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Influence of metal sleeves in the accuracy of dental implant placement using guided implant surgery

A thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science

at Virginia Commonwealth University.

by

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<u>Abstract</u>

Influence of metal sleeves in the accuracy of dental implant placement using guided implant surgery

A thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science at Virginia Commonwealth University

Virginia Commonwealth University, 2021

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The fabrication of implant surgical guides through stereolithographic 3D printing has become a staple in dental implant guided surgery over the last couple decades. These surgical guides have typically utilized metal sleeves to assist in guidance of the drills during osteotome preparation. The metal sleeves can be costly and potentially cause deviations if improperly placed during post-processing of the guide. This research explored a novel method for the utilization of sleeve-free surgical guides by comparing the dimensional and angulational deviations between the implant guides with and without a metal sleeve. To achieve this goal, two separate aims were pursued. Our first aim analyzed the implant deviation differences created by a single guide with a metal sleeve and one guide without. Ten implants were placed in ten dental models per each type of surgical guide and the deviations were measured in the mesial, apical, cervical, and angulational dimensions. The second aim of this study was to analyze any angulational and positional differences produced when the sample size of the surgical guides was increased for the two different groups to produce a guide to cast ratio of 1:1. This was achieved by analyzing the same two surgical guide designs and dimensional parameters but increasing the number of surgical guides produced to yield one guide per dental model with a total of 10 pairs of guide-cast per group. The results provided no significant difference in implant deviations between the guides with and without a metal sleeve except for the mesial dimension in the second aim. This study concluded that the surgical guide without a metal sleeve. Thus, metal sleeves may not be required for accurate implant placement.

Key words: 3D printing; Dental Implants; Guided Surgery; Stereolithography; Surgical Guide

List of Abbreviations

2D- Two Dimensional **3D-** Three Dimensional AM- Additive Manufacturing SLA- Stereolithography apparatus STL- stereolithography **DED-** Directed Energy Deposition PBF- Powder Bed Fusion LOM- Laminated Object Manufacturing UAM- Ultrasound Additive Manufacturing VPP- Vat Photopolymerization UV- Ultraviolet **DLP-** Digital Light Processing CLIP- Continuous Liquid Interface Production CAD/CAM- Computer-Aided Design/ Computer-Aided Manufacturing **CEREC-** Chairside Economical Restorations of Esthetic Ceramic CBCT- Cone Beam Computed Tomography TSV- Tapered Screw Vent

CHAPTER 1

HISTORY AND DEVELOPMENT OF GUIDED IMPLANT SURGERY

1.1 History of Additive Manufacturing

In engineering as well as in dentistry, there are three main techniques for manufacturing or fabricating appliances or devices. These techniques are firstly, formative manufacturing which is exemplified by mold forming atop an existing device. Subtractive manufacturing such as milling which is the removal of existing material to create a device. Lastly, is additive manufacturing that involves adding material particles to create a device. (Oberoi et al. 2018) It is interesting to note that dentists and dental lab technicians apply all three of these principles to fabricate devices.

The history of additive manufacturing (AM) also known as rapid prototyping, and layered manufacturing branches into three different eras in the order of prehistory (before the invention of computers), precursors, and modern (after the invention of computers) processes. (Bourell, 2016, Hu, 2017) The initial era of prehistory highlights the processes of AM without the assistance of a computer, they relied upon manual labor to construct their designs. The first of the three AM prehistoric processes was called Photosculpture created by François Willème in 1860. (Bourell, 2016) The process consisted of a subject being positioned in a room and a photograph was taken simultaneously 360° by 24 equally spaced cameras. The photo's silhouettes were then used to assemble a full sculpture of the individual.

The second prehistoric process was called Topography, invented in 1892 by an J.E. Blanther. Topography uses a flat feedstock method that relies upon either cut and stack or stack and cut approaches. Blanther's invention was exemplified when he utilized 3D tools to create topographical maps from aerial photographs. He would lay wax sheets atop the aerial photographs and cut along the elevation lines. The pieces of wax were then stacked to create a top and bottom die that was then smoothed and backed. (Bourell, 2016)

The third prehistoric process was called Material deposition and was introduced by Baker in 1925. This process concerns a moving source that deposits material at a constant rate. Baker illustrated this idea by using a moving weld head to create ornamental welded parts. (Bourell, 2016)

Following the prehistoric era, the precursor era consisted mostly of modern AM technology, without the computer as we know it today. This stage of AM technology existed from the 1950s to the 1980s. The first precursor process that is similar to stereolithography was invented by Munz in 1956. His process used a layer-wise exposure of a photosensitive polymer to a piston that lowered between layers to solidify the polymer into the desired shape. Next, Ciraud in 1972 created a process that utilized metal powder that was directed into a localized heat source and melted into the desired shape. (Bourell, 2016)

The transition from precursor to modern AM technology occurred with the introduction of the Macintosh computer, a first of its kind due to its intuitive graphical user interface. Computers had existed during the years prior but none employed a system meant for the average individual. This computer introduced a new age of AM that created the world of 3D printing shown today.

Helisys was the first modern AM company founded by Feygin in 1985. This company mostly manufactured laminated object manufacturing (LOM), a sheet lamination process. Shortly after the introduction of 3D printing a group of French engineers filed for a patent for their stereolithographic process but was abandoned due to a "lack of business prospective." (Bourell, 2016) Three weeks later, Chuck Hull and Raymond Freed founded a company called 3D Systems with a patent for their own stereolithographic process. Chuck Hull, sometimes referred to as the father of 3D printing, invented the STL (stereolithography, standard triangle language, or standard tessellation language) file format, introduced digital slicing, and created the idea of infill. (Bagaria et al. 2018) Together, Hull and Freed produced the first modern AM machine called SLA-1. This machine cured a polymerizable medium by ultraviolet light at precise points. (Bourell, 2016)

With the introduction of SLA (stereolithography apparatus) printers, the STL file format was created. (Wu & Cheung, 2006) The STL is a backronym for"Standard Triangle Language" or "Standard Tessellation Language. In order for a part to be 3D printed, the object must be sliced into layers because the printing process utilizes a layer-by-layer build scheme. An STL file is defined as a raw, unstructured triangulated surface by the unit normal and by three vertices (ordered the right-hand rule) of the triangles using a three-dimensional Cartesian coordinate system. (Hu, 2017) STL files have the ability to define the surface dimensions of a 3D object based on point coordinates. These points come together to form the triangular facets that create the object. The resolution of the object can be enhanced by increasing the number of points present in the space. These files can be stored in either text (ASCII) format or binary format. (Wu & Cheung, 2006) The text format is typically only used as a testing tool due to its larger size, while the binary format is much more compact and efficient for data processing.

1.2 Types of Additive Manufacturing

As time progressed, many different styles of 3D printing evolved. These processes are as follows Binder jetting, Directed Energy deposition, Materials extrusion, Material jetting, Powder bed fusion, Sheet lamination, and Vat Photopolymerization. Each one of these has its own style and process of 3D object production but all attempt to create an object under the concept of additive manufacturing. (Shahrubudin et al. 2019)

Binder jetting is a rapid prototyping and 3D printing process where a liquid binding agent is deposited to join powder particles at precise locations along a build platform. (Shahrubudin et al. 2019) These binder droplets (80 µm in diameter) form spherical aggregates of binder liquid and powder that also bind to the previously deposited layer. Once a layer has been deposited, the powder bed is lowered and a new layer of powder is spread on top of it. This method is relatively quick and comes at a lowered cost due to its lack of heat production. The medical use for this process is the fabrication of color models for coding of anatomy. (Gibson et al. 2021, Aimar et al. 2019)

Directed energy deposition (DED) is considered a more complex process typically used to repair or add to existing objects. (Shahrubudin et al. 2019) The process occurs by directing energy into a narrow, focused region to heat a substrate. Material is deposited and simultaneously melted to add to the melted pool of substrate. DED processes are specific for melting material as it is deposited and not melting a pre-laid powder. Each pass of the DED head creates a track of solidified material and this continues until the object is built. DED most exclusively deals with metals however it can still be used with polymers and ceramics. (Gibson et al. 2021)

Material extrusion can be utilized to print multi-materials and multi-color printing of plastics, food and even living cells. (Shahrubudin et al. 2019) These machines are by far the most widely used in the field of additive manufacturing. This process occurs through extrusion of heated bulk material through a nozzle that then deposits the material along a plane. There are two common approaches when using extrusion. More commonly the temperature of the material is

used to control the material state. Molten material is liquefied inside a reservoir so that it can flow out the nozzle to bond with previously laid material before solidifying. An alternative approach is to utilize a chemical reaction to cause solidification. In this approach, paste materials that require drying to become fully stable are used and allow for biochemical applications where materials must have biocompatibility with living cells. (Gibson et al. 2021)

Material jetting is a 3D printing process that occurs through a drop-by-drop mechanism of photosensitive material that is selectively deposited and solidified under ultraviolet light. Previously, material jetting was limited to waxes and polymers but today it has expanded to ceramics, composite, and biologicals. This printing process is shown to create prints with smooth surfaces and high resolution. (Shahrubudin et al. 2019, Aimar et al. 2019) Uses for material jetting in the dental field include the fabrication of dental casts, dental implant guides, bone models, and other prosthetic components. Companies such as Stratasys (Object, Connex) and 3D systems (Projet) utilize this printing process. (Aimar et al. 2019)

Powder bed fusion (PBF) processes were among the first commercialized AM processes. PBF includes electron beam melting, selective laser sintering, and selective heat sintering print techniques. This technique typically uses either an electron beam or laser to melt/fuse a material powder together. The material rests within a powder bed that is heated to just below the melting temperature of the powder. As the material is fused together, layers begin to form. This is repeated until the desired object is created. Materials can include metals, ceramics, polymers, composites, or a hybrid combination. This process can be used in the medical field to fabricate devices that require a lattice structure such as implants and fixations. (Shahrubudin et al. 2019, Aimar et al. 2019) Sheet lamination is the process where sheets of material are bonded together to produce an object. The example of this printing form is used in laminated object manufacturing (LOM) and ultrasound additive manufacturing (UAM). LOM manufactures complex geometrical parts at a low cost and UAM utilizes sound to merge layers of metal. This print process is advantageous because it has the ability to do full color prints, its inexpensive, and excess material from excess sheets can be reused. However, this process has shown limited application in the dental field so far but has shown usage in the medical field to create Orthopedic models of bones. (Shahrubudin et al. 2019, Gibson et al. 2021)

Vat photopolymerization (VPP) is one of the most commonly used 3D printing techniques in the dental industry. Photopolymerization makes use of photo-reactive polymers that are cured by several different types of radiation including gamma rays, X-rays, electron beams, UV, and even visible light. Typically, the dental field utilizes irradiation with UV light or visible light where these materials undergo a chemical reaction to become solid in a layer-bylayer fashion. The build platform lowers and raises into the liquid resin to allow layers to be cured over and over in a precise and accurate manner. Three examples of processes using this form of 3D printing include stereolithography (SLA), digital light processing (DLP), and continuous liquid interface production (CLIP). Stereolithography uses a laser to cure resin in precise locations while DLP uses a projector light source that is able to cover the entire vat of liquid in a single pass. Important parameters of VPP include the time of exposure, wavelength, and amount of power applied to the vat. These printers are often used in the medical field for bone models, dental implant guides, dental models, clear aligners, nightguards, and other prosthetic components. Examples of these printers include ProX 950 (3D systems), SprintRay Pro 55 (SprintRay) and Form 3 (Formlabs). (Shahrubudin et al. 2019, Gibson et al. 2021, Aimar et al. 2019)

The photopolymer chemistry of VPP should be analyzed to understand the nature of the materials being used for the dental field. VPP resins consist of several types of compounds including reactive diluents, photo initiators, flexibilizers, stabilizers, and liquid monomers. When using UV radiation, there is a cascade of photo initiators undergoing transformation to become reactive with the monomers. The reaction of the two compounds unifies monomers forming a polymer chain that then continues to cross-link through polymerization to create strong covalent bonds. Basic raw materials such as polyols, epoxides, acrylic acids, and esters are used to produce the monomers and oligomers. The companies that are producing the resin create ready-to-use formulations by mixing the monomers and oligomers with a photo initiator. The role of the photoinitiator is to convert the physical energy of the light into chemical energy in the form of reactive intermediates. These radical intermediates are capable of adding to vinylic or acrylic double bonds which initiate polymerization of the epoxy molecules. (Gibson et al. 2021, Aimar et al. 2019, Yanyan, 2005)

1.3 Utilizations of 3D printing in Dentistry

The introduction of 3D printers into the dental field revolutionized in-house prosthesis fabrication. The company Formlabs was one of the first to produce affordable but accurate SLA type desktop 3D printers. One of these printers, the Form 2, is able to produce products with the high precision necessary for use in the dental field through the SLA process. (Whitley et al. 2017, Horvath & Cameron, 2015, Whitley & Bencharit, 2017) DLP printers also exist in dentistry and are shown to print quicker, but incur a loss of resolution due to the increased rate of production. Thus, SLA is typically used because of its ability to retain resolution but a slower rate of production. These printers are used to print dental models, clear aligners, night guards, surgical guides, immediate denture try-ins and temporary crowns. The use of SLA in dentistry is expanding at an ever-increasing rate with no end in sight. (Whitley et al. 2017)

In line with the progression of 3D printers, the emergence of computer-aided design and manufacturing (CAD/CAM) advanced the applications of AM in the dental profession. CAD/CAM dentistry is the use of a handheld scanner, a computer and a milling machine to fabricate restorations. Duret introduced the first concept of a CAD/CAM system in 1971, but the lack of digitizing and computing power attenuated its full potential. The creation of the CEREC (an acronym for Chairside Economical Restoration of Esthetic Ceramics, or CEramic REConstruction) system by Mormann and Brandestini in Switzerland a decade later continued the progression of CAD/CAM software. (Bührer et al. 2016, Duret, 1992) The evolution of CEREC technology has progressed greatly since its foundation and same day dentistry is now common in most dental practices. (Davidowitz & Kotick, 2016)

The use of 3D printers in the field of dentistry has progressed rapidly since its creation. Increasing developments in digital dentistry in the likes of scanner technology, CAD software and computing power have all assisted 3D printing in the dental field. (Dawood et al. 2015) 3D printing has been applied to multiple specialties of dentistry including Endodontics, Prosthodontics, Oral and Maxillofacial Surgery, Periodontistry and Orthodontics. Endodontics has been able to use Cone-beam computed tomography (CBCT) information to generate 3D printed surgical templates that provide surgeons the ability to target the root apex even in mandibular molars as well as endodontic occlusal access. Prosthodontists have used 3D printing to generate removable prosthetics, both partial and complete. Oral and Maxillofacial surgeons have been using 3D printing for a few decades to generate anatomical models, implant surgical guides, and reconstruction plates. Periodontists have used 3D printed scaffolding for periodontal regeneration that even featured an internal port for the delivery of recombinant human plateletderived growth factor to stimulate bone and periodontium regeneration. Lastly, orthodontic use of 3D printing has grown vastly as the introduction of clear aligners became popular. A company called Invisalign has been using SLA 3D printers since 1998 to print dental models for clear aligner fabrication. (Pillai et al. 2021)

1.4 Applications of Digital Technology in Dental Implant Therapy

As the progression of 3D printers and CAD/CAM technology continued, the use of computer-aided implant surgery arose. Prior to software advances in dental implantology, surgeons placed implants with the free-hand technique and utilized 2D imaging. This process can be accurate and precise but requires years of experience and training. In 1996 a company named Materialise invented Simplant, the first software to aid implant surgery and minimize the need for invasive techniques. ("Materialise," 2021) Their software initially utilized the 2D panoramic radiograph that is limited in its ability to visualize dental structures properly. Since Simplant's initial launch, CBCTs and intraoral scans were introduced and have allowed the software to elevate its status in the guided surgery world. Simplant (later was acquired by Dentsply) at one point was the world largest implant guide producer for implant guided surgery. In the modern era, many companies such as 3Shape have created similar softwares to assist guided implant surgery. (Edelmann et al. 2016, Yeung et al. 2020)

To emphasize the accuracy and precision of implant planning software, a study conducted in 2016 by Edelmann et al compared the planning implant position and the placed

implant position with the use of computer-aided software, Simplant. This study demonstrated that the use of implant planning software mitigated displacements to within 0.5 mm in the mesiodistal dimension, less than 1 mm in the buccolingual dimension and around 1 to 5 degrees in angulational difference. The results for the surgeons placing the implants without guidance showed similar results to the guided surgery. However, many implant placements in today's world are conducted by general practitioners and not always experienced oral surgeons. The need for guided implant surgery is higher than ever as the placement of implants becomes more commonplace in general practice. (Edelmann et al. 2016) In the last decade many studies have been conducted to weigh the differences between conventional surgical guides, free-hand technique and CAD/CAM guided implant surgery. All the results point towards an increase in accuracy and precision when the implants are placed using computer guided surgery. (Yeung et al. 2020, Choi et al. 2017) Many clinicians argue with the fact that guided surgery adds more cost and decreases workflow. This thought process is negated as the benefits of guided surgery far outweigh the negatives. The benefits of guided surgery include reduction of surgery time, reduction of postoperative pain and attenuation of inflammation (perhaps from flapless surgery), as well as an increase in implant placement accuracy in all dimensions. (Pozzi et al. 2014, Yuce et al. 2019)

Guided implant surgery utilizes multiple methods for transferring the desired plan into the surgical field. Two common concepts are the use of surgical guides, which can be divided into two different categories including dynamic and static surgical guides. The dynamic guides utilize a computerized navigational system to provide assistance in both the planning and intraoperative phases of dental implant surgery without any need to produce a surgical guide. This method is not frequently used but has strong potential if the technique further develops. The cost

of the setup and complexity of the armamentarium prevents the use of implant navigation systems in the modern dental practice. (Bashutski & Piche 2016, Jorba-Garcia et al. 2018) The most commonly used method is the static surgical guide. The static guide is a surgical template that is fabricated in a few different ways including conventional free-hand, milling, and CAD/CAM assisted generation. (Arfai, 2007) The conventional methods are shown to provide successful outcomes with experienced implant surgeons. However, these guides are usually created on a study dental gypsum cast without any guidance of underneath osseous structure. Thus, the relationship between the guide directed implant position and the real-life surgically placed position can be dissimilar. (Mukai 2021) The limitations of conventional surgical guides are overcome with the use of CAD/CAM technology. (Ramasamy et al. 2013) The computergenerated surgical guide uses stereolithography to fabricate static guides with high precision and accuracy. (Dalal et al. 2020) These guides are advantageous because they are able to use CBCT volumetric data to generate multi-planar analysis of a patient's anatomy. Improving the visualization of the anatomical structures allows the surgeon to determine precise location, angulation and depth of their drills during implant placement. (Ramasamy et al. 2013) These guides can be either tooth, bone, or mucosa supported and even contain stabilization pins if necessary. (Colombo et al. 2017) The stereolithographic production of surgical guides was outlined by Whitley and Bencharit (2017). These two clinicians used a common computer-aided planning software (Blue Sky Bio) and an in-office 3D printer (Form 2) to produce a seamless workflow for in-office surgical guide fabrication. (Whitley et al. 2017, Whitley & Bencharit. 2015) The accuracy and precision of the in-office 3D printed guide was examined to show cervical deviation of 0.3-0.5 mm and angulation deviation of 0.9-3 degrees which was

comparable to dental laboratory or implant guide manufacturer fabricated guides. (Deeb et al. 2017)

As previously noted, surgical guides have become vital to proper implant placement, however some of the steps in creation of the guides are still time consuming and there are opportunities to further decrease cost. Protocols are steadily being created to streamline the design, print and post-process stages to increase workflow. (Ammoun et al. 2021, Dalal et al. 2020) More recently, a work by Talmazov. et al (2020) demonstrated that a static guided surgery can be done using a set of open-source software to create implant guides with similar accuracy to the previous studies. Similarly, we believe that open-source software may allow us to modify and customize an implant guide in complementary to the commercially available software.

In summary, the introduction of 3D printing technology has revolutionized not only the manufacturing world but the dental one as well. As the technology progresses, it is highly likely that most dental prosthetics will be 3D printed in-office. This will allow patient customization and improved outcomes as the treating clinician will have total oversight of the fabrication. For now however, the 3D printed implant surgical guide has proven to be highly effective at translating the planned implant position to the surgical field. The device has allowed the general practitioner the confidence to accurately and precisely place implants without the extensive surgical experience required.

CHAPTER 2

INFLUENCE OF METAL SLEEVES IN THE ACCURACY OF DENTAL IMPLANT PLACEMENT USING GUIDED IMPLANT SURGERY

2.1 Introduction

Within the last few decades, dental implants have become the primary choice for the restoration of edentulous and partially edentulous areas in patients. The array of implant prosthetics available in the dental field continues to increase, ranging from implant supported crowns to implant supported dentures. The use of implants has improved the current methods of dental care and overall quality of life for many patients. As the placement of dental implants continues to become more common, the quest for implant placement perfection follows.

Guided implant surgery has improved many aspects of implantology including implant placement accuracy and precision as well as overall confidence of the clinician and prevention of complications during surgery. (Yeung et al. 2020, Hutlin et al. 2012) Guided implant surgery has become the leading protocol for proper placement. The reduction in deviations concerning angulation and depth of the implant ensure an improved outcome for the patient's restorative options. If improperly placed, the restorative capabilities can be compromised causing unforeseen damage to not only the implant but surrounding dental structures. (Alevizakos et al. 2019)

To be able to improve upon the conventional surgical guide creation, CAD/CAM (Computer-Aided Design/Computer-Assisted Technology) technology has been utilized. (Yeung et al. 2020) These techniques combined with the rapid advancements of stereolithographic 3D printers has allowed a rapid increase in the clinical efficiency of in-house laboratories to produce these guides. The accuracy of in-house 3D printed surgical guides is comparable to those produced by a laboratory or implant manufacturer. (Deeb et al. 2017, Son & Lee, 2021) Protocols are steadily being created to streamline the design, print and post-process stages to increase workflow. Simultaneously as the 3D printers have improved, the design softwares have as well. In addition to all of these specific advances, time efficiency for providers has also increased while the cost of surgical guides and study models has decreased.

Now that 3D printers, CAD/CAM technology and guided implant surgery operate in harmony, the ability to streamline the workflow of this process is open for improvement. A technique that has been suggested is the use of a software called Blender that has revolutionized 3D mesh mixing and rendering. This software gives users, from amateur to experienced, the tools they need to construct almost any 3-dimensional file. Through the usage of this software, dentists and lab technicians have been able to manipulate STL files with ease. This software gives the dental profession a convenient and cost-efficient way to customize treatment before a procedure such as implant placement. (Talmazov et al. 2020)

Surgical guides have become vital to proper implant placement, however some of the steps in creation of the guides are still time consuming and there are opportunities to further decrease cost. Protocols are steadily being created to streamline the design, print and post-process stages to increase workflow. However, to further improve upon the post-processing step, this paper suggests a different approach to the metal guide sleeve. By utilizing Blender, we believe that the guide sleeve can be designed, meshed and printed as part of the surgical guide without a loss of accuracy or adequate drill tolerance. Thereby, decreasing the extent of the post-processing step and eliminating user error from the insertion of the sleeve before light curing the guide.

The first purpose of this study was to analyze the postoperative angulation and positional differences created by the modification of a single 3D printed surgical guide sleeve in comparison to those of a single surgical guide with metal sleeve. We hypothesized that the overall range of implant deviations generated by the modified surgical guide sleeve would be consistent with those of the metal sleeve. The second purpose of this study was to analyze any angulational and positional differences produced when the sample size of the surgical guides was increased for the two different groups to produce a guide to cast ratio of 1:1. We hypothesized that the increase in the number of surgical guides for the two different groups would yield similar accuracy and precision.

2.2 Materials and Methods

To address the research purpose, a single implant case was chosen within VCU Dental School's implant database. A cone beam computed tomography (CBCT) data set and intraoral scans were obtained from the unidentified patient who was missing a maxillary right central incisor. The CBCT scans were obtained by using the following protocol: i-CAT FLX V10 (Kavo Dental, Brea, CA) with standard implant scan parameters (16 cm in depth, 10 cm in height, 0.3-mm voxel size, 8.9-second scan time, 3.7-second exposure time, 120 kVP, 5 mA, and 501.3 mGy/cm²). The intraoral scans were made by using an intraoral scanner (TriOS 3; a3Shape A/S, Copenhagen, Denmark). By using the CBCT and intraoral scans, the implant treatment planning to replace the maxillary right central incisor was carried out by using the Implant Studio 2021 (3Shape A/S). A treatment plan was made by using a Tapered Screw Vent (TSV) Zimmer Biomet (3.7mm x 13mm) dental implant.

The protocol for fabricating the dental cast and surgical guide is similar to previous studies. (Yeung et al. 2020, Deeb et al. 2017) The intraoral scan was imported into a software program (Implant Studio V; 3Shape A/S), in which the dental cast and surgical guide were designed. The cast was exported in the standard tessellation language (STL) format and was used to print 40 total dental casts (Form 3; Formlabs, Somerville, MA). Twenty Dental Model resin (Formlabs) for the first-round experiment and 20 Dental Clear LT resin V2 (Formlabs) casts for the second-round experiment were printed at a resolution of 0.05 mm.

The Blender 3D software was opened and the proper surgical guide STL was imported. The internal faces/vertices of the guide tube were selected. The wall thickness of the 4.2 mm Zimmer guide tube was measured to be 0.4 mm. The selected areas were then extruded using the 'Extrude Faces Along Normal' to a thickness of 0.38 mm to allow for minimum drill tolerance. The top of the surgical guide was also selected and extruded to the proper height of the surrounding walls. The surgical guide was then exported to be 3D printed. (Fig. 1) **Figure 1. Blender 3D workflow for creation of metal-free surgical guide.** The STL file of the guides were imported into the Blender software to design the digital implant guide sleeve mimicking the conventional metal sleeve.



The two groups of implant surgical guides were exported into a software program (Preform; Formlabs) in the STL format. A total of 22 guides were oriented, and appropriate structural printing supports were designed. The guides were printed in resin (Surgical Guide Resin; Formlabs) at a resolution of 0.05 mm. The Surgical Guide Resin from Formlabs passes all requirements for biocompatibility risks and is considered 'Not Cytotoxic' in accordance with ISO 10993-1:2018. (Formlabs) It is also considered a medical device and in compliance with ISO Standards. After the guides had been printed, the print supports were removed and postprocessed per manufacturer's recommendation using an automated post-processing method (Form Wash and Form Cure, Formlabs). The guide was rinsed twice in isopropanol and airdried, and the surgical guide tube was placed. Finally, the surgical guide was subjected to UV light-polymerization (405 nm) at 60°C for 1 hour and sterilized in an autoclave. (Fig. 2)

Figure 2. Clinical workflow exhibiting implant planning, guide design, 3D printing and implant placement. This figure visualizes the clinical workflow utilized by the study within the first and second aim. Initially, the workflow began by obtaining an intraoral scan and CBCT of the patient. Secondly, the surgical guide was designed within 3Shape implant studio for those with the metal sleeve and redesigned within Blender for those without the metal sleeve. The two different guides were then printed, and implants placed within resin casts for the two different aims. From there, CBCTs were taken of the resin casts with implants embedded and compared to the original planned placement within 3Shape.



The placement of the implants within the resin casts was performed in two rounds for the two aims. For the first round of implant placement only two surgical guides were used, one with

and without metal sleeve to place 20 implants in 20 dental casts ($n_{total} = 20$) to evaluate the implant placement deviations. For the second round of implant placement, 1 cast and 1 guide were used for each implant placed creating 10 sample sets for each group ($n_{total} = 20$) to evaluate the implant deviations resulting from pairs of guide/cast. (Fig. 3) The same surgical guide and implant surgical kit were used for each system to control the variations of guide fitting and drills. The implants were placed based on the manufacturer's recommendation. All osteotomy sites were prepared through surgical guides. The osteotomes were evaluated for depth and width before implant placement. Then, the implants were placed after the removal of the surgical guide per manufacturer's recommendation. Post-operative CBCT scans were made by using a post-operative scanning protocol similar to that of a previous study. (Yeung et al. 2020)

Figure 3. Comparison between Round 1 and Round 2. This figure provides visualization of the two separate aims occurring within this study. Aim 1 utilized a single surgical guide with or without metal sleeve for the placement of 10 implants in 10 resin casts for the two groups. Aim 2 decreased the guide to cast ratio to 1:1 with 1 implant placed with 1 surgical guide from either group within 1 cast.



The dimensions and angulations of the implant position were determined in the mesiodistal and buccolingual planes, similar to previous studies. (Yeung et al. 2020, Deeb et al. 2017, Suriyan et al. 2019, Bencharit et al. 2018) The distances between the most cervical part of the planned implant and the closest adjacent natural tooth root surfaces mesially and distally were recorded as Mesial. The distances between the most cervical part of the planned implant and the outer surface dental cast labially and palatially were recorded as Cervical BL. The distances between the most apex part of the implant and the soft tissue were recorded as Apex BL. The buccolingual implant angulation in relation to the plane of the cast was recorded as BLA, respectively.

Similar to the preoperative measurement, the post-operative positions of the placed implants were measured by using a previously published protocol. (Yeung et al. 2020, Deeb et al. 2017, Suriyan et al. 2019, Bencharit et al. 2018) The post-operative CBCT scans were superimposed onto the planned implant position. The implant positions, mesiodistal, labiopalatal, and the implant angulations in the labiopalatal planes were measured and compared with the planned positions. (Fig. 4) The differences between the planned and placed implant positions in each dimension and at each angulation were recorded. Accuracy of implant placements refers to the mean implant placement deviations. To examine the differences in the accuracy among the surgical guides containing the sleeve and the one without a T-test (α =.05) was used.

Figure 4. Measurements for planned and placed implants A, Measurement for the surgical guide with sleeve B, Measurements for the metal-free surgical guide. This figure visualizes the process of the superimposition of the placed implants in the resin casts atop the original planned placement from 3Shape. Figure 4A shows the measurements for the implants placed by the surgical guide with the metal sleeve. Figure 4B shows the measurements for the implants placed by the surgical guide without metal sleeve.



Planned Implant



2.3 Results

The first round of overall implant deviations were -0.23 ± 0.16 mm mesially (M), 0.48 ± 1.37 mm of the apex region buccolingually (AL), 0.15 ± 0.38 mm of the cervical region buccolingually (CL), 2.23 ± 4.18 degrees in the buccolingual angulation (BLA). Detailed measurements and analysis of the in vitro study are presented in Table 1. Differences between the planned and placed implant positioning are also presented with 95% Confidence Intervals (CIs) for means of within-subject paired differences. Table 1 demonstrates the mean, standard deviation, range, minimum (Min), Q1 (first quartile), Q3 (third quartile), and maximum (Max) values for both the sleeve and sleeveless surgical guides, as well as the P values. Figure 5 demonstrates the box plots of dimension and angulation deviation overall and for both types of guides. The implant deviations for the surgical guide with sleeve were -0.30 ± 0.17 mm mesially, 0.60 ± 1.69 mm buccolingual at the apex, 0.20 ± 0.47 mm buccolingual at the cervical, 2.73 ± 4.80 degrees in the buccolingual angulation. The implant deviations for the surgical guide without sleeve -0.17 ± 0.14 mm mesially, 0.35 ± 1.04 mm buccolingual at the apex, 0.10 ± 0.27 mm buccolingual at the cervical, 1.73 ± 3.66 degrees in the buccolingual angulation.

Table 1. Implant placement deviations and statistical analyses for initial round of implants.

This table highlighted the implant placement deviations occurring within the first aim. The four parameters utilized were mesial, apex buccolingual, cervical buccolingual, and buccolingual angulation. The means, standard deviations and ranges are noted. A t-test was utilized to compare accuracy between the different surgical guide group's means. An F-test was utilized to compare the precision between the two different group's ranges. No statistically significant differences were found between either group with t-test nor F-test.

Deviation	Presence of Sleeve	Mean	SD	Range	Min	Q1	Q3	Max	t-test	F-test
Mesial	Sleeve	-0.30	0.17	0.48	-0.60	-0.39	-0.17	-0.12	0.07	0.24
	No Sleeve	-0.17	0.14	0.42	-0.31	-0.27	-0.12	0.11		
Apex BL	Sleeve	0.60	1.69	5.43	-2.08	-0.16	1.42	3.35	0.69	0.08
	No Sleeve	0.35	1.04	3.53	-1.10	-0.05	0.56	2.43		
Cervical BL	Sleeve	0.20	0.47	1.62	-0.59	0.04	0.38	1.03	0.59	0.06
	No Sleeve	0.10	0.27	0.95	-0.32	-0.04	0.24	0.63		
BL Ang	Sleeve	2.73	4.80	13.91	-5.16	-0.63	5.95	8.75	0.61	0.22
	No Sleeve	1.73	3.66	11.56	-3.35	0.47	1.40	8.21		

Figure 5. Box plots for positional and angulation implant deviations showing first and third quartile box plots and maximal and minimal values. A, M. B, Apex BL. C, Cervical BL. D, Angulation BL. This figure highlights the overall variation of deviations occurring between the two different surgical guide groups of the first aim by using a box plot. All four parameters are exemplified here with 5A. Mesial (M), 5B. Apex buccolingual (Apex BL), 5C. Cervical buccolingual (Cervical BL), and 5D. Angulation buccolingual (Angulation BL). The overall box averages the deviations between the two different groups, while the sleeve and no sleeve show each group individually. The averages between the two guide's deviations are shown by the distance from 0 which is the planned placement from 3Shape. The precision is highlighted by the size of the box plots showing overall variation of deviations that occurred.



In relation to implant accuracy, none of the deviations in the M (P=0.071), AL (P=0.691), CL (P=0.586), nor BLA (P=0.608) showed significant differences. The range for the deviations from those with the sleeve to those without were 0.48 and 0.42 mm mesially, 5.43 and 3.53 mm

of the apex region buccolingually, 1.62 and 0.95 mm of the cervical region buccolingually, 13.91 and 11.56 degrees in the buccolingual direction. The ranges for the guide without sleeve appeared to exhibit a narrower range in the apex region buccolingually and angulation buccolingually.

In terms of precision, referring to the consistency of displacement or the least variation in deviations, the Levene tests for differences in variance (α =.05) suggested no statistically significant differences M (P=0.246), AL (P=0.081), CL (P=0.056), nor BLA (P=0.216).

The second round of overall implant deviations -0.10 ± 0.17 mm mesially, -1.48 ± 1.02 mm mm of the apex region buccolingually, -0.61 ± 0.26 mm of the cervical region buccolingually, -1.57 ± 2.54 degrees in the buccolingual angulation. Detailed measurements and analysis of the in vitro study are presented in Table 2. Differences between the planned and placed implant positioning are also presented with 95% Confidence Intervals (CIs) for means of within-subject paired differences. Table 2 demonstrates the mean, standard deviation, range, minimum (Min), Q1 (first quartile), Q3 (third quartile), and maximum (Max) values for both the sleeve and sleeveless surgical guides, as well as the P values. Figure 6 demonstrates the box plots of dimension and angulation deviation overall and for both types of guides. The implant deviations for the surgical guide with sleeve were -0.15 ± 0.23 mm mesially, -1.50 ± 0.99 mm buccolingual at the apex, -0.60 ± 0.27 mm buccolingual at the cervical, -1.49 ± 2.91 degrees in the buccolingual at the apex, -0.62 ± 0.27 mm buccolingual at the cervical, -1.64 ± 2.26 degrees in the buccolingual angulation.

implants. This table highlighted the implant placement deviations occurring within the second aim. The four parameters utilized were mesial, apex buccolingual, cervical buccolingual, and buccolingual angulation. The means, standard deviations and ranges are noted. A t-test was utilized to compare accuracy between the different surgical guide group's means. An F-test was utilized to compare the precision between the two different group's ranges. A statistically significant difference was found with the F-test in the mesial dimension. The t-test nor the remainder of the other parameter's F-tests highlighted any statistically significant differences.

Table 2. Implant placement deviations and statistical analyses for second round of

	Presence									
Deviation	of Sleeve	Mean	SD	Range	Min	Q1	Q3	Max	t-test	F-test
Mesial	Sleeve	-0.15	0.23	0.66	-0.54	-0.21	0.03	0.12	0.27	0.0005
	No Sleeve	-0.06	0.07	0.19	-0.16	-0.10	0.00	0.03		
Apex BL	Sleeve	-1.50	0.99	2.66	-3.04	-2.23	-0.65	-0.38	0.78	0.44
	No Sleeve	-1.62	1.03	3.13	-2.67	-2.35	-1.38	0.46		
Cervical BL	Sleeve	-0.60	0.27	0.90	-1.26	-0.70	-0.41	-0.36	0.86	0.47
	No Sleeve	-0.62	0.28	0.87	-0.89	-0.76	-0.66	-0.02		
BL Ang	Sleeve	-1.49	2.91	7.90	-5.54	-4.10	0.98	2.36	0.90	0.23
	No Sleeve	-1.64	2.26	6.39	-4.07	-3.27	-0.49	2.32		

Figure 6. Box plots for positional and angulation implant deviations showing first and third quartile box plots and maximal and minimal values. A, M. B, Apex BL. C, Cervical BL. D, Angulation BL. This figure highlights the overall variation of deviations occurring between the two different surgical guide groups of the second aim by using a box plot. All four parameters are exemplified here with 6A. Mesial (M), 6B. Apex buccolingual (Apex BL), 6C. Cervical buccolingual (Cervical BL), and 6D. Angulation buccolingual (Angulation BL). The overall box averages the deviations between the two different groups, while the sleeve and no sleeve show each group individually. The averages between the two guide's deviations are shown by the distances from 0 which is the planned placement from 3Shape. The precision is highlighted by the size of the box plots showing overall variation of deviations that occurred.



In relation to implant accuracy, none of the deviations in the M (P=0.275), AL (P=0.786), CL (P=0.864), nor BLA (P=0.899) showed significant differences. The range for the deviations from those with the sleeve to those without were 0.66 and 0.19 mm mesially, 2.66 and 3.13 mm

of the apex region buccolingually, 0.9 and 0.87 mm of the cervical region buccolingually, 7.90 and 2.32 degrees in the buccolingual direction. The ranges for the guides without sleeves appeared to exhibit a narrower range in the mesial region and angulation buccolingually.

In terms of precision, referring to the consistency of displacement or the least variation in deviations, the Levene tests for differences in variance (α =.05) suggested statistically significant differences in only the M dimension (P=0.0005), but the other dimensions did not show significance with AL (P=0.45), CL (P=0.49), nor BLA (P=0.23).

2.4 Discussion

The utilization of 3D printers in the field of dentistry has increased clinical accuracy and enhanced clinician confidence during preoperative and operative procedures. Being able to easily and efficiently manufacture in-house surgical guides along with preoperative study models is key to improved implantation results in the field of dentistry. (Yeung et al. 2020, Hutlin et al. 2012, Alevizakos et al. 2019, Deeb et al. 2017, Suriyan et al. 2019, Bencharit et al. 2018) Also, 3D meshing and blending software improvements over the past decade have allowed for customization of patient treatment plans. (Ammoun et al. 2021) This paper sought to utilize these features of digital dentistry to exhibit the accuracies of sleeveless 3D printed surgical guides in comparison to the conventional surgical guide that uses metal sleeves.

This study's first aim was meant to determine the range of implant deviations occurring between a surgical guide with a metal guide sleeve and without. Also, to analyze any significant differences between the two. We hypothesized that the differences in deviations between the two different guides would not be significant. The results from this study do in fact support the idea that the sleeveless surgical guide's deviations are consistent with those of the surgical guide with metal sleeve. Our data also appeared consistent with those of previous studies that placed implants using a 3D printed surgical guide. (Yeung et al. 2020) It is interesting to note that the means and ranges for the surgical guide without metal sleeve appear slightly lower than those of the metal sleeve for all four parameters. This could possibly be due to the fact only one surgical guide was used per group thus decreasing the amount of error introduced from the printing process. However, these small differences in overall deviations were in range of the average deviations exhibited by studies that were examining implant deviations through the use of surgical guides. (Yeung et al. 2020, Alevizakos et al. 2019, Deeb et al. 2017)

This second aim of this study wanted to determine the overall differences generated in implant deviations between the two groups of surgical guides from the first aim but decrease the guide to cast ratio to 1:1. We hypothesized that the increase in the number of surgical guides for the two different groups would yield similar accuracy and precision. From this decrease in guide to cast ratio, it was found that that accuracy between the guides with and without metal exemplified similar accuracy. However, in terms of precision there was a statistically significant difference between the two groups within the mesial dimension. This was interesting as it can allow speculation that the guide without metal sleeve is more precise but the remainder of the parameters saw no statistically significant differences so it is simply speculation. Also, the pattern that surgical guides without the metal sleeve saw decreased means and ranges as shown in the first aim did not continue in the second aim. This could be due to that fact that more surgical guides were produced and thus there was an increased possibility of errors introduced during the printing process.

During the initial round of osteotomy and implant placement, it was noticed that there was some fracturing within the models made of Dental Model resin. The switch to the Dental

Clear LT V2 resin decreased the visible fracturing of the model during osteotomy preparation and implant placement. The use of the Dental Clear LT V2 resin during the second round of this study could introduce a new and improved method for future implant studies.

Also, when printing surgical guides there can be a small degree of dimensional deviation. (Vinci et al. 2020) It has been reported that inadequate minimal drill tolerance can account for 2.8 mm of dimensional deviation and 5.9 degrees of angulational deviation at the apex of the implant and the implant axis, respectively. (Son & Lee, 2021, Oh et al. 2021) To account for this, the internal diameter of the metal-free surgical guide was reduced by 0.02 mm to allow for minimum drill tolerance.

Another factor for examining this subject is the overall cost-effectiveness of using a surgical guide that does not contain a metal guide sleeve. By showing that the differences in implant deviation between utilizing a metal guide sleeve and not are minimal, it can be concluded that the clinician will be reducing the cost of the operation while maintaining accuracy. Many clinicians can be pushed away from using a surgical guide due to cost and overall misunderstanding of their fabrication in-house. This study simplifies all those parameters to decrease any complications that could arise during planning and creation of the surgical guides without metal guide sleeves.

Similar studies have been conducted to examine the effectiveness of metal free surgical guides and their results are consistent with those of this study. (Talmazov et al. 2020, Dalal et al. 2020) However, these studies did not utilize the Blender 3D software in such a simple fashion as this study did. This paper is more applicable to general practitioners because it created a novel series of steps that are readily reproducible and allow users to manipulate the guide tube with ease. This is beneficial because a major issue with utilizing these meshing and blending

softwares is that many clinicians do not have experience with them and there is a slight learning curve to be able to properly utilize the features. However, once a basic understanding is established, the softwares can easily be manipulated to the clinician's benefit.

With the success of our hypothesis, we did notice a few limitations within our study. These limitations were consistent with those of a previous study. (Yeung et al. 2020) One of these limitations being that the fitting of the guide atop the resin casts may differ from that of the natural teeth and soft tissue. The minor movements of the natural structures may allow for increased deviations. However, previous papers have shown that the implant deviations within resin models is similar to those of in human studies. (Deeb et al. 2017, Suriyan et al. 2019) Secondly, the deviations of the implant drills when preparing the osteotomies in homogenous polymethyl methacrylate may differ from those in non-homogenous alveolar bone. Lastly, this paper limits itself to only the Zimmer Biomet TSV guided implant system. A review of more implant systems may create a wider array of results to interpret due to the variability of each implant system's protocols.

Future studies should take these limitations into consideration when designing their experiment. An ability to investigate posterior regions of the mouth as well as taking a look at how simulated soft tissue plays a role in the accuracy of sleeveless surgical guides could be useful. Another interesting idea would be for the implant manufacturers to implement a 'no metal sleeve' option into their treatment planning softwares to further streamline the process. It should also be acknowledged that this study only analyzed the Zimmer Biomet TSV implant system and surgical guide. There are differences in each implant system's metal guide sleeves and future studies could attempt to manipulate other system's surgical guides to analyze any differences.

2.5 Conclusions

Based on the results of this study, we have concluded that the sleeve free implant surgical guide demonstrates similar accuracy and precision as the surgical guide with the metal sleeve. Metal sleeves may not be required for an accurate implant placement. We also decided that the use of 3D blending software can be efficiently and effectively utilized in a clinical setting to produce customized patient treatment.

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