

2022

Accuracy, Prosthetic Outcomes, and Patient-related Outcomes with Immediate Loading of 4-Guided Implants Supporting an Unsplinted Maxillary Implant-Retained Overdenture

Nathaniel Chertok
nchertok@mix.wvu.edu

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Accuracy, Prosthetic Outcomes, and Patient-related Outcomes with Immediate Loading of 4-Guided Implants Supporting an Unsplinted Maxillary Implant-Retained Overdenture

Nathaniel Chertok, D.D.S., M.S.

Thesis submitted
to the School of Dentistry
at West Virginia University

in partial fulfillment of the requirements for the degree of

Master of Science in
Prosthodontics

Matthew T Harper, D.D.S., M.S., (Chair)
Shelby Alexander, D.D.S., M.S.
Fotinos Panagakos, D.M.D., Ph.D.
Arif Salman Abdul Shakore, B.D.S., M.S.
Gian Pietro Schincaglia, D.D.S., Ph.D.

Department of Restorative Dentistry

Morgantown, West Virginia
2022

Keywords: Maxilla, Guided Surgery, Dental Implants, Guide Accuracy, Patient-related Outcomes, Prosthetic Outcomes

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ABSTRACT

Accuracy, Prosthetic Outcomes, and Patient-related Outcomes with Immediate Loading of 4-Guided Implants Supporting an Unsplinted Maxillary Implant-Retained Overdenture

Nathaniel Chertok, D.D.S., M.S.

Aim: Assess the accuracy of implant placement using a mucosa-supported surgical guide relative to the planned implant position and examine patient-related outcomes associated with immediately-loaded Mx IOD using a single-attachment abutment system. The secondary aim of the study is to examine the prosthetic complications associated with this treatment.

Materials and methods: Fifteen individuals with edentulous maxillae were included. Each participant received 4 Straumann BLX implants through a stereolithic mucosa-supported surgical guide distributed in the Mx arch to maximize AP spread. Implant lengths ranged from 10 to 14 mm. A post-op CBCT was taken after the surgery to compare the accuracy of the implant placement with the planned position using the Treatment Evaluation Module in CoDiagnostix. Primary outcome variables were 3D offset at apex and platform along with global angular deviation and patient-related outcomes.

Results: Fifteen participants had 60 implants placed. Fifty-nine of those implants were suitable for assessment. The mean global deviation of the implants was $3.28 \pm 1.929^\circ$, the 3D offset of the implants was 0.86 ± 0.484 mm at the platform and 1.036 ± 0.59 mm at the apex. Statistically significant higher 3D offset was observed for the implant platform and apex between posterior and anterior implants at 0.762 vs. 0.984 and 0.862 vs. 1.203 mm respectively.

Conclusion: The accuracy of mucosa-supported surgical guides for Mx IODs is within the acceptable range of error when compared to planned position. Posterior implants show greater deviation than anterior implants. Patient-related outcomes improve immediately after the prosthesis is loaded and continue to improve over the follow-up period.

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ACKNOWLEDGEMENTS

Dahlia: This thesis and my last twelve years of academics are dedicated to you. I would not have accomplished a fraction of my accolades and accomplishments without my beautiful and incredible Wonder-Woman. Your unwavering dedication and constant pushing me to do my best has motivated me from when we first met in Israel. You supported me through the hardest days in residency and laughed with me at the many comical moments in it all. I still do not know how you did it- full-time mom, full-time job, full-time caretaker of me, and all while being the most incredible mother to our two wonderful children. I owe you all that I can give you for allowing me to pursue my passion. My patients and I thank you from every ounce of our beings. You don't just wear one or two hats- you wear ALL the hats and do it with such style and grace. I am lucky to be accompanied by you on this adventure.

Lielle, Noam, and Baby #3: You probably will not remember this time in your lives, but what I hope you take away from my experience is that we should always do our very best to help others and do everything in our power to ensure that our best intentions are aligned with those we care about. Your hugs and greetings after a long day in clinic and lab were the perfect pick-me-up.

My Family: Thank you for all your encouragement and love over the past many years. And, thank you for all the hours of listening to me talk about teeth. This journey would have been so much harder without each of you.

Dr. Matt T. Harper: For continuously challenging me and pushing me to be the most ethical and true provider I can be. I am so thankful that I followed in your footsteps from the time I was in my master's program before dental school. Your dedication to your patients and students does not go unnoticed and is greatly appreciated by everyone you touch.

Dr. Shelby Alexander: For being my motivation, inspiration, and role model throughout my time at WVU. From the first class you taught me until the last day of residency, I have always strived to emulate you and translate my knowledge into practical, meaningful practice. You do it so well and I only hope to do the same.

Dr. G.P. Schincaglia: For your leadership and impeccable skills both clinically and as an educator. Thank you for never setting the bar low, for always pushing me, and for always wanting the best for all your students.

Dr. Arif Salman: For being a supportive and collaborative mentor, and for showing me that a smile on your face can sometimes make everything else melt away.

Dr. DoHeum Choi: For being my counterpart in our research project and making our way together through dental school and our respective residencies- from sitting next to each other in sim lab to conducting our research together.

Lyndsey Gray: For our incredible friendship and having each other to turn to during the insanity of our incredible department. You are the glue that holds our residency together and you are so appreciated by us all. Your laughter and smile always brighten my day.

Dr. Stacey Culp: For taking your time with me and showing me how my abstract statistical numbers all made sense. Your patience and help were instrumental.

Straumann: For sponsoring our research project and investing time and resources to allow us to contribute to the academic and clinical world to improve our clinical outcomes for our patients.

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CHAPTER I: INTRODUCTION

Background

Dental implant therapy has progressed with its versatility and availability in recent years. With recent advances in implant design and understanding of the osseointegration process, the treatment modalities with dental implants has grown. Cone Beam Computed Tomography, CBCT, technology has been utilized in conjunction with stereolithography to fabricate surgical guides for implant placement. Accuracy of the mucosa-borne surgical guides has been demonstrated to be sufficient with in-vitro models. Flapless, minimally invasive surgeries allow for decreased patient morbidity.

Statement of problem

The accuracy of mucosa-borne stereolithic guides for edentulous maxillae in in-vivo study has not been examined. Additionally, immediate-loading of non-splinted implants retaining a Mx IOD has not been demonstrated in a clinical trial to determine the prosthetic complications and patient-related outcomes.

Significance of problem

The goal of treatment should be to accurately and predictably improve the patient's wellbeing and minimize morbidity during the treatment process. Stereolithography is a tool that can be used in association with CBCTs to allow for a predictable method of treatment that minimizes invasiveness and increases patient comfort throughout treatment. Clinical trials regarding this treatment modality are lacking and evidence is necessary to demonstrate to the dental community if and how this treatment modality is possible.

Hypothesis

Implant deviation, both global deviation and 3D offset at the platform and apex of the implant, differs slightly from planned implant position using stereolithic surgical guides when comparing surgical sleeve height, implant position in the maxilla, mucosa thickness, and bone density. The quality of life assessment demonstrates improvement after treatment completion.

Null hypothesis

Implant position does not differ from planned implant position using stereolithic surgical guides. The quality of life assessment demonstrates no improvement after immediate-loading of Mx implant-retained overdenture.

Definitions of terms

STL: Standard Tessellation Language is the type of file used in CAD software which allows the user to visualize a 3D object.

IOD: Implant-retained overdenture. Tissue-supported prosthesis that can be for either maxilla or mandible.

CBCT: Cone Beam Computerized Tomography is an imaging method which allows the user to distinguish between hard tissues in a biologic subject. It images slices in sagittal, coronal, and frontal planes and splices them together to provide a 3-dimensional representation of the object being radiographed.

FDP: Fixed Dental Prosthesis is either an implant or tooth supported restoration that represents teeth composed of a prosthetic material. Its length and span can vary depending on the edentulous space present.

Mx: Maxilla is the bone connected to the base of the skull composed of basal bone more apical and alveolar one which supports teeth. The periodontal apparatus encompasses the bone which is composed of ligaments, nerves, blood supply, and possibly teeth (if present).

OHIP: Oral Health Impact Profile is a questionnaire given to patients to assess the impact of a prosthesis on their quality of life and well-being.

BLX: Bone Level Extreme implant made by Straumann.

CAD CAM: Computer Aided Design and Computer Aided Manufacturing.

KG: Keratinized Gingiva. Also known as Attached gingiva is firmly attached to the underlying bone.

PI: Plaque Index is a measuring index using to assess the quantity of plaque present on or around teeth, gingiva, or dental implants and their components.

BoP: Bleeding upon probing using a stainless-steel UNC-15 periodontal probe.

PD: Pocket depth, the height of the periodontal pocket from the platform of the implant to the crestal height of the soft tissue.

ISQ: Implant Stability Quotient is the resonance frequency relative to the surrounding bone and structures around the implant.

DICOM: Digital Imaging Communication in Medicine. A type of file that reads radiographic imagery digitally.

s-CAIS: static, computer-aided surgery.

Assumptions

1. Superimposition of CBCTs was accurately done for pre-and post-op assessment.
2. Fiducial markers were superimposed appropriately from DICOM files on each of the dual scans.

Limitations

1. Movement or blurriness in CBCT leading to poor CBCT analysis and assessment for superimposition.
2. Form2 printer was used for the first 12 guides vs. Form3B printer for the last 3 guides.

3. Did not complete a finite analysis on the Novaloc PEEK inserts.
4. Different surgeon for the last 3 surgeries.
5. Use of OHIP-14 instead of OHIP-EDENT questionnaire.
6. QoL not assessed based on palatal coverage or no palatal coverage.
7. Homogenous population demographically- Gender: females have less bone and poorer quality.

Delimitations

At this time, there are no delimitations in this analysis and study based upon this thesis.

CHAPTER II: LITERATURE REVIEW

Dental Implants for Edentulous Patients: Fixed vs. Removable Prosthetics

Depending on patient-related, clinical, anatomical, and restorative factors, the prosthetic options for patients who are interested in incorporating implant therapy into their treatment include removable prostheses that are either implant supported or retained to a fixed implant supported prosthesis. When treatment planning removable prostheses retained by implants, the following factors must be evaluated for successful therapy: lip support, flange, restorative space, patient dexterity, and opposing arch restorative material.¹ If the patient presents with a skeletal class III arrangement, a retruded maxilla or a protruded mandible, a removable prosthesis that has a buccal flange can compensate for the skeletal discrepancy between the skeletal arches.¹ To appropriately position implants for sufficient restorative space for the materials, evaluation of the space from the platform of the implant to the cameo surface of the prosthesis is necessary. For a maxillary implant-retained overdenture, the necessary range of restorative space required is 7-14 mm which would include the space needed for gingival tissue, abutment height, reciprocal housing in the prosthesis, thickness of acrylic necessary for strength.^{2,3}

For fixed implant supported prosthetic treatment plans, depending on the material and design of the final prostheses, the necessary vertical space can vary from 8 mm (fixed FDPs) to 14 mm (metal-acrylic fixed-detachable prosthesis). Planning and placement of the implants should be prosthetically driven for ideal incorporation of implants to the prosthesis.²

Distribution of the implants is critical in designing a prosthesis that will maximize the utilization of the implants but not overload or cause damage to the implants due to excessive forces.⁴ Maximizing the anterior-posterior (AP) spread of the implants is more critical for fixed prostheses as those prostheses are implant supported and not tissue supported. To extend the occlusal surfaces posteriorly past the most posterior implant, the forces and distance need to be controlled. English established in 1990 that the acceptable length a cantilever is 1.5 times the distance from the center of the most anterior implants with the distal part of the most distal implants.⁵ Others debated if distal cantilevers should be less than 15 mm or go beyond 20 mm.⁶ The “rule of thumb” of 1.5 times the length of the distance from the center of the most anterior implants with the distal part of the most distal implants has been questioned, and it has been established that, though it is a critical component of the treatment planning, there is no set amount of cantilever for fixed prostheses; rather, the focus should be minimizing the cantilever and maximizing the spread.⁷ The AP spread can be maximized by two methods: 1. adding implants posteriorly if the bone is available, the sites are grafted with sinus augmentation in the maxilla, or other means of placing implants (pterygoid or zygomatic implants), 2. by tilting the implants distally. When tilting implants, the AP spread can be maximized even more to reach further back and minimize the cantilever since you can now reach further back under the body of the implant and have less prosthetic structure in the cantilever region. Guenin in 2020 examined the minimum number of implant necessary for a Mx IOD and concluded that, though patient satisfaction was not affected by how many implants, a minimum of 4 implants was necessary for implant survival rate to be appropriate and minimize prosthetic complications.⁸

In the treatment planning phase, assessment of how much masticatory force can be applied is critical for properly predicting the prognosis of the treatment modality chosen.⁹ Jemt et al. compared fixed versus removable prostheses supported by implants. Jemt assessed the variables of maximal tension force, compressive force, load moments, and bending moments. They found that compressive forces for fixed prostheses observed were 25 N while the maximal tension force for removable prostheses supported by implants was 20 N.⁹

Maxillary Implant-retained Overdenture: Splinted vs. Unsplinted Implants

Restorative componentry for maxillary implant-retained overdentures is approved in two primary ways. The implants can be splinted together with a prosthetic supra-structure, or the implants can be unsplinted, as single implants with individual abutments (magnets, ball attachments, Locator attachments, Novaloc, ERA, O-rings).¹⁰ Factors influencing which treatment route is best in that clinical situation include implant position, angulation, patient desires, cost, and restorative space. A bar-retained implant overdentures allows for force distribution, angle correction of implant angle deviation by fabrication of a passive-fitting metal (titanium, cobalt-chromium, or gold) supra-structure that allows for reciprocal attachments within the prosthesis to attach and detach to the bar as opposed to the implants directly. The individual implant-abutment attachment system allows for each implant to have its own reciprocal in the intaglio surface of the prosthesis but can accommodate only a certain amount of angle deviation between the abutments. The most popular systems have guidelines of generally 20° of deviation per abutments or 40° total. More deviation than the specified amount can cause excessive wear of the abutments and inserts, increasing the prosthetic complications for the patient and provider to manage.

Individual abutments are cheaper, simplify the treatment process (no need to fabricate a supra-structure), and are more easily maintained by patients.¹⁰ Supra-structures treatment modality is viable if the patient is taught and can maintain appropriate hygiene around the supra-structure; however, the high lab costs, and individualized home and office-care involved deter many providers from utilizing this treatment option as much these days.¹⁰ When implants were being utilized for removable prostheses, it was thought that they must be splinted to withstand the forces of the denture. Recent literature has shown that even in immediately-loaded Md IODs, individual abutments do not cause detrimental trauma to the bone, soft tissue, or implants if maintained appropriately.¹¹

Locator abutment system is one of the most used system today for implant-retained overdenture with no supra-structure present. Zest manufactures this abutment for countless implant designs. Locators are beneficial by improving retention without splinting the implants. The retention is dependent on the severity of wear on the components (housing-both internally and externally) and the abutment. The retention can also be increased with changing the nylon inserts. Chung compared ERA, Hader, and Locator (white and pink) attachment systems and the forces necessary to dislodge them. They found that white Locator nylon inserts have moderate load-to-dislodgement force ability of about 28.95 N. Load-to-dislodgement is the force needed to detach the nylon insert from the Locator abutment.¹² Evtimovskva followed up on Chung's research and examined the

peak load-to-dislodgement of more Locator nylon inserts and found that Hader clips and white Locator inserts had similar wear patterns and decreased their retention by 25% after multiple attempts to remove the prosthesis.¹³ This seems to indicate that the initial wear of the nylon insert is significant and might require more frequent replacement of the nylon inserts. Arnold compared the retention force of Locator and Novaloc inserts and found that their retentions were comparable to one another.¹⁴ Arnold also indicated that as the angulation between the abutments increases, the retention force decreases. Perlis investigated how the wear is affected by thermocycling and it was found that corrosion of the metal occurred along with wear of the other components.¹⁵ Polyetheretherketone (PEEK) has shown some promising in-vitro results to replace the nylon inserts. In 2020, Wichmann compared PEEK, nylon, and Polyetherketoneketone (PEKK) inserts and their wear patterns.¹⁶ Both PEKK and PEEK systems showed higher wear resistance when compared to the nylon inserts. Novaloc is an abutment/insert system that utilizes PEEK inserts and allows for angled abutments of 15°. When Arnold et al. compared Locator attachments to Novaloc, both angled and straight abutments, they found that Novaloc performed better when comparing the loss of retention force of each of the systems after thermocycling (26% decrease for Novaloc while 77% decrease in Locator).¹⁴ This indicates that Novaloc's use of PEEK can have a clinical relevance and applicability.¹⁴

Endosseous Implant Design

Endosseous dental implant micro and macro designs are continuously evolving to improve and increase the quality of the osseointegration and longevity. Factors that influence the design of the implant include material of fabrication, length, diameter, surface type, shape, and thread type.¹⁷ Dental implant properties are carefully chosen to maximize the benefit to the body and to not cause any local or systemic harm. Dental implants used today are bio-inert and can be categorized into three main categories based on their material composition- titanium, zirconia, and an alloy of titanium-zirconium. The alloy of titanium and zirconium has shown positive results when compared to pure titanium implants.¹⁸ One of the titanium-zirconium alloys is Straumann's Roxolid implant, comprised of 83-87% titanium and 13-17% zirconium (TiZr1317).¹⁹ The biomaterial of the implant should meet the criteria of an appropriate modulus of elasticity. Cortical bone's modulus of elasticity ranges between 10-20 GPa with it generally being around 18 MPa.²⁰ The implant should exhibit similar modulus of elasticity so the force and stress distribution will not compromise the surrounding biologic structures and the level of deformation of both the implant and the bone are similar.²¹ To be functional, the implant must have the ability to transfer and distribute the stress of the forces, meaning the tensile and compressive properties of the implant must be sufficient. Another aspect of the implant properties is the ductility of the implant, as it is critical in the fabrication of the implant and shaping it.²¹ The ADA has specified that the minimum ductility of an implant should be 8%.

Researchers have attempted to use many different types of surface modifications to improve both osteoblast attraction and primary stability and integration, including acid etching and oxidation.¹⁹ Rough surface dental implants have increased surface area and integrate to the bone directly, as opposed to smooth surface implants which require the surrounding bone to advance and grow

toward the implant.²² Straumann developed the SLA and SLActive surfaces which are acid etched with large particles and are sandblasted. The SLActive also increases the hydrophilicity of the implant.¹⁹ The goal of the roughened surface is to increase the bone-to-implant contact, which Buser demonstrated with the SLActive surface to be 30-40% .²³

Literature has debated how to categorize implant diameter. A recent systematic review categorized diameter ranges as narrow diameter (3-3.4 mm), regular (3.75-4 mm), and wide (5-6 mm).²⁴ When assessing the fatigue of the implants at 1-and 3-year follow-ups, the researchers found no difference when basing the implant success on the diameter alone.²⁵ Javed found a similar conclusion in 2013 when examining the long-term survival of implants in the posterior maxilla.²⁶ Javed found that implant diameter was secondary in its importance to other factors such as primary stability, oral hygiene, and surgical protocol.²⁵ Threads can be designed on the external surface of the implant in a multitude of ways to improve primary stability and bone-to-implant contact. One method of grouping implants is whether the implants are self-tapping or pre-tapping. Self-tapping implants create their own threads in the bone when the implant is placed. These implants are recommended to use in less dense bone, as in the posterior maxilla. Pre-tapping threads have a tapered design and are meant for denser bone, as in the mandibular anterior region.¹⁷

CBCT/Dual Scan Protocol

Cone beam computer tomography, CBCT, has been used to predictably evaluate the anatomical structures during treatment planning of implants and for surgical guide fabrication.²⁷ In an edentulous maxilla, there are no intraoral anatomical markers that assist in determining the planning and placement of implants in a prosthetically driven manner. Placing implants with a prosthetically driven plan improves the restorative options possible, longevity of the implant survival, and functionality of the patient with their prosthesis.²⁸ In a CBCT scan, images are captured in the x, y, and z axes and are saved in a DICOM, Digital Imaging Communication in Medicine, format. This format stitches the captured images together and renders a 3-dimensional view of the captured area. Soft tissue, bone, nerves, restorative materials, and implants have differing density levels which translate to the view as either more radiolucent (soft tissue, nerves) or more radiopaque (bone, restorative materials, implants).²⁹ According to the ALARA (As Low As Reasonably Achievable) radiology rules, the ideal is to minimize the radiation exposure to the patient while still capturing the necessary distinctive anatomy for the assessment and evaluation of treatment planning. According to Apostolakis et al, maintaining a voxel size of 200 μm is enough to evaluate teeth and alveolar bone while maintaining a mA that is as low as possible.³⁰ Ritter analyzed the accuracy of the CBCT scan when compared to intraoral scans and found errors on the CBCT of 0.03-0.14 mm compared to the source.³¹ A dual scan technique has been utilized in patients with metal artifacts due to implants, crowns or any other radiopaque objects fixed to the skull or mandible.^{32, 33} This technique can also be translated to patients who are edentulous as there is no alternate way to prosthetically design a case through the virtual implant planning software.^{33, 34} Radiopaque fiducial markers are placed in or on the prosthesis, and the prosthesis is scanned separately by the CBCT. The patient then inserts and fully seats the prosthesis with the fiducial markers in the mouth and the CBCT is taken again. This allows the provider to

superimpose the prosthesis scan over the scan of the patient's jaw using the fiducial markers as reference marks.³⁴

Guided Implant Surgery

It has been established that dental implant success is improved when they are placed in a prosthetically driven manner. The treatment planning begins with a site that is deemed appropriate for implant therapy in terms of anatomy, restorability, and biologically. For single tooth implant therapy, a diagnostic cast and wax up cast allow the surgeon and restorative provider to plan the surgical and restorative phases of treatment prior to any invasive surgery occurring. This minimizes the patient negative outcomes and improves the accuracy, efficiency, and success of this treatment. The casts can either be physical or digital models of the intraoral environment. For complete edentulism implant planning, a wax up or duplicate of a prosthesis is necessary to evaluate where the implants are planned to be placed and this is more critical since there is no reference of teeth to guide the surgery with regards to restorative space, depth of implant platform, or position of implant in buccal, lingual, mesial, or distal directions.

When implant therapy was developing at the elementary stage, the implants were planned manually, and complex, cumbersome methods were used to overlap current intraoral situation with the planned implant position. This requires hours of lab work and the accuracy was far from ideal. In recent years and with the advances of intraoral scanning, lab scanning, and CBCT protocols, the dental community has been able to alleviate those challenges by incorporating the digital advances to improve the efficiency and efficacy of this treatment. Navigation systems have been developed to allow for clinicians to improve the patient experience and clinician experience making this treatment more possible in many more situations. Surgical guide protocols have been developed to allow the user to guide either partial osteotomy preparation, full osteotomy preparation, or fully guided surgery with guided implant placement. Additionally, surgical guides can come in various forms, giving the user either dynamic navigation systems, or static navigation systems. The dynamic systems allow for the user to either control the surgical device while duplicating the drill and its whereabouts on a screen that is projecting, in real-time, the position of the drill in relation to the surrounding anatomy. Other dynamic navigation systems include the use of robotic devices that lock into certain positions to minimize deviation from the surgical plan and the human element aids the robotic device in navigating to the appropriate position.³⁵ The most prohibitive factors to these navigation systems are difficult a high learning curve, bulkiness, and cost. Alternatively, static computer aided implant surgery, s-CAIS, guides can offer a more affordable, simple, and non-invasive method to guided surgery.³⁶ s-CAIS guides can be fabricated by using thermoplastic polypropylene or can be printed using additive stereolithography technology.³⁷ Stereolithography can be used and recent meta-analyses have shown that the expected accuracy of a mucosa-supported s-CAIS guide can range up to 3.5° global deviation from the planned position with 1 mm linear deviation at the platform of the implant and 1.5 mm at the apex.^{36, 38, 39} D'haese defined global deviation as measuring the 3D position of a point on the implant (either coronal or apical point) on the planned virtual implant with the actual position of the implant.^{40, 41} Linear deviations are calculated by drawing a line along the long-axis of the

implant at both the coronal and apical positions and calculating the linear distance between the planned virtual position of the implant with the physical position of the implant after the surgery.^{40, 41} s-CAIS guides can be supported by one of three anatomical components- teeth, bone, or mucosa. The current literature supports the accuracy of these different types of surgical guides as the most accurate being teeth-supported, followed by mucosa-supported and bone-supported respectively.⁴² To improve patient outcomes, ensure ease of surgical and prosthetic procedures, guided surgery has demonstrated to be advantageous even in surgeons with minimal surgical experience (graduate residents).^{28, 43, 44} In 2012, the European Association for Osseointegration met at the consensus meeting and addressed the accuracy of s-CAIS guides based on the research presented at the time and concluded that the accuracy of these guides are clinically acceptable.⁴² The consensus additionally concluded that the use of fixation of the guide to the edentulous arch improves the accuracy drastically.⁴² Contrary to these results, D'haese found a great amount of variability present in s-CAIS guides mainly in ex-vivo studies of edentulous mandibles and zygomatic implants using bone-supported guides.^{40, 41} More recently, meta-analyses and systematic reviews have categorically shown that mucosa-supported guides used in either arch and for fixed or removable prostheses have an acceptable accuracy range for treatment.^{37, 45}

3D Printing/Stereolithography

With recent advances in research and development in additive manufacturing, the dental community has been at the forefront of utilizing stereolithography to improve patient-outcomes and efficiency of treatment. Computer aided design and manufacturing (CAD CAM) has been heavily incorporated in the development and advance of dental treatment.⁴⁶ Additive manufacturing has allowed for rapid and predictable production in fabrication of fixed dental prostheses, removable prostheses, and interim prototypes. Additive manufacturing utilizes a design software in which a surgical guide can be designed with its coverage of the anatomy and pre-fabricated. Holes can be designed in which surgical sleeves can fit into to guide the drill during surgery.⁴⁷ For dentate cases, the surgical guide is designed from a diagnostic cast or scan that be scanned using an intraoral or lab scanner to convert the cast to an STL (Standard Tessellation Language) file. However, for edentulous cases in which a mucosa-supported guide is designed, transferring the data of where the teeth are on the prosthesis is not as simple as getting a CBCT of the patient with the denture. Since the CBCT captures and renders a 3D depiction of the radiographed site based on relative densities of the materials in the field of view (FOV), a denture made of acrylic will not be distinguishable sufficiently in the CBCT to evaluate the prosthetic aspect of the case.³⁰ Therefore, a dual scan CBCT protocol is implemented and the denture is used as the base for the guide.

The International Organization for Standardization and American Society for Testing Materials International Standard (ISO/ASTM 52900:2015) subdivides 3D printing into 7 categories: binder jetting, directed energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination, and vat photopolymerization.^{48, 49} Vat photopolymerization is defined as “the process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization.”⁴⁸ This type of additive manufacturing (AM) in turn uses photoactive polymers that are applied layer

by layer and cured using a light source. The light source can change depending on the type of 3D printer with either laser/stereolithography (SLA), digital light processing (DLP), or an LCP light source.³⁰ Consumer available 3D printers' range and cost depending on the company, size, accuracy, and light source.⁵⁰ The most widely available 3D printer is the SLA printer. The SLA printer directs a laser beam through a sequence of mirrors to the resin tank which holds liquid resin (dispensed by a liquid resin cartridge) (Figure 1). The liquid is composed of many small monomer chains, that when hit with a certain wavelength of light cure and harden. The surgical guide is built layer by layer; each layer being selectively cured. When cured, the monomers join and create an



Figure 1: Diagram of Form2 SLA printer. Diagram is taken with permission from FormLab: Intro to Stereolithography 3D Printing.

inflexible item (surgical guide) with varying levels of resolution depending on the properties of the printer, resin, and settings. The vat photopolymerizing printers can print with a resolution of 50-100 μm . Studies have evaluated the accuracy of the surgical guides printed using SLA and DLP printers with variables that can be altered: orientation of surgical guide on the build platform and post-processing steps. When comparing the DLP and SLA printers in accuracy, they were found to be comparable.^{47, 51} The orientation of the surgical guide affects the accuracy and dimensional stability of the print but can differ from one resin type to another.^{52, 53} Horizontally oriented guides on the print platform have been shown to have the highest accuracy and least distortion with a seating accuracy of 543.8 μm compared to vertically positioned guides of 1,278 μm .⁵⁴ The resin used needs to be biocompatible and non-cytotoxic and must allow for sufficient flexural and compressive strength to withstand a surgical procedure. FormLab Surgical Guide resin has a flexural of 103 MPa with tensile strength of 73 MPa.⁵⁵ D'haese evaluated the accuracy of a printed mucosa-supported guide in-vitro and found that the accuracy was within 3.35°.⁵⁶

Prosthetic Complications

Maxillary implant-retained overdentures have demonstrated great potential for improvement of quality of life, great but there are complications that can occur with this treatment modality. Conventional dentures, as is the nature of removable prostheses, allow for more movement on the mucosa, creating more “give” in the system. This can either exacerbate irritation of the mucosa with ill-fitting prostheses or allow for some wiggle-room with well-fitting prostheses. With implant-retained overdentures, however, the prosthesis is retained with implants, which decreases the possible movement of the prosthesis and secures it to the arch.⁵⁷ This is a positive effect of the

treatment modality as it allows for more chewing force, comfort of the patient, security of the prosthesis in place. If the prosthesis intaglio surface is not adjusted to the set location of how the abutments are attached, further tissue complications and damage.^{57, 58} Some of the prosthetic complications that are commonly seen with implant-retained overdentures include occlusal adjustments, housings coming loose, denture teeth coming out, inserts wearing out.⁵⁸ The most common complication reported by Leao in unsplinted maxillary implant-retained overdentures were fracture of prosthetic teeth and replacement of matrix components, though most of these were seen in studies utilizing ball attachments when implants were unsplinted.⁵⁸ Cehreli reported that the most common complication was replacement of the matrix-patrix system for the abutments. Both researchers identified all possible complications that occur during the treatment.^{57, 58} Many of the complications can be minimized by appropriate follow-up care and ensuring there is sufficient restorative space to allow for prosthetic components. Verifying that the vertical dimension of occlusion is correct, and the restorative space, occlusion, and the prosthesis fabrication are done appropriately are beneficial in minimizing these complications. Studies have compared splinted and unsplinted Mx IODs and found there is no statistically significant increase in complication rate between the two.^{59, 60}

Patient-related Outcomes

Assessment of patient perception of treatment and its benefits is instrumental in developing treatment that improves the quality of life of the patient. Various instruments have been created to assess and quantify the changes in perceived health outcomes. Researchers began evaluating the impact of edentulism, its treatment, and impact on the patient in the 1970s. The first indices were structured in ordinal scores to measure both the extent and severity of the impact on the patient.⁶¹ As time progressed, the assessment indices evolved to include more comprehensive assessments that allow for a better understanding of the impact edentulism and prostheses have on the patient’s social, functional, and comfort aspects of oral health. In 1988, Locker developed a model of oral health (Figure 2) which illustrates the progression from the disease state and its impact on oral well-being and impairment.⁶² Impairment leads to patient discomfort and functional limitations

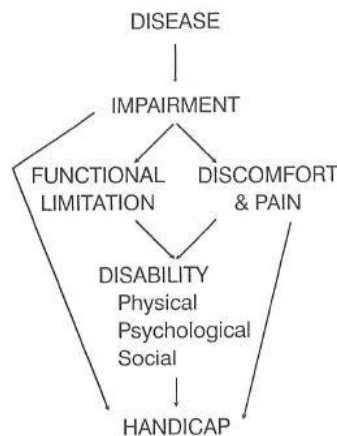


Figure 2: Model of Oral Health; Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. Community Dent Health. 1994 Mar;11(1):3-11.

which translate to disability and handicap. Pointed questions were created by Locker to ascertain

the level of extent of each of those areas mentioned by Locker in his model.⁶² This became the Oral Health Impact Profile (OHIP), an assessment index to quantify the level of handicap a patient might experience in their current oral health state. Locker's initial OHIP questionnaire was made up of 7 dimensions which totaling to 49 questions.⁶² The subsections were overarching topics which Locker pinpointed in his analysis of how to assess the oral health impact: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap.⁶³ Slade and Locker demonstrated that these questions have helped in localizing the factors that affect the well-being of a patient as being partial/full edentulism, caries, and periodontitis.^{61, 64} The OHIP-49 questionnaire, however, is cumbersome and lengthy, making the use of it difficult in a clinical setting. Slade adapted the questionnaire and proved the concept of the consolidated 14 question questionnaire in 1997.⁶³ In this consolidated questionnaire, there are two questions per dimension. Montero-Martin further demonstrated that the OHIP-14 is transferable to other languages and is a valid and reliable tool to use to assess the health impact of edentulism on patients and their perception of health.⁶⁵

CHAPTER III: MATERIALS AND METHODS

Project Overview

The primary objective of this study is to assess the implant success and survival rates upon immediate-loading of the Mx IOD. Secondary outcomes of the study, and the primary objectives of this thesis, were assessing the accuracy, prosthetic complications, and patient-related outcomes of implant placement using a mucosa-supported surgical guide in the edentulous maxilla.

Patient Enrollment

IRB approval (Protocol ID: 1801929813) was completed prior to patient recruitment. Patient recruitment occurred from January 2019 through March 2022. Flyers were placed around the Health Sciences Center at WVU and distributed to patients. Patients were also recruited from both the graduate departments and dental student clinic. Patients who showed interest in the study were evaluated clinically and radiographically. During the clinical assessment the Mx ridge was assessed for good oral health and hygiene, no active disease, and adequate ridge height and width. The Mx prosthesis was examined to ensure it was at the appropriate VDO and sufficiently extended with appropriate retention and support. The patient's current prosthesis construction must be favorable for possible attachment of implant components. Patient's medical history was reviewed to ensure there were no exclusionary criteria. Informed consent was read to the patient and reviewed with each patient and any questions were addressed. Patient and provider signed the informed consent and a signed copy was given to the patient. The patients were then assigned a separate identifying ID number for the study. Study records of each patient, identified by their ID number, were stored in a locked cabinet while the documents correlating the patients to their ID number for the study was locked in a separate cabinet. Pantographic film was assessed for 2D evaluation of sinus pneumatization and pathology. OHIP-14 questionnaire was completed by the patient for baseline assessment. Tables 1A, 1B show the inclusion and exclusion criteria.

Table 1A: Inclusion Criteria for patient enrollment in the study.

Inclusion Criteria
Males and females age ≥ 21 years old
Fully edentulous maxilla with implant sites healed for at least 4 months post-extraction
Wearing complete dentures deemed adequate
Orthopantomogram available (OPT)
Adequate amount of bone at least to the 2 nd premolar position to house a 3.75 x 10 mm implant
No bone grafting necessary
Implant IT ≥ 20 N/cm

Table 1B: Exclusion Criteria for patient enrollment in the study.

Systemic Exclusion Criteria	Local Exclusion Criteria
Conditions requiring chronic routine prophylactic use of antibiotics	Local inflammation including untreated periodontitis
Conditions requiring prolonged use of steroids	Mucosal disease such as erosive lichen planus
History of leukocyte dysfunction and deficiencies	History of local irradiation therapy
Bleeding disorders	Osseous lesion
History of neoplastic disease requiring use of radiation or chemotherapy	Severe bruxism and clenching habits
Uncontrolled endocrine disorder	Active infection with suppuration or fistula track
Metabolic bone disorders	Persistent intraoral infection
Use of any investigational drug or device within the 30-day period prior to implant surgery	Lack of primary stability <20Ncm. In this instance, the patient must be withdrawn and treated according to the standard protocol.
Smoking more than 10 cigarettes a day	Inadequate oral hygiene or unmotivated home care.
Alcoholism or drug abuse	Bone grafting
Patient infected with HIV	Inadequate bone volume for implants insertion as measured on the per-treatment CBCT
Condition or circumstances, in the opinion of the investigator, which would prevent completion of study participation or interfere with analysis of study results, such as history of non-compliance, unreliability.	

Variables: Independent and Dependent

The independent variables assessed in the study were patient age, gender, diabetes status, tobacco-use status, implant length, bone quality, implant position, insertion torque, mucosa thickness, and opposing dentition. The dependent variables assessed in the study were prosthetic complications, patient-centered outcomes, and implant deviation (global and 3D offset at the platform and apex of the implants).

CBCT Planning

Upon completion of the screening visit, informed consent was reviewed and signed with the patient. Patient was given a copy of the signed informed consent. Six to eight fiduciary markers were placed on the cameo surface of the denture on both lingual and facial/buccal surfaces (Figures



Figure 3: Occlusal view of maxillary denture with 7 fiduciary markers.



Figure 4: Frontal view of maxillary denture with 4 of the 7 fiduciary markers visible.

3, 4). Dual scan protocol was completed in which the patient's denture with the fiduciary markers was scanned. The CBCT parameters were set for all patients at 10x5 cm size with the radiographic settings being 90 kV, 4 mA, and 180 voxel size. The prosthesis was then inserted and confirmed that it was fully seated. Cotton rolls were placed on the occlusal surfaces to create an "open bite"



Figure 5: Occlusal view of surgical guide design with 3 fixation pins (blue), surgical sleeves (green).

CBCT. The CBCT was taken to include the zygomatic arches and anterior nasal spine for later superimposition of the pre-and post-op CBCTs. Once the patient was dismissed, the DICOM files were imported into CoDiagnostiX and the denture was superimposed using the fiducial markers as references for the prosthesis superimposition. 3.75 mm diameter Straumann BLX implants and

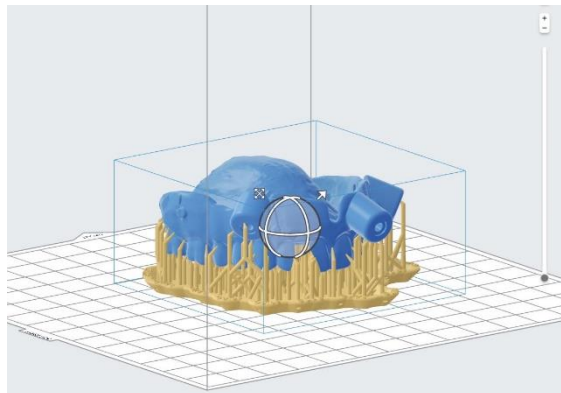


Figure 6: Lateral view of Surgical guide in PreForm software in a horizontal orientation to the build platform.



Figure 7: s-CAIS printed surgical guide with PEEK sleeves present (seen in white).

Novaloc abutments with either straight or 15° angle correction were planned. A surgical guide was designed with three 1.8 mm fixation pins interspersed between the implants (Figure 5). 5-mm guide sleeves were planned within the confines of the prosthesis to maintain the flapless approach to the surgery. A mucosa-supported surgical guide was designed with 0 mm offset. The guide was exported from CoDiagnostix and imported into the PreForm (Formlabs, USA) software. A raft and supports (0.4 mm diameter) were added to the guide for printing accuracy. The guide was oriented horizontally with the build-platform (Figure 6). Surgical guide resin was used and the Form2 printer was connected and printed the guide. Manufacturer's recommendations were followed for post-processing of the surgical guide as follows: 5 minutes in a "dirty" and "clean" 100% isopropyl alcohol bath and air-dry for 30 minutes after which the surgical guide was placed in the curing oven for 30 minutes at 60-degrees Fahrenheit. 5-mm diameter BLX PEEK sleeves were inserted into the guide, and the guide was then placed in glutaraldehyde cold sterilization for 9 hours prior to surgery (Figure 7).

Surgical Procedures/Prosthetic Procedures

The surgical guide was tried in and a centric relation (CR) record was taken with Regisil Rigid (Dentsply, USA), a polyvinylsiloxane bite registration material, to verify the seating of the guide. Patient was given 2 grams of amoxicillin (if allergic, 600 mg of clindamycin) and rinsed with chlorhexidine gluconate 0.12% for 30 seconds. Local anesthetic was administered. Patient was transferred to the surgical suite under a sterile environment to perform the surgical procedure. The surgical procedures were completed by one of two surgeons. The guide was fixed to the Mx using the 1.8 mm diameter fixation pins (Straumann, USA). Osteotomies were completed through the surgical guide in accordance with the planned drill and key sequence and 3.75 mm Straumann BLX implants with lengths of either 10, 12, or 14 mm were placed through the guide (Figure 8).

As per protocol, if implant primary stability was >20 N/cm, gingival height was measured and the Novaloc abutments in their appropriate orientation were placed and torqued to 15 N/cm (Figure 9). If primary stability was <20 N/cm, patients healing abutments with corresponding gingival heights were placed on the implants and the denture was relined with CoeSoft (GC America, USA), a soft reline material until completed osseointegration of the implants at 6-8 weeks. Baseline standardized periapical radiographs were taken of each of the implants. Maxillary denture was relieved where abutments were located until passive seating of denture without binding. Blockout

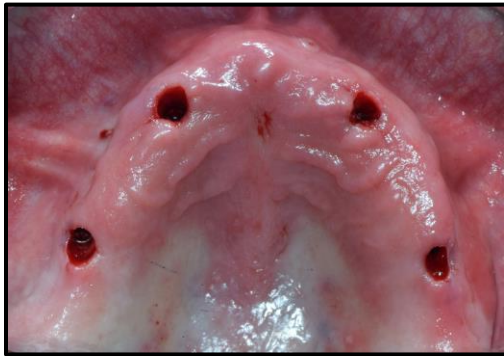


Figure 8: Occlusal view of BLX implants placed in a flapless technique, thus minimizing morbidity.



Figure 9: Occlusal view of BLX implants with Novaloc abutments (anterior implants are straight, posterior implants are angled).

rubber rings and titanium housings were placed on the abutments and attached to the denture using Bosworth repair resin (TruRepair, USA). Excess material was removed from the intaglio surface of the prosthesis and Red PEEK inserts were placed. Occlusion was assessed and adjusted as needed. Patient was instructed to keep the maxillary prosthesis in for the duration of the following week, until the next follow-up visit. At-home-care instructions were given to the patient.

Second CBCT Assessment

Prior to the patient leaving after the surgical procedure, a second CBCT scan was taken of the maxilla. As in the pre-op CBCT, the zygomatic arches and anterior nasal spine were included in the scan. The DICOM files were exported and then uploaded into CoDiagnostix. The CBCT was imported to the Treatment Evaluation Module. Manual alignment of the maxillae (Figure 10) and each implant was completed and deviation between implants at platform, apex, and global deviation were assessed (Figure 11).

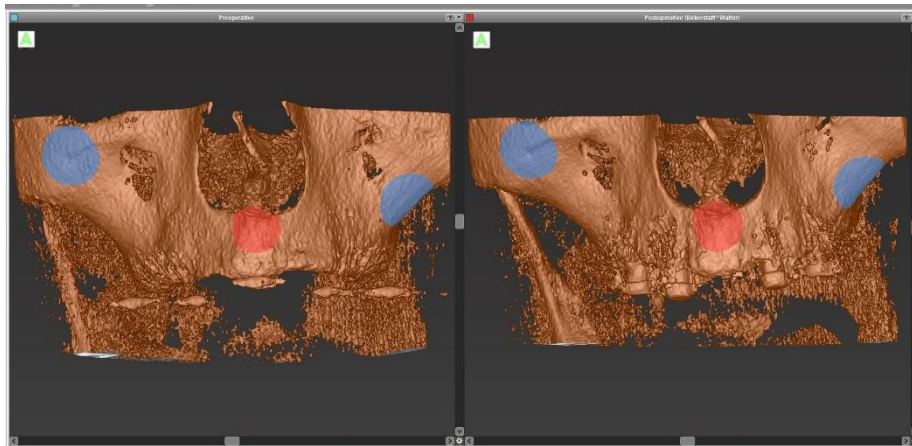


Figure 10: Pre- (left) and post- (right) op CBCTs were superimposed using the anterior nasal spine and the zygomatic arches.

Follow-ups

Patients were seen for six follow-up visits at 1, 2, 4, 12, 26, 52 weeks post-surgery. At the 1-week follow-up visit, the prosthesis was removed, an intraoral exam was completed, oral hygiene was reviewed, and clinical photographs were taken. At the 2-week follow-up, the OHIP-14 questionnaire was completed, the prosthesis was removed, an intraoral exam was examined, oral hygiene was reviewed, and clinical photographs were taken. At the 4-week follow-up clinical photographs were taken, clinical exam was completed along with assessment around each implant of pocket depth (PD), bleeding on probing (BoP), keratinized gingiva (KG) width and thickness, and plaque index (PI). At the 12-week follow-up, the OHIP-14 questionnaire was completed, clinical photographs were taken, the Implant Stability Quotient (ISQ) was recorded, clinical exam was completed along with assessment around each implant of pocket depth (PD), bleeding on

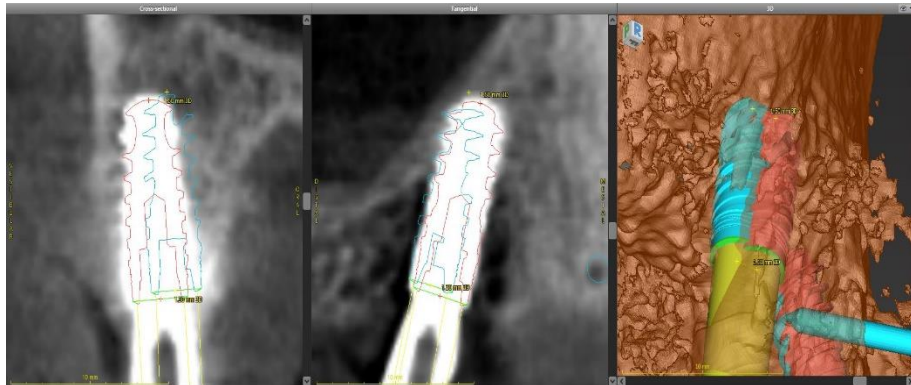


Figure 11: Global deviation visualization by superimposing the planned implant position (blue) with the actual implant position (red).

probing (BoP), keratinized gingiva (KG) width and thickness, and plaque index (PI). At the 26- and 52-week follow-ups, the OHIP-14 questionnaire was completed, clinical photographs were taken, the Implant Stability Quotient (ISQ) was recorded, periapical radiographs were taken, an intraoral exam was completed along with assessment around each implant of pocket depth (PD), bleeding on probing (BoP), keratinized gingiva (KG) width and thickness, and plaque index (PI).

At the 12-, 26-, and 52-week follow-ups patients received a gift card as part of their participation in the follow-up assessment of the research study.

Measurement Criteria

Mucosa Thickness and Bone Density

In the statistical analysis, mucosa thickness and bone density were measured to assess if any of the biologic factors had an effect on the global deviation of the implants. Mucosa thickness was measured by using the Distance Tool (Figure 12) and by measuring from the crest of the alveolar ridge to the intaglio surface of the prosthesis (measured in mm). Bone density was measured using Hounsfield units that is calculated in the CoDiagnostix software and given at any specific implant site on the CBCT.

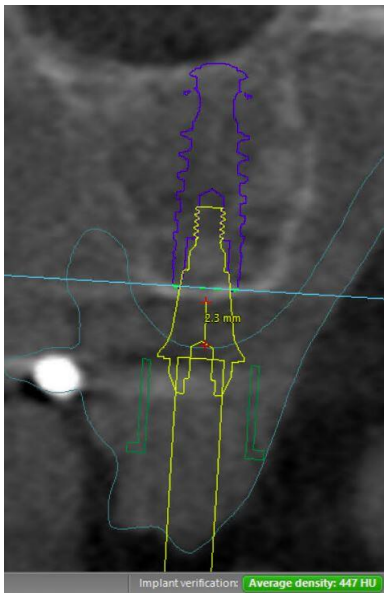


Figure 12: Mucosa thickness can be seen measured and indicated by the yellow line and red markers in the center. Hounsfield units can be seen at this specific site in the lower right corner.

H-Setting

The H-setting of the surgical sleeve in the surgical guide was recorded. There are three possible settings for the position of the surgical sleeve that is based on mm increments away from the most coronal part of the implant (H-2, H-4, H-6), as seen in Figures 13A, 13B, 13C.



Figure 13A: H-2 surgical sleeve position, encircled in red.

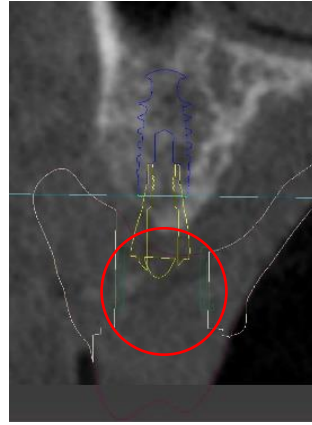


Figure 13B: H-4 surgical sleeve position, encircled in red.



Figure 13C: H-6 surgical sleeve position, encircled in red.

Insertion Torque

Primary insertion torque was measured at the time of implant insertion using a manual torque wrench with indicator marks at 15 and 35 N/cm and a surgical torque wrench with indicator marks at 0, 35, 50, and 80 N/cm. Implants were grouped into one of three categories <20, 20-50, and >50 N/cm.

Statistical Analysis

Pre- and post-op CBCTs were superimposed with one another using the zygomatic arches, anterior nasal spine, and palate. Implants were then manually superimposed over the post-op CBCT. The Treatment Evaluation module was used to provide the global angle deviation, and 3D offset deviation at both the apex and platform of the implants. Data was put into Excel (Microsoft, USA) and then imported into JMP 15 (SAS Institute, USA) statistical software. Descriptive statistics (mean, sum) of demographics (Age, Sex, Diabetic Status, and Tobacco Use Status), implant length characteristics, implant insertion torque, abutment characteristics, prosthetic complications, and OHIP-14 characteristics. Inferential statistics (paired t-test) were used to compare and assess global deviation, 3D offset at both the platform and apex of the implants. Pearson's R correlation was used to compare implant 3D deviation with mucosa thickness and bone density. 1-way ANOVA was used to evaluate implant 3D deviation with the H-setting (position of the sleeve in the surgical guide), implant insertion torque.

CHAPTER IV: RESULTS AND DISCUSSION

Results

Fifteen patients were enrolled in the study to date of this analysis. Twenty-nine patients were screened at the time of this analysis. Of those, seven failed the screening process due to medical history exclusionary factors, excessive smoking, and/or insufficient bone volume as assessed by the CBCT analysis. The remaining twenty-two patients enrolled in the study. Three patients withdrew due to lack of interest prior to the surgical visit. Two patients were unable to be contacted. Two patients are still awaiting their surgery. Fifteen patients were included in the analysis for the implant accuracy since the implants were placed guided and the second CBCT was taken the day of surgery. Two patients had the implants placed but the insertion torque was too low for immediate loading so were excluded from the follow-up but were included in the CBCT analysis since the implants were placed guided. Twelve patients were followed up after the surgery who had their implants loaded and prostheses attached. One patient was excluded after the 4-week follow-up due to denture not having been loaded and not attaching appropriately to the Novaloc abutments. One implant was placed free-hand, and that implant was not included in the guide accuracy analysis. One patient missed his/her 12-week follow-up visit due to lack of transportation ability. Demographics of the patients included can be seen in Table 1. 73.3% of the patients were male. Average age of the participants is 62.8 ± 12.2 years with a range of 27 to 79 years at the time of surgery (Table 2).

Table 2: Demographic characteristics of the enrolled patients.

Age (y) Mean \pm SD (range)	Sex		Diabetic Status (no.)		Tobacco Use Status (no.)	
	Male	Female	Diabetics	Non-diabetics	Tobacco User	Non-Tobacco User
62.8 \pm 12.2 (27-79)	11	4	3	12	1	14

Tobacco use status was assessed and one of the patients reported using tobacco. Table 3 illustrates the distribution of implant length based on implant position in the maxillary arch. Implants were loaded if the insertion torque was greater than 20 N/cm. Figure 14 demonstrates the distribution of insertion torques. As mentioned previously, two patients were excluded on the day of surgery due to low insertion torque of the implants when they were placed, and one patient was excluded after the 4-week follow-up due to the denture not attaching appropriately to the Novaloc abutments. For those excluded on the day of surgery, their dentures were relined with Coe-Soft and Novaloc abutments were placed on the implants only once osseointegration occurred. One implant was lost during the 4-week follow-up appointment due to mobility of the implant. Novaloc abutments were characterized as either angled (15°) or straight. Distribution of abutment type can be seen in Figure 15.

Table 3: Implant length characteristics.

Implant Position	10 mm No. of implants (%) (n=xx)	12 mm No. of implants (%) (n=xx)	14 mm No. of implants (%) (n=xx)
#4	46.7% (7)	40.0% (6)	13.3% (2)
#7	26.7% (4)	73.3% (11)	00.0% (0)
#10	33.3% (5)	53.3% (8)	6.7% (1)
#13	33.3% (5)	66.7% (10)	00.0% (0)
Total	35.0% (21)	58.3% (35)	1.7% (3)

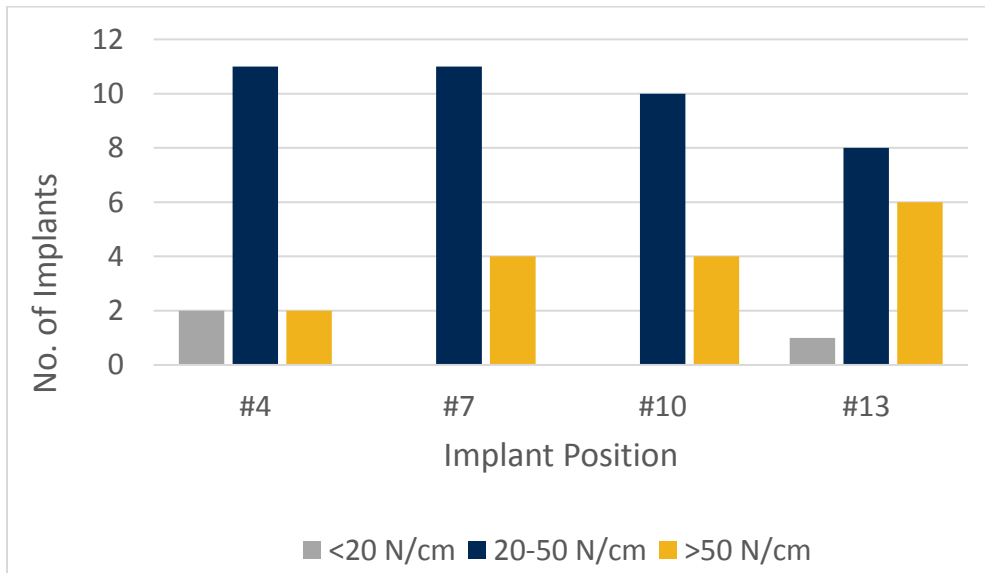


Figure 14: Insertion Torque Distribution.

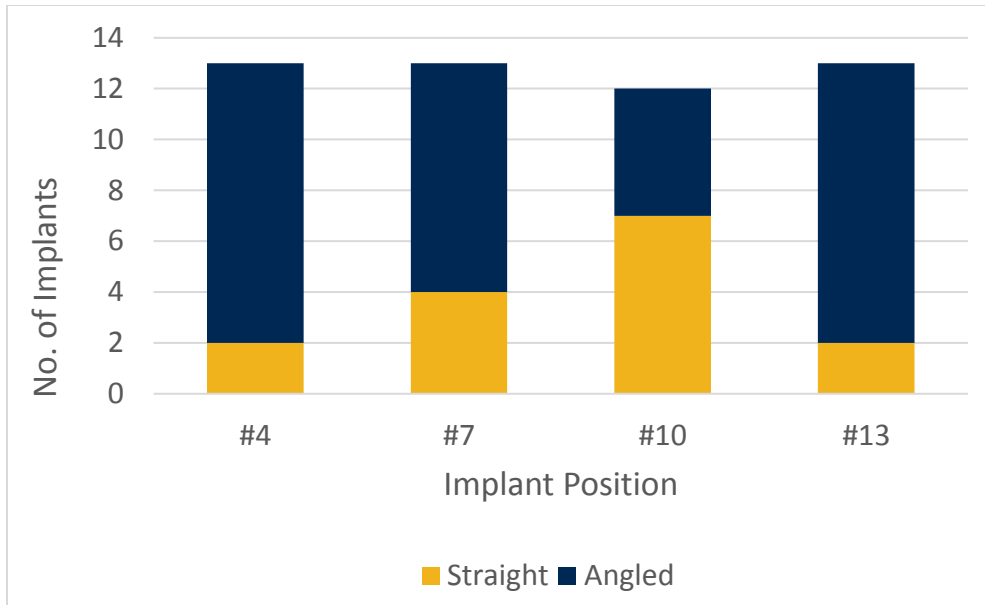


Figure 15: Abutment characteristics.

Prosthetic complications were recorded as the patients reported them either on their scheduled appointments or during extra visits. The distribution of the prosthetic complications can be seen in Table 4. For two patients the prosthesis was not attaching to the Novaloc abutments due to soft tissue impingement, five Novaloc abutments needed to be replaced due to the height of the retentive element of the Novaloc being equi-gingival. When the abutments were replaced, the housings were removed from the prosthesis and were re-picked up using Bosworth repair acrylic. PEEK inserts were replaced 10 times throughout the 52-week follow-up period. Two of those were due to the patient feeling the red inserts were not retentive enough while the other eight were due to the new housings being placed and needing new white inserts. In one patient, the abutments could not be torqued the day of surgery using the torque wrench due to minimal insertion torque (20 N/cm). Those abutments were finger tightened and loaded. In the subsequent 4 weeks, two of those abutments became loose and needed to be re-tightened. On a separate patient, a #4 abutment became loose and was tightened to 15 N/cm. Prosthetic adjustments to the intaglio surface were minimal and were mainly seen due to soft tissue impingement after loading of the prosthesis.

Table 4: Prosthetic complications and maintenance visits.

Prosthetic Complication	# of Occurrences
Insert Change	10
Abutment Replacement	5
Abutment Loosening	3
Housing Re-pick up	11
Denture Tooth Fracture	1
Denture Adjustment	3
Total	33

Implant deviation was calculated for each implant placed and three data points were collected for each: global deviation, 3D offset at the platform of the implant, and 3D offset at the apex of the implant. The mean global deviation was $3.143 \pm 1.64^\circ$ with a range of 0.00-10.3°. The 3D offset at the platform and apex are 0.914 ± 0.513 mm (range: 0.19-2.32 mm) and 0.976 ± 0.568 mm (range: 0.26-2.665 mm) respectively (Table 5, Figures 16-18).

In comparing the global deviation and 3D offset for different positions, the anterior (#7, 10 implants) and posterior (#4, 13 implants) were dichotomized. There was a statistical difference when comparing the global deviation and 3D offset at the platform with the anterior implants having a mean deviation of 0.762 ± 0.440 mm and the posterior implants with 0.984 ± 0.497 ($p \leq 0.0396$). Additionally, the deviation at the apex of the implant was statistically different with a $p \leq 0.0251$ and the mean deviation of the anterior implants 0.862 ± 0.505 mm and posterior implants 1.203 ± 0.627 mm (Table 6).

Table 5: Mean and range of implant global deviation and 3D offset of the implants.

Measurement	Implant (n=x)	Mean	Std Dev	Range	Upper 95%	Lower 95%
Global Deviation (°)	59	3.283	1.929	(0.00-10.3)	3.786	2.780
3D offset-platform (mm)	59	0.857	0.484	(0.19-2.32)	0.983	0.731
3D offset-apex (mm)	59	1.036	0.591	(0.26-2.65)	1.190	0.882

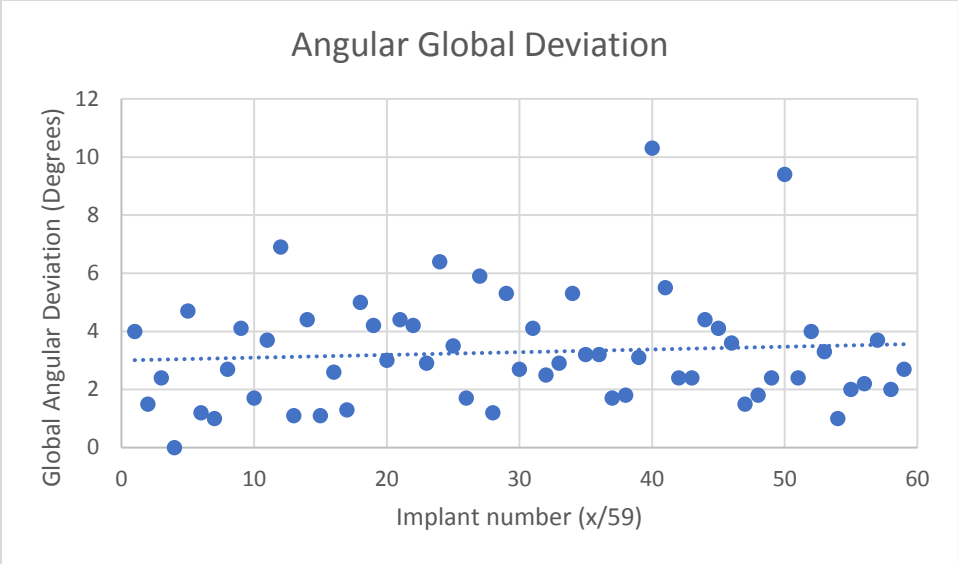


Figure 16: Plot diagram of global angular deviation.

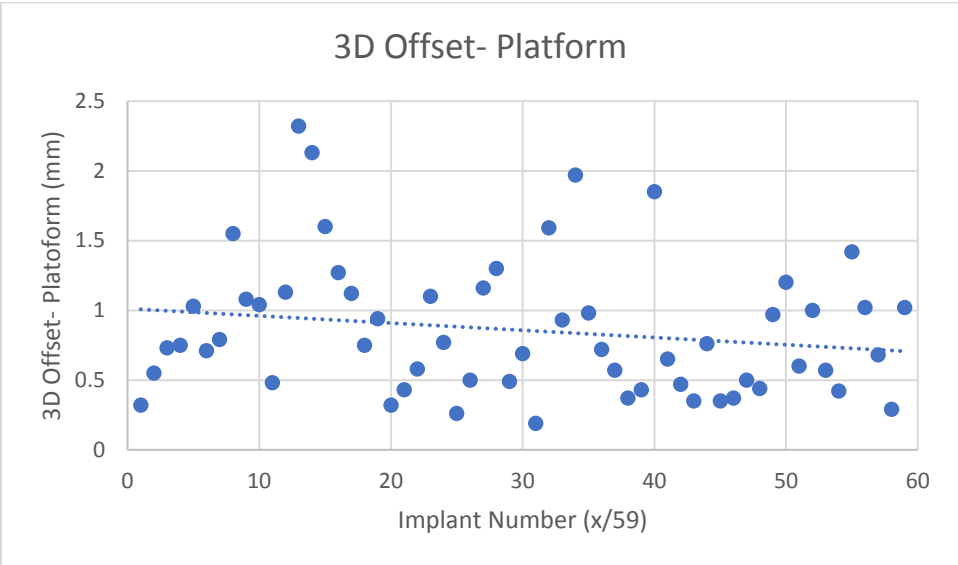


Figure 17: Plot diagram of 3D offset at the platform.

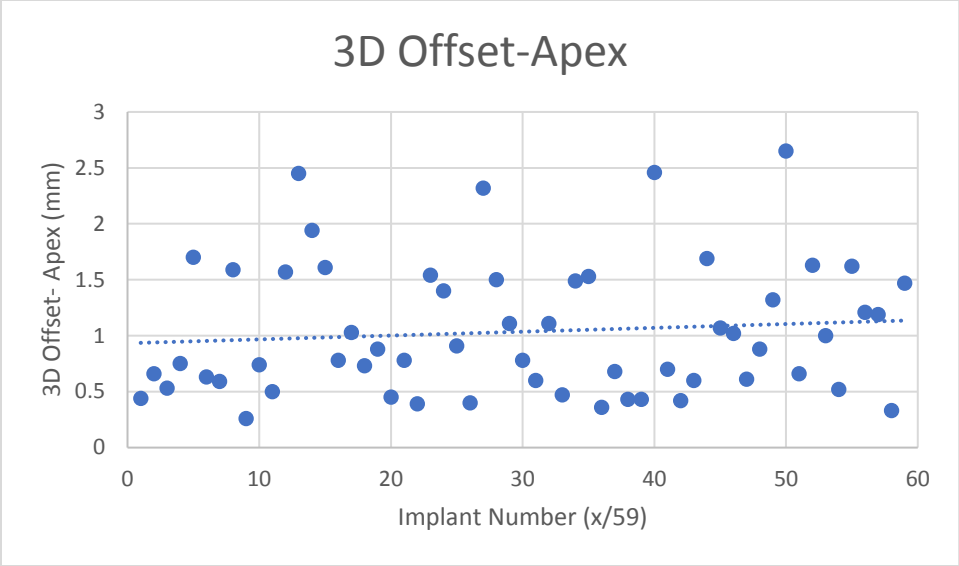


Figure 18: Plot diagram of 3D offset at the apex.

Table 6: Implant global deviation and 3D offset when comparing anterior and posterior implants (paired t-test).

Measurement	Implant Position	Implant (n=x)	Mean	Std Dev	t-stats	p-value
Global Deviation (°)	#7, 10	29	3.210	1.831	0.283	0.778
Global Deviation (°)	#4, 13	30	3.353	2.048		
3D offset- platform (mm)	#7, 10	29	0.762	0.440	2.107	0.0396
3D offset- platform (mm)	#4, 13	30	0.984	0.497		
3D offset- apex (mm)	#7, 10	29	0.862	0.505	2.303	0.0251
3D offset- apex (mm)	#4, 13	30	1.203	0.627		

Pearson’s R correlation test was used to see if the mucosa thickness and bone density had a statistical relationship and effect on the implant global deviation and 3D offset. As Tables 7 and 8 show, there is no correlation between those factors and implant deviation and 3D offsets. Bone density is very close to having a correlation between the global deviation and the bone density (p<0.0551).

Table 7: Correlation between implant global deviation and 3D offset and mucosa thickness (Pearson R Correlation).

Measurement	Correlation	p-value
Global Deviation (°)	-0.0715	0.5904
3D offset- platform (mm)	0.0105	0.9392
3D offset- apex (mm)	-0.1218	0.3581

Table 8: Correlation between implant global deviation and 3D offset and bone density (Pearson R Correlation).

Measurement	Correlation	p-value
Global Deviation (°)	0.251	0.0551
3D offset- platform (mm)	0.107	0.4219
3D offset- apex (mm)	0.068	0.6111

To assess if H-setting and insertion torque had any relationship with the implant deviation and 3D offsets, a 1-way ANOVA test was used to analyze the data. No statistical correlation was demonstrated between these factors and the implant deviation (Table 9, 10).

Table 9: 1-way ANOVA comparing H-setting with global and 3D offset.

Measurement	H-Setting	N	Mean	StDev	Lower 95%	Upper 95%	F-ratio	p-value
Global Deviation (°)	2	5	2.920	1.802	0.683	5.157	0.2231	0.801
Global Deviation (°)	4	35	3.217	1.803	2.598	3.834		
Global Deviation (°)	6	19	3.500	2.243	2.419	4.581		

3D offset- platform (mm)	2	5	0.926	0.447	0.370	1.482	0.7254	0.489
3D offset- platform (mm)	4	35	0.794	0.455	0.638	0.950		
3D offset- platform (mm)	6	19	0.955	0.548	0.690	1.219		
3D offset- apex (mm)	2	5	1.202	0.568	0.497	1.907	0.3013	0.741
3D offset- apex (mm)	4	35	0.995	0.627	0.780	1.210		
3D offset- apex (mm)	6	19	1.067	0.548	0.803	1.332		

Table 10: 1-way ANOVA comparing insertion torque with global and 3D offset.

Measurement	Torque	N	Mean	StDev	Lower 95%	Upper 95%	F- ratio	p-value
Global Deviation (°)	<20	3	3.33	1.18	0.39	6.28	0.507	0.605
Global Deviation (°)	20-50	40	3.12	2.02	2.47	3.76		
Global Deviation (°)	>50	16	3.69	1.82	2.72	4.67		
3D offset- platform (mm)	<20	3	1.28	0.26	0.64	1.93	1.242	0.297
3D offset- platform (mm)	20-50	40	0.84	0.50	0.68	1.00		
3D offset- platform (mm)	>50	16	0.82	0.47	0.57	1.07		
3D offset- apex (mm)	<20	3	1.36	0.50	0.11	2.60	0.527	0.593
3D offset- apex (mm)	20-50	40	1.04	0.62	0.84	1.24		
3D offset- apex (mm)	>50	16	0.97	0.53	0.69	1.25		

To assess the patient-related outcomes of the treatment, the OHIP-14 questionnaire was completed by thirteen patients at 5 visits throughout the 52-week follow-up period (Visits 1, 4, 6, 7, 8). The recorded responses and trends can be seen in Figure 19. Table 11 illustrates the inter-patient means

of the responses based on the patient-reported outcomes. In all the OHIP-14 subsections the baseline responses ranged with responses of “Fairly often”, “Occasionally”, and “Hardly ever.” At the 2-week follow-up visit when patients completed the questionnaire for the first time after treatment, a dramatic change was recorded in response to “Hardly ever” and “Never”. The mean range at baseline was 1.65-2.96 and at the 52-week follow-up the range was 1.00-1.94.

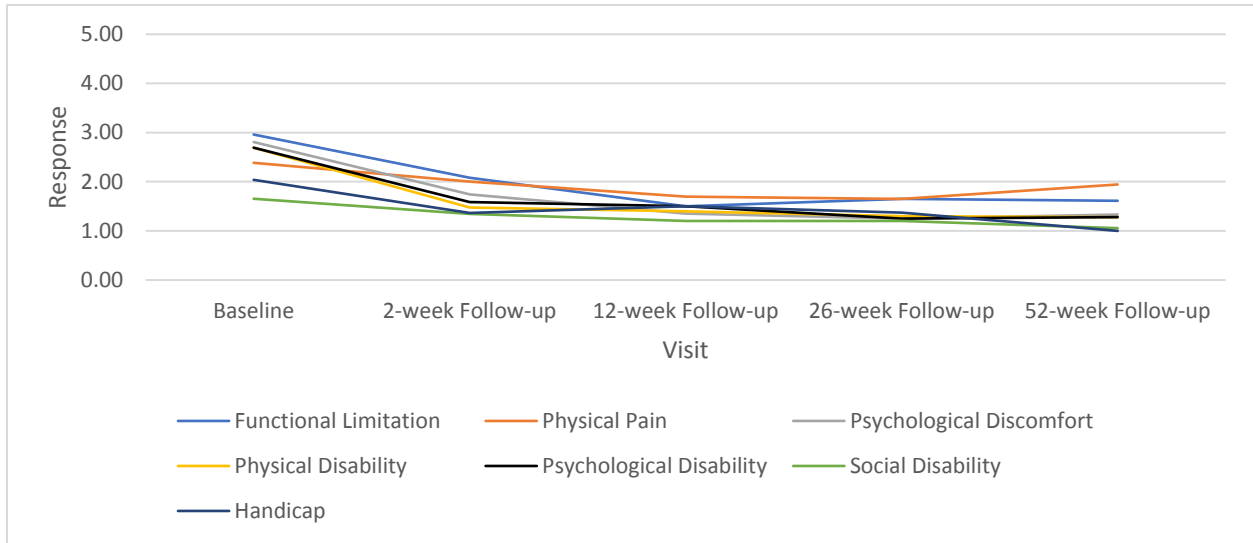


Figure 19: OHIP-14 characteristic trends from baseline to 52-week follow-up.

Table 11: OHIP-14 responses divided by the 7 subcategories with responses in Likert scale of “Never” being a “1” and “Very often” being a “5.”

OHIP Subsections	Baseline	2-week follow-up	12-week follow-up	26-week follow-up	52-week follow-up
Functional Limitation	2.96	2.08	1.50	1.65	1.61
Physical Pain	2.38	2.00	1.70	1.65	1.94
Psychological Discomfort	2.81	1.74	1.35	1.25	1.33
Physical Disability	2.69	1.48	1.40	1.30	1.28
Psychological Disability	2.69	1.58	1.50	1.25	1.28
Social Disability	1.65	1.35	1.20	1.20	1.06
Handicap	2.04	1.36	1.50	1.37	1.00

Discussion

The results of this study indicate that the accuracy of a mucosa-supported static surgical guide fits within the range of acceptable error for implant placement using s-CAIS guides. 3.28° of global angular deviation was found when comparing the planned position of the implant with the post-op CBCT of the implants placed using the mucosa-supported guide. The results found in this study are consistent with the previous literature regarding the range of accuracy for mucosa supported stereolithic surgical guides.^{38, 45, 66, 67} The range of clinically acceptable global deviation is 2.6° to 4.67°.^{38, 45, 56} Tahmaseb et al. concluded in a systematic review and meta-analysis that practitioners should understand that when using a mucosa-supported surgical guide, they need to account for a 2 mm discrepancy between the planned position and surgical placement of the implants.³⁸ From the results in the current study, the range of deviation present at both the apex and platform of the implants went up to 2.32 mm and 2.65 mm respectively. Statistically significant difference was seen when comparing 3D offset deviation at both the apex and platform (Table 4). This could be explained by one of two potential reasons: the first being the ability for the surgeon to access the posterior regions of the mouth., and the second being that the design of all the surgical guides had the 3 fixation pins interspersed between the 4 maxillary implants. Thus, no fixation pins were present posterior to the most posterior implant. The surgical guide extended as far as the denture anatomical features, so there could have been a torquing effect when compressive pressure was placed on the surgical guide in the posterior regions. Potentially designing the two posterior fixation pins posterior to the most posterior implants might eliminate this error from occurring. Further investigation is needed to evaluate this.

Various factors can influence the accuracy of the implant placement including surgical skill, guide fabrication and design, implant type, bone density, mucosa thickness, and H-setting of the sleeves in the surgical guide. Bone density and mucosa thickness has been shown in the literature to affect the accuracy of the implant placement with denser bone and thinner mucosa demonstrating more accurate results. Cassetta concluded these findings in patients who smoked and thus had thinner mucosa, the implant accuracy was greater than those with thicker mucosa.⁶⁶ Additionally, Ochi performed both in-vitro and in-vivo assessment of mandibular bone density while using a mucosa-supported guide and found that greater bone density allowed for less deviation from the planned implant position.⁶⁸ Kivovics et al assessed bone density and surgical skill level and found that, while the surgical skill level does not correlate with the implant accuracy, that denser bone allows for higher levels of accuracy while using mucosa support surgical guide. This study randomized patients into surgical groups with either novice or experienced surgeons and found no statistical difference between the two groups with regards to accuracy.⁶⁹ Furthermore, mucosa thickness varied greatly throughout the study ranging from 0.4-4.9 mm. Our statistical tests did not show any correlative relationship between the deviation of the implants and the mucosa thickness.

There is a lot of ambiguity in assessing and defining bone quality.²⁷ Quality of the bone can be examined by assessing the type of bone morphology present and by volumetric assessment of both height and width of the bone. Additionally, the type of bone present, the amount of cortication of the bone, the density of trabeculation can also help in assessing the quality of the bone.²⁷ CBCT interpretation occurs by reading the levels of gray scale present and translating this information

into bone density measured in Hounsfield units. CBCTs evaluate the gray scales captured by the various densities in the field of view. Such measurements can be unreliable since the parameters set to calculate these are dependent on the machine used, the settings on the machine, and the field of view.²⁷ CoDiagnostiX provides the Hounsfield units at any given site on the CBCT. Our evaluation using the given Hounsfield units illustrated no correlation with the accuracy of the implant placement in either global angular deviation or 3D offset at the platform or apex of the implants.

Van Assche et al discussed the multiple non-biologic factors that can affect the accuracy of the surgical placement of the implant through a mucosa supported guide.³⁹ These factors include length of implant and distance of implant from the entrance of the guide to the apical position of the implant.³⁹ In our study, we assessed the position of the sleeve (H-setting) which can change in 2-mm increments from the platform of the implant depending on the surgical access, height of the mucosa, and thickness of the prosthesis used for the surgical guide template. The global deviation did increase as the distance between the sleeve in the guide and the platform of the implant grew (H-2 mean: 2.9°; H-4 mean: 3.2°; H-6 mean: 3.5°) but it was not statistically significant ($p \leq 0.801$). It can be inferred, however, that there might be an advantage in implant placement accuracy if you are able to get closer to the implant platform with the surgical sleeve.

Conventional removable prostheses have been seen to affect the patient quality of life and the patients' integration and comfort in social settings.⁷⁰ Limitations of the conventional prostheses are due to the lack of security of the prosthesis to the edentulous arch, movement of the prosthesis under function and discomfort of the prosthesis.⁷¹ Utilization of implants to secure the prosthesis to the edentulous arch has been demonstrated to improve patient perception of treatment and patient related outcomes.⁷¹⁻⁷³ Our results showed marked improvements on the OHIP-14 scores from baseline to the end of the 52-week follow-up. Patients showed improved scores from the 2-week follow-up after the surgery with scores improving as the year progressed. The OHIP-14 questionnaire was only completed by the patients included in the follow-up of the immediate loading of their prostheses but those demonstrated improvements in all subcategories of the questionnaire. This demonstrates that immediate loading of maxillary overdentures using Novaloc attachments can improve the patient's quality of life, and physical and psychological comfort.

The literature is scarce with regards to prosthetic complications occurring during immediate loading of implant-retained overdentures, regardless of the edentulous arch. One of the challenges encountered in one specific patient was that the implants were placed at minimal torque, 20 N/cm. Due to that, the protocol was deviated, and the abutments were not torqued due to concern of loss of primary stability. That patient returned on multiple visits with loose Novaloc abutments, dislodged prosthesis, inability of prosthesis to attach appropriately to the abutments, and eventually loss of an implant. In two other patients at the one-week follow-up visit, the abutments which were attached the day of surgery were no longer attaching due to soft tissue inflammation. New abutments needed to be replaced in some instances along with re-attaching the housings to the abutments. Once the implants were integrated, fewer prosthetic adjustments and replacements occurred. Anadioti's retrospective analysis of prosthetic complications demonstrated similar complication rates as our results. Her study did not indicate if the prosthetic complications were

grouped within the same subset of patients or were for each individual patient in the study.⁷⁴ Our prosthetic complications occurred mostly in 2 patients who had the complications of loose abutments, ill-fitting abutments, replacement of housings and inserts.

Several limitations to the study have been identified. One is the possibility of some movement during capturing the CBCT that led to poor CBCT quality and further challenges of analysis and superimposition of the CBCTs. Further, prior to the three last patients' surgical guide being fabricated, the Form2 3D printer malfunctioned and a new Form3B 3D printer was therefore used to fabrication the last three guides. The Form2 3D printer is a stereolithography printer while the Form3B printer is a Low Force Stereolithography printer. This difference in printer could change the accuracy, surface roughness, peel force, and materials with high viscosity and low green strength (FormLab). According to FormLab, the Form2 uses two galvanometers that direct the laser beam to a mirror that reflects the beam to the build platform while the Form 3B uses a light processing unit that moves only in the X direction while the other galvanometer moves in the Y direction. Another limitation with the guide fabrication process was that the printer was never calibrated or cleaned routinely between prints. Resin can cure to the tank if it remains there too long and can cause errors in the printing process. Another limitation is that the prosthetic complications were assessed based on clinical findings and patient reports. The assessment of when to replace the PEEK inserts in the housings was based on clinical, visual wear of the insert, patient reporting low retentive force, or loss/change of housing. No finite element analysis was completed in this study to assess the wear on the insert itself. Thus, the actual improvement of using PEEK inserts (Novaloc) versus nylon (Locator) could not be quantified. Further in-vivo analysis is needed to measure the wear on the PEEK inserts. Additionally, the first twelve surgical procedures were performed by one surgeon while the last three surgical procedures were performed by a different surgeon. However, no statistical difference was seen in the accuracy between the surgeons and Kivovics demonstrated that surgeon skill level does not affect the accuracy of implant placement while using mucosa-support guides.⁶⁹ Finally, the OHIP-14 questionnaire was used for the assessment of patient related outcomes for the study, this questionnaire is an improved and revised version compared to previous iterations; however, the OHIP-EDENT is a newer and cleaner version of the questionnaire that has been shown to be more appropriate for use and could be better at assessing prosthetic complications in edentulous patients.⁷⁵

Earlier literature discusses that one of the main advantages to maxillary overdentures is improvement in outcomes with removal of the palatal coverage.^{4, 76} Though the force distribution is better with full palate prostheses, the comparison of full-palate vs. open-palate prostheses and its effect on patient related-outcomes was not assessed in this study.

CHAPTER V: SUMMARY AND CONCLUSION

Maxillary s-CAIS mucosa-supported guides used for immediate loading of maxillary implant-retained overdentures are a viable treatment option for patients. The accuracy of the guide based on 3D deviation at the apex and platform of the implant along with global angular deviation, as seen in this study, is within the acceptable realm of acceptable deviation error supported by the most current literature. Patient-related outcomes improved in patients whose prostheses were immediately loaded. The OHIP-14 scores continued to improve as time progressed, demonstrating continued improvements as the prosthesis was under function. Though prosthetic complications occurred, these complications are within the expected complications for both immediate loaded and single attachment-retained implant overdentures. The following conclusions can be made based on the above study:

1. Mucosa-supported guides for maxillary overdentures have a global angular deviation of 3.28° when compared to planned position.
2. Posterior implants show greater deviation than anterior implants at both the apex and platform of the implants.
3. Patient-related outcomes, assessed with the OHIP-14 tool, improve immediately after the prosthesis is loaded and continue to improve over the follow-up period.
4. Prosthetic complications exist during this treatment modality but are within the acceptable and expected complications for this type of treatment.

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