Accuracy of a New Method To Combine Digital Impressions With CBCT Scans Of The Edentulous Mandible

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The candidate confirms that the work submitted is his own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

Background and Aims:

The treatment of edentulous arches with dental implants offers significant benefits over traditional removable prosthetics. However, current implant placement methods, whether freehand or guided, present challenges in terms of accuracy, invasiveness, and postoperative discomfort. The primary aim of this thesis was to address the concern of placement inaccuracy in fully edentulous patients and introduce a more precise method.

Materials and Methods:

A novel approach, the "Fixed Edentulous Implant Guide" (FEIG), is introduced. Unlike conventional tooth-based guides, the FEIG employs three two-part screws to aid matching of reference points to precisely align digital impressions with CBCT scans during virtual planning. This research explored the method's efficacy through in vitro studies and comprehensive literature reviews along with a novel approach to the calculation of the implant position used in the final study.

Results:

The findings of both the preliminary and final studies show that the novel method presented in this thesis is more accurate than both existing methods of edentulous guided surgery (mucosal borne and bone guides) and dentate guided implant surgery. Through statistical analysis with an independent samples t-test, the final study revealed that the significance is less than than 0.05 for each comparison between the novel FEIG method and the conventional mucosal borne edentulous guided surgery ($p<0.001$), and a statistically significant difference between the two methods is

concluded. The evidence suggests that this approach is both safe and precise, especially when referencing the model to the CBCT scan.

Conclusions:

The final objective of the thesis was to examine whether it is both safe and accurate to place implants with flapless surgery with this new method that references the model to the CBCT scan. The study findings suggest that this statement can be upheld, and given the accuracy in terms of trueness and precision, it is concluded that the novel method provides an accurate method to place implants in an edentulous arch.

Furthermore, as guided implant surgery can often mean that bone can be utilised in an angular or unconventional approach to avoid grafting, using this method may mean that patients with a medical contraindication to conventional flapped surgery may also benefit from full arch rehabilitation.

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List of Abbreviations

3D - Three Dimensional

AM - Additive Manufacturing

BPE - Basic Periodontal Examination

CAD - Computer Aided Design

CAM - Computer-Aided Manufacturing

CDLP - Continuous Direct Light Processing

CBCT - Cone Beam Computed Tomography

CNC - Computer Numerical Control

CT - Computed Tomography

CTU - Clinical Trials Unit

CV - Curriculum Vitae

DIOS - Digital Intra Oral Scanner

DLP - Direct Light Processing

DMC - Data Monitoring Committee

DT - Decayed and Treated

EU - European Union

FDM - Fused Deposition Modeling

FFF - Fused Filament Fabrication

GDC - General Dental Council

GDP - General Dental Practitioner

ITI - International Team for Implantology

MJDF - Membership of the Joint Dental Faculties

OVD - Occlusal Vertical Dimension

PEEK - Polyether Ether Ketone

PhD - Doctor of Philosophy

PICO - Population, Intervention, Comparison, Outcome

PIS - Patient Information Sheet

RCT - Randomised Control Trial

SAE - Serious Adverse Events

SLA - Stereolithography Apparatus

STL - Standard Tessellation Language

TMJ - Temporomandibular Joint

Voxel - In 3D printing, a voxel represents a value on a regular grid in a three-dimensional space, like a pixel with volume.

Introduction

This thesis will discuss the principal problem of accuracy when using guided implant placement on fully edentulous patients. The thesis describes a new, novel method, the 'Fixed Edentulous Implant Guide (FEIG)', that has been proposed by the author to enable the matching of reference points in a digital impression and a CBCT scan to create an implant drill guide with the potential for more accurate positioning than current edentulous soft tissue guides.

With current techniques in edentulous implant surgery, the patient is faced with either invasive surgery and substantial healing or using drill guides with potentially inaccurate implant placement. The novel approach and design of using orthodontic screws to reference the soft and hard tissues as investigated in this study may mean that an edentulous patient can have implants placed safely, accurately and with minimally invasive surgery.

This thesis therefore proposes a novel approach to guided implant surgery in edentulous cases with an approach that could minimise post operative problems with morbidity, pain and infection risks, whilst also increasing overall accuracy so as to reduce overall deviations from planned position and misplacements.

The thesis is divided into a background discussion of the history of implants and the problem at hand and then chapters detailing the factors affecting accuracy along with studies of these components leading to a definitive *in vitro* study.

Chapter 1 - Literature Review

1.1 The Prevalence Of Edentulism And The Benefits Of Implant Treatment in Edentulous Arches

Edentulism is the state of being edentulous, or without natural teeth. Approximately 6% of the population are edentulous in England, Wales and Northern Ireland.(Steele et al., 2012)

Complete edentulism in the population is a prevalent and complicated disability worldwide. To give a scale to the problem that the study aims to address, it was found by Vos et al in 2012 (Vos et al., 2012) that the worldwide burden of fully edentulous people in 2010 was approximately 2.3% of the population i.e. 158 million people. This percentage is higher in the UK where it was reported by Murray (Murray, 2011) as 6% of the population in the Adult Dental Health Survey in 2009.

The fully edentulous mouth has effects on the body in general both locally and systemically, depending on whether the support and mastication ability is preserved/replaced. Facial support is reduced causing the ‘sunken-in’ appearance which further reduces muscle tone and definition. Decreased OVD leads to or contributes to effects on the muscles of mastication and TMJ. Without teeth, speech which relies on tongue-to-tooth contact becomes difficult and lastly with reduced masticatory efficiency there is an effect on the nutrition and therefore on the body as a whole.

The options for treating edentulous patients have until recently been limited to dentures, but over the past two decades there have been advances in implantology and techniques to provide fixed and removable options for these patients. A consensus statement made by McGill in 2002 concluded

that the basic standard of care for edentulous patients should no longer be conventional dentures, but rather "*two-implant overdentures should become the first choice of treatment for the edentulous mandible*".(McGill, 2002)

However, whilst implant therapy for edentulous patients is often preferable, the treatment is not without risks. The risks can be general and related to factors such as medical conditions or can be localised.
Localised complications can arise from misplacement of the implant. This misplacement can occur horizontally and vertically, with angular deviations also occurring.
The factors affecting misplacement can be related to the type of surgery performed, through analogue placement and conventional flap raising or digitally planned guided surgery. There are several inherent risks and problems associated with this, where patients are missing teeth, including the raising of a large flap. This can, potentially cause an increased morbidity and traumas. The process can interrupt the blood supply to the surgical site, impair healing, and potentially cause necrosis of the flap. Postoperative complications such as pain and swelling can affect the patient's comfort and the quality of life. Furthermore, the surgical site is at risk for infection to prolong itself and negatively impact the success of the procedure altogether. Inadvertent harm to surrounding tissues and structures as well further complicates the postoperative management. The challenges in edentulous patients require detailed pre, peri-and postoperative care with meticulous surgical planning and execution when performing extensive flap elevations procedures.

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Allen et al showed that subjects who were provided with implant retained over-dentures, as opposed to conventional removable prosthetics, had Oral Health Impact Profile (OHIP) change scores that "*were significantly greater for patients receiving implants than for those who refused them*." (Allen et al., 2006a)

Chai et al (Chai et al., 2006) also concluded that "*hospitalized geriatric patients should identify edentate patients without a set of complete dentures for the possibility of malnutrition*".

When we consider providing fixed prothesis as an option for elderly edentulous patients we should also consider that elderly patients might have reservations and anxieties about surgery as Ellis showed in his paper about elderly oral care.(Ellis, 2011) Elllis highlights the mental and health advantages associated with preserving oral function and appearance through non-invasive ways in older individuals. The fixed prosthesis can restore mastication, esthetic, and phonetics. Through acknowledging Ellis's perspective, dental providers can make wise choices when delivering empathetic, ethical care, appropriate to each elderly edentulous patient's specific needs.

If therefore, the edentulous patient can be helped not only with a well fitting and appropriately designed prosthesis, but a fixed prothesis, the detrimental effects of living with edentulism can be reduced if not mitigated entirely.

1.2 Classifications and Descriptive Analysis of Edentulous Mandibular Ridges

The classifications of edentulous mandibular ridges are instrumental in understanding the inherent challenges and formulating optimal,

individualized treatment plans for the patient, whether those plans be Prosthodontic with the provision of a denture or surgical in nature with the intended placement and subsequent restoration of implants.

Mandibular edentulous ridges are predominantly classified into four distinct types according to Atwood's seminal classification (Atwood, 1971) and we can discuss the challeges associated with each type as follows;

Type I (Well-rounded Ridge):

Description: This ridge type is marked by well-rounded contours, exhibiting adequate bone volume and density, offering an optimal environment for implant placement.

Challenges: The challenges are minimal, and standard implant protocols are generally applicable, making it a favorable scenario for implantologists.

Type II (Knife-edge Ridge):

Description: Characterized by a sharp, thin ridge, as a result of extensive bone resorption.

Challenges: The inadequate bone width usually necessitates bone augmentation and/or ridge expansion techniques for implant placement to be possible. This therefore adds layers of complexity to the procedure.

Type III (Flat Ridge):

Description: This ridge type is characterized by a flat morphology with reduced overall vertical height.

Challenges: The diminished bone height potentially necessitates vertical bone augmentation to secure implant stability, and again poses additional challenges in achieving successful outcomes.

Type IV (Depressed Ridge):

Description: This type is marked by a concave or depressed ridge due to severe bone loss.

Challenges: Advanced bone grafting and ridge augmentation are imperative to restore ridge anatomy and enable successful implant placement.

1.3 The History Of Dental Implants

Historically, there is evidence that mankind has used various methods to replace missing teeth in one form or another for centuries if not thousands of years, as discussed by Blomstedt.(Blomstedt, 2013) However it was not until the 20th century when dental implants became more common place in an attempt to provide function as well as aesthetics with various degrees of success.

1.3.1 Greenfield Basket

Greenfield et al in 1913 (Greenfield, 1913) discussed the use of a “Greenfield basket” that was an iridioplatinum implant basket buried into the bone. This apparently had been shown to last a number of years and showed evidence of osseointegration but was then superseded by osseointegrated titanium.

1.3.2 Osseointegrated Titanium

Bothe et al (Bothe, 1940) used titanium as an implantable metal in 1940 and made observations showing that the bone grew close to the surface of titanium screws which proved difficult to extract. This idea was expanded on and later marketed by Per-Ingvar Brånemark (Brånemark, 1983) and termed "*osseointegration*" in 1965.

From 1952, Branemark adopted the Cambridge University design of titanium "ear chambers" for the use in rabbit femurs in a study of the healing and regeneration of bone. Following the study, on attempt at retrieval Brånemark observed that the bone had grown into close adaptation the surface of the titanium implant. Brånemark continued these studies, expanding them into human patients. He used the mouth due to the ease of access and the fact that there was a widespread population of subjects available with an edentulous arch. He consistently observed that the titanium implant had adhered to the bone and termed this phenomenon as 'osseointegration'. (Brånemark, 1983)

1.3.3 Evolution of design

As time has passed since 1965, the design and surface of dental implants has evolved. Typically, dental implants are now root form and there is a great deal of variation from different manufacturers across the globe. Dental implants generally consist of a titanium screw of varying size and diameter. Esposito et al in a Cochrane study (Esposito et al., 1993) showed that long term, there is no evidence to show that one variety is more successful than another. However a recent systematic review has discussed how more

recent thread design and macro geometry may have an impact on osseointegration (Kreve et al., 2022)

Over recent decades, the implant surface has also evolved to increase the surface area and improve the osseointegration potential as well as various surface treatment changes to increase the speed of such integration. The surface texture is currently varied through manufacturers by etching, oxidation or blasting the surface with various types of media. (Reza, 2007)

1.3.4 Platform

As the design of the implant screw has evolved, so too did the connection between the dental implant and the dental prosthesis. In the 1980's wider implants were introduced to supply dentists with an alternative that might better replace molar teeth. Up to this point the diameter of the implant and the diameter of the connecting abutment would match. This was later termed platform-matching.(Lazzara and Porter, 2006)

With the introduction of wider implants, a lack of commercially available restorative components led to the use of smaller diameter abutments and restorative prosthetics than the implant diameter placed. Clinical reports began and later studies e.g. Canullo et al (Canullo et al., 2010) showed that this change in diameter led to a noticeable reduction in crestal bone loss around the alveolar bone during healing and remodelling. This change in diameter was later coined the "platform switch".

The rationale of this maintenance of crestal bone is not currently well understood but investigations have discovered a zone that is formed around the implant-abutment junction where there is a proposed inflammatory cell infiltrate as discussed by Ericsson et al in 1995. (Ericsson et al., 1995)

Lazzara et al (Lazzara and Porter, 2006) have recently theorised that the benefit of the platform switch occurs as the platform switch moves this zone of inflammatory infiltrate away from the implant-abutment junction and within the width of the platform switch. Atieh et al (Atieh et al., 2010) have concluded in a systematic review that the difference of the bone level from the platform switch is statistically significant if the width of the platform switch is more than 0.4mm i.e an overall mismatch of 0.8mm. They discussed that this zone of inflammatory cell infiltrate is most likely connected to the idea of a biological width.

1.4 The importance of precise implant placement position

If the implant is positioned poorly then this will impact the final result in a variety of ways;

1.4.1 Biologic Width

Teeth in the natural dentition exhibit a minimum thickness of soft tissue that surrounds the tooth. In 1997 Cochrane et al (Cochrane et al., 1997) discussed that dental implants placed into the osteotomy prepared also exhibit this minimum thickness. Gargiulo et al (Gargiulo et al., 1961) described this as being around 1-2mm of epithelium with a 1mm layer of underlying connective tissue. When placing dental implants in edentulous patients, acknowledging the relevance of the soft tissue thickness around the implant is crucial, as highlighted by Gargiulo et al. (Gargiulo, 1961). The presence of a minimum of 1-2mm of epithelium and a 1mm layer of underlying connective tissue is essential to maintain the health and stability of the implant, prevent peri-implant diseases, and ensure the long-term

success of the implant in restoring function and aesthetics in edentulous patients.

Hermann et al (Hermann et al., 1997) theorised that as the prosthetic components of the dental implant are removed several times during impression-taking and component exchanging etc, the tissue surrounding the aforementioned implant abutment junction never creates a reliable soft tissue attachment. In response, the alveolar bone retreats to provide the necessary vertical dimension for the soft tissue thickness required. At one point this was considered to occur until the first thread of the implant was reached but this idea has now been dismissed as research on the platform switch has progressed.

1.4.2 Horizontal crestal separation between implants

Tarnow et al (Tarnow et al., 2000) reported a reduction in crestal bone loss between two implants when the distance between them exceeded 3mm; however, it is crucial to note that this study primarily focused on two-dimensional aspects and did not incorporate the complexities of the three-dimensional bone structure underlying the soft tissue, which may impact the applicability of the findings. Tarnow et al theorised that at least 3 mm of bone being required to support the biological width of interproximal papilla between the two implants. Through platform switching, the increase in room for the biological width can help maintain both crestal bone and interproximal papilla in especially important areas such as the aesthetic zone.

Teughels et al (Teughels et al., 2009) conducted a systematic review into the critical dimensions required around implants for optimal aesthetic outcomes. The review concluded that the optimal distance between tooth and implant based on various literature and studies was 3-4mm based on

one cross-sectional and two prospective case series (which in 75-87% of the time led to complete papillary infill).

1.4.3 Buccal Plate thickness

If the implant has been placed with less than 1.5mm of buccal plate bone remaining, Rodriguez et al (Rodríguez-Ciurana et al., 2009) summarised that the buccal bone will recede approximately 1.5- 2mm to allow the biological width necessary. This can have serious long-term effects and lead to complications and/or failures of implants with regards to facial aesthetics.

A retrospective review from Evans and Chen (Evans and Chen, 2007) analyzed the aesthetic outcomes of 42 non adjacent implant restorations and after function related their bucco-palatal position to the amount of gingival recession that occurred. The paper concluded that implants positioned more buccally showed nearly three times more recession than implants that were positioned more palatally.

Spray et al (Spray et al., 2000) studied the amount of buccal bone recession or gain on the placement position of over 3000 implants. The study concluded that for implants placed with more than 1.8-2.0mm of buccal facial bone present on placement, the vertical height of bone on the facial aspect of the implant either increased or bone loss was significantly reduced compared to those implants with less than 1.8mm present on placement.

1.4.4 Vital Structures

Anatomical structures possibly encountered when placing implants in the maxilla or mandible that have varying degrees of consequence of severity if disturbed or damaged. These include the nasopalatine nerve, the nasal floor and the maxillary sinus, along with nerves and blood vessels such as the infraorbital nerve, the inferior alveolar nerve and the mental nerve.

From the above, we can confidently conclude that precise implant placement is therefore paramount to optimise patient function and aesthetics. Accordingly, a more comprehensive, structured literature review was carried out on prosthetically designed implant placement and the introduction of drill guides to facilitate accurately placing implants.

1.5 Surgical Difficulties and Rehabilitation Strategies for Edentulous Mandibular Ridges

For each edentulous manbible ridge type, there is a unique anatomical variation and bone resorption pattern. Each type requires meticulous planning and execution for implant surgery success. Types II, III, and IV often require additional surgical interventions such as bone grafting, ridge expansion, and augmentation procedures due to the lack of adequate bone volume. (Misch, 1990) By increasing the treatment complexity, the overall treatment duration is extended, and can potentially impact the prognosis of implant therapy with morbidity and infection risk. (Esposito et al., 1998)

1.5.1 Implant Rehabilitation Strategies:

The treatment and restorative rehabilitation of edentulous mandibular ridges through implantology can be approached through various surgical options, including Free hand, Soft tissue guide, and Bone level guide with and without surgical fixation screws.

Free Hand:

Description: With the free hand approach, the surgeon places the implant(s) without any guidance of a surgical template, and relys on clinical judgment and surgical experience.

Considerations: Both the success and difficulty of the treatment are dependent on the anatomical situation and the complexity involved with a particular edentulous ridge. As a result there is a high level of expertise and surgical precision required to avoid complications.

Soft Tissue Guide:

Description: Otherwise known as a mucosal borne guide, a soft tissue guide is a surgical guide that rests on the soft tissue to aid in the accurate placement of implants. It can be used with or without a fixation pin to aid stability.

Considerations: The aim of a surgical guide is to provide more accuracy compared to the free hand approach but a soft tissue borne guide requires careful consideration of underlying bone anatomy and has inherent issues related to mucosa thickness, compressibility and movement.

Bone Level Guide with and without Surgical Fixation Screws:

Description: This approach employs a guide that is fixed to the bone once the mucosa has been reflected through incision and raised surgical flap. The aim of a bone level guide is again to better the precision of implant placement, with the option of using surgical fixation screws for added stability.

Considerations: As the bone level guide is more invasive it requires meticulous planning and surgical execution. Notably because of the inherent issues with the raising of a larger flap.

Overall, when a surgeon is considering the appropriate strategy for implant rehabilitation in the edentulous mandibular arch, each option has its own surgical and anatomical considerations and inherent challenges to achieve a successful outcome.

1.6 Literature Search On Prosthetically Designed Implant Placement And The Introduction Of Drill Guides

1.6.1Literature search terms

An electronic search using MEDLINE (Pubmed), EMBASE and Cochrane databases was conducted. The results were crossed to reduce the possible loss of information.

The search was also widened to include search engine data to obtain information on newer technologies that are used such as that with 3D printers, 3D light based lab scanners and CBCT technology.

1.6.1.1 Literature found

A total of 66 papers were identified which contained information relating to one of the search terms. These papers were screened and many clinical studies were identified, relating to either studies of just virtual implant

planning accuracy or studies comparing the accuracy of different types of implant guides when measured against their 3D planned counterparts.
The literature review is therefore based on retrospective and prospective cohort studies that were gathered from the search.
Once articles had been identified, they were analysed according to what methodology was used, the risk of bias and the interpretation of the findings and the conclusions drawn.
Further inclusion criteria were implemented to focus the number of studies to be reviewed by selecting studies more comparable to the objectives laid out above.
References to information such as with the accuracy of 3D printers and history of implants were included.

1.6.1.2 Reasons for study exclusion

The reasons some search results were excluded in the literature review were;

-Results that were based on older technologies that had now been superseded with newer more accurate technologies.

- Data affecting the discussion or results that was unrelated to the search terms.

There were a low number of studies based on guided implant placement in general and an even lower number of studies as it relates to edentulous guided surgery whether it be flapless or not, hence the low number of search results gathered with 43 papers included following review.

1.6.2 Data obtained

The main data obtained was relevant to the accuracy of the different ways of creating a digital impression. There were a number of articles included in the literature review that concerned measuring or reflecting on other studies that measured the accuracy of the various types of implant drill guides currently on the market.

The lowest number of articles found were studies related to the SMOP drill guide system with only 5 papers found using this system.

1.6.3 Results of literature reviewed

The results given in literature related to guided surgery can be summarized according to the steps in which guided implant surgery is traditionally carried out;

After the advent of dental implants, their use has become more prevalent and so have implant related complications and their sequelae. Improper design, planning and surgical placement without adhering to the principles set out as discussed above as well as placement not considering the final prosthetic design has led to an increased demand for ways to minimise these errors. To try and overcome these potential problems, over time as technology has improved, surgical guides have become more prevalent. Implantologists have embraced recent technological advancements which also presents an increased number of patients potentially exposed to the complications of limitations in the accuracy of current guided surgery. These guides have developed from simple analogue, lab made prosthetic envelopes to fully guided digital designed and produced guides that aim to increase accuracy, better surgical execution and prevent iatrogenic damage.

However, we still have limitations with edentulous surgery due to problems with referencing the digital impression and the CBCT scan and also surgical complications arrived from deviations and misplacement due to the fit and/or use of the edentulous guide as the mucosa compresses or rotates.

1.7 Accuracy & Data Matching in Virtual Implant Planning

When we plan the implant surgery in a 3D program, the eventually produced template is designed on the 3D impression, (an STL file that is produced in the first stage). This is however just the surface of the oral environment. The 3D CBCT scan is a separate image and the two data sets are then combined to provide a whole representation of the patient that can be used for guided surgery implant planning. Referencing the 3D impression data to the CBCT involves either manual or computer aided matching of common elements that can be seen on both 3D image sets.

Data matching has been evolving and the most recent software algorithms used in the main computer aided guide design software packages have an automatic calibration and matching function. This is optional in some cases. As discussed by Behneke et al 2009 (Behneke et al, 2009) if the impression data is referenced poorly, but printed accurately, it will fit well but will guide the drills and the implant placement in the wrong position. Accurate referencing and data matching are therefore critically important.(Becker et al., 2018)

Figure 1 shows 3D printed guides in place. This figure is an example of a two stage approach for edentulous guided implant surgery where an initial

guide is used that sits onto the remaining dentition for the preparation of some of the osteotomy sites. The remaining dentition is subsequently extracted and then the second guide is placed. This second guide fits securely onto the implants placed with the initial guide before the remaining osteotomies are created.

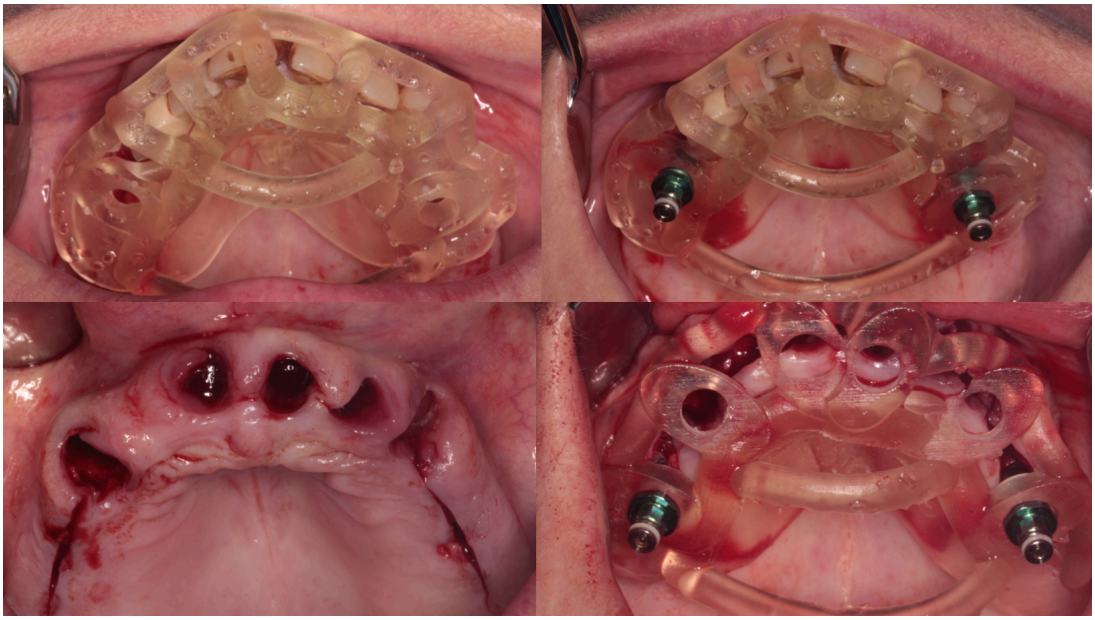

Figure 1. Two Staged Dentate, Then Edentulous guided Implant Surgery.

The initial theory suggested that as mucosa is not a fixed platform, the bone supported drill guides would be more accurate. However, studies suggest (Arisan et al., 2010) this is not the case as it is difficult to expose the bone surface in a way that replicates the digital version of the bone surface used to create the drill guide due to both the fact that not all of the soft tissue can be completely removed on flap creation and also the accuracy of the bone surface extraction algorithm that chooses where the boundary of the bone is (Arisan et al., 2010).

1.7.1. Stage 1 - Digital Model Accuracy

A comprehensive literature review of factors affecting the accuracy of intraoral digital scanners and lab digital scanners in creating a digital impression of an edentulous arch given in Section 1.10.

Becker et al (Becker et al., 2018) studied the accuracy five of the most common light based model 3D scanners and eight of the most common CBCT scanners that are able to digitise models into a 3D STL. The study involved the digitisation of 10 patient models. The digitised models and their corresponding surfaces were compared using mesh lab v1.3.4. A statistical analysis using box plots, a paired t-test and a Friedmans test were used to compare with a significance level of 5%.

The light based 3D scanners had a minor mean deviation with median distances between CBCT and optically digitized casts of 0.064 + - 0.005 mm..

They concluded that light based scanners were more accurate where the paired t-test revealed average difference in measured distance between light and CBCT scanners was 0.046 mm.

However, colour heat maps of the light-based scanners still showed regions in the palate of up to 1mm deviation. When we are looking at guided surgery studies, such as this research study, this is more clinically relevant as these areas of poor fit from a poor scan will cause the overall guide to sit improperly and result in implants placed in the wrong position.

Another point of discussion is that the Becker paper used dentate orthodontic models which would result in more favourable alignment in guided implant surgery software.

1.7.2 Stage 2 - CBCT & Digital model Data Matching

A comprehensive literature review of the factors affecting dental CBCT scanner accuracy and overall accuracy when combining data from CBCT and intraoral impression scans is given in Section 1.11

1.7.2.1 Accuracy & Data Matching in SMOP Guided Surgery Planning Software

As discussed above, referencing the 3D impression data to the CBCT involves either manual or computer aided matching of common elements that can be seen on both 3D image sets.

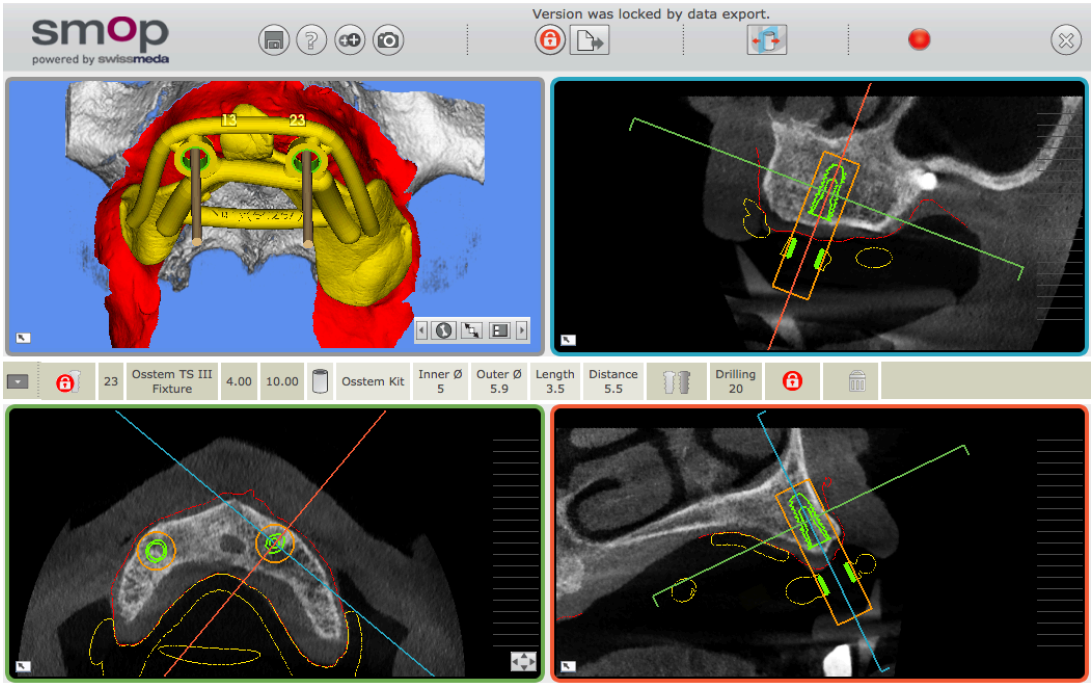

Figure 2. Air Border STL matching with SMOP Guided Surgery Planning Software

Historically this was done manually with transfer devices but with the evolution of digital software this is becoming more commonly autonomous.

For example, with the SMOP guided surgery planning software as seen in Figure 2, there is an automatic calibration of the air border STL matching. Kernen et al (Kernen et al., 2015) conducted a study to compare the accuracy of manual lab-based matching, involving the fabrication of manual transfer devices, with that of digitally designed printed templates. The inaccuracies were measured in terms of deviation from the intended position, with the mean lab-based matching showing a deviation of 0.31/0.32mm in the two horizontal planes and 0.5mm apically. These deviations were measured at specific reference points on the implant to ensure consistency and reliability in the comparison. In contrast, the digitally planned templates exhibited a mean deviation of 0.16-0.23mm horizontally and 0.25mm apically. These measurements are crucial as they reflect the precision of implant placement, impacting the overall success and longevity of the implant.

Kernen concluded that templates that had a surface scan matched with CBCT data was statistically significantly more accurate than laboratory fabricated templates. "*Within the limits of the study, it can be concluded that a higher accuracy may be achieved if templates are virtually designed and printed after superimposing a surface scan with a CBCT in order to transform the virtual plan into reality, applying the smop-technology*"(Kernen et al., 2015)

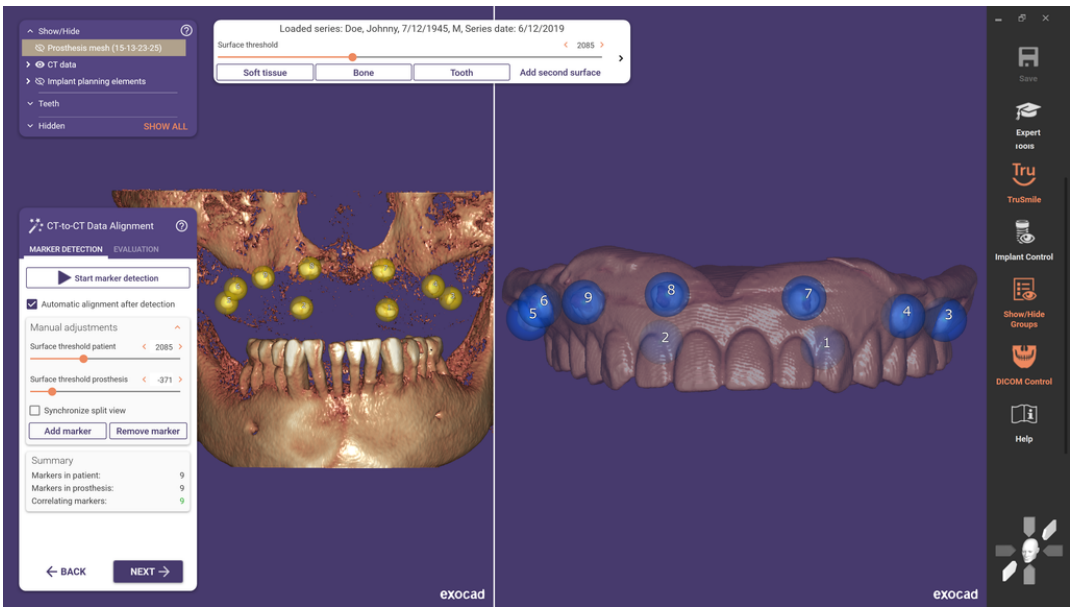

Figure 3. CBCT To CBCT Dual Scan Data Matching with ExoPlan Software

Data matching has been evolving and the most recent software algorithms used in the main computer aided guide design software packages have an automatic calibration and matching function. For example in Figure 3, exoplan guided implant surgery software has an automated dual scan data matching feature which automatically recognizes markers placed on the prosthetic device. (Exocad, 2019)

1.7.3 Stage 3 - Types of Drill Guide to be produced for the edentulous arch

When considering the planning and placement of several implants in the edentulous arch, there are different types of implant drill guides that may be produced.

- Mucosa Borne

- Bone supported.

Fixation pins can be used to secure these two types in place and the position and depth of these fixation pins are designed within the drill guide design software, as can be seen designed in Exoplan software in Figure 4. (Exocad, 2019)

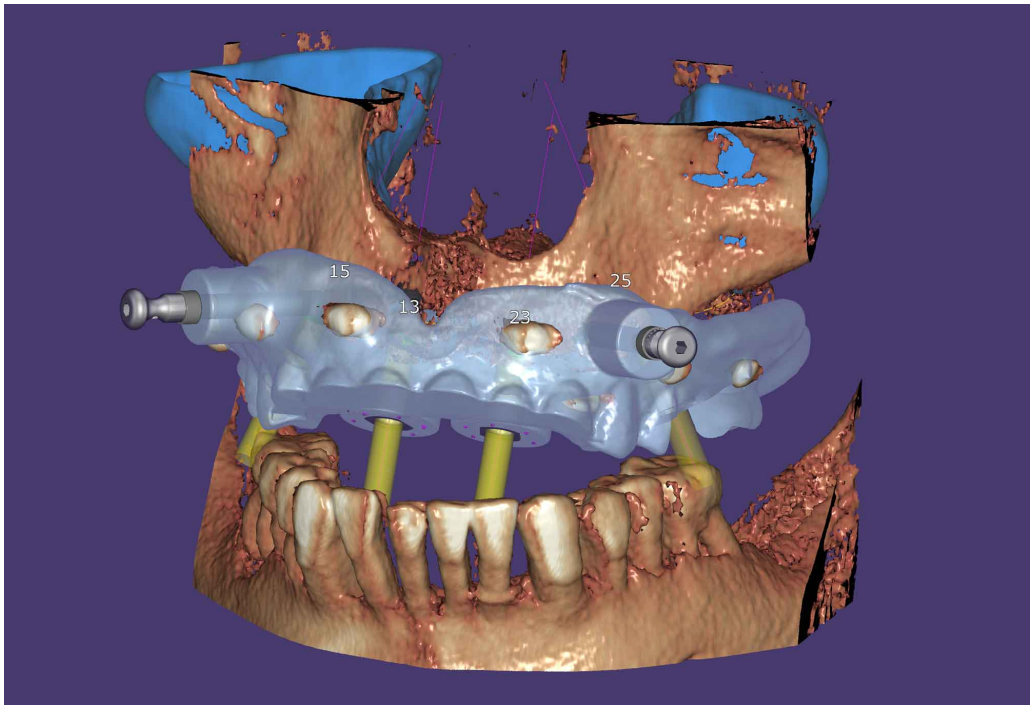

Figure 4. Fixation Pins Added Buccally To The Edentulous Mucosa Borne Guide (Exocad, 2019)

The mucosa borne drill guides can be used with or without a crestal incision to expose the buccal bone surface whereas obviously the bone supported drill guide requires full exposure of the bone with large incisions and full flaps reflected.

Arisan et al. (2010) conducted a comprehensive in vivo study, demonstrating that mucosa borne guides yielded more accurate results in comparison to other methods. This extensive study involved 54 patients and the planning and placement of 294 implants using 60 guides, including varying types of

edentulous stents, mucosa borne, tooth borne, fixed, and with multiple parts. A post-operative CBCT was utilized to compare the planned and actual positions of the implants, with statistical analysis conducted using Kruskal-Wallis and Mann-Whitney U tests, considering a p value of 0.05.

The study concluded that bone-supported guides exhibited the highest mean deviations, whereas the lowest deviations were observed with mucosa-supported guides. This seemingly counter-intuitive result underscores the challenges associated with digitally extracting a clean bone surface from the CBCT.

It's plausible that the unexpected findings of Arisan et al. (2010) could be attributed to the limitations in technology available in 2010. During this period, the precision and reliability of digital imaging and planning software may not have been as advanced as current standards, potentially contributing to inaccuracies in bone surface extraction and implant planning. The error might have originated from the difficulty in obtaining clear and accurate CBCT images, coupled with potential inaccuracies in the digital planning process, leading to deviations in the actual placement of the implants.

1.7.4 Stage 4 - Accuracy of the 3D printer

A comprehensive literature review of 3D printing technologies, materials and factors affecting accuracy of resin-based 3D Printers is presented in Section 1.12.

In summary, 3D Printers are of various types. The most common type of 3D printer used in medicine and dentistry are SLA or DLP printers which use a laser or a light projector to cure resin in a chamber as the mount rises. There

are two types of accuracy in the printing of models and guides with 3D printers of this type; the Z plane accuracy and the X/Y plane accuracy.
All 3D prints also require supports to be virtually added to the 3D STL of the designed guide so that the object prints accurately with no distortion. Proper orientation and placement in the print software is therefore crucial so that the fitting surface has no supports in contact with the fitting surface or where the guide components such as keys, spoons or drills fit.
The X/Y plane accuracy is the most crucial as this depends on the spot size of the laser.(Mangano et al., 2020) The laser spot size of the Form 2 SLA printer and the Form 3 SLA printer (commonly used 3D Printers in dental surgery due to the biocompatible SG SLA resin being commonly available and constant developments of other resins for dentures, models etc) is 140 microns and 85 microns respectively and the accuracy to within a 95% confidence is around 10 microns above or below this. With more expensive 3D Lab based SLA printers, accuracy can be less than this of up to 25microns.
The variable factors of the 3D printer that may affect accuracy are the spot size of the laser, the size of the steps in between each layer and the Z-plane movements. Larger Z plane steps mean that each layer or “slice” is thicker and therefore the overall print time is reduced. Formlab’s own study of accuracy used 9 prints of different Form2 printers measuring 7 different dimensional components with the resulting standard deviation of “*95% of prints measured to within 240 µm or less (0 24 mm) of the designed dimension*”.(Mangano et al., 2020). It is important to note that this level of deviation might be considered clinically inappropriate for demanding fixed

prosthodontic work, but acceptable for removable prosthodontic and orthodontic work.

Newer printers than the Form 2 aim to reduce this deviation.

The manufacturers of the 3D printers recommend that the guides are oriented either vertically or with up to a 45 degree angulation to benefit from less need for supports and also to utilise the extra accuracy from the Z plane.

1.7.5 Stage 5 - Type of Guided Implant Surgery Drill & Placement Protocol

Once the data matching has been completed, the next step in the guided implant placement procedure is using the drills with the drill guide that has been created. The methodology of guided surgery varies depending on how "guided" the process is. We can categorise the variations of drilling protocol into three varieties;

1) Freehand final drilling

The initial drill is the only part of the drilling sequence of widening the osteotomy that is guided by the template. Widening and/or lengthening the initial pilot hole is then done manually.

2) Freehand placement

All drilling sequences are guided but placement of the implant into the osteotomy created is freehand after the removal of the surgical guide.

3) Fully guided drill sequence and placement.

This is the most recent evolution of guided surgery where every step of both the creation of the osteotomy and the placement of the implant using a guide mount is done through the surgical guide.

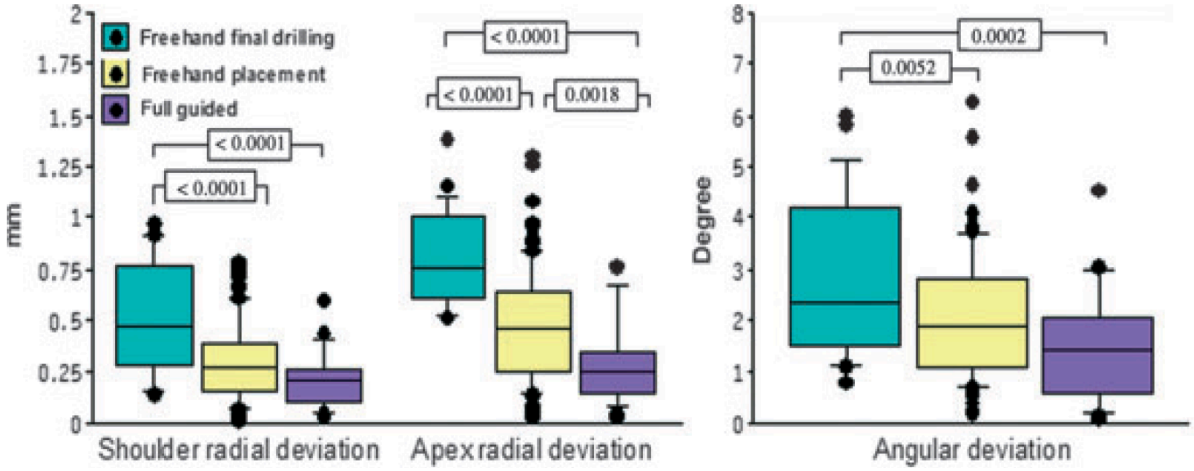

Figure 5. Behneke et al Investigated Error From Guided Surgery With Various Implementations (Behneke et al., 2012)

The accuracy of this step would factor into how accurate the overall procedure is. Behneke et al (Figure 5,) investigated the factors that would influence the drilling protocol. The study measured the final placement against the virtual in three respects (Figure 6,)

- Coronal radial deviation
- Apex radial deviation
- Angular deviation

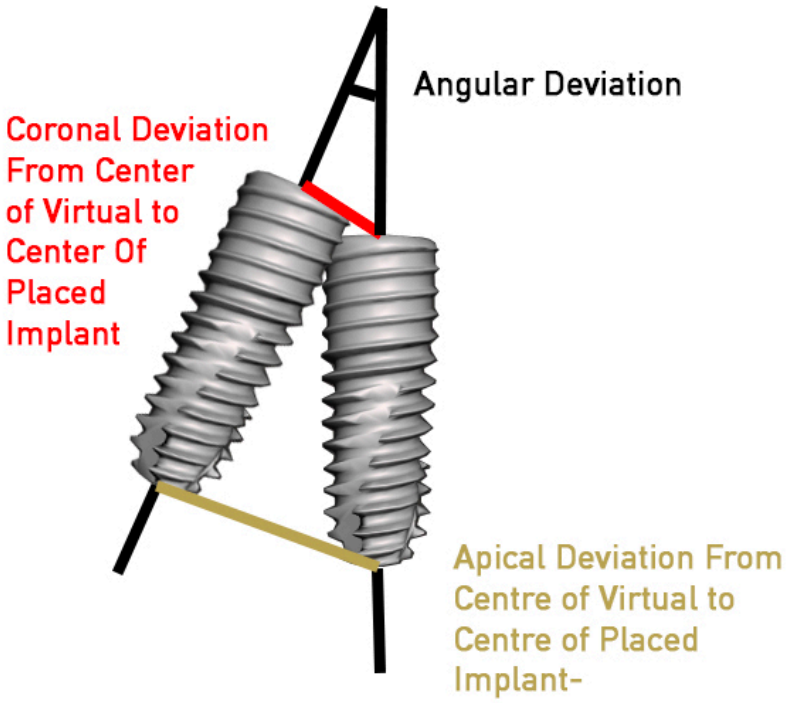

Figure 6. The Positions Used as Reference Points for the Coronal, Apical, and Angular Deviations (Behneke et al., 2012)

The study was a comparatively large *in vivo* study with 52 partially edentulous patients having a total of 132 implants placed. Of the 132 implants placed, half were placed with an open surgical flap and half were placed flapless. 86 of the implants were placed completely freehand, 24 guided only with the pilot drill and 22 fully guided drilling and placement protocols.

The results showed that the fully guided drill sequence and implant placement was significantly more accurate than the less fully guided approach which in turn was more accurate than the freehand final drilling and placement approach.

1.7.6 Accuracy of Flap vs Flapless surgical technique

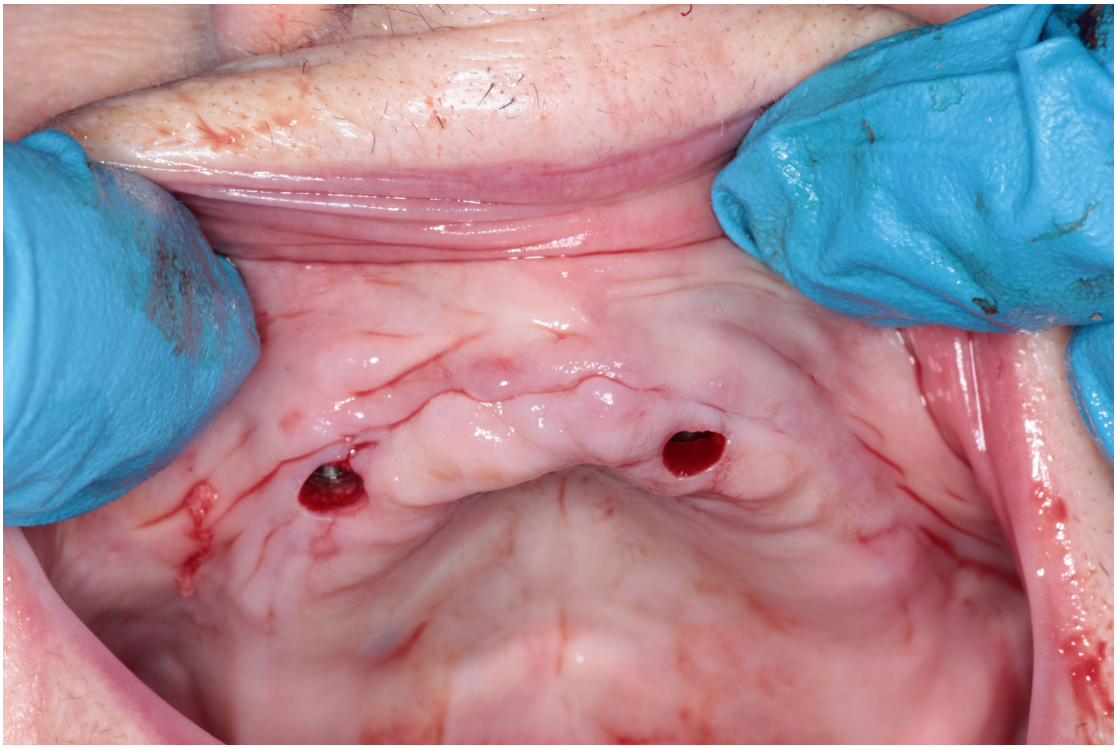

Figure 7. Flapless Guided Implant Surgery In An Edentulous Arch

Behneke et al (Behneke et al., 2012) also studied the accuracy of various types of guides including flapless edentulous guides such as in Figure 7 and whether a flap was introduced into the guided surgery procedure would impact accuracy. They stated in the conclusion that "*flap elevation did not negatively influence the positioning of the tooth-supported surgical templates and that the natural dentition allowed a sufficient anchorage*" based on the results showing no statistically significant differences in the linear deviation

at the apex whilst there was a small borderline statistically significant (P = 0.027) effect on the difference in coronal radial deviations."

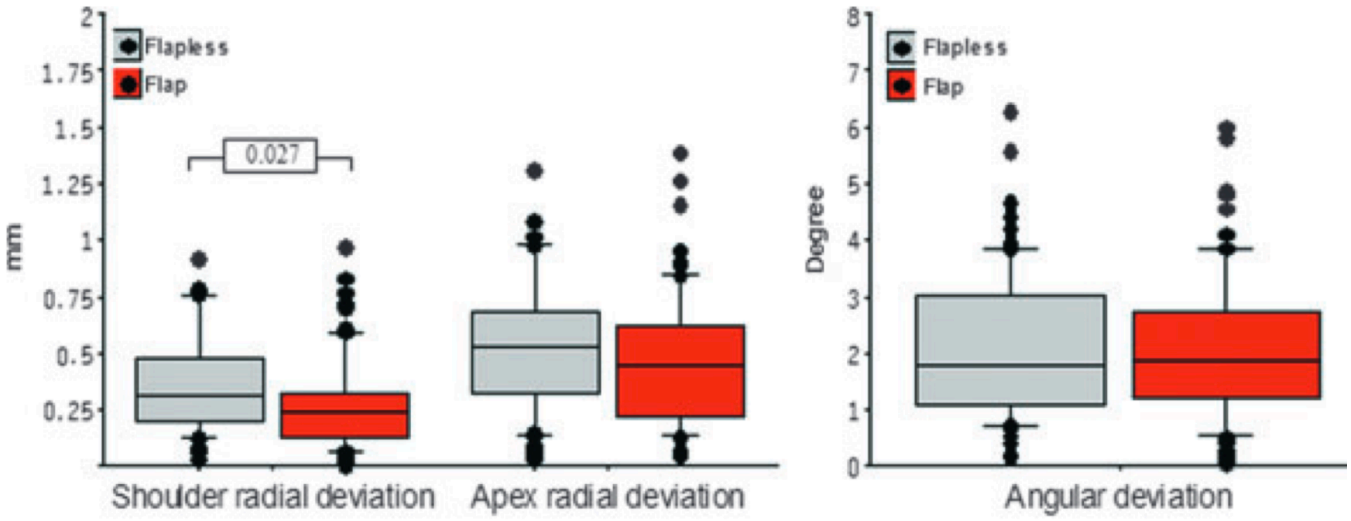

Figure 8. Behneke et al (Behneke et al., 2012) Investigated Error From Guided Surgery Flapless And With Flap

Behneke's study (Behneke et al., 2012) (Figure 8) correlates with another study (Ersoy et al., 2008) which also did not find a difference in accuracy. Flapless surgery can therefore be said to not introduce new levels of errors whilst raising a surgical flap allows any errors that do occur to be seen.

1.7.7 Overall Accuracy

1.7.7.1 Accuracy of guided implant placement;

Van Assche et al (Van Assche et al., 2012) carried out a retrospective study into the accuracy of guided implant placement as measured across various clinical studies. "*Meta analysis revealed a mean error of 0.99 mm (ranging from 0 to 6.5 mm) at the entry point and of 1.24 mm (ranging from 0 to 6.9 mm) at the apex. The mean angular deviation was 3.81° (ranging from 0 to*

24.9°). Significant differences for all deviation parameters were found for implant-guided placement compared to placement without guidance. Number of templates used was significant, influencing the apical and angular deviation in favour for the single template. Study design and jaw location had no significant effect."

Schneider et al (Schneider et al., 2009) also conducted a systematic review, isolating eight articles out of 3120 titles regarding the accuracy of guided implant surgery and ten regarding the clinical performance. The authors conducted a meta-regression analysis across the literature gathered and found that the mean deviation at the entry point was 1.07mm (95% CI: 0.76-1.22 mm) and the mean apex deviation was 1.63mm (95% CI: 1.26 - 2mm). However the studies included in this meta analysis were based on differing technologies and on both artificial bone blocks and in the mouth and the meta analysis considered studies prior to 2009 and therefore the meta analysis is difficult to compare to current guided surgery methods as both software and guide drill systems have materially progressed since these studies were undertaken.

1.7.8 Factors influencing both dental implant success and the application of digital planning

In the previous sections the need for accurate placement in terms of biological positioning was discussed. Digital planning can have an impact on the success of implant placement in terms of the below factors;

1.7.8.1 Bone resorption;

Gingival height and width to maintain papilla and prevent recession for long term soft tissue stability. Teughels et al (Teughels et al., 2009) conducted a systematic review of articles on Pubmed, Cochrane and the ISI databases to identify eligible human studies discussing the aesthetic outcomes of implants to give a reflection into the critical dimensions required around implants for optimal aesthetic outcomes. The review concluded that the optimal distance between tooth and implant based on various literature and studies was 3-4mm based on one cross-sectional and two prospective case series (which in 75-87% of the time led to complete papillary infill).

1.7.8.2 Implant Bucco-Palatal Position;

Evans and Chen (Evans and Chen, 2007) carried out a retrospective review that analyzed the aesthetic outcomes of 42 non adjacent implant restorations and after function related their bucco-palatal position to the amount of gingival recession that occurred. The paper concluded that implants with a buccal coronal position (1.8mm + - 0.83) showed nearly three times more recession than implants that were positioned more palatally (0.6mm + - 0.55mm). However the study involved teeth that had a mean function time of 18.9 months but the results were found to be highly statistically significant (P=0.000).

1.7.8.3 Implant positioning effects on soft tissue stability;

Nowhere is the effect on soft tissue stability more important that in the aesthetic zone i.e. around the exposed anterior teeth. Soft tissue recession

can play a major role on whether the restoration placed is deemed a success or a failure.

When a tooth is extracted, the bone resorbs and the soft tissue therefore is unsupported. (Spray et al., 2000)

1.7.9 The clinical advantages of computer guided implant placement

Hultin et al discussed that conventional manual manufacturing of guides are complex and labour intensive and that manual errors are possible. (Hultin et al., 2012) In contrast, computer designed guided surgery is centralized, fully automated and accurate. However the costs are higher and may be slower if shipping is involved. Hutling et al also discussed reported complications in the retrospective results;

-fracture of splints

- misplacement due to misfabrication of guide,

- lack of primary stability

- insertion of wider implants than planned

- limited oral aperture restricting usage of tools

- misfit of guides

- uncontrolled gingival removal.

1.7.9.1 Types of drill guide sleeve

Different implant manufacturers utilise “spoons”, “keys” or cylinder “sleeves” to sit within the drill guide template. This is so that there is a barrier between the drills and the plastic the drill guide is made from.

For example, the drill kit from Osstem (Figure 9), as used in this research study, uses exchangeable “keys” which sit into the guide. Increasing lengths of drills are then used which take the osteotomy to full length before the key is exchanged and the osteotomy widened

Figure 9. The Osstem Guided Surgery Drill Kit (Osstem, 2017)

Other systems have “spoons” which are larger and require a second hand providing support such as in Figure 10

Figure 10. Straumann drill spoons. (Straumann, 2017)

An alternative is also the use of “sleeves” which permanently sit into the guide as in Figure 11

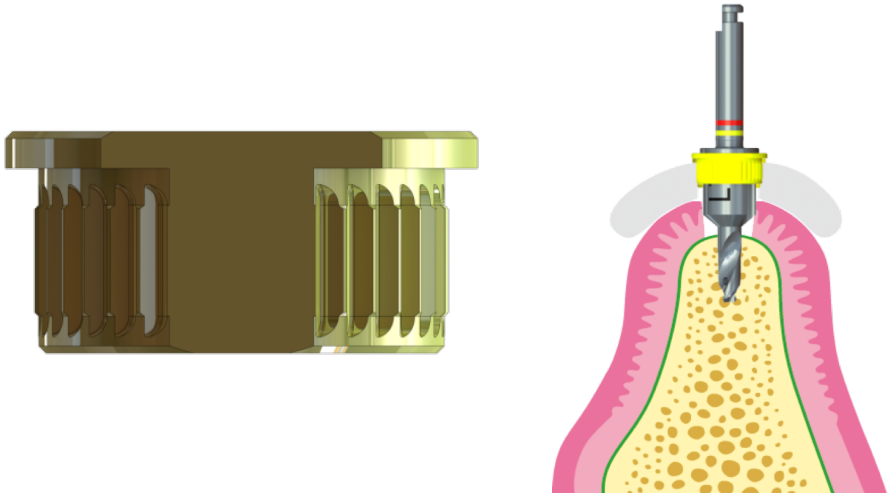

Figure 11. Camlog drill guide sleeves and an example of drills in use. (Camlog, 2017)

The drills themselves have height stops which prevent the drills and the implant guide mount from going deeper than that planned; (Figure 12)

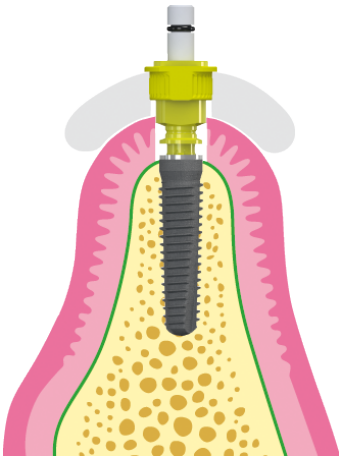

Figure 12. An example of a Camlog implant with guide mount in use. (Camlog, 2017)

1.7.9.2 Sleeves or Sleeveless Approach

Prosthetically guided implant placement has revolutionised dental implantology by offering enhanced precision and predictability. Within this technique, the use of a metal sleeve as a drilling guide has been widely adopted. However, it is vital to understand the scientific reasoning behind how the utilisation of metal sleeves impacts the accuracy of implant placement compared to sleeveless drill approaches. This discussion will summarise the results and conclusions from relevant literature and provide insight into the underlying mechanisms influencing accuracy.

Studies investigating the impact of metal sleeves on implant placement accuracy have consistently demonstrated improved precision. El Kholy et al. (El Kholy, 2019) conducted a study comparing the accuracy of guided implant placement using metal sleeves versus sleeveless drills. They found that the use of metal sleeves significantly reduced deviations in implant angulation and position. The metal sleeve acted as a stabilising guide during drilling, minimising the potential for errors and enhancing overall accuracy. These findings align with a systematic review conducted by Van Steenberghe et al. (Van Steenberghe, 2005), which encompassed various studies exploring the accuracy of computer-guided implant placement with metal sleeves. The review concluded that the use of metal sleeves led to superior accuracy in terms of implant position and alignment with the desired prosthetic outcome. The metal sleeve provided guidance and stability during drilling, reducing the likelihood of deviations.

The scientific reasoning behind the improved accuracy with metal sleeves can be attributed to several factors. First, the metal sleeve acts as a guide, ensuring precise alignment of the drill with the planned implant position. It

eliminates the potential for manual errors that may arise when using sleeveless drill approaches, where the operator relies solely on visual estimation or hand-eye coordination. The rigid nature of the metal sleeve minimises deviations caused by unintentional hand movements, leading to enhanced accuracy.

Furthermore, the metal sleeve offers stability during the drilling process. It prevents lateral movement of the drill, reducing the risk of deflection or deviation. The precise fit between the sleeve and the drill restricts any wobbling, ensuring that the drilling occurs along the intended trajectory. This stability contributes to maintaining the planned angulation and position, thereby improving the overall accuracy of implant placement.

However, it is essential to consider other factors that may influence accuracy when utilising metal sleeves. Oh KC et al. (Oh, 2021) conducted a study investigating the impact of drilling depth, sleeve design, and bone density on implant placement accuracy with metal sleeves. They highlighted the significance of selecting an appropriate drilling depth, as inadequate depth may lead to incomplete seating of the sleeve, potentially compromising accuracy.

While metal sleeves have shown significant advantages in accuracy, studies exploring sleeveless drill approaches have presented comparable results. Lee et al. (Lee, 2013) conducted a study comparing implant placement accuracy using a sleeveless drill technique with guided surgery using metal sleeves. The results demonstrated similar levels of accuracy between the two approaches. This suggests that sleeveless drill approaches can be a viable alternative, especially in cases where the operator possesses a high level of proficiency and dexterity in achieving precise implant placement.

However, sleeves also have the added benefit of a predictable control in all guides versus the sleeveless approach, which may not be fully encapsulated to the full depth of the sleeve in the production guide. With sleeveless approaches, the STL impression determines the guide sleeve shape as the fitting surface is cut from this.

This problem does not occur with metal sleeves. The printed holder of the metal sleeve is cut away, but with the metal sleeve present this restores full size of the hub which therefore improves control and hold around the drill.

In conclusion, the use of metal sleeves in prosthetically guided implant placement has consistently demonstrated improved accuracy compared to sleeveless drill approaches. The scientific reasoning behind this improvement lies in the metal sleeve's ability to provide guidance and stability during drilling, reducing deviations in angulation and position. However, factors such as drilling depth, sleeve design, and bone density should be carefully considered to optimise accuracy when utilising metal sleeves. While sleeveless drill approaches have shown comparable.

1.8.1 Factors Affecting the Accuracy of Intraoral Digital Scanners and Lab Digital Scanners in Creating a Digital Impression of an Edentulous Arch

Rather than performing conventional alginate or polyvinyl silicate impressions, dental impressions may now be captured through advancements in computerization, optics, downsizing, and laser technology. (Birnbaum and Aaronson, 2008) For more than 20 years, three-dimensional intra oral scanners have been used in dentistry, and they are still being developed and improved to take virtual impressions of the intra-oral environment. This paradigm shift has enabled CAD/CAM dental technologies to provide data from precise digital scans of teeth directly to CAM manufacture that can make restorations out of ceramic or composite resin blocks without the need for a physical duplicate of the prepared, neighbouring, or opposing teeth. (Birnbaum and Aaronson, 2008) However, using these technologies to capture a completely edentulous arch using intraoral digital scanners poses more of a challenge than a lab based digital scanner that captures the impression data of a conventional impression. Digital impression creation is an essential component of restoratively driven guided implant surgery and to produce a correctly fitted drill guide, the scanning impression procedures must be precise. This section examines the different approaches to virtualising the intra-oral soft tissue impression with both an intra-oral scanner and a lab scanner.

1.8.2 Introduction

Dr. Francois Duret pioneered the use of CAD/CAM principles in dental applications in his thesis ‘Empreinte Optique’ (‘Optical Impression’) written at the Université Claude Bernard, Faculté d'Odontologie in Lyon, France in

1973. In 1986, he invented a CAD/CAM device, which he exhibited at Chicago in 1989.(Birnbaum and Aaronson, 2008)

The most often used digital format is the open STL (Standard Tessellation Language) or closed STL file format. Other file formats for recording the colour, transparency, and texture of dental tissues have also been created (such as Polygon File Format, PLY files).(Richert et al., 2017) The application of these 3D intra-oral scanners have evolved from lightly powdering to now simply scanning the surface in full colour in a streamlined fashion.(Birnbaum and Aaronson, 2008)

Taking digital impressions of edentulous jaws requires more thought and control to scan with an intraoral scanner as there is less surface topography and therefore less data matching points for the scanner software to merge each frame. As the intra-oral scanner software builds the overall 3D virtual shape through the combination of smaller frame captures, the ability of the scanner to reference and map each frame with an overlap impacts the overall accuracy.(Kanazawa et al., 2018) For the use in CAD and CAM prosthesis or in the use of restoratively driven guided implant surgery, the quality and accuracy of the 3D image is critical.

1.8.3 Discussion of Accuracy of Intraoral (IOS) and Extraoral Lab Scanners

The emergence and use of intra-oral scanners in dental clinics has provided a better experience for the patient and an easier way of creating an impression model in a more predictable and repeatable way to alleviate problems or complications encountered in a conventional workflow using traditional methods with a tray-based impression. (Moörmann, 2006) When

the digital intra-oral scanners were introduced in the 1980s, the fully digital workflow became a reality.

Several recent technical improvements have made the intra-oral digital scanner a central part of modern dental surgery, enabling same-day dentistry, reducing the need for conventional impressions, or even replacing them entirely. Many clinicians are now starting to use a digital scanner, and there are a number of well-performing scanners on the market.

There are many clinical advantages compared to conventional impression taking. Namely, speed, patient comfort, efficacy, and several new ways dentists can predictably work once the intra-oral situation is digitised. Also, a significant factor is that the use of a digital scanner can reduce costs in the long run. (Kim et al., 2018a) (Lee et al., 2019) (Chun et al., 2017)

An alternative way of digitising the intra-oral environment is through the capture of either an impression or cast model in a lab scanner, but this study will focus on the use of direct intra-oral scanners and compare their relative accuracy to a base level lab scanner.

The technology used in scanners varies, and therefore the ease of use, efficacy, and accuracy in terms of trueness and precision may vary. The scanner will measure a number of intra-oral readings and create a three-dimensional image using a mathematical algorithm. Due to the limited field of view of an intra-oral scanner, the single point cloud map generated with each scan frame cannot cover all of the teeth' surfaces. Thus the scanner software overlaps these frames with subsequently captured frames to create a unified 3d mesh representing the full arch. (Park et al., 2015) Depending on the manufacturer and the scanning technology employed, various

algorithms and stitching methods combine these individual images. However, these methods inherently contain a degree of error that can accumulate across the dental arch when a full arch scan is performed. (Mao et al., 2013) (Nedelcu and Persson, 2014) (Fisher B, 2013) The outcome of the digital models is based on how reproducible, and accurate the scan is. The varying degree to which the scanners perform this stitching function will mean that the choice of the scanner may influence the overall accuracy of the resulting scan. (Richert et al., 2017, Zimmermann et al., 2020) Scanners used in dentistry are comparatively new on the market, and few studies have evaluated their 'precision' and 'trueness',(Sason et al., 2018) which are two factors that influence the accuracy of a dental impression. One such study by Patzelt et al.(Patzelt et al., 2013b) used four intra-oral scanners to digitise two typical edentulous jaw models, then imported the data sets, tried to impose them, and compared them for accuracy using 3D evaluation software. The use of intra-oral scanners to digitise edentulous jaw models appears to be viable, but the scanners' accuracy varies substantially. Only one scanner was found to be sufficiently accurate. The authors found that intra-oral scanners for *in vivo* digitalization of edentulous jaws were for the most part unable to accurately produce a 3D impression of the edentulous arch.(Patzelt et al., 2013b)

The accuracy of full-arch stereolithographic (SLA) and milled castings made from *in vitro* scans of three intra-oral scanners was tested by Patzelt, Sebastian BM, et al. who used a laboratory reference scanner and three intra-oral scanners to scan a polyurethane model.(Patzelt et al., 2014) They scanned the images and created five dental casts, which they scanned with

the reference scanner (n = five scans per intra-oral scanner). The authors compared and overlaid the data sets using 3D evaluation tools. They found that except for one intraoral scanner system, all tested systems showed a comparable level of accuracy for full-arch scans of prepared teeth. Patzelt et al. found that the largest variations are likely to occur in the virtual models' distal regions.(Patzelt et al., 2014) Whilst these studies have considered these comparisons, the true variations in full-arch accuracy between traditional and digital impression techniques varies depending on the user and the technique in clinic, despite whether a digital system (either intra-oral or lab based) or conventional impression is used. Higher local variations of the full-arch scans are shown by digital impression systems and when compared to an exceptional conventional impression, digital intraoral scanners do not exhibit greater accuracy. However, when the proper scanning method is used, they offer good clinical outcomes within their indications.(Ender et al., 2016)

Zarone et al. assessed the accuracy of 3D technology on completely edentulous maxilla.(Zarone et al., 2020) The intraoral scanner was used to create 10 digital models of the reference case using consistent scanning methods. These were then compared with 10 polysulfide impressions, which were then scanned using a laboratory scanner. Ten other Type IV stone casts were then poured and scanned using a laboratory scanner. The scans were imported in STL format into a comparison tool, and the trueness and accuracy were calculated. In addition to descriptive statistics, 1-way ANOVA followed by the Bonferroni test or the Kruskal-Wallis and the Dunn tests were used to examine differences between groups (Level of significant 0.05;

confidence interval 95%). In this study, Zarone found that immediate intraoral scanning of a completely edentulous maxilla produced greater precision and trueness than using a lab scanner to scan polysulfide impressions or even stone casts.(Zarone et al., 2020). There is an issue with these and similar studies in that they tend to measure accuracy (eg GOM inspect-type surface deviations) which is not directly clinically applicable. Also the model scanners they use are highly variable, and not ideal. In a more recent study be Chebib et al (Chebib et al. 2022) they scanned edentulous arches with intraoral scanners and also took conventional impressions to compare the results clinically with an intraoral scanner taking a static impression and the conventional silicone based impression providing a muco-compressive impression. They printed two baseplates and measured the in vivo retentive force. The intraoral scans were much poorer in retention both statistically and clinically.

1.8.4 Conclusion

The accuracy of intraoral and extraoral digital impressions to capture a fully edentulous arch have been discussed in several papers. These findings can be used to argue that the accuracy of these impressions is sufficient for the purpose of capturing a edentulous arch and using a virtual impression in guided implant surgery. However, since these intraoral scanners capture static impressions, the fully digital method is difficult to perform, and the scientific data on the subject is sparse, analogue aids such as lab scanning an occlusal rim are still a requirement for the majority of cases.

1.9.1 History of 3D Printing Technologies

In this chapter, we delve into 3D printing technologies. We explore the main components of error that occur outside of the surgery itself. Additionally, we discuss the inherent error from tolerances associated with various parts of the manufacturing process in 3D printing. This includes an examination of materials, printer technology, and brand.

The term 3D printing is commonly used to depict an assembling method whereby the final form of an object is the result of the addition of different layers to build the frame of an object. This procedure is more accurately portrayed as additive manufacturing and is likewise alluded to as ‘fast prototyping’. Although 3D printing is relatively new, and it has been an active part of modern developments in dentistry. (Dawood et al., 2015) A significant amount of publicity encompasses the evolution of 3D printing, which is hailed as an innovation that will perpetually change CAM manufacturing, notably within the dental sector.

The utilisation of 3D printing that requires sub-millimetre precision has piqued the interests of authorities in medicine, and they began to develop the process in the 1990s. However, the inception of 3D printing began in the 1980s. In 1983, Charles Hull printed a three-dimensional object for the first time using stereolithography. (Zaharia et al., 2017) Since then, 3D printing has become increasingly integral to the production workflows of dental laboratories and dental surgeries in a chair-side setting, augmenting possible workflows using the digital technology available with CAD/CAM machinery.

Figure 13. An Example of A 3D Printer Used in Dentistry, the IDDA 3D Printer (IDDA, 2018)

In prosthetic design, for example, modernised 3D printing allows prototyping as well as the production of final parts and frameworks with flexural strengths of 80 MPa and higher. (Zaharia et al., 2017) In turn, the CAD/CAM applications used in dentistry have followed the advancement of 3D printed parts. Oberoi et al. (Oberoi et al., 2018) state that the motivation behind advancement in 3D printing for medicine and dentistry stems from the production of small-scale creations that facilitate the sharing of patient information and the creation of planning tools to better patient care. This pattern is reflected by the expanding number of discussions on the subject of 3D printing.

1.9.2 Relationship with Utilisation of Intraoral Scanners

The increased utilisation of intraoral scanners has led dentists to incorporate 3D printing to make a physical model of the scanned dentition. Although every case may not require printing a 3D model, it may be incorporated in many parts of the planning and manufacturing processes involved with dental treatments. For example, a 3D model may be used to portray the eventual outcome of treatment from a digital mock-up using tooth libraries. Dawood et al. (Dawood et al., 2015) stated that some examples of the uses of 3D printing include '*the production of drill guides for dental implants, the production of physical models for prosthodontics, orthodontics, and surgery, the manufacture of dental, cranio-maxillofacial, and orthopaedic implants, and the fabrication of copings and frameworks for implant and dental restorations*'.

The use of orthodontic clear aligners to align a patient's teeth is now vastly easier because of the development of 3D printed models for their production. Since orthodontic alignment occurs over a period of months or years, many aligners are required. The fast prototyping of models lends itself to this process as several models in the orthodontic sequence can be printed easily and quickly.

Many users have also utilised 3D printing innovations to make novel dental creations with a permeable or detailed surface. For example, 3D printing can deliver complex geometries, such as a bone-like morphology, which may not be created by processing alone to aid in treatments such as implant planning and guided implant surgery.

In a study by Brown et al. (Brown et al., 2018) rapid prototyping was used to transition a traditional clinical workflow to a fully digital one. The accuracy of the conversion from digital impressions to 3D printed models was compared to alginate to poured stone casts. The study found that 3D printing produced clinically acceptable models, and the fully digital workflow should be considered an entirely viable option for dental clinics.

Dental laboratory facilities can now create restorations, models, and various orthodontic appliances using techniques that collect patient data in the form of a 3D intraoral scan and then use 3D printing and CAD/CAM to prototype or manufacture the eventual prosthesis. Kim et al. (Kim et al., 2018b) discussed that 3D printing has been used for the production of models for quite some time, and it was now becoming more ubiquitous in the production of restorative implant guides and prostheses. Computerised innovation and 3D printing have fundamentally changed the involvement of the dental lab regarding restorative and implant dentistry, resulting in a greater refinement in the production capability and the overall accuracy.

1.9.3 Use in Education

Along with increased involvement in both the chairside and laboratory setting, Oberoi et al. (Oberoi et al., 2018) assessed the increased number of research projects and studies involving 3D dentistry. Through this increased number of studies, 3D printing is now considered more favourably, and therefore, consumer confidence it the process has also grown. Moreover, 3D printing and the research setting have also lead to the inclusion of this technology in the education setting, both in postgraduate programs, such as the International Digital Dental Academy, and in a growing number of

undergraduate universities to help prepare and advance the abilities of trainees and students. Through a combined approach of research, training in dentistry and clinical treatment, it is conceivable that 3D printing and fast prototyping can provide a plethora of alternate scenarios for education in which characteristics such as porosity, design, and surface texture may be adjusted quickly and easily. (Prasad et al., 2018)

1.9.4 Use in Orthodontics

As digital dentistry has evolved, procedures that were once complex and tedious have been transformed into streamlined and effective processes, easily manageable both in laboratory settings and during chairside procedures. Furthermore, 3D printing has allowed orthodontic procedures to more quickly adapt to changes in treatment requirements over the conventional workflow process as new intraoral scans can be incorporated to amend/refocus alignment at any stage. (Choi and Kim, 2015) By incorporating the digital dentistry element, the orthodontist can drastically accelerate treatment time and reduce chair time for the patient, whilst also minimising storage space and material waste. The future of 3D printing and orthodontics ultimately lends itself naturally to the direct 3D printing of orthodontic clear aligners. This development will be more efficient and less wasteful, but it will rely on the development of elastomeric resins that retain their shape after deforming. Mahamood, Khader, and Ali (Mahamood, 2016) conclude that with a 3-D printer doing the diligent work, dental labs can remove the manual workflow through the use of 3D printing to further develop their business. Conventionally, the majority of orthodontics have heavily relied on using alginate as an impression material. These replicas

are used for plaster models to fabricate structural orthodontic oral structures including mouth guards, retainers, expanders, and space maintenance devices. However, the advancement in the digital manufacturing technologies have allowed the use of 3D printing to fabricate dental and orthodontic appliances from 3D model designs. (Jain, 2016)

Figure 14. An Example of Direct-3D printed Aligners printed from STLs using an Asiga Max UV DLP 3D Printer and an experimental resin

1.9.5 Use in CAD/CAM Dentistry

When manufacturing parts or objects required during treatment, one can use either subtractive or additive manufacturing techniques. Subtractive manufacturing is generally more common. The process requires a block of material from which the virtual shape of the objective part or object is carved, ground, or milled by evacuating material to obtain the final 3D object. This technique can be used in the chairside setting to create veneers, inlays, crowns, and bridges by using computer-aided design (CAD) or computer-

aided manufacturing (CAM) software. The virtual 3D CAD design of the restoration is then converted to instructions to direct and drive the CNC milling machine to shape the part in an inherently destructive and wasteful process. While machining smaller parts is common for dental laboratories and some chairside clinics, it is impractical for these settings to machine larger full arch models through a subtractive process. Thus, subtractive engineering and manufacturing have limitations, and these larger models have historically been produced through the analogue/manual production of mould stone casting.

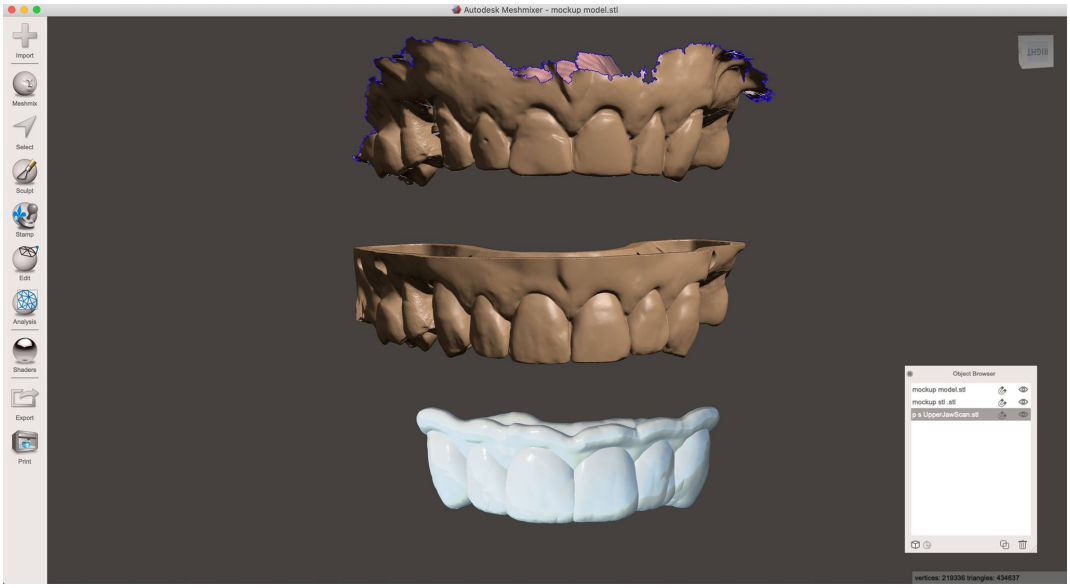

Figure 15. An Example of a CAD restorative Mockup and a direct 3D printed stent based on the mockup printed in a flexible clear resin.

Three dimensional printing is also known as additive manufacturing (AM), fast prototyping, layered assembling, or strong freestyle creation. Jain, Supriya, and Gupta (Jain, 2016) described the manufacturing procedure where layers of material are laid continuously under programmed control to make a three-dimensional item. The protocol of this manufacturing strategy is that the virtual 3D structure is ‘sliced’ into layers of a set thickness. The 3D

printer then produces each layer one at a time to form the overall geometric structure. (Bhargav et al., 2017)

The advantages of additive manufacturing over subtractive include more efficient use of the material with little waste, the capacity to dispose of specific manual procedures, adaptability of the machine to re-produce complex object geometry, intricacy, and an assortment of available materials. As promising as additive manufacturing is, and despite the incredible speed of progression, there are a few limitations at present. However, even though 3D printing hardware and materials have historically been expensive, they are now being produced at highly competitive prices. This cost limitation will most likely be overcome quickly. Other current limitations include the appearance of the final object because of the layering of the material and the long-term strength of biocompatible materials, which requires further development and study. In any case, additive manufacturing has been an significant development in contrast to subtractive manufacturing, as the former provides access to newer 3D printing hardware that is ever-evolving and growing in features, accuracy, and speed.

Overall, three-dimensional design and viewing as well as CAD/CAM have had a significant effect on the advancement in all areas of dentistry, with 3D printing playing a central role in current developments. With the assistance of intra-oral 3D scanners, it is conceivable to use 3D printing to make precise, accurate, and complex geometrical structures with a wide assortment of materials.

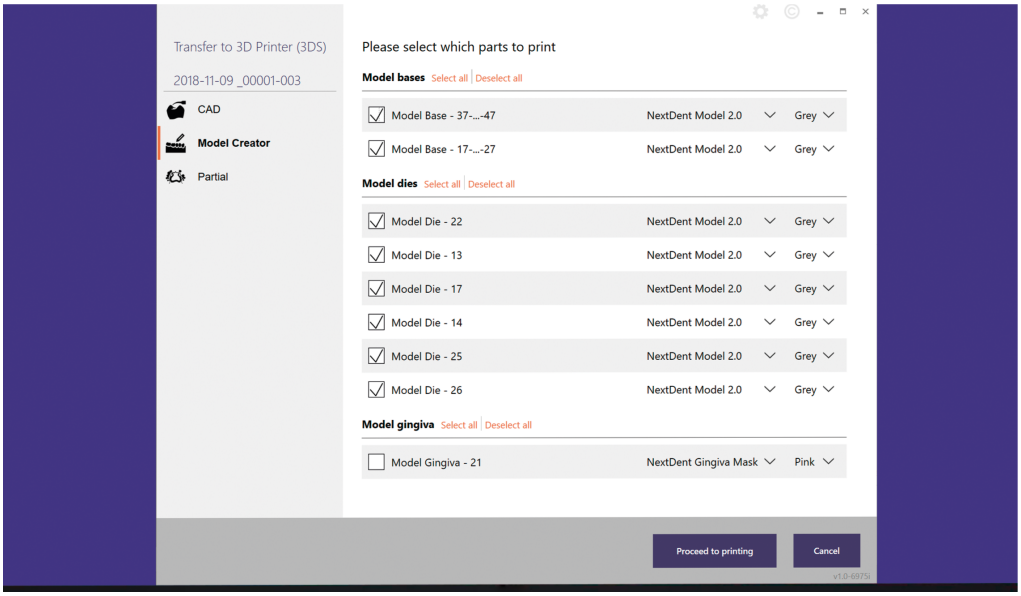

Figure 16. ExoCAD and other CAD software directly integrating the 3D Printing slicer software. (Exocad, 2020)

Today, AM has been considered a breakthrough technology that represents the fourth industrial revolution by transforming the production processes of manufacturing objects. The conventional manufacturing methods involved several steps of converting raw materials to a fully finished, assembled, and usable end-product. (Ligon et al., 2017) In addition to being time-consuming, conventional manufacturing technologies are associated with high production costs and high energy consumptions, and they lack flexibility of end-product design.

1.9.6 Improved Production Efficiency

The 3D printing technologies evidence a paradigm shift that eliminates the complex processes in conventional manufacturing by reducing energy consumption and the cost of production. (Katreva et al., 2016, Lansard, 2018) Additive manufacturing is characterised by the increased capacity and ability to manufacture a wide range of functional products on market demand due to increased design flexibility. In addition, the manufacturing

processes are cost-effective, result in reduced waste, and blend unique materials to improve the performance of the end-product and to extend its durability. (Katreva et al., 2016)

The technologies used in additive manufacturing are found in several industrial applications such as in healthcare, aerospace, automotive, and consumer electronic devices. (Bhargav et al., 2017) In the healthcare sector, the potential of 3D printing technology to fabricate customized patient-specific implants with needed precision and accuracy has increasingly been employed in different healthcare specialties, including orthopaedic, cardiology, and dentistry. Some examples of 3D printing technologies in healthcare include implantable bones, rib cages, and heart valves. (Lansard, 2018, Oberoi et al., 2018)

Furthermore, a number of diverse materials such as metals, ceramics, and polymers have been processed to fabricate numerous implants using 3D printing. (Nayar et al., 2015b) In the context of dentistry, the applications of 3D printing technologies involve maxillofacial implants, dentures, and other prosthetic aids. It has been shown that 3D printing technologies can easily create anatomical models for surgical training, diagnostic planning, and orthodontic setups in various areas of dentistry. (Groth, 2018)

1.9.7 Types of Technology

Today, several different 3D printers are available in the market for application in dentistry. The primary 3D printing technologies adopted include stereolithography, photopolymer jetting, and digital light processing that uses light to cure resin. (Oberoi et al., 2018)

1.9.7.1 Stereolithography (SLA)

Stereolithography (SLA) is the most popular and oldest 3D printing technology, which comprises a vat of photosensitive resin as a platform for the model-building and an ultraviolet laser to cure the resin. The SLA uses a high-powered laser to convert the photosensitive liquid resin contained in the reservoir into the desired 3D solid-shaped plastics in a layer-by-layer fashion using a low-power laser through the process known as photopolymerisation. (Al-Imam et al., 2018)

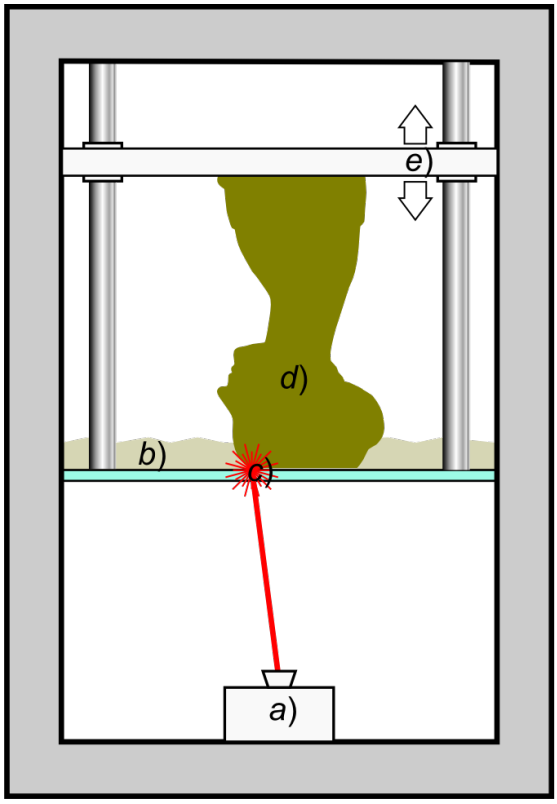

Figure 17. Schematic Representation of Stereolithography: (Scopigno et al., 2015)

In Figure 17 we can see the components of a 3D SLA printer. A light-emitting device a) (a laser or DLP) selectively illuminates the transparent bottom c) of a tank b) filled with a liquid photo-polymerising resin. The

solidified resin d) is progressively dragged up by a lifting platform e) (Scopigno et al., 2015)

In SLA, two motors known as galvanometers control the x and y axes respectively and work together to angle a pair of mirrors to aim a laser beam across the print area in the resin vat to solidify the resin. The layers of the 3D object are then built following a particular direction to cure a photosensitive vat containing the resin based on the CAD design. (Prasad et al., 2018) After each layer is cured, the build platform is raised to allow resin to flow into the area cured and then lowered by moving back along the z-direction to allow the second layer to be cured. The process is repeated consistently until a 3D product is wholly fabricated. (Oberoi et al., 2018) The underlying technology used in SLA has primarily remained the same for several years. Nevertheless, recent technological advancements have led to the next generation of 3D printers, which are smaller, relatively inexpensive, and more efficient compared to the traditional SLA technique. (Al-Imam et al., 2018) The SLA 3D printing technologies also offer several advantages, including the reduction of resin volume and the elimination of an oxygen inhibition layer on the surface, which consequently minimises the total amount of porosity trapped in the final product. The SLA technique has also been shown to offer high manufacturing accuracy along the x-y axis. (Alharbi et al., 2016b, Alharbi et al., 2016a) Using the z-direction, the accuracy of SLA technique in 3D printing technology is more important as it depends on multiple factors. (Lebon et al., 2015, Tapie, 2015) These factors include CAD design, layer thickness, material properties,(Alharbi et al., 2016b) data processing, post-processing/slicing procedures, and building orientation of

the virtual model, particularly in curved or angled surfaces.(Alharbi et al., 2018)

The entire fabrication process of the SLA technique involves three different phases. The preparatory phase involves selecting the build orientation, slicing the STL file, and generating the support structure. The actual build is enhanced in the second phase, whereas the third phase encompasses the removal of the support structure and then post-curing the fabricated structure. (Tapie, 2015) In these phases, the build parameters are commonly interrelated and have been reported to influence mechanical properties and dimensional accuracy of the complete fabricated structure significantly. (Tapie, 2015) (Lebon et al., 2015) Additionally, the total build and finishing are also dependent on the build parameters set. (Puebla et al., 2012) A study by Alharbi, Osman, and Wismeijer (Alharbi et al., 2016b) examined the effect of build angle and support configuration (thick versus thin support) on the dimensional accuracy of 3D printed full-coverage dental restorations. In this study, the mean deviation value and colour map results suggested that the build angle and support structure configuration have a significant effect on the dimensional accuracy of 3D printed crown restorations. It was concluded that "*the selection of build angle should offer the crown the highest dimensional accuracy and self-supported geometry. As a result, this allows for the smallest necessary support surface area and reduces the time needed for finishing and polishing*."(Alharbi et al., 2016a)

1.9.7.1.1 Print Effect and Direction of Object

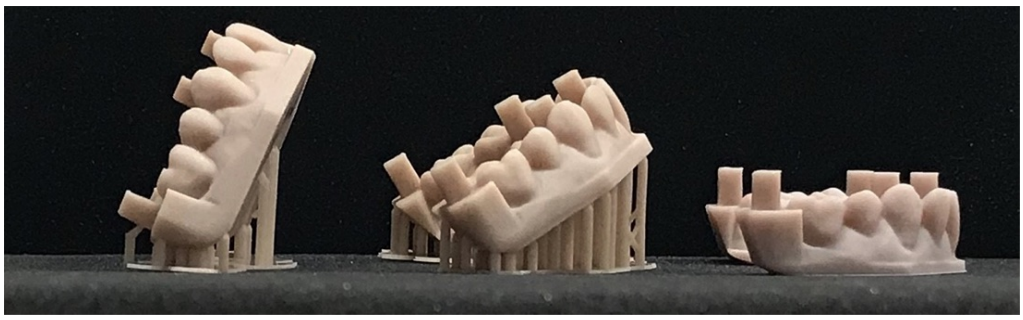

Figure 18. Print Effect and Direction of Object (Brenes et al., 2020)

In a study by Brenes et al. as shown in Figure 18, the authors considered the impact of print layout and direction but found that the effect was specific to each printer type and resin used.(Brenes et al., 2020)

In another study examining whether build direction affects the mechanical properties of 3D printed complete coverage interim dental restorations, it was reported that materials printed vertically (90°) had higher compressive strength than those printed horizontally (0°). (Alharbi et al., 2016a) A recent study by Alharbi, van de Veen, Wismeijer, and Osman (Tapie, 2015) found that the built angle or layer orientation influences the flexural strength of the hybrid resin material printed using the SLA technique. It was reported that the vertically printed specimens had a significantly lower mean flexural strength of 88.2 MPa compared to the 90.5 MPa of those printed horizontally.(Tapie, 2015)

1.9.7.2 DLP Technologies

In addition to SLA, other 3D technologies that use light to cure the resin include digital light processing (DLP) as well as photopolymer jetting, also known as PolyJet or the inkjet-based system. Both photopolymer jetting and DLP techniques embrace the use of AM technologies to fabricate a layer-by-layer 3D model based on digital models (Al-Imam et al., 2018). Furthermore, the 3D printing technologies used in PolyJet and DLP differ from those used in the SLA technique

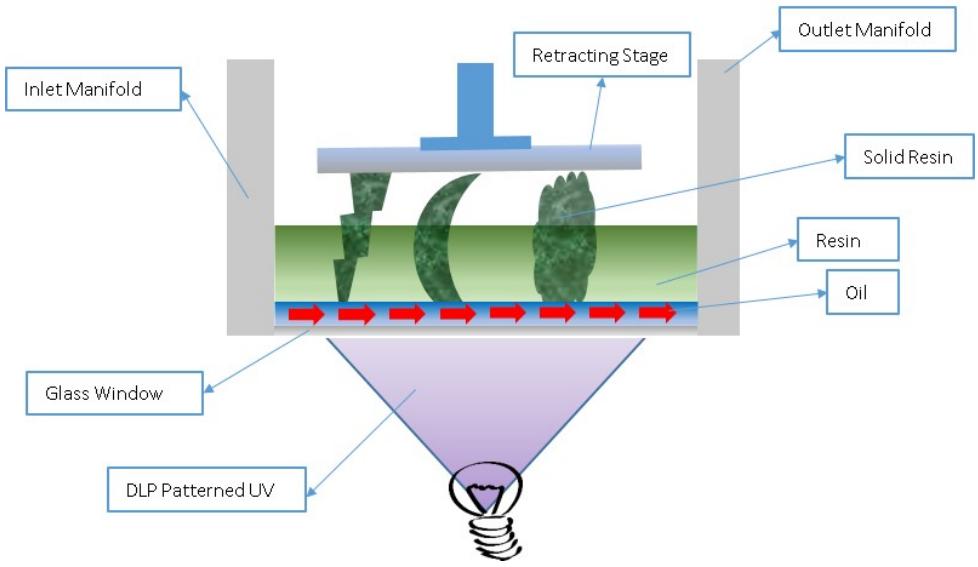

Figure 19. Schematic Representation of DLP 3D Printing Technology. (Scopigno et al., 2015)

In Figure 19 we can see that as the light is patterned through a projector or LCD to cure the resin layer before the retracting build platform peels and moves up before returning to cure the next layer.

Typically, DLP uses a conventional light source such as a liquid crystal display panel or light projection source to cure the surface layer of a vat with

photopolymerising resin in a specific direction based on the digital model. The utilization of light to cure resin is a notable commonality between SLA and DLP 3D printing techniques.(Prasad et al., 2018) However, the 3D printing technologies used in DLP involves the use of a projector screen or arc lamp as the source of light rather than a laser as in the case of SLA. (Rovelo, May 25, 2016) The DLP technique utilizes a digital projector screen to flash a single image of each layer in square pixels across the entire platform, with the resolution of the DLP 3D printer being determined by the pixel size. This method contrasts with the SLA technique, which generates images using a laser to create spots of light, typically resulting in lower resolution compared to DLP, as in general, the laser spot size in SLA is larger than the light pixel size in DLP, affecting the precision and detail level of the printed objects. Given these differences, the DLP technique is considered an alternative advancement in the SLA 3D printing process. (Oberoi et al., 2018, Rovelo, May 25, 2016)

1.9.7.3 Laser Sintering and PolyJet

In the context of the PolyJet 3D printing technique, a moving piston dispenses a known amount of raw powdered-form material, through which a roller is consequently used to distribute and compress the powder at the top of the fabrication chamber. The multi-channel jetting head then drains a liquid adhesive material in a 2D pattern on the powder, allowing it to bond and create a layer of the object.(Farjood et al., 2017) Once a layer has been formed completely, the piston helps spread and join the powder to the next layer. As a result, the continuous layer-by-layer method progressively achieves a complete build-up of a prototype. The unbound powder is subsequently swept up through a heating process, leaving the object’s

fabricated part strong and complete. (Azari and Nikzad, 2009) The main similarity between the SLA and PolyJet 3D printing technologies is that they both use ultraviolet light to cure the photosensitive polymer resin by building it into successive layers. In both techniques, the initial layer of resin is cured onto a build platform where each subsequent layer is directly cured to the previous layer of the cured resin in the z-axis to create a 3D object. (Oberoi et al., 2018) Nevertheless, the photopolymer jetting differs from the SLA technique as it does not use a light-sensitive laser to cure a vat of photopolymer resin by building it to a successive layer. Instead, photopolymer jetting utilises ink type print-head jets to spray the polymerised resin into the desired print areas where ultraviolet light source cures each sprayed layer as it passes through. (Prasad et al., 2018)

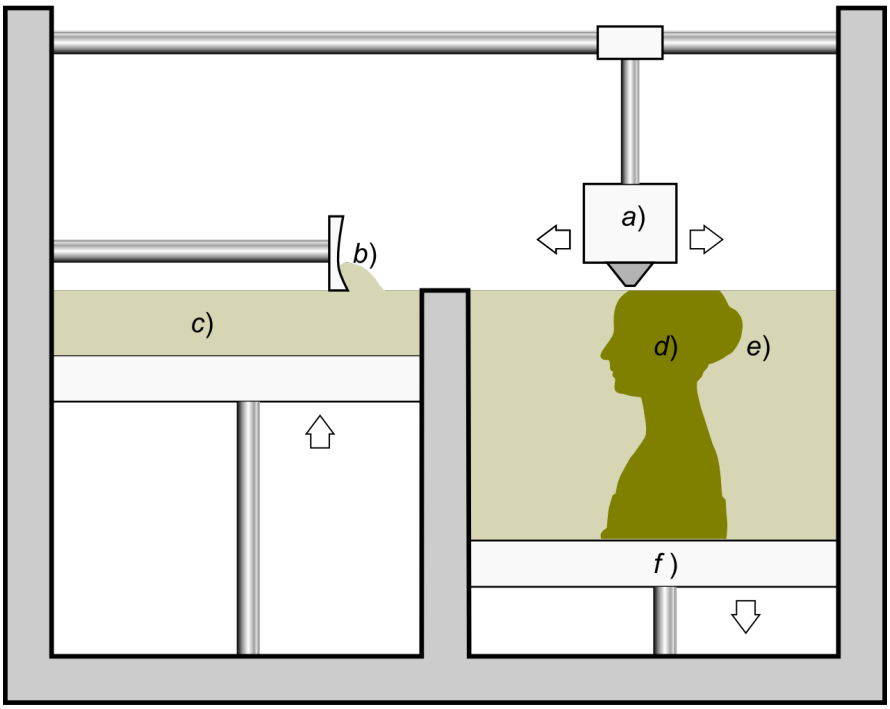

Figure 20. Schematic Representation of the 3D Printing Technique Granular Binding. (Scopigno et al., 2015)

With 3D granular binding, or SLS manufacture, (Figure 20) a moving head a) selectively binds the surface of a powder bed by dropping glue or by laser sintering; e) a moving platform f) progressively lowers the bed and the solidified object d) rests inside the unbound powder. New powder is continuously added to the bed from a powder reservoir c) by means of a levelling mechanism b). (Scopigno et al., 2015)

Moreover, 3D printing technologies have led to the adoption of several techniques, such as selective laser sintering (SLS) and fused deposition modelling (FDM). In the SLS and electronic beam melting technologies, the powder is sintered in a heated chamber to a level below its melting point, where the scanning laser is subsequently used to build the 3D object. (Prasad et al., 2018) The SLS technique uses a computer-controlled laser to fuse layers of particular powder material into a 3D model. The powdered material is distributed over the surface of a build cylinder by a roller, in which the powdered material is spread layer-by-layer on the top of the previous hardened layer and sintered repeatedly. (Azari and Nikzad, 2009) A laser beam is then directed to the surface of the firmly compressed layer of powder to bond all the parts of the 3D model layer-by-layer. (Han et al., 2019) SLS technique has numerous advantages in dentistry as different thermoplastic materials such as casting wax, nylon composite, ceramics, and metallic materials can be used in different areas of prosthodontics. Although SLS can be used to fabricate objects from metals and polymers, the technique is not only expensive due to its high capital expenditure and maintenance costs, but it also poses health risks associated with accidental explosion and dust inhalation.(Prasad et al., 2018)

1.9.7.4 FDM

For fused deposition modelling (FDM), a nozzle releases small beads of thermoplastic material to construct a 3D model. Most of the 3D printers that adopt the FDM technique are highly penetrated at the domestic level; hence, they are often referred to as ‘home printers’.(Dawood et al., 2015) The FDM is a fast-prototyping technique that ejects a thermostatic material layer-by-layer from a nozzle controlled by temperature. In the FDM technique, a filament of the thermoplastic material feeds into the temperature-controlled FDM expulsion dome, which is subsequently heated to a free-flowing semi-liquid form. The head of the nozzle then directs the material into place with adequate precision where it is solidified layer-by-layer within 0.1s. After the ejected material from the nozzle bonds to the layer below, the supporting structures of the object are then artificially derived by cutting them out from the 3D object model design.(Azari and Nikzad, 2009)

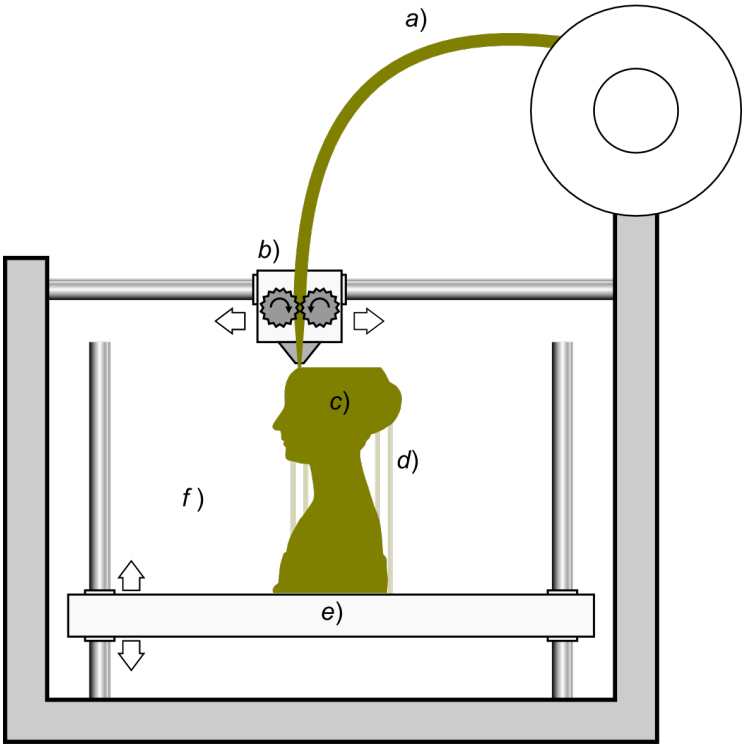

Figure 21. Schematic Representation of the 3D Printing Technique Fused Filament Fabrication. (Scopigno et al., 2015)

In Figure 21 we can see how FDM printing occurs. “A filament a) of plastic material is fed through a heated moving head b) that melts and extrudes it, depositing it layer after layer in the desired shape c). A moving platform e) lowers after each layer is deposited. For this kind of technology additional vertical support structures d) are needed to sustain overhanging parts.” (Scopigno et al., 2015)

1.9.8 Review on Accuracy

Judging the dimensional accuracy of the resulting printed part requires comparison and conformity between the 3D printed model and its virtual counterpart. The resolution and accuracy of 3D model samples are determined by a wide array of factors depending on the technology used and related factors such as the print head/laser spot size/screen resolution, build orientation, materials, geometric features, and their topology. Other factors that affect dimensional accuracy include the precision of the linear stage positioning, post-treatment procedures, particle size, and layer thickness.(Dimitrov et al., 2006, Puebla et al., 2012, Favero et al., 2017) Regarding each of the above manufacturing technologies, the dimensional accuracy of a component part can be evaluated through its size and shape by changing the printing parameters and/or fabrication processes. While the underlying technology used in 3D printing methods have largely remained the same in recent years, nevertheless, the recent technological advancements have led to the next generation of 3D printers, which are smaller, relatively inexpensive, and more efficient compared to the traditional SLA techniques.(Al-Imam et al., 2018) Some new printers such as the Asiga

Max UV also have in-built technology such as pressure sensors in the DLP display to increase speed by detection of separation.

1.9.9 Fabrication Process

The entire fabrication process of SLA technique involves three different phases. The preparatory phase involves the use of a CAD or slicing software to set the build orientation which generates the support structure and ‘slice’ or ‘layer’ of the model and supports. The actual build is constructed in the second phase, and the third phase involves post-curing the fabricated structure, removing of the support structures, and then finishing and polishing the finished product.(Tapie, 2015) In these phases, the build parameters are commonly interrelated and have been reported to have a significant influence on the surface quality, mechanical properties, and dimensional accuracy of the complete fabricated object.(Tapie, 2015) Additionally, the build time and the time required for finishing of the printed object are also dependent on the selected build parameters.(Puebla et al., 2012) For example, if the build has thinner layer heights, then the total print time will increase as the object will be divided into more layers.

A study by Alharbi, Osman, and Wismeijer examined the effect of build angle and support configuration (thick versus thin support) on the dimensional accuracy of 3D printed full-coverage dental restorations.(Alharbi et al., 2016b) In this study, the results suggest that the build angle and support structure configuration have a significant influence on the dimensional accuracy of 3D printed restorations. The study concludes that a build angle of 45°–90° should offer the model print the highest dimensional accuracy

and self-supported geometry. As a result, this allows for the smallest necessary support surface area and reduces the time needed for finishing and polishing. However, a trade-off is created as the increased angulation may increase the total model height, and therefore, it will increase print time. In another study that examined whether build direction had an effect on the mechanical properties, it was reported that materials printed vertically have higher compressive strength than those printed horizontally.(Alharbi et al., 2016a) A more recent study found that the build angle or layer orientation influenced the flexural strength of the hybrid resin material printed using the SLA technique. The study discussed that vertically printed specimens had a statistically significantly lower mean flexure strength of 88.2 MPa compared to 90.5 MPa of those printed horizontally.(Alharbi et al., 2018)

1.9.10 Degree of Accuracy Compared in Different 3D Printing Techniques

Dental prostheses manufactured using 3D printing technologies have been shown to have an acceptable degree of accuracy and precision compared to prostheses made using conventional plaster cast models.(Han et al., 2019) In a study by Dietrich, Ender, Baumgartner, and Mehl, the accuracy (trueness and precision) of two different rapid prototyping techniques were compared to the physical reproduction of 3D digital orthodontist resin casts using SLA and PolyJet systems.(Dietrich et al., 2017) The results of this study indicated higher trueness in PolyJet replicas than in the SLA models, but the precision measurements favoured the SLA techniques. However, the study observed that both replicas have a maximum deviation of 127μm in the dimensional errors, which was far below the recommended range of

300–500 μm for clinically relevant accuracy in orthodontic tests as discussed by Sweeney, Smith, and Messersmith (2015).(Sweeney et al., 2015) Furthermore, the results showed that polyvinyl siloxane materials provide more accurate interocclusal recordings for a successful articulation of digital models compared to other materials such as Regisil Rigid, Futar Scan, Byte Right, and Aluwax.(Dietrich et al., 2017) It is worth pointing out that much of the literature shows 3D printing is clinically acceptable – but its in the context of orthodontics.

Many readers have taken those conclusions and assumed that it translates to prosthodontics; however, the reader needs to be careful which dental discipline the authors conclusions are being drawn for.

Kim et al. explored the precision and trueness of 3D printed dental models by assessing the differences in dimensions between the 3D printed models, made by fused filament fabrication (FFF), SLA, DLP, and PolyJet techniques, versus digital reference models.(Kim et al., 2018b) The ‘trueness’ was defined as the proximity of a model to a true value, in which the least accurate 3D printing model produced replica casts within 260 μm of the reference models, which was still below the clinically relevant guidelines that Kim et al. were prepared to accept. The study showed that statistically significant differences existed between the various 3D printing technologies. The results found that both the PolyJet and DLP techniques had a higher precision compared to the FFF and SLA techniques, with the highest precision associated with the PolyJet technique.(Kim et al., 2018b)

Several other studies have also studied how both DLP and PolyJet are 3D printing technologies that provide exceptional accuracy and surface finish in dentistry. (Katreva et al., 2016, Revilla-León and Özcan, 2017, Oberoi et al.,

2018) Given that DLP and PolyJet printers are two 3D printing techniques commonly used in dentistry, Brown et al. conducted a study to assess the accuracy of using a digital model created from digital intraoral impression scanners. Various points were used to compare dimensional change including mesiodistal (crown width) and incisal/occlusal-gingival (crown height) and intercanine and intermolar widths.(Brown et al., 2018) The significance of this comparison aimed to evaluate the accuracy of the entire digital workflow. As stated in the previous studies, the findings indicated that both the DLP and PolyJet printers had clinically acceptable accuracy in the 3D printing models produced, and therefore, they can be considered as alternatives to plaster-cast storage in orthodontic practice.

A recent study evaluated the accuracy of 3D printed retainers compared with the conventional vacuum-formed retainers and commercially available vacuum-formed retainers (Cole et al., 2019) The results from this study showed that traditional vacuum-formed retainers have the least deviation from the original reference models (0.10–0.20 mm), followed by commercially formed retainers (0.10–0.30 mm), whereas the greatest deviation (0.10–0.40 mm) was found in 3D printed retainers. However, all three workflows produced retainers that are within 0.5mm accuracy and are therefore deemed clinically acceptable for the assessment of digital articulation, albeit again for the purposes of orthodontic articulation, not restorative or implant dentistry where a much higher degree of accuracy is required.(Dietrich et al., 2017)

It is worth emphasising that much of the 3D printing literature is related to orthodontics. Many of the papers discuss an acceptable level of accuracy,

but orthodontic applications only require approximately 0.5mm accuracy to ensure PAR scores do not change.

1.9.11 3D Printed Models

Recently, the advancement of 3D printing in dentistry has been associated with an increased accuracy of printed dental casts. Orthodontics continues to have a clear direct-printed model of a retainer that is clear, reproducible, and aesthetic. (Oberoi et al., 2018) Although orthodontics have relied on the use of alginate impressions of dental materials in dentistry, the digital scans of the patients' dentition can be used to directly fabricate oral appliances, such as a retainer, even without the use of a physical dental model. In 2014, a selective laser sintering (SLS) 3D printer was successfully used to fabricate a retainer directly from a digital model of cone-beam computed tomography (CBCT) without a physical model, as reported by Nasef, El-Beialy, and Mostafa. (Nasef et al., 2017) Although the accuracy of fabricated retainer appliances has not been assessed, the 3D printing technologies using CBCT provide simplicity, accuracy, speed, and patient satisfaction. The study results indicate that 3D virtual retainers with user-friendly software seem to be a promising technique that will eventually change the practices in present-day dentistry and pave the way for designing and manufacturing custom orthodontic appliances, leading to the new digital orthodontic era. (Nasef et al., 2017)

A recent study compared the accuracy between orthodontic 3D printed and thermoformed retainers, in which 3D printed retainers were reported as more accurate and reliable than the conventional vacuum formed retainer. (Nasef et al., 2017) In this study, CBCT was used to create the digital file to

fabricate the two retainers. Furthermore, the two retainers were compared based on the linear measurements conducted manually using digital callipers. However, previous studies have shown that calliper measurements generated from iTero dental 3D model scanners are slightly more accurate than those produced from intraoral digital images in CBCT scans, which do not account for gingival tissue. (Akyalcin et al., 2013)

Another study evaluated the accuracy of 3D retainers compared to both conventional vacuum-formed retainers and commercially available vacuum-formed retainers.(Cole et al., 2019) The results from this study show that traditional vacuum-formed retainers have the least deviation from the original reference models (0.10–0.20 mm), followed by commercially-formed retainers (0.10–0.30 mm), whereas the most significant deviation (0.10–0.40 mm) was found in 3D printed retainers. (Cole et al., 2019) According to this study, all three retainers provide measurements within 0.50 mm, which has been previously considered clinically acceptable for the assessment of digital articulation in orthodontic applications. (Dietrich et al., 2017)

A dental impression is a routine procedure for diagnostic and treatment planning, including the fabrication of dental prosthesis. In practice, the dental impression should be “practical, accurate, predictable, and easy to implement.” (Abduo, 2019) Traditional methods of taking dental impressions, using materials like alginate (ALG) or polyvinyl siloxane (PVS), often come with several challenges. These include discomfort for the patient, ongoing expenses, the necessity for trays that fit well, and the immediate need to cast the impressions in dental stone (Ceyhan et al., 2003). Furthermore, the quality of these conventional impressions is highly dependent on how well

the materials are handled. This involves potential distortion of the impression and the stone material, impacting the accuracy of the cast images that represent various intraoral conditions.(Abduo, 2019)

The recent advancement of digital technologies and an easier digital work flow has led to increased adoption of the use of these technologies in clinic. Increasing the ease of taking impressions, printing models, or producing dental prostheses can significantly benefit dental clinics through efficiency and productivity. A major step of the digital workflow has been digital impressions with an intraoral scanner (IOS), which captures images of arch details using an intraoral camera. (Kuhr et al., 2016) One of the most common applications of digital workflow in clinical practice is the CAD/CAM system, which has become popular in allowing the production of provisional dental restorations within a single given clinical appointment. (Atieh et al., 2017) Nevertheless, the limitations of the choice of materials, prosthesis durability and long term life expectancy, and reduced possibilities of veneering and customisation of the dental restorations are some of the drawbacks associated with digital workflow systems. (Ender et al., 2016)

A modified version of the in house digital workflow has also been used to address the aforementioned limitations, in which a virtual 3D model of the arch is generated using the intra-oral scanner before this digital impression is then either used with CAD software in house before sending to a milling centre or to manufacturing technicians to produce the CAD design for the dental restorations. (Abduo, 2019) The advantage of this digital workflow is supporting technicians, milling centres, and commercial dental laboratories in implementing the use of more durable materials, hence, ensuring that accurate proximal and occlusal contacts are achieved through longer span

prostheses. The IOS-generated image is then converted to an STL file format that is then used to produce a physical cast by 3D printing that relates to the adjacent and opposing teeth, which dental technicians can use to create customised dental restorations. (Al-Imam et al., 2018)

A quantitative clinical case study conducted by Piedra Cascón et al. (Piedra Cascón et al., 2018) describes an analogue and digital workflow from the CAD design of a digital template for the analogue fabrication of long-term interim injected composite resin restorations. The study employed a specific dental CAD software and an SLA printer to fabricate the diagnostic template, which was then used as a reference to prepare injected composite resin interim restorations. The main benefit of this approach represents the materialisation of the digital diagnostic waxing, where conventional waxing procedures are eliminated. The patient in this scenario can also see the result via placement before preparation. Since the entire process is automated, it does not require most laboratory and clinical procedures such as exothermic heat phase of the material, residual monomers, and trimming or polishing the finishing lines in direct methods. This technique also eliminates the use of conventional master casts in indirect methods since the 3D models of the teeth can be prepared with more accuracy by injecting a light-body polyvinyl-siloxane impression material into the template to duplicate and place the restoration. (Piedra Cascón et al., 2018)

In clinical dental practices, this approach has been shown to improve laboratory workflow with minimal intervention of the lab technicians. The 3D printed diagnostic template provides a visual tool for both clinicians and patients to visualise the virtual diagnostic wax-up in the patient’s mouth and

assess proportions of the face. In addition, the diagnostic template can be used for provisional restorations, surgical guides and reference models. A discussion paper by Revilla-Leon suggests that the fabrication technique provides a predictable workflow. Long-term injected resin composite restorations could be obtained from a 3D printed aesthetic diagnostic template, which improves the laboratory and chair-side procedures.[43]

The findings of this thesis have been supported by a recent study by Abduo [42] comparing the accuracy of casts produced from conventional and digital workflows. The traditional method of dental impression casts involve materials like whole arch alginate (ALG) and polyvinyl siloxane (PVS), whereas the digital workflows include casted images in the intraoral scanner (IOS) and laboratory scanner (LS). In this study, the results indicate that conventional impressions (ALG and PVS) are more accurate than digital models (IOS and LS) due to errors related to the span of scanning. The whole arch cast accuracies were highest for PVS, followed by lab scanner, alginate impressions and finally intra-oral scanner. The digital impression casts from intra-oral scans and lab scans were considerably more affected at the posterior region of the teeth, particularly due to distorted material such as fossae and worn-out regions. However, the digital workflows had a higher single tooth accuracy compared to the conventional impressions. (Abduo, 2019)

1.9.12 Conclusion

The recent advancement in digital dentistry has modernised both dental practices and dental laboratories through computer-aided design (CAD) technology. The use of 3D printing has led to 3D digital models being

produced in clinics more regularly with intraoral scanners. The digital files produced from the intra-oral and lab scanners can be easily manipulated to allow diagnosis and treatment planning for more predictable and efficient treatment of patients. Digital files also eliminate the need for storage space and facilitates the retrieval and transfer of 3D models for use within all dental modalities. Overall 3D printing is a prime example of the fourth industrial revolution as it has a tremendously beneficial impact on patient care within dentistry.

1.10.1 3D Printing Materials in Dentistry

The current generation of 3D printers is lighter, cheaper, and smaller, making them more accessible to the chairside digital dentist than ever before. In general 3D printers used in both the industrial and chairside settings work with various types of materials, including ceramics, polymers, and metals. Evidence presented in many studies shows that an ideal material used for dental restorations is characterised by several properties related to durability, cost-effectiveness, and high performance.(Rayyan et al., 2015) The materials selected for provisional dental restorations should meet several criteria. They should be non-toxic and biocompatible to ensure patient safety. Additionally, they should be inert and reasonably inexpensive. Aesthetic stability is also crucial, meaning there should be no change in color or appearance after fabrication and complete resin polymerization through curing.(Balkenhol et al., 2009) Furthermore, any material for dental restoration should be easy to manipulate, dimensionally stable under all conditions through sufficient strength and resilience, and easy to polish and repair. The material also needs to be chemically stable in the oral cavity by

being insensitive to water sorption and dehydration, which prevents expansion, shrinkage, or cracking.(Vaidyanathan et al., 2016)

1.10.2 Current Materials

Currently, a wide range of materials are used in the dental sector of 3D printing. These are summarised in Table 1, which offers a more in-depth description of the most widely used materials specifically used in dentistry.

Printing Technology	Materials Available
Polyjet Printing	Photopolymers
Multi-Jet Printing	Plastics, Ceramics and Metals
Fused Deposition Modelling (FDM)	ABS, Polypropylene, Polycarbonates, Polyesters
Selective Laser Sintering (SLS)	Plastics, Ceramics and Metals
Selective Laser Melting (SLM)	Metals
SLA / DLP	Photopolymers, Plastics and Ceramics

Table 1. Materials Used with 3D Printing in Dentistry Grouped by Manufacturing Technology

1.10.3 Current Long Term 3D Printed Ceramics and Restorative Resins

In terms of long-term dental resins used in 3D printing, the field is relatively new and as such the range of materials available for use in 3D printed dental restorations is limited. Furthermore, the fabrication process of CAM milling manufacture requires high temperatures to convert ceramic materials into restorations suitable for placement in the mouth. Currently, the use of 3D printed ceramics is considerably limited in dentistry. They are manufactured by binding fine ceramic powder to a binder through the traditional process of

ceramic restoration in which lithium disilicate is ground from ceramic blocks in the chairside setting.(Elizabeth, 2014) Ceramic materials have several ideal properties for use in long-term dental restorations; they are lead-free, non-toxic, and watertight. However, ceramics are complex materials to design a 3D object as they require many considerations in design due to the different structural and dimensional changes the object may undergo during the finishing process. The current 3D printers developed for dental applications are limited in their use of metals and ceramic materials to produce provisional dental restorations and are accuracy may be affected by print orientation. (Brenes et al., 2020)

Most 3D printing materials used in dental restorations are polymers. Unlike ceramics and metals, the chemical and physical properties of polymers are characterised by elasticity and tensile strength, which potentially provide high-performance and durability features required for use as a dental restorative material.(Vaidyanathan et al., 2016) In restorative practice, 3D printing technologies using polymer materials have produced a wide array of prosthetics for dental restorations, such as denture bases, artificial teeth, temporary crowns, bridge and crown facings, and implants.(Oberoi et al., 2018, Stewart, 2018)

Studies have also reported the use of polymers in 3D printing technologies for dental applications, including implant fixture construction and intervention, maxillofacial reconstruction,(Fernandes et al., 2016) and metal bridges.(Gebhardt et al., 2010) Other studies have reported the application of 3D printing in manufacturing dental prosthetics used in dentistry such as

orthodontic appliances (Al Mortadi et al., 2015) as well as the fitting surfaces and the frameworks of removable partial dentures.(Carter et al., 2017)

Figure 22. A Variety Of Dental Resin Materials (Formlabs, 2019)

Most polymers used as dental restorative materials are prepared using the methods of addition polymerisation and SLA and DLP technologies in particular. Most dental resins are based on methacrylates due to their relatively easy processing, costs, and aesthetics. Denture base materials are often supplied in either gel or powder-liquid form.(Vaidyanathan et al., 2016) The powder consists of acrylic or copolymer heads, an initiator like benzoyl peroxide, pigments (cadmium sulphide, or dyes), and opacifiers, where one of the most effective is titanium dioxide. They also contain dyed synthetic fibres to simulate the blood vessels underlying the oral mucosa, plasticisers, and inorganic particles such as glass fibres and beads or zirconium silicate.(Abdulmohsen et al., 2016) Conversely, the liquid form is composed of a monomer, particularly methyl methacrylate; an accelerator; an inhibitor;

a plasticiser; and an across-linking agent. The gel form of denture base materials effectively contains all the components of particle-liquid form, but it lacks chemical accelerators. The dental materials in gel form are also commonly stored in refrigerators since the material's shelf life is significantly affected by the amount of inhibitor present and its storage temperature.(Hayden, 2015)

Figure 23. Surgical Guides are an example of the use of biocompatible resins used in dentistry (Formlabs, 2019)

The current dental restorative materials applied in dentistry encompass photosensitive resins alone or as particle-reinforced composite. Biocompatible polymers are widely used in dentistry for general restorative procedures, and the most common 3D printers available to use chairside accommodate similar polymer-based 3D printing resins. Moreover, 3D printed indirect dental restorations may involve either particle-reinforced composites, which are similar to the direct restorative composites, or fibre-reinforced composites.(Hayden, 2015) The particle-reinforced composites are typically produced in the dental laboratories to improve the materials' physical and mechanical properties, such as density, elasticity, and strength,

using the polymerisation process through heat and pressure. Alternatively, the fibre-reinforced fibreglass composites are produced using the same technology used to make fibreglass sports equipment where fibre mesh is embedded in polymers.(Peñate et al., 2015)

Figure 24. Temporary 3D Printed teeth for use in a 3D printed denture (Formlabs, 2019)

Dental resin-based composites are structures comprising a highly cross-linked matrix reinforced by a dispersion of glass / ceramics and resin filter particles and/or short fibres. (Balkenhol et al., 2009, Hayden, 2015) Many of these resin-based composites are now highly aesthetic with exceptional translucency; as such, they are becoming the most popular of the aesthetic or tooth-coloured filling materials for use in dental clinics.(Nayar et al., 2015a) The resin materials can also be made in various consistencies by altering the glass particle size and consistency as well as the filler content, which allows the material to be easily manipulated and moulded to a tooth shape that is long lasting and durable once polymerised and fully

cured.(Anusavice, 2013) Polymeric resins are increasingly being used in dentistry for dental restorations as well as replacing tooth structures and missing teeth. One advantage of these polymeric resins is their ability to bond with other resins, directly to the tooth structure or to other restorative materials such as amalgam. For example, a denture base with an attached denture could be used to restore chewing ability when all teeth are missing. Most of these restorative and prosthetic applications are based on photo-polymerisable methacrylate resins.(Balkenhol et al., 2009, Peñate et al., 2015)

Furthermore, several manufacturers are working on 3D printed resin versions of these same polymers for use in orthodontic clear aligners, denture bases, artificial teeth, and surgical guides. As one of the largest vendors of 3D printing materials, Stratasys has been reported to have developed various types of dental 3D printing materials such as wax deposition modelling (WDM) and PolyJet materials.(Hayden, 2015) The WDM material is used to manufacture highly accurate diagnostic wax-ups, paired with a removable wax-blend material called TrueSupport, which can be removed at relatively low temperatures. It has been reported that Stratasys' 3D printers using WDM produce the most accurate wax-ups in the dental industry. There is a high cost to polyjet printers compared to SLA. This limits their use to dental laboratories rather than chairside dental applications. As 3d printing is relatively new compared to milling, it is envisaged that prices may fall in the future.

An advantage to polyjet printing is that reliability is generally better with polyjet, and orientation is not an issue. Another advantage is no supports, so you don't have to decide which surface to 'compromise' in terms of accuracy.

A large disadvantage is cost. Additionally, other 3D printing benefits of WDM include the ability to directly produce from digital files, the lack of waste disposal issues, high-quality casting with minimal post-processing procedures, and registered for safety with the appropriate health and safety directives.(Stratasys, 2017)

iii) Metals

A material commonly used in dentistry is metal, which is popular for the use in strengthening restorations or incorporation into frameworks. This has led to these materials being researched and developed for additive manufacture, mainly through selective laser sintering (SLS). The use of SLS in partial removable frameworks is a prime example of a benefit of digital workflows. It produces much more consistent frameworks than traditional wax patterning/casting (which is operator dependent and can warp during metal cooling). And unlike milling it is cost-effective and can handle intricate shapes.

Due to their favourable levels of strength, cobalt-chromium and titanium metals have primarily been used in recent developments.(Khaing et al., 2001)

Figure 25. SLS 3D printed metal partial denture framework in CoCr (Formlabs, 2019)

1.10.4 PEEK & Nylon

3D printing materials of recent development for use in dentistry have been polyether materials such as polyether ether ketone (PEEK) and nylon. These materials have been used in frameworks, to strengthen other materials, and in 3D printed flexible dentures. Since these materials have a higher melting point, they require a fused deposition modelling (FDM) printer with a high temperature, high precision nozzle tip.(Dizon et al., 2018)

Similar to most 3D printing applications, 3D printed metals, PEEKs, and nylons offer many benefits. In particular, they have faster processing times, the additive manufacturing process is less wasteful than subtractive manufacturing, and they entail less manual labour and less labour-intensive processes. However, there are limitations to the fabrication of restorations

and frameworks using additive manufacturing. Rather than a homogenous structure, fabrication of these materials with 3D printing may result in porous structures which are inherently susceptible to staining, fracture, and cracking.(N. Turner et al., 2014, Dizon et al., 2018) Given these challenges, other materials are still being developed and researched.

1.10.5 Proposed Materials for Exploration

1.10.5.1 Reinforced Composites

The most popular and commonly used polymeric denture base material within dentistry is known as polymethylmethacrylate (PMMA). It is a significantly stable and transparent thermoplastic that does not discolour in the presence of UV light, and it exhibits remarkable ageing properties.(Anusavice, 2013) As a resin-based material, PMMA has been used in 3D printing technologies to fabricate dental provisional restorations to protect oral structures, such as pulpal tissue from thermal sensitivity, physio-mechanical pain, and bacterial contamination.(Balkenhol et al., 2009) For the purposes of implant treatment, larger framework restorations, and dentures, these PMMA 3D printed prostheses require high tensile and flexural strengths to be adequate for long term use. This underscores the importance of using materials with sufficient wear resistance and mechanical strength in clinical practice.(Abdulmohsen et al., 2016)

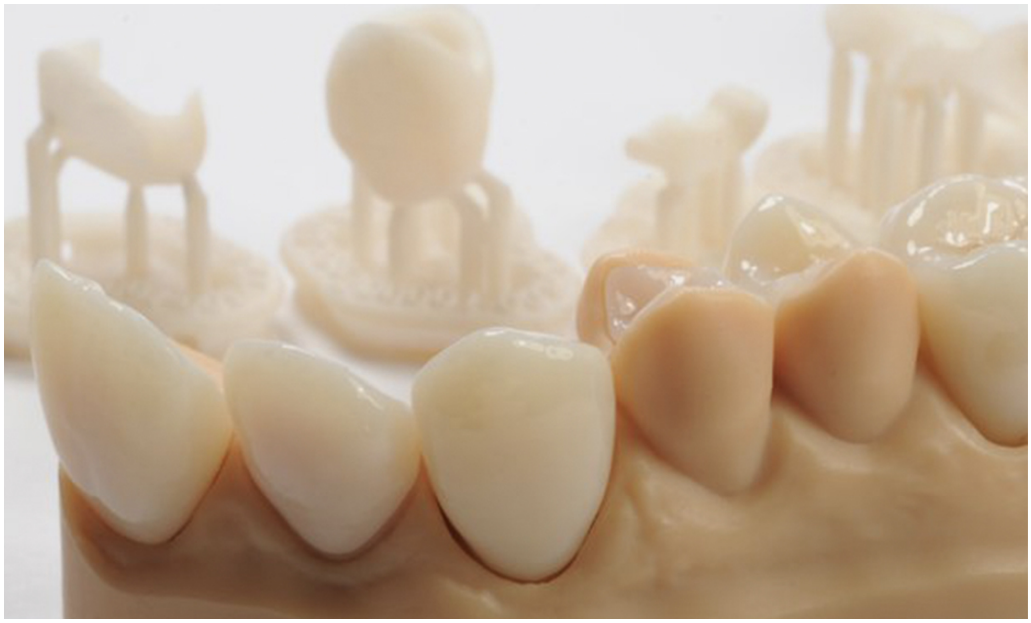

Figure 26. Permanent Composite Crown Resin (Bego, 2020)

Conventional self-polymerising PMMA-based resin materials have been shown to exhibit a number of limitations, including high polymerisation shrinkage, water sorption, and heat generation. Thus, there are concerns that these limitations may affect 3D printed PMMA restorations.(Patras et al., 2011)

Furthermore, chemically polymerised materials available for provisional dental restorations, using either PMMA or resin-based composites, have unique properties, which depend on the composition of the chemical monomer.(Oba et al., 2014) It has been demonstrated that different monomers vary in their chemical effects, such as polymerisation shrinkage, exothermic reactions, marginal fit, colour stability, periodontal responses, and fracture strength.(Bona et al., 2015) The fracture strength of the provisional restorative materials relates to the mechanical properties.(Kim and Watts, 2007)

Conventional fabrication using PMMA with a mixture of self-polymerising powder and liquid requires longer cure times than would be practical for a chairside setting.(Patras et al., 2011) Considering that one of the advantages of digital manufacturing is speed and efficiency, the use of 3D printed resin materials needs to be a viable alternative to conventional resin materials to support long-term dental applications in orthodontic practice.(Patras et al., 2011)

In particular, the recent advancements in routine dental practices with chairside CAD/CAM dentistry such as 3D printed prosthodontic treatments have been driven by the introduction of new processing technologies and dental materials. A number of dental laboratory processes can be used to fabricate either fixed or removable dental prostheses such as crowns using a variety of dental materials.(Chen et al., 2017) The advancement of both casting gold alloys and the associated accuracy in dental casting technologies has contributed to the persisting use of these prostheses.(Bajraktarova-Valjakova et al., 2018)

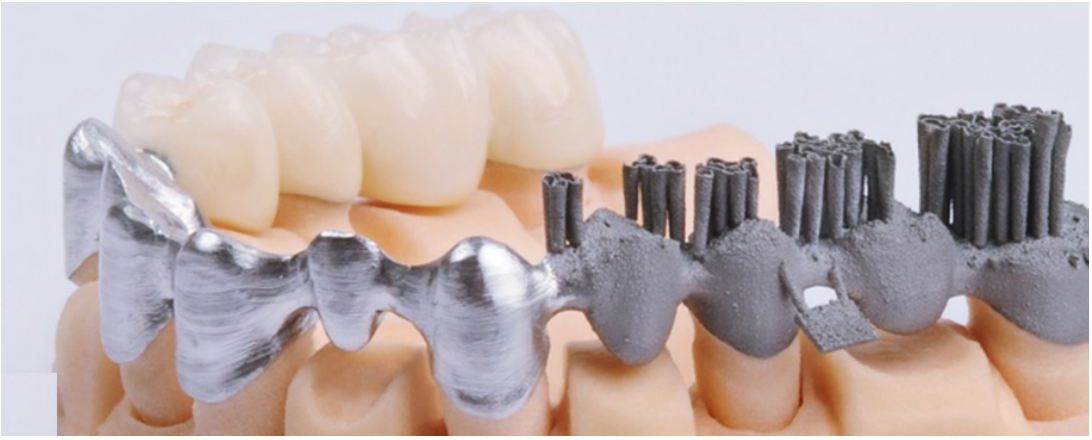

Figure 27. 3D Printed Metal Framework (Formlabs, 2019)

New dental ceramic materials such as glass ceramics as well as lithium silicates/disilicates and zirconia-based ceramics have been successfully used by CAD/CAM-enabled dental clinics, and several studies have shown exceptional long-term success rates.(Miyazaki et al., 2013)
A significant challenge for 3d printing is creating consistent results (and strong materials). Milling utilizes well controlled factory processes to create the blocks/discs under heat/vacuum etc making for very reliable and strong milling blocks. SLA in particular suffers from the unpredictability of viscous flow, impurities in the tank, and the inability to create dense materials under pressure. Therefore, any new 3D printing material must be equal to or show alternate benefits to these well-studied materials as well as ensure biosafety and aesthetics. (Guess et al., 2011)

1.10.5.2 Zirconia-based Materials

Among all dental ceramics, zirconia is the most popular biomaterial of choice in contemporary dental restorations in dentistry, particularly as a structural material for crowns, bridges, inserts, and implants.(Miyazaki et al., 2013)
Zirconia (zirconium dioxide) provides the optimum properties of a material for dental use, including tensile strength, fatigue resistance, and outstanding wear properties and biocompatibility.(Bona et al., 2015) Zirconium (Zr) has similar biochemical properties to titanium (Ti) metal, and both are commonly used in implant dentistry as they lack the capacity to hinder the bone forming cells (osteoblasts) to facilitate osseointegration.(Grandin et al., 2012)
Although zirconia is characterised as a useful dental biomaterial, zirconia-based materials present several challenges in dental practice applications as they are difficult to adhere to compared to other glass ceramics and composite materials.(Bona et al., 2015)

The adhesive bond between ceramics and resin-based materials comes through a combined micro-mechanical and chemical interaction across the contact interface. The overall bond strength is highly dependent on the surface treatment and the surface energy through silanation of the glass ceramic to increase its wettability.(Della Bona et al., 2014, Bona et al., 2015) It has been reported that for all types of acid-resistant bonding for ceramic dental restorations such as glass ionomer (GI) and hydrophobic phosphate monomers containing 10-methacryloyloxydecyl-dihydrogen-phosphate (MDP) monomer, resin-based composite systems are the most popular and effective for high bond strength among a wide range of materials.(Della Bona et al., 2007, Bona and Kelly, 2008)

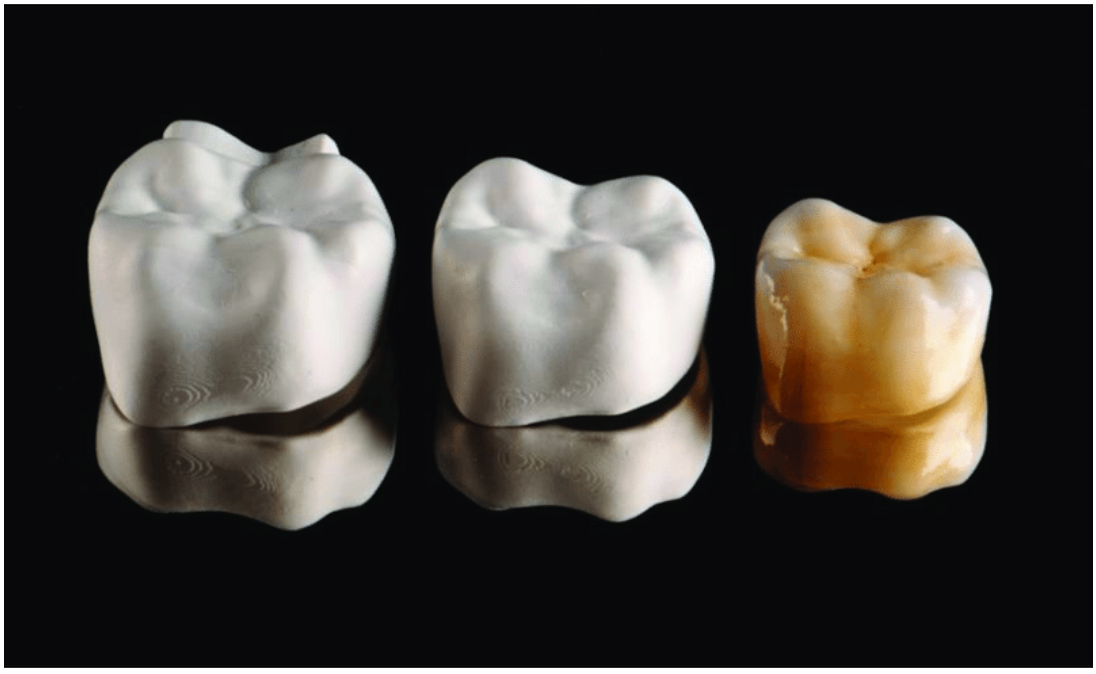

Figure 28. 3D Printed Zirconia Resin (Schweiger, 2021)

Several studies have shown that the quality and durability of the micro-mechanical and/or chemical bond between glass ceramic and resin-based

materials has a high impact on the long-term success rates of the placed prosthesis.(Bona et al., 2007, Bona and Kelly, 2008) The non-reactive or acid-resistant surface of zirconia often poses a major concern related to poor adhesion or the reduction of bond strength to other substrates.(Bona et al., 2007)

In terms of mechanical strength and physical properties, the superiority of zirconia has largely been utilised for aesthetic dental restoratives, including crowns and bridges.(Karaokutan et al., 2015) Zirconia is typically veneered with feldspathic porcelain due to its insufficient translucency; nevertheless, the strength of the veneering porcelain has been indicated as inadequate in its function as a dental restorative.(Miyazaki et al., 2013) The main clinical feature of failed zirconia-based restorations has been reported to be due to the wear and fracture of the laminated porcelain layer.(Alp et al., 2018) However ‘full contour’ zirconia-based restorations without a porcelain layer have been shown to be problematic in some cases with the wear of the opposing teeth causing gross fracture and the ultimate total failure of the prosthesis.(Bona et al., 2015, Cha et al., 2017)

In a study by Park et al., wear resistance of the 3D printed resin material was compared to the milled and the conventional self-cured resin materials as opposed to zirconia and metal antagonists (CoCr alloy).(Astudillo-Rubio et al., 2018) The basic component of the three resin materials was similar, but the study found differences in wear patterns between the materials and the cast cobalt-chromium (CoCr) alloy denture abraders. This study suggests that the properties of PMMA-based resin materials could vary according to the fabrication methods used. When the CoCr alloy metal abrader was applied to the 3D printed resins, cracks occurred as well as

separation of the inter-layer bonds between layers of resin. This outcome occurs when the bond between layers is weaker than the bond formed between each consecutive 3D printed layer.(Park et al., 2018) Despite this challenge, the results of this study indicate that the clinical use of 3D printing technologies presents a more convenient and promising technique to fabricate provisional dental restorations and increase productivity in dentistry.(Park et al., 2018)

1.10.6 Limitations

Another limitation of 3D printed materials is that the surface of these materials is vulnerable to oxygen inhibition. Since these prostheses would be subject to immediate exposure to saliva through direct patient contact, the long-term mechanical strength, long-term dimensional stability and long-term colour stability could be reduced.(Balkenhol et al., 2009) Conversely, material blocks used in CAD/CAM systems are constructed with the optimum polymerisation conditions in place for complete and uniform polymerisation without inhibition. Studies have shown that provisional dental restorations fabricated from materials in CAD blocks (monomethacrylate or dimethacrylate) have superior mechanical properties compared to those fabricated by both conventional and 3D printing technologies.(Peñate et al., 2015, Rayyan et al., 2015)

A meta-analysis study by Astudillo-Rubio et al. (Astudillo-Rubio et al., 2018) found no significant difference between monomethacrylates (PMMA) and dimethacrylates (PEMA) in regard to their fracture strength the ability to prevent the propagation of cracks. However, both groups vary according to the way they interrupt the crack propagation, where dimethacrylate materials

are less susceptible to crack propagation in the presence of water.(Abdulmohsen et al., 2016, Astudillo-Rubio et al., 2018) Therefore, PEMA may be a potential avenue for increased strength in future 3D printing materials since they are less brittle than PMMA based materials.(Peñate et al., 2015, Rayyan et al., 2015) Over time, water absorption by non-cross-linked polymers subsequently weakens the material, which gradually diminishes the plasticising effect and the associated fracture toughness.(Balkenhol et al., 2009)

Currently, polymethylmethacylate (PMMA) resin remains one of the most commonly used materials for provisional dental restorations within dentistry due to the provision of greater flexural strength compared to PEMA. It has also been reported that provisional dental restorations based on PMMA have many advantages including colour stability, aesthetics, marginal fit, tensile, and strength. Furthermore, a number of PMMA dental models can be easily fabricated, polished, and repaired using the 3D printers, which not only reduces the production time but also allows multiple 3D copies to be produced without altering the dental anatomy.(Cha et al., 2017, Alp et al., 2018, Park et al., 2018) However, as the studies above have shown, the flexural strength of PMMA decreases gradually over time, meaning that current formulations may be inadequate for use as long-term restorations. Studies have also reported that the use of PMMA resin materials in dental restoration causes irritation of oral tissues, has low wear resistance, and has high-volume shrinkage due to leaching of the free monomer.(Patras et al., 2011, Park et al., 2018)

1.10.7 Future Developments with Graphene and Fibreglass Reinforcement

Based on evidence presented in the meta-analysis by Astudillo-Rubio et al., (Astudillo-Rubio et al., 2018) several studies have reported that the '*structure of the provisional dental restorations could be reinforced with fibreglass or graphene to improve their flexural strength and fracture toughness*' and this could be a possible route for 3D printer materials to provide more suitable long-term restorations.(Kim, 2004, Hamza et al., 2014) Although these strengtheners may not make the material completely immune to fracture, they may simply change the fracture path to allow easy repair of chips rather than a full catastrophic fracture leading to ultimate failure of the prosthesis.(Astudillo-Rubio et al., 2018) Therefore, if 3D printing resin can incorporate graphene or polyethylene fibres into the polymer matrix, this should result in a stronger restoration.(Gopichander et al., 2015, Nayar et al., 2015b) Hamza, Johnston and Schricker (Hamza et al., 2014) assessed this reinforcement effect following the addition of 1% of the polyhedral oligomeric silsesquioxane (POSS). The results indicate that 'the reinforcement effect of POSS on flexural strength depended on the brand', suggesting that particular chemical composition of the provisional materials determines the ability of POSS to improve its mechanical properties, which may mean that some 3D printer resin brands may perform better than others even if they are based on similar material technology.

1.10.8 Summary

Current materials in 3D printing offer a wide range of possibilities for more predictable workflows as well as for greater efficiency through less wasteful additive manufacturing in CAD/CAM procedures. Incorporating a 3D printer and a digital workflow into a dental practice is challenging, but the wide range of manufacturing options and materials available mean that the dentist should be well-prepared to treat patients with a more predictable and cost-effective treatment pathway. As 3D printing continues to become a commonplace addition to chairside dental clinics, the evolution of these materials, in particular reinforced PMMA, resin-incorporating zirconia, and glass-reinforced polymers, offers increased speed and improved aesthetics that will likely replace subtractive manufacturing milling machines for most procedures.(Gopichander et al., 2015, Nayar et al., 2015b)

1.11.1 Factors Affecting Accuracy of Resin-based 3D Printers

Digital dentistry has advanced rapidly in the last decades, especially since the advent of CAD/CAM imaging and milling technology, which have successfully established a new clinical modality. Given these advancements, 3D printing is at the foundation of the most recent wave of technological development in digital dentistry. New 3D printing techniques using newly released hardware and technologies continue to appear on the market and in scientific publications at an ever-increasing rate. This chapter discusses the factors affecting the accuracy of resin-based printers which aids in the overall thesis discussion of the effect this has on the global accuracy with the 3D printed implant drill guide using the envisaged novel method. The following key words were used in the literature search: 3D printing

techniques, CAD/CAM imaging, digital dentistry, milling technology, and 3D printed restorative dental materials

1.11.2 Introduction

Three-dimensional printers and rapid prototyping systems are changing the future of product development and production in dentistry. In terms of adding and bonding materials in layers to construct objects, conceptual modelling, functional prototyping, and manufacturing tools for end-use components are all being investigated using this technology.(Andonović, 2010) In terms of producing a 3D printed drill guide, the first step is a CT scan of the patient using a dental CBCT scanner. The dental surgeon then combines the hard and soft tissue intra-oral 3D impression using a masking technique to generate a 3D computer representation of the patient. Once a virtual plan and eventual guide design is built using this virtual 3D representation, a 3D STL of the drill guide is exported that is ready to be 3D printed layer by layer using photopolymer resin. The customised drill guide, as well as a 3D printed model, are then used for surgery.(Andonović, 2010, Dawood et al., 2015) The intricacy of implant placement necessitates the accurate reproduction of the intricate geometry of the implant drill guide.(Witkowski et al., 2006) Unlike the subtractive manufacture of guides that use four or five axes milling machines, 3D printing is particularly well-suited for complex structures that can be made out of a range of materials with characteristics that are ideal for dentistry and surgery. Since multi-axis CAD/CAM milling is slow and wasteful and accuracy is limited by the object's complexity, tooling size, and material properties, overall precision is therefore limited to the

application and CAD design being manufactured. (Sykes, 2004, Jindal et al., 2020)

1.11.3 Factors that Affect the Accuracy of Resin-based 3D Printers in the Dental Market

A variety of printing processes exist on the market, and each offers its own set of characteristics. The high cost of the equipment, materials, and maintenance, which is frequently ‘accompanied by the need for messy cleaning, difficult post-processing, and sometimes onerous health and safety concerns’, are some of the most common characteristics of more functional and productive equipment.(Dawood et al., 2015)

1.11.3.1 Printing technology type

In a study conducted by Ibrahim, Danilo, et al. rapid prototyping (RP) techniques such as selective laser sintering (SLS), three-dimensional printing (3DPTM), and PolyJetTM were used to create prototypes from virtual biological images.(Ibrahim et al., 2009) These models must correctly represent the craniofacial skeleton to be utilised in maxillofacial surgery. For the SLS, 3DPTM, and PolyJetTM models, the dimensional errors were 1.79%, 3.14%, and 2.14%, respectively. The models successfully replicated anatomic features, with the SLS and PolyJetTM prototypes exhibiting better dimensional precision and more precisely reproducing mandibular anatomy than the 3DPTM model. The SLS prototype was more accurate in terms of dimensions than the PolyJetTM and 3DPTM versions. Anatomic features of the mandible were recreated more precisely using the PolyJetTM technology.

A study by Emire et al assessed the accuracy and precision of complete-arch models printed using three different 3D printing methods. The digital master model was printed 10 times utilising stereolithography (SLA), direct light processing (DLP), and PolyJet technology (n = 30) on 3D printers using software (RapidForm XOR2, 3D Systems Inc., USA). (Emir and Ayyildiz, 2021) The digital models were created by scanning the printed models with an industrial scanner. All the digital models were compared to the master model, and model superimposition with Geomagic Control software (3D Systems, Rock Hill, SC, USA) was used to assess trueness. Each case's precision was calculated by superimposing some combination of the 10 datasets in each group. The trueness of the DLP printer was 46.2 μm, the SLA printer was 51.6μm, and the PolyJet printer was 58.6μm. By a significant margin (p =.005), the DLP models outperformed the PolyJet models. Despite this, the PolyJet (30.4 μm) models were more precise than the SLA (37.6 μm) and DLP (43.6 μm) models as although the Polyjet models dimensional accuracy was furthest from the actual situation they were consistently so. (p =.016). Furthermore, the SLA (11.8 μm) was the most accurate printer in the z-direction (p =.016, p =.002). The precision and accuracy of complete-arch measurements differed significantly amongst the 3D printing methods. Despite the fact that DLP was more true than the other 3D printers evaluated, the accuracy of all 3D printed models was within clinical tolerance, and they were clinically acceptable to be used to make fixed restorations.(Emir and Ayyildiz, 2021) In a study by Brown et al, both DLP and PolyJet printers generated clinically acceptable models and were determined to be regarded as feasible choices for clinical use.(Brown et al., 2018) In this investigation, 30 patients gave digital and alginate impressions

of their mouths, digital imprints were then used to build 3D models utilising DLP and PolyJet printing technologies, and ultimately alginate impressions were poured into stone. The measurements of the three models were compared to the stone models (digital, DLP, and PolyJet). The intercanine and intermolar widths as well as the arch depth were all measured. The repeated measurement error's intraobserver reliability was determined using intraclass correlation coefficients. All recorded measurements had exceptional intraclass correlation values, suggesting that all measurements on all model types were repeatable. With the exception of the crown height measurements between the stone and DLP models, where the mean discrepancy was statistically significant, there was exceptional agreement between all sets of models and all measurements.(Mangano et al., 2020)

With each of the different technologies and manufacturers, there are some common resins and materials as well as some manufacturer specific.

1.11.3.2 Manufacturer and Resin

Mangano et al. tested the accuracy of six widely available desktop 3D printers in dentistry. A parallelepiped (PP) with known geometry and holes of varying sizes was designed and printed using six desktop 3D printers (Sheraprint 40®, Solflex 350®, Form 2®, MoonRay D75®, Vida HD®, and XFAB 2000®). (Mangano et al., 2020) For each printer, nine PPs were made using proprietary materials that were not cured and were dimensionally analysed using optical microscopy and precision probing. A file representing a dentate model was also printed using the aforementioned printers. Each printer received three models, each with its own set of materials. These models were scanned using a desktop scanner, then superimposed on a

virtual reference model after one month to determine trueness. The dependability of the 3D printed models was highlighted by dimensional analysis using optical microscopy and precision probing. Although some inaccuracies are acceptable for clinical usage, the statistically significant discrepancies between the machines were found in both linear and diameter measurements. The digital model's trueness was low one month after printing, indicating that they had undergone dimensional contraction over time, but there were variations across printers. Although statistically significant variations were observed across the 3D printed models, they demonstrated acceptable accuracy.(Mangano et al., 2020)

A study was conducted by Yoo n et al. with the goal to determine the accuracy of 3D printed models that were teeth-prepped for three-unit fixed prosthesis, especially at the margin and proximal contact regions.(Yoo et al., 2021) A desktop scanner was used to scan the prepared dental model. Digital light processing (DLP), multi-jet printing (MJP), and stereo-lithography apparatus (SLA) techniques were used to create test models using this reference file. The study determined the correctness (trueness and precision) of 3D printed models on 3D planes as well as the deviations of each measured point at the buccolingual and mesiodistal planes. In addition, the surface roughness of resin-printed models was investigated. In terms of total 3D analysis, MJP performed substantially better than DLP and SLA methods in terms of trueness; nevertheless, there was no statistically significant difference in precision. Furthermore, MJP provided considerably accurate findings for molar tooth margin deviations and distance to proximal contact; however, there was no significant difference between the groups for

premolar tooth deviations. The surface roughness of the models created using the MJP process was found to be the lowest, according to 3D colour maps of printed models. The precision of DLP, MJP, and SLA 3D-printed resin models revealed a clinically acceptable range for use as a working model for producing dental prosthesis.(Yoo et al., 2021)

1.11.4 Build Orientation

Depending on the material used, several features vary from printer to printer that can impact the quality of the 3D printed output. For example, the quality of the printed model or guide may be impacted by the emission of light on the progressively added layers of photo-polymerisable monomer.(Nayar et al., 2015a, Alharbi et al., 2016b, Stansbury and Idacavage, 2016) The precision of 3D-printed materials varies substantially depending on the orientation of the printed portion and the size of the construction. In these studies, the average percentage error in the generated structures was less than 2% when simply the length of the 3D-printed samples was evaluated, and samples printed in a 90° orientation to the print bed were the most accurate. When printing samples with a 0° orientation, the samples are created by exposing the monomer to light as they thicken, in other words the greater length is horizontal. When the model or guide is printed at a 90° orientation, the longer part of the model is vertical and the horizontal width is more constant. Since printing orientation had no effect on the length of the samples in these studies, this suggests that the lateral resolution of the light emitted is the rate limiting factor preventing more precise printing of the tested material.

1.11.5 Layer Thickness

Since the 3D printed output is built up with layers, the thickness of these layers can be varied. If a thicker layer is employed, the total number of slices is less, which therefore shortens the overall print time. However, when these layers are thicker, they cannot portray the overall shape as accurately as steps between layers will be more obvious as the layer thickness increases.(Cheng et al., 1995) Apart from accuracy, if a thicker layer is employed, then the strength will be higher as the cure between layers is less strong than the layer itself (Chockalingam et al., 2006). Loflin et al. used the cast-radiograph evaluation to assess printed samples with different layer thicknesses, and the results demonstrated that an optimal layer has a thickness of 100 µm.(Loflin et al., 2019)

1.11.6 Resin Type

Another consideration is that printing precision varies greatly from one material to the next. The accuracy of samples printed with a control clear resin provided by the printer manufacturer and set to the same dimensions as printable resins of other types and opacities.(Tahayeri et al., 2018) Stereolithography printing precision is therefore somewhat dependent on the controlled penetration of light to a specific depth through the resin and on the monomer blend that is used.(Bhattacharjee et al., 2016, Urrios et al., 2016)

1.11.7 Postprocessing

Postprocessing is a requirement for 3D printed objects, and it is used to harden the object to improve its performance. After production, the 3D printed object— the drill guide, in the case of guided implant surgery—has

any printing supports removed, and then the object is washed in IPA alcohol. After washing, the object is then cured in a UV light chamber, sometimes heated at the same time. Jindal et al. found that postprocessing and curing significantly improves the 3D printed object's ability to resist pressure loading. (Jindal et al., 2020)

1.11.8 Ageing

After postprocessing, an object, such as an implant drill guide, that is 3D printed with resin can undergo age-related changes due to environmental factors. Ottemer and Colton's study of the effect of aging on light-curing resins shows that a humid environment impacts mechanical properties.(Ottemer and Colton, 2002) A study by Mansour et al. showed that the elastic modulus, ultimate tensile stress, flexural modulus, and strength all increased with age, but significant contraction occurred.(Mansour et al., 2007)

1.11.9 Conclusion

A variety of factors can impact the accuracy of a 3D printed object, such as an implant drill guide printed using biocompatible resin. Even though 3D printers are becoming more affordable and a wider variety of both manufacturers and materials are available, the associated factors impacting accuracy during manufacturing need to be understood. Clinicians must also be aware that strict postprocessing protocols that follow manufacturers' recommendations for biocompatible resins must be carefully considered.

1.12.1 A Literature Review of The Factors Affecting Dental CBCT Scanner Accuracy

Cone beam computerised tomography (CBCT) has been used in dental, oral, and maxillofacial surgical practices for many years. CBCT provides a relatively lower dosage compared to conventional hospital-based CT scans and the advanced visualisation available in 3D mean that the number of uses has expanded considerably. It has multiple practical uses regarding dental imaging or maxillofacial diagnosis. For the purpose of guided implant surgery, 3D visualisation enables a completely virtual environment to plan the case. In terms of the overall global accuracy when considering edentulous guided implant surgery, the accuracy of the CBCT scan must be discussed when assessing the resultant deviations.

1.12.2 Introduction

Evidence based dentistry is the foundation of successful dental treatment and its prognosis. The effective treatment of edentulism with implants is highly influenced by imaging tools used during the initial diagnosis of the problem. Therefore, cone beam computerized tomography is a crucial tool that provides the essential information about soft and hard tissues in the oral cavity and surrounding areas.(Kiarudi et al., 2015) Current studies show that CBCT is widely and conveniently used by dental practitioners around the globe, and therefore, quality assurance, accuracy, and optimization of CBCT scanners is important to maintain accuracy within acceptable levels.(Pauwels et al., 2015) Therefore, further research should discuss how various components impact its accuracy.

1.12.3 Hardware components

In terms of the hardware required for dental CBCT scanners, the machine has three major components: the X-ray tube, the rotational arm, and the detector. The arm is C-shaped which enables patients to sit or stand while the imaging process is underway, and it can move freely in a horizontal direction. The X-ray tube and detectors are on either side of this arm. The distances from the source to the object (SODs) and from the object to the detector (ODDs) vary widely between different scanners. These distances, along with the size of the focus spot, play a crucial role in determining the clarity of the projected images. A longer SOD typically results in clearer images, but it also leads to decreased magnification, as noted by Pauwels et al. (Pauwels et al., 2015)

Figure 29. A CBCT Machine (Pauwels et al., 2015)

Furthermore, X-ray detectors are essential components of the imaging chain, because they convert incoming X-ray photons to an electrical signal. Different types of detectors are utilized in dental CBCT imaging. Flat panel

detectors (FPDs) that are currently used are distortion-free, have a better dosage efficiency, a broader dynamic range, and can be manufactured with either a smaller or larger FOV.(Pauwels et al., 2015)

1.12.4 Exposure

While the underlying acquisition concept is the same for all CBCT devices, when comparing acquisition techniques and settings, significant variations emerge. Some X-ray tubes allow for pulsed exposure, which ensures that no exposure occurs between projections. Pulsed exposure is used by some CBCT systems, resulting in a wide gap between scan time (the period between the first and final projection) and the exposure duration. Other X-ray tubes only allow for continuous exposure, which means the scan and exposure durations are the same throughout. The dose is determined by multiplying the exposure time by the tube current. The rotation arc is the second dose related factor in differing systems. While most CBCT scanners capture projections along a 360° angle (i.e., a complete rotation of the tube and the detector), for reconstruction of a total field, a rotation of 180° plus the beam angle is also sufficient. In terms of quality, partially spinning reduces the overall image quality, which is most noticeable in the amount of noise associated with lower mAs. A 180° rotation procedure might result in a modest or more significant increase in noise than a 360° rotation treatment, depending on the mA. Decreased image quality is associated with a shorter scanning, as seen by a minor increase in view interference associated with a reduced number of projections (Pauwels). The mA may be adjusted to keep the detector signal constant depending on the tube location, the size and position of the required field of view, and the X-ray attenuation. In lateral

views, the mA would be lower, whereas in posterior/anterior views, the mA would be greater.(Pauwels et al., 2015)

1.12.5 Spatial Resolution, Contrast & Noise

Evaluating the fundamental quality of a medical image involves considering several key characteristics: resolution, contrast, noise, and artifacts in the final image. The precise meanings of those characteristics and how to judge them is specific for different kinds of medical images. These aspects have a tendency to overlap, calling for a more detailed analysis of all these attributes to determine the quality of an image. For example, spatial resolution has an unmistakable interdependency with noise. (Pauwels et al., 2015)

Also important when evaluating image quality is understanding the intended use of the imaging — whether this is for finding problems in hard tissue or soft tissue — and to make sure your evaluation goals line up with what you want to see on the resultant image. One of the crucial characteristics of the camera is spatial resolution or sharpness, and this parameter decides on the ability of the picture to show small objects. Several parameters determine the spatial resolution in CBCT imaging such as the size of the focused spot, the detecting element, the filtering method, and the pixel size reconstruction. CBCT often employs multiple detectors and offers lower spatial resolution in comparison with hospital-based CT due to smaller detector components. (Pauwels et al., 2015)

An essential method to measure and describe the spatial resolution is contrast, which depends on how the image can distinguish varying densities of tissue or material. According to Pauwels et al. (Pauwels et al., 2015) the

sharpness and contrast of an image have a significant impact on the ability of both clinicians and guided surgery software to accurately register digitally captured impression STL onto three-dimensional CBCT imagery. This translates that the detail and resolution of the output image is key in order to have accurate alignment and overlay for the overall accuracy and credibility of the imaging process within guided implant surgery.

1.12.6 Accuracy of CBCT

A comparison of images from two CBCT units (NewTom 9000, QR S.R.L., Verona, Italy and Arcadis Orbic 3D, Siemens Medical Solutions, Erlangen, Germany) with routine panoramic radiography revealed that 'CBCT provides more details than radiographs for locating impacted and retained teeth, root resorption, cleft lip and palate, and third molar evaluations'.(Korbmacher et al., 2007) In another research conducted by Lund et al. (Lund et al., 2010), it was discovered that the error in measuring in vivo root lengths was around 0.2 mm. This study aimed to compare the discrepancy in root length between direct measurements and those obtained radiographically through CBCT, revealing an average discrepancy of 0.05 mm, with a standard deviation (SD) of 0.75 mm.

To delve deeper into the clinical implications of these findings, it's crucial to understand that the term 'trueness' refers to the closeness of the measurements to the actual (true) values. In this context, the trueness indicates that the measurements are relatively close to the true root lengths over multiple exposures. However, the 'precision' denotes the consistency and repeatability of the measurements. The poor precision, represented by a variability of 3/4 mm and 2 standard deviations equal to 1.5 mm, signifies

that the measurements are not consistently close to each other, even if they are close to the true value.

These discrepancies and variabilities are not trivial in clinical settings. A discrepancy of 0.05 mm and variability of up to 1.5 mm can be significant, especially in procedures requiring high precision, such as the placement of dental implants or orthodontic treatments. It underscores the necessity for meticulous attention and consideration of these errors and variabilities in clinical decision-making and treatment planning to avoid potential complications and to achieve optimal treatment outcomes.

Since multiple exposures cannot be taken, for obvious reasons, this lack of precision must be borne in mind clinically. Over a small scale these are relatively large discrepancies when compared to the deviations seen in guided implant surgery. It is therefore important to assess the measurement errors over a larger scale to understand the accuracy of the data merge process over the full arch.

Cephalograms generated by using CBCT data show no statistically significant changes in linear or angular measurements when compared to traditional cephalograms.(Farman and Scarfe, 2006) However, measurements used in planning can be based on clinical need and usage and can be unrelated to the ability of the guided implant surgery software to match a virtual impression to the CBCT scan.

Assessing the accuracy of the data match between the CBCT and the digital intra-oral impression data is therefore important. Schnutenhaus et al. assessed this topic in a prospective controlled clinical study. To calculate this data match accuracy, the DICOM was converted into a 3D data

set.(Schnutenhaus et al., 2018) The impression model was then manually superimposed using three different methods based on an X-ray template and computer-assisted automation. In this study, the data match accuracy was found to be approximately 0.2mm on average. The authors found that the error corresponded to the resolution of the CBCT itself, which in their study was 0.2 voxels. The authors also found no statistical difference between the various methods of data matching and that '*X-ray templates can be dispensed with saving the patient a substantial amount of time and money*'.(Schnutenhaus et al., 2018)

A similar study by Ritter et al. compared the registration accuracy of the digital impression to the CBCT scan using entirely automated computer driven registration.(Ritter et al., 2011) Their results were more accurate with mean distances between CBCT and 3D surface data between 0.03(±0.33) and 0.14(±0.18) mm. A similar conclusion was made in that '*registration of 3D surface data and CBCT data works reliably and is sufficiently accurate for dental implant planning. Thereby, barium-sulphate scanning templates can be avoided and dental implant planning can be accomplished fully virtual*'.(Ritter et al., 2011) The benefit of not using a barium-sulphate lined prosthesis is overall speed of treatment and cost.

It is worth noting that both this study and the one mentioned above were in dentate subjects. This allows matching from the 3D scan and the CBCT imaging of the dentition (which is easier to threshold). One core aspect of this thesis (and the proposed technique) is that it tackles the edentulous case. Therefore, although the accuracy seems encouraging from these two studies, the edentulous case will be much poorer due to difficulties in

thresholding out the bone/soft tissue surfaces, tissue compressibility and lack of strong anatomical/topological features upon which to align.

1.12.7 Summary

For the purposes of planning virtual implant positioning using a CBCT and then producing a guided implant surgery drill guide template in a dentate patient, the major limitation in accuracy is the voxel size of the detector used.

With regards to edentulous guided implant surgery there is a much greater potential for error.

Through the same of literature reviewed, the overall discrepancy between CBCT and aligned 3D surface data varies between 0.03-0.14mm which we need to consider in the relevance to the overall procedure accuracy in the final study of this thesis.

1.13.1 Analyzing Accuracy in Integrating CBCT and Intraoral Scans for Implant Drill Creation in Guided Surgery

The previous chapters discuss the various inaccuracies that occur in each stage within the planning and construction of the edentulous implant drill guide, and the resulting deviation is potentially limited in terms of achieving completely accurate final positioning. Several variable factors may create errors in this process, including CBCT scans that have inherent distortion, the capture of the surface impression data, the 3D printing of the designed drill guide, mucosal compression, distortion at all stages, and drill wobble due to tolerance gaps.

In a fully edentulous arch, preoperative planning is critical for effective restorative outcomes in full mouth rehabilitation.(Hultin et al., 2012) The use of computerised implant planning using CBCT has increased dramatically in recent years. Through this process, dental implant placement is made through the use of implant drill guides used to create the osteotomy with the final prosthetic position in mind.(Mandelaris, 2010)

Advances in CAD/CAM technology have made it possible to combine surgical plan digital data with prosthetic designs for immediate restoration at the time of implant placement. Through computer guided implant placement, the clinician can effectively and accurately replace the tooth with a temporary one that is premade at the time of implant placement. In some situations, elevating the mucosal flap to assess the bone is not required, resulting in a flapless surgical operation.(Brodala, 2009)

Kernen et al. (Kernen et al., 2015) have posited that utilizing 3D printed templates, created from surface scan and CBCT matching data in virtual planning, can potentially enhance the accuracy of implant placement. However, it’s crucial to delve deeper into the practicality and limitations of this approach, especially in more complex full arch implant cases. In such cases, the deviations tend to be larger, making the creation of a pre-placement, premade temporary more challenging. Achieving passivity in each implant connection for a full arch restoration is also notably difficult, necessitating meticulous planning and execution.

While the utilization of an implant drill guide is acknowledged for improving precision and reducing the risk of complications like mandibular nerve damage, sinus perforation, fenestrations, and dehiscences, it’s essential to consider the varying degrees of success and the potential for unforeseen

challenges. The assertion by Nickenig and Eitner (Nickenig and Eitner, 2007) that ‘prosthetically directed implant placement using computer software can ensure precise placement and predictable outcomes’ needs to be interpreted with caution. While advancements in technology and software have indeed facilitated more precise and predictable implant placements, the outcome is also contingent on various factors including the complexity of the case, the practitioner's skill and experience, and the patient’s anatomical considerations.

Therefore, while these techniques and tools provide valuable aids in implant placement, it’s imperative to approach them with a balanced perspective, acknowledging their benefits while being cognizant of their limitations and the inherent variability and unpredictability in clinical scenarios.

In the creation of implant drill guides after digital planning, the discussions in this thesis have considered what errors are possible during this planning, osteotomy creation with drills, and placement process. A full arch guide created from a virtual plan for edentulous cases has its own specific factors relating to accuracy.(Komuro et al., 2021) A phenomenon known as shrinkage has been seen in which CBCT readings were smaller than the real values. In this context, shrinkage refers to the discrepancy observed when the dimensions recorded by CBCT are smaller than the actual, real-world values of the object being measured. This can occur due to various reasons, including the limitations in the resolution of the imaging technology or distortions introduced during the imaging process. When the plaster model or intraoral scanners values indicate shrinkage at the same rate as the CBCT data, the matching of digital data is considered to be trustworthy. However, if the shrinkage rate varies dramatically from one sample to the

next, the digital data acquired becomes untrustworthy. Komuro et al. found results in their study of this shrinkage that '*All values measured with CBCT were significantly smaller than that of model scanner, iOS, and control ($p < 0.001$). The model scanner shrinkage was 0.37%–0.39%, iOS shrinkage was 0.9%–1.4%, and CBCT shrinkage was 1.8%–6.9%. There were statistically significant differences among the shrinkage with iOS, CBCT, and model scanner ($p < 0.001$)*'.(Komuro et al., 2021)

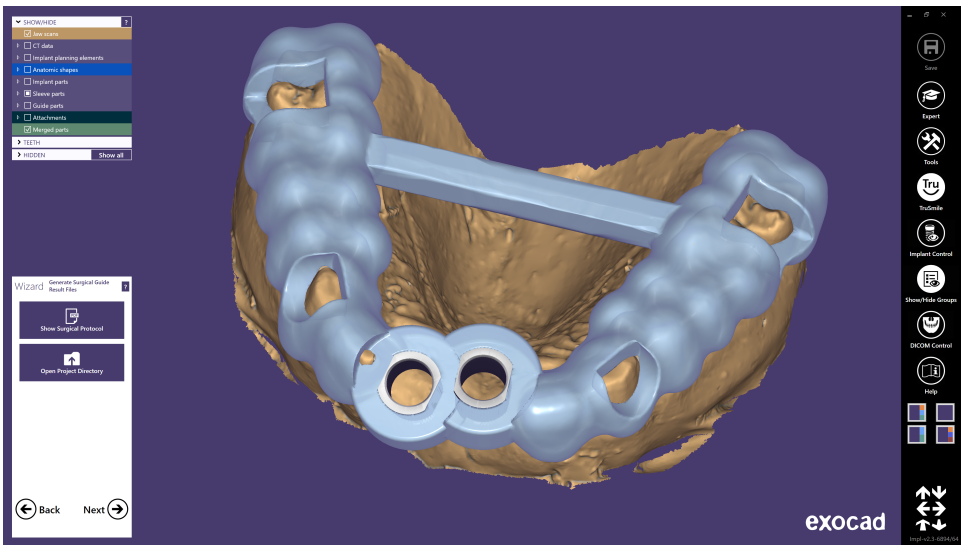

Figure 30. Designing the Surgical Guidance for Implant Placement with Exoplan Guided Surgery Software (Exocad, 2019)

Komuro also found that numerous factors, including technology, software, and human error, may cause CBCT findings to deviate from their true values.(Komuro et al., 2021) Edge enhancement and metal artifact reduction procedures increase the amount of software correction required. Regarding human error, it is generally agreed that the person who is taking the measurements is the most at fault, as the user my find it is difficult to see a precise margin in a CBCT scan. Machine learning and AI data matching can help this process where average values can be used to create a more

accurate overall match. Up to date software is therefore paramount.(Ting-shu and Jian, 2014)

Computer-guided implant placement has the potential to be considerably more accurate than unguided placement, but there are risks associated with it.(Van Assche et al., 2012) By using the digital plan created during the virtual planning procedure and then sending the 3D position from the presurgical planning to the dental laboratory, it is possible through CAD/CAM to manufacture a prefabricated fixed prosthesis that can be attached directly to newly placed implanted fixtures. In an edentulous case this is a significant advantage to the patient where the period of edentulism can be minimised during the healing period.(Van Steenberghe, 2005) However, for this pre-planned prosthesis to fit passively, the placement of the implant through the drill guide must be accurate to follow the virtual plan created. If inaccuracy results in deviation from this plan, the variations in fit may mean that this prosthesis either does not fit or does not fit passively. Another factor that can impact placement that has not yet been discussed in this thesis is the variation in surgical guide drill systems amongst different manufacturers. Depth control is possible through certain steps in some systems but not in others, which use indication lines instead. In some systems a pilot preparation is made, whereas in others the full osteotomy is prepared through the guide. Finally, some systems also provide a mechanism of placing the implant itself through the guide. There is also the limitation of the drill and component tolerance which causes wobble, leading to deviations through mechanical means. These deviations would be increased the further from the point of wobble, therefore guide-to-bone distance would influence deviation. These various components may lead to

error in placement in the coronal position, apical position, and angulation. (Van Assche et al., 2012)

A study by Sarment et al. assessed these deviations by comparing the effects of different drill systems. An angular deviation of 3.81° with a high of 24.9°, was observed across all systems in general. Although these discrepancies seem to be significant, there is no *in vivo* randomised controlled trial (RCT) that compares computer-guided versus conventional surgery (with or without the use of any form of surgical template) to support a claim of guided implant surgery being more or less accurate. Several minor *in vitro* investigations compared surgical deviations for conventional analogue surgery with surgical deviations for computer-guided surgery. In all cases of deviation, a statistically significant improvement was shown in favour of guided surgery. When the angular deviations were compared, for example, they were 4.5° for guided and 8.0°, 4.2°, and 10.4°, respectively.(Pinsky et al., 2006)

Several other important factors such as the following may also have an impact on overall accuracy: (Mandelaris, 2010)

- Determination of bone volume in CBCT viewing. The accuracy and precision with which a clinician can determine the precise position of a thin piece of tooth or scanning appliance in a CBCT scan;
- The reliability of the 3D intraoral scan;
- The accuracy of the data merging process;
- The reliability of the 3D printed surgical template;
- Surgical guide movement and fit during the clinical placement of the implant.

It is critical to understand the accuracy of each of the steps discussed in the chapters within this thesis to form a full conclusion on the overall accuracy of the novel method to combine data sets and perform minimally invasive edentulous guided surgery.

Chapter 2 - Thesis Aim and Objectives

2.1 Thesis Aim and Objectives

2.1.1 Aim

The primary aim of this thesis is to critically evaluate the precision and accuracy of the Fixed Edentulous Implant Guide (FEIG) in dental implant placements for edentulous arches. This involves comparing the actual implant positions with the preoperative virtual planning on CBCT models. The research expands to assess the method's efficacy through in vitro studies, detailed literature reviews, and a novel approach to calculating implant positions used in the final study. Additionally, the thesis aims to investigate the accuracy of nine intraoral scanners (IOS) and twelve 3D printers, examining their influence on the overall accuracy of the implant placement process. By integrating these components, the research strives to provide a comprehensive analysis of the FEIG method's reliability and the contributing factors to its accuracy in clinical practice.

2.1.2 Objectives

- Assess the coronal, apical and angular deviation of the placed implants compared to the planned virtual position
- Use the deviation measurements to determine the accuracy of the placed implants using the novel method to accurately reference the digital intraoral impression STL data and the CBCT radiographic data compared to their virtual counterparts on the CBCT planning model.

- To examine whether it is both safe and accurate to place implants with flapless surgery with this new method of referencing the model to the CBCT scan.
- Conduct a thorough review of the current literature to compare the FEIG method's outcomes with existing edentulous guided surgery techniques.
- Investigate the accuracy and reliability of nine intraoral scanners (IOS)
- Assess the precision of twelve 3D printers by evaluating the discrepancy between the 3D printed models and the digital designs.

2.1.3 Hypotheses for preliminary and final studies

Null Hypothesis (H0):

There is no significant difference in the positional error of implants placed in an artificial edentulous mandible using a tissue-borne surgical guide compared to implants placed using the Fixed Edentulous Implant Guide in an in vitro edentulous mandible simulation.

Alternative Hypothesis (H1):

The Fixed Edentulous Implant Guide (FEIG) method will exhibit a significant difference in positional error, demonstrating superior precision and accuracy in implant placements compared to a tissue-borne surgical guide in an in vitro edentulous mandible simulation.

2.1.4 Hypotheses for A Comparison of Full Arch Trueness and Precision of 9 Intraoral Digital Scanners and 4 Lab Digital Scanners in a Dentate Arch

Null Hypothesis (H0):

The null hypothesis was that no differences would be found between the various scanners regarding trueness and precision.

A secondary null hypothesis was that there would be no difference between the lab scanners and intra-oral scanners regarding trueness and precision.

2.1.5 Hypotheses for A Comparison of Trueness and Precision of 12 3D Printers used in Dentistry

Null Hypothesis (H0):

The null hypothesis of the study was that no differences would be found between the various different 3D printer technologies regarding trueness and precision.

2.2 Method of Use

In an attempt to overcome the issues of mucosal movement and referencing inaccuracies during guided implant placement, the author of this study is proposing a novel method that uses three two-part screws to accurately reference the two data sets (CBCT and digital scan) in virtual planning and to fix the guide in place during the drilling protocol

To summarise its components, The ‘fixed edentulous implant guide’ contains the following parts when in use;

- three two-part screws
- An edentulous implant surgical guide

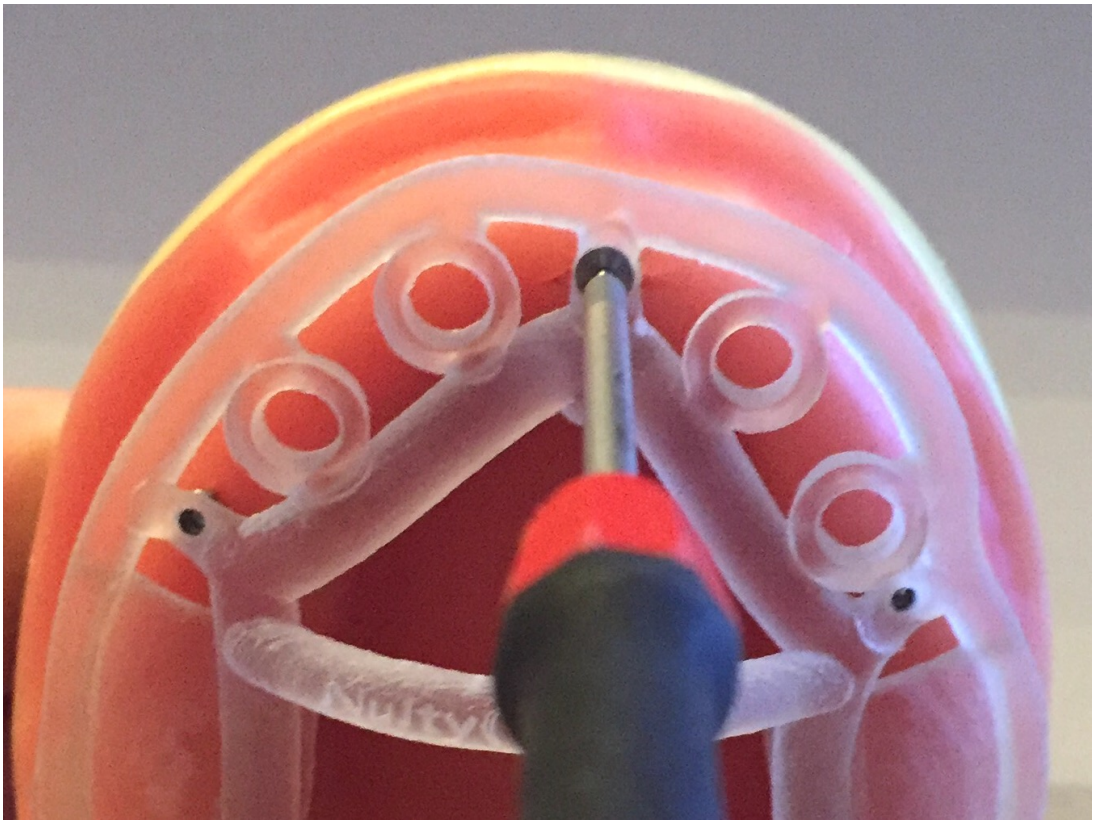

Figure 31. The Fixed Edentulous Implant Guide in Place.

In the above image can be seen the 3D printed guide, sitting over three fixed implant screws. The second part of the two-part screws secures the guide and anchors it in place by screwing into the initial screw that has been placed into the bone.

The proposed method of using this novel approach and the manufacturing process can be summarised as follows;

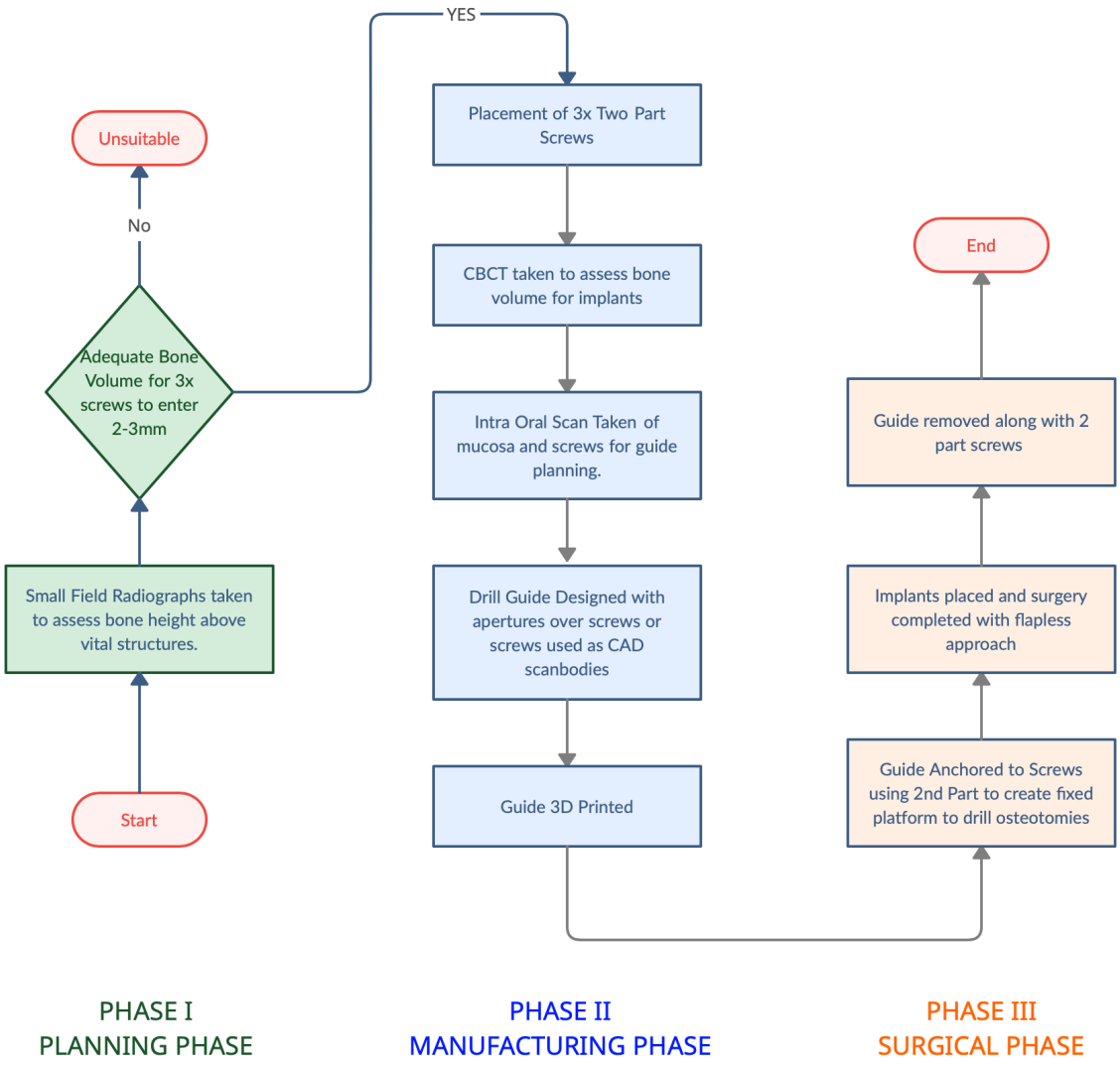

Figure 32. A Flow Chart of the Planning, Manufacturing and Surgical Phases of the Fixed Edentulous Implant Guide

In the flow diagram above we can summarise the proposed process as follows;

2.2.1 Phase 1: Planning Phase

In this phase, an initial set of 2D radiographs are taken to assess proximity of the bone margin to vital structures such as ID nerve and sinus. The two-part screws will engage the bone by 2-3mm.

If there is less than this amount plus a safety zone of approximately 1.5-2mm then the procedure should be abandoned and an alternative prosthesis designed as there will be inadequate height for implants if there is inadequate height for these two part screws.

2.2.2 Phase 2: Manufacturing phase

This is the data collection and virtual implant planning phase. By combining a CBCT taken after the two-part screws are placed with an intra-oral scan of the edentulous mucosa also after two-part screw placement, a virtual placement of implants can be performed and a drill guide designed. This drill guide is then 3D printed.

Manufacturer's Details;

Dental CBCT Device – Carestream 8100 3D

Surgical Guide Planning Software – SMOP by Swissmeda

3D Printer – Formlabs Form2 in preliminary study

Asiga Max UV in final study

3D Printing Resin - Formlabs SG Resin in preliminary study

Nextdent SG Resin in final study

Artificial Bone Blocks – Sawbones D2 Artificial Bone

Implants – Osstem TSIII Replica Implants

Implant surgical guide kit – Osstem Oneguide Guided Surgery Kit

2.2.3 Phase 3: Surgical Phase

In this final phase, the guide is placed over the initial screws from two-part screws and anchored into place using the second part. The guide is then used to complete a fully guided flapless procedure to create the osteotomies and placement of the implants. Finally all components are removed allowing the implant sites to heal and integrate.

This phase is pivotal, as it involves the actual placement of the guide and the execution of the surgical procedure. The guide, developed in Phase 2, is positioned over the initial screws from the two-part screws and is securely anchored using the second part screws ensuring precision during the creation of the osteotomies. Subsequently, all components are removed to allow the implant sites to heal and integrate.

Importance of Precision in Phase 3:

The precision and accuracy achieved in the Manufacturing Phase (Phase 2) can be significantly compromised if meticulous care is not taken during the Surgical Phase (Phase 3). The introduction of implant sleeves and spanners presents a potential source of error, and any misalignment or improper use of these components can lead to deviations from the planned implant positions. Such deviations can negate the benefits of the accuracy meticulously achieved in the previous phase.

Addressing Potential Errors:

In order to reduce the risk of complications during this stage, it is essential to make sure that the surgical guide is correctly applied and fixed, and the implant sleeves and spanners are used with the maximum of precision and

attention. Calibration, checking, and supervision of the instruments used are also mandatory, along with monitoring the surgical procedure, to preserve the quality of the implant placement and obtain the advantages of pre-designed accuracy.

Recognizing and mitigating the risks in this key stage will help clinicians maximize the performance of the surgery and realize the value earned from precise planning and production.

2.3 Sources of Inaccuracy;

The sources of inaccuracy in the proposed method can be found in phases two and three; In phase three the errors, whilst important as discussed above, are unavoidable, relating to drill wobble due to tolerance and possibly operator-dependent deviation. The severity of these errors will be dependent on the drill kit used as described in the earlier literature review.

Therefore, the sources of error in Phase 2, namely intraoral scanner accuracy, CBCT accuracy, and 3D printed guide accuracy are the sources of error that need to be investigated further to attempt to understand and minimise them so as to validate and optimize the proposed FEIG method. Each of these errors will be addressed separately in the following chapters.

Chapter 3 - Outline of Potential Sources of Inaccuracy in the Manufacturing of the Edentulous Fixed Screw Implant Guide

3.1 Introduction

The FEIG is an original concept and as such a preliminary study was undertaken before each potential source of inaccuracy could be investigated further. The aim of the study was to measure the accuracy of the placed implants using a novel method to reference the digital intraoral impression STL data and the CBCT radiographic data compared to their virtual counterparts on the CBCT planning model. The objective of the study was to examine whether it was both safe and accurate to place implants with flapless surgery with this new method of referencing the model to the CBCT scan.

3.2 Methodology

This *in vitro* experiment aimed to simulate an *in vivo* study.

The method involved virtually planning the case using SMOP guided surgery software. Then a low dose CBCT scan was used to compare the 3D position of the planned and placed implants in terms of angular deviations and linear deviations by overlapping the pre and post-operative CBCT scans.

The results would be used to calculate the trueness and precision of actual position relative to the planned position on the virtual model.

Null hypothesis (H_0) for the study;

The null hypothesis (H0) posits that the implant placements executed using the new Fixed Edentulous Implant Guide (FEIG) method will result in implant

placements that exhibit deviations exceeding the clinically acceptable limits from the planned positions.

Clinically acceptable limits;

Van Assche et al (Van Assche et al., 2012) carried out a retrospective study into the accuracy of guided implant placement as measured across various clinical studies. Meta analysis revealed across these studies mean error of 0.99 mm at the entry point and of 1.24 mm at the apex. The mean angular deviation was 3.81°.

Therefore the best of these results means (0.5mm deviation and 2 degrees angulation) was chosen before the study as clinically acceptable tolerances.

3.3 How do the results of the literature search influence the design of this study

3.3.1 Prior Accuracy Research

3.3.1.1 Sample size

Using a power of 80% and a level of significance chosen at $p<0.05$ and Arisan et al's meta analysis of edentulous guided surgery (Arisan et al., 2010) data using the mean of 1.99mm and SD 0.64mm, a sample size calculation performed with BioMATH calculator with the results of previous edentulous guided surgery studies which resulted in a sample size of 16.

All equipment used in the study was calibrated and serviced before the start of the study.

To enable the measurement of accuracy and understand where the errors in final implant position is attributable to which cause, each step in the workflow was examined.

3.3.2 The creation of more a more biologically accurate model.

Various artificial bone blocks were ordered from Sawbones, an artificial bone supply company in the UK supplying to trainers in medical technology. These blocks were radiographed both with and without an artificial gum layer from the same manufacturer. The edentulous study models available were found to have a inverse relationship with the radiographic density in that the bone radiographed less dense than the mucosa as shown in Figure 33. Because of this it was deemed that it was more important to use the combination of manufacturer's models that most closely resembled human bone in density to drilling in a human mandible. These were ordered to be large enough to place at least four implants. The block dimensions measured 12cm by 5 cm by 5 cm.

It's crucial to note that the artificial bone blocks used in this study were rectangular in shape, not resembling the anatomical structure of the mandible. This is an unfortunate yet significant limitation of the preliminary study as the shape and anatomical features of the mandible could potentially introduce varying degrees of inaccuracies in CBCT scans, which are not accounted for when using rectangular blocks, but within the limitations of this thesis this was all that was available at the time of the preliminary study. The use of anatomically accurate mandibular shaped pieces of artificial bone would have provided more clinically relevant insights and a more accurate representation of the potential inaccuracies and distortions in CBCT scans. Acknowledging this limitation is essential for interpreting the results of the study and for considering the application of the findings in clinical settings. Future studies aiming to assess the inaccuracies of CBCT scans should

consider using anatomically accurate models to yield results that are more representative of clinical scenarios.

The human mandible was chosen as the author considers accuracy in the mandible is more important to prevent potential iatrogenic damage to structures such as the inferior alveolar nerve being more serious in potential morbidity effects than surrounding structures in the maxilla. A more accurate model was created by experimenting with different materials and scanning until the following combination was found to be equivalent;

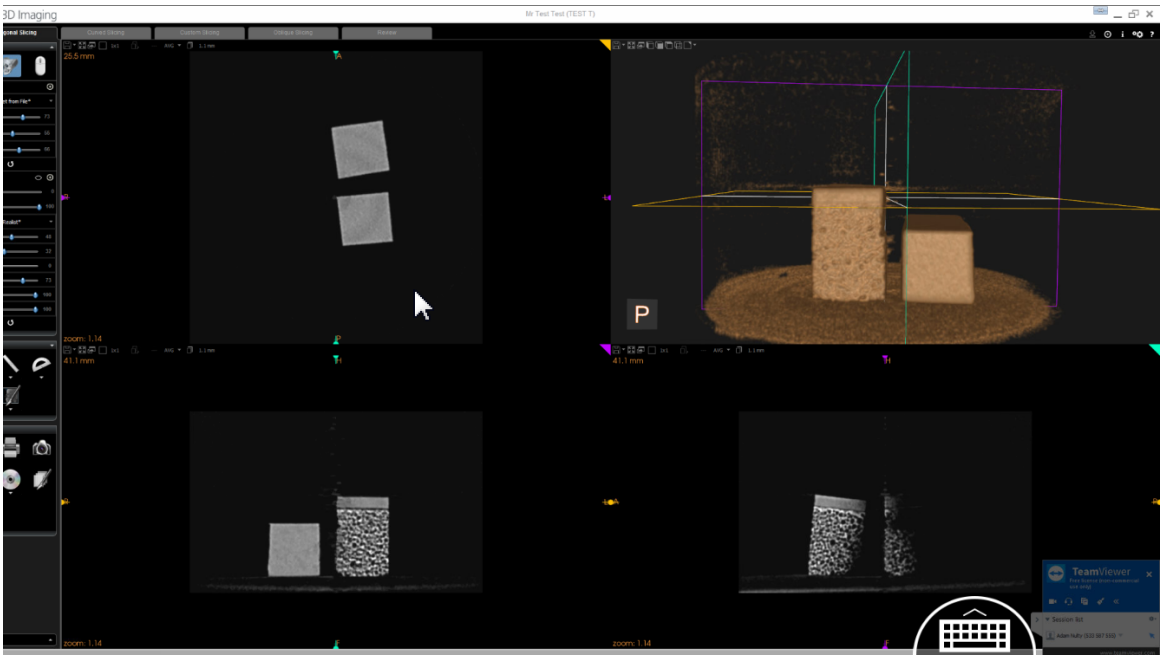

Figure 33. Artificial bone blocks being scanned in a CBCT

This was done so that the “bone” of the model was similar to human bone in density with a less dense “gingival” covering.

3.3.3 Aligning a light model 3D STL scan of the model with 3D STL of the screws placed into the model.

Three non-integrating titanium PSM Benefit Two Part orthodontic screws (figure 35) were then inserted in a triangular fashion into the model created in the first step above. The CBCT of the block with screws inserted was taken at a voxel dimension of 0.2 with standard settings for a lower arch on the care stream 81003D.

Figure 34. PSM Benefit Two Part Screws (PSM, 2018)

The model with the inserted screws was then scanned with a Rexcan DS2 (Solutionix, Seoul, Korea) lab light scanner at maximum resolution using 20 frames per scan with the corresponding Ezscan software to obtain the STL data impression of the surface of the model.

The 3D CBCT volume and the surface STL were combined in the SMOP guided surgery planning software.. The 3D volume STL of the said screws were then matched with the visible coronal portion of the screws on the surface of the model through the SMOP ‘data combining function’ within the planning software. As the three points of the two part screws are present on

both the STL scan and the CBCT scan, it is possible to select the common feature on both data sets. The planning software algorithm then combines the data sets according to the position of the three points chosen

This combined data set was then used to create a full 3D version of the model and a guided surgery plan created with SMOP guided surgery software with a virtual plan for the placement of four Osstem TSIII dummy implants of size 4mm x 10mm was prepared.

A drill guide was designed as per Figure 36. A Form2 printer was used to print the guides which has a Z-plane print accuracy of around 25 microns (Mangano et al., 2020) Formlabs SG Guide resin was used to print the guides and cured fully as per manufacturer's instructions

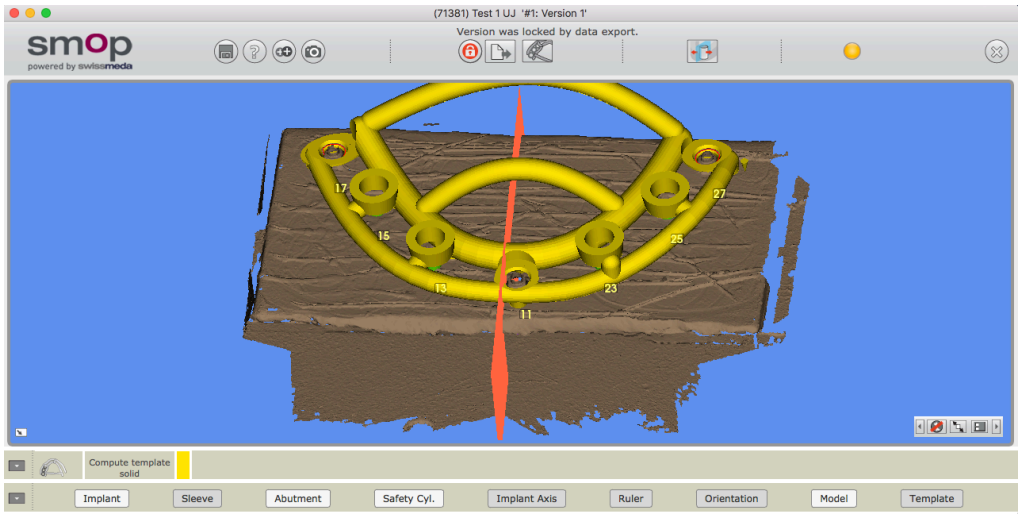

Figure 35. The Swissmeda SMOP Guide creation on the artificial bone blocks

3.3.4 Guide placed with Screws

The printed guide was then placed and locked onto the model with the two-part screws and the osteotomies prepared before placing the dummy implants with a fully guided protocol.

64 Implants were then placed into 16 artificial bone blocks using the same drill kit and the same methodology of osteotomy preparation with a fully guided approach. i.e. and increased length and then an increasing width of implant drill with every drill guided through guide cylinders. The implants themselves were then placed guided using guide mounts through the guide into the prepared osteotomy.

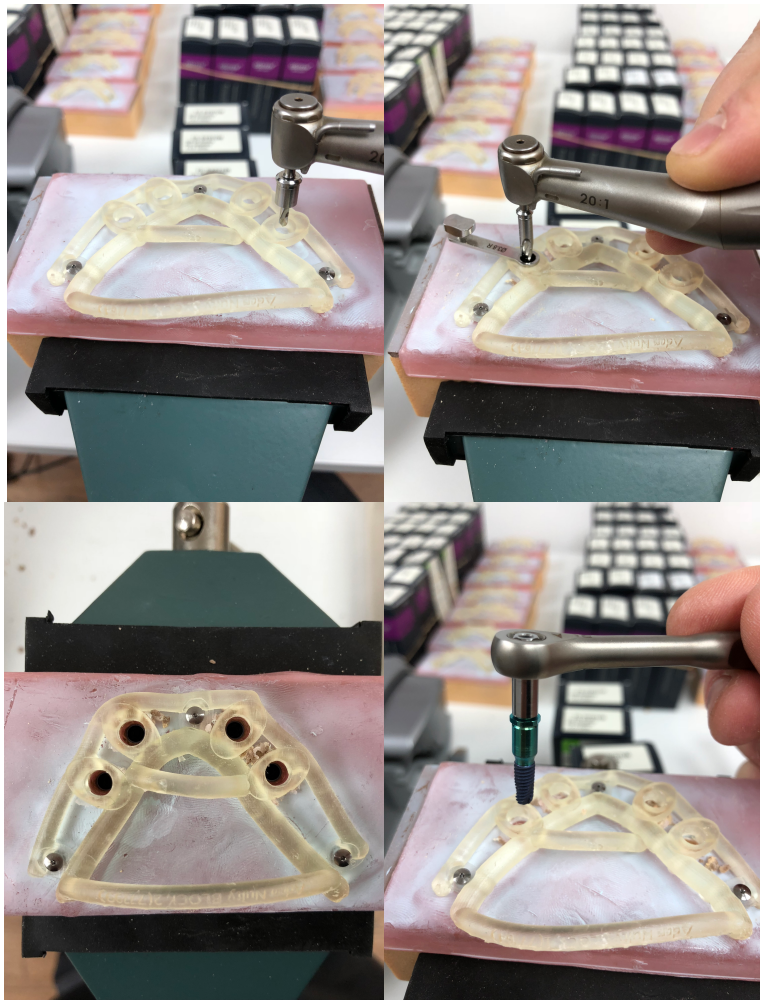

Figure 36. The test block osteotomies and dummy implant placement.

3.3.5 CBCT Accuracy with Digital Subtraction

The CBCT scan and the 3D model were then compared with digital subtraction using specially designed virtual planning comparison software to give results on the;

- Angular deviation
- Insertion horizontal deviation
- Vertical depth deviation

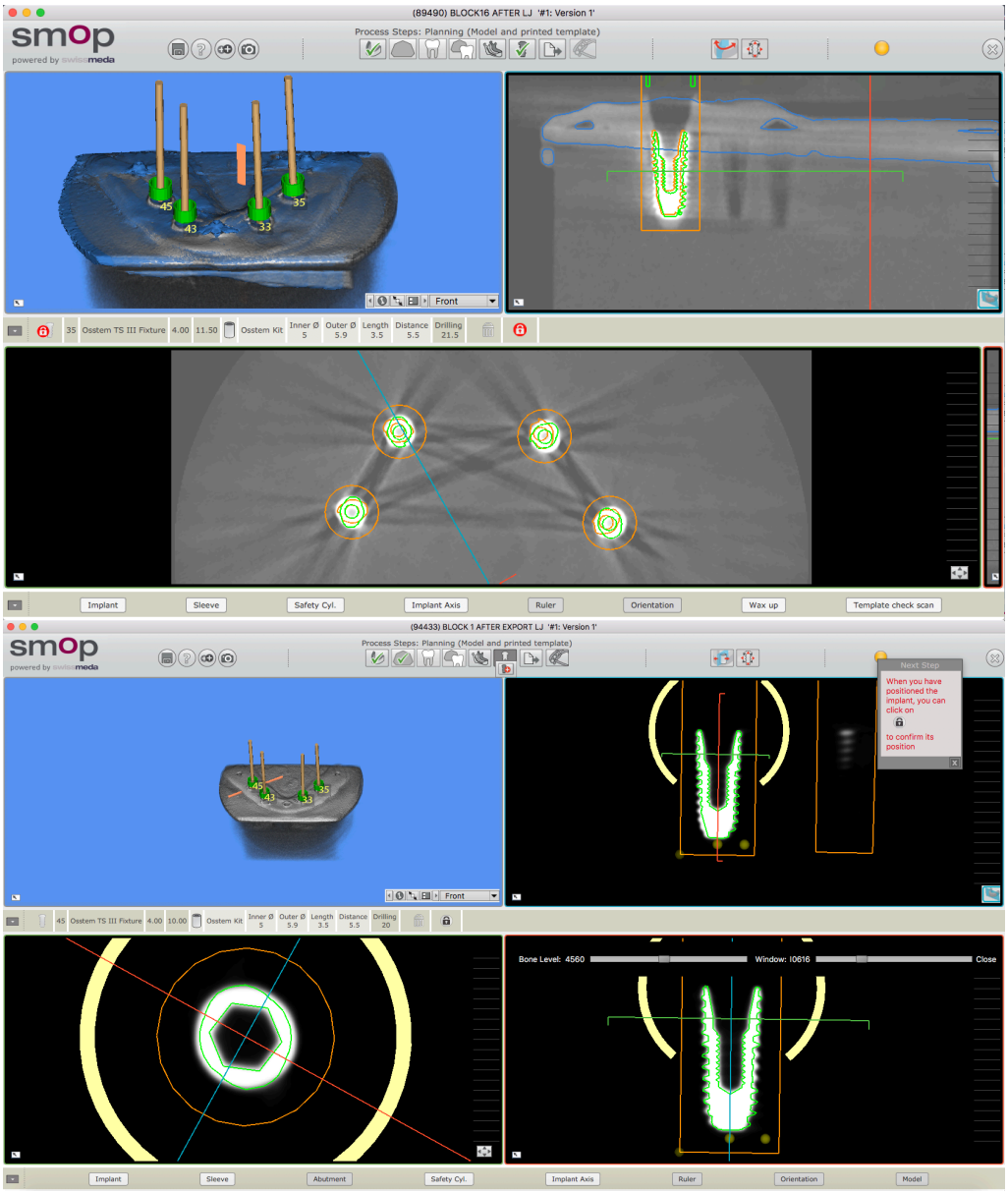

Figure 37. The Swissmeda ZZM Comparison tool

3.3.6 Data Collection Methods;

In this preliminary study the data was collected via a main method on 16 artificial bone blocks and then this main method was repeated ten times on the first block to check validity and precision. A second method was then

used to measure the first block ten times to verify the data and check the accuracy.

3.3.7 Main Method

As SMOP guide planning software was used to plan the positions of the implants, the “ZZM study precision” (Swissmeda, 2017) functionality of the software could be used to compare pre and post implant positions. This involves converting the post placement CBCT into an STL point cloud which the software then calibrates with a virtual position of the post placement. This virtual position is then compared in X&Y horizontal, angulation and height Z point cloud coordinates were compared between the planned and placed positions for both the coronal end and apex. Once the comparison is completed the numerical analysis is added to the clipboard and recorded into a table.

3.3.7.1 Repeat on Block 1 - Same Method

The above method was repeated on the first block a subsequent 9 times to provide ten sets of data and enable an analysis of how precise this method was. The first block from the main data was used to repeat. The aim of this repeat set of data was to show the precision of the main data set.

3.3.7.2 Repeat on Block 1 10x - Second Method

For this second method the planning data was extracted from SMOP and the post placement CBCT scan converted to a point cloud STL through SMOP’s surface extraction software. These two sets of point cloud data were compared through cloudcompare STL mapping comparison software. The centre point of the implant coronal end and the apex were marked on each implant. The X&Y horizontal and height Z point cloud coordinates were

compared between the planned and placed positions for both the coronal and apex. This was then used to calculate the deviation angle.

This second repeat of data was then used to analyse how accurate the data collection was in the first method.

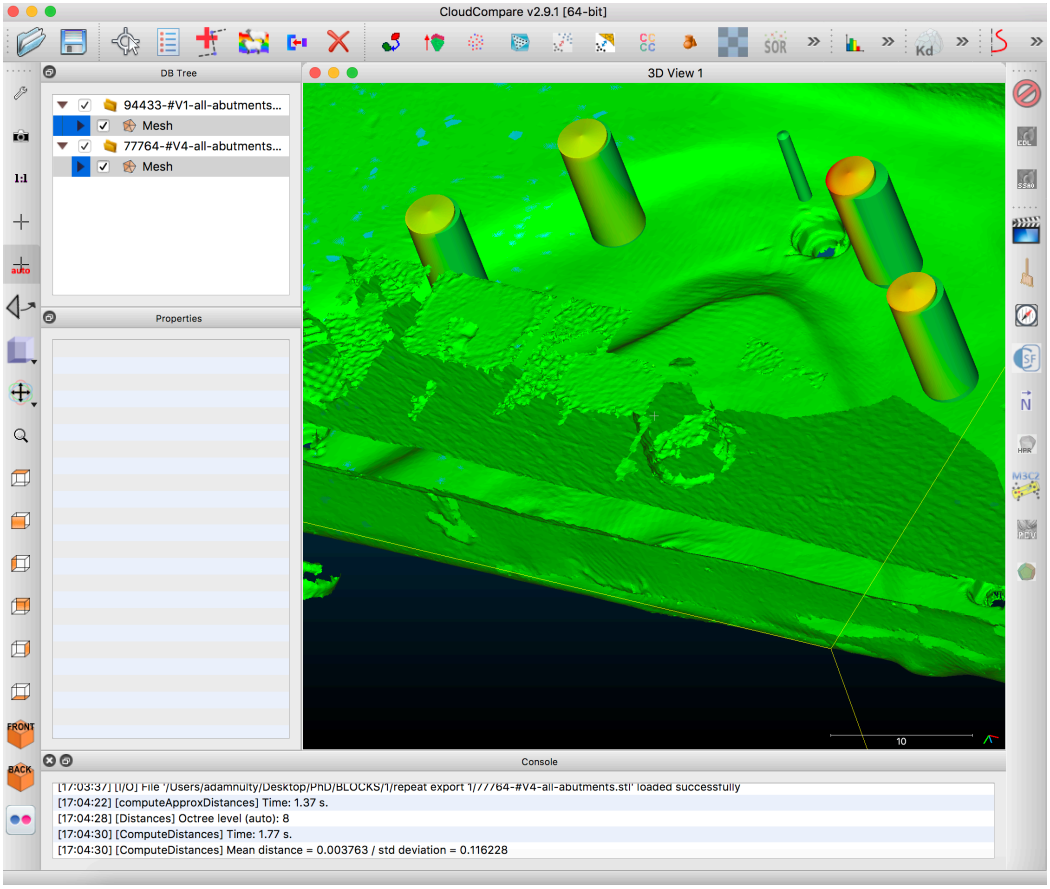

Figure 38. Cloudcompare position comparison

3.3.8 Statistical analysis

Statistical analysis was performed using SPSS 25 statistical analysis software. (George and Mallery, 2019)

The statistics were performed in four separate groups as each block has four implants. The data from these four positions were not independent as they had the same guide sitting in the same position. The results were therefore distinguished into four data sets for the 16 blocks in positions 35, 33, 43, 45

for the comparison to the repeats of the first block data with the intention to analyse with a t-test.

The data recorded was as follows. This can be visualized in Figure 6.

- Coronal X – This was the deviation in mm from the centre of the virtual planned position to the centre of the placed position in the X axis at the coronal end of the implant.
- Coronal Y – This was the deviation in mm from the centre of the virtual planned position to the centre of the placed position in the Y axis at the coronal end of the implant.
- Overall coronal radial Deviation – This was the overall maximum diagonal deviation in mm from the centre of the virtual planned position to the centre of the placed position at the coronal end of the implant.
- Apical X – This was the deviation in mm from the centre of the virtual planned position to the centre of the placed position in the X axis at the apical end of the implant.
- Apical Y – This was the deviation in mm from the centre of the virtual planned position to the centre of the placed position in the X axis at the apical end of the implant.
- Overall apical radial deviation – This was the overall maximum diagonal deviation in mm from the centre of the virtual planned position to the centre of the placed position at the apical end of the implant.

Angle – This was the angular deviation in degrees from the long axis of the virtual planned position to the long axis of the placed position as recorded at the apical end of the implant.

Software and Data Grouping:

Software Used: SPSS 25 statistical analysis software was employed for the analysis.

Grouping: The analysis was categorized into four distinct groups, each representing a block with four implants. These groups were not independent due to the shared guide and position.

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Statistical Methods:

A normality test was meticulously conducted using SPSS to assess whether the data collected in the study adheres to a normal distribution. The Shapiro-Wilk test was employed within SPSS.

The results indicated that the p-value was greater than the significance level of 0.05 for each variable, suggesting the data did not provide sufficient evidence to conclude that the distribution of the sample data significantly deviates from a normal distribution.

A Paired Sample T-Test was chosen as the statistical method to compare the means of the two groups: placements with the Fixed Edentulous Implant Guide (FEIG) and placements without it. The rationale behind selecting a Paired Sample T-Test lies in the inherent structure of the study and the nature of the collected data.

Reasoning:

Non-Independence of Observations:

In each group, the four implants were non-independent of each other, sharing the same guide and position. This interdependence within groups

violates the independence assumption of an Independent Sample T-Test and one-way ANOVA, making them unsuitable for this analysis.

Comparison of Related Groups:

The Paired Sample T-Test is designed to compare the means of two related groups. Given that the implants within each block are related due to the shared guide and position, this test is apt for analyzing the difference in means between the placements with and without the FEIG method.

Objective of Comparison:

The primary objective was to assess the difference in implant placements with and without the FEIG method. The Paired Sample T-Test effectively allows for the comparison of means between two related groups, providing insights into the impact of the FEIG method on the accuracy of implant placements.

The utilization of a Paired Sample T-Test in this study is justified due to the non-independence of the four implants within each group and the necessity to compare the means of two related groups to discern the efficacy of the Fixed Edentulous Implant Guide in improving the accuracy of implant placements.

3.4 Results

3.4.1 Repeat of Block 1 10x;

BLOCK REPEAT	Position	Coronal X	Coronal Y	Overall Coronal Radial Deviation	Height Z	Apical X	Apical Y	Overall Apical Radial Deviation	Angle
1	35	0.17	0.19	0.25	-0.05	2.1	0.36	2.13	0.5
2		0.07	0.34	0.35	0.04	1.9	0.06	1.90	0.67
3		0.23	0.13	0.26	0.41	1.2	0.18	1.21	0.34
4		0.17	0.18	0.25	-0.03	2.4	0.13	2.40	0.24
5		0.01	0.02	0.02	-0.09	1.2	0.01	1.20	0.22
6		0.17	0.19	0.25	0.2	2	0.3	2.02	0.56
7		0.06	0.35	0.36	0.2	1.7	0.05	1.70	0.64
8		0.54	0.45	0.70	-0.08	1.6	0.11	1.60	0.72
9		0.04	0.26	0.26	0.03	1.6	0.04	1.60	0.54
10		0.27	0.64	0.69	-0.14	1.6	0.27	1.62	0.92
1	33	0.38	0.42	0.57	-0.03	3.1	0.73	3.18	0.82
2		0.19	0.52	0.55	0.08	2.1	0.49	2.16	0.72
3		0.03	0.31	0.31	0.05	3.3	0.27	3.31	0.8
4		0	0.04	0.04	0.04	3	0.19	3.01	0.53
5		0.2	0.26	0.33	-0.2	2.3	0.4	2.33	0.61
6		0.39	0.43	0.58	0.07	3.3	0.49	3.34	0.87
7		0.29	0.45	0.54	0.33	2.6	0.55	2.66	0.81
8		0.27	0.47	0.54	0.12	3.2	0.52	3.24	0.82
9		0.21	0.51	0.55	0.18	2.5	0.46	2.54	0.86
10		0.59	0.71	0.92	0.03	3.2	0.87	3.32	0.69
1	43	0.43	0.2	0.47	-0.11	1.1	0.52	1.22	0.02
2		0.27	0.02	0.27	0.07	1.6	0.54	1.69	0.06
3		0.11	0.3	0.32	0.58	1.3	0.31	1.34	0.17
4		0.14	0.29	0.32	0.11	1.2	0.07	1.20	0.3
5		0.08	0.15	0.17	0.07	1.2	0.29	1.23	0.16
6		0.39	0.17	0.43	0.36	0.8	0.47	0.93	0.28
7		0.21	0.06	0.22	0.63	1.5	0.3	1.53	0.05
8		0.6	0.35	0.69	0.22	1.4	0.66	1.55	0.25
9		0.34	0.18	0.38	0.2	1.5	0.6	1.62	0.18
10		0.43	0.18	0.47	0.19	1.3	0.84	1.55	0.25
1	45	0.46	0.09	0.47	-0.02	1	0.6	1.17	0.2
2		0.33	0.11	0.35	0.56	2	0.68	2.11	0.16
3		0.22	0.18	0.28	0.72	1.1	0.42	1.18	0.18
4		0.05	0.22	0.23	0.25	0.9	0.39	0.98	0.16

5	0.12	0.09	0.15	0.16	1.3	0.33	1.34	0.04
6	0.34	0.26	0.43	0.5	1.3	0.57	1.42	0.31
7	0.23	0.24	0.33	0.69	0.4	0.25	0.47	0.3
8	0.38	0.18	0.42	0.29	0.4	0.58	0.70	0.45
9	0.45	0.03	0.45	0.24	0.7	0.58	0.91	0.03
10	0.58	0.39	0.70	0.29	0.9	0.62	1.09	0.46

Table 2. Repeat of Block 1 10x data

Table 2 presents the repeated measurements data for Block 1, conducted ten times. This table provides insight into the variability and consistency of the measurements within the first block, offering a preliminary understanding of the precision of the method under consideration. Each row represents a separate repetition, detailing the deviations and discrepancies observed in each instance.

A box plot of the 1st method repeat block data output categories as given by the SMOP ZZM tool is shown in Figure 39.

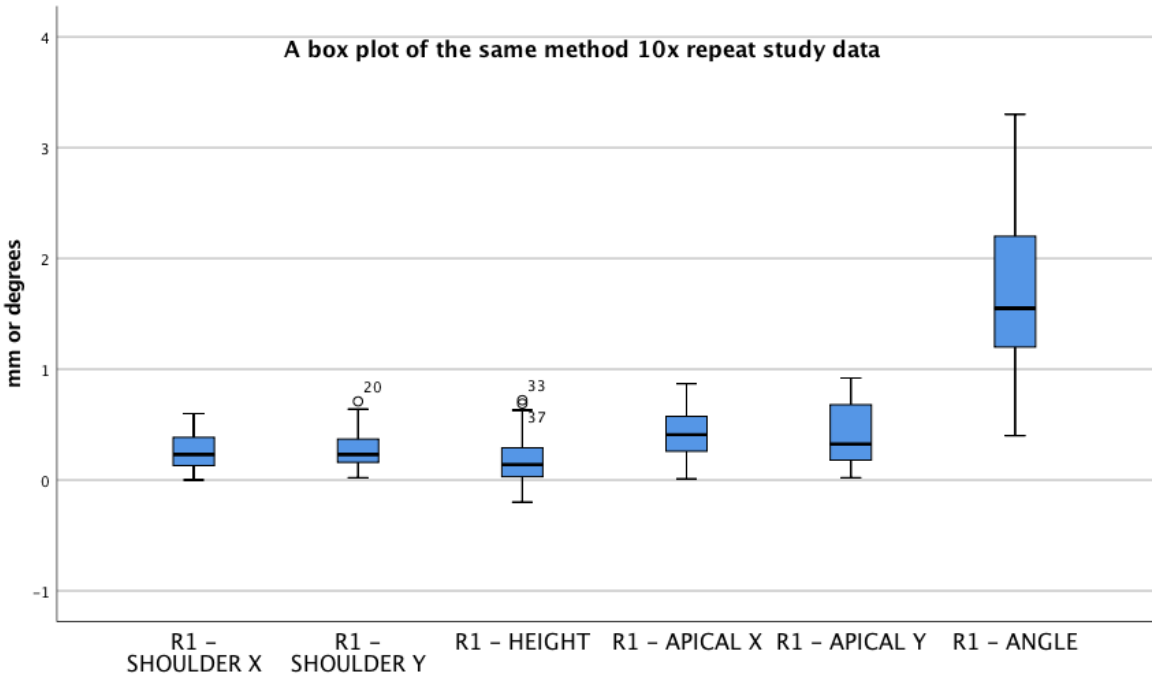

Figure 39. A box plot of the same method, 10x repeat study data

3.4.2 Repeat of Block 1 10x (Second Method)

BLOCK REPEAT	Position	Coronal X	Coronal Y	Overall Coronal Radial Deviation	Height Z	Apical X	Apical Y	Overall Apical Radial Deviation	Angle
1	35	0.07	0.09	0.11	0.042	0.21	0.52	0.56	1.68
2		0.05	0.17	0.18	0.043	0.23	0.29	0.37	2.16
3		0.12	0.18	0.22	0.04	0.34	0.32	0.47	2.64
4		0.15	0.17	0.23	0.04	0.28	0.28	0.40	1.56
5		0.05	0.16	0.17	0.041	0.36	0.52	0.63	3.72
6		0.17	0.2	0.26	0.041	0.1	0.38	0.39	-0.84
7		0.23	0.23	0.33	0.041	0.35	0.5	0.61	1.44
8		0.22	0.2	0.30	0.042	0.23	0.45	0.51	0.12
9		0.03	0.16	0.16	0.04	0.32	0.44	0.54	3.48
10		0.02	0.18	0.18	0.043	0.27	0.51	0.58	3.00
1	33	0.34	0.4	0.52	0.07	0.44	0.68	0.81	1.57
2		0.3	0.24	0.38	0.07	0.46	0.67	0.81	2.50
3		0.2	0.45	0.49	0.05	0.47	0.71	0.85	4.23
4		0.3	0.37	0.48	0.08	0.46	0.72	0.85	2.50
5		0.29	0.34	0.45	0.04	0.43	0.7	0.82	2.19
6		0.2	0.51	0.55	0.08	0.45	0.71	0.84	3.91
7		0.29	0.42	0.51	0.07	0.46	0.69	0.83	2.66
8		0.27	0.55	0.61	0.09	0.43	0.75	0.86	2.50
9		0.22	0.45	0.50	0.07	0.54	0.76	0.93	5.01

10		0.27	0.36	0.45	0.06	0.45	0.73	0.86	2.82
1	43	0.34	0.23	0.41	0.3	0.4	0.19	0.44	0.94
2		0.34	0.15	0.37	0.18	0.42	0.26	0.49	1.25
3		0.38	0.17	0.42	0.2	0.44	0.24	0.50	0.94
4		0.36	0.18	0.40	0.26	0.45	0.19	0.49	1.41
5		0.37	0.22	0.43	0.27	0.38	0.15	0.41	0.16
6		0.32	0.17	0.36	0.27	0.5	0.2	0.54	2.82
7		0.32	0.15	0.35	0.28	0.44	0.18	0.48	1.88
8		0.31	0.3	0.43	0.3	0.39	0.17	0.43	1.25
9		0.31	0.32	0.45	0.25	0.34	0.23	0.41	0.47
10		0.35	0.32	0.47	0.33	0.44	0.15	0.46	1.41
1	45	0.31	0.15	0.34	0.3	0.44	0.21	0.49	1.20
2		0.36	0.27	0.45	0.35	0.43	0.22	0.48	1.68
3		0.35	0.16	0.38	0.32	0.43	0.22	0.48	1.56
4		0.28	0.23	0.36	0.31	0.43	0.19	0.47	1.08
5		0.28	0.16	0.32	0.31	0.48	0.19	0.52	1.08
6		0.37	0.22	0.43	0.28	0.45	0.23	0.51	1.68
7		0.3	0.18	0.35	0.32	0.43	0.21	0.48	1.08
8		0.37	0.19	0.42	0.27	0.52	0.24	0.57	1.56
9		0.32	0.18	0.37	0.35	0.46	0.21	0.51	1.32
10		0.31	0.18	0.36	0.35	0.44	0.28	0.52	0.36

Table 3. Repeat of Block 1 10x data - Second Method

Table 3 shows the repeated measurements data for Block 1 using a second method, conducted ten times as well. This table contrasts the results obtained from the second method with those from the first.

A box plot of the Data output categories as given by the SMOP ZZM tool is shown in Figure 40.

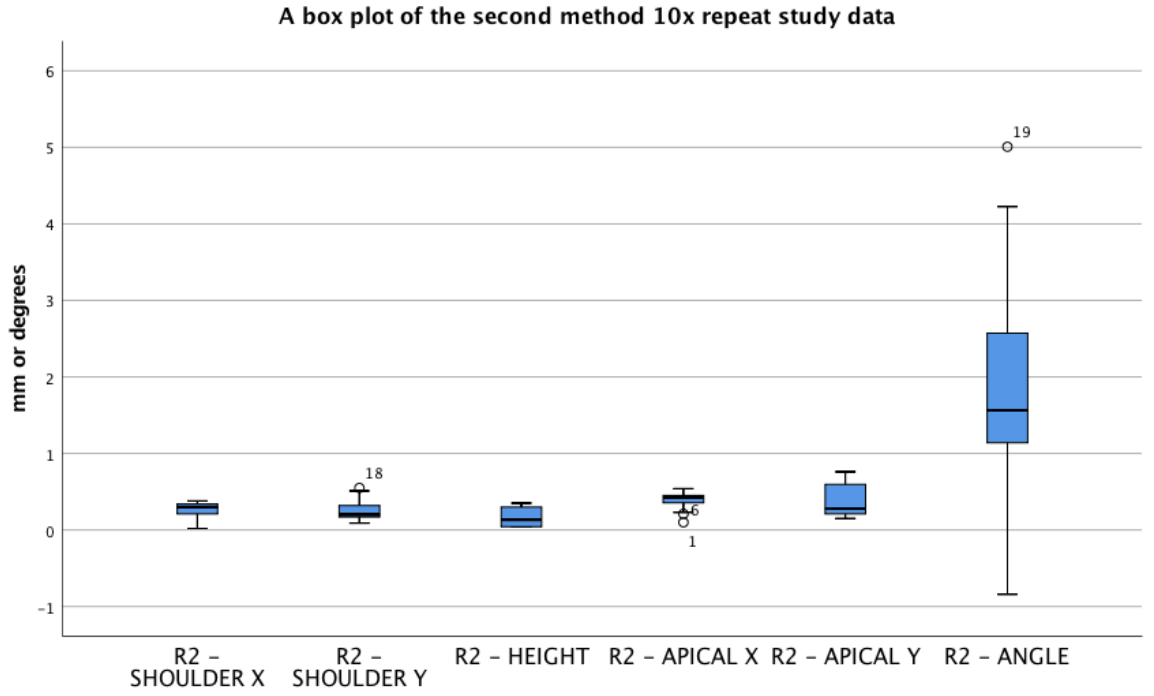

Figure 40. A box plot of the second method 10x repeat study data

3.4.3 Main Data results;

BLOCK	Position	Coronal X	Coronal Y	Overall Coronal Radial Deviation	Height Z	Apical X	Apical Y	Overall Apical Radial Deviation	Angle
1	35	0.17	0.19	0.25	-0.04	0.36	0.5	0.62	2.1
	33	0.38	0.42	0.57	0	0.73	0.82	1.10	3.1
	43	0.43	0.2	0.47	-0.1	0.52	0.02	0.52	1.1
	45	0.46	0.09	0.47	-0.02	0.6	0.02	0.60	1
2	35	0.09	0.3	0.31	0.28	0.01	0.46	0.46	1
	33	0.04	0.13	0.14	0.15	0.15	0.13	0.20	0.6
	43	0.08	0	0.08	0.22	0.07	0	0.07	0
	45	0.11	0.07	0.13	0.43	0.31	0.07	0.32	1.1
3	35	0.41	0.27	0.49	-0.3	0.37	0.41	0.55	0.8
	33	0.46	0.3	0.55	-0.37	0.49	0.29	0.57	0.2
	43	0.36	0.29	0.46	-0.48	0.36	0.48	0.60	1.1
	45	0.13	0.42	0.44	-0.44	0.08	0.77	0.77	2.4
4	35	0.28	0.18	0.33	0.1	0.39	0.17	0.43	0.7
	33	0.36	0.24	0.43	0.22	0.6	0.24	0.65	1.4
	43	0.39	0.32	0.50	0.34	0.54	0.48	0.72	1.3
	45	0.48	0.27	0.55	0.42	0.48	0.35	0.59	0.5
5	35	0	0.13	0.13	0.42	0.01	0.17	0.17	0.3
	33	0.09	0.1	0.13	0.51	0.15	0.16	0.22	0.5
	43	0.27	0.31	0.41	0.73	0.49	0.36	0.61	1.3
	45	0.1	0.15	0.18	0.63	0.26	0.18	0.32	0.9
6	35	0.25	0.03	0.25	0.22	0.25	0.21	0.33	0.9
	33	0.18	0.11	0.21	0.26	0.18	0.11	0.21	0
	43	0.45	0.12	0.47	0.46	0.69	0.12	0.70	1.2
	45	0.24	0.15	0.28	0.58	0.24	0.15	0.28	0
7	35	0.02	0.11	0.11	-0.24	0.02	0.11	0.11	0
	33	0.33	0.02	0.33	-0.26	0.41	0.02	0.41	0.5
	43	0.42	0.09	0.43	0.09	0.5	0.17	0.53	0.7
	45	0.13	0.14	0.19	0.19	0.11	0.14	0.18	1.4
8	35	0.01	0.01	0.01	0.1	0.25	0.23	0.34	2
	33	0.09	0.13	0.16	0.11	0.07	0.03	0.08	1.3
	43	0.39	0.32	0.50	0.25	0.47	0.32	0.57	0.5
	45	0.12	0.04	0.13	0.32	0.2	0.04	0.20	0.5
9	35	0	0.24	0.24	-0.26	0.24	0.33	0.41	1.5
	33	0.06	0.15	0.16	0.17	0.31	0.24	0.39	1.5
	43	0.07	0.1	0.12	0.21	0.07	0.06	0.09	0.9
	45	0.08	0.12	0.14	0.34	0.31	0.47	0.56	2.4
10	35	0.03	0.31	0.31	-0.45	0.03	0.79	0.79	2.8

	33	0.01	0.22	0.22	-0.36	0.01	0.54	0.54	1.8
	43	0.05	0.06	0.08	-0.03	0.05	0.06	0.08	0
	45	0.04	0.23	0.23	0.02	0.04	0.31	0.31	0.5
11	35	0.12	0.24	0.27	0.18	0.14	0.36	0.39	0.8
	33	0.35	0.32	0.47	0.49	0.54	0.5	0.74	1.3
	43	0.13	0.07	0.15	0.52	0.03	0.08	0.09	0.5
	45	0.09	0.12	0.15	0.33	0.04	0.2	0.20	1
12	35	0.1	0.21	0.23	0.23	0.19	0.58	0.61	1.9
	33	0.13	0.12	0.18	0.07	0.23	0.4	0.46	1.5
	43	0.04	0.14	0.15	0.39	0.04	0.32	0.32	0.9
	45	0.09	0.26	0.28	0.45	0.09	0.35	0.36	0.5
13	35	0.18	0.12	0.22	0.44	0.22	0.2	0.30	0.5
	33	0.32	0.02	0.32	0.17	0.34	0.21	0.40	0.9
	43	0.21	0.15	0.26	0.46	0.3	0.18	0.35	0.5
	45	0.36	0.12	0.38	0.33	0.54	0.12	0.55	0.9
14	35	0.18	0.07	0.19	0.31	0.19	0.19	0.27	0.6
	33	0.27	0.24	0.36	0.28	0.32	0.35	0.47	0.6
	43	0.4	0.06	0.40	0.25	0.34	0.01	0.34	0.4
	45	0.44	0.02	0.44	0.09	0.6	0.13	0.61	1
15	35	0.28	0.09	0.29	-0.45	0.38	0.2	0.43	0.8
	33	0.02	0.3	0.30	0.08	0.14	0.47	0.49	1
	43	0.07	0.05	0.09	0.14	0.04	0.08	0.09	0.6
	45	0.06	0.14	0.15	0.15	0.13	0.11	0.17	0.9
16	35	0.41	0.26	0.49	0.46	0.38	0.53	0.65	1.4
	33	0.48	0.05	0.48	0.27	0.53	0.05	0.53	0.6
	43	0.05	0.25	0.25	0.24	0.02	0.21	0.21	0.5
	45	0.11	0.01	0.11	0.5	0.17	0.07	0.18	0.5

Table 4. Main study results data

Table 4 encompasses the primary results data of the main study. It compiles the measurements and findings from all the blocks. It includes the deviations, angular discrepancies, and other pertinent data points collected during the study, serving as the foundation for the subsequent statistical analysis and interpretation of the study's results.

A box plot of this Data output categories as given by the SMOP ZZM tool is shown in Figure 41;

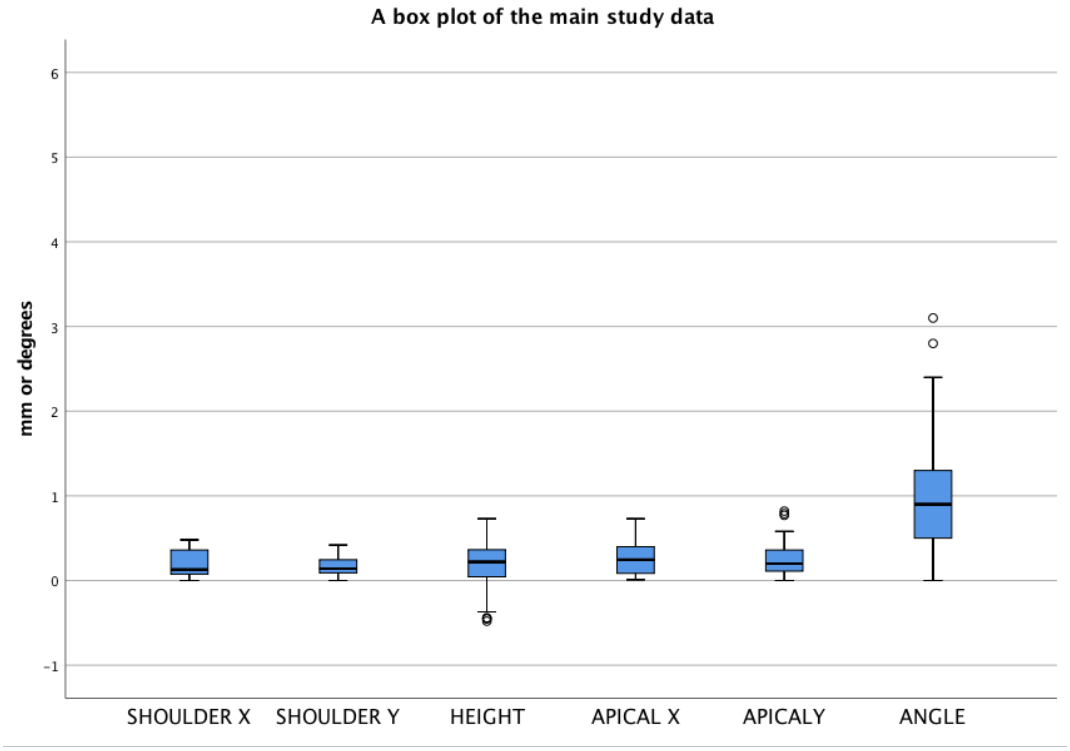

Figure 41. A box plot of the main study data

3.4.4 Statistical Analysis of Data Sets;

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
35 SHOULDER X	16	.00	.41	.15	.13
35 SHOULDER Y	16	.01	.31	.17	.09
35 HEIGHT	16	-.45	.46	.06	.31
35 APICAL X	16	.01	.39	.21	.14
35 APICAL Y	16	.11	.79	.34	.19
35 ANGLE	16	.00	2.80	1.13	.75
33 SHOULDER X	16	.01	.48	.22	.16
33 SHOULDER Y	16	.02	.42	.17	.11
33 HEIGHT	16	-.37	.51	.11	.25
33 APICAL X	16	.01	.73	.32	.20
33 APICAL Y	16	.02	.82	.28	.21
33 ANGLE	16	.00	3.10	1.05	.75
43 SHOULDER X	16	.04	.60	.27	.18
43 SHOULDER Y	16	.05	.32	.16	.10
43 HEIGHT	16	-.48	.73	.21	.28
43 APICAL X	16	.02	.69	.29	.22
43 APICAL Y	16	.01	.48	.18	.15
43 ANGLE	16	.00	1.30	.71	.41
45 SHOULDER X	16	.00	2.40	.32	.57
45 SHOULDER Y	16	.01	.77	.17	.17
45 HEIGHT	16	-.02	.63	.28	.20
45 APICAL X	16	-.44	.60	.23	.26
45 APICAL Y	16	.02	.47	.21	.13
45 ANGLE	16	.00	2.40	.76	.58
Valid N (listwise)	16				

Table 5. Main data descriptive statistics

Table 5 shows the descriptive statistics of the main study data, as produced by SPSS, offering a summarized view of the central tendencies, spread, and distribution of the collected data. This table includes measures such as

mean, median, standard deviation, and range, providing a concise and coherent summary of the main study results.

3.5 Accuracy (Trueness and Precision)

In the context of this in vitro study, "trueness" and "precision" are terms used to describe the accuracy of the implant placements using the Fixed Edentulous Implant Guide (FEIG) method as it compares to conventional soft tissue borne guided implant placement, and is defined as follows; (Ender and Mehl, 2013)

Trueness:

Trueness refers to the degree to which the mean measurements of repeated implant placements align with the actual or true value. It is a measure of the closeness of agreement between the true value (the planned position in this study) and the average of repeated measured values (the actual placed position). In essence, trueness is concerned with the systematic errors and provides an indication of the bias in the measurements.

Precision:

Precision, on the other hand, is concerned with the closeness of agreement between the individual measurements within a dataset. It relates to the spread of the measured values and is independent of trueness. A method is said to be precise if the repeated measurements under unchanged conditions show little variation or scatter, indicating that the method has low random error.

Application in the Study:

In this study, trueness would be evaluated by comparing the mean values of the implant placements using the FEIG method to the planned positions,

assessing how close the average of the measured values is to the true value. Precision would be assessed by analyzing the spread or variation in the individual implant placements around the mean value, indicating the consistency and reliability of the FEIG method in repeated measurements.

3.5.1 Paired Sample T-Test - Main Data vs Repeat Method 1 (Precision);

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	35 SHOULDER X - R1 - SHOULDER X 35	-.04	.20	.06	-.19	.09	-.73	9	.48
Pair 2	33 SHOULDER X - R1 - SHOULDER X 33	-.05	.28	.09	-.26	.15	-.60	9	.56
Pair 3	43 SHOULDER X - R1 - SHOULDER X 43	.04	.24	.07	-.13	.22	.54	9	.59
Pair 4	45 SHOULDER X - R1 - SHOULDER X 45	.08	.78	.24	-.46	.64	.36	9	.72
Pair 5	35 SHOULDER Y - R1 - SHOULDER Y 35	-.09	.18	.05	-.23	.03	-1.63	9	.13
Pair 6	33 SHOULDER Y - R1 - SHOULDER Y 33	-.23	.22	.07	-.39	-.06	-3.21	9	.01
Pair 7	43 SHOULDER Y - R1 - SHOULDER Y 43	-.00	.07	.02	-.05	.05	-.04	9	.96
Pair 8	45 SHOULDER Y - R1 - SHOULDER Y 45	.02	.21	.06	-.12	.18	.40	9	.69
Pair 9	35 HEIGHT - R1 - HEIGHT 35	-.06	.36	.11	-.32	.19	-.57	9	.58
Pair 10	33 HEIGHT - R1 - HEIGHT 33	-.02	.37	.11	-.29	.24	-.20	9	.84
Pair 11	43 HEIGHT - R1 - HEIGHT 43	-.08	.45	.14	-.41	.24	-.58	9	.57
Pair 12	45 HEIGHT - R1 - HEIGHT 45	-.10	.35	.11	-.35	.14	-.93	9	.37
Pair 13	35 APICAL X - R1 - APICAL X 35	.04	.15	.04	-.06	.15	.87	9	.40
Pair 14	33 APICAL X - R1 - APICAL X 33	-.18	.35	.11	-.43	.06	-1.67	9	.12
Pair 15	43 APICAL X - R1 - APICAL X 43	-.06	.38	.12	-.34	.20	-.56	9	.58
Pair 16	45 APICAL X - R1 - APICAL Y 45	-.00	.35	.11	-.25	.24	-.05	9	.95
Pair 17	35 APICAL Y - R1 - APICAL Y 35	-.19	.20	.06	-.34	-.05	-3.06	9	.01
Pair 18	33 APICAL Y - R1 - APICAL Y 33	-.49	.27	.08	-.69	-.29	-5.70	9	.00
Pair 19	43 APICAL Y - R1 - APICAL Y 43	.04	.16	.05	-.07	.16	.80	9	.44
Pair 20	45 APICAL Y - R1 - APICAL Y 45	.01	.25	.08	-.17	.19	.12	9	.90
Pair 21	35 ANGLE - R1 - ANGLE 35	-.52	.92	.29	-1.18	.14	-1.78	9	.10
Pair 22	33 ANGLE - R1 - ANGLE 33	-1.77	.95	.30	-2.45	-1.08	-5.86	9	.00
Pair 23	43 ANGLE - R1 - ANGLE 43	-.48	.66	.21	-.95	-.00	-2.28	9	.04
Pair 24	45 ANGLE - R1 - ANGLE 45	-.26	1.05	.33	-1.01	.49	-.77	9	.45

Table 6. Paired Sample T-Test - Main Data vs Repeat Method 1 (Precision)

3.5.2 Results

20 of the 24 pairs of data sets above were not significantly different as the sig/p value was greater than 0.05, as shown in Table 6.

The difference between Apical horizontal Y position for positions 35, 33 and the Angulation of positions 35 and 43 were significantly different but out of these the mean was under 0.5mm which one could argue was not clinically significant.

3.5.3 Paired Sample T-Test - Repeat Method 1 vs Repeat Method 2

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	R1 - SHOULDER X 35 - R2 - SHOULDER X 35	.06	.14	.04	-.03	.16	1.38	9	.19
Pair 2	R1 - SHOULDER X 33 - R2 - SHOULDER X 35	-.01	.17	.05	-.13	.11	-.23	9	.82
Pair 3	R1 - SHOULDER X 43 - R2 - SHOULDER X 43	-.04	.18	.05	-.17	.09	-.68	9	.51
Pair 4	R1 - SHOULDER X 45 - R2 - SHOULDER X 45	-.00	.15	.04	-.11	.10	-.18	9	.85
Pair 5	R1 - SHOULDER Y 35 - R2 - SHOULDER Y 35	.10	.16	.05	-.02	.22	1.88	9	.09
Pair 6	R1 - SHOULDER Y 33 - R2 - SHOULDER Y 35	.00	.19	.06	-.13	.14	.04	9	.96
Pair 7	R1 - SHOULDER Y 43 - R2 - SHOULDER Y 43	-.03	.10	.03	-.10	.04	-.97	9	.35
Pair 8	R1 - SHOULDER Y 45 - R2 - SHOULDER Y 45	-.01	.10	.03	-.09	.06	-.38	9	.71
Pair 9	R1 - HEIGHT 35 - R2 - HEIGHT 35	.00	.17	.05	-.11	.13	.14	9	.89
Pair 10	R1 - HEIGHT 33 - R2 - HEIGHT 33	-.00	.12	.04	-.09	.09	-.02	9	.98
Pair 11	R1 - HEIGHT 43 - R2 - HEIGHT 43	-.03	.24	.07	-.20	.14	-.41	9	.68
Pair 12	R1 - HEIGHT 45 - R2 - HEIGHT 45	.05	.23	.07	-.11	.22	.69	9	.50
Pair 13	R1 - APICAL X 35 - R2 - APICAL X 35	-.11	.18	.05	-.24	.01	-2.02	9	.07
Pair 14	R1 - APICAL X 33 - R2 - APICAL X 33	.03	.20	.06	-.10	.18	.58	9	.57
Pair 15	R1 - APICAL X 43 - R2 - APICAL X 43	.04	.23	.07	-.12	.20	.53	9	.60
Pair 16	R1 - APICAL X 45 - R2 - APICAL X 45	.05	.14	.04	-.05	.15	1.12	9	.28
Pair 17	R1 - APICAL Y 35 - R2 - APICAL Y 35	.11	.21	.06	-.03	.26	1.68	9	.12
Pair 18	R1 - APICAL Y 33 - R2 - APICAL Y 33	.04	.11	.03	-.03	.12	1.15	9	.27
Pair 19	R1 - APICAL Y 43 - R2 - APICAL Y 43	-.02	.11	.03	-.10	.05	-.65	9	.53
Pair 20	R1 - APICAL Y 45 - R2 - APICAL Y 45	.00	.12	.04	-.08	.10	.22	9	.83
Pair 21	R1 - ANGLE 35 - R2 - ANGLE 35	-.16	1.6	.52	-1.35	1.02	-.31	9	.76
Pair 22	R1 - ANGLE 33 - R2 - ANGLE 33	-.12	1.0	.34	-.91	.65	-.37	9	.71
Pair 23	R1 - ANGLE 43 - R2 - ANGLE 43	.03	.86	.27	-.57	.65	.13	9	.89
Pair 24	R1 - ANGLE 45 - R2 - ANGLE 45	-.25	.51	.16	-.62	.10	-1.59	9	.14

(Trueness);

Table 7. Paired Sample T-Test - Repeat Method 1 vs Repeat Method 2 (Trueness)

3.5.4 Results;

24 of the 24 pairs of data sets above were not significantly different as the sig/p value was greater than 0.05, as shown in Table 7.

Whilst this experiment was an *in vitro* study and the methodologies are different, we can look at the overall results from this preliminary *in vitro* study along with *in vivo* edentulous studies.

3.5.5 Summary of Means;

Data Set	Coronal X	Coronal Y	Overall Coronal Radial Deviation	Height Z	Apical X	Apical Y	Overall Apical Radial Deviation	Angle
Main data	0.2 (SD 0.15)	0.16 (SD 0.10)	0.28 (SD 0.15)	0.17 (SD 0.29)	0.27 (SD 0.20)	0.25 (SD 0.19)	0.41 (SD 0.22)	0.96 (SD 0.66)
Repeat - Same Method	0.26 (SD 0.17)	0.26 (SD 0.17)	0.40 (SD 0.19)	0.17 (SD 0.23)	0.40 (SD 0.22)	0.42 (SD 0.28)	0.65 (SD 0.25)	1.72 (SD 0.81)
Repeat - 2nd Method	0.26 (SD 0.10)	0.25 (SD 0.11)	0.37 (SD 0.12)	0.17 (SD 0.12)	0.40 (SD 0.09)	0.39 (SD 0.22)	0.58 (SD 0.17)	1.85 (SD 1.19)

Table 8. Summary of Means

3.6 Discussion

If the mean results of this study are compared to similar published studies, there appears to be promise in this method and it merits further clinical study.

Using the values from Arisan et al (Arisan et al., 2010) - a study on conventional mucosal borne edentulous guided surgery with a sample size of 147, Mean Angular deviation of 2.9 degrees (SD 0.39) and an insertion horizontal deviation of 0.70 mm (SD 0.13 mm) a one-sample t-test was performed separately for each of the positions in the data set.

It's crucial to note that the study by Arisan et al. was a clinical trial, conducted in a real-world clinical setting, whereas the preliminary study was a laboratory trial, conducted in a controlled environment. The results from the preliminary study suggest that the new placement method could potentially be more accurate compared to the results of Arisan's study. However, this comparison should be interpreted with caution due to the fundamental differences in the study contexts.

Comparing clinical trials to laboratory trials involves contrasting real-world, patient-centered research with controlled, experimental research. The inherent variability and complexity of clinical settings can introduce numerous variables and potential sources of error that are not present in the more controlled environment of a laboratory trial. Therefore, while the preliminary study's results are promising, further clinical trials are necessary to validate the efficacy and accuracy of the new placement method in real-world clinical scenarios.

By conducting further research that aligns more closely in methodology and context with Arisan et al.'s study, a more accurate and reliable comparison

can be made, contributing to the development of more effective and precise placement methods.”

Using the values from Kernan et al (Kernen et al., 2015) - a study on tooth borne conventional guided surgery based with SMOP guide software with a sample size of 34, Mean Angular deviation of 2.9 degrees (SD 0.39), Insertion horizontal deviation of 0.23 mm (SD 0.21 mm) and Vertical depth deviation 0.20 mm (SD 0.14 mm) a one-sample t-test was performed separately for each of the positions in the data set.

The results from the preliminary study above *suggest* the new placement method is potentially more accurate when compared to the results of Kernan’s study with regards to mean angular deviation but comparable to the mean of the horizontal coronal deviation.

Using the values of mean from Behneke et al (Behneke, 2009) - which focused on various types of guided surgery—specifically data from the flapless tooth borne guided surgery with a sample size of 66, exhibiting a Mean Angular deviation of 2.11 degrees (SD 3.11) and an Insertion horizontal deviation of 0.36 mm (SD 0.45 mm)—a one-sample t-test was conducted separately for each of the positions in the data set. The results from the preliminary study suggest that the new placement method could potentially be more accurate compared to the results of Behneke’s study.

It is crucial to acknowledge a significant caveat in these comparisons. The studies from Arisan, Kernan, and Behneke were conducted in vivo, involving live subjects, whereas the presented study is an in vitro study, conducted in

a controlled laboratory setting. This distinction is paramount as in vivo and in vitro studies have inherent differences, variabilities, and limitations.

Implications and Future Directions:

The comparison of in vitro results to those obtained from in vivo studies should be approached with caution, and the conclusions drawn should be considered preliminary. It is essential to compare the new method with other methods under similar conditions, preferably through lab studies, to ensure the reliability and validity of the comparisons made. The inherent complexities and variabilities of live subjects in in vivo studies introduce different dynamics and challenges that are not present in controlled in vitro environments.

To truly validate the efficacy and accuracy of the new placement method, it is imperative to conduct further in vitro studies comparing it with other lab studies of similar methods. Additionally, subsequent in vivo studies will be crucial to assess the method’s applicability, effectiveness, and reliability in real-world clinical scenarios.

The null hypothesis was that the new method of alignment results in implant placement which was not within acceptable clinical tolerances (0.5 mm apical and coronal deviation and 2 degrees axis deviation) of the planned position.

However it has been shown that there is no difference in the clinically acceptable tolerances, between the planned and actual implant placement position. Therefore the null hypothesis is rejected.

Within the results, it is evident that the first block, when repeated ten times, shows consistency. A paired sample t-Test was conducted, comparing the main data with repeat method 1. Out of 24 pairs of data sets, 20 were not

significantly different, as indicated by a sig/p value greater than 0.05. Therefore, we can conclude that the methodology used to measure the difference in position after placement was precise for these data sets.
The first block was repeated ten times with a different method and a paired sample t-Test was carried out on the main data vs the second method repeated. All 24 of the 24 pairs of data sets above were not significantly different as the sig/p value was greater than 0.05. It can therefore be said that for these data sets the methodology used to measure the difference in position after placement was true as two different methodologies of measurement produced data that was not significantly different statistically.
Whilst looking at the results from the existing in vivo literature, the results from this experiment can lead to the conclusion that that the novel approach to edentulous guided surgery shows potential for improved accuracy over existing techniques. Further work is therefore justified to investigate (in an *in vivo* study) if this new methodology is significantly more accurate than previous studies have been shown to be for conventional tooth borne, edentulous or flapless surgery to be.
The full benefits of template-guided implant placement for an edentulous patient cannot be quantified in this preliminary study such as healing, morbidity etc but if the results of the preliminary study can be repeated clinically then it could pave the way for a predictable and more accurate way of treating edentulous patients.

The data in this preliminary study is potentially comparable and in some respects potentially more accurate than clinical studies as discussed above.

In Van Assche's (Van Assche et al., 2012) meta analysis on 19 publications the mean error was 0.99mm (ranging from 0.01 - 6.5mm) at the implant coronal tip and 1.24mm (ranging from 0.0 - 6.9mm) at the apex. The mean angular deviation was 3.81 degrees (ranging from 0.04 to 24.9 degrees) and statistically comparable or again significantly more accurate to that of other edentulous guided surgery studies.

This preliminary study does however benefit from ideal scenario results. In conventional patient-based computer assisted guided implant surgery there are several factors that will increase error, one of which would be with the manual data combination of the CBCT and the STL Impression data sets. In a patient, the accuracy of the CBCT is influenced by the artefacts such as metal structures, motion artefacts or poor protocols e.g. without cotton roll placement as discussed by Holberg. (Holberg et al., 2005)

There are several limitations within this in vitro study that must be considered when interpreting the results. One significant limitation is the lack of biological factors within this in-vitro study. With the absence of biological and physiological interactions and responses that are typically present within an in vivo scenario, the results within an in-vitro environment may significantly impede the extrapolation of the findings to in-vivo contexts, thereby affecting the interpretation of the results.

Furthermore, the controlled and stable conditions inherent to in-vitro studies do not adequately represent the myriad of clinical variables and the inherent unpredictability encountered in clinical settings such as mucosal compressibility, variation in anatomy and patient movement. The omission of variables may result in discrepancies between the study's findings and

actual clinical outcomes, potentially impacting the applicability and reliability of the results in clinical scenarios.

Additionally, the simulated materials in this in-vitro study may not accurately replicate the properties of human tissues and anatomical structures, which is another pivotal limitation.

In this study, the utilization of a small orthodontic Temporary Anchorage Device (TAD) screw as opposed to a two-part screw specifically designed for the Fixed Edentulous Implant Guide (FEIG) poses a notable limitation. The employment of a TAD screw, which is not inherently designed for this specific application, may introduce variables and potential inaccuracies that would not be present with a screw designed for the FEIG. The specialized design of a two-part screw for the FEIG would likely offer enhanced compatibility and functionality, ensuring optimal interaction with the guide and potentially improving the precision and trueness of implant placement. The use of a non-specialized screw may compromise the reliability and validity of the study's findings, necessitating careful consideration when interpreting the results and extrapolating them to scenarios where the specifically designed two-part screw is employed.

Whilst the in-vitro study utilizing the FEIG method provides invaluable insights and initial assessments, the aforementioned limitations underscore the imperative for cautious and discerning interpretation and application of the findings.

Therefore it is hoped that this research can be continued with an *in vivo* study, the goal being making flapless edentulous guided surgery more

accurate, reducing morbidity risks and making implant surgery in the provision of full arch restoration more accurate and more predictable.

3.7 Conclusion

The method of using the measuring software/method has been shown to be precise and therefore a potentially useful clinical tool.

Trueness and precision of the angular, apical and coronal positions when using a novel guided implant placement system *in vitro* were shown to be within clinically acceptable limits.

3.8 Clinical Significance

As guided implant surgery can often mean that bone can be utilised in an angular or unconventional approach to avoid grafting, using this method may mean that patients with a medical contraindication to conventional flapped surgery may also benefit from full arch rehabilitation.

Another important area where the result of this study may be beneficial would be in a potential future era of antibiotic resistance as flapless surgery would provide a minimal surgical intervention.

Chapter 4 - A Comparison of Full Arch Trueness and Precision of 9 Intraoral Digital Scanners and 4 Lab Digital Scanners in a Dentate Arch

4.1 Introduction

This study has focused on the precision and trueness of nine modern intra-oral digital scanners and four digital lab scanners. Accuracy consists of trueness and precision (ISO 5725-1). (International Organization for Standardization, 1997) Trueness is, by definition, an indication of how similar a measurement is to a known measured value. (Ender and Mehl, 2013) In the present study, trueness describes the deviation of the measurements in the data set compared to the actual dimensions of the scanned object. Therefore, high trueness indicates that the scanner delivers a result that is very close to the actual dimensions of the object being scanned. Precision expresses the degree of reproducibility or agreement between repeated measurements. In the present study, precision describes how close each measurement in the data set is to the other measurements taken by the same scanner. Therefore, higher precision means that a scanner is capable of taking consistently repeatable scans. As the scan data obtained in a clinical situation is the basis of the planning and design, it is of great importance that the scan is recording an accurate reading in a reproducible way. While there have been several previous studies comparing the accuracy of intra-oral scanners, there are no currently published studies that compare the scanners available in 2020, namely those in the present study, (Braian and Wennerberg, 2019) (Medina-Sotomayor et al., 2019) (Jung et al., 2019) (Fukazawa et al., 2017) (Uhm et al., 2017) which can, given the speed at which the technology is changing, be seen as a gap in the literature

that must be studied. It has been suggested that using a digital intra-oral scanner for a full arch scan is less acceptable as the longer scan distance may introduce a possible error. (Park et al., 2019)

The null hypothesis was that no differences would be found between the various scanners regarding trueness and precision.
A secondary null hypothesis was that there would be no difference between the lab scanners and intra-oral scanners regarding trueness and precision.

4.2 Materials and Methods

4.2.1 Study Model

The present study used the International Digital Dental Academy [IDDA] Calibration Model (Figure 43), which represents three different situations in the maxilla;
A fully dentate arch. Four regular structures in the form of columns of known width and separation. A high degree of surface morphology. As the only studies present were of dentate arches, this calibration model was chosen as we could look to compare the design master STL with the lab scanners and the intra-oral scanners.

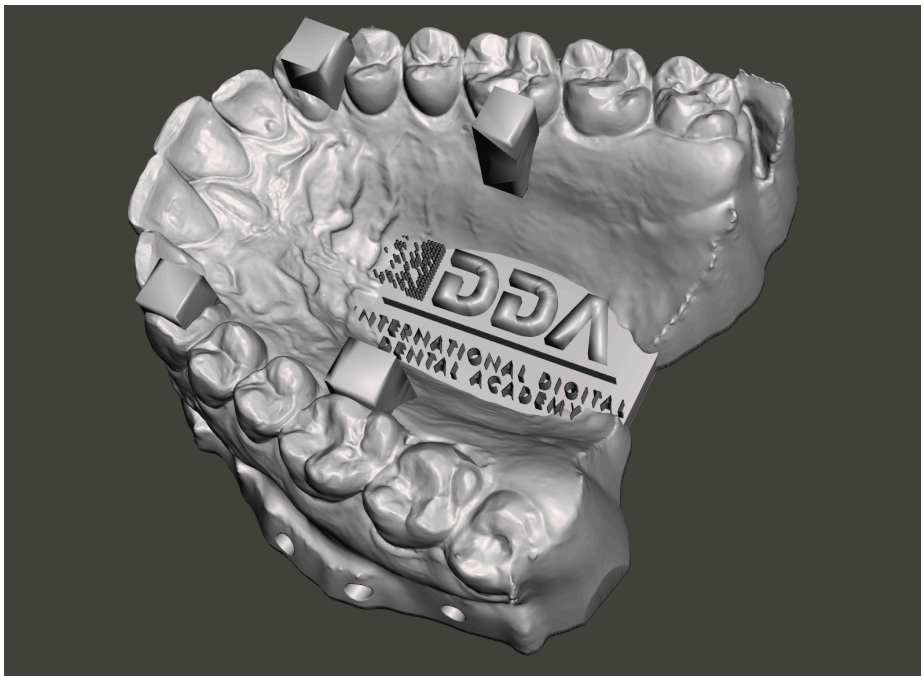

Figure 42. The IDDA Calibration Model (IDDA, 2019)

This master model was printed using an Asiga Max UV and NextDent Model Resin at 50 micron layer height. This printer and resin combination was chosen for high precision and low reflectivity to facilitate the acquisition with the intraoral scanners used in the study. (Etemad-Shahidi et al., 2020) Scans were completed within the same day.

4.2.2 Scanners in the study

The scanners used in the present *in vitro* study are summarised in Table 9.

Name	Manufacturer	Technology	STL Export	PLY/OBJ Colour Export
Omnicam 4.6	Dentsply-Sirona, York, Pennsylvania, USA	Structured light - Optical triangulation and confocal microscopy	YES	NO
Omnicam 5.1	Dentsply-Sirona, York, Pennsylvania, USA	Structured light - Optical triangulation and confocal microscopy	YES	NO
Primescan	Dentsply-Sirona, York, Pennsylvania, USA	Structured light – Confocal microscopy with Smart Pixel sensor.	YES	NO
CS3600	Carestream Dental, Atlanta, Georgia, USA	Structured LED light-Active Speed 3D Video™	YES	YES
Trios 3	3-Shape, Copenhagen, Denmark	Structured light – Confocal microscopy and Ultrafast Optical Scanning™	YES	YES
Trios 4	3-Shape, Copenhagen, Denmark	Structured light – Confocal microscopy and Ultrafast Optical Scanning™	YES	YES
Runyes	Ningbo Runyes Medical Instrument Co., China	Structured light-Active Speed 3D Video™	YES	YES
Launca DL206	Guangdong Launca Medical Device Technology Co., Ltd, Dongguan, China	Structured light-Active Speed 3D Video™	YES	YES
I500	Medit, Seongbuk-gu, Seoul, Korea	Structured light-Active Speed 3D Video™	YES	YES

Name	Manufacturer	Technology	STL Export	PLY/OBJ Colour Export
Einscan SE	Shining 3D, Hangzhou, Zhejiang, China	Optical Blue Structured Light	YES	NO
UP3D 300E	Shenzhen UP3D Tech Co., Ltd., Shenzhen, China	Optical Blue Structured Light	YES	NO
E2	3-Shape, Copenhagen, Denmark	Optical Blue Structured Light	YES	NO
Ineos X5	Dentsply-Sirona, York, Pennsylvania, USA	Optical Blue Structured Light	YES	NO

Table 9. The Digital Scanners Used In This Study

4.2.3 Design of the study

The present *in vitro* study compared nine different intra-oral scanners (Omnicam with 4.6 Software, Omnicam with 5.1 Software and Primescan, Dentsply Sirona, York, Pennsylvania; CS 3600, Carestream Dental, Atlanta, Georgia USA; Trios 3 and Trios 4, 3Shape, Copenhagen, Denmark; Runyes Quickscan, Ningbo Runyes Medical Instrument Co., China, and i500, Medit, Seongbuk-gu, Seoul, KoreaSeongbuk-gu, Seoul, Korea; DL206, Guangdong Launca Medical Device Technology Co., Ltd, Dongguan, China.) as well as four lab light scanners (Einscan SE, Shining 3D, Hangzhou, Zhejiang, China; UP3D 300e, Shenzhen UP3D Tech Co., Ltd., Shenzhen, China; E2, 3Shape, Copenhagen, Denmark, and Ineos X5, Dentsply Sirona, York, Pennsylvania) to investigate the accuracy of each scanner by examining the overall trueness and precision.

The master model was acquired with each of the above scanners and compared with the Ineos X5 Lab Scanner. This structured light lab scanner is accredited to be accurate within 2.1 microns (ISO, 2015) A sample size of 10 for each scanner was determined by using a sample size calculation with 95% confidence level and a margin of error of 5%. This has been confirmed by several authors to be acceptable to obtain statistically significant results. (Nedelcu and Persson, 2014, Mangano et al., 2017)(Mangano et al., 2019)

A single operator, an expert in digital dentistry familiar in use and experienced with multiple manufacturers of scanners, then began to scan the master model using each of the scanners available, capturing ten scans in total for each scanner. To avoid operator fatigue, the sequence of scans was randomised with intervals between each scan. The scanner used for each scan was also randomised to prevent bias.

The randomization was executed using a computer-generated random sequence to determine the order of the scanners and the intervals between each scan. This method ensured that the operator did not follow a predictable pattern, which could introduce bias, and that each scanner had an equal probability of being selected for each scan. The intervals between scans were also varied randomly to avoid any patterns that could influence the operator’s performance or the results.

By employing a rigorous and unbiased randomization process, the study aimed to ensure the reliability and validity of the results, minimizing any potential influence from the operator’s familiarity or fatigue, and preventing any preferential treatment or bias towards any specific scanner.

In each scan, the method of scanning followed the International Digital Dental Academy Scan Training Model (International Digital Dental Academy) (Figure 44): starting on the upper left most distal molar, continuing occlusally across the full arch, pivoting to the palatal side to capture the palatal surfaces, and then returning along the buccal surface, with a constant progression.

Figure 43. The IDDA Scan Method Training Model (IDDA, 2019)

This scanning method captures a little of the palatal and buccal surface when scanning the occlusal arc, capturing the areas of interest of each surface while maintaining a common framework for the meshes to align. The

scans were exported as an STL format file using the manufacturer's proprietary and recommended conversion pathway.

The scans were then imported into Meshlab (ISTI-CNR, Pisa, Italy) (Kalke and Helm, 2021) (an open-source system for processing and editing 3D triangular meshes) and aligned.

This method was repeated with each of the intra-oral scanners and lab scanners in the study. Once all of the scans were aligned, the surface meshes were digitally cut using a template and exported to give ten resulting meshes for each scanner to be used to compare the trueness and precision evaluations.

4.2.4 Evaluating Trueness

For trueness, the master model scans using the Ineos X5 were used as a baseline measurement against the Original STL of the IDDA Calibration Model. The reason for using the Ineos X5 scans as a baseline was due to its established reputation for high precision and accuracy in the field of digital dentistry. The Ineos X5 scanner is known for its advanced technology and reliable performance, making its scans a suitable reference point for evaluating the trueness of other scanners.

Each of the ten aligned and cut scans from each of the scanners in the *in vitro* study was brought into CloudCompare (an open 3D point cloud and mesh processing and comparison software), where the scans were further aligned and calibrated using the fine alignment algorithm. Each data set was then compared with the master STL using the CloudCompare 3D analysis best-fit algorithm. Trueness was defined as the mean deviation value for the superimposition of each scan. The results were recorded along with the standard deviation for each scan.

4.2.5 3D Deviation

The CloudCompare software allows the generation of a colorimetric map of the deviation across the surface of the STL mesh as compared to the master STL, quantified at specific points. The colour map indicates deviation inward (blue) or outward (red), while green indicates minimal deviation. The same C2M colour deviation scale was employed to illustrate the minimum and maximum deviations for each comparison. The colour scale ranged from a maximum and minimum deviation of + 200 (outward/red) and − 200 μm (inward/blue).

4.2.6 Evaluating Precision

All possible pairwise comparisons were made using a one-way analysis of variance (ANOVA) for independent groups, with a Tukey significance level of 0.05, of multiple comparisons using SPSS 26 by IBM.[22] Bartlett's test was used to test the homogeneity of variances. Precision was defined from the superimposition between the different scans made with the same intraoral scanner. The comparisons available for each scanner were calculated and the precision of each scanner was then expressed as a mean.

4.2.7 Surface Detail Observational Comparison

Finally, an illustration of the surface features was made by capturing the wireframe of the premolar/molar region incorporating the calibration column.

4.3 Results

Trueness and Precision results are summarised in Tables 10 and 11 and in Figures 46 and 47.

Name	Mean (μm)	Std. Deviation (μm)	P Value
Ineos X5	0.0	1.9	1.000
3Shape E2	3.6	2.2	0.125
UP3D 300E	12.8	2.7	0.029
Einscan SE	14.9	9.5	0.004
Primescan	17.3	4.9	<000.1
Trios 4	20.8	6.2	<000.1
Medit i500	25.2	7.3	<000.1
CS3600	26.9	15.9	<000.1
Trios 3	27.7	6.8	<000.1
Runyes	47.2	5.4	<000.1
Omnicam 5.1	55.1	9.5	<000.1
Omnicam 4.6	57.5	3.2	<000.1
Launca DL206	58.5	22.0	<000.1

Table 10. Mean Trueness and Standard Deviation of Each Scanner in comparison to the Master Scan from the Ineos X5 in order of ascending mean deviation and the significance compared to the Ineos X5 results.

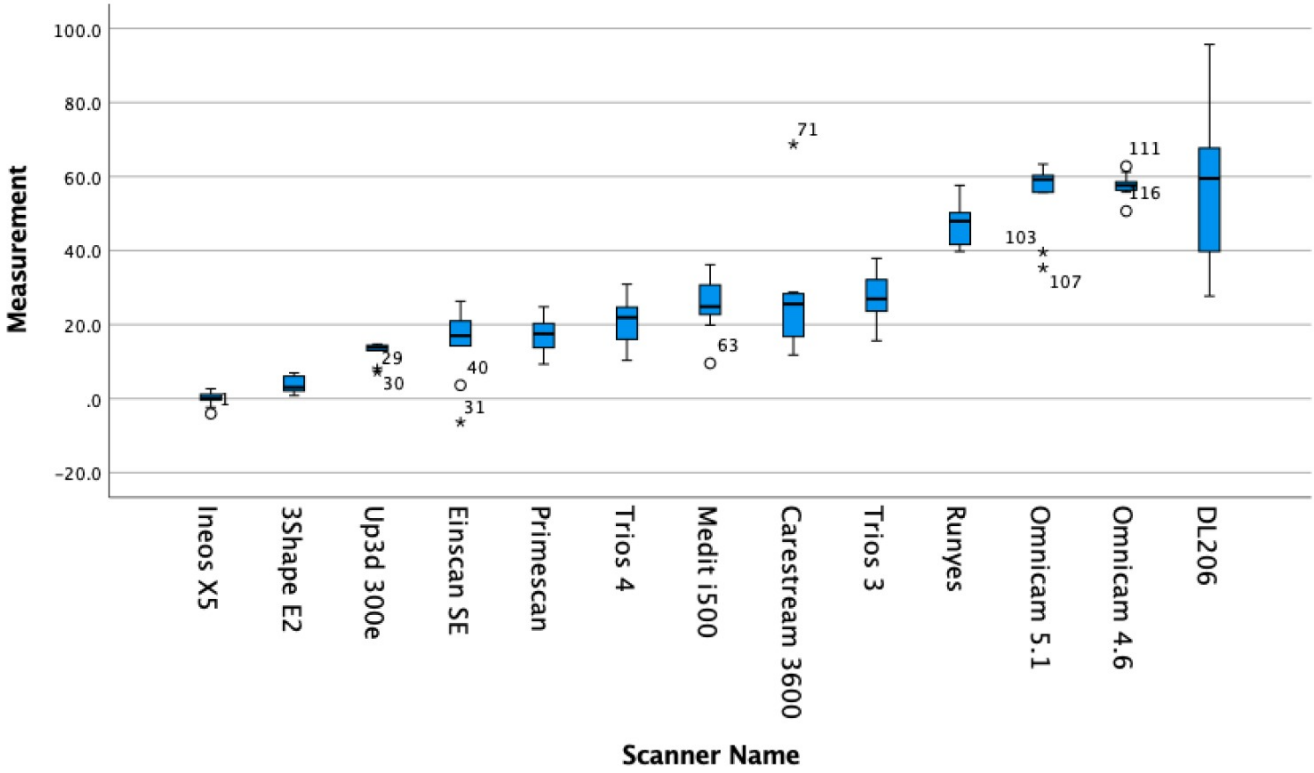

Figure 44. Box Plot of Each Data Set for Each Scanner in the Present Study

Name	1	2	3	4	5
Ineos X5	0.000				
3Shape E2	3.7	3.7			
UP3D 300E	12.8	12.8	12.8		
Einscan SE		15.0	15.0	15.0	
Primescan		17.3	17.3	17.3	
Trios 4			20.9	20.9	
Medit i500			25.2	25.2	
CS3600			26.9	26.9	
Trios 3				27.7	
Runyes					47.2
Omnicam 5.1					55.2
Omnicam 4.6					57.6
Launca DL206					58.5
P Value (Sig)	0.125	0.072	0.051	0.123	0.271

Table 11. Tukey Homogenous Subsets of Compared Means (Subset for alpha = 0.05)

Anova					
Measurement	**Sum of Squares**	**Df**	**Mean Square**	**F**	**Sig.**
Between Groups	28324.784639	8	3540.598080	29.235153	0.000
Within Groups	9809.712588	81	121.107563		
Total	38134.497226	89			

Table 12. Anova Sig. Between groups.

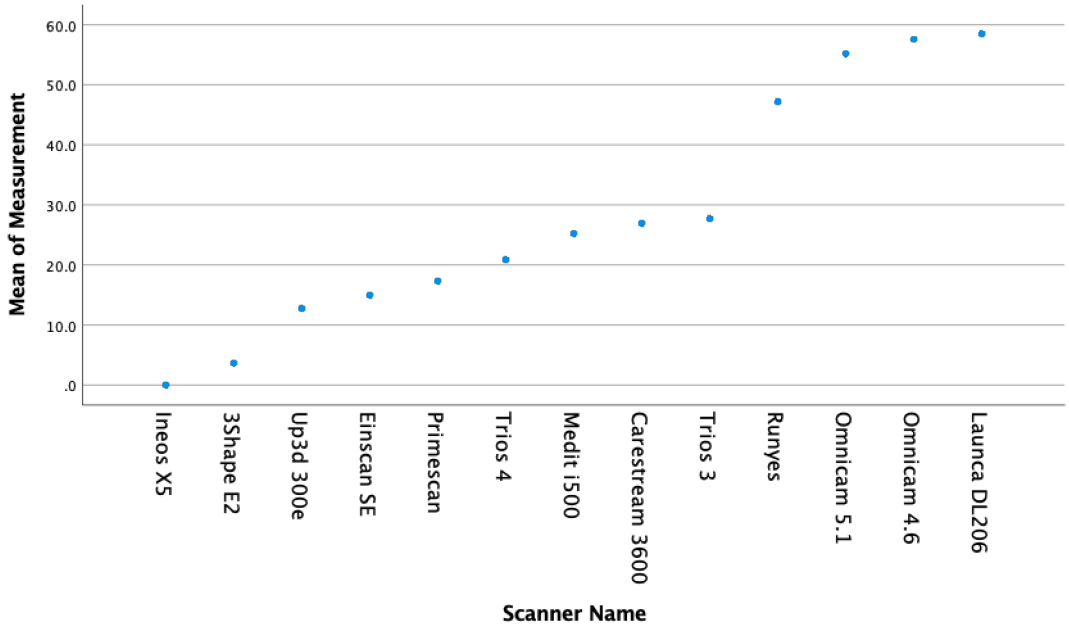

Figure 45. Means Plot of Precision for each Scanner.

In the present study, the Primescan had the best overall trueness as shown in Figure 44. (17.3 ± 4.9). Followed by (in order of increasing deviation) the Trios 4 (20.8 ± 6.2), i500 (25.2 ± 7.3), CS3600 (26.9 ± 15.9), Trios 3 (27.7 ± 6.8), Runyes (47.2 ± 5.4), Omnicam 5.1 (55.1 ± 9.5), Omnicam 4.6 (57.5 ± 3.2) and Launca DL206 (58.5 ± 22.0). We can see that the scanners that employ the confocal microscopy technology have the highest levels of trueness.

With regards to the lab light scanners, compared to the Ineos X5 which was used as the gold standard, the overall trueness in order of increasing deviation was the 3Shape E2 (3.6 ± 2.2), Up3D 300E (12.8 ± 2.7) and Einscan SE (14.9 ± 9.5)

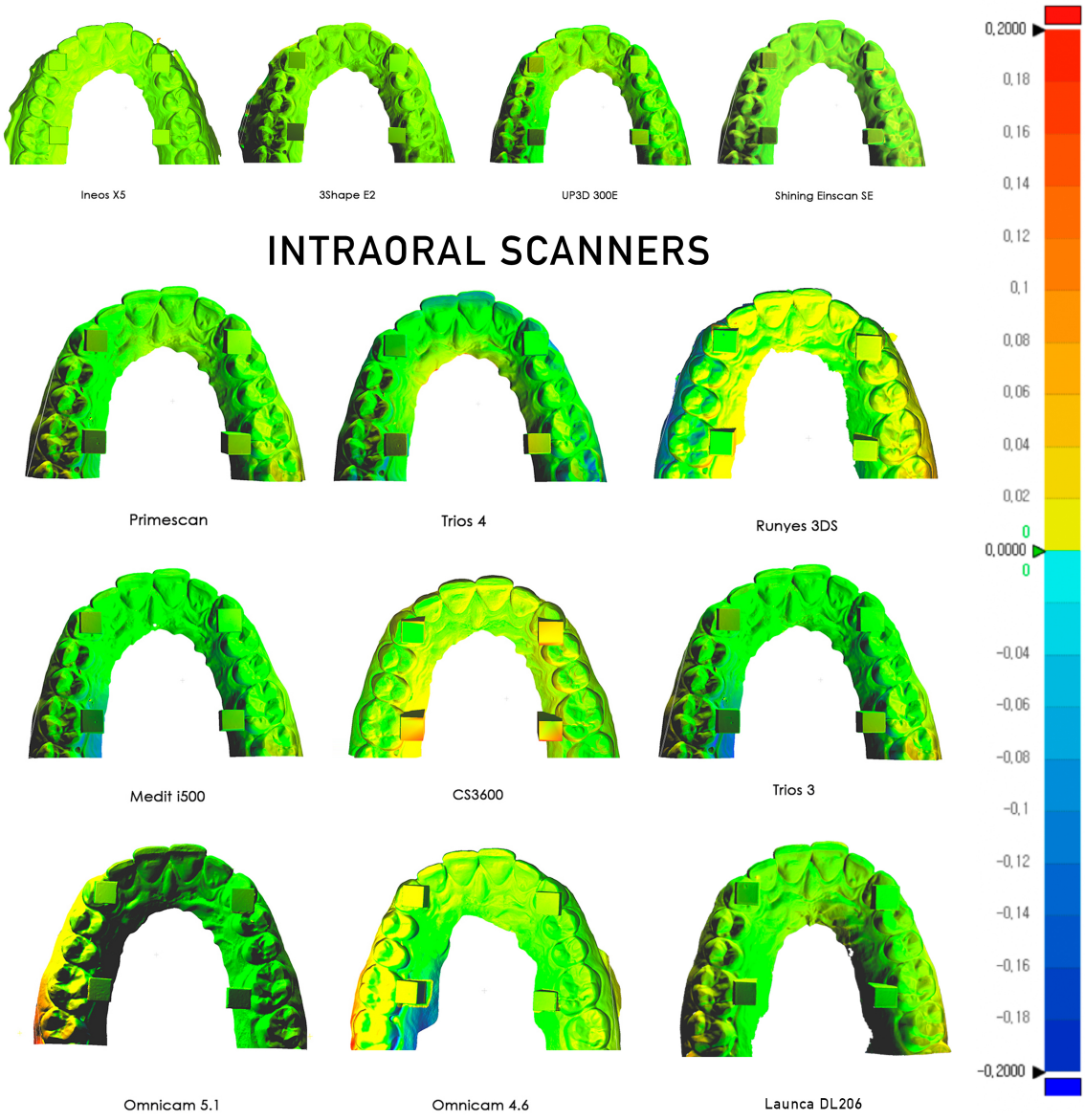

Figure 46. Colorimetric map of the deviation

The precision results are summarised in Table 11. In brief, the Ineos X5 was statistically more precise than all of the intra-oral scanners. The Primescan intra-oral scanner was the only intra-oral scanner statistically grouped in precision with desktop lab scanners E2 and 300E. Six of the intra-oral scanners, the Primescan, Trios 4, i500, 3600, and Trios 3, were statistically more precise than the Runyes, Omnicam, and DL206.

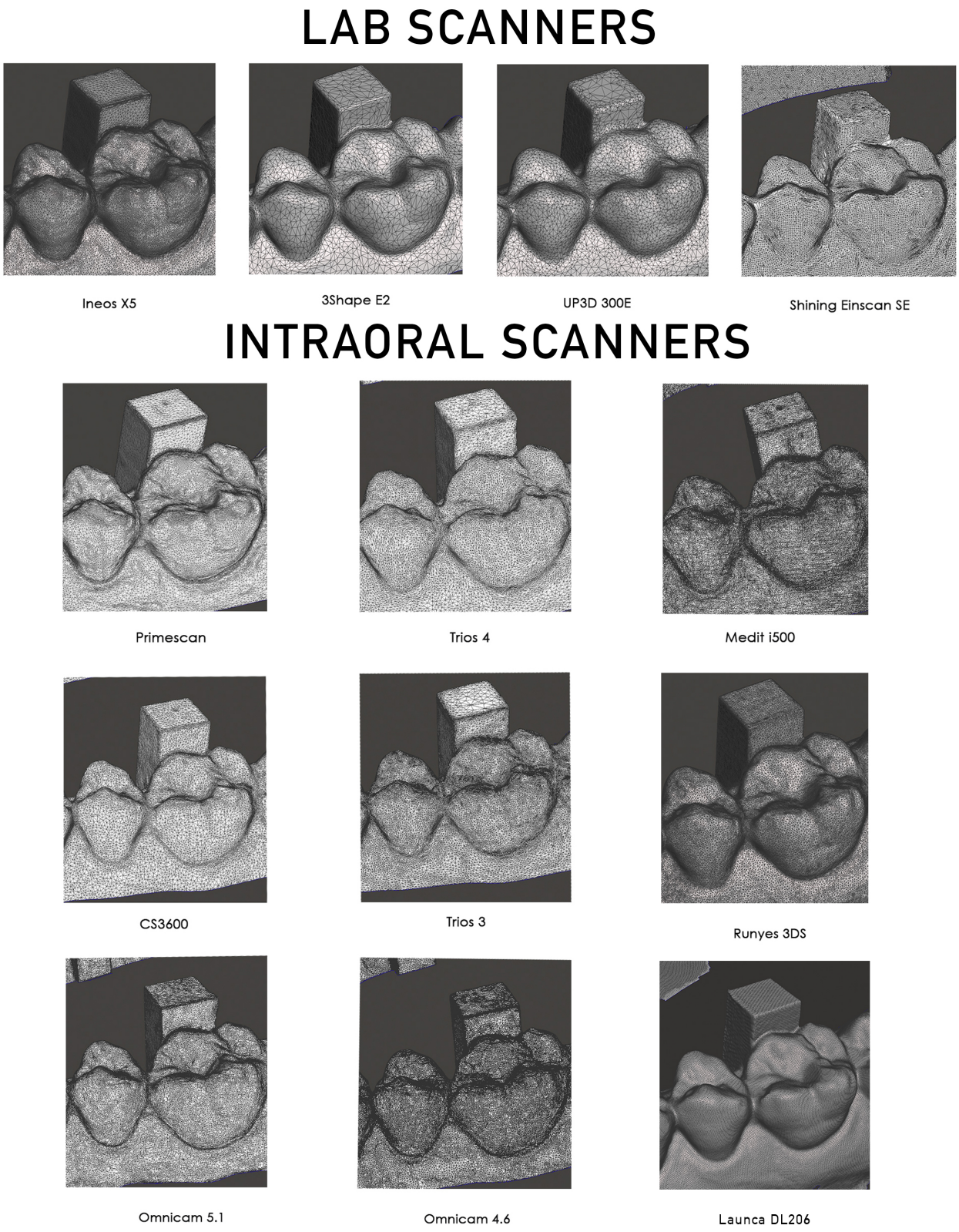

Figure 47. Comparison of Triangular Meshes

All intra-oral scanners present a mean error below 60 microns across a full arch comparison. Five current-generation scanners in the study (excluding the Runyes, Omnicam, and Launca) provide a mean error below 30 microns with a low deviation which confirms a high level of reliability of the Primescan, Trios 3 and 4, i500 and CS3600. The oldest model of scanner, the Omnicam, was tested with two varieties, running software version 4.6 and version 5.1. The current 5.1 hardware and software is credited as having improved the accuracy of this scanner which has been on the market for over eight years. Our results show that while the mean deviations were higher than that of the other scanners, the later software version has improved both the mean accuracy and lowered the standard deviation. Interestingly, the Einscan SE lab scanner produced results with a high degree of trueness (15.6 ± 9.5). However, this was overall trueness to the master STL, and on observational inspection of the triangular meshes, it is evident that the surface detail is lacking. (Figure 48.)

4.4 Discussion

The null hypothesis was rejected, in that significant differences were found among some of the digital Intra-oral scanners and lab scanners regarding trueness and precision.

With regards to the secondary null hypothesis, that there would be no difference between the lab scanners and intra-oral scanners regarding trueness and precision, this was partially rejected as one intra-oral scanner, the Primescan, whilst having a statistically significant difference to the Ineos X5 lab scanner, proved the secondary null hypothesis correct as in terms of comparison to the other lab scanners.

The evolution of intra-oral scanners to lead to one performing at a statistically significant level in comparison to lab scanners is remarkable. Whilst clear differences between the scanners were found, the performance of these scanners can be seen to be exceptional with all lab and intra-oral scanners performing with overall trueness under 60-µm. The emergence of intra-oral scanners has intended to provide a better experience for the patient and also an easier way of creating a model in a more predictable and repeatable way to alleviate problems/complications encountered in conventional methods/impressions.(Moörmann, 2006)

As digital intra-oral scanners are becoming more prevalent in practice, it has allowed us to provide same day dentistry in a predictable and efficient way. This has led to the advent of same day dentistry where indirect restorations can be placed in the same visit. There has, however, been a lot of discussion around the accuracy and reproducibility of digital intra-oral scanners versus the conventional analogue techniques - eg digital vs analog impression. (Menini et al., 2017) (Pesce et al., 2018) (Sakornwimon and Leevailoj, 2017) Authors such as Amin et al have shown in studies how "*digital implant impressions were significantly more accurate than the conventional impressions*", but full arch scans are more controversial and technique sensitive with the particular scanner being used playing a big part in the overall accuracy and precision of the digital model created. (Amin et al., 2016) (Patzelt et al., 2013a)

The purpose of this study is to address these issues around precision/trueness and accuracy for a full arch scan. We have studied these parameters for 7 digital intra-oral scanners and 2 lab scanners. This is the most up to date study on the most recent scanners that have been released

as of the start of 2021. However, this study did not replicate an actual clinical situation and has several limitations. In most patients, multiple surfaces and materials are scanned, including various restorative materials, dentine, enamel and soft tissues. Inherent anatomy related changes in arch shape on jaw opening mean that this *in vitro* study is fundamentally limited and *in vivo* studies using these scanners would be important to further illustrate the differences in accuracy. Further studies should be completed to determine whether these factors may affect full arch accuracy in these current generation scanners.

In the present study, only one clinician performed the scans on the master model to produce the data set for each scanner. This is important as variation in scan strategy can affect the accuracy of stitching which in turn would impact on the significance of the results comparison. (Ender and Mehl, 2013) (Lim et al., 2018) (Nagy et al., 2018)

It is crucial to acknowledge that the choice of having only one clinician perform the scans is a significant limitation of this study. Variations in scan strategies among different clinicians can lead to different results from different intra-oral scanners. The exclusion of this variable means that the study's findings are primarily applicable to the scanning strategies of the single clinician involved, limiting the generalizability of the results to the broader population of clinicians with varying scanning strategies and experiences.

This limitation underscores the importance of conducting further studies involving multiple clinicians with diverse scanning strategies to assess the variability and its impact on the accuracy of different intra-oral scanners. By including a diverse range of clinicians and scanning strategies, future

research can provide more comprehensive and generalizable insights into the performance of intra-oral scanners under varying conditions and usage patterns.

Understanding the variability among different clinicians is pivotal for developing more robust and versatile intra-oral scanners that can deliver consistent and accurate results across different users and scanning strategies, thereby advancing the field of digital dentistry.

The terms trueness and precision have been prescribed in ISO 5725-1 to represent the accuracy of the measurement method to evaluate digital intra-oral scanners.(Ender et al., 2016) Lab scanners are known to be more accurate, as they use lasers or structured light with a stable camera head, as opposed to the limited field of view and wand-shake of digital intra-oral scanners. They also exhibit less inhibiting factors (For example; lens wetting, reflections from scanned surfaces, movement of the tongue / soft tissues etc) to deal with when scanning, (Kang et al., 2019) and have therefore been used in this study as benchmark for the accuracy and precision of the scanners.

There are many published studies that compare the accuracy of digital intra-oral scanners (Mangano et al., 2017, Menini et al., 2017, Sakornwimon and Leevailoj, 2017, Mangano et al., 2019, Rech-Ortega et al., 2019) - they compare different generations of scanners and do not necessarily compare new technology and software updates for the older technology scanners - eg the Omnicam with 4.6 software compared to the Omnicam running 5.1 software. Mathematical and software developments of the stitching algorithm (Ettl et al., 2009, Weise et al., 2011) have improved and this is clear in the results of this study where the later software version combined with more

recent computer hardware has resulted in a more accurate data set. It has also been shown that calibration plays a very big part in the accuracy and precision of the scanner, (Rehmann et al., 2017) and in the present study all scanners were calibrated immediately prior to the capture of the scans in each data set.

A number of limitations are suggested in this *in vitro* study, namely the lack of *in vivo* complications such as saliva, blood, patient interaction, etc. These need to be accounted for and may impact the results in an *in vivo* patient setting.

When examining the observational comparison of the triangular meshes, distinct differences in the capabilities of lab and intra-oral scanners to accurately depict surface features and marginal integrity become evident. Triangular meshes are a method used in 3D computer graphics to represent the surface geometry of 3D models, including scans from intra-oral and lab scanners. These meshes are composed of numerous interconnected triangles that form the surface of the 3D model.

It’s pivotal to understand that the use of triangular meshes inherently brings certain limitations. The resolution and accuracy of the meshes can significantly impact the portrayal of intricate details and surface features. The limitations of triangular meshes can affect the ability of scanners to accurately represent the geometry and details of scanned objects, potentially leading to deviations in trueness and precision.

For lab scanners, it is observed that an increase in deviation in trueness corresponds to a decrease in detail representation. However, this correlation is not as straightforward for intra-oral scanners. These scanners exhibit

substantial variation in depicting occlusal anatomy and, in some cases, struggle to process flatter areas efficiently.

Whilst it may seem appropriate to look at the total triangle count for the scans, each scanner processes the point clouds differently, converting the point cloud created during scanning to a useable CAD triangle mesh. The more well known brand scanners from Dentsply Sirona, 3Shape and Carestream show obvious variation in the triangular mesh size and density whilst the newer scanners from Medit, Runyes and Launca are very regular in their mesh density. This may be because these scanners have a longer history of research and development and as such the algorithms employed to convert the point clouds recorded into triangular meshes will have had more time to be optimised. One of the most impressive meshes on first observation was the Launca DL206 scan. This scanner has just been released as of the start of 2021 and whilst the trueness is on par with the Runyes and Omnicam scanners, the triangular mesh of this scanner shows an impressive level of detail. However without a full understanding of the manufacturers particular patented methods of algorithmic conversion from point cloud to triangular mesh, this is a potential limitation of comparing the appearance of triangular meshes and total triangle count.

Acknowledging the limitations of triangular meshes is essential in interpreting the observed differences and variations in scanner performances. The inherent constraints of triangular meshes in representing intricate details and surfaces necessitate careful consideration when evaluating the accuracy and reliability of different scanners. A comprehensive understanding of these limitations is crucial for developing improved scanning technologies and methodologies that can overcome

these constraints and offer more accurate and detailed representations of scanned objects.

The fast pace changes and developments in modern dentistry within CAD/CAM, digital impression registration and chair-side production are remarkable and likely to quickly become an even greater factor in developing modern dentistry. A central part of the modern digital dentistry office is registering a true and accurate scan of the intra-oral anatomy. The use of digital intra-oral scanners is well established and a number of well tested scanners are available on the market. Needless to say, it is a competitive field for the manufacturers of dental equipment and we can look forward to ongoing improvements. It is widely accepted that the use of a digital intra-oral scanners enhance the patient experience. The in-house workflow gives the clinician opportunities to capture a detailed three-dimensional picture of the intra-oral situation, thus enabling same day dentistry and many new opportunities.

An abundance of data indicate that although we can very accurately record the situation and produce reliable digital models of preparations we have limited data of trueness and accuracy across the variety of devices commercially available. Some studies suggest that scanners can replace impressions for dental preparations but it is not clear if they can replace a conventional impression in every situation. (Andriessen et al., 2014, Ng et al., 2014, Mangano et al., 2016)

Several recent studies have shown that digital intra-oral scanners are accurate, but some variations are noted. The older studies suggesting that accuracy of scanners is limited and suggest using scanners for smaller prosthetic situations seem to be based on limited numbers of scanners, and

notably older scanners. (Nedelcu et al., 2018) The present study includes the latest scanners and shows a very different situation as the majority of current scanners, with the latest software, produced results that were accurate to within 30 microns.

4.5 Conclusions

At the time of completing the present study, there have been very few studies comparing the accuracy of the various current intra-oral scanners to assess full arch accuracy.

The present study aimed to compare the full arch trueness and precision of the leading intra-oral scanners available in 2020 (specifically the Dentsply Sirona Primescan and Omnicam (both 4.6 and 5.1 version), 3Shape Trios 3 and 4, Carestream 3600, Launca DL206, Runyes, and Medit i500) as well as a low-cost lab light scanner (Shining Einscan SE) and more mainstream dental lab scanners (Dentsply Sirona Ineos X5, 3Shape E2, and UP3D 300e).

Each scanner took ten scans, and all data sets were compared using Cloudcompare to evaluate the trueness and precision. The study results showed that the Primescan produced a very low amount of overall deviation and recorded the most accurate results, which were statistically similar to all lab scanners except the Ineous X5. The Primescan was followed closely by the Trios 4, Medit i500, CS3600, and Trios 3 as the second most accurate data set of intra-oral scanners with no statistical difference between the overall results of the current range of scanners; Primescan, Trios 3 and 4, i500 and 3600. The results confirmed a statistical difference between these scanners and the previous generation scanner, the Omnicam, and the

Runyes and Launca DL206. However, the later generation hardware and software version of the Omnicam did produce more accurate results, and these results of these three scanners were still within an acceptable range for clinical usefulness.

While this and other studies have looked at the accuracy of these scanners, an interesting observational outcome of the present study was examining the close-up anatomical detail shown by the triangular meshes. There is a very clear and noticeable difference in the level of detail shown by the Ineos X5 to the other lab scanners and similarly with the Primescan. The scanners show a variation in their ability to efficiently portray the flat surfaces while also showing higher concentration in triangular mesh around important surface features and angles. The two newer scanners, the Runyes and particularly the Launca DL206, show an impressive level of detail, with the Launca DL206 scanner mesh being evenly rendered with a very dense mesh. This is noticeable in the Launca DL206's STL file size being larger than all other scanners.

This study confirms that all of the intra-oral digital scanners can capture a reliable, reproducible full arch scan in dentate patients. However, the scanning of an edentulous full arch is more challenging and deserves further investigation.

Following this study, further research is needed on these scanners in various settings, and the evidence must be confirmed in a clinical setting.

Chapter 5 - A Comparison of Trueness and Precision of 12 3D Printers used in Dentistry

5.1 Introduction

This study has focused on the precision and trueness of twelve 3d printers used within dentistry.

The present study involves some of the recently released 3D printers that have not yet been studied for their accuracy. Since these new printers will replace current models that may have been included in the previous studies in the literature, it is important to study whether they are statistically more or less accurate and to discuss whether these results are clinically relevant.

The null hypothesis of the study was that there will be no significant differences in trueness and precision between the various 3D printer technologies when compared to the master STL file, and there will be no significant differences in trueness and precision in comparisons between the different printers.

5.4 Materials and Methods

For the purposes of this study, the use of a standardised printable object was used to measure the accuracy of these recent 3D printers.

5.4.1 Test Block Sourcing

The test blocks were sourced from existing 3D printer units that are regularly used in dental practice by the International Digital Dental Academy committee and board. Some test blocks were also sourced from manufacturers who complied with the data collection methods below. Other than the data collection method, no specific information was given regarding the actual virtual block size to rule out user bias. Where blocks could only be

sourced individually, other sources were found to give a more rounded and less biased production. The resin used for each printer was the manufacturers own Dental Model Resin.

5.4.2 3D Printers in the Study

The printers used in the present in vitro study are summarised in Table 13. This table provides a comprehensive overview of various 3D printers used within the study, each characterized by several attributes listed under distinct columns. The Name column specifies the model or designation of the 3D printer. The Manufacturer column reveals the company or entity responsible for producing the printer. The Technology column denotes the type of 3D printing technology utilized, such as FDM or SLA. The Build Platform Size column presents the dimensions of the build platform, indicating the maximum size of an object that can be printed. The Max Print Speed column enumerates the utmost speed at which the printer can operate, typically measured in millimeters per second (mm/s). Lastly, the Specification column furnishes additional details or specifications of the printer, such as resolution and layer height. This legend serves as a guide to comprehending the information and abbreviations used within the table, ensuring clarity and understanding of the presented data.

Table Legend;

Name: Name of the 3D Printer

Manufacturer: Company or entity that manufactured the printer

Technology: Technology used by the 3D printer

Build Platform Size: Maximum size of the object that can be printed

Max Print Speed: Maximum speed at which the printer can print, measured in mm/s

Specification: Additional details or specifications of the printer

Name	Manufacturer	Technology	Build Platform Size	Max Print Speed	Specification
Photon	**Anycubic, Shenzhen, China**.	LCD-based SLA 3D Printer （wavelength 405nm）	115mm *65mm *155mm	20mm/h	XY DPI : 47μm (2560*1440)
Photon S	**Anycubic, Shenzhen, China**.	LCD-based SLA 3D Printer （wavelength 405nm）	115mm *65mm *165mm	20mm/h	XY DPI : 47μm (2560*1440)
MAX UV	**Asiga, Sydney, Australia**	DLP (UV LED 385 or 405 nm)	119 × 67 × 75mm	20mm/h	XY DPI : 62μm (1920*1080)
Mars	**Elegoo, Shenzhen, China**	LCD-based SLA 3D Printer （wavelength 405nm）	119 × 68 × 155mm	22.5mm/h	XY DPI : 47μm (2560*1440)
Vida HD	**Envisiontec Inc, USA**	DLP (UV LED 385 nm) cDLM	140 × 79 × 100mm	47mm/h	XY DPI : 73μm (1920*1080)
ONE	**Envisiontec Inc, USA**	DLP (UV LED 385 nm) cDLM	180 x 101 x 175 mm	45mm/h	XY DPI : 93μm (1920*1080)
Form 2	**Formlabs, USA**	SLA (UV laser 405 nm)	350 x 330 x 520 mm	20mm/h	Laser spot 140 μm
Form 2	**Formlabs, USA**	SLA (UV laser 405 nm)	145 × 145 × 185 mm.	30mm/h	Laser spot 85 μm

Name	Manufacturer	Technology	Build Platform Size	Max Print Speed	Specification
Nextdent 5100	**3D Systems, Netherlands**	DLP (UV LED 405 nm)	124.8 x 70.2 x 196 mm	65mm/h	XY DPI : 65µm (1920*1080)
Creo	**Planmeca, Finland**	DLP (UV LED 405 nm)	130 x 81.5 x 130 mm	10mm/h	XY DPI : 68um (1920*1080)

Table 13. The 3D Printers Used In This Study

5.4.3 Design of the Study

5.4.3.1 Data Collection Method

All test blocks were printed using the same settings with 100 micron Z layer thickness, orientated so the base of the cube was flat to the build platform and the print time set to standard where applicable. The reason for choosing 100 micron layers was the layer height that all printers within the study could select with their model resin. Some printers would select in integers of 25 microns, some completely selectable, but all would print at 100 microns.

Post print processing and treatments were conducted in accordance with the manufacturers' instructions, and the workflows included an alcohol wash and light curing.

All print test blocks were printed using the same positioning, in other words they were centralised on the print build platform. No supports were used to print each model as the test STL was printed square on to the Z-Axis. All prints were printed using the manufacturers software with all software being the latest available version as of April 2021.

All printers were calibrated prior to use according to the manufacturers' recommendations and instructions.

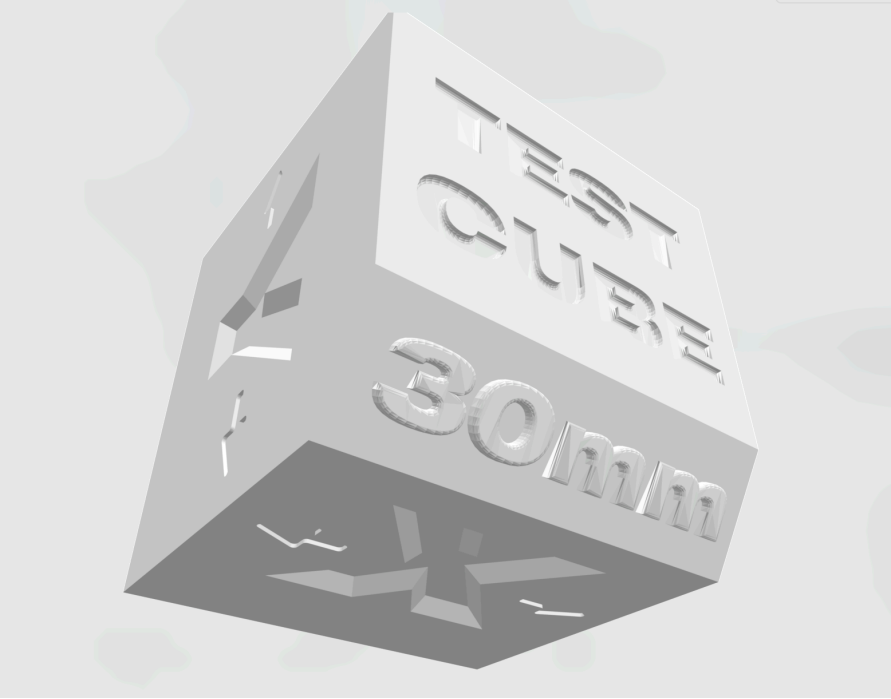

Figure 48. The Test Cube STL

The resins used were the manufacturers' own dental model resins and were mixed or rolled before printing according to standard recommendations and procedures.

5.4.3.2 Measurement

To measure the resulting blocks a digital measurement was taken using an Ineos X5 to measure the XYZ dimensions of each block produced on each printer to the nearest 0.01mm.

The master model was acquired with each of the above printers and compared with the Ineos X5 Lab Scanner. This structured light lab scanner is accredited to be accurate within 2.1 microns (ISO 12836) (Sirona) A sample size of 10 for each printer was determined by using a sample size calculation with 95% confidence level and a margin of error of 5%. This has

been confirmed by several authors to be acceptable to obtain statistically significant results. (Nedelcu RG, 2014, Mangano et al., 2017, Mangano et al., 2019)

Each measurement was taken from the central axis of that dimension and the measurements compared to the master stl.

5.4.3.3 3D Deviation

The CloudCompare software allows the generation of a colorimetric map of the deviation across the surface of the STL mesh as compared to the master STL, quantified at specific points. The colour map indicates deviation inward (blue) or outward (red), while green indicates minimal deviation. The same C2M colour deviation scale was employed to illustrate the minimum and maximum deviations for each comparison. The colour scale ranged from a maximum and minimum deviation of + 200 (outward/red) and − 200 µm (inward/blue). The software allows measurement deviation across planes of XYZ.

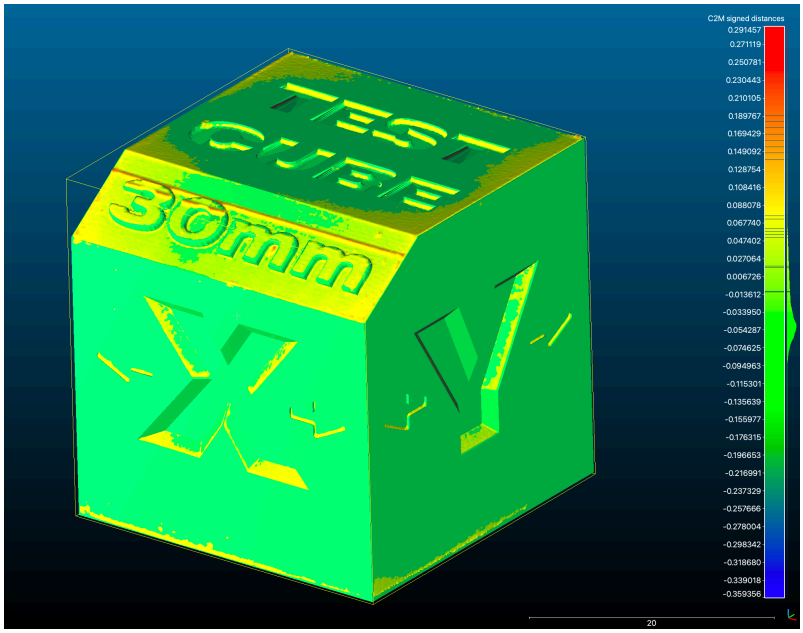

Figure 49. CloudCompare Colour Map of scanned test object overlaid with Master STL

5.4.4 Main Method

The method of the study involves the use of a standardised test block STL created with dimensions of 30mm by 30mm. This test block will then be printed on each printer several times based on the sample size calculation then using the data collection method above;

Assessing the deviation of the X (horizontal) dimension of the printed test cube compared to the planned virtual test object.

Assessing the deviation of the Y (vertical) dimension of the printed test cube compared to the planned virtual test object.

Assessing the deviation of the Z (lateral) dimension of the printed test cube compared to the planned virtual test object.

5.4.4.1 Evaluating Trueness

For trueness, the CAD file was used as the baseline gold standard, against which to measure each 3d printed Model. Each of the ten aligned and cut scans from each of the printers in the *in vitro* study was brought into CloudCompare (an open 3D point cloud and mesh processing and comparison software), where the scans were further aligned and calibrated using the fine alignment algorithm. Each data set was then compared with the master STL using the CloudCompare 3D analysis best-fit algorithm. Trueness was defined as the mean deviation value for each of the XYZ dimensions. The results were recorded along with the standard deviation for each.

5.4.4.2 Evaluating Precision

All possible pairwise comparisons were made using a one-way analysis of variance (ANOVA) for independent groups, with a Tukey significance level of 0.05, of multiple comparisons using SPSS 26 by IBM.(IBM, 2019) Bartlett's

test was used to test the homogeneity of variances. Precision was defined from the superimposition between the different scans made with the same intraoral scanner. The comparisons available for each printer were calculated and the precision of each printer was then expressed as a mean.

5.5 Results

The results are summarised in Tables 14 and 15 and in Figures 51 and 52.

Name	X Axis Error Mean (±SD)	Y Axis Error Mean (±SD)	Z Axis Error Mean (±SD)
Asiga Max UV	0.031 (±0.083)	0.032 (±0.038)	-0.021 (±0.020)
Form 2	0.142 (±0.111)	0.149 (±0.094)	0.146* (±0.012)
Form 3	0.116* (±0.042)	0.108 (±0.067)	-0.047 (±0.064)
EnvisionTec Vida	0.045 (±0.047)	-0.019 (±0.045)	0.262* (±0.026)
EnvisionTec One	-0.035 (±0.045)	-0.028 (±0.037)	0.030 (±0.021)
Planmeca Creos	0.038* (±0.016)	-0.036 (±0.022)	-0.053* (±0.027)
Anycubic Photon	0.064 (±0.103)	0.061* (±0.026)	-0.016 (±0.025)
Anycubic Photon S	0.064 (±0.101)	0.068* (±0.026)	-0.016 (±0.025)
Nexdent 5100	0.053 (±0.048)	0.051 (±0.049)	0.019 (±0.079)
Elegoo Mars	0.072 (±0.083)	0.056 (±0.051)	-0.044 (±0.035)
Significant*	**≤ 0.05 (C.I. 95%)**	**≤ 0.05 (C.I. 95%)**	**≤ 0.05 (C.I. 95%)**

Table 14. Mean Deviation of Each Printer in comparison to the Master STL

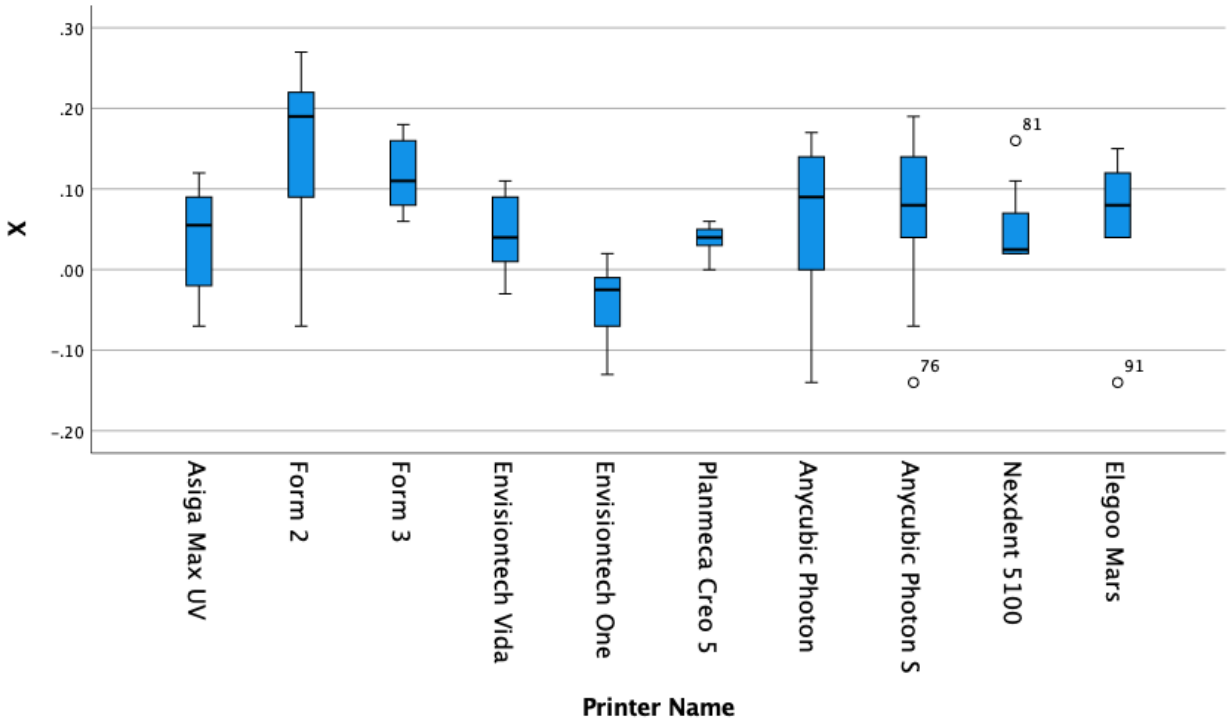

Figure 50. Box Plot of X Data Set for Each Printer in the Present Study

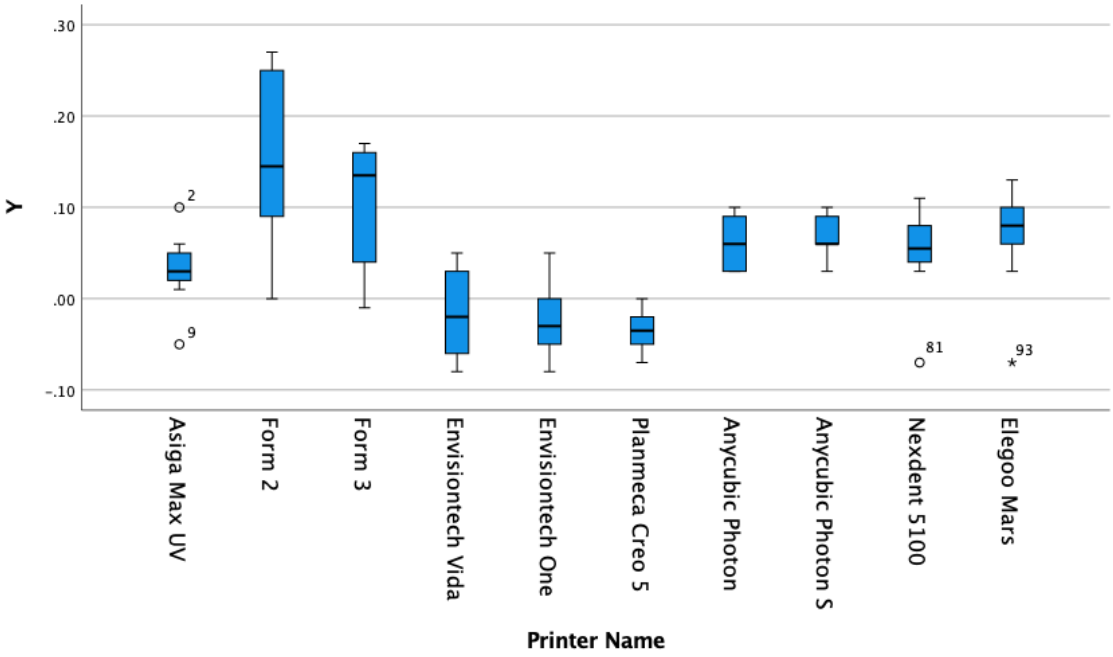

Figure 51. Box Plot of Y Data Set for Each Printer in the Present Study

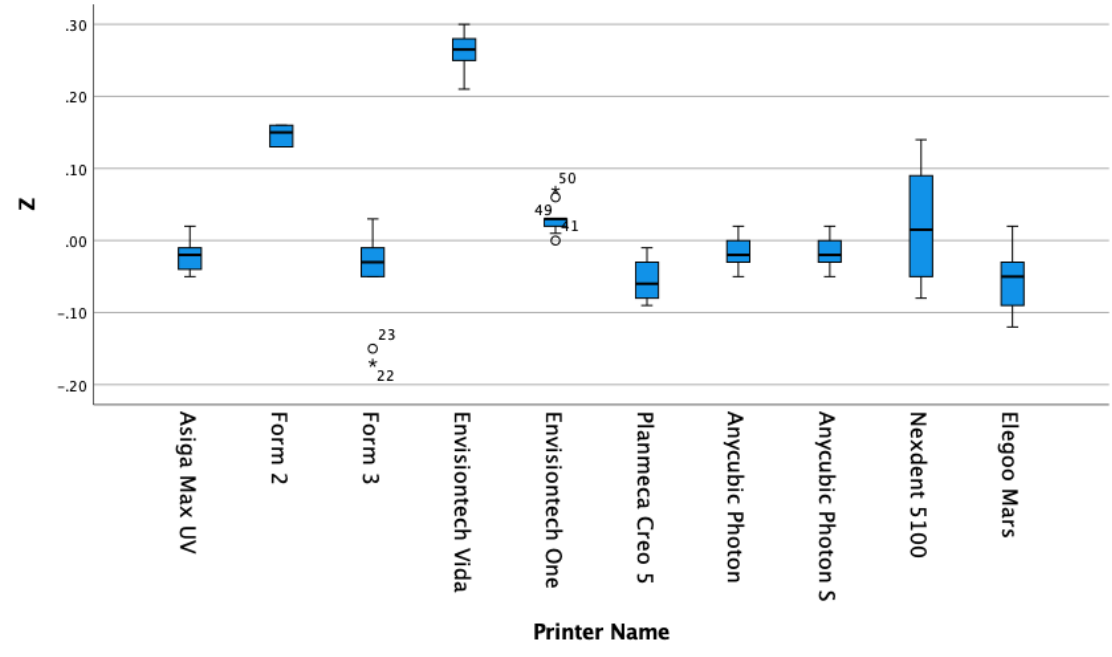

Figure 52. Box Plot of Z Data Set for Each Printer in the Present Study

X

	Printer Name	N	Subset for alpha = 0.05	
			1	2
Tukey HSD[a]	Envisiontech One	10	-.035	
	Planmeca Creo 5	10	.038	.038
	Asiga Max UV	10	.041	.041
	Envisiontech Vida	10	.045	.045
	Nexdent 5100	10	.053	.053
	Anycubic Photon S	10	.064	.064
	Anycubic Photon	10	.064	.064
	Elegoo Mars	10	.065	.065
	Form 3	10		.116
	Form 2	10		.142
	Sig.		.07	.05
Tukey B[a]	Envisiontech One	10	-.035	
	Planmeca Creo 5	10	.038	.038
	Asiga Max UV	10	.041	.041
	Envisiontech Vida	10	.045	.045
	Nexdent 5100	10	.053	.053
	Anycubic Photon S	10	.064	.064
	Anycubic Photon	10	.064	.064
	Elegoo Mars	10	.065	.065
	Form 3	10		.116
	Form 2	10		.142

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 10.000.

Table 15. Tukey Homogenous Subsets of Compared Means for the X Measurement (Subset for alpha = 0.05)

Y

	Printer Name	N	Subset for alpha = 0.05				
			1	2	3	4	5
Tukey HSD[a]	Planmeca Creo 5	10	-.036				
	Envisiontech One	10	-.028				
	Envisiontech Vida	10	-.019	-.019			
	Asiga Max UV	10	.032	.032	.032		
	Nexdent 5100	10		.051	.051	.051	
	Anycubic Photon	10			.061	.061	
	Elegoo Mars	10			.066	.066	
	Anycubic Photon S	10			.068	.068	
	Form 3	10				.108	.108
	Form 2	10					.149
	Sig.		.09	.07	.85	.27	.73
Tukey B[a]	Planmeca Creo 5	10	-.036				
	Envisiontech One	10	-.028	-.028			
	Envisiontech Vida	10	-.019	-.019			
	Asiga Max UV	10		.032	.032		
	Nexdent 5100	10			.051	.051	
	Anycubic Photon	10			.061	.061	
	Elegoo Mars	10			.066	.066	
	Anycubic Photon S	10			.068	.068	
	Form 3	10				.108	.108
	Form 2	10					.149

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 10.000.

Table 16. Tukey Homogenous Subsets of Compared Means for the Y Measurement (Subset for alpha = 0.05)

Z

	Printer Name	N	Subset for alpha = 0.05			
			1	2	3	4
Tukey HSD[a]	Elegoo Mars	10	-.054			
	Planmeca Creo 5	10	-.053			
	Form 3	10	-.047			
	Asiga Max UV	10	-.021	-.021		
	Anycubic Photon	10	-.016	-.016		
	Anycubic Photon S	10	-.016	-.016		
	Nexdent 5100	10		.019		
	Envisiontech One	10		.030		
	Form 2	10			.146	
	Envisiontech Vida	10				.262
	Sig.		.51	.13	1.00	1.00
Tukey B[a]	Elegoo Mars	10	-.054			
	Planmeca Creo 5	10	-.053			
	Form 3	10	-.047			
	Asiga Max UV	10	-.021	-.021		
	Anycubic Photon	10	-.016	-.016		
	Anycubic Photon S	10	-.016	-.016		
	Nexdent 5100	10		.019		
	Envisiontech One	10		.030		
	Form 2	10			.146	
	Envisiontech Vida	10				.262

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 10.000.

Table 17. Tukey Homogenous Subsets of Compared Means for the Z Measurement (Subset for alpha = 0.05)

A wide variation in the results exists in the present study, and the printers could be grouped according to their consistent accuracy.

However, when grouped into homogenous subsets, the cheapest 3D printers in the group, namely the Anycubic printers and the Elegoo Mars, are

statistically not dissimilar to the higher priced Asiga Max UV or even the mid-priced Formlabs printers, as shown in Tables 15,16 and 17.
Although these printers use different technologies to print, no specific type of printer technology is more accurate than the others.

5.6 Discussion

The null hypothesis was proved to be true, in that no significant differences were found among the various technologies of 3D printing regarding trueness and precision. The evolution of 3D printers that leads to budget printers being as statistically accurate as expensive printers is remarkable. Whilst clear differences in the mean error between the printers were found, the performance of these printers is considered exceptional. Their speed and availability in general dental practice can therefore benefit patients with an easier way of creating a model in a more predictable and repeatable way to alleviate problems or complications encountered in conventional methods when making impressions.(Torabi, 2015)
The purpose of this study is to address the issues regarding precision/trueness and accuracy by comparing different printer technologies. This study assessed these parameters for 10 3D printers using four different technologies to print resin models chairside. This study is the most up to date research on the most recent printers that have been released as of the end of 2021. In the present study, only one clinician performed the measurements on the models to produce the data set for each printer, and each measurement was taken on a recently calibrated printer and within the same time frame after the same postprocessing. A sole clinician performing

these measurements is important as variation in either of these can affect the accuracy of the model in terms of contraction and final shape.(Azari and Nikzad, 2009, Hazeveld et al., 2014, Park and Shin, 2018)

The fast-paced changes and developments in modern dentistry within CAD/CAM, digital impression registration, and chairside production along with the quick development of new software options mean that 3D printing will most likely be more frequently used within dentistry as the technology develops further. Moreover, 3D printing is likely to quickly become an even greater factor in developing modern dentistry. Whilst an abundance of data indicates that quick and accurate data capturing of the intra oral environment is possible, there is a paucity of data relating to the conversion of this data to the 3D printed model, especially with newer machines.(Revilla-León et al., 2017, Richert et al., 2017, Revilla-León et al., 2018, Rovelo, May 25, 2016)

The study included in this thesis on the latest printers shows that they can produce results that are accurate to within 30 microns. For the errors of the printers in the present study, the overall combined error should be within a clinically acceptable level of under 100 microns. (Dietrich et al., 2017) These printers exceeded expectations and they are all worthwhile to use in clinical practice.

There were limitations present to this study. The shape was simply cuboid so this assessed overall dimensional trueness and precision.

Another limitation of this study in terms of its shape as a cube, is that complex dental restorations and fine surface anatomic details resolution are far more challenging to reproduce accurately and reliably. It was beyond the purpose of this study to analyse the capability of a 3D printer to reproduce complex shapes. Resolution was also not considered, but, for example, the

reason we make a crown on type 4 stone rather than plaster is that there is a 1950's standard ensuring particle sizes of <10 microns in the former, but more like 50 microns in the latter. Thus while a 3D printed model might be suitable to check for contact points, it should not be recommended for checking marginal integrity (or occlusion).

5.7 Conclusions

This study shows that the current range of 3D printers can produce clinically acceptable levels of accuracy. The findings substantiate the null hypothesis, demonstrating no significant differences in trueness and precision among the different 3D printer technologies, including the Asiga Max UV and Envision One. This underscores the consistent and clinically acceptable levels of accuracy achieved by both budget and premium printers, reflecting their reliability and reproducibility in creating models. This study confirms that all of the 3D printers can produce a reliable, reproducible model.

It is also crucial to consider the potential impact of the printing materials on the observed accuracy. Differences in printing accuracy could potentially be attributed to the characteristics of the materials used, rather than the inherent accuracy of the printers per se. The properties of the printing materials, such as their resolution, stability, and adherence, can significantly influence the fidelity and details of the printed models.

However, the printing of dental arches and restorations is more challenging in terms of complex and fine details and this deserves further investigation. Following this study, further research is needed on these printers in various settings, and the evidence of their accuracy and strength of materials must be confirmed in a clinical setting.

Chapter 6 - Development Of A 2 Part Screw Device To Use With The Fixed Edentulous Implant Guide

6.1 Introduction

This chapter details the design process for the screws to be used for the final study.

The initial study used Benefit Orthodontic screws. These screws were of limited purpose. Namely because;

- The screws were CE marked for orthodontic purposes
- The screw head was too small for a guide to sit on.
- The screw head was of a very square shape. This prevents full seating if multiple screws have divergent angles.

However the screws length was adequate.

A new design was therefore made to correct these issues.

6.2 Design Process

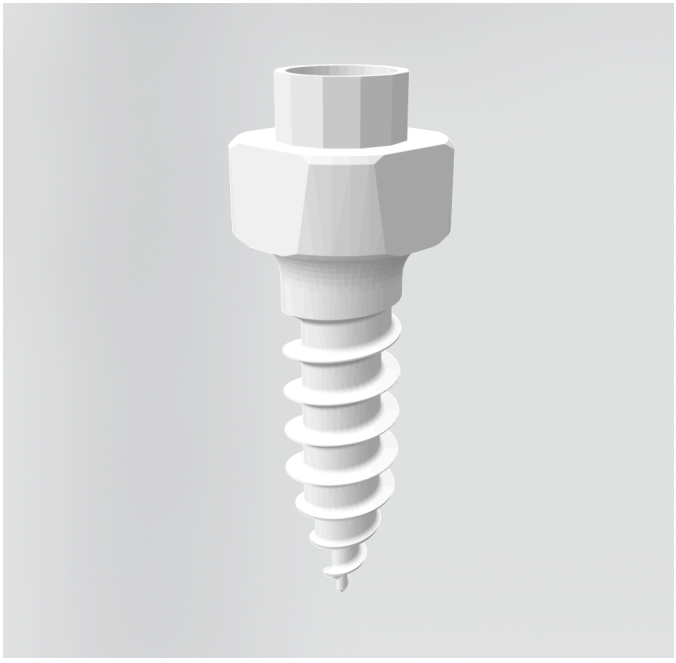

Figure 53. 3D Design Of Benefit Orthodontic Screw Used in Preliminary Study

Reasons & Need for Changes and discussions with Osteocare Implant Manufacturers in the UK;

- Benefit screw only CE marked and intended for orthodontic purposes. See Figure 54

TÜV NORD

ZERTIFIKAT / *Certificate*

gem. / acc. EN ISO 13485 : 2012 + AC : 2012

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

PSM Medical Solutions
Moltkestrasse 41
78532 Tuttlingen
Deutschland

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2012 / EN ISO 13485 : 2012 + AC : 2012 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2012 / EN ISO 13485 : 2012 + AC : 2012 - Medical devices - Quality management systems - Requirements for regulatory purposes. This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung und Vertrieb von chirurgischen Instrumenten, nicht-aktiven Implantaten, sterilen einmal- und wiederverwendbaren Medizinprodukten, Sterilgut-Containersystemen und Zubehör

Design, manufacturing and marketing of surgical instruments, non-active implants, sterile single use and reusable medical devices, sterilization boxes and accessories

Reg.-Nr. / *Reg.-No.* 44 221 160677
Bericht Nr. / *Report No.* 3518 1721

Gültigkeit / *Validity*
von / *from* 2016-09-16
bis / *until* 2019-03-31
(bis 2019-09-15 bei Umstellung auf EN ISO 13485:2016)
(until 2019-09-15 in case of Upgrade to EN ISO 13485:2016)
Edition 1

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-09-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-05-01

Figure 54. Benefit screw CE Mark Certificate (PSM, 2018)

- Head of screw too small and hex shaped therefore possible to interfere with guide if not calculated well. See Figure 56 and 57.

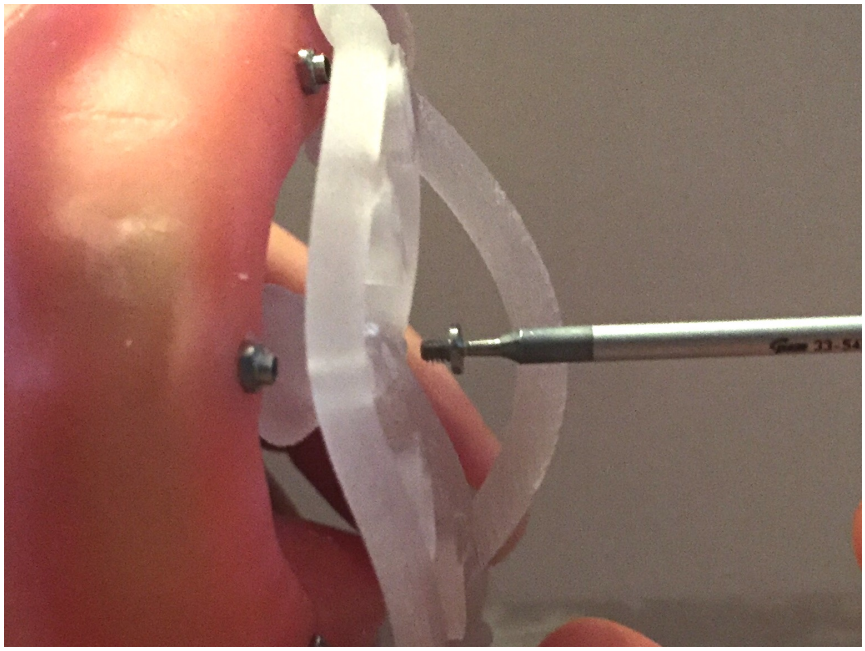

Figure 55. Benefit Screw in use, lateral view

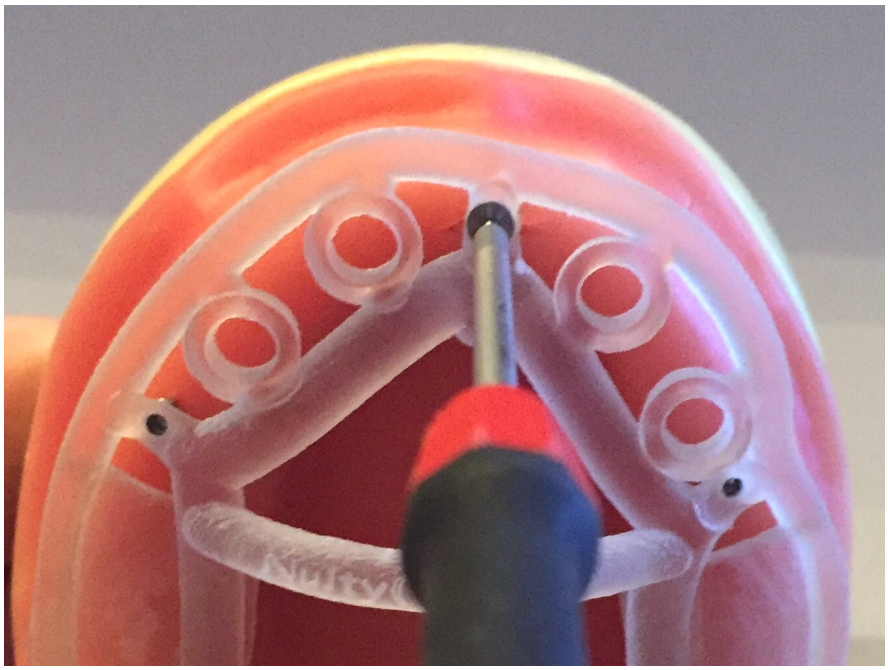

Figure 56. Benefit Screw in use, occlusal view

- Not easily scannable to reproduce virtual position
- Made of titanium as intended to integrate

On talking with the CE marking companies in Europe and they were under the impression that the screw should be made in medical grade stainless steel and be classed as a Class I transient usage surgical device ie. similar to a fixation screw.

The CE marking companies all suggested that the screw actually just needed to be considered as a tool in a surgical kit i.e. manufactured in medical grade stainless steel and supplied non-sterile as a consumable in that kit that would then be replaced as sharpness wears but otherwise re-usable for a limited number of uses with cleaning and sterilisation.

The thinking with this was that;
- they would be less invasive than osteotomy drills
- they would have to be in the mouth as part of that procedure only
- example usage: the patient comes, has three screws placed, has a CBCT taken, has the guide designed and printed on site, then the drill kit above or indeed any drill kit is used to create the implant osteotomies and then everything is removed in a matter of hours.
- a good analogy would be paralleling pins in drill kits or fixation screws as part of edentulous kits.
- fast printers like the Asiga Max UV or the Envision One can print a guide in 10-15 mins so its use as transient is realistic too as the full sequence would still be far quicker and less invasive than a full flap opening.

The point was that there would be no difference in material, how long it's in the mouth, how it's made, how it's delivered etc to an implant guide screw or fixation pin.

These are classed as class I invasive transient surgical tools and are sold as such as a part of guide kits to fix the guide in place already.

There are just differences in the way they are used and the timing of placement but the principle with regards to CE marking remains the same.

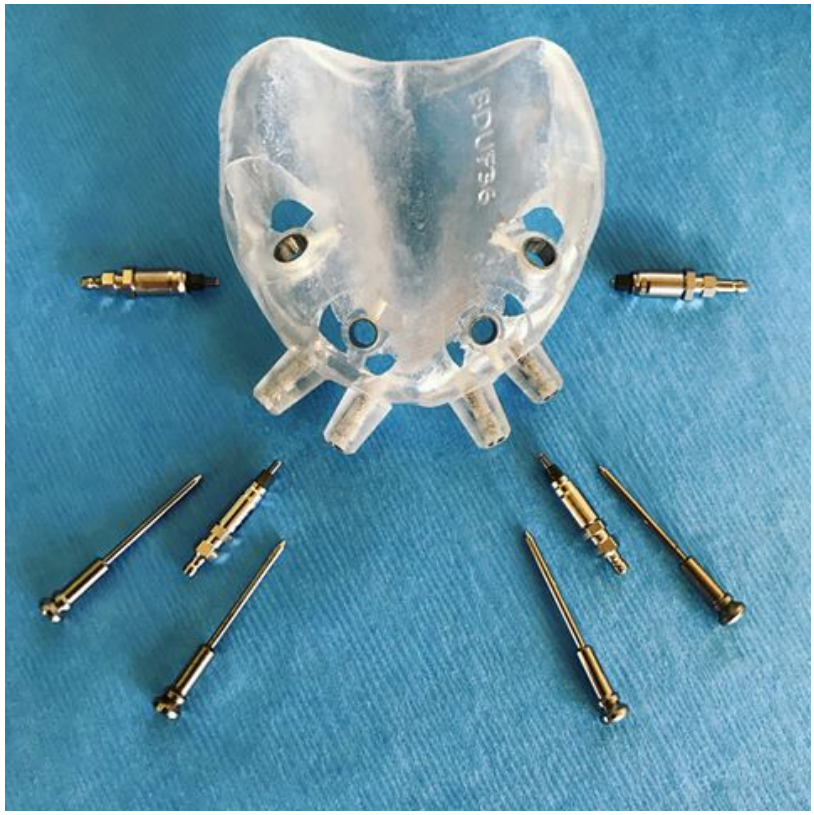

Figure 57. Conventional surgical guide fixation pins (PSM, 2018)

To clarify the timing of use;

A) Conventional fixation pin/screw

- guide placed

- screw placed

- implants placed
- screws removed
- guide removed

B) The proposed novel design of screws;

- screws placed
- guide placed
- implants placed
- guide removed
- screws removed

These are therefore the same steps, yet a different order.
Different design, similar principles, same material, similar manufacture.

The classification was confirmed using the European Guidance document on the Classification of medical devices (attached) which appears to confirm the advice from the CE companies t that it be considered a Class I surgical device of transient nature not IIa Short term use up to 30 days or indeed longer as per the following extract;

“3.1.3. Invasiveness
Invasive devices
A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
Body orifice

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device

An invasive device which penetrates inside the body through the surface of the body, with the aid of or in the context of a surgical operation.

A Reusable surgical instrument

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out (Section 1.3 of Annex IX of Directive 93/42/EEC). “

This seems to be the most accurate description of the novel screw and its use a an Implantable device;

Any device which is intended:

- to be totally introduced into the human body or,

Which it is not

- to replace an epithelial surface or the surface of the eye,

Which it is not;

by surgical intervention which is intended to remain in place after the procedure.

Which it is not.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

This also is not the case.

6.3 Practical example

A simple wound drainage device has three components that must be taken into consideration: the cannula, the tubing and the collector unit. If the device is sold without a cannula, then the classification of the cannula does not need to be taken into account. It is assumed here that the device is used for short term duration, i.e. that uninterrupted intended use is more than 60 minutes and less than 30 days. It is furthermore assumed that the collected liquids are not intended to be re infused into the body nor reprocessed for eventual re infusion and that the device is not intended to be connected to a powered suction system.

A simple wound drainage device has three components that must be taken into consideration: the cannula, the tubing and the collector unit. If the device is sold without a cannula, then the classification of the cannula does not need to be taken into account. It is assumed here that the device is used for short term duration, *i.e.* that uninterrupted intended use is more than 60 minutes and less than 30 days. It is furthermore assumed that the collected liquids are not intended to be re infused into the body nor reprocessed for eventual re infusion and that the device is not intended to be connected to a powered suction system. **Intended uses**	Rule	Class
Surgically invasive cannula to reach a wound site in the pleural cavity to drain the cavity	7	IIa
Non-invasive tubing to evacuate body liquids towards the collector.	1	I
Non-invasive collector to receive the body liquids.	1	I

The clear conclusion here is that the manufacturer would have a choice of applying Class II A to the whole device or carrying out separate conformity assessment procedures for the cannula on one hand and the tubing and collector on the other hand.

This would then lead one to think that it is a Class IIa Invasive Surgical Device. However this is then clarified;

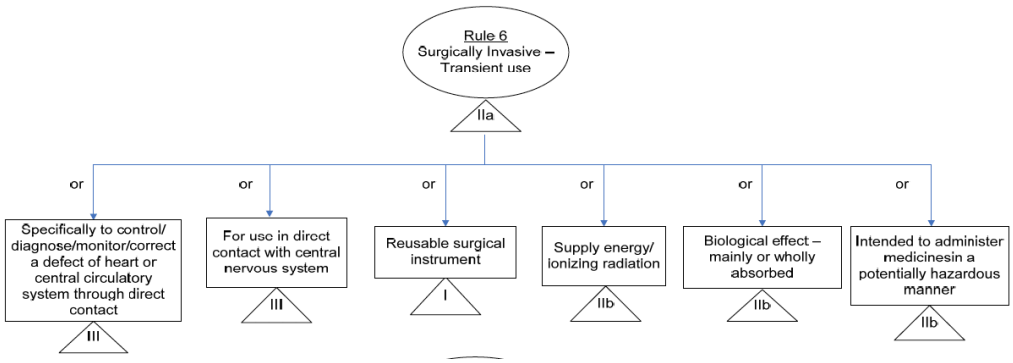

Figure 58. Classification of Surgical Device

As the device is in the “ORAL CAVITY” and it is of use less than 30 days and in in fact transient then it then reverts to a Class I Surgical device;

Timing wise as this is for the nature of surgery as clarified in the document, after placement of the screws and the taking of a CBCT, at a minimum with the fastest form of guide designing, printing, and an exceptionally fast clinician ;

1) Design of Guide 5 to 10 minutes

2) Printing of Guide 10–20 minutes (plus 10 minutes wash and cure)

3) Usage of Guide 10 - 20 minutes to create osteotomies.

4) Removal of Guide and screws.

The above was forwarded to MHRA for clarification and to confirm they are happy with the classification as Class I but would need full Class IIa CE marking to be safe for over 60 minutes use which is more realistic as the usage of the Fixed Implant Edentulous Guide will most likely be delayed by the printing and usage in most cases.

However, the path to a valid CE mark is long and expensive and beyond the scope of this PhD thesis.

6.4 Final Design

Initially the final design was conceived to be as follows;

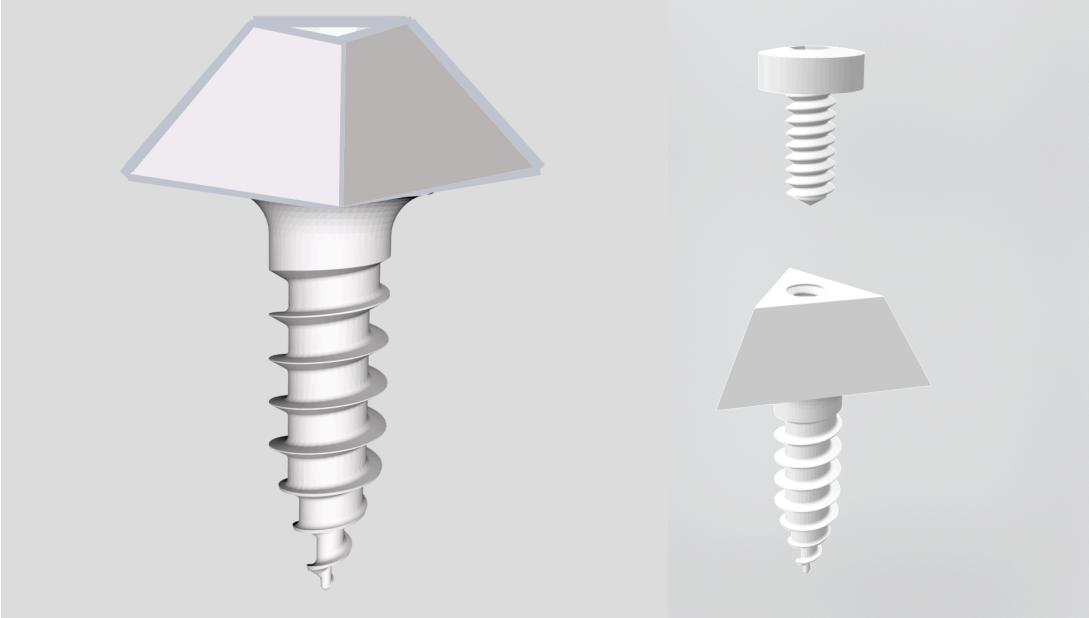

Figure 59. Views of both two part screws from initial 3D CAD design

This design was later altered as it was considered possible that a problem might arise where a slight rotation of this screw would lead to a guide that was impossible to fit.

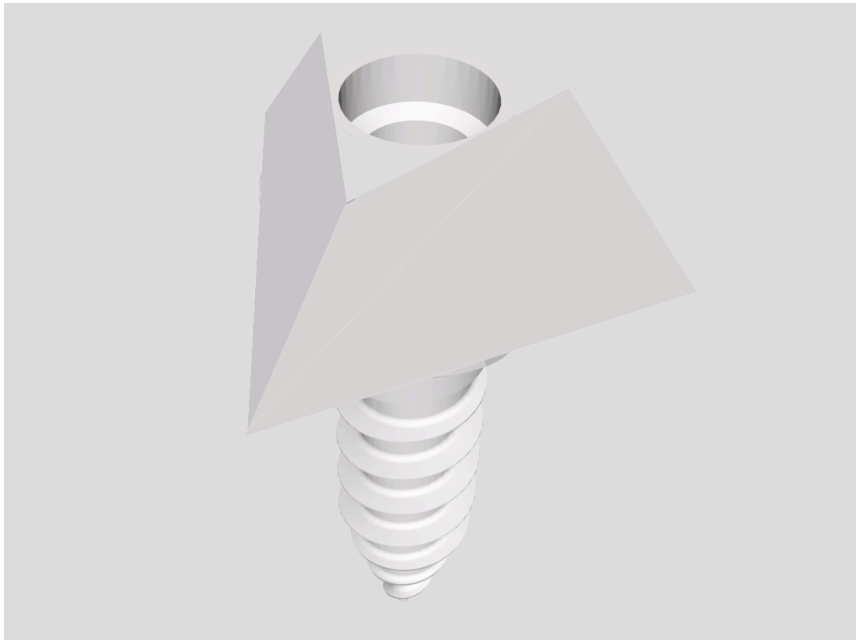

Figure 60. The triangular shape may cause fitting problems if the screw rotated slightly before guide fit.

To correct this issue the design was adjusted to be circular.

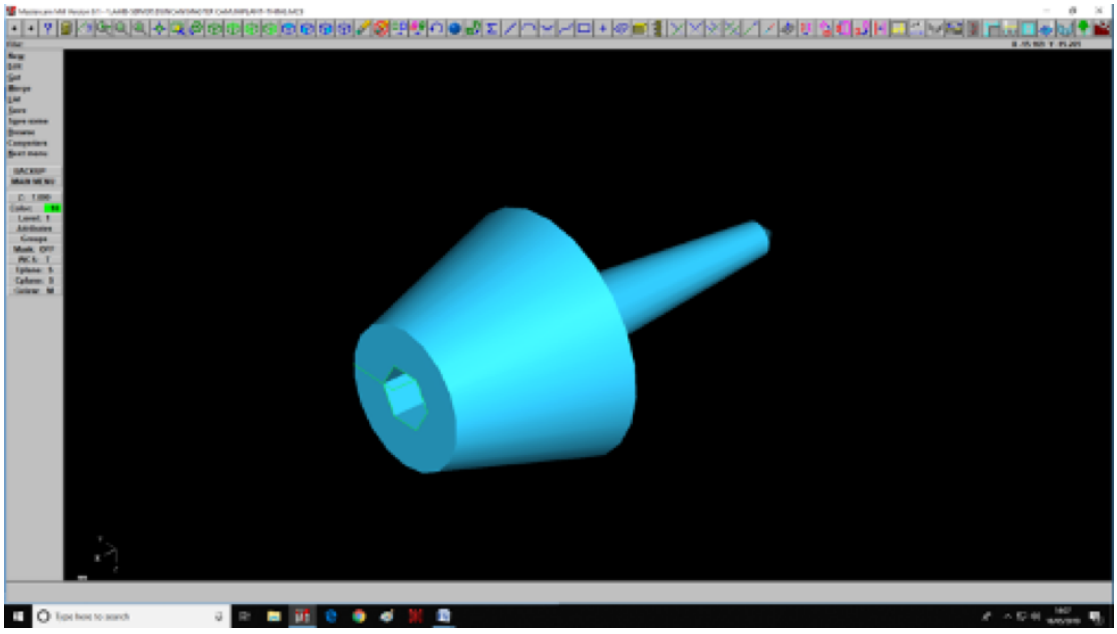

Figure 61. Proposed new circular design of primary screw.

The dimensions would be 6mm across the top and 10mm on the base. Height of scan body part 7mm, driven in with a 2.2 hex driver. The bottom part will have a thread on this is 6mm long, so 2-3mm in soft tissue and 2-3mm in bone it is approx 2.8mm diameter.

It's essential to address the fundamental comparison made between the two-part screw and a mini implant with a uni abutment. While at a glance, the two-part screw might resemble a mini implant, the design and intention behind the two-part screw are distinctly different. The two-part screw is non-integrating and is specifically designed to engage the bone by only 2/3 mm, minimizing the risk of causing any iatrogenic damage.

The choice of a non-integrating design over a mini implant is deliberate. A mini implant typically has a rough surface throughout, which could potentially serve as a plaque trap and cause inflammation if not entirely buried. This could lead to complications, especially in areas with soft tissue. In contrast, the proposed two-part screw is designed with a polished surface, reducing the risk of plaque accumulation and inflammation and thereby enhancing the safety and reliability of the guide.

Additionally, the two-part design ensures that the head is fixed about the gingival level, allowing the top second part screw to be added and removed without the risk of unscrewing any abutment. This feature is crucial for maintaining the integrity, position and stability of the screw structure during procedures.

Given that this is a novel design, there is potential for innovation for future development in material selection. For instance, the head of the screw could

be fabricated from a material like PEEK. This would reduce scatter on the CBCT, allowing for more accurate data merge and enhancing the precision and reliability of the implant guide in clinical applications.

These are the final milled screws in use to be used on the final study.

Figure 62. Final manufactured screws designed and fitted to an edentulous model.

Chapter 7 – A Novel Methodology and Software Development for Analyzing Dental Implant Positioning Change from a Virtual Planned Position to Post Placement without the use of a CBCT

7.1 Introduction

Historically, the approximation of dental implant positions in both in vitro and in vivo studies has been achieved through the comparison of post-placement Cone Beam Computed Tomography (CBCT) scans with stereolithography (STL) files. This method involves aligning an STL file to the post-placement CBCT scan and comparing the STLs to determine overall discrepancies using software like CloudCompare.

7.2 Limitations of Using CBCT Scan Post Implant Placement for Comparing Implant Position to Pre-Planned Virtual Position

Cone Beam Computed Tomography (CBCT) scans are pivotal in pre-planning for guided surgery software and post-implant placement analysis. However, there are several inherent limitations and problems associated with using CBCT scans for comparing the implant position to the pre-planned virtual position within guided surgery software.

1) Radiation Dose:

One of the significant concerns with using CBCT scans for both pre implant placement planning and post placement analysis and/or comparison is the exposure to radiation. The necessity to take two CBCT scans doubles the radiation dose, posing a potential risk to the patient. While CBCT scans generally have a lower radiation dose compared to conventional CT scans,

the cumulative effect of multiple scans should be considered, especially when evaluating the risk-benefit ratio.

2) Artifacts and Scatter:

CBCT scans are known to produce artifacts and scatter, especially around metal objects such as dental implants. (Schulze, 2011) This phenomenon can significantly impact the accuracy of post-placement position analysis. The presence of metal induces beam hardening and scattering, leading to streak artifacts and degradation of image quality. This means that the post-placement position can only be approximated with inherent error, affecting the reliability of the comparison between the actual implant position and the pre-planned position.

3) Inherent Error and Approximation:

Due to the artifacts and scatter, the post-placement position derived from CBCT scans through approximation may potentially mean inherent error. This limitation can potentially affect the clinical outcomes and the assessment of the accuracy of implant placement in relation to the pre-planned virtual position. The approximation and inherent error introduce a level of uncertainty in evaluating the success and precision of the implant placement procedure.

Overall, whilst CBCT scans are invaluable in dental implantology for pre-planning and post-implant placement analysis, the associated problems such as increased radiation dose, artifacts, and scatter around metal objects, and the resultant inherent error and approximation in post-

placement position, pose significant challenges. These limitations necessitate cautious interpretation of CBCT data and underscore the need for advancements in imaging technology and methodologies to enhance accuracy and reliability in comparing implant positions.

7.3 Novel Approach

In this thesis, a novel approach was developed to compare identical meshes, specifically, the pre-planned implant position and the post-implant placement position. This was achieved by comparing the STLs containing identical vertices for both pre planned position and post placement position through exporting the pre-planned implant STL from the guided surgery planning software and through scanning a scan body then exporting the post-placement virtual implant STL from within the Computer-Aided Design (CAD) software. This innovative method allows for a more precise and accurate comparison of implant positions, focusing on clinically relevant keypoints, such as apical and coronal midpoints of the implant.

7.3.1 Incorporating Pose-Detection in Implant Position Analysis

A pivotal aspect of this novel methodology is the utilization of pose-detection, which is fundamentally different from approximation of implant position through the use of a post placement CBCT scan. This approach aligns with ISO standards, which, interestingly, also employ pose detection rather than scanner resolution, albeit inadvertently. This discrepancy in standards has been exploited by some companies to assert that their scanners possess an accuracy of single digit microns, a claim that is widely regarded within the industry as implausible. The inherent strength of the

methodology presented in this thesis lies in its ability to harness the power of pose-detection, notwithstanding the actual resolution limitations of the scanners.

By focusing on pose-detection, the methodology circumvents the challenges posed by the actual scanner resolution, providing a robust framework for analyzing and comparing implant positions in the artificial bone post placement. This approach not only enhances the precision of the comparison but also mitigates the issues related to CBCT scanner resolution, discrepancies related to scatter and the nature of radiographic technology and the resultant associated inaccuracies in implant position analysis.

7.3.2 Understanding Pose Detection in Dental Implantology

Pose detection involves determining the spatial orientation and position of an object within a three-dimensional space. In the context of dental implantology, this translates to identifying the precise location and orientation of an implant or a scan body within the oral cavity or a scanned model. The concept of pose detection is not new and has been employed in various technological and medical applications.

In robotics, for instance, pose detection is crucial for navigating robots through a physical space by recognizing their position and orientation relative to their environment (Siciliano and Khatib, 2016). Similarly, in computer vision, pose estimation is used to determine the position and orientation of objects within a visual frame, facilitating augmented reality experiences and object tracking (Szeliski, 2010).

In the realm of dental implantology, leveraging pose detection as opposed to high-resolution scanning offers a pragmatic approach to analyzing implant positions. The methodology developed in this thesis utilizes this principle by focusing on the position and orientation of the implants, enabling a precise comparison between pre-planned and post-placement positions without being constrained by the actual resolution of the intra-oral or CBCT scanners. This approach not only mitigates the challenges posed by scanner resolution limitations but also provides a robust and reliable framework for implant position analysis, which is less susceptible to inaccuracies stemming from scanner resolution discrepancies.

7.4 Alignment Process

The alignment process is crucial to ensure a valid result with optimum alignment. The process involves ignoring the actual implant initially and aligning the post placement scan of the edentulous arch with scan bodies with the pre planning edentulous scan using the dental surfaces and gingivae. The alignment process was meticulously executed in several steps:

1. Export of the original virtual implant planning as native implant STLs, labeled according to each artificial edentulous mandible.
2. Scanning of the implant scan bodies in the bone post-implant placement procedure of the artificial jaw with a lab scanner.
3. Utilization of CAD software to align the scan bodies and export pure native post-placement STLs of the implants.
4. Exportation of each individual post-placement virtual implant with maintained XYZ position.

6. Specific nomenclature was used for each exported implant STL based on the artificial jaw number and position.

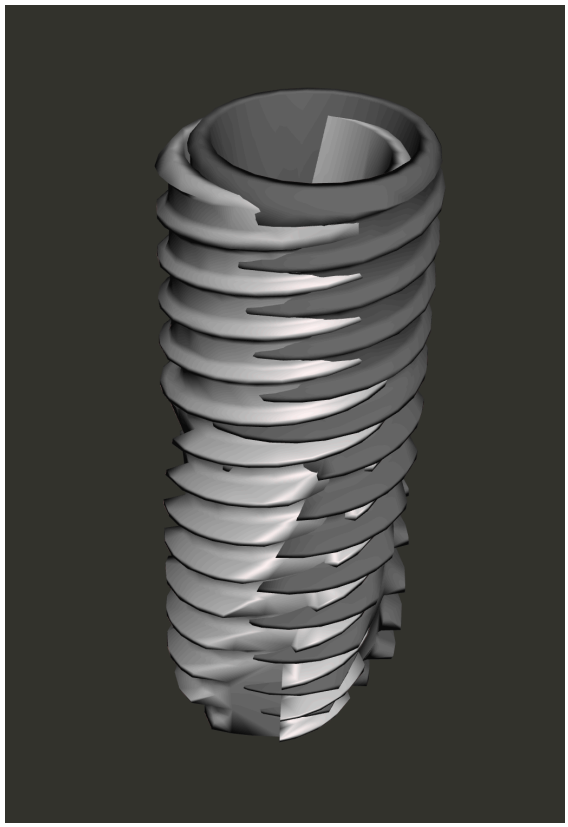

Figure 63. The Pre-planned Position and Post-placed Position STL of the Implants overlaid to see the change in position in 3D space

7.5 Data Measurements and Analysis

Once the alignments were validated, the deviation of the actual CAD implant from the plan was measured. Several methods were considered for this process, including Proscrustes transformation, decomposition of the matrix into translation and rotation, and linear measurement from clinically relevant keypoints between the two meshes. A custom-made C++ program developed by Andrew Keeling at Leeds University was utilized to calculate the XYZ positional changes of the STLs as the pre planning virtual STL and the post placement virtual implant STL were exactly the same with the same vertices focusing on key linear deviation magnitudes for statistical analysis. The results were recorded into a table and could easily be imported into statistical software like Excel or SPSS for further analysis.

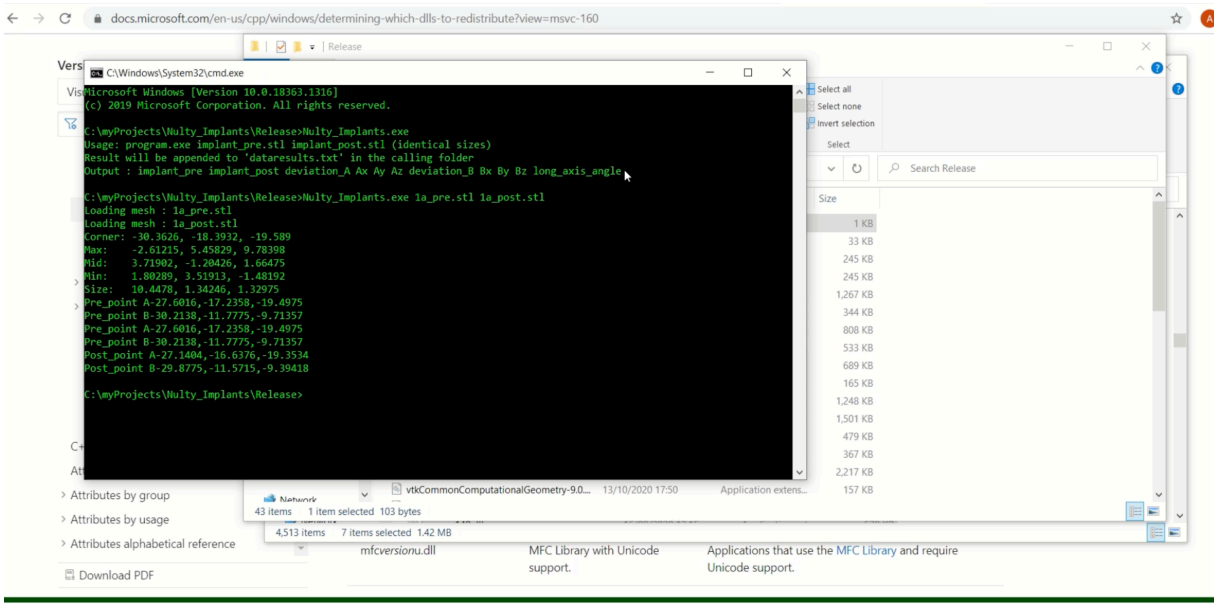

Figure 64. The Positional Change Calculator Created at Leeds University (Keeling 2021)

7.6 Challenges and Solutions

One of the challenges encountered was the inconsistency in the ordering of the vertices in STL files. One issue with STL files in general is that they sometimes jumble the ordering of the vertices, meaning that although you have the same number of triangles and vertices in both files, the vertex ids are different.

Instead, the code does the following;

1) Measures the angle between the long axes of the two implants (This is important because we now ignore rotational angle errors caused simply by the screw thread).

2) Calculates two points, A and B, which sit centrally and at either end of the implant.

3) Measures the distance between point A on pre to point A on post, and similarly for point B

4) Saves both filenames, the A-to-A distance, the X,Y,Z coordinate of point A on the post implant, the B-to-B distance, the X,Y,Z coordinate of point B on the post implant, and finally the angle between long axes in degrees.

This method allowed for the identification of apical and coronal ends and the measurement of key outcomes like apical deviation and angular deviation.

7.7 Conclusion

The novel method and use of the software developed by Andrew Keeling in this thesis provides a new approach to analyzing dental implant positioning in in-vitro mandible studies. This innovative method allows for more accurate and precise comparisons than an approximation of implant position through

the use of a post placement CBCT, focusing on clinically relevant keypoints and overcoming the challenges associated with traditional methods. The results obtained through this method have significant implications for the field of dental implantology, contributing to the enhancement of implant placement accuracy and the overall success of dental implant procedures. Further refinements can be made to report apical deviations with respect to the long axis of the post implant, providing insights into how much the implant apex deviated 'down' and laterally. The automation of the task of creating the text file of the results through a batch script written by the thesis author signifies the potential for further advancements and automation in this domain.

Chapter 8 - An *In Vitro* Study of the Fixed Edentulous Implant Guide using a Novel Approach to Edentulous Guided Surgery Using a Developed Two Part Screw

8.1 Introduction

The final part of this thesis was originally envisioned to be an *in vivo* study. However, the COVID-19 pandemic impacted these plans, which is presented as the final chapter after this conclusion, discussing a possible post-doctoral research study.

The aim of the study was to measure the accuracy of the placed implants using a novel method to reference the digital intraoral impression STL data and the CBCT radiographic data compared to their virtual counterparts on the CBCT planning model. The study used a newly designed anatomical model with representative gingiva and bone.

The objective of the study remained as indicated in the initial preliminary study to examine whether it is safe and accurate to place implants with flapless surgery using this new method of referencing the model to the CBCT scan.

The method was adjusted and improved following knowledge gained from the preliminary study.

The implant planning still involved virtually planning the case using SMOP guided surgery software, but rather than using a low dose CBCT scan to compare the 3D position of the planned and placed implants in terms of angular deviations and linear deviations by overlapping the pre- and post-operative CBCT scans, the final study would use an export of the planned positions via 3D STL and the actual positions of the placed implants through the use of a digital scan body used to provide the 3D position of the exact

same planned STL. In this manner the planned and post placement STL shapes could be compared in position directly using an algorithm developed by the digital research laboratory at Leeds School of Dentistry to compare STL shape movements and angulation changes in three planes.(Keeling, 2021) The results would be used to calculate the trueness and precision of actual position relative to the planned position on the virtual model.

The null hypothesis (H0) for the in-vitro study is that there is no difference in the positional error of implants placed using a tissue-borne surgical guide compared to implants placed using a novel screw-retained guide in an in vitro edentulous mandible simulation.

8.2 Methodology

8.2.1 Sample size

Using the data from the original study, a power of 80%, and a level of significance chosen at $p < 0.05$, a sample size calculation performed with BioMATH calculator resulted in a sample size of 5 for each group. All equipment used in the study was calibrated and serviced before the start of the study. To enable the measurement of accuracy and understand which errors in the final implant position are attributable to which cause, each step in the workflow was examined.

8.2.2 The creation of more a more biologically accurate model

This study aims to provide a more accurate comparison of the novel method versus an ordinary edentulous arch through the use of a lower model with gingiva that is flexible and allows for the gingiva to compress in use with an

implant guide as there would be potential for an *in vivo* situation. The artificial bone was sourced from Sawbones as an artificial D2 density mandible. To provide for this, the surface of the mandibular models was 3D scanned. The 3D anatomy of the jaw model was then extruded by 1.5mm, the average thickness of edentulous mucosa,(Dong J, 2015) and a 3D cover designed that would accurately adapt over the bone model. This 3D STL of the gum was then 3D printed using Asiga Dental Gum resin.(Asiga)

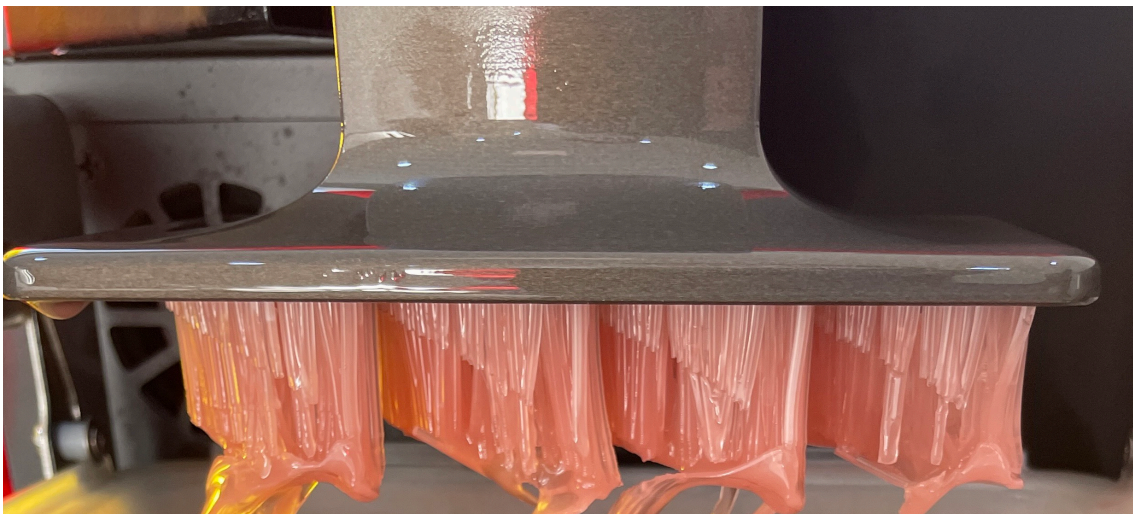

Figure 65. 3D Printed Gingiva to attach to the Artificial Mandibles

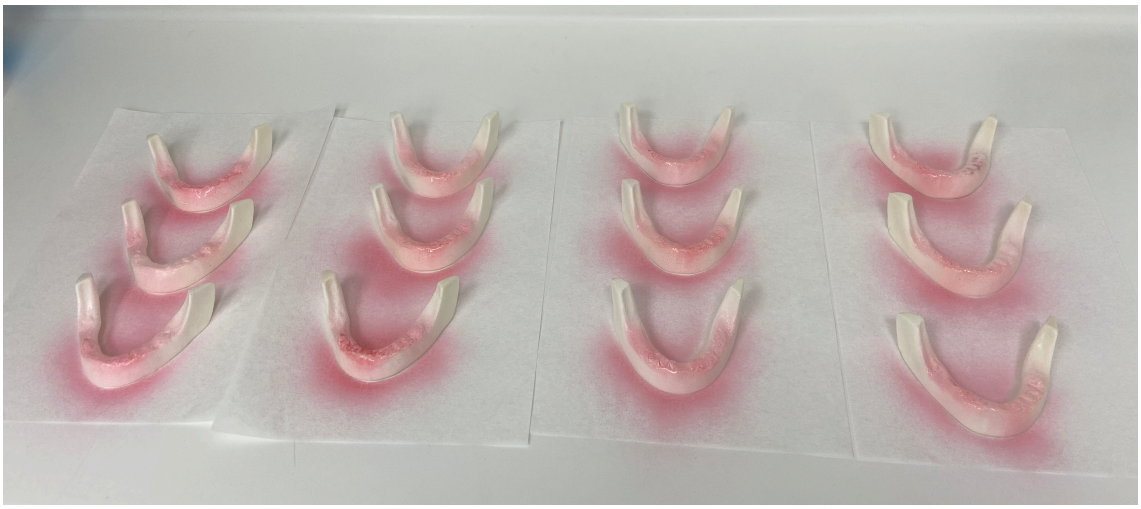

Figure 66. Artificial Mandibles are sprayed with adhesive to bond the artificial gum layer

The human mandible was chosen as the author considers that accuracy in the mandible is more important to prevent potential iatrogenic damage to structures, such as the inferior alveolar nerve which is more serious in potential morbidity effects than surrounding structures in the maxilla.

In terms of classification of the resulting artificial jaw, the edentulous mandible model was a smooth mandible, with simulated extensive resorption and loss of ridge detail, which would likely be classified as an Atwood Class V, (Atwood, 1971) that is characterized by a nearly flat residual ridge. However, as the artificial jaw is being used for in-vitro study, it may not strictly adhere to clinical classifications like Atwood's, as it might be designed to represent a generalized or simplified version of an edentulous mandible without focusing on the specific anatomical details related to ridge resorption.

The novel scan flags designed in the previous chapter were then placed in a triangular formation on half of the models.

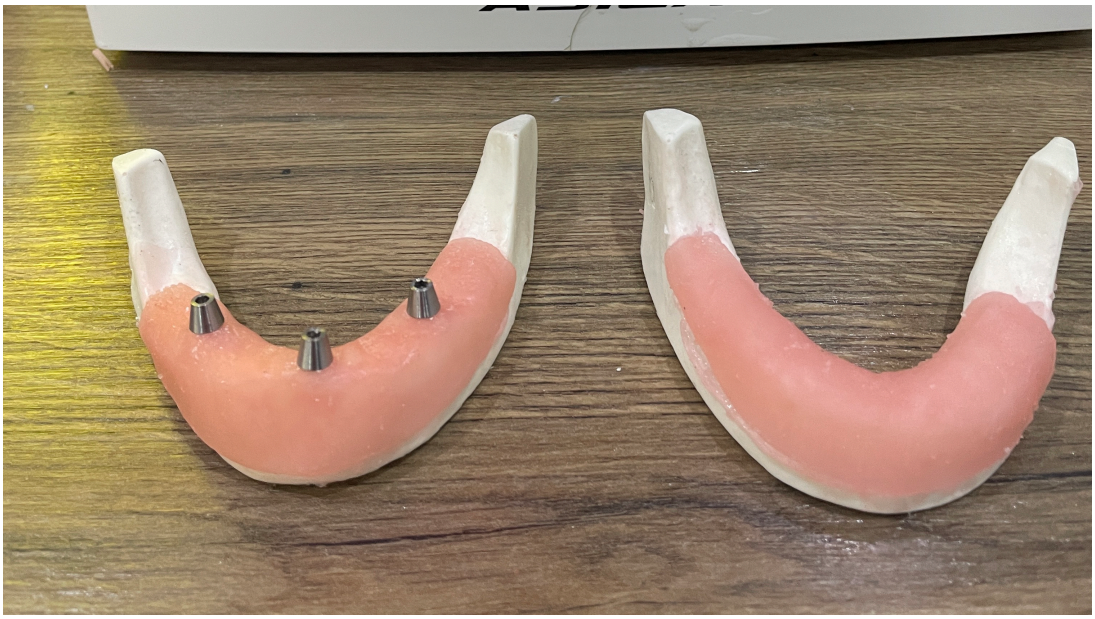

Figure 67. Artificial Bone Model Type A - With Novel Two Part Screws and Type B - Without screws.

Each of the models was then marked and numbered before being powdered and scanned with a lab scanner (Up3D 300e, Seoul, Korea). The 300e was

used as the most accurate lab scanner available at the time of the study.

Figure 68. Each Model was scanned with an Up3D 300e lab light scanner.

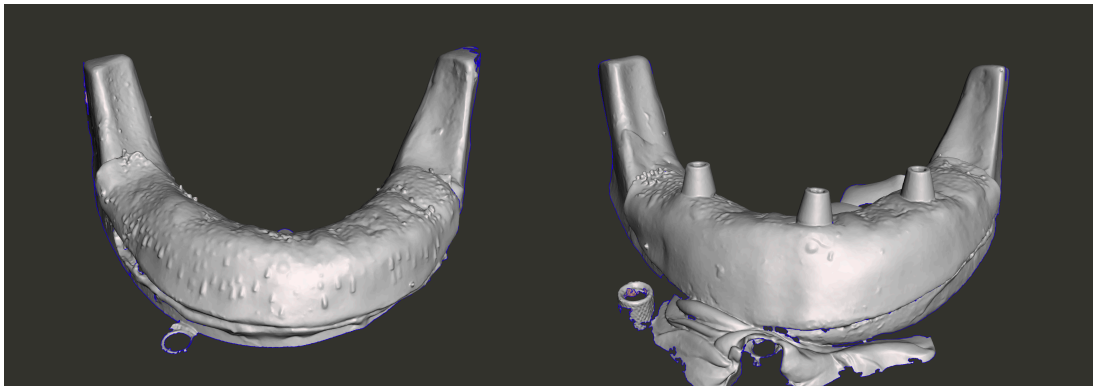

Figure 69. The 3D STL scan of each model type.

8.2.3 Data alignment and virtual implant planning

The 3D volume STL of the screws were then matched with the visible coronal portion of the screws on the surface of the model. The CBCT was taken at a voxel dimension of 0.2 with standard settings for a lower arch on the Carestream 81003D.

This scan was then used to create a full 3D version of the model and a guided surgery plan to place four dummy implants into the artificial bone block created with SMOP guided surgery software.

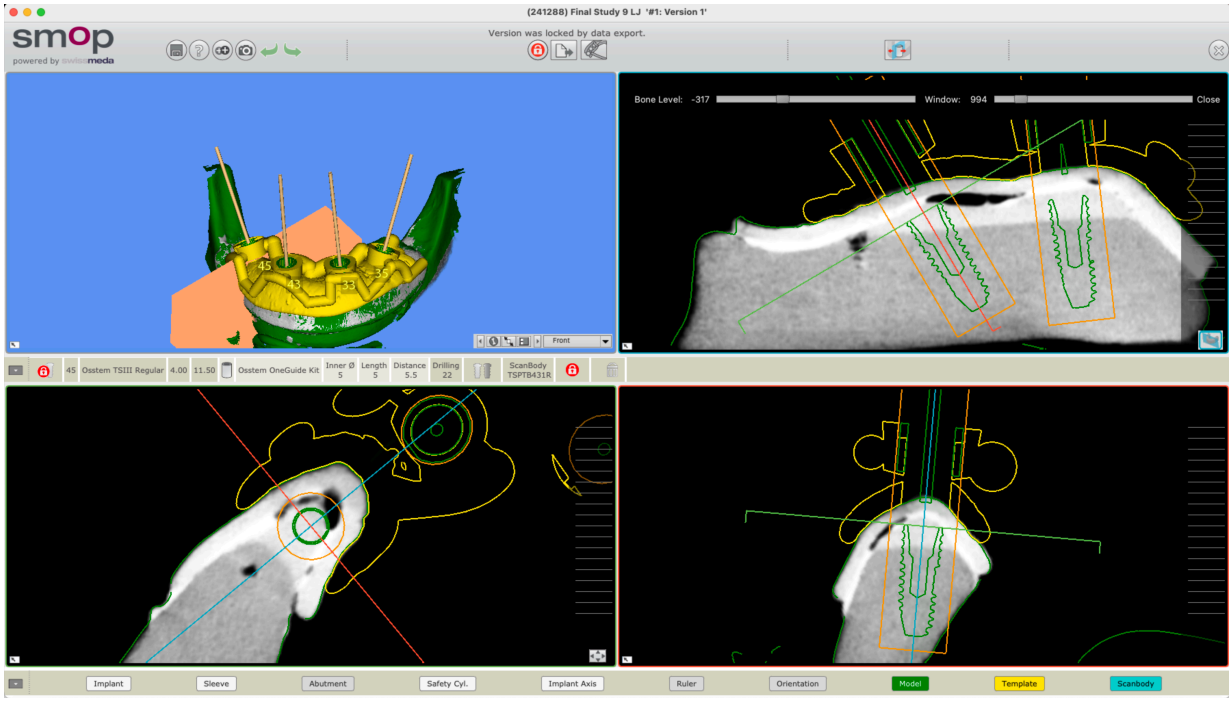

Figure 70. The Swissmeda SMOP Implant Planning

8.2.4 Printing of the surgical guide

Nextdent SG Guide resin was used to print the guides with a calibrated Asiga Max UV 3D printer with slice thickness set at 25microns, followed by fully following the manufacturer's instructions to post process, wash and cure each guide.

8.2.5 Guide Placed with Screws

The printed guide was then placed and locked onto the model with the two-part screws and the osteotomies prepared before placing the dummy implants with a fully guided protocol, with the non FEIG guide being a conventional soft tissue borne guide without fixation screws.

In total 40 implants were placed into 10 artificial bone models using the same drill kit (i.e., the Osstem Oneguide Sleeveless drill kit). The gingival coverage for each osteotomy site was removed by using the tissue punch within the drill kit. The same methodology of osteotomy preparation was used with a fully guided approach. In other words, an increased length and an increasing width of implant drill with every drill guided through guide cylinders. The implants were then guided using guide mounts through the guide into the prepared osteotomy for a fully guided approach

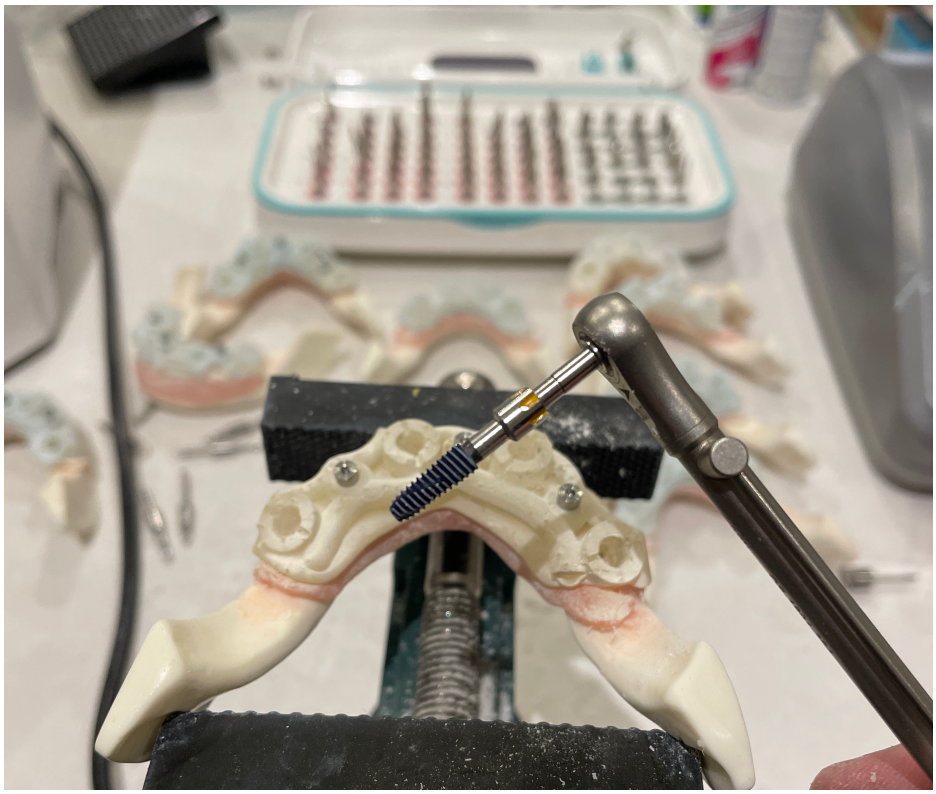

Figure 71. The test block osteotomies and dummy implant placement.

8.2.6 Data Collection Methods

In the final study the data was collected through from 10 artificial bone models discussed in Chapter 8.2.2.

8.2.6.1 Method for Calculation of Implant Position

The virtual portion of the planned implants were exported for each model.

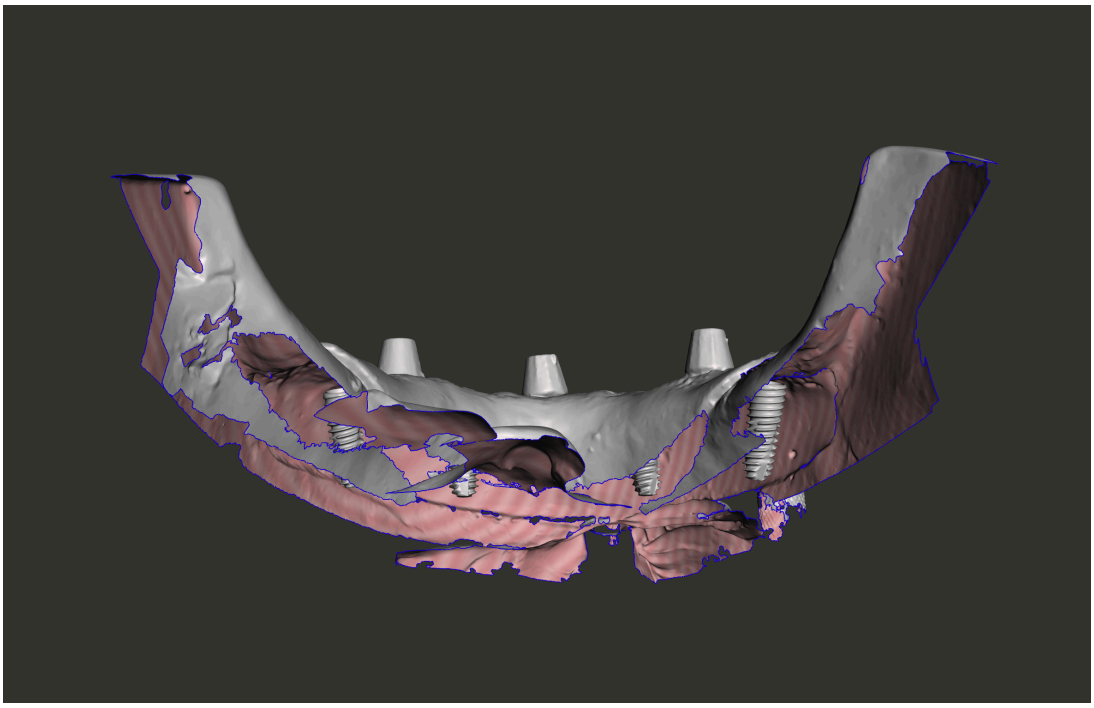

Figure 72. An STL Export of the Original Impression Data and the Export of the Planned Virtual Implant STLs

The planned and placed model 3D STL scans were calibrated and aligned through Meshlab software. The implant position of the placed implants were

exported by way of a scan body to provide the position in a 3D manner relative to the model.

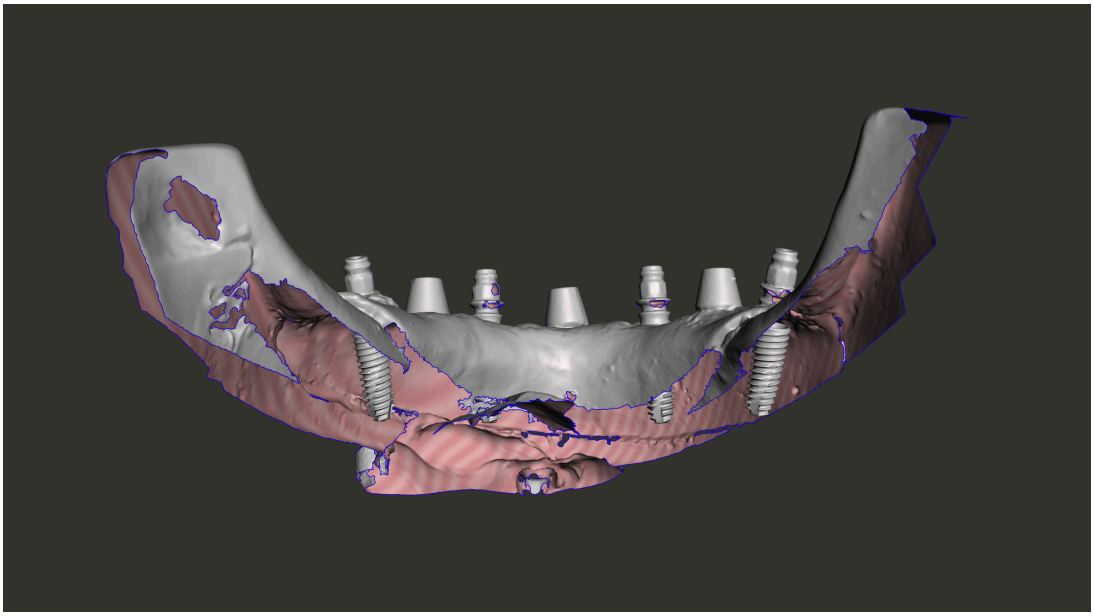

Figure 73. An STL Export of the Post-placement Impression Data. The image shows the calculated implant position below the gingiva calculated from the Scan Bodies shown above the gingiva.

Each specific implant STL was then exported with a nomenclature based on the model number and position from A to D along with whether it was a pre-planned position or a post-placed position. This process resulted in a folder with identical implant STLs apart from the 3D XYZ coordinates of each STL. Through this method the following changes in 3D position were calculated:

- Deviation of the centre of the coronal aspect of the implant in terms of X, Y, and Z
- Deviation of the centre of the apical aspect of the implant in terms of X, Y, and Z
- Vertical angulation change

A custom made C++ program was then used to calculate the XYZ positional changes of the STLs as described in Chapter 7. (Keeling 2021)
The X,Y,Z values are the absolute positions recorded. Deviation A and Deviation B are calculated as sqrt(X*X + Y*Y +Z*Z) and are the key linear deviation magnitudes used for statistical analysis of the results.
Once the comparison was completed the numerical analysis was added to the clipboard and recorded into a table.

8.3 Results

8.3.1 Statistical Analysis

Statistical analysis was performed using SPSS 27 statistical analysis software (IBM, SPSS Inc., Chicago, IL). The statistics were performed in four separate groups as each block has fours implants. The data from these four positions were not independent as they had the same guide sitting in the same position. The results were therefore distinguished into four data sets for the 16 blocks in positions A, B, C, and D for the comparison to the repeats of the first block data with the intention to analyse with a t-test.

8.3.2 Data Obtained

BLOCK REPEAT	Position	Coronal Deviation A (mm)	Apical Deviation B (mm)	Angle Error (Degrees)
1	a	0.76	0.50	2.22
1	b	0.43	0.41	1.15
1	c	0.53	0.43	1.00
1	d	0.55	0.41	3.06
2	a	0.55	0.25	2.19
2	b	0.47	0.19	2.32
2	c	0.54	0.38	2.11
2	d	0.62	0.50	2.58
3	a	0.34	0.23	2.15
3	b	0.36	0.33	0.69
3	c	0.32	0.16	1.38
3	d	0.11	0.16	0.21
4	a	0.23	0.31	2.26
4	b	0.33	0.14	1.40
4	c	0.28	0.09	1.59
4	d	0.60	0.36	4.62
5	a	0.36	0.09	2.27
5	b	0.64	0.17	3.35
5	c	0.44	0.18	1.44
5	d	0.57	0.31	1.83
6	a	1.03	1.13	1.97
6	b	2.59	1.75	6.96
6	c	1.21	1.45	2.25
6	d	2.84	1.56	7.25
7	a	1.89	0.70	6.40

7	b	1.38	1.10	2.40
7	c	0.92	0.92	0.31
7	d	1.29	0.67	3.24
8	a	0.72	0.54	1.23
8	b	1.01	0.68	2.24
8	c	0.73	0.54	1.13
8	d	0.73	0.69	1.61
9	a	0.98	0.61	3.81
9	b	1.07	0.93	2.58
9	c	1.45	1.53	1.37
9	d	1.08	0.67	3.53
10	a	0.28	0.31	1.41
10	b	0.84	0.64	1.34
10	c	1.28	0.81	3.34
10	d	1.14	0.65	3.00

Table 18. Test Data Recorded from Comparison of Implant Positions

A box plot of the data output categories as given by the batch calculator tool is shown in Figure 74,75 and 76.

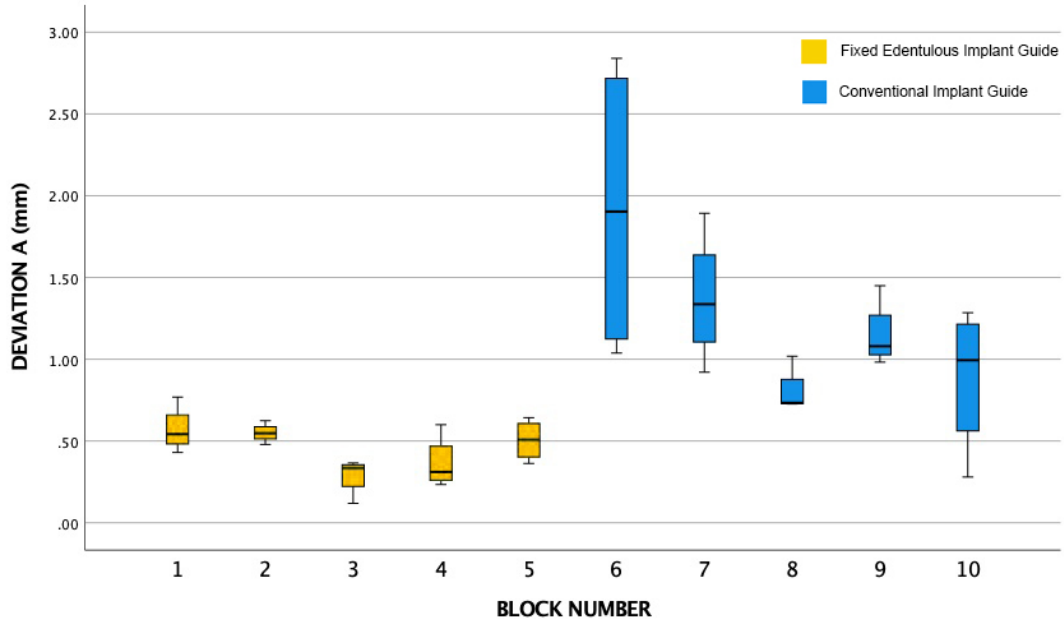

Figure 74. Box Plot of the Data Output Categories for the Overall Coronal Deviation A. Blocks 1-5 are with the Fixed Edentulous Implant Guide. Blocks 6-10 are with a conventional edentulous implant guide.

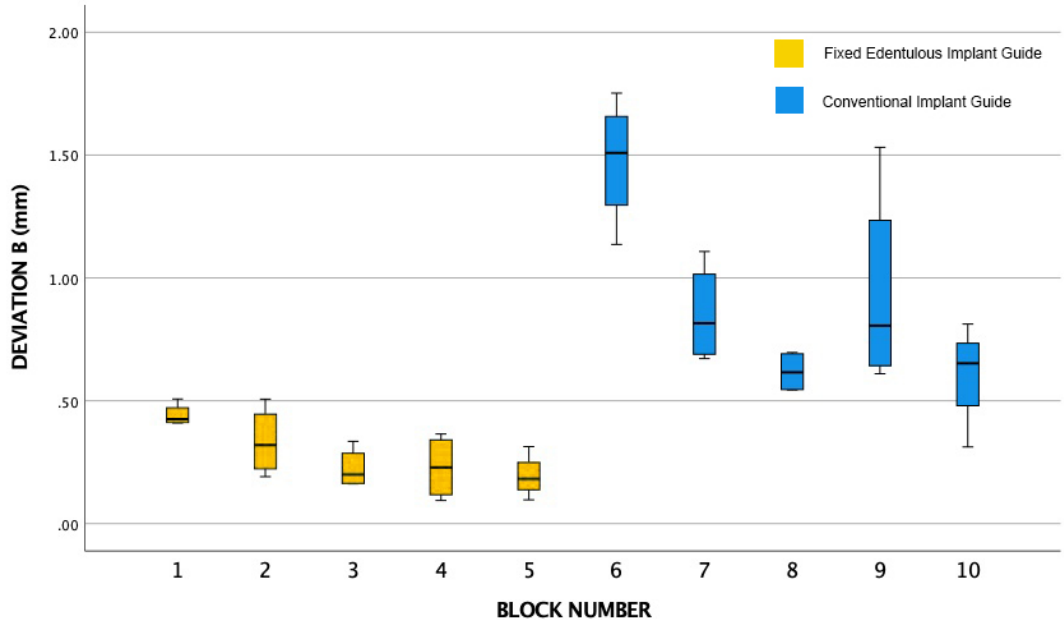

Figure 75. Box Plot of the Data Output Categories for the Overall Apical Deviation B. Blocks 1-5 are with the Fixed Edentulous Implant Guide. Blocks 6-10 are with a conventional edentulous implant guide.

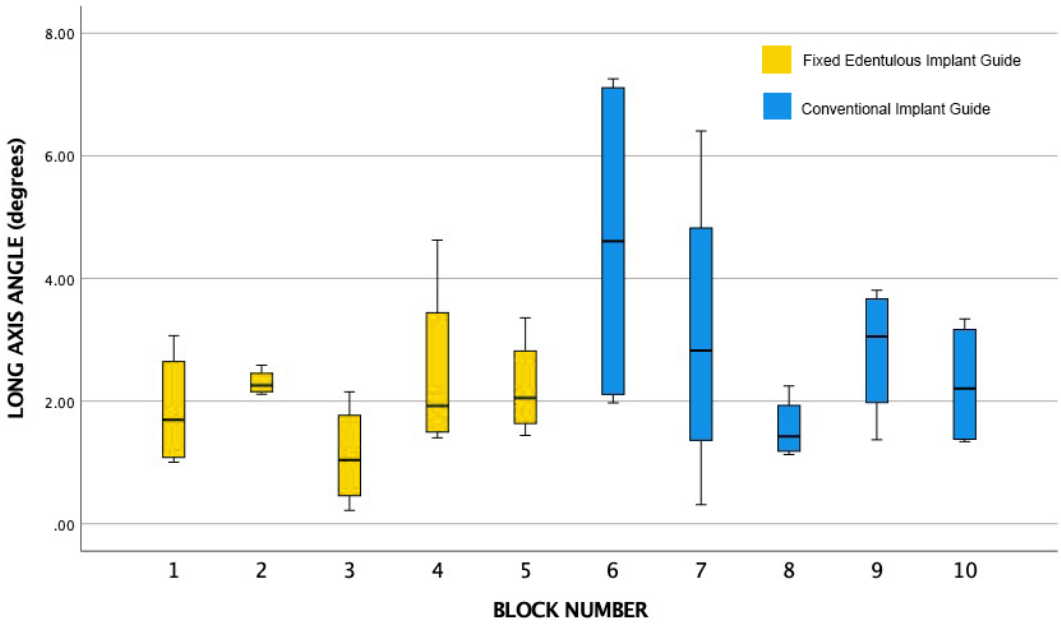

Figure 76. Box Plot of the Data Output Categories for the Overall Vertical Angular Deviation. Blocks 1-5 are with the Fixed Edentulous Implant Guide. Blocks 6-10 are with a conventional edentulous implant guide.

The box plots are not presented as two groups due to the inherent structure and dependencies within the data. Given that the study involved four separate groups, each with four implants, the data from these four positions are not independent, as they share the same guide sitting in the same position. This interdependence necessitates the segregation of results into distinct datasets corresponding to each block, rather than amalgamating them into two broader groups. This categorization enables a more precise comparison to the repeats of the block data. The intention to analyze with a t-test further underscores the need for maintaining the integrity of these individual datasets, as pooling them into two groups could obscure the

subtleties and variances inherent to each position, potentially leading to inaccurate or misleading statistical inferences.

8.3.3 Statistical Analysis of Data Sets

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
DEVIATION A	Equal variances assumed	8.15	.00	-5.46	38	.00	-.77	.14	-1.05	-.48
	Equal variances not assumed			-5.46	21.58	.00	-.77	.14	-1.06	-.47
DEVIATION B	Equal variances assumed	16.22	.00	-6.54	38	.00	-.61	.09	-.80	-.42
	Equal variances not assumed			-6.54	23.10	.00	-.61	.09	-.80	-.41
LONG AXIS ANGLE	Equal variances assumed	5.38	.02	-1.79	38	.08	-.87	.48	-1.86	.11
	Equal variances not assumed			-1.79	28.05	.08	-.87	.48	-1.87	.12

Table 19. Main Data Descriptive Statistics

Method 1 (Screw) and Method 2 (No Screw)				
	Method	Mean	Std. Deviation	Std. Error Mean
Deviation A (mm)	**1**	0.45	0.15	**0.03***
	2	1.22	0.61	0.13
Deviation B (mm)	**1**	0.28	0.13	**0.02***
	2	0.89	0.39	0.08
Long Axis Angulation Deviation (Degrees)	**1**	1.99	0.98	**0.22***
	2	2.87	1.95	0.43

Table 20. Independent Samples T-Test: Novel Method 1 versus Regular Method 2

The group statistics reveals that the Novel Method 1 has a lower mean for each type of deviation, be it overall deviation coronally, apically, or the angulation change, as shown in Table 19.

Furthermore, the mean for the overall deviation A and B are both over half for the novel method.

Regarding the independent samples t-test, Levene's test for equality of variances is less than 0.05 for each of the deviation types, which means that the variability in each of the types of deviation between each method is not the same and is significantly different.

The t-test results as shown in Table 20, reveal that the significance is less than than 0.05 for each comparison ($p<0.001$), and a statistically significant difference between the two methods is concluded. Furthermore, the differences between condition means are not likely due to chance, and the novel method is significantly more accurate in terms of coronal and apical deviation. However the same is not true for the overall angulation error ($p=0.081$). Here the t-test shows that there is no statistically significant difference between the two methods. The differences between condition means are likely due to chance.

8.4 Discussion

This study aimed to measure the accuracy of the placed implants using a novel method to reference the digital intraoral impression STL data and the CBCT radiographic data compared to their virtual counterparts on the CBCT planning model. The study used a newly designed anatomical model with representative gingiva and bone.

The method in this study compared to the preliminary study was improved in terms of a model that more accurately resembled a lower jaw with bone and mucosa. However, this is still an *in vitro* study with potential differences in how the artificial tissue responds to compression and movement compared to an in vivo study using living tissue. Despite these differences, the study serves as a proxy for the expected outcomes of the novel method.

The measurement method using the custom program is both repeatable and valid as the program measures changes in 3D XYZ spaces of identical STL representations of the pre-placement planned positions and the final position matched with a scan body. The method had *a priori* knowledge of the vertex indices in the STL file, meaning precise locations on the implant could be identified and measured automatically.

Mean coronal deviations of the novel method were 0.45mm (+- 0.15mm) compared to that of the conventional tissue borne edentulous guide at 1.23mm (+- 0.6mm), whereas the mean deviation of the apex in the novel method was 0.28mm (+- 0.13mm) as opposed to the conventional method producing a mean of 0.90mm (+- 0.40mm).

The angular deviations of the novel method had a mean of 1.99° (+-0.98) whereas the conventional method produced results with a mean of 2.87° (+- 1.95).

The values of the conventional method compare well with other published literature such as Behneke et al, whilst the novel method produced results that were statistically significantly different in apical and coronal deviation, with approximately three times less deviation in both. (Behneke et al., 2009)

There was also a trend towards lower angular deviation when using the screw method, but this was not statistically significant (p=0.081). This lack of

significance may in part be due to the power of the study (low number of samples).

Further investigation in terms of a post-doctoral *in vivo* study is justified based on these initial findings.

The null hypothesis for the trial as a prospective cohort trial was that there is no difference in the positional error of implants placed using a tissue-borne surgical guide compared to implants placed using a novel screw-retained guide in an in vitro edentulous mandible simulation. This study disproves the null hypothesis as the mean deviation of the coronal deviation and apical deviation was within 0.5mm, and the angular deviation was within 1°.

By rejecting the null hypothesis, the alternative hypothesis is proposed that there is a significant difference in the positional error of implants placed using a tissue-borne surgical guide compared to implants placed using a novel screw-retained guide in an in vitro edentulous mandible model.

There were several limitations to this in vitro study that must be addressed. The study was conducted in vitro using an anatomical model designed to resemble a lower jaw with bone and mucosa. While this model represents an improvement over the previous preliminary study, it cannot fully replicate the complexities and variabilities of living tissues found in in vivo settings. The artificial tissues used in the study may respond differently to compression and movement compared to living tissues, potentially impacting the generalizability of the findings.

The study compared the novel method with a conventional tissue-borne edentulous guide. While the values of the conventional method align well with published literature, the absence of comparisons with other novel or emerging methods limits the understanding of how the new method performs

relative to other innovative approaches in the field. For example whether the conventional edentulous soft tissue guide would be more stable with a fixation pin(s).

The study primarily focused on the accuracy of implant placement and did not assess long-term outcomes such as implant survival, integration, or complications. The absence of long-term data limits the ability to draw conclusions about the overall efficacy and safety of the novel method in clinical practice which would be able to be studied through an in vivo study. The findings of this study are also based on a specific anatomical model and a particular set of conditions. The generalizability of the results to diverse patient populations, varying anatomical structures, in particular for different Atwood edentulous ridge classifications (Atwood, 1971) and different clinical settings which therefore remains uncertain and warrants further investigation through an in vivo study.

The lack of statistical significance in some comparisons, such as angular deviations, suggests a need for cautious interpretation of the results and highlights the importance of conducting further studies with larger sample sizes to validate the findings.

It’s also important to address the limitations regarding the guide design. The guide, as it appears, utilizes a hole made from the printed material through which the drill is guided, contrasting with surgical guides that incorporate a metal tube or sleeve to guide the drill. This design choice raises potential limitations about the potential for guide material to contaminate the implant field. It’s essential to acknowledge this risk and to consider modifications or additional steps to mitigate the possibility of contamination, ensuring the safety and purity of the implant field during procedures.

Additionally, the length of the guide tube, a factor discussed in the literature review of this thesis, is a significant confounding factor, that was not addressed within this in vitro study due to the limitations imposed with the available drill guide system for the dummy implants used. Future developments and in vivo trials should delve into the implications of guide tube length and its role in the overall efficacy and safety of the FEIG guided implant placement system.

Addressing these limitations in future research, particularly through in vivo studies and investigations involving diverse methodologies and larger sample sizes, will be crucial to validate and build upon the initial findings of this study.

8.5 Conclusion

The method of using the measuring software/method has been shown to be precise, and therefore, it is a potentially useful clinical tool. There was a significant improvement in implant placement position when using the novel FEIG guided implant placement system *in vitro*.

This therefore warrants further clinical investigation.

Chapter 9
Thesis Summary, Conclusion, Implications, and Recommendations for Further Studies

9.1 Introduction

This final chapter of this thesis presents an overall summary of the findings, followed by the related conclusions. This chapter also discusses the implications of this study and the recommendations for future research.

9.2 Summary of the Study

Throughout this thesis the main research question was presented and discussed through *in vitro* studies. Furthermore, literature reviews of the potential factors that affect the accuracy of each component used in the in vitro study were also presented. The objective of the thesis was to explore the principal problem of inaccuracy when using guided implant placement on fully edentulous patients. The thesis and the *in vitro* study discussed a new, novel method using the “Fixed Edentulous Implant Guide” that has been proposed to enable the matching of reference points in a digital impression and a CBCT scan to create an implant drill guide with the potential for more accurate positioning than current tooth-based guides.

The objectives of the preliminary study were the following:

- Assess the deviation in the angulation of the placed implants compared to the planned virtual position.
- Assess the deviation in the coronal position of the placed implants compared to the planned virtual position.

- Assess the deviation in the apical position of the placed implants compared to the planned virtual position
- Use the deviation measurements to determine the accuracy of the placed implants using the novel method to accurately reference the digital intraoral impression STL data and the CBCT radiographic data compared to their virtual counterparts on the CBCT planning model.
- Examine whether it is safe and accurate to place implants with flapless surgery with this new method of referencing the model to the CBCT scan.
- Compare the trueness and precision of the new method to the literature on the current best practice with tooth borne guided implant placement.

The null hypothesis (H0) for the comprehensive in vitro study is that there is no difference in the positional error of implants placed using a tissue-borne surgical guide compared to implants placed using the "Fixed Edentulous Implant Guide" in an in vitro edentulous mandible simulation.

9.3 Summary of Findings

This study disproves the null hypothesis as the mean deviation of the coronal deviation and apical deviation was within 0.5mm, and the angular deviation was within 1°.

By rejecting the null hypothesis, the alternative hypothesis is proposed that there is no clinically significant difference in the planned and actual placement position.

Both the preliminary study and the final study of the thesis have shown that there is no difference in the clinically acceptable tolerances between the

planned and actual implant placement position. Therefore, the null hypothesis is rejected, and the alternative hypothesis is proposed that there is no clinically significant difference in the planned and actual placement position. The findings of both the preliminary and final studies show that the novel FEIG method envisaged in this thesis is more accurate than both existing methods of edentulous guided surgery (mucosal borne and bone guides) and dentate guided implant surgery.

The objectives for the study of the novel method for edentulous guided surgery using the “Fixed Edentulous Implant Guide” were met through the preliminary study and expanded through examination of the steps involved through literature review and subsequent further studies. In this thesis, the findings of the literature reviews and the study on the accuracy of intraoral scanners and 3D printers suggest that the accuracy of each step is related to the specific technology and manufacturer used. However, each of these steps produce total mean error in terms of sub 100 microns. The findings also suggest that evolving software improvements have improved the accuracy of manufacturers devices, which is encouraging as there is some variation between manufacturers.

Some of the larger variations in error in terms of discrepancy between planned shape or position and the eventual outcome/output part were found in 3D printing. In the 3d printer accuracy study within this thesis, a wide range of discrepancy was found with some printers such as the Form 2, which was limited by their laser spot size, meaning a potential error of 140 microns. This could in turn lead to an error in implant placement of 0.14mm,

which is potentially a large component of the error seen in the preliminary and final studies. The potential errors in each of these steps suggest that it is impossible to be 100% accurate in terms of matching the planned implant position to the final implant position with guided implant surgery, no matter whether edentulous, dentate, or with the novel method discussed in this thesis.

9.4 Limitations of the study

While the in vitro study provided insights and advanced the understanding of implant placement accuracy using the novel “Fixed Edentulous Implant Guide,” several limitations inherent to the study design and methodology must be acknowledged:

1. Lack of Biological Variability:

The in vitro nature of the study implies the absence of biological variability and host responses that are typically encountered in in vivo settings. The artificial models used cannot replicate the diverse anatomical, physiological, and biochemical conditions present in living tissues, potentially affecting the extrapolation of the findings to clinical scenarios.

2. Artificial Tissue Response:

The study utilized anatomical models with representative gingiva and bone, but the response of these artificial tissues to compression and movement may differ significantly in an in vivo study. This difference in

tissue response can impact the generalizability of the results to real-world clinical applications.

3.Limited Generalizability:

The findings are based on specific models and conditions, and their applicability to a diverse range of patient populations, anatomical structures, and clinical settings remains uncertain. The generalizability of the results is further constrained by the absence of comparisons with a variety of existing methods, limiting the understanding of the novel method's relative performance.

4. Absence of Clinical Conditions:

The in vitro environment lacks several clinical conditions such as saliva, blood, and patient movements, which can influence the implant placement process and its accuracy. The absence of these factors may lead to overestimation or underestimation of the method's accuracy in clinical practice.

5. Technology and Manufacturer Dependence:

The accuracy of each step in the study was found to be related to the specific technology and manufacturer used. This dependence implies that variations in technology and manufacturing processes can introduce variability in the results, affecting the reproducibility and consistency of the findings across different settings.

Addressing these limitations in future research, especially through well-designed in vivo studies and investigations involving diverse methodologies, patient populations, and clinical scenarios, will be crucial to validate and refine the novel method and to enhance its applicability and reliability in clinical practice.

9.5 Conclusions

The final objective of the thesis was to examine whether it is both safe and accurate to place implants with flapless surgery with this new method that references the model to the CBCT scan. The study findings suggest that this statement can be upheld, and given the accuracy in terms of trueness and precision, it is concluded that the novel method provides an accurate method to place implants in an edentulous arch.

This study challenges the null hypothesis, demonstrating that the mean deviation of both the coronal and apical deviations was within 0.5mm, and the angular deviation was within 1°. Consequently, the null hypothesis is rejected, leading to the proposition of the alternative hypothesis, asserting that there is no clinically significant difference between the planned and actual placement positions.

Both the initial and the conclusive studies of this thesis corroborate that the clinically acceptable tolerances between the planned and actual implant placement positions are consistent, thereby reinforcing the rejection of the null hypothesis. The alternative hypothesis, suggesting no clinically significant difference between the planned and actual placement positions, is thus substantiated.

Significant variations were noted in error, particularly in terms of deviations from planned configurations or positions to the actual outcomes, and these were most pronounced in 3D printing. The investigation into the accuracy of 3D printers presented in this thesis highlighted notable discrepancies with certain printers. For instance, the Form 2 printer, limited by its laser spot size, exhibited a potential error margin of 140 microns. This discrepancy has the potential to result in a 0.14mm error in the placement of an implant, contributing notably to the errors identified in both preliminary and final studies. The inherent errors in each of these steps underscore the impracticality of achieving absolute accuracy in aligning the planned implant position with the final implant position in guided implant surgery, irrespective of whether the cases are edentulous, dentate, or are utilizing the novel method delineated in this thesis.

Furthermore, as guided implant surgery can often mean that bone can be utilised in an angular or unconventional approach to avoid grafting, using this method may mean that patients with a medical contraindication to conventional flapped surgery may also benefit from full arch rehabilitation.

The findings in this thesis regarding the accuracy of each step illustrate that each component used in the construction of an implant drill guide is inherently susceptible to error. This error can vary, and it is worthwhile for any prospective implant surgeon to understand these potential errors and to reflect on them when surgery results in an imperfect position. The findings of the background research also evidence that it is imperative for clinicians to understand the principles that guide implant planning so that virtual implant

planning is performed correctly and so that the clinicians can reflect on the position once placed to recognise any error that occurs.

9.6 Implications of the Study

As discussed above, using this novel method may mean that patients with a medical contraindication to conventional flapped surgery may also benefit from full arch rehabilitation. Without a flap being raised, there is less risk from morbidity, and further complications can be avoided as long as there are adequate bone volumes present to allow the placement of implants within the field required.

As discussed in the initial chapters of this thesis, the York statement of the British Society of Prosthodontics (BSSPD) concludes "*There is now a large body of evidence that supports the proposal that a two-implant supported mandibular overdenture should be the minimum offered to edentulous patients as a first choice of treatment.*"

The "Fixed Edentulous Implant Guide" studied within this thesis provides a far more accurate pathway for edentulous patients to receive at least two implants for an implant supported prosthesis to be offered. The accuracy is such that a flapless approach could be offered to an increased number of potentially suitable patients, enabling the patients to benefit from decreased risk of morbidity and infection.

While this study primarily focuses on the precision and efficacy of the FEIG guided implant placement system, it's important to cautiously consider its potential implications in broader contexts, such as antibiotic resistance. The

rise of antibiotic resistance is a pressing global concern, and there is a variance in practice regarding antibiotic prophylaxis, despite guidance from bodies like NICE.

The notion that the results of this study could contribute to minimizing surgical interventions through flapless surgery is however speculative. While the concept of clean surgery with minimal surgical sites requiring wound dressing or sutures is indeed beneficial in the context of antibiotic resistance, directly extrapolating the findings of this study to such broad and complex issues would be an overreach.

In addressing the implications of this thesis, a balanced perspective considering its limitations and acknowledgment that the primary contributions of this study are within the realms of implant placement accuracy and methodology.

The growing concern of antibiotic resistance necessitates innovative solutions and approaches to minimize the reliance on antibiotics. However, any assertion that the methods and findings of this study offer a direct solution to such global concerns needs to be substantiated with rigorous research and evidence, focusing specifically on the interactions between surgical methods and antibiotic reliance.

Another implication of the thesis unrelated to the novel method of implant placement relates to the intraoral scanner study, particularly related to the Primescan scanner by Dentsply Sirona. This device was the sole scanner to be statistically similar in terms of trueness and precision to lab-based scanners. Whilst this related to a dentate arch in an *in vitro* setting, further studies could investigate whether this accuracy level is maintained in the edentulous arch.

9.7 Recommendations for Further Studies

The final study has addressed the main question of the thesis; however, it is in an *in vitro* setting and would benefit from ideal scenario results. As previously discussed, a number of factors will increase potential error and result in misplacement in comparison to the virtually planned position. This outcome is particularly true in terms of an *in vivo*, clinical situation where the accuracy of these steps could be influenced through discrepancies in impressions due to patient movement, irregularities in 3D impression scan data, or CBCT artefacts such as metal structures, motion artefacts, or poor protocols, such as lacking cotton roll placement. The proposal for a post doctoral *in vivo* study is discussed in the next chapter.

The edentulous arch is particularly variable in ridge shape between patients, and it may be flatter with less anatomy or more ridged. Conversely, this variety may make it more or less difficult for an intraoral scanner to make a digital impression accurately over a full arch. Therefore, it is recommended to expand on this study and develop a further *in vivo* study on the accuracy and ability of intraoral scanners to detect various ridge types. Given this suggestion, it is hoped that this research can be continued with a post-doctoral *in vivo* study. The goal of such a study would be to make flapless edentulous guided surgery more accurate at reducing morbidity risks and making implant surgery in the provision of full arch restoration more accurate and more predictable.

Appendices

APPENDIX A.1	A Comparison of Full Arch Trueness and Precision of 9 Intraoral Digital Scanners and 4 Lab Digital Scanners in a Dentate Arch Published in the Dentistry Journal; Published 23 June 2021 https://doi.org/10.3390/dj9070075
APPENDIX A.2	History and Literature Review of 3D Printing Technologies. Published in Clinical Dentistry. Published 23 Nov 2021
APPENDIX A.3	A comparison of trueness and precision of 12 3D printers used in dentistry. Published in BDJ Open. 2022 May 26;8(1):14. doi: 10.1038/s41405-022-00108-6. PMID: 35618716; PMCID: PMC9135705.

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