 0.2cm^3 (95% CI for median difference of 0.1 to 0.4 cm^3) difference between the two systems, Table 4.5.

4.4.4 Upper lip simulated volume

For the simulated volume added to the upper lip the median volume was 2.0cm^3 using Di4D SNAP and 2.6cm^3 using Bellus3D, Table 4.3. Again, the mean values were similar to the medians. In

Table 4.5 Difference in volume between the known volume of $2cm^3$ for each facial region.

Region	Bellus3D	Di4D SNAP				
	Median (cm^3)	Median (cm^3)	Median Difference (cm^3)	95% CI for median difference (cm^3)		p-value*
				Lower	Upper	
Left paranasal	2.2	2.0	0.2	-0.1	0.4	0.099
Right paranasal	2.2	1.9	0.2	0.1	0.4	**0.017**
Upper lip	2.6	2.0	0.6	0.4	0.8	**0.001**
Chin	2.5	1.9	0.5	0.2	0.7	**0.001**

* Following a Mann-Whitney test

addition, the range of values were larger for Bellus3D than for DI4D SNAP, with a larger maximum volume (3.3cm^3) using Bellus3D. The median difference in volume measurement between Bellus3D and DI4D SNAP was 0.6cm^3 and following a Mann-Whitney test this difference was statistically significant ($p = 0.001$), Table 4.5. As a percentage both Bellus3D and Di4D SNAP overestimated the mean volume. However, Bellus3D overestimated it by 21.0% (95% CI 3.3 to 38.7%). Whilst Di4D SNAP overestimated the mean volume by only 1.0% (95% CI -3.3 to 5.4%), Table 4.4.

4.4.5 Chin simulated volume

For the chin simulated volume the mean and median volume measurements were similar, a mean volume of 2.5 ± 0.5cm^3 for Bellus3D and 2.0 ± 0.4 cm^3 using Di4D SNAP, Table 4.3. The median difference in volume between the two imaging systems was 0.5cm^3 (95% CI for median difference of 0.2 to 0.7cm^3). This difference following a Mann-Whitney test was statistically significant ($p = 0.001$), Table 4.5. As a percentage Bellus3D overestimated the mean volume by 8.4% (95% CI -15.1 to 31.8%). Whilst Di4D SNAP underestimated the mean volume by 0.6% (95% CI -7.35 to 6.3%), Table 4.4.

4.5 COMPARISON OF USING COONS PATCH & TCM ALGORITHM

4.5.1 Left paranasal region simulated volume

For the left paranasal region, the median simulated volume on the left paranasal region were 2.2 cm^3, based on the use of a Coons patch and 2.0 cm^3 using the TCM algorithm, Table 4.6.

Table 4.6 Volume measurements for the simulated volume ($2cm^3$) captured using Di4D SNAP and the volume measured using the TCM and the Coons patch.

	Mean (cm^3)	SD (cm^3)	Minimum (cm^3)	Median (cm^3)	Maximum (cm^3)	IQR (cm^3)
Left paranasal region						
Coons patch	2.2	0.3	1.6	2.2	2.9	0.5
TCM	2.0	0.3	1.1	2.0	2.8	0.2
Right paranasal region						
Coons patch	2.5	0.9	1.3	2.5	3.0	0.5
TCM	1.9	0.3	1.3	1.9	2.5	0.2
Upper lip						
Coons patch	2.1	0.7	0.7	2.1	3.5	0.9
TCM	2.0	0.2	1.1	2.0	2.7	0.2
Chin						
Coons patch	2.0	0.4	1.2	2.0	3.0	0.6
TCM	2.0	0.4	1.0	1.9	2.6	0.4

The median volume difference between the two was 0.3cm^3 (95% CI for median difference of 0.1 to 0.4 cm^3). This difference was statistically significant (p = 0.001) following a Mann-Whitney test, Table 4.7. As a percentage the Coons patch overestimated the mean volume by 9.7% (95% CI 4.2 to 15.3%). Whilst the TCM algorithm underestimated the mean volume by 2.2% (95% CI -8.4 to 4.0%.), Table 4.8.

4.5.2 Right paranasal region simulated volume

Based on the use of a Coons patch the median volume measurements for the simulated volume on the right paranasal region was 2.5 cm^3 whilst using the TCM algorithm it was 1.9 cm^3, Table 4.6. The median volume difference between the two techniques was 0.6cm^3 (95% CI for median difference of 0.4 to 0.7 cm^3). Following a Mann-Whitney test this difference was statistically significant (p = 0.001), Table 4.7. As a percentage the Coons patch overestimated the mean volume by 23.5% (95% CI -16.8 to 30.1%). Whilst the TCM algorithm underestimated the mean volume by 4.8% (95% CI -9.8 to 0.1%), Table 4.8.

4.5.3 Upper lip simulated volume

Based on the use of a Coons patch the median volume measurements for the simulated volume on the upper lip was 2.1 cm^3 whilst using the TCM algorithm was 2.0 cm^3, Table 4.6.

Table 4.7 Difference in volume between the known volume of 2cm³ for each facial region. captured using Di4D SNAP and the volume measured using the TCM and the Coons patch.

Region	Coons Patch	TCM				
	Median (cm^3)	Median (cm^3)	Median Difference (cm^3)	95% CI for median difference (cm^3)		p-value
				Lower	Upper	
Left paranasal	2.2	1.9	0.3	0.1	0.4	**0.001**
Right paranasal	2.5	2.0	0.6	0.4	0.7	**0.001**
Upper lip	2.1	2.0	0.1	0.3	0.8	0.481
Chin	2.0	1.9	0.1	-0.2	0.2	0.858

*Following a Mann-Whitney test

Table 4.8 Difference in volume between the known volume of $2cm^3$ for each facial region as a percentage error. A positive value indicates the method of volume measurement (TCM and Coons patch) overestimates the volume, whilst a negative value indicates an under estimate in volume.

	Mean % error	95% CI for the mean % error	
		Lower	Upper
Left paranasal region			
Coons patch	9.74	4.18	15.31
TCM	-2.18	-8.36	4.00
Right paranasal region			
Coons patch	23.48	16.78	30.10
TCM	-4.82	-9.77	0.13
Upper lip			
Coons patch	3.06	-9.01	15.13
TCM	1.02	-3.33	5.36
Chin			
Coons patch	0.86	-7.08	8.87
TCM	-0.55	-7.35	6.26
OVERALL			
Coons patch	**9.39**	**4.97**	**13.61**
TCM	**-1.63**	**-4.37**	**1.11**

The median volume difference between the two techniques was 0.1cm^3 (95% CI for median difference of 0.3 to 0.8 cm^3. Following a Mann-Whitney test this difference was not statistically significant (p = 0.481), Table 4.7. As a percentage the Coons patch overestimated the mean volume by 3.1% (95% CI -9.0 to 15.1%). The TCM algorithm also overestimated the mean volume by 1.0% (95% CI -3.3 to 5.4%), Table 4.8.

4.5.4 Chin region simulated volume

For the chin region the median simulated volume was 2.0 cm^3 based on the use of a Coons patch and 1.9 cm^3 using the TCM algorithm, Table 4.6. The median volume difference between the two was 0.1cm^3 (95% CI for median difference of -0.2 to 0.2 cm^3). This difference was not statistically significant (p = 0.858) following a Mann-Whitney test, Table 4.7. As a percentage the Coons patch overestimated the volume by 0.9% (95% CI -7.1 to 8.9%). Whilst the TCM algorithm underestimated the mean volume by 0.6% (95% CI -7.4 to 6.3%), Table 4.8.

4.5.4 Overall

Overall, as a percentage the Coons patch overestimated the mean volume by 9.4% (95% CI 5.0 to 13.6%). Whilst the TCM algorithm underestimated the mean volume by 1.6% (95% CI -4.4 to 1.1%), Table 4.8.

CHAPTER 5

DISCUSSION

5.1 DISCUSSION

The present study was conducted to compare the accuracy of volume measurement between a commercially available professional 3D facial imaging system (Di4D SNAP) and an “App” based system (Bellus3D). Both systems are based on similar technology i.e. stereophotogrammetry but are vastly different in size and cost. The Di4D SNAP system is based on six high-resolution cameras, supported on a tripod with two adjacent professional light sources. The system is a passive 3D facial capture system based on the principle of triangulation and the use of corresponding points between image pairs, hence the need for high resolution cameras. This gives the Di4D SNAP system a footprint of around $6m^2$ and a cost of around £30,000. In comparison Bellus3D is the size a conventional Tablet and can be even smaller if based on a mobile phone, and at a fraction of the cost, around £1000 or less.

Belllus3D utilises some aspects of the facial recognition camera technology built into the newer Apple iPhones, which includes the “TrueDepth camera system”, neural networks and a bionic neural engine. The TrueDepth camera system can recognise a human face with a flood illuminator, even in the dark. One aspect of the facial recognition system relies on the built-in infrared camera taking the image, whilst a dot projector simultaneously projects over 30,000 invisible infrared dots onto the face. For facial recognition the system uses the infrared image and dots and pushes them through neural networks to create a mathematical model of the face. Bellus3D uses the infrared camera and dot projector to form the basis of active stereophotogrammetry, similar to other commercial 3D imaging systems i.e. 3dMD. This means that, providing the individual has the correct phone or Tablet and camera configuration, it is now possible to have a pocket sized active stereophotogrammetry system in the palm of your hand. For Bellus3D to be clinically valid it needs to be equivalent in its ability to capture the correct surface topography as the more expensive commercially available Di4D SNAP system. This question formed the basis of this study.

Volume measurements were of interest in this study as changes in facial volume have notable applications in both medicine and dentistry, in particular in orthodontics, maxillofacial surgery and plastic surgery. These specialities assess changes in facial volume because of an intervention or as part of ageing and are of interest in dermatology and aesthetic medicine. A well-known consequence of ageing is the loss of facial volume (Shue, Kurlander and Guyuron, 2018), the demand to reverse or slow down this loss of volume has led to several treatment options for patients including laser treatment, fillers and fat transplant. Measuring volume change provides an objective method to potentially assess the success of these procedures and contribute to a wider outcome measure. The reduced cost, reduced size and portability of the Bellus3D camera make it an attractive alternative to the larger more expensive systems. There has been limited studies to assess the accuracy of Bellus3D; the majority assessing linear and angular measurements, rather than volume. Interestingly, a recent study reported Bellus3D to be less accurate compared to other scanners (Amornvit and Sanohkan, 2019). However, to date, no studies have assessed the accuracy of Bellus3D to measure facial volume changes.

This prospective study was carried out on a convenience sample of volunteers drawn from the staff and students at the Birmingham Dental Hospital and School. The exclusion criteria was in line with previous studies and excluded patient's with craniofacial conditions, and those who had recently undergone facial or dental treatment including those currently undergoing orthodontic treatment (Hajeer *et al.*, 2005). This was to reduce bias or confounding factors due to volume changes or irregularities related to the procedures and conditions. The decision to exclude patients with craniofacial conditions would in turn reduce the generalizability of the results. In reality this specific exclusion criteria was unnecessary as both systems are capable of capturing human faces, the fact that the individual has a craniofacial condition is potentially irrelevant, if the explants adhere to the skin surface and were clearly visible. For this reason and the fact that neither system can capture the skin beneath facial hair, it was necessary to exclude individuals with facial hair. A further requirement for volume measurement, based on pre and post images, is the need to superimpose both images on large surface areas e.g. the forehead. In view of this, individuals with head coverings were unable to be recruited for this study.

A formal *prior* sample size was calculated to be thirty using a power of 80%, significance level of 0.05. A similar study by Hajeer *et al.* (2005) was designed to validate a new system for volume measurement used 30 scans of a dummy head and one individual (Hajeer *et al.*, 2005). Attrition was not accounted for as volunteers were required for this study not patients as such the risk of dropouts was deemed to be low and as expected no volunteers were lost during the course of this study.

The volume changes in the present study were simulated using a polyvinylsiloxane putty, this material was chosen as it can be closely adapted to the skin surface, required no adhesive and had a low risk of a adverse reaction and has previously been utilised for the same process (Hajeer *et* *al.*, 2005). Close adaption of the material to the skin meant that there were no undercuts as stereophotogrammetry relies on direct line of site and any undercuts would not have been captured by either imaging system but would have contributed to the volume measured. During preliminary testing the material was found to adhere well to the skin surface, only in the absence of facial hair. At the time of data collection, the Covid-19 PPE requirements meant that many of the male staff and students were clean-shaven and so this inclusion criteria did not pose a particular practical or ethical problem during recruit of volunteers.

The true volume of the putty explant was measured using the “water displacement technique”, first described by Academies, to obtain a gold standard. The water displacement technique has been extensively studied in previous literature and proven to be a reliable method of volume measurement (Stranden, 1981). A preliminary study was carried out to validate and confirm the actual volume of the putty explant added to the face. This was repeated a week later to test for the reliability of the known volume. The results showed good reliability and consistent water displacement measurement confirming the gold standard volume measurement of $2cm^3$.

The areas of the face studied, right and left paranasal regions, upper lip and the chin, were chosen as they were deemed to be clinically relevant in the field of orthodontics and oral & maxillofacial surgery. The soft tissue region of the cheeks and upper lip would potentially experience volume changes following maxillary advancement surgery or orthodontic retraction of the upper labial segment during orthodontic treatment. Soft tissue chin changes would occur following mandibular advancement or set-back. The chosen facial areas were generally located in the mid-facial region in the sagittal plane as well as in more lateral regions of the face, again these regions are where soft tissues changes are known to occur during a Le Fort I procedure. The present study cannot be extrapolated to other region of the face, such as the angle of the mandible or neck region. This is a potential limitation of the study and will reduce the generalizability of the results; for example, measuring the gonial region of the face and neck following third molar removal.

Even using the plastic mannequin head and a controlled in vitro environment Bellus3D recorded a larger mean percentage difference in volume compared to the gold standard. When comparing Bellus3D with two different volumes ($2cm^3$ and $4cm^3$), there was a systematic error with increasing error with increasing volume measurement from $2cm^3$ to $4cm^3$, from 5.8% to 10.7%. A similar relationship was seen for Di4D SNAP but the mean percentage difference in volume compared to the gold standard was only -0.1% to -2.2%. During in vitro testing Di4D SNAP calculated the volume more accurately than Bellus3D across all the facial regions. The results indicated that the median volume difference using Bellus3D and Di4D SNAP compared to the known $2cm^3$ volume were statically significantly larger for all the facial regions assessed excluding the left cheek. With respect to the mean percentage difference in volume measurement, using Bellus3D compared to the gold standard measurement, the left cheek region showed the lowest error (5.9%). This would suggest Bellus3D captures the left side of the face more accurately than the right and mid facial regions. The reason for this is unclear but during image capture using Bellus3D, the individual is asked to turn to the right first allowing capture of the left side of their face first, for some reason this seems to produce a more accurate image.

The results also highlighted a relatively narrower interquartile range for the median volume measurement using Di4D SNAP compared to Bellus3D. This was also supported by the wide 95% confidence intervals for the mean difference in volume between the gold standard known volume and each facial region. For example, the $2cm^3$ volume in the chin region in the present study was calculated at 8.4% greater (approximately $2.2cm^3$) using Bellus3D. However, the difference could be -15.1% ($1.7cm^3$) to 31.8% ($2.6cm^3$) in the larger population; this would probably be clinically significant.

A previous in vivo and in vitro study reported on the validation of volume measurement of a new 3D imaging system (C3D) using three different algorithms. The study compared the volumes produced by the different algorithms to a gold standard volume determined by water displacement (Hajeer *et al*., 2005). The three volume measurement methods described were the Tetrahedron Formation Method (TFM), Back Plane Construction Method (BPCM) and the Projection Method (PM). All three methods rely on closing off the volume, for instance by superimposing the pre and post intervention 3D images, then creating a triangular mesh and computing the volume. The "back-plane construction method" (BPCM) projects the chosen region or patch onto an arbitrary plane and calculates the volume enclosed between each region and the arbitrary plane. The difference between the two volumes is then calculated as the final volume. In the TFM, the closed triangular volume is projected to construct a tetrahedron and the volume calculated. In the "projection method" (PM) each triangle is projected onto an arbitrary plane and the volume between each triangle and the arbitrary plane calculated. Based on the mean percentage error between the volumes obtained by water displacement and the three methods of volume measurement, the study reported the highest level of accuracy using the TFM, compared to the BPCM and PM. The average percentage error for the TFM was 2.82% (95% CI -0.85 to 6.48%), followed by 13.36% (95% CI 8.15 to 18.58%) for the PM and 15.85% (11.47 to 20.23%) for the BPCM.

The present study compared the TFM used by the DI4D SNAP software and a Coons patch. The advantage of the Coons patch is that it does not rely on a second surface to close the volume but instead makes its own "back wall" surface based on the information provided by the shape of the boundary. The Coons patch is constructed between four arbitrary boundary curves, chosen by four landmarks. The patch is constructed purely from information provided by the shape of the existing boundary. The aim of the function is to blend four separate boundary curves together to give a single well-defined surface. It is important to place the four landmarks on the "normal" anatomy, close to but not including the region of interest. The results of the present study confirm that the mean percentage error in volume measurement using the TFM method using DI4D SNAP (mean = -1.63%, 95% CI -4.37% to 1.11%) was similar to the previous study (mean = 2.82%, 95% CI -0.85% to 6.48% (Hajeer *et al.,* 2005). The Coons patch on the other hand over-estimated the volumes (mean = 9.39%, 95% CI 4.97 to 13.61%), Table 5.1. The present study confirms that the TCM technique is an accurate algorithm for determining 3D volume measurements, and that the Coons patch would potentially be more accurate than the BPCM and PM methods previously described (Hajeer *et al.,* 2005).

Table 5.1 Mean percentage error for $2cm^3$ volume (gold standard) and 95% CI for the difference between a previous study (Hajeer *et al.,* 2005) and the present study.

	Mean percentage error	95% CI of percentage error	
		Lower	Upper
Hajeer et al., 2005			
TFM	2.82	-0.85	6.48
BPCM	15.85	11.47	20.23
PM	13.36	8.15	18.58
Present study			
Di4D SNAP	-1.63	-4.37	1.11
Coons patch	9.39	4.97	13.61

The volumes based on surface imaging in the present study were calculated using two different algorithms; TCM which relies on two images being superimposed and a Coons patch, which only requires one surface. The facial image capture technique was also different between Di4D SNAP and Bellus3D. Di4D SNAP captures the left, right and centre portion of the face simultaneously i.e. the entire face in one instance, this means that the lateral width and curvature of the face is recorded and constrained. For Bellus3D the camera continuously captures the facial surface as the individual rotates their head from right to left and back again. This means there is no potential width or curvature control, in other words the face could be wider or narrow at the posterior aspects of the image. So if the two Bellus3D images were of different widths then following superimpositions there would be, by default, “a volume”. This could be the case and may explain the larger errors associated with Bellus3D over Di4D SNAP. However, there is also a volume error using one surface i.e. the Coons patch. This would suggest that there is a difference in surface topography in the Bellus3D scan. The two together may be contributing to the errors seen using Bellus3D.

The results showed that in general the Coons patch over-estimated the volume in all areas except the chin; this is an unusual finding, which suggests that the back wall created by the Coons patch may be lower than the actual skin surface. The cause of this is unclear but as the Coon patch uses the surrounding tissue surface topography to estimate the back-wall position, the graduation of these areas may have suggested a deeper back wall than present. The Coons patch performed better on the chin; this again is unusual as the anatomy of the chin area is slightly more complex so you would assume that estimating the back wall would be more difficult. The difference in volume measurement between the Coons patch and pre-image back wall was statistically significant for both right and left paranasal regions.

There are several limitations of the study, these include explant placement and image capture. When applying the putty if it is not closely adapted to the skin a void under the body of the putty or an undercut around the peripheral aspect will be created. A void under the body will cause an over-estimation of the volume. An undercut at the peripheral border of the putty may affect image capture and volume measurement. Errors may also have occurred during the process of image capture. These may be caused by incorrect patient position, or patient movement errors during the Bellus3D scan capture. Di4D captures an image in 1ms therefore there is little opportunity for patient movement error as long as the operator takes time to position the patient correctly prior to image acquisition. In comparison with Bellus3D the patient is more actively involved in the image capture process which increases the opportunity for patient related errors to occur. The volunteer is given specific instructions prior to the Bellus3D scan and is asked to follow the directions given by the app. Variations in patients ability to following these instructions is likely to introduce errors related to image capture. Notably during scanning volunteers failed to fully turn their face to the maximum extent to the right and left. Although this may have introduced errors, these problems can be expected if this application was used on real patients in “real world situations” and so although it may affect our ability to compare the two systems it increases the real-world applicability of the results.

CHAPTER 6

CONCLUSIONS

6.1 CONCLUSIONS

6.2 COMPARISON OF DI4D SNAP & Bellus3D

The results of the present study would suggest Bellus3D overestimated volume compared to Di4D SNAP, expressed as a mean percentage error in volume measurement. The clinical error, averaged out across the four different regions of the face, could be close to 10% using Bellus3D. For Di4D SNAP the same magnitude of the error was close to 2%. Bellus3D captures simulated volume changes of the left side of the face with greater accuracy than the right side of the face. This mean percentage error in volume measurement using Bellus3D may be clinically significant and questions its use clinically for volume measurement.

6.2.1 The null hypothesis is rejected

The null hypothesis was rejected as there was a statistically significant ($p<0.05$) difference in volume measurement between Bellus3D and Di4D SNAP. Bellus3D consistently overestimated the volume.

The difference in volume measurement between Bellus3D and Di4D SNAP for the left paranasal region was not statistically significant ($p<0.05$).

6.3 COMPARISON OF USING COONS PATCH & TCM ALGORITHM

The results of the present study would suggest that use of the TCM algorithm is more accurate than the Coons patch. The Coons patch overestimated the volume compared to TCM, expressed as a mean percentage error in volume measurement. In addition, there was a wide 95% confidence interval for the difference. The clinical error, averaged out across the four regions of the face, could be close to 10%. For Di4D SNAP the same error was less than 2%. This difference in volume using a Coons patch could be clinically significant and suggests using the TCM algorithm would be clinically valid.

6.3.1 Secondary outcome measures

The null hypothesis was rejected, for the lip and chin region, as there was a statistically significant ($p<0.05$) difference in volume measurement between the Coons Patch and TCM. The use of the Coons patch consistently overestimated the volume.

CHAPTER 7

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7.1 REFERENCES

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CHAPTER 8

APPENDICES

UNIVERSITY OF BIRMINGHAM | SCHOOL OF DENTISTRY

Version 1 / 25th March 2019

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

CONSENT FORM

Title of project: Validity of a Tablet based device for 3D facial capture
Name of Researcher: Professor Balvinder Khambay

Please initial box

1. I confirm I have read and understand the information sheet dated 25th March 2019 (version 1.1) 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 withdraw my data within 12 weeks of participation without giving any reason, without my 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 volunteer	Date	Signature

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Name of Person taking consent	Date	Signature

Va d ty of a Tab et based dev ce for 3D fac a capture		
Consent sheet	Vers on 1	25th March 2019

UNIVERSITY OF BIRMINGHAM | SCHOOL OF DENTISTRY

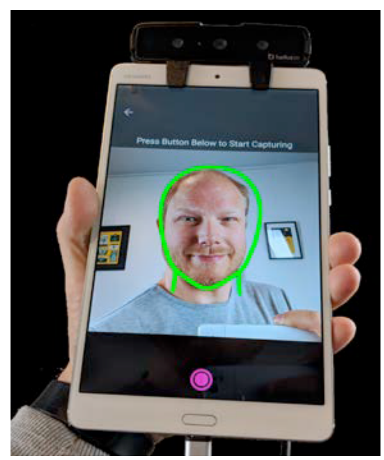
The title of the research project
Validity of a Tablet based device for 3D facial capture

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 a new Tablet based device (Bellus3D) can capture your face in 3D. At present we use an expensive non-mobile camera system (3dMD system), located at the Birmingham Dental Hospital, to routinely photograph patients. We are hoping the Bellus3D Tablet based system will be able to replace the 3dMD. This will allow more research to be carried out in other hospitals.

3dMD system

Bellus3D

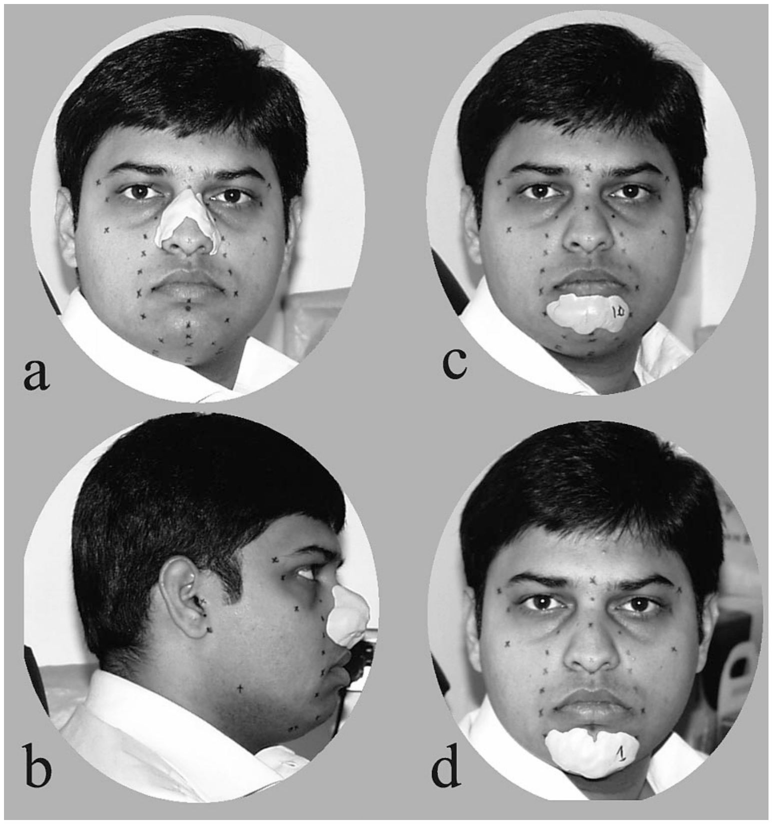


Why have I been chosen?
We are looking for 50 volunteers between the ages of 18 and 50.

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.

We will place around 35 dots on your face using an eye-linear pencil (washes off afterwards) and take a 3D image of your face at rest and smiling using both the 3dMD system and the Bellus3D system.

In addition we will mould some modeling clay material onto your face to work out how well Bellus3D can measure volume. We will take images of your face at rest, with and without the modeling clay on your face, using both the 3dMD system and Bellus3D Tablet.



From: Hajeer MY, Mao Z, M ett DT, Ayoub AF, S ebert JP. A new three d mens ona method of assess ng fac a vo umetr c changes after orthognath c treatment. C eftPa ate Cran ofac J. 2005 Mar;42(2):113 20.

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. Your data will be treated in accordance with the Data Protection Act 2018.

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 on the 25th March 2019 and ethics reference ERN_19-0165.

Va d ty of a Tab et based dev ce for 3D fac a capture		
Informat on sheet	Vers on 1.1	25th March 2019