OFFICE-BASED VIRTUAL SURGICAL PLANNING FOR DENTAL IMPLANT SURGERY

by

CHAD SAMPSON

Submitted in partial fulfilment of the requirements for the degree of
Master of Science

at

Dalhousie University
Halifax, Nova Scotia
December 2023

Dedication

I would like to dedicate this work to my loving wife Katie and to our greatest joy, our daughter Kai.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

The purpose of this study was to determine the accuracy of office-based virtual surgical planning for dental implant surgery using tooth-supported surgical guides. Secondary outcomes included determining risk factors potentially affecting accuracy, as well as a time and cost analysis. A total of 81 implants were placed in 46 patients. Implants were placed either pilot guided (n=42), partially guided (n=28) or fully guided (n=11). The accuracy of implant placement was clinically acceptable and comparable to that of outsourced planning. The only modifiable risk factor affecting accuracy was guide type. Implants in the anterior zone demonstrated less angle deviation. Variables that did not affect accuracy included age, sex, number of days since first patient, implant length, history of bone grafting, surgeon, number of obviously restored teeth, adjacent crowns and dental arch treated. This approach is cost effective and requires approximately 48 minutes of active attention to fabricate a single surgical guide.

LIST OF ABBREVIATIONS USED

3D – three-dimensional

CBCT – cone beam computed tomography

CAD – computer-aided design

CAM – computer-aided manufacturing

dCAIS – dynamic computer assisted implant surgery

DICOM – digital imaging and communications in medicine

EAO – European Association for Osseointegration

FDI – Fédération Dentaire Internationale

FG – fully guided

ICC – intraclass correlation coefficients

IOS – intraoral scan

PG – pilot guided

sCAIS – static computer assisted implant surgery

SLA – stereolithography apparatus

STL – surface tessellation language

VSP – virtual surgical planning

ACKNOWLEDGEMENTS

I would like to thank Dr. Curtis Gregoire, my project supervisor. Thank you Dr. Gregoire for your thoughtful recommendations and guidance throughout this project.

I would also like to thank the VG Oral and Maxillofacial Surgery team including, the staff surgeons and residents for enrolling patients in the study and following the study protocol. I would also like to thank the VG OMFS administrative staff for arranging appointments and the dental assistants for their involvement in record taking.

I would like to thank my summer research students Breanna Bodle and Mariam Elaghil for their contributions. Breanna worked tirelessly on the project. I'm especially grateful for her assistance.

I would also like to thank the readers of this thesis, Dr. Curtis Gregoire, Dr. Jean-Charles Doucet and Dr. Mark Vallee. I appreciate your insights and constructive feedback.

I would also like to thank Dr. Hong Gu and Yurunyun Wang for their contributions to the statistical analysis and interpretation of data.

I would also like to thank Straumann and Nobel Biocare for providing discounts and complimentary products for fabrication of the surgical guides.

Lastly, I would like to thank the Canadian Association of Oral and Maxillofacial Surgeons Trust for providing funding for the project.

CHAPTER 1 – INTRODUCTION

Rehabilitation with dental implants assists with restoration of proper form, function, and esthetics of the dentition. The process, starting from the edentulous, or partially edentulous stage to a reconstructed dentition, involves both a surgical and a prosthetic phase. The ideal prosthetic position primarily dictates the planned location for the dental implant. However, ultimately the position of the dental implant depends on the available bone [1]. Once the ideal implant position has been determined, the surgical operator creates an osteotomy and places the dental implant. The implant is subsequently restored with prosthetic components to reconstruct the dentition.

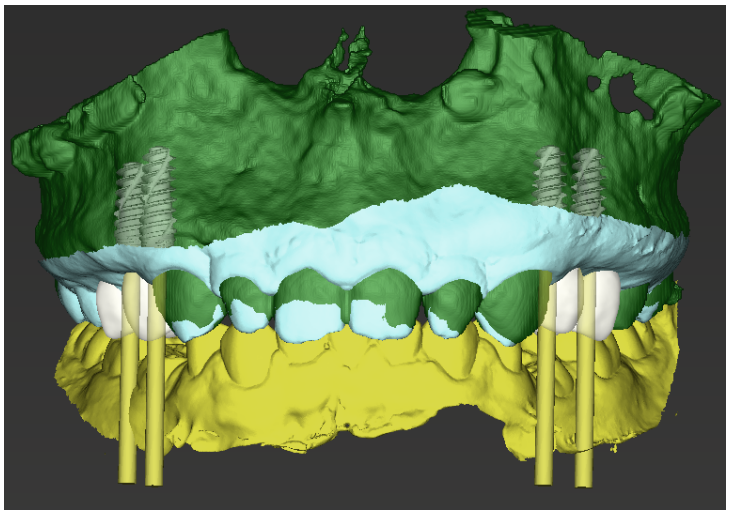
The surgical procedure is complex, and ideal placement of the dental implant(s) is crucial to obtain a successful outcome. Neglecting the prosthetic demands often leads to an unfavourable prosthesis, with a compromised occlusal scheme, poor esthetics and/or unfavourable biomechanics [2]. Inherent risks of dental implant surgery include potentially serious complications such as damage to neurovascular structures, the maxillary sinus, and adjacent teeth [3-5]. For this reason, many surgical operators choose to employ a surgical guide to improve the accuracy and decrease the risks of the surgical procedure.

Planning for dental implant surgery requires acquisition of pre-operative records. These records are typically taken when the patient presents for a dental implant consultation. The patient is clinically and radiographically examined. Often radiographic examination begins with acquisition of an orthopantomogram. The orthopantomogram is a two-dimensional image that helps the operator determine if the patient is a potential candidate for dental implant surgery. In addition to the clinical exam, this image allows the operator to determine the general state of the remaining dentition and provides some limited information related to the quantity and quality of the available bone. If the patient is deemed to be a potential candidate for treatment with dental implants, then a cone beam computed tomography (CBCT) scan is taken.

CBCT is a widely available, technically simple, low-cost, rapid acquisition radiographic procedure providing images with high spatial image resolution at relatively

low radiation dose [6]. CBCT allows the operator to determine the three-dimensional bone volume available for placement of the dental implant(s). CBCT imaging is always required when using virtual surgical planning, but is not a strict requirement for preforming dental implant surgery without 3D planning. The CBCT also enhances patient safety, by allowing 3D visualization of adjacent vital anatomical structures [7].

However, CBCT alone does not display the teeth accurately enough for the manufacturing of an implant surgical guide. Therefore, a virtual model of the teeth derived from an intraoral scan is required for fabrication of a digitally designed and 3D printed implant surgical guide [8]. The intraoral scan (IOS) provides a highly accurate representation of each dental arch and the patient's occlusion. It provides no additional radiation, risk, or harm to the patient. Digital scans of the dentition have been evaluated and demonstrated to be a valid alternative to conventional impressions [9]. The virtual model can then be utilized for fabrication of implant surgical guides.

A. 

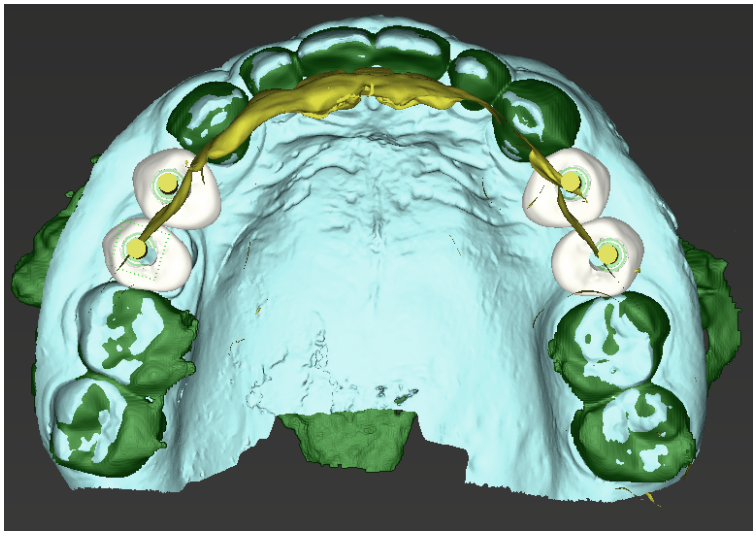
B. 

Figure 1. Virtual prosthetically driven implants planned with coDiagnostiX™

A. Frontal View

B. Occlusal View

The use of computer-aided three-dimensional (3D) virtual surgical planning has been implemented to improve the accuracy and reliability of surgical implant placement [6,10,11]. The virtual 3D plan (Figure 1) thus becomes the interface between the design and the physical patient [12]. Computer-based virtual surgical planning (VSP) for dental implant surgery allows simultaneous 3D visualization of the osseous topography as well as the superimposed dental occlusion. This allows for planning the implant position based on future prosthetic requirements and vital anatomic structures [11,13]. An optimal implant plan

is strongly related with an accurate matching of the radiographic data with the intra-oral scan [14]. Matching errors are smallest when both buccal and lingual surfaces are used to match the CBCT file with the IOS file [15].

Most often, practitioners outsource implant guide fabrication with the task delegated to third-party dental laboratories. The patient's CBCT and IOS files are sent to the third-party company. A video-conference meeting is then held between a representative from the third-party company and the operator. The operator is then able to make any necessary modifications and verify the plan. Once the final surgical plan has been confirmed, a patient specific dental implant surgical guide is designed, and fabricated by the third-party company. The surgical guide is then sent to the operator prior to the procedure. The surgical guide is subsequently used intra-operatively so that the operator can perform the osteotomy at the desired position dictated by the virtually planned surgery. The literature has demonstrated accurate and predictable implant placement when using laboratory-fabricated surgical guides based on computed tomography [16]. Despite the benefits of guided implant surgery, not all practitioners routinely employ guided surgery. The reason for this, above all, is the high production cost of the surgical guides [5].

There are significant resource requirements involved in the 3D virtual surgical planning process for dental implant surgery. Third party fees are expensive. The additional time required for communication and modification of the plan, along with shipping of the printed surgical guides can be inconvenient and can ultimately delay the surgical and restorative treatment phases. Many dental and surgical offices have CBCT machines and intra-oral scanners, thus it is practical to consider an office-based approach to virtual surgical planning for dental implant surgery. There is limited additional equipment and associated expenses to keep the whole surgical guide fabrication process office-based. Namely, the major additional costs associated with this process are the software for virtual planning and fabricating the surgical guides as well as machines for 3D printing, washing, and curing the surgical guides. Recently, these pieces of equipment have become more affordable, thus making their acquisition more feasible for dental

offices [17]. The use of fully office-based production of implant surgical guides can potentially reduce treatment time, reduce the cost of production, allow for customization of treatment as the clinician has autonomy over the case, and has clinically acceptable precision [12].

To date, there are very few studies that use a fully digital, office-based protocol for virtual surgical planning for dental implant surgery. Furthermore, there have been no studies that we are aware of, that evaluate the accuracy and feasibility from a time and cost perspective of an office-based approach.

CHAPTER 2 – PURPOSE

The primary objective of this study is to determine the accuracy of an office-based workflow for virtual surgical planning for dental implant surgery using tooth-supported dental implant guides.

Secondary outcomes include:

1. An assessment of the risk factors potentially affecting the accuracy of guided implant surgery.
2. An assessment of the time required for office-based virtual surgical planning.
3. A cost analysis, including the cost of implementation of office-based virtual surgical planning as well as a cost per case analysis.

CHAPTER 3 – METHODOLOGY

3.1 Subject Selection

The study was completed in the department of Oral and Maxillofacial Surgery at the Victoria General Hospital in Halifax, Nova Scotia. This study was designed to be a prospective case series evaluating a group of patients undergoing dental implant surgery.

Prior to obtaining Research Ethics Board approval, a radiological review was completed and approved by the Nova Scotia Health Radiation Safety Program. A Medical Physicist in the Radiology Research Office reported that the CBCT images are 11uSv each, for a total dose estimate of 22 uSv (0.022mSv). The Radiological Review Application was completed with the Nova Scotia Health Authority Radiation Safety Program on September 27, 2021. The approved Radiation Risk wording for the Research Ethics Board approved consent form stated "You will receive two CT imaging procedures after you are enrolled in the study. These procedures will expose you to radiation. This radiation exposure is for research purposes only. The imaging will be done using established procedures of this institution and be performed by authorized persons. The amount of extra radiation exposure you will receive is approximately equal to the amount you would receive over two days from natural background radiation."

The study was approved by the Nova Scotia Health Authority Research Ethics Board on October 20, 2021. REB file number was 1027154.

Participants were recruited from July 2022 until September 2023. Patients referred for dental implant surgery were screened for participation if they met the inclusion criteria and were not excluded by the exclusion criteria.

Inclusion criteria:

1. Missing tooth/teeth and/or tooth/teeth treatment planned for removal.
2. Patients referred to have edentulous space(s) restored with dental implant(s).

Exclusion criteria:

1. Limited mouth opening restricting the ability to use a surgical guide.
2. Patients with less than three remaining teeth in the dental arch being treated.
3. Placement of dental implants in a site where a secondary tooth with a fully developed root was removed less than three months ago, or patients who have previously had a dental implant in that same site less than three months ago.
4. Conditions that affect bone metabolism, history of bisphosphonate treatment, and/or history of radiation therapy.

Informed consent for dental implant surgery was obtained the same day as the patient's dental implant consultation appointment. At this visit, a resident or staff member of the surgical team explained the research project and obtained consent if the patient wanted to participate in the project.

3.2 Data Acquisition

In addition to history and physical exam, CBCT and intra-oral scans were obtained at the consultation appointment. The CBCT images were obtained using a Dexis iCAT Flx v17 (Quakertown, PA) CBCT scanner**.** A pre-operative CBCT was taken having the patient separate their teeth by occluding on tongue depressor(s). Field of view was determined per patient to include adequate anatomical features. A field of view of 512 x 512mm, tube voltage of 120 kVp, and a tube current of 5 mA was maintained with all CBCTs taken. The intra-oral scan was obtained using a Dentsply Sirona Primescan (Charlotte, NC) intraoral optical scanner. A scan of the maxillary and mandibular arches as well as the occlusion in maximum intercuspation was obtained.

3.3 3D Planning Procedure

One Oral and Maxillofacial Surgery Resident performed all the surgical planning using the coDiagnostiX™ Producer implant planning software (Version 10.5, Dental Wings GmbH, Chemnitz, Germany).

Within the software, there are embedded links to training videos that were completed by the user of the software prior to implementation. The software integrates an intuitive, stepwise approach to the surgical planning.

3.3.1 Importation of the CBCT

The digital imaging and communication in medicine (DICOM) data from the CBCT was imported into the implant planning software to be prepared for the designing and fabrication process.

3.3.2 Segmentation and Matching

The CBCT file was segmented to isolate the arch being treated (Figure 2). The patient coordinate system was then aligned in the sagittal, coronal and axial views. The panoramic curve was manipulated to allow for a less distorted panoramic image. If the implant planning was for the mandibular arch, the mandibular canal was mapped out. The IOS STL file for the arch being treated was imported and matched with the CBCT DICOM files based on multiple dental anatomical landmarks. The most anatomically distinguishable landmarks were chosen for each case. Effort was made to include both buccal, occlusal and lingual/palatal surfaces of the teeth if possible [15]. This allowed for accurate evaluation of the dental occlusion in relation to the bone of the maxilla and/or mandible. The opposing arch IOS STL file was then imported using the “copy alignment” function, so that the patient’s occlusion in maximum intercuspation could be assessed.

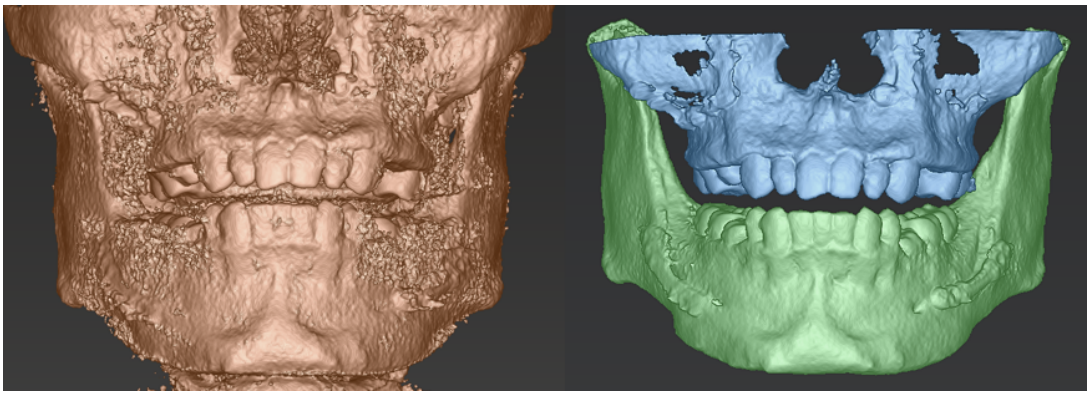


Figure 2.
Before (left) and after (right) manual segmentation of imported cone beam computed tomography scan in coDiagnostiX™.

Teeth were positioned to fill the partially edentulous spaces being treated. The size and position of the teeth was adjusted to allow for the planned prosthetic outcome. The occlusion was evaluated in maximum intercuspation. Once the ideal restorative position was confirmed, the dental implants were virtually placed within the software. The position of the dental implant was then finely tuned based on the available bone volume and anatomic structures.

3.3.3 Choosing the Guide Type

Although patients with as few as three teeth were eligible for inclusion in the study, all of the surgical guides manufactured for this study ended up being bilateral guides supported by at least seven teeth. Guide type was chosen based on operator preference, and sometimes limited by the space available for the surgical sleeve. The appropriate surgical guide sleeve was chosen for use of either pilot guided, partially guided, or fully guided surgery. For Straumann, there are three options for the offset from the bottom of the guide sleeve to the top of the implant, either H2, H4 or H6. The numbers following the letter “H” signify the number of millimetres from the bottom of the guide sleeve to the top of the implant. For Straumann, the position closest to the level of the bone was chosen, unless there was anticipated to be interference with the bone, soft tissue, or adjacent teeth.

Pilot guided was defined as surgery that was only guided by the 2mm twist drill. Partially guided was defined as surgery that was guided by the 2mm twist drill as well as at least one more drill to prepare the osteotomy, up to and even including the last drill to prepare the osteotomy, however the implant itself was not placed through the surgical guide. Fully guided was defined surgery that was completely guided to prepare the osteotomy as well as for placement of the implant itself through the surgical guide.

3.3.4 Custom Guide Sleeves

The implant manufacturer and system selected for each case was based upon the referring source request. When no specific request was made, the chosen implant system was based on either experience with the referral source, communication to clarify the plan, or when there was no restorative preference, the implant was chosen by the surgical operator placing the dental implant. There were three implant manufacturers that were used during the study. Nobel Biocare (50 implants), Straumann (30 implants) and Astra (1 implant). Nobel Biocare keeps their guide sleeve information proprietary. Therefore, to use the coDiagnostiX™ software to place Nobel Biocare implants using genuine Nobel Biocare guide sleeves, the user of the software designed a custom sleeve system. This allowed for printing a defect in the surgical guide that allowed for near-perfect insertion of the guide sleeve into the surgical guide. To accomplish this task, a digital caliper was used to measure the different Nobel Biocare guide sleeves. The result was rounded to the nearest 0.1mm and entered into the software. Next, trial and error were performed to print different surgical guides with the correct hole parameters to accommodate the Nobel Biocare guide sleeves. These parameters were fine tuned to as little as 0.01mm at a time to ensure the best possible fit for the guide sleeves. It is important to note that Nobel Biocare guided surgery components are all 10mm longer than the standard Nobel Biocare drills to accommodate for the surgical guide and to give space for irrigation under the surgical guide.

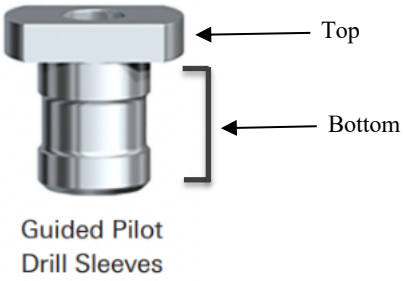


Figure 3: Pilot Guided Drill Sleeve for Nobel Biocare

Photo adapted from "Guided (Pilot Drill) Sleeves, Guided Anchor Pin Sleeves and Mounting Tools – Instructions for use" pamphlet published by Nobel Biocare.

Table 1: Guided Pilot Drill Sleeve 2.0mm REF 300440 for Nobel Biocare

Parameter	Digital Caliper Measurement (mm)	Measurement listed in coDiagnostiX (mm)	Size of defect planned in coDiagnostiX to allow room to passively insert guide sleeve
Height (Total)	4.48	4.5	
Top (Height)	0.97	1	1.1
Top (Diameter)	4.55		4.75
Top (Width)	2.89		
Bottom (Outer Diameter)	2.82	2.8	3
Bottom (Inner Diameter)		2.2	

Distance to top of implant was set at 5.5mm in the software. This was calculated by knowing that the Nobel Biocare guided surgery drills are 10mm longer than the standard drills. The height of the guide sleeve was listed as 4.5mm in the software, leaving 5.5mm from the bottom of the guide sleeve to the top of the implant platform.

Figure 4: NP, RP and WP Guided Sleeves for Nobel Biocare

Photo adapted from "Guided (Pilot Drill) Sleeves, Guided Anchor Pin Sleeves and Mounting Tools – Instructions for use" pamphlet published by Nobel Biocare.

Table 2: NP, RP and WP Guided Sleeves for Partially Guided or Fully Guided Surgery using Nobel Biocare

Sleeve	Digital Caliper Height and Height listed in coDiagnostiX (mm)	Digital Caliper Diameter (mm)	Diameter listed in coDiagnostiX (mm)	Distance to top of implant (mm)
NP REF #32754	3.5	4.72	4.9	6.5
RP REF #32765	3.5	5.95	6.13	6.5
WP REF #32766	3.5	6.97	7.2	6.5

Distance to top of implant was set at 6.5mm in the software. Again, this was calculated by knowing that the Nobel Biocare guided surgery drills are 10mm longer than the standard drills. The height of the guide sleeve was listed as 3.5mm in the software, leaving 6.5mm from the bottom of the guide sleeve to the top of the implant.

3.3.5 Designing and Printing the Surgical Guide

The surgical guide was then designed. The path of insertion for the surgical guide was determined. The amount of resin contacting the surface of the teeth is specified and the sleeve mount diameters were adjusted. An offset between 0.15-0.20mm was chosen as clearance between the guide and the patient's occluding contact surface. Generally, if the patient's IOS scan was performed in close temporal proximity to their surgery date a

lower offset was chosen, whereas if surgery was planned for many months in the future, then a larger offset was chosen. The wall thickness of the guide was uniformly set at 3.00mm. Large connectors were applied to increase stability of the guide when required. Custom inspection windows were added. Usually, an inspection window was designed into the buccal/labial portion of nearly every tooth to allow for intra-operative confirmation that the guide is fully seated. Inspection windows were also created at the sites of the sleeve mounts to allow for additional room for the implant hand-piece. Labels were added to the guide. Rotation markers were added for fully guided surgery.

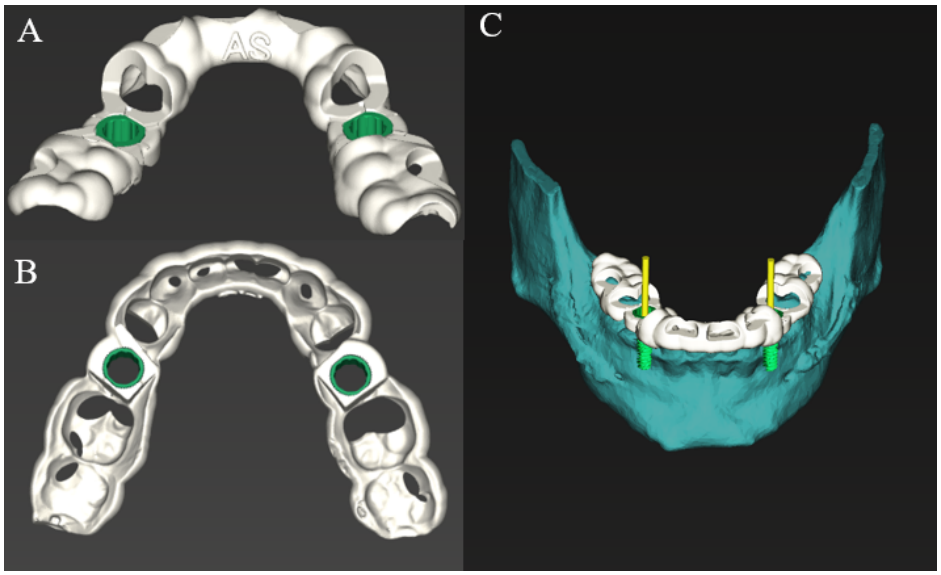


Figure 5.

Implant surgical guide virtually designed with coDiagnostiX™.

A. Superior view of mandibular surgical guide for sites 3.5 and 4.5
B. Inferior view of mandibular surgical guide for sites 3.5 and 4.5
C. Three-dimensional model of guided implant surgical plan for sites 3.5 and 4.5

The final design (Figure 5) was uploaded to the Form Labs Preform Software Version 3.22.1 (Somerville, Massachusetts). The raft settings for all surgical guides were as follows: full raft at a density of 0.50 and touchpoint size of 0.45mm with internal supports added.

A Form Labs Form 3B+ SLA three-dimensional printer located in the Oral and Maxillofacial Surgery Department in the VG hospital was used for 3D printing for the entirety of the study. Form Labs Surgical Guide V1 Resin (RS-F2-SGAM-01) was used. The guides were printed with a 0.100mm layer thickness. The surgical guide was oriented on the build platform so that the resin guide supports contacting the surgical guide were in contact with the outer portion of the surgical guide, as to ensure they did not obscure the inner aspect of the surgical guide that would ultimately be contacting the occlusal surface of the teeth. Biocompatible resins, such as Dental Surgical Guide Resin, are biologically safe for specific types and lengths of exposure to the human body, class I resin (EN-ISO 10993-1:2009/AC:2010).

The guides were subsequently washed using the Form Labs Form Wash machine (FH-WA-01). Each guide was washed for 30 minutes with 99% isopropyl alcohol. The printed guide was inspected to ensure that all parts were clean and dry. No residual alcohol, excess liquid resin, or residue particles remained. A post cure procedure was performed using Form Labs Form Cure machine (FH-CU-01) with 405 nm wavelength ultraviolet light at a temperature of 70°C for 30 minutes. All settings were determined according to the Form Lab's equipment manual recommendations.

3.3.6 Guide Sleeve Application

The resin guide supports were manually removed. The guides were thoroughly inspected to verify that the guide was not damaged or cracked and maintained integrity after processing. The guide sleeves that were chosen were all genuine implant system specific guide sleeves, except for the single Astra implant that was placed in the study. Similar to Nobel Biocare, Astra also keeps their guide sleeve information proprietary. Therefore, a Nobel Biocare pilot sleeve was used for the single pilot guided Astra implant in the study. For Nobel Biocare components, the guide sleeves were fixated to the surgical guide per the recommendations listed in the "Guided (Pilot Drill) Sleeves, Guided Anchor Pin Sleeves and Mounting Tools – Instructions for use" pamphlet published by Nobel Biocare [18]. Straumann guide sleeves do not require special components for insertion as

they are cemented when they are seated flush with the surgical guide. A 701 bur was used to drill a hole through both the buccal/labial as well as the palatal or lingual aspect of the surgical guide where the guide sleeve was to be positioned. This created two ports at each guide sleeve site. These ports allowed for injection of the resin cement around the guide sleeve for added retention. The guide sleeves were positioned and cemented with RelyX™ Unicem 2 – Self-Adhesive Resin Cement (Neuss, Germany). The resin was dual cured to ensure proper polymerization. All guide sleeves were inspected thoroughly to verify that they were seated flush with the guide and that no excess cement was present in the internal diameter of the guide sleeve.

3.4 Surgical Protocol

Surgical guides were disinfected with 0.12% Chlorhexidine Gluconate prior to the surgical procedure. The surgical guide was used intra-operatively to assist in transferring the virtual surgical plan to the operating room for placement of the dental implant(s). Following the surgery, the actual implant specifications used were recorded. It was also recorded whether or not a bone graft was used and to what degree the implant placement was guided, either pilot, partial or fully guided.

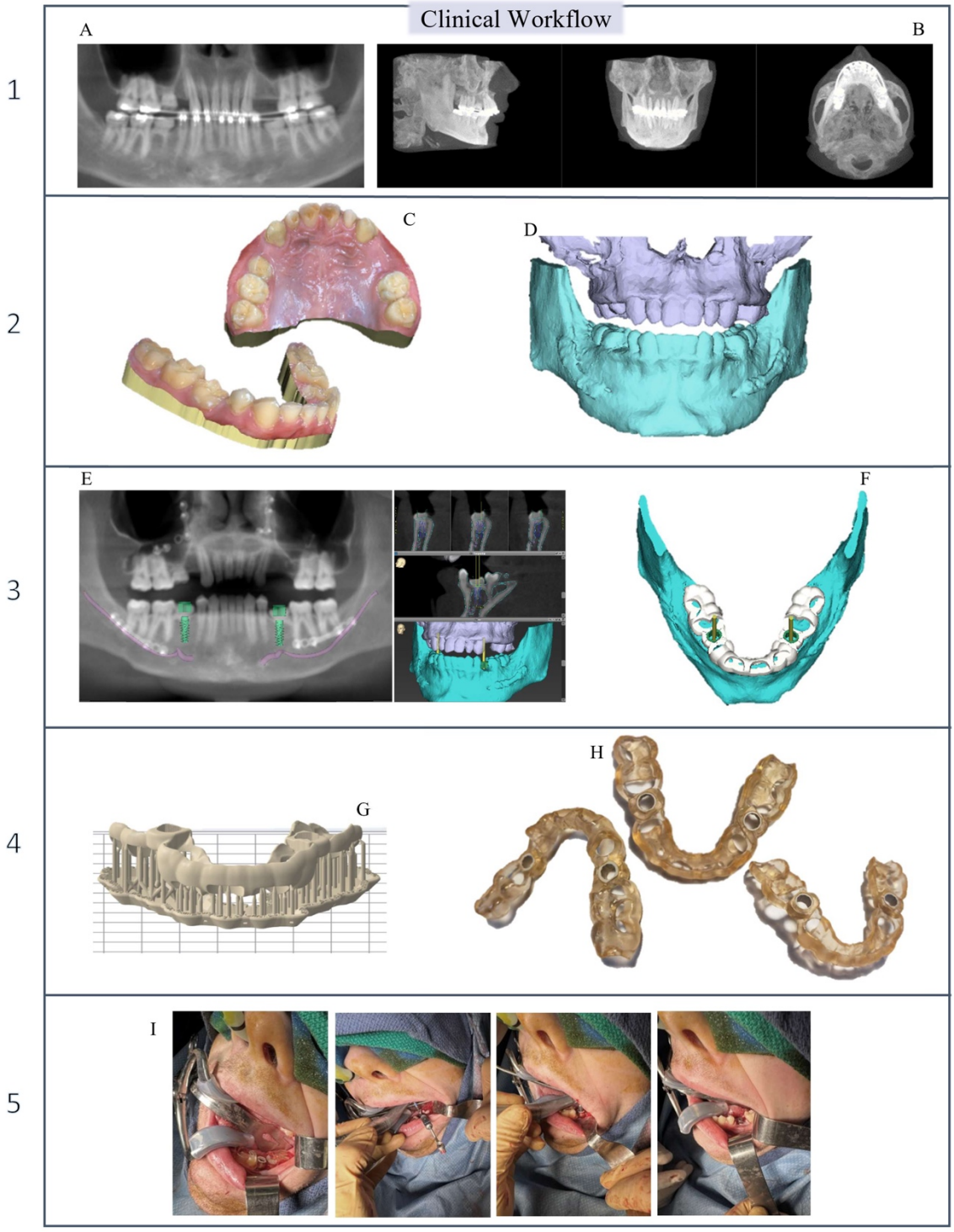


Figure 6. Clinical Workflow Demonstrating an Office-Based Approach

1. Radiographic Examination
    A. Orthopantomogram

B. Presurgical CBCT scan

2. Data Acquisition and Importation into Planning Software
    C. Intra-oral scan
    D. Segmentation of the CBCT and matching of the STL file from the IOS with the DICOM file from the CBCT
3. Virtual Planning
    E. Virtual planning of implant and prosthetic positions
    F. Final virtual surgical plan
4. Guide Fabrication
    G. Virtual surgical guide design
    H. Final 3D printed product with guide sleeves inserted
5. Surgical Protocol
    I. Implant placement with surgical guide

3.5 Accuracy Measurement

On the same day as implant placement, a post-operative CBCT of the treated dental arch(es) was taken with the Dexis iCAT Flex v17 having the patient separate their teeth by occluding on tongue depressor(s). A field of view of 512 x 512mm, tube voltage of 120 kVp, and a tube current of 5 mA was maintained with all CBCTs taken.

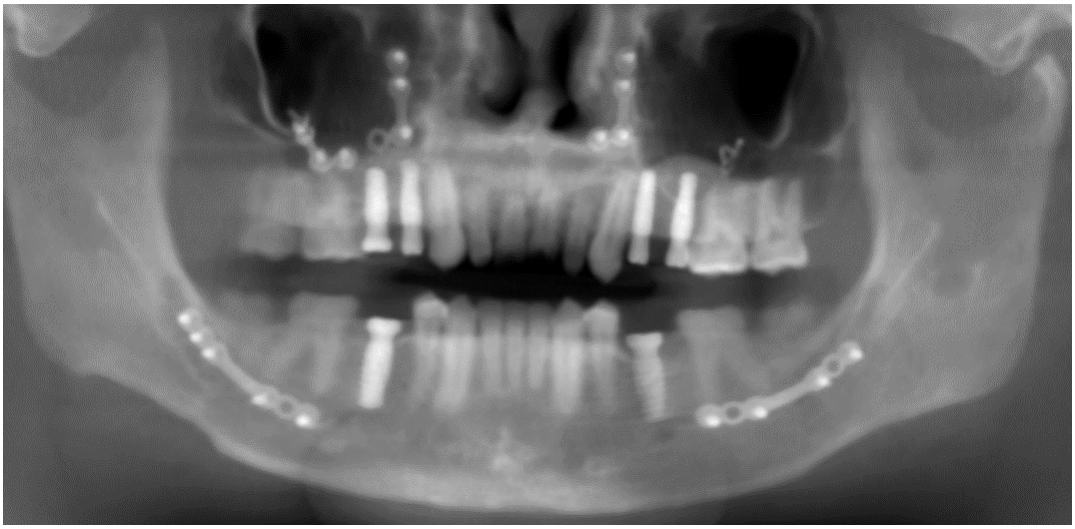


Figure 7.

Orthopantomogram derived from the postoperative CBCT showing placed implants using a fully in-office virtual protocol.

The post-operative CBCT was imported into the coDiagnostiX™ software, and the treated arch was segmented. The Treatment Evaluation tool allows matching of the pre-operative CBCT including the virtually planned surgery with the post-operative CBCT showing the actual implant position (Figure 8). Two calibrated clinicians then superimposed a virtual image of the implant that was placed during the surgery in a position of best fit over the actual position of the implant fixture as visualized on the post-operative CBCT, shown by the hyper-density of the implant in sagittal, coronal, and axial planes (Figure 9). The two observers performing the analysis included a sixth-year Oral and Maxillofacial Surgery Resident and a second-year Dentistry student. Calibration of the methodology was performed by having both observers work together using the Treatment Evaluation tooth for the first fifteen placed implants in the study. This was performed on September 15, 2023. The results obtained from the calibration were not utilized in the accuracy analysis. This step was performed only to ensure adequate calibration between the observers. Based on the selected superimposition overlay, the "Treatment Evaluation" tool in coDiagnostiX™ then provided a quantitative analysis that detailed the deviation of the planned versus actual result in all dimensions (Figure 9).

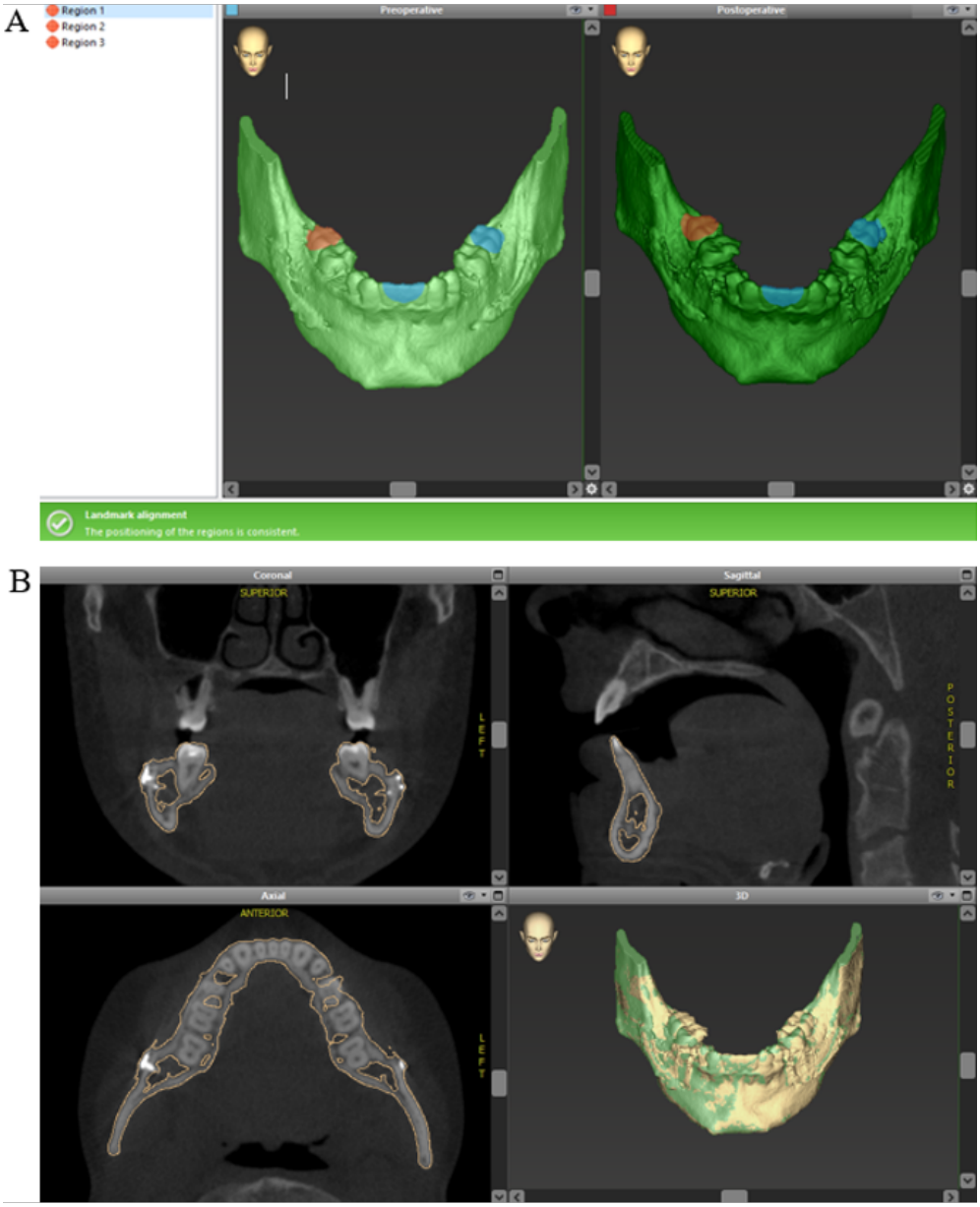


Figure 8.

Matching protocol using coDiagnostiX™

A. Anatomical landmarks selected from preoperative and postoperative cone beam computed tomography scans of the same patient.

B. Superimposed registration of the preoperative and postoperative CBCT scans after matching.

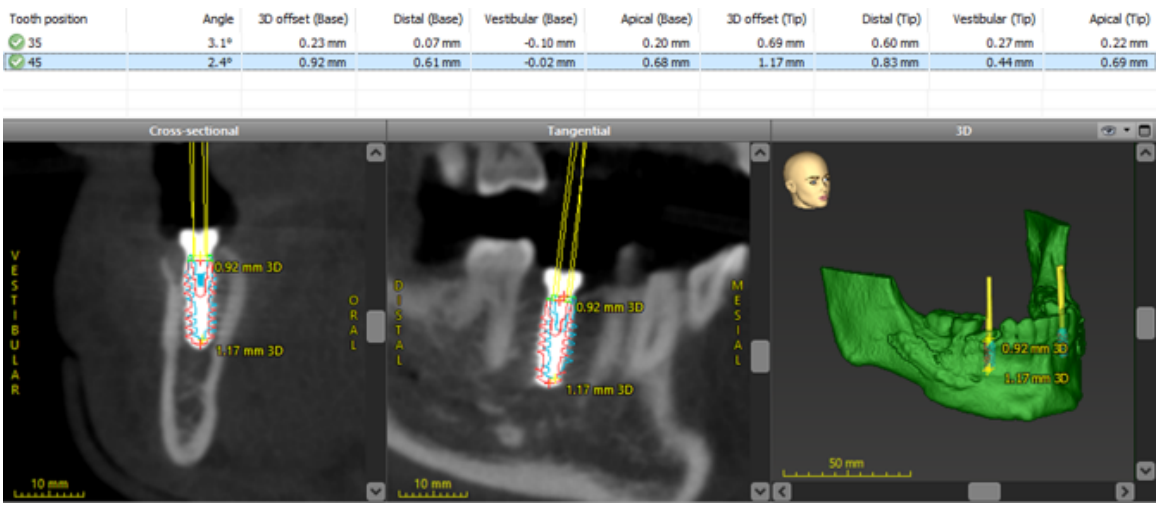


Figure 9.

Interface of the Treatment Evaluation Tool Plug-in for CoDiagnostiX™

Coronal view (left) showing the buccolingual dimension, tangential view (middle) showing the mesiodistal dimension, 3D view (right) showing the planned and actual implant position.

Accuracy analysis was completed using the Treatment Evaluation tool to superimpose the preoperative CBCT including the virtually planned implant with the postoperative CBCT showing the actual implant position. A position of best fit, represented by an outline of the placed implant in red, is superimposed with the actual implant position observed from the CBCT, shown by the hyperdensity of the implant in sagittal, coronal, and axial (not shown) planes. The blue outline of the implant represents the virtually planned implant position. It is important to note, that during the accuracy analysis, the person performing the measurements does not see the virtually planned implant position while they are superimposing the outline of the implant that was placed in red. This keeps the person performing the measurements blinded to the pre-operative plan.

Based on the selected superimposition overlay, the Treatment Evaluation tool then provides a quantitative analysis that details the deviation of the planned versus actual result in all dimensions. Accuracy of the actual implant position achieved is compared to the virtual surgical plan using angle deviation in degrees and distance deviations at the implant platform and apex in millimeters. The parameter listed as “Base” in the

Treatment Evaluation tool indicates the deviation at the platform of the implant. The parameter listed as “Tip” in the Treatment Evaluation tool indicates the deviation at the apex of the implant.

Dependent Variables Assessed in Accuracy Analysis

1. Angle Deviation: angle between the central axes of the planned versus actual implant, in degrees (Figure 10)
2. 3D Offset (Platform and Apex): linear 3-dimensional deviation from the center of the implant platform or apex of the planned versus actual implant, in millimeters (Figure 10)
3. Distal Deviation (Platform and Apex): linear 2-dimensional displacement from the center of the implant platform or apex in the x-axis (distal versus mesial direction), of the planned versus actual implant, in millimeters (Figure 11)
4. Apical Deviation (Platform and Apex): linear 2-dimensional displacement from the center of the implant platform or apex in the y-axis (apical versus coronal direction), of the planned versus actual implant, in millimeters (Figure 10)
5. Vestibular Deviation (Platform and Apex): linear 2-dimensional displacement from the center of the implant platform or apex in the z-axis (vestibular/labial versus palatal/lingual direction), of the planned versus actual implant, in millimeters (Figure 11)

Based on the selected reference points a quantitative analysis was performed to detail the deviation of the planned versus actual result in all dimensions. Accuracy of the virtual surgical plan compared to the actual implant position post-operatively was assessed using angle deviation in degrees and distance deviations at implant platform and apex in millimetres.

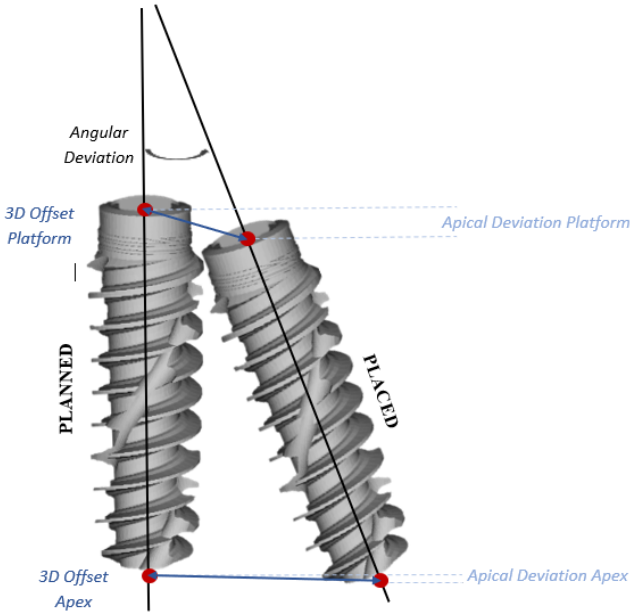


Figure 10.

Schematic diagram illustrating the deviation measurements evaluated comparing planned and placed implant position.

Angular Deviation: angle between the central axes of the planned versus actual implant, in degrees.

3D Offset Platform: linear 3-dimensional deviation (x, y, and z)* from the center of the implant platform of the planned versus actual implant, in millimeters.

3D Offset Apex: linear 3-dimensional deviation (x, y, and z)* from the center of the implant apex of the planned versus actual implant, in millimeters.

Apical Deviation Platform: linear 2-dimensional displacement from the center of the implant platform in the y-axis* (apical versus coronal direction), of the planned versus actual implant, in millimeters.

Apical Deviation Apex: linear 2-dimensional displacement from the center of the implant apex in the y-axis* (apical versus coronal direction), of the planned versus actual implant, in millimeters.

*See Figure 12 for coordinate system

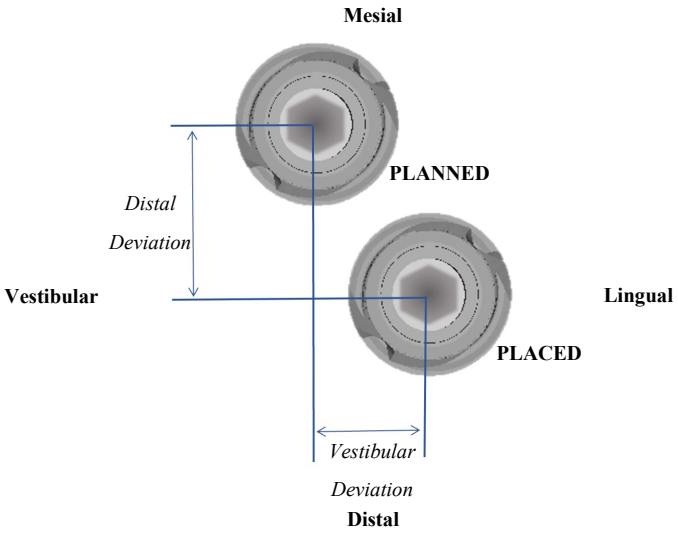


Figure 11.

Schematic diagram illustrating the 2D horizontal deviation measurement outcomes of the planned versus placed implants.
Distal Deviation: linear 2-dimensional displacement from the center of the implant platform or apex in the x-axis* (distal versus mesial direction), of the planned versus actual implant, in millimeters.
Vestibular Deviation: linear 2-dimensional displacement from the center of the implant platform or apex in the z-axis* (vestibular/labial versus palatal/lingual direction), of the planned versus actual implant, in millimeters.

*See Figure 12 for coordinate system

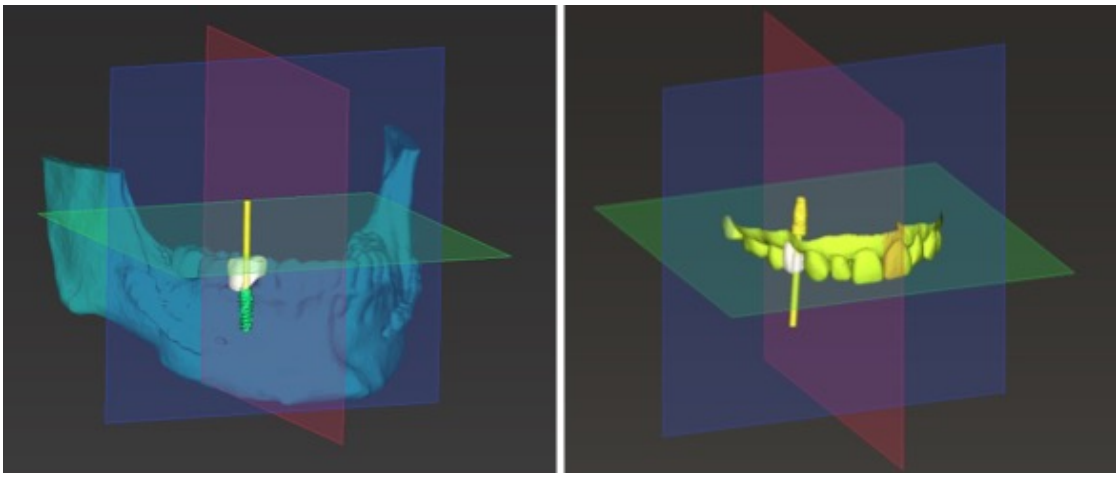


Figure 12.

Coordinate system using coDiagnostiX™ virtual planning software. X-axis (green) corresponds to distal deviations, Y-axis (red) corresponds to apical deviations, and Z-axis (blue) corresponds to vestibular deviations as indicated by the software's treatment evaluation tool plug-in. 3D offset deviations determined by XYZ-axes.

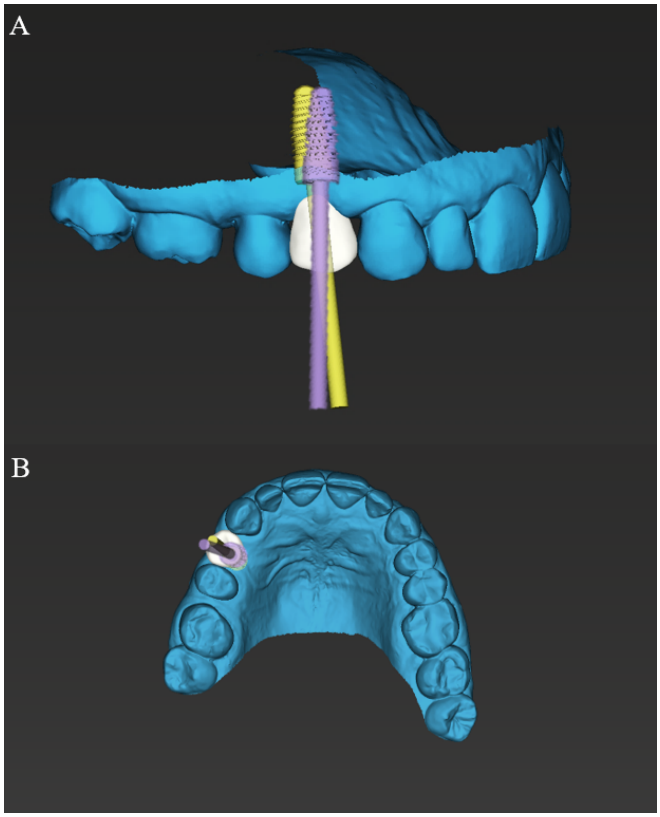


Figure 13.

Three-dimensional model demonstrating an example of deviations of planned (yellow) versus placed implants (purple) using coDiagnostiX™.

A. View from the buccal aspect of planned versus placed implant for the right maxillary first premolar.
B. Occlusal view of planned versus placed implant for the right maxillary first premolar.

3.6 Analysis of Data

3.6.1 Statistical Analysis

Statistical analysis was performed using RStudio (Posit PBC; Boston, Massachusetts). Data was analyzed by Dr. Hong Gu and Yurunyun Wang, third-party statisticians in the Department of Mathematics and Statistics at Dalhousie University. These services were funded by a Mitacs research grant.

Accuracy of the workflow was analyzed using the mean and standard deviation with 95% confidence intervals for the mean estimate. Multiple linear regression models according to the smallest Akaike Information Criteria (AIC) were selected. The response variables were not normally distributed. A square root transformation on the response variables was performed so that the residuals were more normally distributed. This was completed for each of the dependent variables, including angle deviation, 3D offset at implant platform and 3D offset at implant apex. Regression model diagnostic checking confirmed that using square root of each variable resulted in the models fitting better than using the variables directly. Analysis of variance (ANOVA) tests were performed for the variables selected by the models to determine their significance. Tukey multiple comparisons of means using 95% family-wise confidence intervals were used to assess categorical variables with at least three levels of comparison.

Inter-observer and intra-observer reliability was assessed according the intraclass correlation coefficients (ICC). When the ICC value is less than 0.5, this is classified as poor reliability. When the ICC is greater than or equal to 0.5 and less than 0.75 the reliability is moderate. When the ICC is greater than or equal to 0.75 and less than 0.9 the reliability is good. When the ICC is greater than or equal to 0.9, the reliability is excellent. Accuracy of all the implants was measured three times. The first time the data was assessed, it was performed by a single sixth-year OMFS resident. This was performed throughout the length of the study, after the post-operative CBCTs were obtained. The second and third times that the data was assessed, it was performed all within the same week in September of 2023 by two different observers. These observers included the same OMFS resident who assessed the data the first time, and a second-year dental student. Prior to performing the second and third measurements of the data, the first fifteen implants that were performed in the study were assessed by both the OMFS resident and the dental student together. This allowed for calibration of the measurements. The OMFS resident and dental student discussed the protocol of accuracy assessment and practiced it together to ensure that both observers utilized the same methodology.

3.6.2 Sample Size Estimation

A sample size estimation was performed for each of the accuracy variables assuming a standard error for the distance deviations as 0.1mm, which resulted in a sample size requirement of 22 implants to obtain statistical power to assess 3D offset at the implant platform and 63 implants to adequately assess 3D offset at the implant apex. For angle deviation, standard error was set at 0.4°, which resulted in a sample size of 63 implants to obtain statistical power to assess angle deviation. The results of the sample size calculation are presented in tables 3 and 4.

Table 3: Sample Size Estimation for Measurement Data in Millimeters

Accuracy Variable	Sample Size (number of implants)				
	SE (mm) 0.09	SE (mm) 0.1	SE (mm) 0.11	SE (mm) 0.12	SE (mm) 0.13
3D Offset Implant Platform (mm)	28	22	19	16	13
Distal Platform (mm)	23	19	16	13	11
Apical Platform (mm)	52	43	35	30	25
Vestibular Platform (mm)	37	30	25	21	18
3D Offset Implant Apex (mm)	78	63	52	44	38
Distal Apex (mm)	94	76	63	53	45
Apical Apex (mm)	53	43	36	30	26
Vestibular Apex (mm)	145	117	97	82	70

Table 4: Sample Size Estimation for Measurement Data in Degrees

Accuracy Variable	Sample Size (number of implants)		
	SE (degrees) 0.35	SE (degrees) 0.40	SE (degrees) 0.45
Angle Deviation (degrees)	82	63	50

Abbreviation: SE = Standard Error

CHAPTER 4 – RESULTS

4.1 Patient Demographics

This study included 81 implants that were placed in 46 patients over a duration of 405 days. Of the 46 patients, 27 of them were female and 19 of them were male. Forty-five implants were placed in female patients and thirty-six implants were placed in male patients. The median age of the patients included in the study was 50 years old. The mean age was 46.8 years old. The age of patients enrolled in the study ranged from 19-87 years old.

4.2 Inter-observer and intra-observer reliability

The intra-observer reliability between OMFS resident measurement 1 and OMFS resident measurement 2 was found to be excellent (0.9653) for angle deviation, good (0.8538) for 3D offset at implant platform and excellent (0.9569) for 3D offset at implant apex.

The inter-observer reliability between the OMFS resident measurement 2 and the dental student measurement was found to be excellent (0.9686) for angle deviation, good (0.8830) for 3D offset at implant platform and excellent (0.9665) for 3D offset at implant apex.

Between OMFS Resident measurement 2 and dental student measurement, the absolute value average angle deviation was 0.61°, 3D offset at implant platform was 0.08mm and 3D offset at implant apex 0.15mm. These values depict the average differences in the measurements of each accuracy parameter.

In summary, the intra-observer reliability was good to excellent in all variables. Similarly, the inter-observer reliability was also good to excellent between the OMFS resident measurement 1 and the dental student measurement, as well as the OMFS resident measurement 2 and the dental student measurement. Overall, the best reliability was observed in the OMFS resident measurement 2 and the dental student measurement.

Thus, these values were averaged to obtain the results. Averaging these measurements to obtain the data allowed for more robust results. Although the intra-observer reliability was also good to excellent, the data was not averaged between the three different measurements to avoid biasing the results from the OMFS resident, who would have measured the data twice, compared to only measuring the data once from the dental student. An additional advantage of averaging the OMFS resident measurement 2 with the dental student measurement was that these measurements were temporally related after the calibration of the methodology was performed.

Table 5: Intra-observer and inter-observer reliability according to ICC

Accuracy Variable	Intra-observer Reliability (OMFS Resident Measurement 1 and OMFS Resident Measurement 2)	Inter-observer Reliability (OMFS Resident Measurement 1 and Dental Student Measurement)	Inter-observer Reliability (OMFS Resident Measurement 2 and Dental Student Measurement)
Angle Deviation (degrees)	Excellent – 0.9653	Excellent – 0.9536	Excellent – 0.9686
3D Offset Implant Platform (mm)	Good – 0.8538	Good – 0.8648	Good – 0.8830
Distal Platform (mm)	Excellent – 0.9239	Good – 0.8952	Excellent – 0.9081
Apical Platform (mm)	Good – 0.8753	Excellent – 0.9043	Excellent – 0.9253
Vestibular Platform (mm)	Excellent – 0.9394	Excellent – 0.9575	Excellent – 0.9332
3D Offset Implant Apex (mm)	Excellent – 0.9569	Excellent – 0.9450	Excellent – 0.9665
Distal Apex (mm)	Excellent – 0.9661	Excellent – 0.9433	Excellent – 0.9653
Apical Apex (mm)	Good – 0.8796	Excellent – 0.9077	Excellent – 0.9258
Vestibular Apex (mm)	Excellent – 0.9762	Excellent – 0.9782	Excellent – 0.9850

4.3 Risk Factors Potentially Affecting Accuracy

Table 6 reports the independent variables which were assessed as risk factors potentially affecting accuracy.

In Table 6, the different risk factors were broadly categorized into the groups: patient demographics, implant factors, implant site factors, surgical guide factors, and additional factors. Each risk factor is identified in the table. Where applicable, each risk factor has been subdivided into groups. The total number of implants in each group is also summarized.

Table 6: Independent Variables

Factor Category	Risk Factor	Group	Number of Implants (Total = 81)
Patient Demographics	Age (years)	Numerical (19-87)	81
	Sex	Female	45
		Male	36
Implant	Implant System	Nobel Replace CC	37
		Nobel Parallel CC	13
		Straumann BLX	19
		Straumann TLX	8
		Straumann BLT	3
		Astra EV Straight	1
	Implant Diameter (mm)	Narrow (≤3.75)	28
		Regular (3.75 - <5)	32
		Wide (≥5)	21
	Implant Length (mm)	Shot (<8)	3
		Standard (8-12)	70
		Long (>12)	8
Implant Site	Dental Arch Treated	Maxilla	53
		Mandible	28
	Implant Location	Anterior	24
		Premolar	28
		Molar	29
	Implant site	FDI System	Not tabulated
	Bone Grafts	No Bone Graft	46
		Allogeneic Particulate Graft	10
		Block Graft	7
		Sinus Lift	15
		Combination of Block Graft and Sinus Lift	3
Surgical Guide	Guide Type	Pilot Guided	42
		Partially Guided	28
		Fully Guided	11
	Number of Teeth Supporting the Guide	7	4
		8	2
		9	17
		10	25
		11	21
		12	10
		13	2
	Number of Obviously Restored Teeth	0	1
		1	4
		2	15
		3	7
		4	2
		5	10
		6	12
		7	8
		8	3
		9	8
		10	7
		11	3
		13	1
	Number of Unrestored Teeth	0	6
		2	3
		3	19
		4	3
		5	9
		6	9
		7	8
		8	6
		9	9
		10	4
		11	1
		12	1
		13	3
	Adjacent Crowns	Between Two Crowns	66
		Free-end	15
Additional Factors	Surgeon	A	1
		B	3
		C	13
		D	31
		E	21
		F	12
	Number of Days Since First Patient	Numerical (0-405)	Tabulated Individually

4.3.1 Implant Factors

Three different implant manufacturers were used during the study. Fifty implants were placed using Nobel Biocare. Of these fifty implants, thirty-seven were Nobel Replace CC and thirteen were Nobel Parallel CC. Thirty implants were placed using Straumann. Of these thirty implants, nineteen were BLX, eight were TLX and three were BLT. A single Astra implant was placed. It was an OsseoSpeed EV Straight implant.

The diameter of the implants placed in the study were categorized into narrow, with a platform of less than or equal to 3.75mm; regular, with a platform between 3.76 to less than 5.00mm; and wide, with a platform of greater than or equal to 5.00mm. Twenty-eight implants were narrow, thirty-two implants were regular, and twenty-one implants were wide.

The length of the implants placed in the study were categorized into short, with a length of less than 8mm; standard, with a length between 8-12mm; and long, with a length of greater than 12mm. Three implants were short, seventy implants were standard, and eight implants were long.

4.3.2 Implant Site Factors

Fifty-three implants were placed in the maxilla and twenty-eight implants were placed in the mandible. Twenty-four implants were placed in the anterior region, including the incisors and/or canine sites. Twenty-eight implants were placed in the premolar region. Twenty-nine implants were placed in the molar region. Specific implant sites were recorded, according to the Fédération Dentaire Internationale (FDI) notation system. However, the implant site was not specifically analyzed in the accuracy analysis.

Forty-six implants were placed into bone with no history of previous bone grafting. Ten implants were placed into sites that had been grafted with allogeneic particulate graft only. Seven implants were placed into sites that had been block grafted. Fifteen implants were placed into sites that where the maxillary sinus had been augmented with allogeneic bone. Three implants were placed into sites where there was previously a combination of block graft and sinus augmentation.

4.3.3 Surgical Guide Factors

Forty-two implants were placed using pilot guided surgery, twenty-eight implants were placed using partially guided surgery, and eleven implants were placed using fully guided surgery.

The number of teeth supporting the guide ranged from 7-13. The number of obviously restored teeth in the dental arch being treated ranged from 0-13. The number of unrestored teeth in the dental arch being treated ranged from 0-13.

Sixty-six implants were placed between two adjacent crowns. Fifteen implants were placed into a site with one adjacent crown, with the remainder of the ridge as a free-end.

4.3.4 Additional Factors

Implants were placed by five different staff Oral and Maxillofacial surgeons and three different Oral and Maxillofacial surgery residents. Staff surgeon A placed 1 implant. Staff surgeon B placed 3 implants. Staff surgeon C placed 13 implants. Staff surgeon D placed 31 implants. Staff surgeon E placed 21 implants. Oral and Maxillofacial surgery residents were grouped together and placed 12 implants in Group F.

Number of days since first patient was tabulated from 0-405 days throughout the study. This was recorded for each patient starting from zero days for the first patient's surgery and counting until each patient's implant surgery date. This was recorded to determine if accuracy improved with increased experience with the workflow.

4.4 Primary Outcome – Accuracy Analysis

Refer to table 7 for a summary of the accuracy analysis.

4.4.1 Angle Deviation

For all implants in the study, the mean and standard deviation of angle deviation of planned versus achieved implant position was 4.97 ±3.16°.

A square root transformation was performed to normalize the angle deviation variable. Regression model diagnostic checking confirmed that using square root of angle deviation resulted in the model fitting better than using the angle deviation variable directly. The linear regression model according to the smallest AIC (Akaike Information Criteria) is the model:

Square Root Angle Deviation ~ Number of Days Since First Patient + Implant Diameter + Guide type + Number of Obviously Restored Teeth + Number of Unrestored Teeth + Implant Location

The F statistic for this regression was 5.025 on 9 and 71 degrees of freedom with a p-value of 3.073×10^{-5}. Therefore, the model is statistically significant. The multiple R-squared for this model was 0.3891. The adjusted R-squared for this model was 0.3117. Therefore, approximately 31% of the total variance in angle deviation can be explained by the current model with these predictor variables. The significant variables from the Analysis of Variance (ANOVA) for this model include implant location with a p-value of 0.0018, guide type with a p-value of 0.0035 and number of unrestored teeth with a p-value of 0.026.

4.4.1.1 Implant Location Versus Angle Deviation

A comparison of the mean and standard deviation for anterior, vs. premolar, vs. molar locations demonstrated an angle deviation of 3.99 ±1.92°, vs. 5.20 ±3.66°, vs. 5.56 ±3.37° respectively. Tukey multiple comparisons of means with 95% family-wise confidence intervals was performed for implant location. This test demonstrated a statistically significant difference between anterior and premolar locations with a p-value of 0.010. There was also a statistically significant difference between anterior and molar locations with a p-value of 0.049. There was no statistically significant difference between premolar and molar locations with a p-value of 0.787. Therefore, anterior

implant location resulted in the least angle deviation compared to premolar and molar locations. This result was statistically significant.

4.4.1.2 Guide Type Versus Angle Deviation

A comparison of the mean and standard deviation for pilot guided, vs. partially guided, vs. fully guided surgery demonstrated an angle deviation of 5.38 ±3.16°, vs. 5.47 ±3.25°, vs. 2.15 ±0.63° respectively.

Tukey multiple comparisons of means with 95% family-wise confidence intervals was also performed for guide type. This analysis demonstrated no statistical difference between pilot guided and partially guided surgery for angle deviation with a p-value of 0.989. This analysis did demonstrate a significant difference between pilot guided and fully guided surgery, as well as a significant difference between partially guided and fully guided surgery, with p-values of 0.0092 and 0.018 respectively.

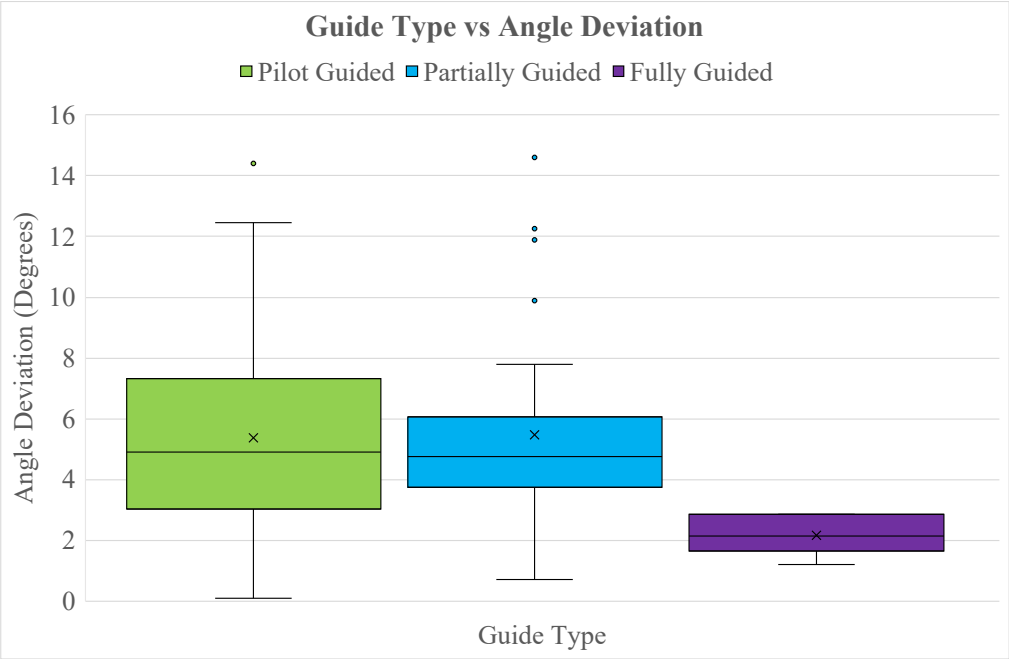
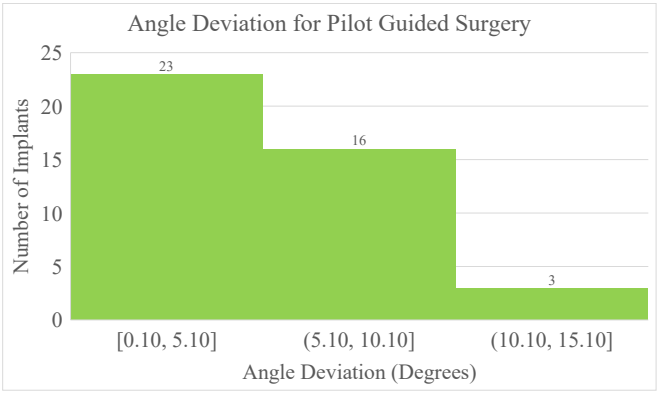


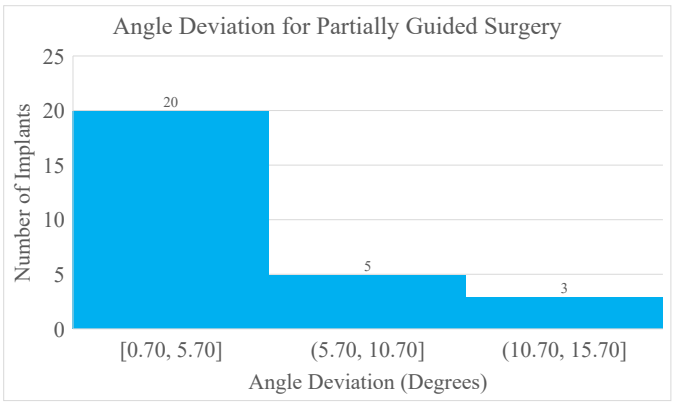
Figure 14: Box Plot of Guide Type vs. Angle Deviation

The box plot shows a five number summary. The minimum and maximum values are shown by the boundaries and are calculated by excluding outliers. The coloured portion represents the first quantile to the third quantile. The median angle deviation is represented by the horizontal line in the middle of each box plot. The mean angle deviation is marked by the "X". Interquantile range (IQR) is the third quantile minus the first quantile. Outliers are defined as larger than median by +1.5*IQR or less than median -1.5*IQR. The outliers are the circles shown outside the boundary. There was one outlier in the pilot guided group with an angle deviation of 14.40°. There were four outliers in the partially guided group with angle deviations of 9.90°, 11.90°, 12.25° and 14.60°. There were no outliers in the fully guided group.

A:



B:



C:

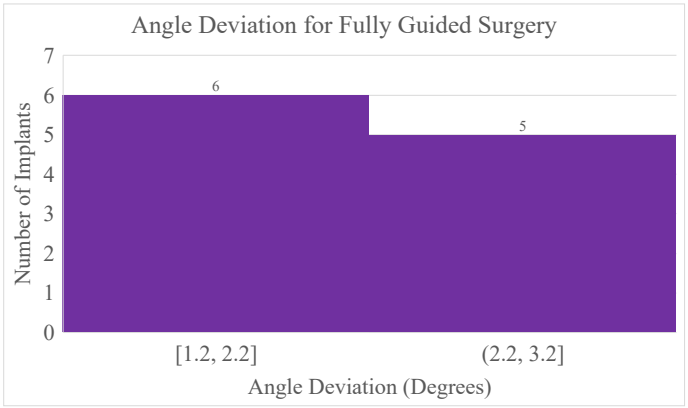


Figure 15: Histograms of Angle Deviation as a Function of Guide Type

A: Pilot Guided, B: Partially Guided, C: Fully Guided. On the x-axis, angle deviation in degrees is categorized into different ranges, shown by the numbers in brackets. On the y-axis, the number of implants is plotted. For pilot guided and partially guided surgery, angle deviation is right skewed. This means that most of the implants fall into the categories of lower angle deviation, with some outliers affecting the mean. For fully guided surgery, the maximum angle deviation was 2.85°.

4.4.1.3 Number of Unrestored Teeth Versus Angle Deviation

Number of unrestored teeth was also demonstrated by the regression analysis to result in significantly different means for angle deviation with a p-value of 0.026. However, there are thirteen different groups for number of unrestored teeth, with some groups having only a single implant. Additionally, there is no linear relationship relating the number of unrestored teeth to angle deviation. Therefore, there are no meaningful conclusions relating the number of unrestored teeth to the angle deviation achieved.

4.4.1.4 Summary for Angle Deviation

In summary, implant location, guide type, and number of unrestored teeth had a significant effect on angle deviation. Implants placed in the anterior region resulted in the least angle deviation. Angle deviation in the anterior region was significantly less than angle deviation in the premolar and molar regions. Fully guided surgery resulted in significantly less angle deviation compared to pilot guided and partially guided surgery.

4.4.1.5 Variables with no Effect on Angle Deviation

Age, sex, number of days since first patient, implant system, implant diameter, implant length, history of bone grafting, surgeon, number of teeth supporting the guide, number of obviously restored teeth, adjacent crowns and dentoalveolar arch treated did not have an impact on angle deviation.

4.4.2 3D Offset at Implant Platform

For all implants in the study, the mean and standard deviation of 3D offset of the planned versus achieved implant position at the platform of the implant was 0.84 ±0.47mm.

A square root transformation was performed to normalize the 3D offset at the implant platform variable. Regression model diagnostic checking confirmed that using square root of 3D offset at the implant platform resulted in the model fitting better than using the 3D offset at implant platform variable directly. The linear regression model according to the smallest AIC (Akaike Information Criteria) is the model:

Square Root 3D Offset at Implant Platform ~ Implant System + Implant Diameter + Surgeon + Number of Teeth Supporting the Guide + Number of Obviously Restored Teeth + Number of Unrestored Teeth

The F statistic for this regression was 2.76 on 15 and 65 degrees of freedom with a p-value of 0.0024. Therefore, the model is statistically significant. The multiple R-squared for this model was 0.3891. The adjusted R-squared for this model was 0.2481. Therefore, approximately 25% of the total variance in 3D offset at the implant platform can be explained by the current model with these predictor variables. The significant variables from the Analysis of Variance (ANOVA) include implant system with a p-value of 0.0069, implant diameter with a p-value of 0.013 and number of unrestored teeth with a p-value of 0.016.

4.4.2.1 Implant System Versus 3D Offset at Implant Platform

Tukey multiple comparisons of means with 95% family-wise confidence intervals was performed for implant system. It was found that Straumann BLX were associated with significantly less 3D offset at the implant platform, compared to than Nobel Replace CC with a p-value of 0.0020. The mean and standard deviation of Straumann BLX implants versus Nobel Replace CC implants for 3D offset at the implant platform were 0.56 ±0.30mm vs. 0.99 ±0.45mm respectively. Implant system was found to be confounding with guide type. The linear regression model for square root of 3D offset at implant platform was refit using the variable guide type instead of implant system. This resulted in the model:

Square Root 3D Offset at Implant Platform ~ Guide Type + Implant Diameter + Surgeon + Number of Teeth Supporting the Guide + Number of Obviously Restored Teeth + Number of Unrestored Teeth

The F statistic for this regression was 2.191 on 12 and 68 degrees of freedom with a p-value of 0.022. Therefore, this model was still statistically significant. The multiple R-squared for this model was 0.2788. The adjusted R-squared for this model was 0.1515. Therefore, approximately 15% of the total variance in 3D offset at the implant platform

could be explained by the refit model with the predictor guide type. This contrasts with the previous model including the variable implant system, in which approximately 25% of the total variance in 3D offset at the implant platform could be explained by the predictor variables. Therefore, this refit model did not explain the variance in the data as well as the original model. The reason this model was created was to show the effect of the variable guide type, which was found to be confounding with implant system. The significant variables from the Analysis of Variance (ANOVA) for this model include guide type with a p-value of 0.0041 and implant diameter with a p-value of 0.036.

4.4.2.2 Guide Type Versus 3D Offset at Implant Platform

A comparison of the mean and standard deviation for pilot guided, vs. partially guided, vs. fully guided surgery has demonstrated 3D offset at the platform of the implant to be 0.92 ±0.52mm, vs. 0.86 ±0.39mm, vs. 0.47 ±0.18mm respectively. Using the model refit for guide type, Tukey multiple comparisons of means with 95% family-wise confidence intervals was performed for guide type. There was no statistical difference between pilot and partially guided surgery for 3D offset at the implant platform with a p-value of 0.677. There was a significant difference between pilot guided and fully guided surgery, as well as a significant difference between partially guided and fully guided surgery, with p-values of 0.0028 and 0.023 respectively.

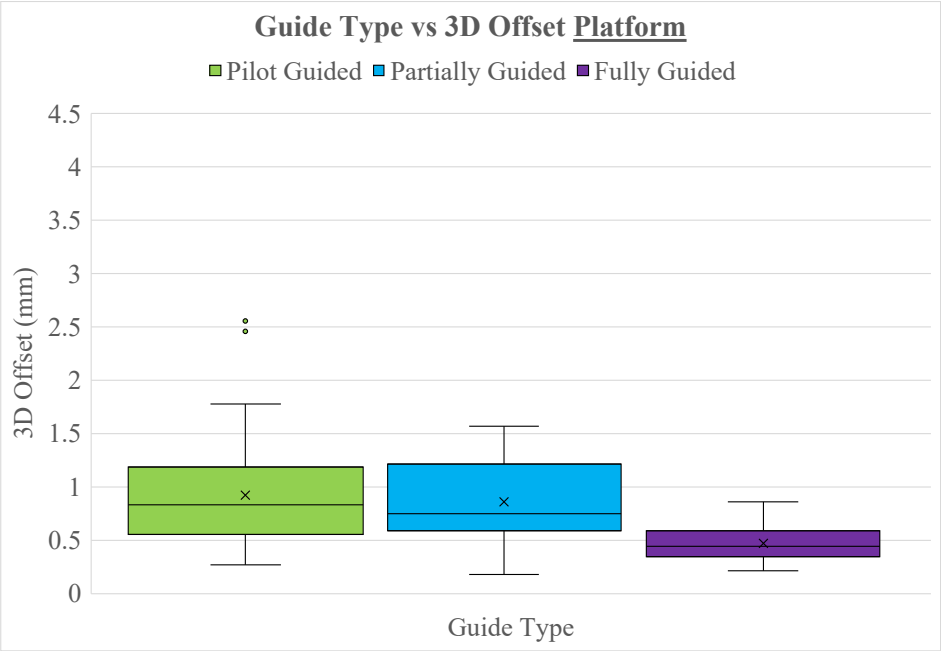
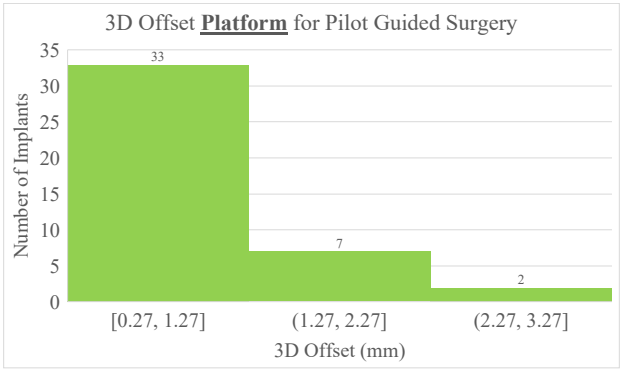


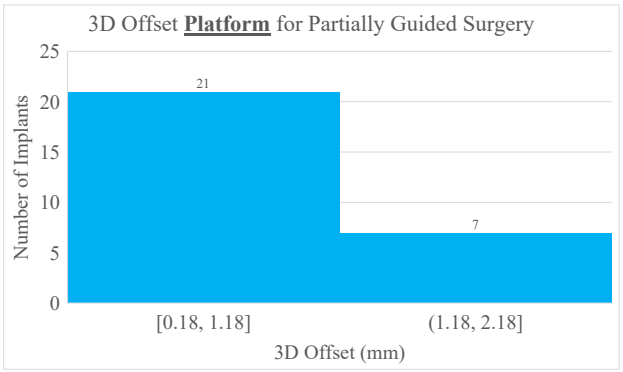
Figure 16: Box Plot of Guide Type vs. 3D Offset at Implant Platform

There are two outliers in the pilot guided group, at 2.46mm and 2.56mm. There are no outliers in the partially guided or fully guided groups.

A:



B:



C:

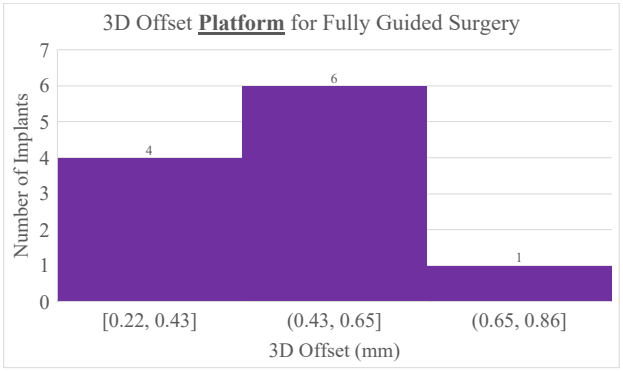


Figure 17: Histograms of 3D Offset at Implant Platform as a Function of Guide Type

A: Pilot Guided, B: Partially Guided, C: Fully Guided. On the x-axis, 3D offset at the implant platform in millimeters is categorized into different ranges, shown by the numbers in brackets. On the y-axis, the number of implants is plotted. For pilot guided and partially guided surgery, 3D offset at the implant platform is right skewed. This means that most of the implants fall into the categories of lower 3D offset at the implant platform, with some outliers affecting the mean. For fully guided surgery, the maximum 3D offset at the platform of the implant was 0.59mm.

4.4.2.3 Implant Diameter Versus 3D Offset at Implant Platform

A comparison of the mean and standard deviation for narrow diameter, vs. regular diameter, vs. wide diameter has demonstrated 3D offset at the platform of the implant to be 1.03 ±0.58mm, vs. 0.78 ±0.38mm, vs. 0.67 ±0.34mm respectively.

Using the original model, according to the smallest AIC with the variable implant system, implant diameter was found to be significant by ANOVA with a p-value of 0.013. Tukey multiple comparisons of means with 95% family-wise confidence intervals was performed for implant diameter. Using this analysis, implant diameter did not have a significant impact on 3D offset at the implant platform.

In the refitted model with the variable guide type replacing the variable implant system, implant diameter was again found to be significant by ANOVA, with a p-value of 0.036. Tukey multiple comparisons of means with 95% family-wise confidence intervals was also repeated for implant diameter using this refitted model. There was a significant difference between narrow platform and wide platform with a p-value of 0.035. There was no significant difference between narrow platform and regular platform, or regular platform and wide platform, with p-values of 0.284 and 0.453 respectively.

In summary, implant diameter was shown to be significant by the ANOVA test for both models. However, Tukey multiple comparisons of means with 95% family-wise confidence intervals demonstrated that implant diameter had variable significance on 3D offset at the implant platform depending on the model chosen. Where implant diameter demonstrated a significant difference, it was between narrow diameter and wide diameter implants, with wide diameter implants associated with less 3D offset at the implant platform. This effect was marginally significant with a p-value of 0.035.

4.4.3.4 Summary for 3D Offset at Implant Platform

In summary, implant system, implant diameter and number of unrestored teeth had a significant effect on 3D offset at implant platform. Straumann BLX were associated with significantly less 3D offset at the implant platform, compared to than Nobel Replace CC implants. However, implant system was found to be confounding with guide type.

Fully guided surgery resulted in significantly less 3D offset at the implant platform compared to pilot guided and partially guided surgery. Implant diameter was variably shown to be significant for affecting 3D offset at the implant platform. Where implant diameter demonstrated a significant difference, wide platform implants were associated with less 3D offset at the implant platform compared to narrow platform implants. However, this effect was only marginally significant.

4.4.3.5 Variables with no Effect on 3D Offset at Implant Platform

Age, sex, number of days since first patient, implant length, bone grafting, surgeon, number of teeth supporting the guide, number of obviously restored teeth, adjacent crowns and dentoalveolar arch treated and implant location did not have an impact on 3D offset at the implant platform.

4.4.3 3D Offset at Implant Apex

For all implants in the study, the mean and standard deviation of 3D offset of the planned versus achieved implant position at the apex of the implant was 1.33 ±0.79mm.

A square root transformation was performed to normalize the 3D offset at the implant apex variable. Regression model diagnostic checking confirmed that using square root of 3D offset at the implant apex resulted in the model fitting better than using the 3D offset at the implant apex variable directly. The linear regression model according to the smallest AIC (Akaike Information Criteria) is the model:

Square Root 3D Offset at Implant Apex ~ Implant System + Implant Diameter + Number of Teeth Supporting the Guide + Number of Unrestored Teeth + Implant Location

The F statistic for this regression was 4.589 on 11 and 69 degrees of freedom with a p-value of 3.302×10^{-5}. Therefore, the model is statistically significant. The multiple R-squared for this model was 0.4225. The adjusted R-squared for this model was 0.3304. Therefore, approximately 33% of the total variance in 3D offset at the apex of the implant can be explained by the current model with these predictor variables. The significant

variables from the Analysis of Variance (ANOVA) include implant system with a p-value of 0.00037, number of teeth supporting the guide with a p-value of 0.0020 and implant diameter with a p-value of 0.038.

4.4.3.1 Implant System Versus 3D Offset at Implant Apex

Tukey multiple comparisons of means with 95% family-wise confidence intervals was performed for implant system. Straumann BLX implants had significantly less 3D offset at the implant apex compared to Nobel Replace CC implants and Nobel Parallel CC implants with p-values of 0.00012 and 0.032 respectively. The mean and standard deviation of Straumann BLX versus Nobel Replace CC versus Nobel Parallel CC implants for 3D offset at the implant apex was 0.79 ±0.34mm, vs. 1.60 ±0.74mm, vs. 1.49 ±1.02mm respectively. There were no other significant differences for 3D offset at the implant apex between the implant systems.

Similar to 3D offset at implant platform, the variables guide type and implant system were confounding variables for 3D offset at implant apex. The linear regression model for square root of 3D offset at implant apex was refit using the variable guide type instead of implant system. This resulted in the model:

Square Root 3D Offset at Implant Apex ~ Guide Type + Implant Diameter + Number of Teeth Supporting the Guide + Number of Unrestored Teeth + Implant Location

The F statistic for this regression was 3.161 on 8 and 72 degrees of freedom with a p-value of 0.0040. Therefore, this model was still statistically significant. The multiple R-squared for this model was 0.2599. The adjusted R-squared for this model was 0.1777. Therefore, approximately 18% of the total variance in 3D offset at the implant apex could be explained by the refit model with the predictor guide type. This contrasts with the previous model including the variable implant system, in which approximately 33% of the total variance in 3D offset at the implant apex could be explained by the predictor variables. Therefore, the linear regression model including the variable implant system was overall a better model for explaining the variance in 3D offset at the implant apex,

compared to including the variable guide type. Nonetheless, when the variable implant system was replaced with the variable guide type to refit the linear regression model, guide type demonstrated a significant effect on 3D offset at the implant apex. Depending on the variable chosen for the linear regression model, both demonstrated a significant effect on 3D offset at the implant apex. The only significant variable from the Analysis of Variance (ANOVA) for this model was guide type with a p-value of 0.0034.

4.4.3.2 Guide Type Versus 3D Offset at Implant Apex

A comparison of the mean and standard deviation for pilot guided, vs. partially guided, vs. fully guided surgery has demonstrated 3D offset at the apex of the implant to be 1.43 ±0.63mm, vs. 1.42 ±1.01mm, vs. 0.70 ±0.28mm respectively. Using the model refit for guide type, Tukey multiple comparisons of means with 95% family-wise confidence intervals was performed for guide type. There was no statistical difference between pilot and partially guided surgery for 3D offset at the implant apex with a p-value of 0.854. There was a significant difference between pilot guided and fully guided surgery, as well as a significant difference between partially guided and fully guided surgery, with p-values of 0.0025 and 0.012 respectively.

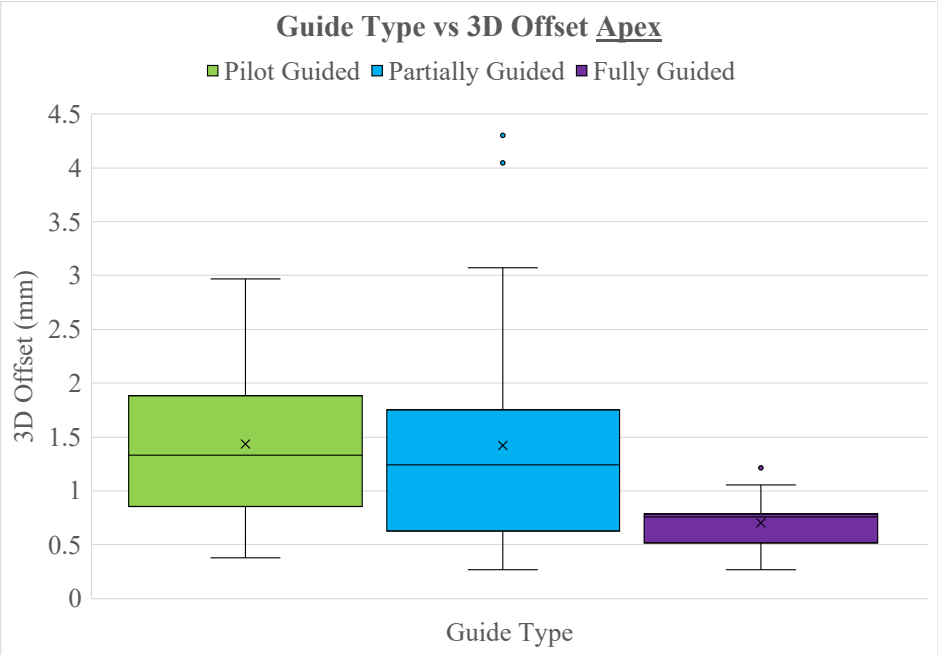
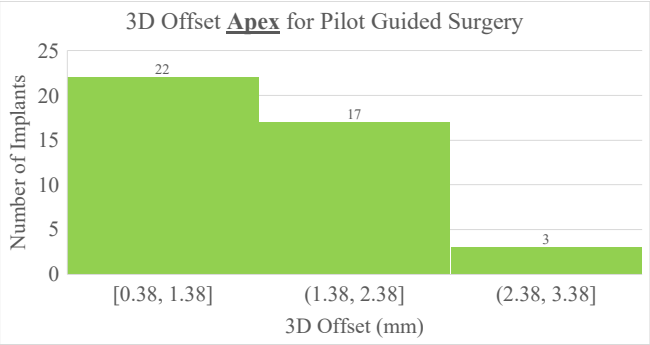


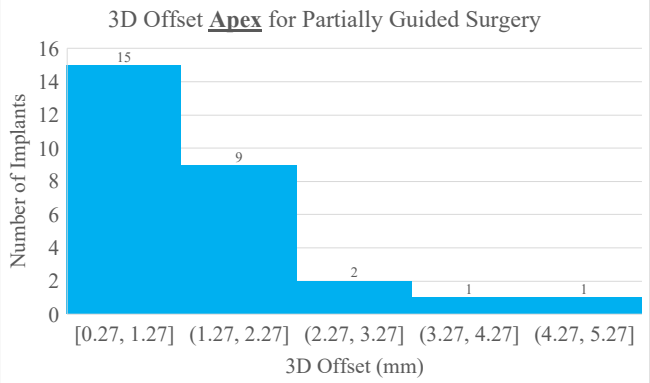
Figure 18: Box Plot of Guide Type vs. 3D Offset at Implant Apex

There are no outliers in the pilot guided group. There are two outliers in the partially guided group at 4.05mm and 4.30mm. There is one outlier in the fully guided group at 1.22mm. The apical vector of inaccuracy in this outlier was 0.73mm. This was the implant with the greatest apical deviation in the fully guided group.

A:



B:



C:

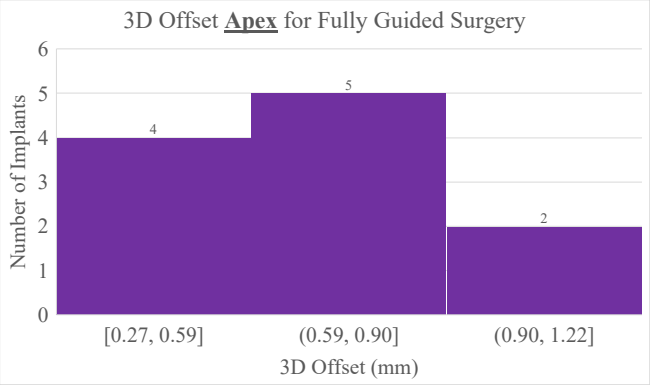


Figure 19: Histograms of 3D Offset at Implant Apex as a Function of Guide Type

A: Pilot Guided, B: Partially Guided, C: Fully Guided. On the x-axis, 3D offset at the implant apex in millimeters is categorized into different ranges, shown by the numbers in brackets. On the y-axis, the number of implants is plotted. For pilot guided and partially guided surgery, 3D offset at the implant apex is right skewed. This means that most of the implants fall into the categories of lower 3D offset at the implant platform, with some outliers affecting the mean. For fully guided surgery, the maximum 3D offset at the apex of the implant was 1.22mm.

4.4.3.3 Number of Teeth Supporting the Guide Versus 3D Offset at Implant Apex

Number of teeth supporting the guide also had a significant effect on 3D offset at the implant apex with a p-value of 0.0020. However, there are seven different groups for number of teeth supporting the guide, with some groups having as few as two implants. Additionally, there is no linear relationship relating the number of teeth supporting the guide to 3D offset at the apex of the implant. Therefore, there are no meaningful conclusions relating number of teeth supporting the guide to the 3D offset at the implant apex.

4.4.3.4 Implant Diameter Versus 3D Offset at Implant Apex

A comparison of the mean and standard deviation for narrow diameter, vs. regular diameter, vs. wide diameter has demonstrated 3D offset at the apex of the implant to be 1.60 ±0.88mm, vs. 1.18 ±0.75mm, vs. 1.21 ±0.65mm respectively. Using the original model, according to the smallest AIC with the variable implant system, implant diameter was found to be significant by ANOVA with a p-value of 0.038. However, Tukey multiple comparisons of means with 95% confidence intervals was also performed and there was no significant difference between the means of the groups for 3D offset at the implant apex.

4.4.3.5 Summary for 3D Offset at Implant Apex

In summary, implant system, number of teeth supporting the guide and implant diameter had a significant effect on 3D offset at implant apex. Straumann BLX implants had significantly less 3D offset at the implant apex compared to Nobel Replace CC and Nobel Parallel CC implants. However, implant system was found to be confounding with guide type. Fully guided surgery resulted in significantly less 3D offset at the implant apex compared to pilot guided and partially guided surgery. There were no meaningful conclusions to draw regarding number of teeth supporting the guide and 3D offset at the implant apex. Implant diameter was significant by ANOVA, however the effect was only marginally significant and Tukey multiple comparisons of means with 95% family-wise

confidence intervals did not demonstrate any difference between the means of narrow vs. regular vs. wide diameter implants.

4.4.3.6 Variables with no Effect on 3D Offset at Implant Apex

Age, sex, number of days since first patient, implant length, bone grafting, surgeon, number of obviously restored teeth, number of unrestored teeth, adjacent crowns and dentoalveolar arch treated and implant location did not have an impact on 3D offset at the implant apex.

4.4.4 Accuracy Analysis – Deviation in the X, Y and Z Axes

The Treatment Evaluation tool for each case calculated the deviation at the implant platform and apex for the parameters in the X-axis (Distal), Y-axis (Apical) and Z-axis (Vestibular). Within the Treatment Evaluation tool, for the X-axis, distal is denoted as a positive number whereas mesial is denoted as a negative number. For the Y-axis, towards the apex is denoted as a positive number, whereas towards the platform is denoted as a negative number. For the Z-axis, towards the vestibule is denoted as a positive number and towards the palate or lingual aspect is denoted as a negative number.

4.4.4.1 Average Deviation at X, Y and Z Axes at Implant Platform and Apex

The average deviation at the implant platform for the different axes, including Distal, Apical and Vestibular are 0.07mm, 0.00mm and -0.01mm respectively. For each axis, a t-test was performed with the null hypothesis that each mean is equal to zero. The p-value of these tests were all > 0.05. Therefore, the null hypothesis cannot be rejected. This means that the average deviation at the platform of the implant in each axis is not significantly different from zero. An ANOVA analysis was also performed with the null hypothesis that each axis has the same mean. The p-value of this test was 0.631. Therefore, the null hypothesis cannot be rejected. This translates to the finding that the means of the different axes are not significantly different from each other. Tukey multiple comparisons of means with 95% family-wise confidence intervals also confirms that the means are not significantly different from each other. This informs us that at the platform

of the implant inaccuracies in implant placement were on average statistically equal in both the positive and negative vectors for each of the different axes.

The average deviation at the implant apex for the different axes, including Distal, Apical and Vestibular are 0.05mm, 0.06mm and 0.17mm respectively. Again, for each axis, a t-test was performed with the null hypothesis that each mean is equal to zero. The p-value of these tests were all > 0.05. Therefore, the null hypothesis cannot be rejected. This means that the average deviation at the apex of the implant in each axis is not significantly different from zero. An ANOVA analysis was also performed with the null hypothesis that each axis has the same mean. The p-value of this test was 0.619. Therefore, the null hypothesis cannot be rejected. This translates to the finding that the means of the different axes are not significantly different from each other. Tukey multiple comparisons of means with 95% family-wise confidence intervals also confirms that the means are not significantly different from each other. Similar to the platform of the implant, the inaccuracies in implant placement at the apex were on average statistically equal in both the positive and negative vectors for each of the different axes.

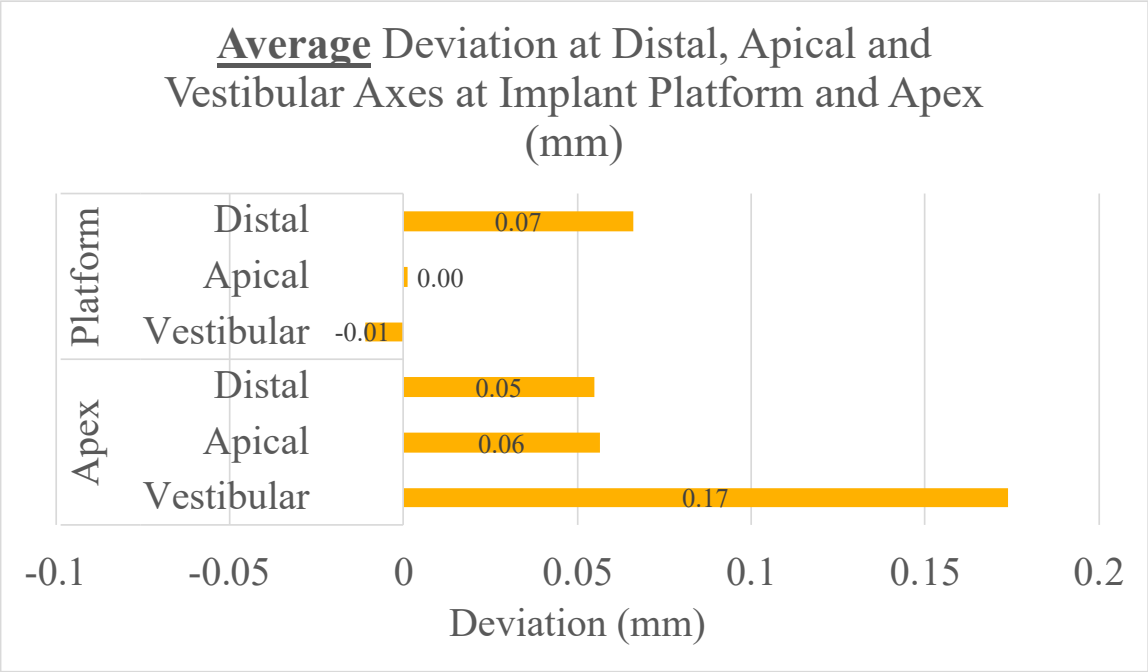


Figure 20: Average Deviation at Apical, Vestibular and Distal Axes at Implant Platform and Apex (mm)

4.4.4.2 Average Absolute Value Deviation at X, Y and Z Axes at Implant Platform and Apex

The average absolute value deviations were also calculated. These values depict on average, how inaccurate the implant placement was in each axis regardless of the vector of the inaccuracy.

The average absolute value deviation at the implant platform for the different axes, including Distal, Apical and Vestibular were calculated as 0.33mm, 0.47mm and 0.41mm respectively. A test that the mean absolute values at the different axes are equal is rejected, with a p-value of 0.041. Therefore, the mean of the absolute values are significantly different each other. Tukey multiple comparisons of means with 95% family-wise confidence intervals confirmed distal and apical are significantly different from each other with a p-value of 0.031. There is no significant difference between vestibular and apical axes, with a p-value of 0.482. There is also no significant difference between vestibular and distal axes, with a p-value of 0.349.

The average absolute value deviation at the implant apex for Distal, Apical and Vestibular were calculated as 0.68mm, 0.48mm and 0.78mm respectively. A test that the mean absolute values at the different axes are the equal is rejected, with a p-value of 0.0066. Therefore, the mean of the absolute values are significantly different from each other. Tukey multiple comparisons of means with 95% family-wise confidence intervals confirmed apical and vestibular significant differences with a p-value of 0.0053. There was no significant difference between distal and apical with a p-value of 0.094. There is also no significant difference between distal and vestibular, with a p-value of 0.542.

Figure 21 summarizes the average absolute value deviations at the different axes of the implant at the platform and apex. These values demonstrate on average, how inaccurate implant placement was in each axis regardless of the vector of inaccuracy. At the implant platform apical deviation is significantly more than distal deviation. At the implant apex, vestibular deviation is significantly more than apical deviation. There were no other significant differences at the implant platform or apex.

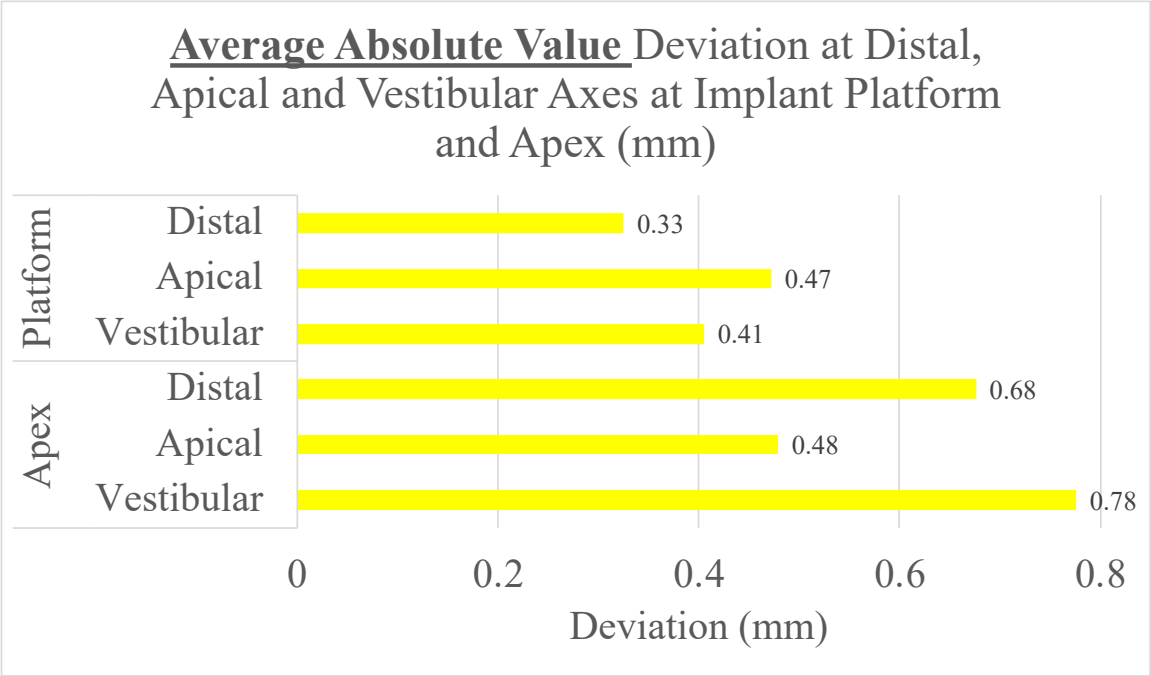


Figure 21: Average Absolute Value Deviation at Apical, Vestibular and Distal Axes at Implant Platform and Apex (mm)

4.4.5 Summary of Variables Affecting Accuracy

Table 7: Summary of Variables Affecting Accuracy

Risk Factor	Group	Number of Implants	Angle Deviation (degrees)					3D Offset Platform (mm)					3D Offset Apex (mm)				
			Mean	SD	95% CI Lower Bound	95% CI Upper Bound	p-value	Mean	SD	95% CI Lower Bound	95% CI Upper Bound	p-value	Mean	SD	95% CI Lower Bound	95% CI Upper Bound	p-value
Grouped Data	All Cases	81	4.97	3.16	4.28	5.66		0.84	0.47	0.74	0.94		1.33	0.79	1.16	1.50	
Implant Location	Anterior	24	3.99	1.92	3.18	4.80		0.98	0.51	0.76	1.19		1.30	0.58	1.05	1.55	
	Premolar	28	5.20	3.66	3.78	6.62	0.00018***	0.83	0.50	0.64	1.03		1.39	1.03	1.00	1.79	0.172
	Molar	29	5.56	3.37	4.28	6.85		0.73	0.37	0.59	0.87		1.30	0.70	1.03	1.56	
Implant System	Nobel Replace CC	37	5.67	3.18	4.61	6.73		0.99	0.45	0.84	1.14		1.60	0.74	1.35	1.85	
	Nobel Parallel CC	13	5.98	3.30	3.99	7.98		0.89	0.62	0.52	1.27		1.49	1.02	0.87	2.10	
	Straumann BLX	19	2.69	1.33	2.05	3.33		0.56	0.30	0.42	0.70	0.0069**	0.79	0.34	0.63	0.96	0.00037***
	Straumann TLX	8	6.34	3.94	3.05	9.63		0.70	0.42	0.35	1.05		1.16	0.92	0.39	1.93	
	Straumann BLT	3	2.50	0.63	0.94	4.06		0.94	0.44	-0.16	2.05		1.03	0.38	0.10	1.96	
	Astra EV Straight	1	5.9	-	-	-		0.74	-	-	-		1.83	-	-	-	
Number of Teeth Supporting the Guide	7	4	2.81	0.14	2.58	3.04		1.18	0.37	0.59	1.76		1.39	0.68	0.31	2.47	
	8	2	5.03	1.87	-11.81	21.86		0.90	0.16	-0.50	2.29		1.05	0.27	-1.34	3.43	
	9	17	4.82	3.17	3.19	6.45		0.86	0.40	0.66	1.07		1.15	0.50	0.89	1.41	
	10	25	5.09	3.59	3.61	6.58		0.80	0.53	0.58	1.02	0.909	1.35	0.90	0.98	1.72	0.0020**
	11	21	4.72	2.73	3.48	5.96		0.74	0.50	0.52	0.97		1.20	0.72	0.87	1.53	
	12	10	6.51	3.72	3.85	9.17		0.92	0.45	0.59	1.24		1.84	1.11	1.05	2.64	
	13	2	4.00	2.05	-14.42	22.42		1.06	0.55	-3.87	5.98		1.56	0.13	0.38	2.73	
Guide Type	Pilot Guided	42	5.38	3.16	4.40	6.36		0.92	0.52	0.76	1.08		1.43	0.63	1.24	1.63	
	Partially Guided	28	5.47	3.25	4.21	6.73	0.0035**	0.86	0.39	0.71	1.01	✦0.0041**	1.42	1.01	1.03	1.82	✦0.0034**
	Fully Guided	11	2.15	0.63	1.73	2.58		0.47	0.18	0.35	0.59		0.70	0.28	0.51	0.89	
Implant Diameter (mm)	Narrow (≤3.75)	28	5.49	3.15	4.27	6.72		1.03	0.58	0.81	1.26	0.013*	1.60	0.88	1.25	1.94	
	Regular (3.75 - <5)	32	4.54	3.32	3.35	5.74	0.136	0.78	0.38	0.64	0.92	✦0.036*	1.18	0.75	0.91	1.45	0.038*
	Wide (≥5)	21	4.93	2.96	3.58	6.27		0.67	0.34	0.52	0.83		1.21	0.65	0.92	1.51	
Number of Unrestored Teeth	0	6	3.88	2.52	1.23	6.52		1.08	0.42	0.64	1.52		1.57	0.49	1.05	2.09	
	2	3	4.63	2.17	-0.75	10.02		0.51	0.14	0.16	0.86		1.16	0.57	-0.25	2.58	
	3	19	5.18	2.78	3.84	6.52		0.96	0.45	0.74	1.18		1.45	0.85	1.04	1.86	
	4	3	8.52	5.31	-4.68	21.71		0.98	0.31	0.22	1.74		2.08	1.95	-2.78	6.93	
	5	9	5.13	4.04	2.03	8.25		1.00	0.65	0.50	1.49		1.42	0.80	0.81	2.04	
	6	9	7.33	2.34	5.53	9.12		0.68	0.31	0.45	0.92		1.42	0.60	0.95	1.88	
	7	8	4.11	2.16	2.30	5.92	0.026*	0.90	0.41	0.56	1.25	0.016*	1.19	0.58	0.71	1.68	0.075
	8	6	4.90	3.95	0.75	9.05		0.67	0.47	0.18	1.17		1.14	0.98	0.11	2.17	
	9	9	3.68	3.57	0.94	6.42		0.50	0.19	0.35	0.64		0.90	0.55	0.47	1.33	
	10	4	5.94	1.87	2.96	8.92		1.28	0.86	-0.09	2.65		1.93	0.69	0.83	3.03	
	11	1	1.60	-	-	-		0.68	-	-	-		0.55	-	-	-	
	12	1	2.70	-	-	-		0.59	-	-	-		1.06	-	-	-	
	13	3	2.00	0.52	0.70	3.30		0.52	0.11	0.25	0.78		0.58	0.27	-0.10	1.25	

✦ Refit Model

Significant codes: 0 ***, 0.001 **, 0.01 *

4.5 Dropouts

There were sixty-one patients recruited to the study. Fifteen patients were excluded. Four patients were excluded because the surgery date was moved up and the researchers were not informed. Four patients were originally enrolled, but ultimately removed due to meeting the exclusion criterion. Three of those patients had limited mouth opening, the fourth patient was edentulous. Two patients were removed since no post-operative CBCT was taken. One patient was excluded due to an error message in coDiagnostiX™ that the surgical guide did not match the treatment plan. The researchers could not be certain if the treatment plan changed before or after printing the surgical guide. One patient was excluded because the guide did not fit well. One patient was excluded because the surgeon did not like the surgical plan and preferred to place the implant free-handed. One patient cancelled their surgery. For one patient, the guided surgery kits were not available the day of the surgery.

4.6 Time Analysis

The time required for in-office fabrication of implant surgical guides was recorded for a subset of the data. Starting with patient number twenty-nine, the fabrication process was timed for seventeen patients. On average it took 28 minutes to plan each implant case on coDiagnostiX™. 3D printing of the guides was not timed, however the time required to print a single surgical guide is relatively consistent and took approximately 65 minutes. The alcohol wash and the curing each take 30 minutes, for a combined 60 minutes. Then final inspection, insertion and cementation of the guide sleeves and printing of the plan takes another 20 minutes on average. This results in 48 minutes of active attention required for fabrication of a single surgical guide with a single guide sleeve.

4.7 Cost Analysis

Expenses throughout the study were tracked. Expenses were categorized into variable expenses that were consumable and could be amortized over several surgeries, and fixed expenses that we constant regardless of the number of surgeries performed. For

the variable expenses, consumption was approximated for some of the variables. The Dental Wings coDiagnostiX™ annual subscription is $700. This was amortized over fifty surgical guides per year. The surgical guide resin was also amortized based on the assumption that one-hundred guides could be made from one litre of resin. This is approximated from the printer, which states that approximately ten millilitres of resin are consumed per surgical guide. It was also approximated that the resin tank and RelyX Self-Adhesive Resin Cement cartridge would require replacement following fabrication of fifty surgical guides. Additional expenses for taxes and shipping were not tabulated. For the variable expenses, another factor to consider is the cost of human resources for guide fabrication. Since approximately 48 minutes of active attention is required for fabrication of a single surgical guide with a single guide sleeve, the human resources cost would be equivalent to 0.8 (48 minutes/60minutes) multiplied by the hourly rate for the staff member that would be fabricating the surgical guide.

Table 8: Variable Expenses

Brand	Product	List Price	Cost Per Case (CND)
Dentsply Sirona	Primescan Intraoral Scanner Disposable Replacement Covers 50/box	300.99	6.02
Dental Wings	coDiagnostiX “Click Fee” (per case)	69	69
	coDiagnostiX Annual Subscription	700	14 *
formlabs	Surgical Guide Resin 1L	249 USD	3.49 💰
	Form 3 Resin Tank V2.1	149 USD	4.17 💰
Additional 3D Printing	Isopropyl Alcohol 99% solution 4L	68.69	2.75
Nobel Biocare	Guided Pilot Drill Sleeve 2.0 mm (single)	33	33
	Guided Pilot Drill Sleeve 2.0 mm (20/package)	601	30.05
	Guided Sleeve NP	33	33
	Guided Sleeve RP	33	33
	Guided Sleeve 6.0/WP	33	33
Straumann	T-sleeve, self-locking, guided, diameter 5mm, height 5mm, PEEK	59	14.75
	T-sleeve, guided, diameter 2.2mm, height 6mm, SS	66	16.50
	T-sleeve, guided, diameter 2.8mm, height 6mm, SS	66	16.50
3M	ESPE RelyX Unicem 2 Automix Self-Adhesive Resin Cement (3-pack)	475.92	3.17
	ESPE RelyX Unicem 2 Automix - mixing tips refill (15 per package)	45.71	3.05

*Based on 50 cases/year

💰 assuming USD to CND conversion rate of 1.4

Table 9: Summary of Variable Expenses Per Case

Type of Guide	Total Expense Per Case* (CND)
Nobel Biocare Pilot Guided Surgery	135.70
Nobel Biocare Fully Guided Surgery	138.65
Straumann Pilot Guided Surgery	122.15
Straumann Fully Guided Surgery	120.40

*Based on 50 cases per year

The estimated cost per case for in-office guide fabrication, paying full price for the components is roughly between $120 to $139 (CND) depending on the guide type used. This would represent a guide with a single surgical sleeve. Additional sleeves add approximately $15 to $33 (CND) per sleeve. This assumes approximately 50 implant guides are being fabricated per year to amortize the coDiagnostiX™ annual subscription fee. This also assumes that the USD to CND conversion rate is 1.4. This does not consider the human resources cost, as it will vary based on the hourly rate for the staff member fabricating the surgical guides.

Table 10: Fixed Expenses

Brand	Product	List Price	Actual Cost (CND)
Dexis	CBCT Machine, i-CAT Flex v17	150 633	150 633
Dentsply Sirona	Primescan Intraoral Scanner	38 995	38 995
Dental Wings	coDiagnostiX Producer Version Software	6900	6900
formlabs	3D Printer, Form 3B+	3951 (USD)	5531.40 💰
	Wash Unit	650 (USD)	910 💰
	Cure Unit	750 (USD)	1050 💰
Nobel Biocare	Mounting Tool Pin Guided Pilot Sleeve 2.0 & Mounting Tool Base Guided Pilot Sleeve 1.5/2.0	106	106
	Guided Cylinder with Pin Conical Connection NP, RP 4.3, RP 5.0 & WP	328	328
	Implant Replica Conical Connection NP, RP & WP	159	159
	Fully Guided Nobel Replace Surgical Kit	7 278	7 278
	Fully Guided Nobel Parallel Surgical Kit	7 278	7 278
Straumann	Fully Guided BLX/TLX Surgical Kit	10 475	10 475
	Fully Guided BLT Surgical Kit	10 295	10 295

💰 assuming USD to CND conversion rate of 1.4

CHAPTER 5 – DISCUSSION

The primary objective of this study was to determine the accuracy of an office-based workflow for virtual surgical planning for dental implant surgery using tooth-supported dental implant guides. The secondary objectives included an assessment of the risk factors potentially affecting the accuracy of guided implant surgery as well as an assessment of the time and expenses involved for office-based virtual surgical planning. The investigators hypothesized that this approach would produce acceptable clinical accuracy that was comparable to the literature for outsourced guided surgery and that this approach would be cost effective.

5.1 Comparison of Accuracy with the Literature

The results achieved for accuracy in this study are generally comparable to the results described in the literature. Especially when comparing the results achieved in the fully guided group compared to the results of other studies that performed fully guided surgery. Additionally, the accuracy achieved using an office-based workflow to guide fabrication has been shown to be approximately equivalent to studies in which surgical guide fabrication was outsourced. The results presented in Table 7 can be used as a reference in comparison to the following studies.

Derksen et al published a study similar to the present study in 2019 [19]. This study assessed the accuracy of fully guided, tooth supported surgical guides that were fabricated using a digital workflow in coDiagnostiX™. The study does not state whether the surgical guides were fabricated in-office or if they were outsourced. One-hundred and forty-five implants were placed in sixty-six patients. The implants were all Straumann TLX. The mean and standard deviation for angle deviation was 2.72 ±1.42°. The mean and standard deviation for 3D offset at the implant platform and apex was 0.75 ±0.34mm and 1.06 ±0.44mm respectively [19].

In 2021, Matsumura et al published a retrospective study which assessed the accuracy of partially guided and fully guided, tooth supported surgical guides that were fabricated using a digital workflow in Nobel Clinician software. One-hundred and eighty-eight implants were placed in one-hundred and ten patients. All the implants were manufactured by Nobel Biocare. Accuracy analysis was performed using coDiagnostiX™ software. The mean and standard deviation for angle deviation was 2.5 ±1.6°. The mean and standard deviation for 3D offset at the implant platform and apex was 0.67 ±0.37mm and 0.92 ±0.47mm respectively [20].

Massuda et al in 2022 published a case series employing fully-guided, tooth supported surgical guides with additional guide stability using one or two fixation pins securing the guide to bone. The guides were fabricated using a digital workflow with ImplantViewer 3.5 software. The surgical guides were printed using a Form Labs printer. Eighteen implants were placed in eleven patients using a flapless technique. The mean and standard deviation for angle deviation was 2.68 ±1.62°, 3D offset at the platform and apex was 0.82 ±0.44mm and 1.14 ±0.44mm respectively [21].

Pirooz et al published a study in 2023 which assessed the accuracy of fully guided tooth supported surgical guides that were fabricated using a digital workflow with Implant Studio software. Three-dimensional printing of the surgical guide was outsourced. Fourteen implants were placed in nine patients. The mean and standard deviation for angle deviation was 5.07 ±2.06°. The mean and standard deviation for 3D offset at the apex of the implant was 1.74 ±0.63mm.

In 2012, the European Association for Osseointegration (EAO) Consensus created recommendations for safety distances using virtual planning software to fabricate stereolithographic guides. The EAO set maximum values for deviations including a maximum angle deviation of 4.7°, a maximum horizontal platform deviation of 1.2mm, and a maximum horizontal apical deviation of 1.7mm [22]. However, these numbers are not necessarily set for clinical acceptance as each patient will have variable margins of error according to the status of the surrounding bone and other anatomical structures.

Generally, most studies are reporting results comparable or less than, these deviations. In our study, the mean 3D offset at the implant platform and apex was less than these stated maximums for all guide types. For angle deviation however, the pilot guided, and partially guided groups demonstrated mean angle deviations slightly greater than these stated deviations at 5.38° and 5.47° respectively. Angle deviation in the fully guided group was significantly lower than the recommended maximum angle deviation at 2.15°.

Of course, the primary outcome of this study was to assess accuracy. We must remember however, that accuracy is defined as the difference between the virtually planned position and the achieved implant position. Accuracy does not inform us of the adequacy of the plan. The authors of this study would argue that there are additional benefits to guide fabrication that go beyond what can be measured with accuracy. Hands-on control over the virtual surgical plan allows the operator to appreciate the anatomy and help anticipate difficulties that may be encountered during the surgery. Additionally, for certain cases, it is often difficult to communicate exactly where to prosthetically position the missing teeth and where to position the implant. There are benefits to having the autonomy to fine tune the position of the implant or trial and error a few different positions. Whether in a virtual meeting or in-person, the authors would advocate for a hands-on approach to virtual surgical planning.

5.2 Evaluating Risk Factors with a Significant Effect on Accuracy

For guided implant surgery, deviations between the planned and achieved implant position can vary for multiple reasons. Some of these factors include imprecision while acquiring or processing surface and radiographic imaging data, inaccuracy in the surgical guide fabrication, deficiency in the fit, movement of the guide during surgery and human error [23]. The loss of precision in guided surgery could be attributed to a sequence of small errors at each stage of the process, including errors in obtaining images and data processing, in the planning and preparation of the guide, and in performing the surgery [21]. A thorough understanding of the potential errors is essential, as it allows for the greatest control over these factors when planning and performing guided implant surgery.

In the study by Matsumura et al. initially described above, in addition to an accuracy analysis, their primary objective was to perform a multivariate analysis of causal factors influencing accuracy of guided implant surgery for partial edentulism. In this study 188 implants were placed in 110 patients. Ten factors that seemed to affect errors in placement were selected. Three factors were missing teeth-derived factors: implant location (anterior, premolars and molars), type of edentulism (between adjacent teeth versus free-end defects) and the distance from the remaining teeth (how many missing teeth separated the planned implant site from the closest adjacent tooth). Four factors were implant-derived factors: type of implant, implant length, number of implants and guide type (partially guided versus fully guided). Three factors were guide design-derived factors: number of teeth supporting the surgical guide, number of anchor pins and presence or absence of a cobalt-chromium reinforcement structure. It was shown that there were many factors influencing angle deviation, including distance from remaining teeth to placement position, guide type, and number of teeth supporting the surgical guide with the method of guidance being the most significant ($p<0.001$) [20]. For the 3D offset at the platform and apex, there were similar factors influencing accuracy including implant length, number of teeth supporting the guide, and method of guidance [20]. Details regarding these findings are listed in the relevant subsections below.

In the present study, the independent variables that were chosen for assessment were selected either to test a hypothesis or because other studies reported these independent variables as significantly influencing accuracy of implant placement achieved.

5.2.1 Implant System and Guide Type

Implant system had a significant effect on the accuracy parameters 3D offset at the implant platform and apex. Straumann BLX implants were associated with more accurate implant placement compared to some of the other implants in the study. The drills used to prepare the osteotomy for BLX and TLX implants are the same. The variable that confounded with implant system was guide type. There were 19 Straumann BLX implants placed in the study, and 58% (11/19) of them were placed using fully

guided surgery. In total, there were only 11 implants included in the fully guided group, and all these implants were Straumann BLX. Our interpretation is that BLX implants are not inherently more accurate. They were only found to be more accurate because they were placed fully guided. There are factors about the BLX implant system however, that make the BLX implant a subjectively ideal candidate when opting for fully guided surgery. There is a perceived ease of the BLX fully guided protocol. Additionally, the ergonomic drill handles lend itself to more easily accomplished fully guided surgery. Furthermore, for the Straumann TLX implant system, fully guided surgery is not always possible, as the implant shoulder diameter of the RT and WT implants are wider than the implant itself, and often cannot fit through the guide sleeve.

Only one Astra implant was placed in the study. This implant was pilot guided using a Nobel Biocare guide sleeve. All other implants in the study had genuine guide sleeves for the implant system that was placed. Both Nobel Biocare and Astra keep their guide sleeve information proprietary. Significant trial and error allowed fabrication of surgical guides that would fit the Nobel Biocare guide sleeves with precision. The single Astra implant in the study was planned for a pilot guide. Additional time was not dedicated to designing an Astra guide sleeve, due to the complexity of the design and since it was expected there would be few Astra implants included in the study. Therefore, the guide sleeve chosen for the single Astra implant was a Nobel Biocare pilot guided sleeve. The authors felt this was relatively inconsequential since the osteotomy would be enlarged past the pilot drill prior to placing the implant. However, this assumption may not be true. There are differences in guide sleeve design and function among manufacturers that could potentially influence implant accuracy. For instance, different guide sleeves have different lengths, different offset distances to the bone, and varying degrees of clearance between the implant drill and the inner walls of the guide sleeve [24]. The Straumann guide sleeves are slightly longer than the Nobel Biocare guide sleeves. For Straumann, the pilot guides are 6mm in length, compared to the Nobel Biocare pilot guides which were measured at approximately 4.5mm in length. For Straumann, the partially and fully guided sleeves are 5mm in length, compared to the Nobel Biocare partially and fully guided sleeves which were measured at approximately 3.5mm in length. Additionally, the Straumann drill handles add an additional 1mm in height for the

single dotted end, or 3mm to the height for the end with three dots. The end of the drill handle that is used depends on the surgical protocol. For Straumann, the offset from the bottom of the guide sleeve to the top implant can be chosen in three different positions, either H2, H4 or H6. The number following the letter "H" represents the number of millimetres from the bottom of the guide sleeve to the top of the implant. For the Straumann implants in this study, the position closest to the level of bone was chosen as long as no interference with bone, soft tissues, or adjacent teeth was anticipated in the planning. For Nobel Biocare, the offset from the top of the guide sleeve to the bone is always set at 10mm. For pilot guided surgery this leaves 5.5mm from the bottom of the guide sleeve to the top of the implant and for partially guided or fully guided surgery this leaves 6.5mm from the bottom of the guide sleeve to the top of the implant. The drill handles for Nobel Biocare are exceptionally thin and do not add significant additional height to the surgical protocol. The amount of clearance between the implant drills and the inner walls of the guide sleeves is not reported for either Straumann or Nobel Biocare.

Matsumura et al also assessed implant type to determine the effect it had on accuracy [20]. In their study, exclusively Nobel Biocare implants were placed. They did not demonstrate any difference in the accuracy parameters between Nobel Replace CC, Nobel Parallel CC or Nobel Active implants [20]. Bencharit et al also published a study in 2018 which reported no difference in the accuracy between the implant systems BioHorizons and Zimmer Biomet [17]. Although these are not the implant systems utilized in the present study.

In summary, implant system and guide type are confounding variables. The linear regression model including the variable implant system was overall a better model for explaining the variance in 3D offset at the implant platform and apex, compared to including the variable guide type. Nonetheless, when the variable implant system was replaced with the variable guide type to refit the linear regression model, guide type demonstrated a significant effect on 3D offset at the implant platform and apex. Depending on the variable chosen for the linear regression model, both demonstrated a significant effect on 3D offset at the implant platform and apex.

Guide type was a significant factor affecting all the accuracy variables. Fully guided surgery resulted in the least angle deviation and 3D offset at both the platform and apex of the implant. The standard deviation is also smallest in the fully guided group for each of the accuracy variables. This demonstrates more reproducible outcomes within this group. There was only one outlier in the fully guided group, for one of the accuracy parameters. This was 3D offset at the implant apex, which was 1.22mm for one implant. This contrasts with the pilot guided and partially guided surgery where the mean and standard deviation of 3D offset at the implant apex was 1.43 ±0.63mm, vs. 1.42 ±1.01mm respectively. Clearly, pilot guided, and partially guided surgery has been shown to be significantly less accurate than fully guided surgery. However, one factor that was not assessed in the present study, is purposeful free-handed changes to the osteotomy position when using pilot guided or partially guided surgery. This might happen if the surgeon does not approve of the initial osteotomy position or angulation and attempts to change it after preparing the osteotomy with the pilot drill or another drill to widen the osteotomy.

The primary factor limiting use of fully guided surgery is a patient who has limited mouth opening. This especially proves difficult in more posterior regions. Also, the fully guided protocol requires use of the drill handles, which is more cumbersome than use of pilot guided surgery.

Other authors have written about the improved accuracy with fully guided surgery compared to pilot guided or partially guided surgery. An office-based study by Bencharit et al in 2018 assessed the accuracy of partially guided versus fully guided surgery using tooth supported surgical guides. Thirty-one implants were placed in sixteen patients. Eleven implants were partially guided, and twenty implants were fully guided. They concluded that fully guided surgery was more accurate than partially guided surgery. Furthermore, Bencharit et al concluded that the accuracy achieved in their office-based protocol was similar to those in previous studies where surgical guide fabrication was outsourced. Matsumura et al similarly concluded that there were larger errors in all accuracy parameters in partially guided surgery compared to fully guided surgery [20].

5.2.2 Implant Location

Implants in the anterior zone (incisor and canine region) were associated with significantly less angle deviation compared to premolar and molar locations. This is likely attributable to more easily achievable guided surgery in the anterior regions, where mouth opening is not usually a factor limiting the use of a surgical guide. In addition, it is often easier to evaluate the angle deviation of an implant in the anterior region due to plentiful surgical access. These results agree with a study performed by Bencharit et al in 2018, where less variation in the deviation of anterior implants was observed compared to posterior implants [17].

5.2.3 Implant Diameter

Implant diameter had a significant effect on 3D offset at the implant platform and apex based on the ANOVA for each respective model. However, variable significance was demonstrated when Tukey multiple comparisons of means with 95% family-wise confidence intervals were performed for 3D offset at the implant platform and apex. Significance was only demonstrated for 3D offset at the platform of the implant. The significance was only marginal with a p-value of 0.035, favouring wide diameter implants compared to narrow platform implants. Although the results for implant diameter have shown to be significant in this study, this is of low clinical value, since the more important factors for selecting implant diameter include available bone volume and the biomechanical stress requirements for the implant site.

5.2.4 Number of Teeth Supporting the Guide

Number of teeth supporting the guide had a significant effect on 3D offset at the implant apex. However, there is no linear trend to make any conclusions regarding the number of teeth supporting the guide versus the accuracy achieved for 3D offset at the implant apex. The researchers hypothesized that with increased number of teeth supporting the guide, there would be increased stability of the surgical guide which would perhaps translate to improved clinical accuracy. This however was not demonstrated in our study. Matsumura et al demonstrated that the 3D offset at the

platform and apex of the implant decreased as the number of teeth supporting the guide increased. The error was smallest around ten teeth. The error then increased as the number of supporting teeth increased further [20]. This is somewhat similar to the results in the present study, where no linear relationship was demonstrated. Matsumura et al also demonstrated that as the number of anchor pins securing the guide to the adjacent bone increased, the angle deviation tended to decrease [20]. No anchor pins were used in the present study, as the guides were exclusively tooth-supported. Similarly, Matsumura et al also demonstrated that there was less angle deviation in surgical guides with a cobalt-chromium reinforcement structure versus guides that were not reinforced [20]. In the present study, the surgical guides were designed with a thickness of 3.0mm making them rigid. They did not flex or deform easily. There was no issues related to surgical guide fracture during a case. An in-vitro study performed by El Kholy et al in 2019 determined that at least four teeth are necessary for accurate implant placement with surgical guides [25]. They also concluded that four teeth provides equal accuracy to full-arch guides in single tooth gap situations [25]. The lowest number of teeth supporting the surgical guide in our study was seven teeth, and all the guides had bilateral support from the dentition. Therefore, the researchers would advocate for bilateral guide support with a minimum of seven teeth supporting the surgical guide, to achieve similar results to those obtained in this study.

5.2.5 Number of Unrestored Teeth

Number of unrestored teeth also had a significant effect on angle deviation and 3D offset at the implant platform. Although there was a significant difference between the means, there are few implants placed within each numerical category of 0-13 unrestored teeth. Additionally, there is no linear trend to make any meaningful conclusions regarding the number of unrestored teeth and the accuracy achieved for angle deviation or 3D offset at the implant platform. Certainly, the more unrestored teeth in the dental arch, the easier it is to match the CBCT and IOS files. Crisp matching of these files is essential for accurate implant placement. The surgical guide is made to fit the STL file. Therefore, even if the matching is inadequate, the guide will still fit the teeth well.

However, the plan made based on the position in the bone will not be executed well. Derksen et al showed that patients having seven or more unrestored teeth performed significantly better in terms of 3D offset at the implant platform and apex compared to having less unrestored teeth [19].

5.2.6 Summary of Risk Factors with a Significant Effect on Accuracy

In summary, with the protocol employed by the study, with fabrication of bilateral tooth supported surgical guides supported by a minimum of seven teeth, surgical guide type is the only modifiable risk factor to consider for improving the accuracy parameters. Implants in the anterior zone are associated with less angle deviation compared to implants placed in premolar or molar locations.

5.3 Distal, Apical and Vestibular (X, Y, Z) Deviation

The average distal, apical, and vestibular deviations at the implant platform and apex were found to be not significantly different from zero. This informs us that the VSP should be carried out with the implant in the exact desired position. There are no consistent errors in implant planning versus execution that need to be accounted for.

The average absolute value apical deviation in the fully guided group was 0.25mm. This means, that regardless of the vector of inaccuracy, implants on average were placed 0.25mm either deeper or shallower than planned. The implant with the greatest apical deviation in the fully guided group was deeper than planned by 0.73mm. This result is almost identical to that published by Derksen et al, who reported a maximum apical deviation at the implant apex to be 0.72mm [19]. While apical deviations on average are of greater magnitude in the pilot guided and partially guided groups, the results for the fully guided group are arguably more clinically relevant. This is because when performing fully guided implant surgery, the operator is not able to directly visualize the depth of implant placement until it has been completed. Therefore, it is crucial that the implant is not placed too deep, which could potentially violate important

anatomical structures, most notably the inferior alveolar neurovascular bundle. Additionally, deeper implant placement in pilot guided and partially guided cases could potentially have been desired by the surgeon during the case. According to the results of this study, when planning fully guided implant surgery caution should still be taken to avoid vital structures, as implant depth may be approximately 1mm deeper than planned.

5.4 Assessment of Risk Factors that did not have a Significant Effect on Accuracy

Variables that did not affect the accuracy included age, sex, number of days since first patient, implant length, history of bone grafting, surgeon, number of obviously restored teeth, adjacent crowns and dentoalveolar arch treated.

Age and sex were recorded to collect basic demographic data. These variables were not anticipated to affect implant accuracy. Number of days since first patient was assessed to determine if implant placement became more accurate as the researchers became more familiar with the established workflow.

Implant length was not a factor contributing to the variance in accuracy. There was a trend to have the least mean and standard deviation for angle deviation with the short implants, slightly larger angle deviation with the standard-length implants and the greatest angle deviation with the long implants at 4.77 ±1.40°, 4.92 ±3.15° and 5.52 ±3.95° respectively. This finding opposes the results reported by Derksen et al where they found that the mean and standard deviation for angle deviation of 8mm, 10mm and 12mm implants to be 3.08 ±1.25°, vs. 2.75 ±1.45° and 1.58 ±1.17° respectively [19]. In their study, the 12mm implants demonstrated significantly less angle deviation compared to the 10mm or 8mm implants [19]. In the present study however, there were only three implants in the short category (<8mm) and only eight implants in the long category (>12mm), with the remaining seventy implants in the standard category (8-12mm). In our study, for 3D offset at the implant platform, there was a progressive trend in increasing deviation as the length of the implant increased at 0.72 ±0.13mm, 0.82 ±0.44mm and 1.04 ±0.70mm for short, standard, and long implants respectively. Implant length was

anticipated to affect 3D offset at the implant apex. This was hypothesized because for any given angle deviation, a longer implant would demonstrate more 3D offset at the implant apex compared to a shorter implant. Matsumura et al in 2021 did demonstrate this finding [20]. They reported significantly greater 3D offset at the implant apex with increasing implant length [20]. This trend was demonstrated in our study. For short, standard, and long implants, the mean and standard deviation for 3D offset at the implant apex was 0.86 ±0.38mm, vs. 1.30 ±0.73mm, vs. 1.75 ±1.25mm respectively. Similarly, Naziri et al in 2016 published a study which demonstrated that increasing implant length had a significant negative influence on mesio-distal deviations at the implant platform and apex [16].

History of bone grafting was thought to potentially affect implant accuracy. The hypothesis was that cases with grafted bone may have poorer bone quality, which could potentially negatively affect implant placement. This was also not demonstrated in the present study.

Number of obviously restored teeth has an impact on the CBCT data. Restored teeth result in beam hardening artifacts that make it more difficult to determine the anatomy of the teeth and therefore make it more difficult to match the DICOM file with the STL file. Other authors have agreed that the presence of artifacts caused by metallic restorations in radiographic data may mask anatomical structures or reference markers and may therefore hamper an accurate registration of data, contributing to these imprecisions [8]. This however was not found to be a significant factor affecting accuracy. A study by Loo and Azpiazu-Flores in 2023 demonstrated that the greater the number of dental restorations in each patient, the lower the registration accuracy [26].

If an implant was placed between two crowns this was expected to result in higher accuracy, as there was improved guide support from the teeth adjacent to the edentulous space. Conversely, implants placed in free-end scenarios were expected to be less accurate as the surgical guide was anticipated to be less stable in the free-end region. Derksen et al did demonstrate significantly higher 3D offset at the implant platform and

apex for the distal implant in a free-end 3-unit bridge situation [19]. Similarly, Naziri et al found that there was significantly smaller angle deviations and less 3D offset at the implant apex for implants placed between teeth rather than in a free-end position of the dental arch [16]. Matsumura et al also found that the error in angle deviation increased as the distance from the remaining teeth to the implant site increased [20]. These findings were not replicated in the present study.

The dentoalveolar arch treated was recorded. This did not influence accuracy.

5.5 Virtual Planning Software

The coDiagnostiX™ software (Version 10.5, Dental Wings GmbH, Chemnitz, Germany) was chosen for use in this study. The main reasons for choosing coDiagnostiX™ implant planning software, was because it is an open-sourced software and is equipped with over thirty different implant manufacturers for the design of a surgical guide. In addition, the Treatment Evaluation tool within the software allowed for the accuracy analysis to be completed comparing the achieved result with the virtually planned implant position. Several in-vitro studies have demonstrated accurate implant placement using the coDiagnostiX™ software [27-29]. In one study performed in 2021, various CAD/CAM software were compared and it was determined that the mean absolute error of linear measurements using coDiagnostiX™ was between 0.43mm and 0.56mm [29]. In a more recent randomized clinical trial by Singthong, et al, it was shown that there was no statistical differences between the accuracy results obtained for twelve implants placed using coDiagnostiX™ and twelve implants using Implant Studio [30]. These reported deviations indicate that accurate implant placement can be achieved utilizing the coDiagnostiX™ software for VSP for dental implant surgery.

5.6 Time and Cost Analysis

One factor to consider for an office-based workflow to surgical guide fabrication is the time required to carry out the workflow. In our study, on average 28 minutes of

planning in the coDiagnostiX™ software was required per implant. Approximately another 20 minutes of post-cure preparation was required for each surgical guide. This equates to 48 minutes of active attention required to fabricate a guide with a single guide sleeve. The time required for 3D printing varies greatly based on the 3D printer used and the layer thickness selected for printing. One of the outcomes assessed by Joda et al in a 2018 systematic review of static computer-aided implant surgery was the economics of guide production. They reported that no trial could be identified estimating the direct costs, a cost-benefit ratio, or a cost-time analysis for the patient and/or the operator [31]. In the present study, the time required to perform the surgical phase of the treatment was not assessed. A study by Wang et al in 2023 reported that the difference in time for pilot guided surgery versus free-handed surgery was 217.25 ±107.00 seconds vs. 196.25 ±85.56 seconds respectively for experienced operators [32]. Based on this study, the difference in operative time between these approaches is minimal, with free-handed surgery on average 21 seconds faster than pilot guided surgery. At the present time, it is up to the individual practitioner to weigh the value of the potentially improved accuracy versus the additional pre-surgical time and costs required for an office-based approach to guided implant surgery.

The variability in the fixed expenses, depends on the products that require acquisition to be capable of performing the surgical workflow. For most general dentistry or specialty dental offices, except for the implant planning software, all the other fixed expenses serve multimodal purposes. For a party interested in starting office-based virtual surgical planning for dental implant surgery, the costs would depend on the sum of the fixed expenses to acquire the necessary equipment to carry out the workflow. The variable expenses for office-based surgical guide fabrication are low compared to outsourced guide fabrication. Especially when the case volume is large enough, as the amortized cost for the implant planning software annual subscription decreases. In general, the variable expenses for office-based guide fabrication range from roughly $120 to $139 (CND) depending on the guide type used. This represents a guide with a single surgical sleeve. Additional sleeves add approximately $15 to $33 (CND) per sleeve. This assumes approximately 50 implant guides are being fabricated per year to amortize the

coDiagnostiX™ annual subscription fee. This also assumes that the USD to CND conversion rate is 1.4. This also does not consider the human resource expense for guide fabrication. Since, it takes approximately 48 minutes to fabricate a surgical guide with a single guide sleeve, the human resources cost would be approximately equal to 0.8 (48 minutes/60 minutes) multiplied by the hourly rate for the person who would be fabricating the guide. In a study by Bencharit et al in 2018, it has was reported that the cost of laboratory or manufacturer-fabricated guides can range from 275 USD to 700 USD or more while fabrication of surgical guides in-house can reduce the cost to 20 USD to 70 USD [17]. In our region, the costs incurred when outsourcing to a dental laboratory, for a single surgical guide with a single guide sleeve are approximately $315 CND. This figure is based on the cost from a single local dental laboratory that our department occasionally outsources our guide fabrication to. Cost reduction has paved the way for affordable desktop printers to be available which are able to provide comparable levels of accuracy to large-scale laboratory printers [33]. The combination of technological advancements with decreased equipment acquisition costs has made it more practical to perform an office-based approach to virtual surgical planning for dental implant surgery.

5.7 Limitations

The main limitation with our study is the relatively low number of patients that were enrolled in the fully guided group. Although the results of the fully guided group were significantly different from the other groups and guide type helped explain variance in the data, the mean of only eleven patients is not stable. Additionally, the results from the fully guided group are biased by use of only the Straumann BLX implant system. Future studies repeating the protocol but ensuring a more balanced number of implants in each guide type category would be ideal. It would also be best to balance use of the different implant systems within the fully guided category. This would help determine if there is indeed any difference in accuracy between the different implant systems and their protocols, or if implant system is only a confounding variable affecting accuracy.

Another limitation of the study was that there was a selection bias for patient enrolment. Not every patient referred our department for dental implant surgery was screened for participation in the study. The predominant reason patients were enrolled in the study was because the staff Oral and Maxillofacial surgeon felt there would be value to having a surgical guide to assist with placing the dental implant. In some of these cases, there was extremely limited bone volume and achieving the surgical plan would be difficult even with perfect execution.

Once patients were recruited to the study, there was a lack of randomization to the different guide type categories. Guide type was selected by surgeon preference. Sometimes guide type was limited by insufficient space between teeth to fit larger diameter guide sleeves.

Another limitation of the study was that the prosthetic outcomes were not assessed. Data-collection was complete following the post-operative CBCT. Therefore, the restorability of the implants was not assessed. It would have been interesting to determine the proportion of implants that could be restored with a screw-retained prosthesis with occlusal or cingulum screw access, compared to the proportion of implants that would require a cement retained prosthesis. Additionally, we did not collect data on implant survival rates. Despite a decreased ability to irrigate while using guided surgery, Derksen et al demonstrated 99.3% implant survival at 12 and 24 months [19]. They concluded that these survival rates could be attributed to ideal prosthetic placement with benefits for proper oral hygiene and well-planned inter-implant distances [19]. It could also be attributed to case selection, as only posteriorly placed implants without simultaneous bone augmentation were included in their study [19]. Finally, they concluded that their success rates could also be attributed to use of the Straumann TLX implant [19].

Additionally, negative surgical outcomes were not assessed. For instance, we did not assess the number of implants which perforated the buccal/labial or palatal/lingual cortex, floor of the maxillary sinus or the mandibular canal. No known cases resulted in perforation of the floor of the maxillary sinus or the mandibular canal. However, there

were a few cases where fenestration defects were present on the buccal/labial or palatal/lingual surface of the implant. Evaluating this information would provide data on the proportion of negative outcomes that occurred with guided surgery.

There are additional risk factors that have been demonstrated by some studies to significantly affect accuracy that were not evaluated in the present study. Matsumura et al demonstrated that as the number of implants placed in each patient increased, there was significantly more error in angle deviation and 3D offset at the implant platform and apex [20]. Derksen et al also reported that if the implant was planned to engage the cortical walls there was significantly greater angular deviation 3.34 ±1.40°, versus implants with no planned cortical wall engagement 2.53 ±1.38° [19]. Again, in this study by Derksen et al, the implant system used was exclusively Straumann TLX [19]. The authors hypothesized that the round apical design of the TLX implant could possibly be pushed away by the crestal bone or cortical wall [19]. This contrasts with implants with a more aggressive apical thread design that might engage the harder cortical bone [19].

In the present study, there was also a lack of observer blinding during the accuracy analysis. The observers performing the analysis did not specifically check the guide type for each accuracy analysis, however it is possible that the observer may recognize the case and know that a certain case was performed using a certain guide type. The Treatment Evaluation tool within coDiagnostiX™ does not display the virtual plan of the implant until after the observer has superimposed an image of the implant that was placed in the surgery over the actual implant position. Once the accuracy analysis had been completed, it was not repeated. Therefore, no secondary attempts were made to change the accuracy achieved.

5.8 Future Technological Advancements

Artificial intelligence will continue to be developed to assist with guided implant surgery. The coDiagnostiX™ software has an artificial intelligence function, however it was not employed in the present study. As this software learns how to plan dental implant

surgery, perhaps many of the labour-intensive steps will become automated. This would make it more efficient to plan guided surgery. Future research repeating the present research protocol, but using artificial intelligence to assist with the labour-intensive steps would help determine if the application of artificial intelligence has an effect on accuracy and time required for surgical planning.

The present study did not employ dynamic surgical navigation. Several authors have written on the accuracy of dynamic surgical navigation. For instance, Jaemsuwan, et al published a study in 2022 where they placed 20 implants free-handed, 20 implants using computer fabricated guides and 20 implants using dynamic protocols in fully edentulous patients. There was no difference between the static and dynamic groups, but both groups demonstrated higher accuracy compared to the freehand protocol [34] . A recent systematic review by Aghaloo et al in 2023 concluded that accuracy of implant placement does not differ markedly between static guided surgery and surgical navigation [35]. Another systematic review published by Albiol et al in 2019 reports on the advantages and disadvantages of implant navigation surgery [36]. They concluded that there is still limited evidence to support dynamic navigation in implant surgery, as in-vitro studies comprise much of the dynamic navigation research [36]. One significant disadvantage of dynamic navigation is the higher cost associated with this system [36]. Certainly, there may be applications for dynamic surgical navigation, especially when patient mouth opening is limited. There is also potentially time saved during the work-up phase since no guide fabrication is required. This is however at least partially offset by the significantly increased operative time required when using dynamic navigation compared to static guided surgery due to the necessary calibration steps throughout the surgical procedure [32]. A study by Wang et al in 2023 reported that the mean and standard deviation of surgical time for use of static pilot guided surgery versus use of dynamic navigation for experienced users was 217.25 ±107.00 seconds vs. 934.75 ±773.24 seconds respectively [37]. It is the author's opinion that static guided implant surgery will continue to serve a valuable purpose due to the benefits of similar clinical accuracy achieved with dynamic navigation, combined with the significant cost and time effectiveness of this approach.

CHAPTER 6 – CONCLUSION

The following main conclusions can be drawn from the results of this study:

1. An office-based workflow for virtual surgical planning for dental implant surgery using tooth supported surgical guides allows for clinically acceptable implant placement that is comparable to the literature for outsourced guided surgery.
2. The most accurate and reproducible outcomes in terms of angle deviation and 3D offset at the implant platform and apex were observed when employing fully guided surgery.
3. Implants in the anterior zone are associated with less angle deviation compared to implants placed in premolar or molar locations.
4. Office-based surgical guide fabrication has been demonstrated to be cost effective.
5. The time required to fabricate a single surgical guide with a single guide sleeve was approximately 2 hours and 53 minutes in total, with 48 of those minutes requiring active attention.

BIBLIOGRAPHY

1. Safi Y, Behzadi S, Shafizadeh M, Amid R, Kadkhodazadeh M. CBCT Evaluation of the maxillary palatine process as a donor site for the regeneration of periodontal defects. J Adv Periodontol Implant Dent 2022;14:20-25.

2. Beretta M, Poli PP, Maiorana C. Accuracy of computer-aided template-guided oral implant placement: a prospective clinical study. J Periodontal Implant Sci 2014;44:184-193.

3. Zhou W, Liu Z, Song L, Kuo CL, Shafer DM. Clinical Factors Affecting the Accuracy of Guided Implant Surgery-A Systematic Review and Meta-analysis. J Evid Based Dent Pract 2018;18:28-40.

4. Jorba-García A, González-Barnadas A, Camps-Font O, Figueiredo R, Valmaseda-Castellón E. Accuracy assessment of dynamic computer-aided implant placement: a systematic review and meta-analysis. Clin Oral Investig 2021;25:2479-2494.

5. Mangano FG, Hauschild U, Admakin O. Full in-Office Guided Surgery with Open Selective Tooth-Supported Templates: A Prospective Clinical Study on 20 Patients. Int J Environ Res Public Health 2018;15.

6. Fokas G, Vaughn VM, Scarfe WC, Bornstein MM. Accuracy of linear measurements on CBCT images related to presurgical implant treatment planning: A systematic review. Clin Oral Implants Res 2018;29 Suppl 16:393-415.

7. Rios HF, Borgnakke WS, Benavides E. The Use of Cone-Beam Computed Tomography in Management of Patients Requiring Dental Implants: An American Academy of Periodontology Best Evidence Review. J Periodontol 2017;88:946-959.

8. Flugge T, Derksen W, Te Poel J, Hassan B, Nelson K, Wismeijer D. Registration of cone beam computed tomography data and intraoral surface scans - A prerequisite for guided implant surgery with CAD/CAM drilling guides. Clin Oral Implants Res 2017;28:1113-1118.

9. Gjelvold B, Mahmood DJH, Wennerberg A. Accuracy of surgical guides from 2 different desktop 3D printers for computed tomography-guided surgery. The Journal of prosthetic dentistry 2019;121:498-503.

10. Putra RH, Yoda N, Astuti ER, Sasaki K. The accuracy of implant placement with computer-guided surgery in partially edentulous patients and possible influencing factors: A systematic review and meta-analysis. J Prosthodont Res 2022;66:29-39.

11. Ku JK, Lee J, Lee HJ, Yun PY, Kim YK. Accuracy of dental implant placement with computer-guided surgery: a retrospective cohort study. BMC Oral Health 2022;22:8.

12. Oberoi G, Nitsch S, Edelmayer M, Janjić K, Müller AS, Agis H. 3D Printing-Encompassing the Facets of Dentistry. Front Bioeng Biotechnol 2018;6:172.

13. Unsal GS, Turkyilmaz I, Lakhia S. Advantages and limitations of implant surgery with CAD/CAM surgical guides: A literature review. J Clin Exp Dent 2020;12:e409-e417.

14. Stefanelli LV, Mandelaris GA, Franchina A, Pranno N, Pagliarulo M, Cera F, et al. Accuracy of Dynamic Navigation System Workflow for Implant Supported Full Arch Prosthesis: A Case Series. Int J Environ Res Public Health 2020;17.

15. Noh H, Nabha W, Cho JH, Hwang HS. Registration accuracy in the integration of laser-scanned dental images into maxillofacial cone-beam computed tomography images. Am J Orthod Dentofacial Orthop 2011;140:585-591.

16. Naziri E, Schramm A, Wilde F. Accuracy of computer-assisted implant placement with insertion templates. GMS Interdiscip Plast Reconstr Surg DGPW 2016;5:Doc15.

17. Bencharit S, Staffen A, Yeung M, Whitley D, 3rd, Laskin DM, Deeb GR. In Vivo Tooth-Supported Implant Surgical Guides Fabricated With Desktop Stereolithographic Printers: Fully Guided Surgery Is More Accurate Than Partially Guided Surgery. J Oral Maxillofac Surg 2018;76:1431-1439.

18. Guided Pilot Sleeves, Guided Anchor Pin Sleeves and Mounting Tools_IFU2009_EN_CA_00.pdf. Nobel Biocare.

19. Derksen W, Wismeijer D, Flügge T, Hassan B, Tahmaseb A. The accuracy of computer-guided implant surgery with tooth-supported, digitally designed drill guides based on CBCT and intraoral scanning. A prospective cohort study. Clin Oral Implants Res 2019;30:1005-1015.

20. Matsumura A, Nakano T, Ono S, Kaminaka A, Yatani H, Kabata D. Multivariate analysis of causal factors influencing accuracy of guided implant surgery for partial edentulism: a retrospective clinical study. Int J Implant Dent 2021;7:28.

21. Massuda CKM, de Carvalho MR, de Moraes JB, Pallos D, Kim YJ. Accuracy of guided dental implant surgery using a fully digital workflow: A case series. The Journal of prosthetic dentistry 2022.

22. Sicilia A, Botticelli D. Computer-guided implant therapy and soft- and hard-tissue aspects. The Third EAO Consensus Conference 2012. Clin Oral Implants Res 2012;23 Suppl 6:157-161.

23. Smitkarn P, Subbalekha K, Mattheos N, Pimkhaokham A. The accuracy of single-tooth implants placed using fully digital-guided surgery and freehand implant surgery. J Clin Periodontol 2019;46:949-957.

24. Apostolakis D, Kourakis G. CAD/CAM implant surgical guides: maximum errors in implant positioning attributable to the properties of the metal sleeve/osteotomy drill combination. Int J Implant Dent 2018;4:34.

25. El Kholy K, Lazarin R, Janner SFM, Faerber K, Buser R, Buser D. Influence of surgical guide support and implant site location on accuracy of static Computer-Assisted Implant Surgery. Clin Oral Implants Res 2019;30:1067-1075.

26. Loo CA, Azpiazu-Flores FX. Radiographic template used to facilitate the alignment of digital scans to computed tomography scans with extensive beam hardening artifacts. J Prosthet Dent 2023;129:520-522.

27. Rothlauf S, Pieralli S, Wesemann C, Burkhardt F, Vach K, Kernen F, Spies BC. Influence of planning software and template design on the accuracy of static computer assisted implant surgery performed using guides fabricated with material extrusion technology: An in vitro study. J Dent 2023;132:104482.

28. Kuhl S, Payer M, Zitzmann NU, Lambrecht JT, Filippi A. Technical accuracy of printed surgical templates for guided implant surgery with the coDiagnostiX software. Clin Implant Dent Relat Res 2015;17 Suppl 1:e177-182.

29. Al-Ekrish AA. Comparative study of the accuracy of CBCT implant site measurements using different software programs. Saudi Dent J 2021;33:355-361.

30. Singthong W, Serichetaphongse P, Chengprapakorn W. A randomized clinical trial on the accuracy of guided implant surgery between two implant-planning programs used by inexperienced operators. J Prosthet Dent 2022.

31. Joda T, Derksen W, Wittneben JG, Kuehl S. Static computer-aided implant surgery (s-CAIS) analysing patient-reported outcome measures (PROMs), economics and surgical complications: A systematic review. Clin Oral Implants Res 2018;29 Suppl 16:359-373.

32. Wang X, Shujaat S, Meeus J, Shaheen E, Legrand P, Lahoud P, et al. Performance of novice versus experienced surgeons for dental implant placement with freehand, static guided and dynamic navigation approaches. Sci Rep 2023;13:2598.

33. Elliott T, Hamilton A, Griseto N, Gallucci GO. Additively Manufactured Surgical Implant Guides: A Review. Journal of prosthodontics 2022;31:38-46.

34. Jaemsuwan S, Arunjaroensuk S, Kaboosaya B, Subbalekha K, Mattheos N, Pimkhaokham A. Comparison of the accuracy of implant position among freehand implant placement, static and dynamic computer-assisted implant surgery in fully edentulous patients: a non-randomized prospective study. Int J Oral Maxillofac Surg 2023;52:264-271.

35. Aghaloo T, Hadaya D, Schoenbaum TR, Pratt L, Favagehi M. Guided and Navigation Implant Surgery: A Systematic Review. Int J Oral Maxillofac Implants 2023;38:7-15.

36. Gargallo-Albiol J, Barootchi S, Salomo-Coll O, Wang HL. Advantages and disadvantages of implant navigation surgery. A systematic review. Ann Anat 2019;225:1-10.

37. Galli M, Mendonça G, Meneghetti P, Bekkali M, Travan S, Wang H-L, Li J. Sleeveless guided implant placement compared to conventional approaches: An in vitro study at healed sites and fresh extraction sockets. International journal of oral implantology (New Malden, London, England) 2023;16:117-132.