The Influence of the Operator Experience on the Accuracy of Implant Placement: An In Vitro Study

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THE INFLUENCE OF THE OPERATOR EXPERIENCE ON THE ACCURACY OF IMPLANT PLACEMENT: AN IN VITRO STUDY

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Abstract

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Purpose: The aim of this study is to evaluate the influence of operator experience in the fully guided placement of implants in dentate patients.

Methods: Three different providers with different level of experience in implant surgery (unexperienced, moderate experienced = 2 years of experience, and experienced = more than 5 years of experience in implant surgery) placed each n=20 implants fully guided or free hand in identical replicas, produced from a CBCT of a partially edentulous patient case. The achieved implant position was digitized by using a laboratory scanner and compared with the planned position. Trueness (planned versus actual position) and precision (difference among implants) were determined. The 3D-offset at the crest of the implant (Root mean square between virtual preoperative planning and postoperative standard triangulation file) was defined as primary outcome parameter. The means, standard deviation, and 95%-confidence intervals were analyzed statistically with 1-way ANOVA and the Scheffe procedure. Intraoperator reliability was calculated with Cronbach's Alpha.

Results: In the analysis of the implants placed using the fully guided protocol, 3D-deviation of the crest for the unexperienced provider (0.56±0.09mm) was statistically different ($p<0.001$) from the moderate experienced provider (0.28±0.08mm) and the experienced provider (0.28±0.17mm). No statistically significant differences between moderate and experienced provider were observed ($p=0.94$). The use of a fully guided approach did not improve the outcome of the implant placement for an unexperienced provider. Significant improvements of the accuracy were seen in the moderate experienced and the experienced providers with significant differences for the angle deviation (free-hand: 1.67±0.77 degree *vs.* fully guided: 1.29±0.52 degree; $p<0.001$) and the 3D-deviation at the crest (0.34±0.17mm *vs.* 0.28±0.08mm; $p<0.01$) for the moderate experienced provider.

Conclusions: Within the limitations of this study, operator experience has an impact on the accuracy and reliability of fully guided implant placement. When using the fully guided system it appears that a certain degree of experience is necessary to achieve high accuracy.

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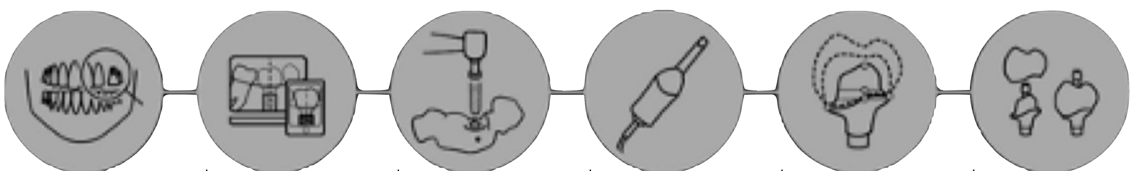
Chapter 1
Introduction

The dental implant has evolved over the past 50 years with the first root form implant designed by Branemark in 1977.[1] Since then advancements in implant materials, surface treatment, and connections have continued to improve the use of dental implants. The survival rates have reached a high 5-year survival rate of 97.7% and 10-year survival rate of 94.9%.[2] With the high survival rates, the attention has since turned to the success of implants. The most classic definition of implant success was proposed by Albrektsson in 1986.[3] This includes:

- immobility of the implant
- no peri-implant radiolucency present
- vertical bone loss less than 0.2mm annually following the implants first year
- absence of irreversible signs and symptoms, including pain, infections, neuropathies, paresthesia, or violation of mandibular canal
- With regards to the first four: minimum of 85% success rate at the end of year 5 and 80% at the end of year 10

Albrektsson's criteria for success focuses mainly on the biology involved with the implant but does not incorporate the restorative and esthetic aspects of successfully implant placement. In 2011, Papaspyridakos, et. al. published a systematic review of the success criteria in implant dentistry.[4] They summarize the most commonly used criteria, which include implant level, soft tissue level, prosthetic level, and patient satisfaction level criteria. The implant level agrees with Albrektsson's criteria, with the exception of bone loss greater than 1.5mm. Soft-tissue level criteria includes presence of bleeding and/or suppuration. Prosthetic level criteria include the occurrence of technical complications/prosthetic maintenance, adequate function, and esthetics during the 5-year period. The patient satisfaction level criteria were discomfort and paresthesia, satisfaction with appearance, and ability to chew/taste.

As the criteria for success evolves and expands, the demand for restoration-driven implant planning and placement grows. Advancements in technology have transformed the workflow of implant planning for a static guide. Using Cone Beam Computed Tomography (CBCT) and a digital intraoral scan can then be used in Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) software to position the implant for the optimal implant supported restoration. An example of a digital work for implant dentistry is seen in Figure 1.



Data collection via CBCT and intraoral, surface scan	Computer-aided design (CAD) of surgical guide based on the digital planning of the restoration and implant placement	Guided surgical protocol to place the implant in the planned location	Data collection via intra-oral surface scan, using a coping attached directly to the implant to transfer implant location	CAD of the implant-supported abutment and restoration.	Delivery of the prosthesis

Figure 1. Digital workflow for dental implant placement and restoration. Adapted from Dentsply Sirona. (Dentsply Sirona, Waltham, MA)

Since the restorations can vary dramatically based on the clinical application, the restoration is designed first, followed by the position of the implant. From this information, the surgeon can then make the decision of what pre-implant site development is needed, which may include sinus augmentation, alveolar ridge augmentation and/or soft tissue augmentation.[5-]

[7] Once the position of the implant is determined, the surgical guide can be designed and fabricated. The static surgical guides can take the form of pilot (or partial) or fully guided systems. Pilot guided implant systems transfer the location and angulation of the planned implant placement for only the first or second twist drills. Some systems, such as Straumann's T-Sleeve pilot guides, also control for depth too. Fully guided protocols include a guide that can control the location, angulation, and depth of the entire drilling protocol and the placement of the implant.

In a recently published article completed by Gargallo-Albiol, et. al. defined half guided and fully guided surgery.[8] Half guided protocol uses the fabricated surgical guide for only the pilot drill or the entire drilling sequence, but not the implant placement. Fully guided protocol uses the surgical guide for the entire osteotomy preparation and the placement of the implant, including the depth of the implant being placed.

Fully guided implant systems have been shown by a numerous of studies to be the gold standard for accuracy. Schneider, et. al. in 2009 completed a systematic review which included eight articles investigating the accuracy and clinical application in static, computer-guided implant placement. The meta-regression analysis results included a mean deviation at the entry point of 1.07mm (95% CL = 0.76-1.22mm) and the apex of 1.63 mm (95% CL = 1.26-2mm).[9] In 2012, Van Assche, et. al. completed another systematic review investigating the accuracy of static fully guided implant placement. The results include nineteen studies and a meta-analysis. The mean error at the crest is 0.99mm (range = 0 -6.5mm), 1.24mm (range = 6.9mm) at the apex, and the mean angulation deviation was 3.81 degrees (range = 0 - 24.9 degrees). One significant difference that was noted was all the deviation parameters were significantly different than between guided placement and free-handed.[10]

Both systematic reviews demonstrate fully guided implant placement is highly accurate, however, a safety margin is still recommended between the planned implant placement and any vital anatomic structures. Using these results, a safety margin of 2mm is recommended.[9, 10]

Investigating the comparison of the accuracy of fully guided, partially guided, and free-handed implants, multiple studies have been completed. Kuhl, et. al. completed a cadaver study with 38 implants placed, half being fully guided and the remaining half with the osteotomy being guided, but not the implant placement (half-guided).[11] The mean differences between the two groups were not statistically different, however, the fully-guided implants were slightly more accurate than half-guided. The difference between the two groups can be seen in Table 1.

Table 1. Results from Kuhl, et. al. in 2013, regarding accuracy of half-guided and fully guided implant placement.

	Half-Guided (range)	Fully guided (range)
Deviation at the Base	1.56mm (0.49-3.43mm)	1.52mm (0.4-3.54mm)
Deviation at the Tip	1.84mm (0.84-3.22mm)	1.54mm (0.33-3.64mm)

One aspect to note with Kuhl's results includes the deviation at the tip of the implant is larger between the two groups than it is at the crest. This difference can be attributed to the increased distance between the guide and the location, however, for this study, the osteotomy was completed with the use of the guide. Valente, et. al., in 2009 completed a clinical study with similar surgical protocol as the half-guided implant placements.[12] The reported results are similar to Kuhl's with horizontal deviation at the crest and tip of 1.4mm and 1.6mm, respectively. The angular deviation reported was 7.9 degrees. This means that even when the implant is placed without the guidance of the static guide, the deviation at the apex, within the less dense, cancellous bone is possible. The increase deviation at the apical tip of the implant was first discussed by Widmann and Bale in 2006.[13] For optimal accuracy, the implant should be placed through the guide.

In 2018, Zhou, et. al published another systematic review evaluating the factors associated with guided implant placement.[14] One aspect that was evaluated was the differences between totally guided and partially guided protocols. For all three of these measurements, the deviations were statistically different between the two surgical protocols, with fully guided implant placement more accurate.

Also, in 2018, Bover-Ramos et. al completed a systematic review and meta-analysis comparing cadaver, clinical, and in vitro studies. The outcomes assessed included horizontal deviation at the coronal and apex of the implant, the angular deviation, and vertical deviation associated the different types of studies. The results showed the differences between the groups for horizontal coronal deviation and vertical deviation were not statistically significant. However, the apical horizontal deviation and angular deviation were significantly different. The following table shows these differences.

Table 2. Results published by Bover-Ramos, et. al. in 2018 regarding accuracy of implant placement in in vitro, cadaver, and clinical studies.

	In vitro studies (95% CI)	Cadaver studies (95% CI)	Clinical studies (95% CI)
Apical horizontal deviation	0.85mm (0.5-1.2)	1.52mm (1.2-1.9)	1.40mm (1.2-1.6)
Angular deviation	2.39^{o}(1.7-3.1)	2.82^{o} (2.0-3.6)	3.98^{o} (3.3-4.6)

As the results show, the accuracy exhibited by the in vitro studies was greater than the cadaver and clinical studies. According to this comparison, the deviation values associated with clinical studies are 1.6 times greater than demonstrated by the in vitro studies. This is important to note when planning for the clinical placement of the implant, the safety margins should reflect the deviations shown by the clinical studies. Decreasing the tolerances of the safety margins down to that values associated with the in vitro studies may result in surgical complications associated apical position of the osteotomy drills and/or implants.

A clinical study was published in 2018 by Younes, et. al., investigating the accuracy of free-handed pilot-drill guided, and fully guided protocols for implant placement in partially edentulous patients.[15] In total 26 implants were placed. The results are summarized in Table 3.

Table 3. Summary of the results published by Younes, et. al., in 2018

	Free-handed (standard error)	Pilot-drill guided (standard error)	Fully guided (standard error)
Angular deviation	6.99^o (0.87)	5.95^o (0.87)	2.30^o (0.92)
Coronal vertical deviation	0.53mm (0.09)	0.68mm (0.09)	0.43mm (0.09)
Coronal lateral deviation	1.27mm (0.11)	0.79mm (0.11)	0.55mm (0.11)
Coronal global deviation	1.45mm (0.10)	1.12mm (0.10)	0.55mm (0.10)
Apical vertical deviation	0.50mm (0.09)	0.68mm (0.09)	0.43mm (0.09)
Apical lateral deviation	1.97mm (0.19)	1.14mm (0.20)	0.81mm (0.21)
Apical global deviation	2.11mm (0.18)	1.43mm (0.18)	0.97mm (0.19)

There is an increase in accuracy across all the outcomes when the fully guided system was used, with pilot-drill guided implants slightly more accurately placed than free-handed implants. The primary outcome of the study was the apical global deviation, which makes sense since it is known to be the location of greatest deviation from planned. Again, this becomes important when the planned cases have anatomic considerations which limited the allowed margin of error. The previously noted safety zone of 2mm circumferentially around the planned implant location is violated by the apical global deviation for the free-handed implants. In these situations, fully guided protocols are recommended. If the clinical situation eliminates the potential use of the fully guided protocol (i.e., limited opening/limited space in the posterior or insufficient space between the clinical crowns) pilot guides are shown to increase the accuracy versus free-handed placement, and the global apical deviation is within the safety margin of 2mm.

When analyzing the placement of the implant, one can evaluate the trueness, accuracy, and precision. It is important to understand definitions of these terms. The International Standards Organization (ISO) defines the accuracy as the closeness of a measured value to a standard or known value. Precision is the agreement or difference between test results within a particular group. Trueness refers to the closeness of the arithmetic mean of a large number of samples or test results and the true or accepted reference value. (ISO 5725-1:1994)

Many of the aforementioned articles described that the use of fully guided protocols improves outcomes of implant placement accuracy. Despite this improvement, there is still error observed when comparing the planned implant position and the actual implant placement. Many authors have begun to investigate the potential sources of error, influencing the outcomes of fully guided implant placement.

Chapter 2
Review of literature

As mentioned with all the referenced studies, there is error in implant placement when compared to planned, even with the use of fully guided systems. The potential factors influencing the accuracy of implant placement using fully guided protocols is becoming more popular. Clinical factors which have been identified as potential sources of influencing the accuracy of the implant placement include residual dentition, method of surgical guide support, reflection of a gingival flap, region of oral cavity, surgical guide component tolerance, and operator experience.

The remaining teeth can be an important factor for the stabilization of the surgical guide. Ersoy, et. al, in 2008 published a retrospective study evaluating the accuracy of the implants placed using stereolithographic surgical guides and the potential clinical factors.[16] When looking at the implants which were placed in single-tooth loss, Kennedy Class I or II edentulous spaces, or fully edentulous cases, the results can be found in Table 4.

Table 4. Results of Ersoy, et. al's study from 2008 regarding accuracy of implants placed in differing edentulous spaces.

	Number of implants	Angular deviation (degrees)	Deviation at neck (mm)	Deviation at Apex (mm)
Single-tooth loss	9	3.71	0.74	0.66
Kennedy Class I or II edentulous spaces	20	4.78	1.23	1.59
Fully edentulous	65	5.10	1.28	1.60

This data shows that as the patient loses more teeth, guide loses it stability and ultimately the accuracy of the implant placement. Furthermore, once the guide loses support on both sides of the edentulous space, the accuracy decreases down to the level of a fully edentulous arch. The logical reason for this is the guide can pivot and rotate around the distal most tooth. One way to avoid this rotation is to add a portion of the guide, distal to the implant placement, which is bone supported. One drawback to this technique is a large surgical site with the need to reflect the soft tissue to expose the bone.

There are several studies looking at the type of guide support and the effects on the accuracy of the implant placed. The previously mentioned clinical study by Ersoy in 2008, specifically looked at the accuracy of the implants placed based on these parameters.[16] The results can be found in Table 5.

Table 5. Results from Ersoy, et. al. in 2008 regarding accuracy of tooth-, mucosa-, and bone-supported guides.

	Angular deviation	Deviation at the neck	Deviation at the tip
Tooth-supported	4.4^{o}	1.1mm	1.3mm
Mucosa-supported	4.9^{o}	1.1mm	1.7mm
Bone-supported	5.1^{o}	1.3mm	1.6mm

When evaluating the data by these parameters, there were no significant differences among the three groups for any of the measurements. Despite the logical reasoning, Ersoy's data does not support the theory of increased support and stability of the guide when it is tooth-supported. One potential explanation of the reduced accuracy would be the distal extension cases, which had shown similar deviations as the fully edentulous cases.

Ozan, et. al, in 2009, completed another clinical trial investigating the accuracy associated with the three differently supported guides.[17] In total, 110 implants were placed into 30 patients, using either a tooth-supported, bone-supported, or mucosa-supported SLA guide.

For this study, all the tooth-supported guides were fabricated for single crown restorations. The tooth supported guided significantly improved the accuracy of the implants placed in terms of angular deviation and horizontal deviation at the tip, in comparison to both bone-supported and mucosa-supported guides. Another important finding was the range of angular deviations shown, which can be related to the precision. The tooth-supported guide was considerably more precise than the other two modalities. This data demonstrates the accuracy and precision of the implant placement using a tooth-supported guide is greater than the bone- and mucosa-supported guides.

In an attempt to stabilize the surgical guide in edentulous cases and improve the precision and accuracy of the implants placed, fixation pins have been implemented. In 2018, Marliere, et. al. published a systematic review evaluating the accuracy of implants placed into edentulous ridges but noted there was only one study which included the comparison between the guide with and without fixation.[18] This study was completed by Cassetta, et. al., in 2014.[19] The study included 18 guides which were fixed during surgery and 10 guides which were not fixed. The results can be found in Table 6.

Table 6. Results from Cassetta, et. al., in 2014, regarding accuracy of surgical guides with and without fixation pins.

	Apical deviation	Coronal deviation	Angular deviation
Fixed	2.09mm (±0.75)	1.66mm (±0.58)	4.09 deg (±2.40)
Not fixed	2.26mm (±0.89)	1.68mm (±0.60)	5.62 deg (±2.80)

Of the differences between the two modalities, only the angular deviation was statistically significant. Another finding from this data involves the apical deviations of both the fixed and not fixed guides. Both methods resulted in a mean deviation outside of the 2.0mm deviation. Not all cases have the benefit of having teeth present, but when they are, it is highly recommended to utilize accuracy associated with tooth-supported guides.

For all Cassetta's edentulous cases, the implants were placed after a full thickness flap was reflected. Several studies have investigated the differences in accuracy between implants placed with flap vs flapless surgical protocols. In 2012, Behneke completed a clinical study evaluating potential factors associated with the accuracy of fully guided implant placement.[20] Sixty-six implants were placed under open-flap or flapless protocols each. The results are as follows:

Table 7. Results from Behneke, et. al., in 2012, regarding open flap versus flapless surgical approaches.

	Shoulder radial deviation	Apex radial deviation	Angular deviation
Flapless	0.36mm	0.53mm	2.11 deg
Open Flap	0.28mm	0.45mm	2.08 deg

The flapless approach resulted in slightly higher deviation values at the shoulder, which were statistically significant. The radial deviation at the apex and the angular deviation were both not statistically significant between the two protocols. In contrast, the results of Zhou's 2018 systematic review shows that the flapless approach was more accurate when comparing the angle deviation and coronal deviation than the open flap approach.[14] There was no statistical difference between the two modalities when evaluating the apical deviation. With the differing results for the flap vs flapless approach, another factor could influence the accuracy. Vasak in 2011 showed for flapless implant placement, the thickness of the mucosa was nearly directly related to the deviation association with the implant placed (beta value of the linear regression is 0.81).[21] This data is an example that the variation in the clinical condition is multi-factorial and is influential on the outcome of the surgery.

Another clinical aspect to consider is anatomic location of implant to be placed, regardless of the teeth remaining. The systematic review completed by Zhou in 2018 stratified the data obtained for the maxilla versus the mandible.[14] This included data from four individual studies, resulting in significantly greater angular deviations associated with the maxillary arch, with the mean difference between 0.89mm. Coronal and apical deviations, however, were not statistically different between the two arches. In comparison with Vasak's data from 2011, the mean angular difference between the maxillary and mandibular implants was 0.13mm.[21] Vasak also stratified the data for the anterior and posterior regions. The angulation deviation and 3D deviation at the apex were statistically insignificant for the two groups, while the linear deviation at the shoulder was statistically different between the two groups. Overall, difference between the maxillary and mandibular arches seem to have a small, but statistically significant role in the accuracy of the guided implant placement, favoring the mandibular arch.

The accuracy transferring the planned implant placement to the oral cavity relies on several steps for the fabrication of the surgical guide, which is then used as part of the system by the clinician. The particular components of the surgical guide have been investigated including the sleeve height and the mechanical tolerances of the components. El Kholy, et. al., published an in vitro study to evaluate the effect of the guide sleeve height and the drilling distance on the accuracy of the implant placed.[22] The general results showed the further the distance from the guide sleeve to the implant tip, the greater the deviation. This deviation was lessened, however, when the guide key height, or the total length the guide is in contact with the drill, was increased. Relating this information to virtually designing the surgical guide indicates the closer the sleeve is to the planned platform, the greater the potential accuracy.

When using the surgical guide intraoperatively, the fitment and stability of the guide is confirmed clinically, however the inherent tolerances in the guide components are a potential source of error. Cassetta, et. al., in 2015 looked specifically at the intrinsic error effects on the total error of fully guided surgery and to determine if limiting this tolerance can reduce the intrinsic error.[23] This was completed by fabricating a metal shell, which attached to the head of the surgical handpiece and allowed for the direct attachment of the guide tubes of differing lengths. In turn, this minimized the amount of movement between the hand piece and the guide tube. For this clinical study, only angular deviation was assessed, with a mean deviation of 2.02^{o} (0.81-3.48^{o}). In comparison to the systematic review completed by Bover-Ramos,[24] mean angular deviation identified in clinical studies was 2.82^{o}. This outcome shows there is significant intrinsic error due to the mechanical components of the fully guided surgical systems, despite all the other clinical sources of error.

With the publications that have been cited, thus far, none of which have stratified the data or specifically analyzed the data to evaluate the effect of operator experience has on the outcome in. There have been a few studies, which have investigated the effects of this factor. The first was completed by Van de Velde in 2008.[25] This in vitro study was completed using resin models with a silicon lining to replicate the overlying gingiva. Eighteen clinicians completed four implant sites per using a flapless, free handed surgical approach. The clinicians included six periodontists, six general dentists, and six students. The resin model included CBCT images were used for the assessment of the location of the implant in comparison to the originally planned implant. The results showed that there were no statistically significant differences between the experience groups for all parameters, except for global deviations between the dentists and students, angle deviations between dentists and students, and horizontal deviations between specialist and students. It is important to note that this study looked at free handed placement of the implants, without the use of a surgical guide.

The second article investigating the effect of operator experience on the accuracy of fully guided implant placement, Cushen, et. al. published an in vitro study using a edentulous mandible replicas.[26] The replicas were based off a CBCT image, converted to an STL file and 3D printed using an SLA-resin printer. Four operators, two with greater implant experience (>100 implants placed clinically) and two with lesser experience (<10 implants placed), placed five implants in to five replicas each, totaling 25 implants placed by each operator. CBCT of the implant mandibles were completed and superimposed over the virtually planned implants. The results are summarized in Table 8.

Table 8. Mean and standard deviations for angular and horizontal deviations published by Cushen, et. al. in 2013

	Angular deviation (^{o})	Horizontal Deviation at Apex (mm)*	Horizontal Deviation at Platform (mm)*
Total	3.28 (±1.60)	0.38 (±0.17)	0.69 (±0.31)
Experienced	2.60 (±1.25)	0.34 (±0.15)	0.63 (±0.28)
Inexperienced	3.96 (±1.64)	0.42 (±0.19)	0.77 (±0.33)

*Statistically significant difference between the experienced and unexperienced groups

Reportedly, there was a significant difference between the two groups for angular deviation and horizontal deviation at both the platform and crest. Important aspects of this study include edentulous nature of the replica they used, with a bone-supported guide. The order they placed the implants was standardized for the first implant placed being the central implant, followed by the operator’s discretion for the following four implants. The implant transfers were left in place, through the guided, which naturally would help stabilize and orient the guide for the subsequent implants. This could potentially result in increased accuracy for the later implants place, however that accuracy would be determined by the position of the surgical guide during the first implant placed. Also, to note, Cushen mentions that one of the limitations of the study was the CBCT of the mandibles with the implants in place produced a lot of scatter, which may have created inaccuracies assessing the actual location of the implants in the mandible. More inaccuracy could have been caused by the fact the edentulous arch does not have the locational landmarks that you would find in the dentulous arch. Overall, this study shows that there is a difference between the experience and unexperienced operators in the accuracy of the implants placed in an edentulous model using a fully guided system.

The only other publication investigating the effect of operator experience on the accuracy of implant placement was published by Cassetta and Bellardini in 2017.[27] This is a randomized controlled, pilot study, including thirty-three implants placed by inexperienced providers and thirty-seven implants placed by experience providers. Operators were considered experienced if they had placed at least 500 implants using computer-guided implantology and inexperienced if they have not had experience with computer-guided implantology but have placed at least 500 implants by conventional methods. Five operators of each category completed the surgery in ten patients in total. All patients were fully edentulous and the surgical guide that was fabricated was mucosa-supported. The guide was indexed using denture duplicates and fixated with at least three fixation screws. The implants were placed using a flapless protocol, following ImplaDent fully guided surgical protocol. Analysis of the placed implants was completed using the same CT device as was used for pre-operative planning and overlapping the CT with the virtual planning. The results for the two groups are found in Table 9.

Table 9. Cassetta and Bellardini's 2017 study on influence of operator experience on the accuracy of fully guided implant placement.

	Angular deviation (º)	Coronal deviation (mm)	Apical deviation (mm)
Inexperienced	3.07 (0.73-9.22)	0.75 (0.51-1.01)	1.02 (0.64-1.99)
Experienced	3.21 (1.41-8.01)	0.60 (0.06-1.00)	0.67 (0.21-1.67)

The only parameter that was found to be better for the inexperienced operator was the angulation deviation of that implants placed. Otherwise, experienced operators appear to have greater deviations in the position of the implants. Within the limitation of this study, operator experience does not appear to influence the accuracy of the implants placed using a computer-guided surgical protocol. The limitations include a small patient sample size, the potential for the conventional experience of the inexperienced operator to play a role in the computer-guided surgeries, and again, only edentulous patients were included.

The aim of this study is to evaluate the influence of operator experience on the trueness (or accuracy) of fully guided surgical protocol in a dentulous, in vitro model. The secondary outcomes include the precision and reliability of fully guided implant placement, with comparison data of free-handed implant. The hypothesis is the trueness, precision, and reliability will be directly correlated to the level of operator experience.

Chapter 3
Materials and Methods

Sample preparation

This study was completed using 120 mandible replicas. The data for the mandible was obtained from the cone beam computed tomography (CBCT) of a partially edentulous patient. The CBCT was indicated solely for medical or dental reasons and not for research purposes. The local IRB approved access to the CBCT for this in vitro study (IRB protocol#: HR-1807025341). The CBCT data was obtained and used in two different ways. First the DICOM file was converted into an STL file to allow for the 3D (stereolithography) printing of the mandible using Preform printing software (Formlabs, Germany) and a Form 2 printer (Formlabs Inc, Somerville, MA 02143, USA). All mandibles were fabricated using the Grey resin, version 4 (Formlabs Inc, Somerville, MA 02143, USA)

The second use of the CBCT data was to upload the DICOM file to into the digital planning software (coDiagnostiX, Dental Wings Inc, Montreal, Canada), and a digital wax up of the edentulous space of #30 (Universal Numbering System) and digital planning of the proposed location of a Straumann Bone Level 4.1x10mm implant (Straumann Ag, Basel, Switzerland) was completed. The design of the surgical guide was then completed with coDiagnostiX (Dental Wings Inc, Montreal, Canada), transferred using Preform printing software (Formlabs, Germany) and stereolithographically printed with the Form 2 printer (Formlabs Inc, Somerville, MA 02143, USA). Once the print was complete and rinsed, a fully guided T-Sleeve (5mm inner diameter, 5mm height) (Straumann Ag, Basel, Switzerland) was press fit into place and the guide was cured.

Study Design

Three different operators were selected based on their level of clinical implant surgery experience. The unexperienced operator had no implant surgery experience. The moderately experienced operator had approximately 2 years of implant experience and the experienced operator had more than 5 years of experience in implant surgery. Each provider was scheduled to place 20 implants using the fully guided protocol and 20 implants using a free-handed protocol.

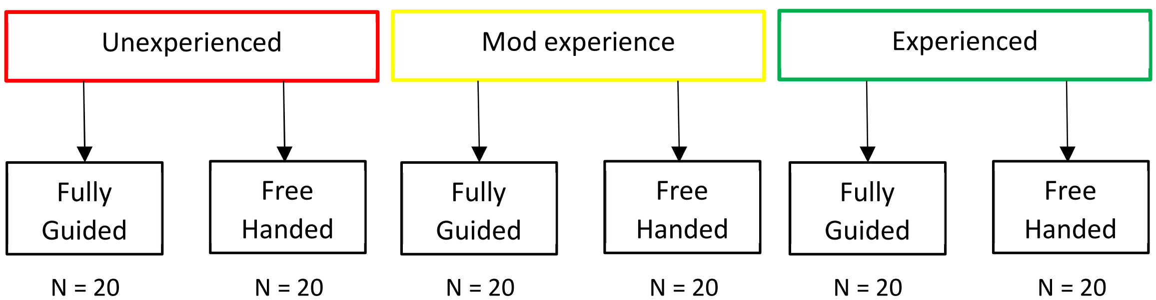


Figure 2. Study design includes placement of 20 Straumann Bone Level 4.1x10mm implants for each group. Each operator will place the implants using fully guided protocol and free hand protocol.

Armamentarium

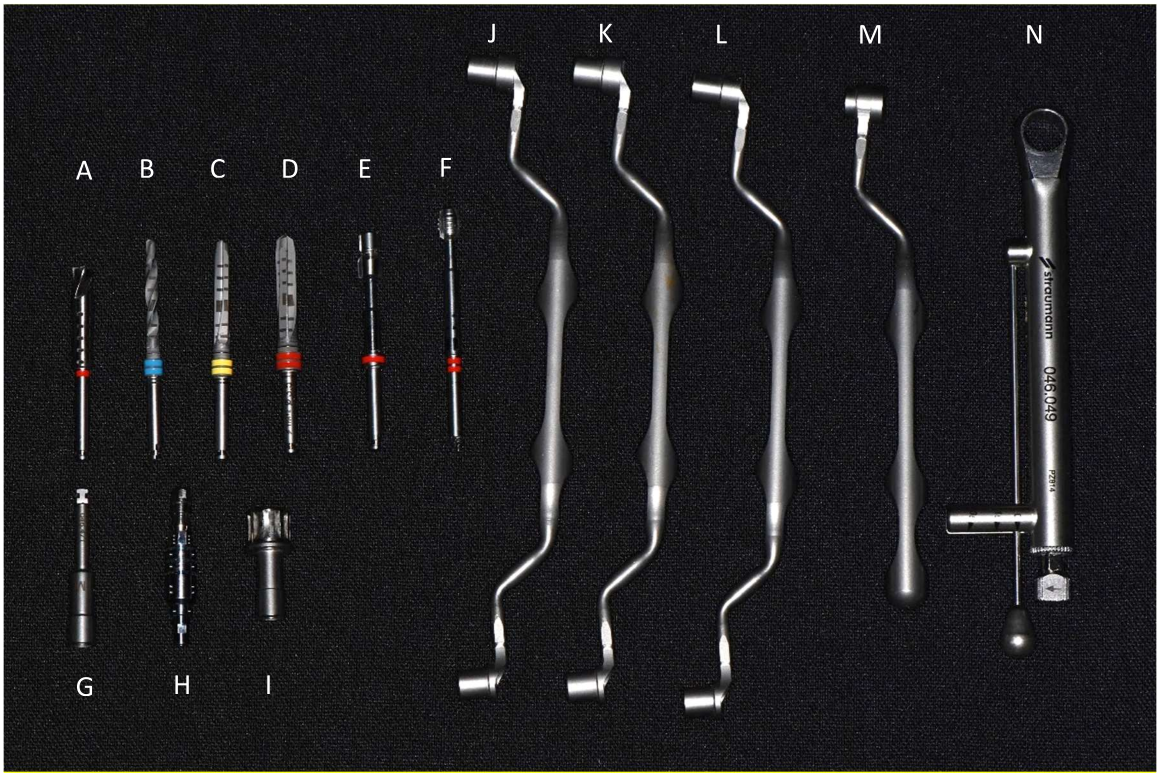


Figure 3. Straumann GuidedSurgery instruments, including A. 3.5mm Milling cutter, B. 2.2 Twist Drill (Long), C. 2.8mm Twist Drill (Long), D. 3.5mm Twist Drill (Long), E. 3.5mm Profile Drill, F. 3.5mm Bone Tap, G. Adapter for handpiece H. Guided Implant transfer, I. Adapter for ratchet, J. 2.2mm Drill handle, K. 2.8mm Drill handle, L. 3.5mm Drill handle, M. C-Handle 4H, N. Ratchet/Torque control device (Straumann Ag, Basel, Switzerland)

Surgical Protocol

Straumann® GuidedSurgery sleeve									
Position	**Milling cutter**	**Pilot drill**	**Guided drill**	**Guided drill**	**Guided drill**	**Profile drill**	**Tap**	**Implant**	**Depth stop**
30	Ø 3.5	Ø 2.2 BLT T1-T4 =	Ø 2.8 BLT T1-T4 =	Ø 3.5 BLT T1-T3 or dense cortex only =		Ø 4.1 BLT T1-T2 or dense cortex only H4	Ø 4.1 BLT T1 H4	021.5310 BLT RC Ø 4.1 10 mm SLActive	H4

Figure 4. Straumann GuidedSurgery Protocol produced from the digital implant planning software, coDiagnostX (Straumann Ag, Basel, Switzerland)

All three operators completed the same surgical protocol (See Figure 4), in the same order, with the same surgical guide. The guide was fitted to the replica mandible and stability was confirmed. Each trial was completed benchtop, with the use of a W&H implant motor and handpiece. The first implants placed were using Straumann's fully guided protocol, using only air to remove debris between each osteotomy preparation step. The coronal 2mm of the osteotomy was flattened using the 3.5mm, guided milling cutter and 3.5 drill handle (Straumann Ag, Basel, Switzerland). The initial osteotomy was completed using an extra-long 2.2 twist drill and the 2.2 drill handle (Straumann Ag, Basel, Switzerland). The extra length of the 2.2. twist drill allows for some extra space at the tip of the osteotomy, which has proven to be effective in allowing the implant to fully seat in the dense, resin model. The osteotomy was then widened using the indicated 2.8mm and 3.5mm diameter twist drills (drill length = long), and the respective drill handle (Straumann Ag, Basel, Switzerland). The osteotomy was completed using the 3.5mm profile drill and associated C-Handle, followed by the 3.5mm, guided bone tap and C-Handle (Straumann Ag, Basel, Switzerland). With the osteotomy completed and debris removed with compressed air, the Straumann BLT 4.1mm x 10mm research implant was placed, through the guide, using the guided implant transfers up to 45 Ncm. If the implant did not completely seat, due to the density of the resin, the implants were seated to depth using the hand torque wrench. The implant transfer was removed, along with the surgical guide. This process was completed nineteen more times, with a new replica mandible each time.

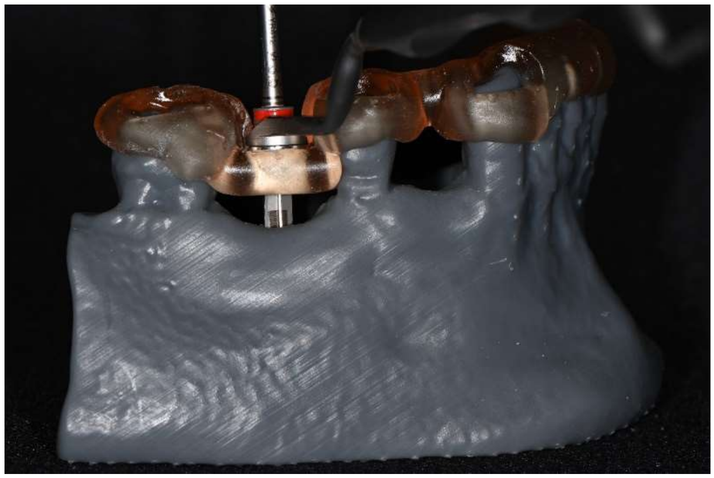


Figure 5. Image of the guided surgical protocol, completing the osteotomy in the resin mandible replica with a 3.5mm twist drill.

The same operator then completed twenty implants using the free-handed protocol for Straumann's BLT 4.1mm x 10mm implant (Straumann Ag, Basel, Switzerland). For reference of the implant's location, the operator had already completed the placement of twenty implants using the fully guided protocol, and the digital planning was available for review prior to beginning. The initial osteotomy was completed using the extra-long 2.2mm twist drill and no surgical guide, to a depth of twelve millimeters. This extra 2mm provides the same relief space to ensure complete placement of the implant. The osteotomy was then widened using the same guided 2.8mm and 3.5mm twist drills to a depth of 10mm, without the use of the guide. The profile drill and bone tap were used to complete the osteotomy. The Straumann BLT 4.1mm x 10mm research implant was then placed using a Loxim implant transfer and the electric handpiece. The manual wrench was again used if the depth of the implant needed to be adjusted. This same protocol was completed nineteen more times, using a new replica mandible for each trial.

Each of the two protocols were completed by the inexperienced, moderately experienced, and experienced providers at separate times. The number of Straumann research implants (n = 20) allowed the fully guided surgical protocol to be completed, followed by the treatment evaluation. Once evaluation was completed the implants were removed from the mandibles and the operator could then complete the free-handed protocol, using the same implants on new mandible replicas.

Treatment evaluation

Following the implant placement of the twenty trials for each protocol, Straumann scan bodies were placed, and hand tightened onto the implants. The replicas, with the scan bodies in place were digitized, using the 3Shape E3 laboratory scanner (3Shape A/S, Copenhagen, Denmark). The output file was a Standard Tessellation Language (STL) file, which then could be used by coDiagnostiX software to complete the comparison of the actual implant location to the planned implant location. Using the software, the post-operative STL file was superimposed over the planning STL file, using three standardized points on the teeth as reference. The implant analog was then identified, providing the location of the placed implant, and thereby providing the data for the comparison. The output data included the angular deviation and the 3D deviation at the alveolar crest and implant apex. This evaluation was completed for each trial.

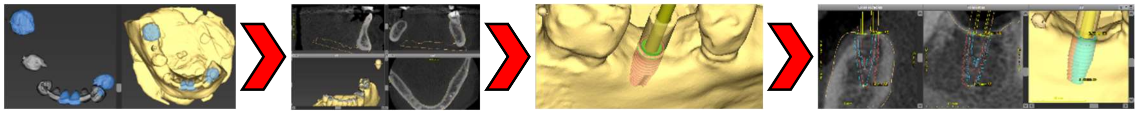


Figure 6. Fixed-point triangulation used to merge the post-operative scan, confirmed by the sagittal sections. The implant scanbody was identify, projecting the location of the placed implant. Finally, comparison of the placed implant to the planned implant location.

Statistical analysis

The data was then inputted into an Excel spreadsheet (Excel, V2101, Microsoft) and statistical computations and analysis was completed using IBM SPSS Statistics 27. Using the same sample size calculation of the pilot study completed by Guentsch, et. al., in 2020, 20 samples per group per experiment, with the p-value ≤ 0.05 and an effect size being 0.42, provided 80% power using ANOVA.[28] Analysis of nine comparisons of the implant position included angular deviation, 3D deviation at the crest and in the bucco-lingual, mesio-distal, and coronal-apical directions, and 3D deviation at the apex and in the bucco-lingual, mesio-distal, and coronal-apical directions. The outcome measures are as follows:

(1) Angular and 3D Trueness (the difference to the reference value) for each of the experimental groups

(2) Angular and 3D Precision (difference between the values within each group)

(3) Reliability of the intragroup values

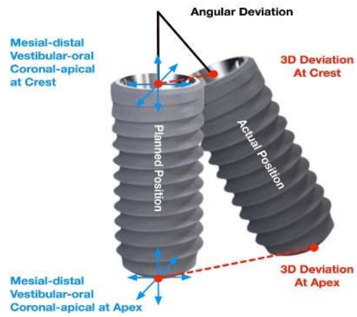


Figure 7. Image describing the comparison of the planned position versus the actual position.

The means, standard deviation, and 95%-confidence intervals were analyzed statistically with 1-way ANOVA and the Scheffe procedure, representing the trueness and precision, respectively. The intra-operator reliability was calculated using Cronbach's alpha.

Chapter 4
Results

The results involving the trueness of the implants place involve significant differences between the inexperience operator and the moderately experienced and experienced operators. The comprehensive data collection of the trueness data can be seen in Table 11. The angular deviation (see Figure 8) for the unexperienced operator was 3.14^o (SD 1.92) and 4.04^o (SD 1.04) for the free-handed implants and fully guided implants, respectively.

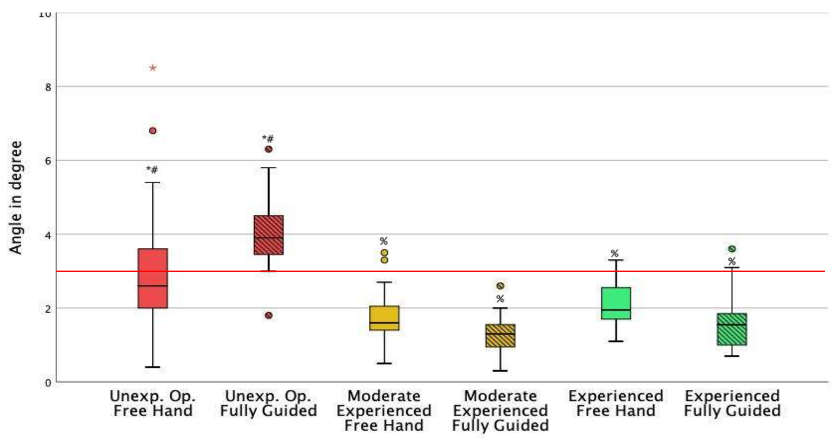


Figure 8. Box plot of the results of the 1-way ANOVA for the angular deviations. (*) = sig. different to moderate experience; (#) = sig. different to experienced; (%) = sig. different to unexperienced operator (p<0.001)

The free-handed angular deviation was significantly different from the free-handed and fully guided implants of the moderately experience operator (1.73^o (SD1.04) and 1.28^o (SD 0.52), respectively) and the fully guided implants (1.62^o (SD 0.76)) of experienced provider. The fully guided implants angular deviation for unexperienced provider was significantly different from all four of the groups including the moderately experienced and experienced provider (angular deviation for the free-handed implants completed by the experienced provider is 2.10^o (SD

0.62)). The angular deviations among the moderately experience and experienced operators were all insignificantly different from one another.

For the 3D deviation of the implants, a similar trend to the angular deviation is noted for both the crestal deviation and the apex deviation (as seen in Figure 5). The 3D deviation at the crest for the unexperienced operator for the free-hand and fully guided implants (0.49mm (SD 0.24) and 0.57mm (SD 0.09), respectively) were significantly different (p<0.001) from both the moderately experienced and experienced operators' fully guided implants (0.30mm (SD 0.09) and 0.28mm (SD 0.16), respectively) and the moderately experienced operator's free-handed implants (0.34mm (SD 0.17)). The differences between the moderately experienced and experienced operators were statistically insignificant.

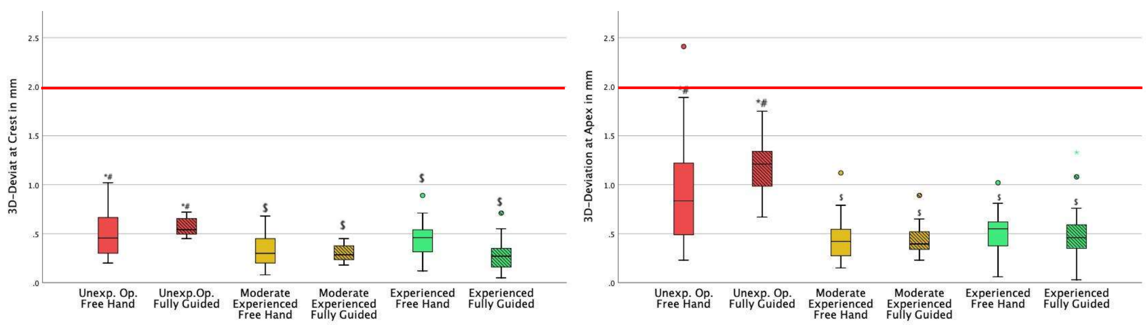


Figure 9. Box plots of the 3D deviations at the Crest and Apex. (*) = sig. different to moderate experience; (#) = sig. different to experienced; (%) = sig. different to unexperienced operator (p<0.001)

The 3D deviation at the apex of the free-handed and fully guided implants placed by the unexperienced operator (0.94mm (SD 0.57) and 1.20mm (SD 0.20), respectively), was also statistically significantly different (p<0.001) from the moderately experienced and experienced, free-handed (0.44mm (SD 0.24) and 0.51 (SD 0.24), respectively) and fully guided implants

(0.44mm (SD 0.16) and 0.52mm (SD 0.29), respectively). Again, the difference among the moderately experience and experienced operator groups was not statistically significant.

Regarding the angular deviation and the 3D deviation at the crest and apex, the deviations decreased for the moderately experience and experienced operators. However, for the unexperienced operator, all three of these parameters increased between the free-handed protocol and the fully guided protocol. Although these trends exist, these differences were statistically insignificant ($p>0.005$).

Analysis of the data for the secondary outcome of precision can be seen in Table 12. Unlike the trends seen in the perspective of accuracy, the general outcome was the use of the fully guided protocol increased the precision in comparison to the free-handed protocol for all providers. For the angulation deviation, the unexperienced provider reduced the difference among the trials from 2.02^{o} free-handed to 1.22^{o} fully guided ($p<0.001$). The reduction was statistically significant for the 3D deviation at the apex, improving from 0.64mm free-handed, to 0.33mm fully guided ($p<0.001$). Although there was an improvement in the precision between free-hand (0.27mm) and fully guided (0.21mm) at the crest, this difference was not statistically significant.

When comparing the precision of the experience level groups to one another, the moderately experienced and experienced operators had statistically insignificant differences ($p>0.05$) for the angulation deviation for each of the free-handed and fully guided groups. The precision of 3D deviation at the crest statistically insignificant ($p>0.05$) between the moderately experienced free-handed value (0.20mm) and experienced operators free-handed (0.19mm) and fully guided (0.19mm) values. The precision of the fully guided trials of the moderately experienced provider (0.10mm) is statistically significantly different from the moderately experienced free-hand and experienced operator's free-hand and fully guided trials ($p<0.001$). A similar trend in the precision is seen at the apex, as it is at the crest. The moderately experienced operator's free-handed (0.24mm) trials were statistically insignificant from the experienced operator's (0.28mm), but the fully guided mean precision at the apex of the moderately experienced operator (0.17mm) was significantly improved in comparison to the experienced operators free-handed and fully guided (0.35mm) trials.

Despite the differences between the groups, the use of the fully guided protocol with the unexperienced provider resulted in a similar precision of the 3D deviations at the crest and apex of the implant as the experienced operator (0.21mm vs 0.19mm and 0.33mm vs 0.35mm, respectively) ($p>0.05$). The precision of the angulation deviation, however, was statistically better for the experienced provider (0.83^{o}), in comparison to the unexperienced provider (1.22^{o}) ($p=0.014$).

Investigation into the reliability of the fully guided protocol, Cronbach's alpha was calculated using the results of accuracy for the experienced, moderately experienced, and unexperienced operators. The results can be seen in Table 10.

Table 10. Cronbach's alpha including the fully guided accuracy measurements of the unexperienced, moderately experienced, and experienced operators.

	Cronbrach's alpha
Angulation	0.937
Crest – 3D	0.854
Crest – Mesial/Distal	0.926
Crest – Buccal/Lingual	0.960
Crest – Apical/Coronal	0.960
Apex – 3D	0.872
Apex – Mesial/Distal	0.935
Apex – Buccal/Lingual	0.975
Apex – Apical/Coronal	0.982

Cronbach's Alpha ranged from 0.854-0.982, with the Cronbach's alpha for angulation equal to 0.937, 3D deviation at the crest equal to 0.854, and 3D deviation at the apex equal to 0.872. This is interpreted as the reliability of the fully guided protocol is excellent for the angulation and good for 3D deviation at the crest and the apex.

Table 11. Trueness Data (1-way ANOVA)

Trueness **As difference to the reference value (Comparing actual vs. planned implant position, n=20 implants each group)**		Unexp. Free Hand **Mean (SD) [95%-CI]**	Unexp. Fully Guided **Mean (SD) [95%-CI]**	Mod. Exp. Free Hand **Mean (SD) [95%-CI]**	Mod. Exp. Fully Guided **Mean (SD) [95%-CI]**	Exp. Free Hand **Mean (SD) [95%-CI]**	Exp. Fully Guided **Mean (SD) [95%-CI]**	***ANOVA***	
								F	***P***
	Angle in degree	**3.14**$^{\S\dagger\&}$ (1.92) [2.24-4.03]	**4.04**$^{\S\dagger\#\&}$ (1.04) [3.54-4.54]	**1.73**$^{*\$}$ (0.83) [1.34-2.14]	**1.28**$^{*\$}$ (0.52) [1.04-1.52]	**2.10**$^{\$}$ (0.62) [1.81-2.39]	**1.62**$^{*\$}$ (0.76) [1.27-1.97]	19.4	<.001
Crest in mm	**Δ3D**	**0.49**$^{\dagger\&}$ (0.24) [0.38-0.60]	**0.57**$^{\S\dagger\&}$ (0.09) [0.53-0.61]	**0.34**$^{\$}$ (0.17) [0.25-0.42]	**0.30**$^{*\$}$ (0.09) [0.26-0.34]	**0.45** (0.19) [0.36-0.54]	**0.28**$^{*\$}$ (0.16) [0.21-0.36]	9.4	<.001
	Mesial-distal	**0.21** (0.20) [0.11-0.30]	**0.16**$^{\#}$ (0.13) [0.10-0.22]	**0.17**$^{\#}$ (0.15) [0.09-0.24]	**0.11**$^{\#}$ (0.10) [0.06-0.15]	**0.33**$^{\$\S\dagger\&}$ (0.19) [0.24-0.42]	**0.09**$^{\#}$ (0.09) [0.05-0.13]	6.5	.004
	Buccal-lingual	**0.37**$^{\dagger\#\&}$ (0.25) [0.25-0.49]	**0.40**$^{\S\dagger\#\&}$ (0.15) [0.33-0.48]	**0.22** (0.13) [0.16-0.28]	**0.18**$^{*\$}$ (0.11) [0.13-0.23]	**0.18**$^{*\$}$ (0.13) [0.12-0.25]	**0.15**$^{*\$}$ (0.19) [0.05-0.24]	8.1	<.001
	Coronal-apical	**0.09**$^{\$}$ (0.07) [0.06-0.12]	**0.31**$^{*\S\dagger\#\&}$ (0.10) [0.26-0.36]	**0.13*** (0.10) [0.09-0.18]	**0.17**$^{\$}$ (0.08) [0.13-0.20]	**0.09**$^{\$}$ (0.06) [0.06-0.12]	**0.12**$^{\$}$ (0.10) [0.07-0.17]	17.9	<.001
Apex in mm	**Δ3D**	**0.94**$^{\S\dagger\#\&}$ (0.57) [0.67-1.20]	**1.20**$^{\S\dagger\#\&}$ (0.27) [1.07-1.32]	**0.44**$^{*\$}$ (0.24) [0.33-0.56]	**0.44**$^{*\$}$ (0.16) [0.37-0.52]	**0.51**$^{*\$}$ (0.24) [0.40-0.62]	**0.52**$^{*\$}$ (0.29) [0.38-0.65]	18.5	<.001
	Mesial-distal	**0.50**$^{\$\S\dagger\&}$ (0.34) [0.34-0.66]	**0.28** (0.20) [0.18-0.37]	**0.24*** (0.20) [0.15-0.34]	**0.15*** (0.10) [0.11-0.20]	**0.36** (0.24) [0.25-0.47]	**0.16*** (0.11) [0.11-0.21]	7.6	<.001
	Buccal-lingual	**0.72**$^{\$\S\dagger\#\&}$ (0.57) [0.45-0.99]	**1.10**$^{*\S\dagger\#\&}$ (0.32) [0.94-1.25]	**0.29**$^{*\$}$ (0.22) [0.19-0.40]	**0.34**$^{*\$}$ (0.21) [0.24-0.43]	**0.30**$^{*\$}$ (0.18) [0.21-0.38]	**0.34**$^{*\$}$ (0.33) [0.18-0.49]	19.0	<.001
	Coronal-apical	**0.08**$^{\$}$ (0.05) [0.06-0.11]	**0.28**$^{*\S\dagger\#\&}$ (0.11) [0.23-0.34]	**0.13**$^{\$}$ (0.10) [0.08-0.18]	**0.17**$^{\$}$ (0.08) [0.13-0.20]	**0.08**$^{\$}$ (0.05) [0.06-0.11]	**0.13**$^{\$}$ (0.09) [0.08-0.17]	15.5	<.001

* significant different to Unexperienced Free Hand

$ significant different to Unexperienced Fully Guided

§ significant different to Moderately experienced Free Hand

† significant different to Moderately experienced Fully Guided

significant different to Experienced Free Hand

& significant different to Unexperienced Fully Guided

Table 12. Precision Data (Scheffe procedure)

Precision As difference or distance among implants (based on n=191 comparisons within each group)		Unexp. Free Hand **Mean (SD) [95%-CI]**	Unexp. Fully Guided **Mean (SD) [95%-CI]**	Mod. Exp. Free Hand **Mean (SD) [95%-CI]**	Mod. Exp. Fully Guided **Mean (SD) [95%-CI]**	Exp. Free Hand **Mean (SD) [95%-CI]**	Exp. Fully Guided **Mean (SD) [95%-CI]**	***ANOVA***	
								F-value	***P***
	Angle in degree	**2.02**[$§†#&] (1.89) [1.75-2.29]	**1.22**[*§†#&] (1.09) [1.07-1.38]	**0.87**[*$] (0.78) [0.76-0.98]	**0.59**[*$] (0.49) [0.52-0.66]	**0.75**[*$] (0.54) [0.67-0.83]	**0.83**[*$] (0.73) [0.72-0.93]	48.1	<.001
Crest in mm	**Δ3D**	**0.27**[§†#&] (0.26) [0.24-0.30]	**0.21**[†] (0.31) [0.17-0.25]	**0.20**[*†] (0.14) [0.18-0.22]	**0.10**[*$§#&] (0.08) [0.09-0.11]	**0.19**[*†] (0.16) [0.17-0.21]	**0.19**[*†] (0.16) [0.17-0.21]	16.5	<.001
	Mesial-distal	**0.30**[$§†#&] (0.21) [0.27-0.33]	**0.15**[*§#&] (0.11) [0.13-0.17]	**0.24**[*$†&] (0.18) [0.21-0.26]	**0.12**[*§#] (0.08) [0.10-0.13]	**0.22**[*$†&] (0.16) [0.20-0.25]	**0.09**[*$§#] (0.09) [0.07-0.10]	55.6	<.001
	Buccal-lingual	**0.32**[$§†#&] (0.22) [0.29-0.35]	**0.18**[*] (0.13) [0.17-0.20]	**0.16**[*†#] (0.11) [0.14-0.17]	**0.22**[*§] (0.17) [0.19-0.24]	**0.23**[*§] (0.16) [0.21-0.25]	**0.20**[*] (0.21) [0.17-0.23]	20.2	<.001
	Coronal-apical	**0.12**[#] (0.09) [0.11-0.14]	**0.11**[#] (0.09) [0.10-0.12]	**0.10**[#] (0.07) [0.09-0.11]	**0.11**[#] (0.08) [0.10-0.12]	**0.07**[*$§†&] (0.05) [0.06-0.08]	**0.11**[#] (0.09) [0.10-0.13]	9.8	<.001
Apex in mm	**Δ3D**	**0.64**[$§†#&] (0.52) [0.57-0.72]	**0.33**[*†] (0.28) [0.29-0.37]	**0.24**[*&] (0.21) [0.21-0.27]	**0.17**[*$#&] (0.15) [0.15-0.20]	**0.28**[*†] (0.21) [0.25-0.31]	**0.35**[*§†] (0.28) [0.31-0.39]	56.5	<.001
	Mesial-distal	**0.40**[$†#&] (0.29) [0.36-0.44]	**0.30**[*†&] (0.21) [0.27-0.33]	**0.34**[†&] (0.26) [0.31-0.38]	**0.17**[*$§#] (0.12) [0.15-0.18]	**0.28**[*†&] (0.21) [0.24-0.31]	**0.18**[*$§#] (0.18) [0.15-0.20]	33.0	<.001
	Buccal-lingual	**0.78**[$§†#&] (0.73) [0.68-0.89]	**0.39**[*#] (0.31) [0.35-0.44]	**0.33**[*] (0.23) [0.30-0.36]	**0.35**[*#] (0.30) [0.31-0.39]	**0.20**[*$†&] (0.15) [0.18-0.23]	**0.36**[*#] (0.35) [0.31-0.41]	48.8	<.001
	Coronal-apical	**0.12**[#] (0.08) [0.11-0.13]	**0.12**[#] (0.09) [0.11-0.13]	**0.11**[#] (0.07) [0.10-0.12]	**0.11**[#] (0.08) [0.10-0.12]	**0.06**[*$§†&] (0.05) [0.06-0.07]	**0.11**[#] (0.08) [0.10-0.12]	14.2	<.001

* significant different to Unexperienced Free Hand

$ significant different to Unexperienced Fully Guided

§ significant different to Moderately experienced Free Hand

† significant different to Moderately experienced Fully Guided

significant different to Experienced Free Hand

& significant different to Unexperienced Fully Guided

Chapter 5
Discussion

The analysis of the outcomes with regards to the trueness of the implant placed showed significant differences for both the angular deviations and 3D global deviations at the crest and implant apex. As shown in Figure 8, the angular deviations exhibited by the unexperienced operator using the free-handed protocol and fully guided protocol were significantly greater than the moderately experience and experienced operators ($p<0.001$). Although not statistically significantly different, the angular deviation for the unexperienced operator increased when the fully guided protocol was used, in comparison to the free-handed protocol (4.04^{o} vs 3.14^{o}, respectively). Also, to note, the red line in Figure 8 demarcates the 3^{o} angle deviation level. Both the free-handed and fully guided implants are exceeding this level. For both moderately experienced and experienced providers, the angular deviation is well below for both treatment modalities. The moderately experienced providers had statistically insignificant differences between all the groups, however, a trend for increased angular accuracy was found for the fully guided implants.

As with the angular deviations, the deviation at the crest and apex was greater for the unexperienced operator, in comparison to the moderately experienced and experienced providers. Also, similar trends were seen in the 3D deviation as the angular deviation. As a result of the angular deviations, the 3D deviation is smaller at the crest than the deviation at the implant apex for each the free-hand and fully guided implants placed by the inexperienced operator. This indicates the location of the implant platform is within 1.0mm of the planned implant location, however, the angulation of the implant has resulted in the greater discrepancy. Two implants placed free-handed by the inexperienced operator resulted it the apex located at or outside of the 2mm safety zone.[9, 10] For the inexperienced operator, the mean

3D deviation at the crest was statistically insignificant between the free-handed implants and fully guided implants (0.49mm and 0.57mm, respectively). The difference in the mean 3D deviation at the apex of the implant, was greater, but not statistically significant (0.94mm vs 1.20mm, respectively). Similar to the angular deviation exhibited by the inexperienced operator, the 3D deviation was greater in the fully guided implants, in comparison to the free-handed implants.

One aspect that has not been addressed yet is the direction of the deviations for the free-handed and fully guided implants. This is best depicted in the bullseye's diagrams of Figure 10 and Figure 11. Figure 10 represents the 3D deviation at the crest and apex of the implant for the free-handed trials and Figure 11 represents the 3D deviation at the crest and apex of the implant for the fully guided trials. When looking at the trends for position at the crest, the moderately experienced and experienced operators deviated in the buccolingual direction, but minor deviation in the mesiodistal direction. The unexperienced operator deviated in both the mesiodistal and buccolingual directions. There is a noted trend for crest of the implant to be placed slightly to the lingual for all three operators, and the unexperienced operator also tended to position the crest of the implant towards the distal. For the apex of the implant, these trends were amplified most notably in the lingual direction for all the operators.

In general, the trueness of the fully guided implant placement improved in comparison to the free-handed implant placement for the moderately experienced and experience providers. However, the same was not true for the unexperienced provider. The trueness of the angulation deviation is significantly ($p<0.001$) degraded with the use of fully guided protocol in comparison to the free-handed implants. The precision of the angulation among the trials for the unexperienced provider was improved. Interpretation of this data indicates the guided surgery protocol allows for some level of deviation within the protocol, but the resulting inaccuracy was relatively consistent, with the mean difference of all the trials was 1.22mm. The use of the guided surgery protocol reduced this difference by nearly half of the deviation of the free-handed trials.

In comparison to other studies looking at the influence of operator experience, the results of this study are relatively more accurate. Van de Velde, in 2008, showed the free-handed angulation deviation for the 3 groups, specialists, dentists, and students was 7.33^{o}, 9.76^{o}, and 6.234^{o}, with the mean of 7.77^{o}.[25] The direct comparison of the free-handed implants placed by unexperienced, moderately experienced and experienced operators was 3.14^{o}, 1.73^{o}, and 2.10^{o} and a mean of 2.32^{o}. The difference between the two is substantial, but the differences can potentially be attributed to the differenced in the models used, Van de Velde using an edentulous model and this study using a dentulous model, with implant being placed between two existing teeth. Ersoy, in 2008, showed that even with use of a surgical guide, implants placed in an edentulous arch were significantly less accurate than those placed in arches with remaining dentitions.[16] For both studies, the hypothesis for the greater the amount experience and training is should result in a greater accuracy of implants being placed was not observed. For free-handed surgical protocols, it appears operator experienced does not have a direct and proportional effect on the accuracy of implant placement.

Cushen in 2013 and Cassetta and Bellardini in 2017 evaluated the effects of operator experience on the placement of surgically guided implant placement.[26, 27] Comparison of the data can be seen in Table 13. Cushen reported greater horizontal accuracy of the implants placed by the experienced provider, but the angulation deviation was insignificantly different. Cassetta reported a similar trend, with the inexperienced operator placing the implants with greater horizontal deviation than the experienced operator and again, an insignificant difference in angular deviation.

Table 13. Comparison of accuracy data from this study, Cushen[26], and Cassetta[27]

	Study Author	Angular Deviation (^{o})	Deviation at Crest (mm)	Deviation at Apex (mm)
Experienced	**Garcia**	1.62	0.28	0.52
	Cushen	2.60	0.63	0.34
	Cassetta	3.21	0.60	0.67
Unexperienced	**Garcia**	4.04	0.57	1.20
	Cushen	3.96	0.77	0.42
	Cassetta	3.07	0.75	1.02

Interpretation and clinical application of these results should be considered within the limitations of this study, however. As an in vitro study, we know from the previously published systematic review and meta-analysis complete by Bover-Ramos, the in vitro study outcomes were approximately 1.6 times more accurate than the clinical studies.[24] Applying this to the results of this study, an estimation the results would be as seen in Table 14. This estimation can then be compared to the clinical studies.

Table 14. The accuracy outcomes in this study, multiplied by 1.6 for approximate comparison to clinical studies.

	Unexp. Free-Hand	Unexp. Fully Guided	Mod. Exp. Free-Hand	Mod. Exp. Fully Guided	Exp. Free-Hand	Exp. Fully Guided
Angulation Deviation	5.02^{o}	6.46^{o}	2.77^{o}	2.05^{o}	3.36^{o}	2.59^{o}
3D Deviation at Crest	0.78mm	0.91mm	0.54mm	0.48mm	0.72mm	0.45mm
3D Deviation at Apex	1.50mm	1.92mm	0.70mm	0.70mm	0.82mm	0.82mm

When comparing this extrapolated data to that of the clinical studies, both the moderately experienced and experienced operators had more accurate outcomes regarding the angulation deviation and apical horizontal deviation reported by Bover-Ramos (Table 2). The unexperienced provider's results, however, are less accurate. The angulation deviation for the fully guided protocol of this study 6.46^{o}, approximately 1.6 times greater than the results reported by Bover-Ramos (3.98^{o}). The horizontal deviation at the apex was also greater for the unexperienced provider by 1.07mm.

Also, in comparison to the results of the clinical study published by Younes, et. al., in 2018, (Table 3), the results are again very similar for the fully guided outcomes angulation deviations of moderately experienced and experienced providers (2.05^{o} and 2.59^{o}, respectively) and the fully guided outcomes by Younes (2.30^{o}). The unexperienced provider, again, had a higher angular deviation than that reported in the clinic study (6.46^{o} vs 2.30^{o}, respectively). Although this comparison is an extrapolation of results of this study, this estimation illustrates the potential influence of the operator experience in a clinical situation. Despite the deviation increasing when unexperienced provider used the fully guided surgical protocol, the recommendation for applying this data to the clinical situation is for clinicians without surgical experience in placing implants to still use the fully guided protocol to assist. This recommendation comes with caution to assess the progress of the osteotomy preparation at each step in the surgical protocol to evaluate the location and angulation and make corrections, if necessary. One aspect the surgically guided protocol positively influenced for the unexperienced provider was the precision of the implants being placed. Knowing the trends for the demonstrated in Figure 7, critique of osteotomy clinically and radiographically, deviations can be spotted and adjusted for prior to implant placement.

As discussed previously, precision is the difference among that implants placed within a group. For this study, precision was calculated using the Scheffe procedure, with inherently calculates the mean difference between all the trials against each other. This results in 191 comparative measurements, which then can be averaged to give you the actual precision of the group. Other studies have defined precision as the standard deviation or the range of the outcome values.[11, 15, 19, 24-26] This method of analyzing the precision is errant, due to the fact difference between samples is not actually calculated. It simply gives you an idea of the extent of the deviation for group, without providing the actual measurement difference between all the trials. The most accurate way of defining the precision of a group of data is the Scheffe procedure.

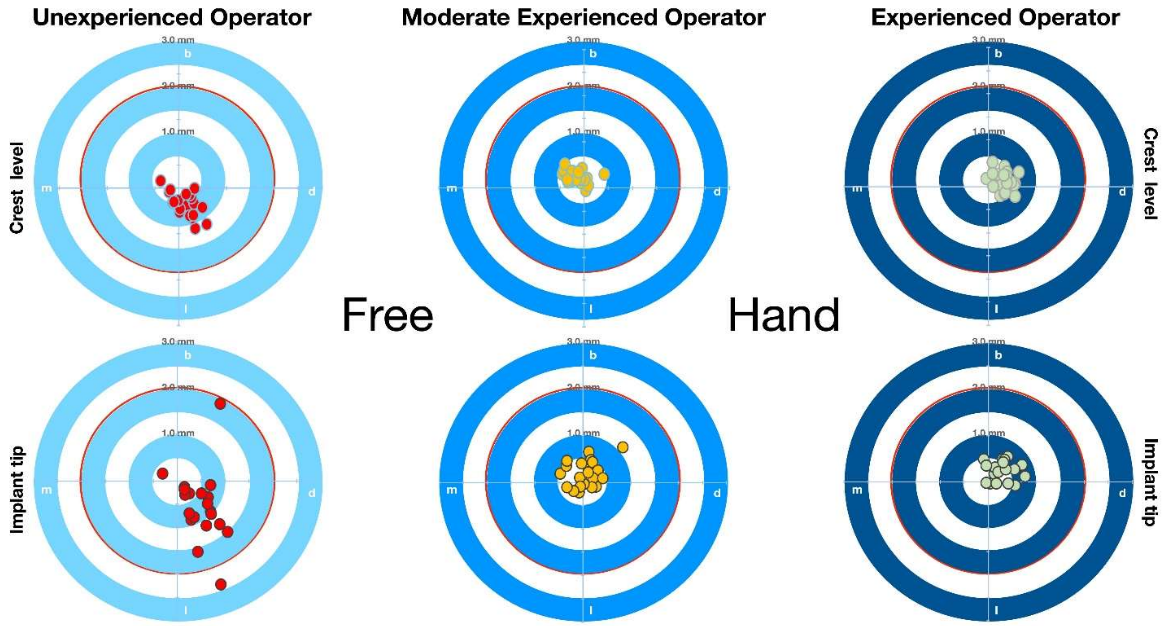


Figure 10. Bull's eye diagrams of the linear deviation including the Free-handed implants.

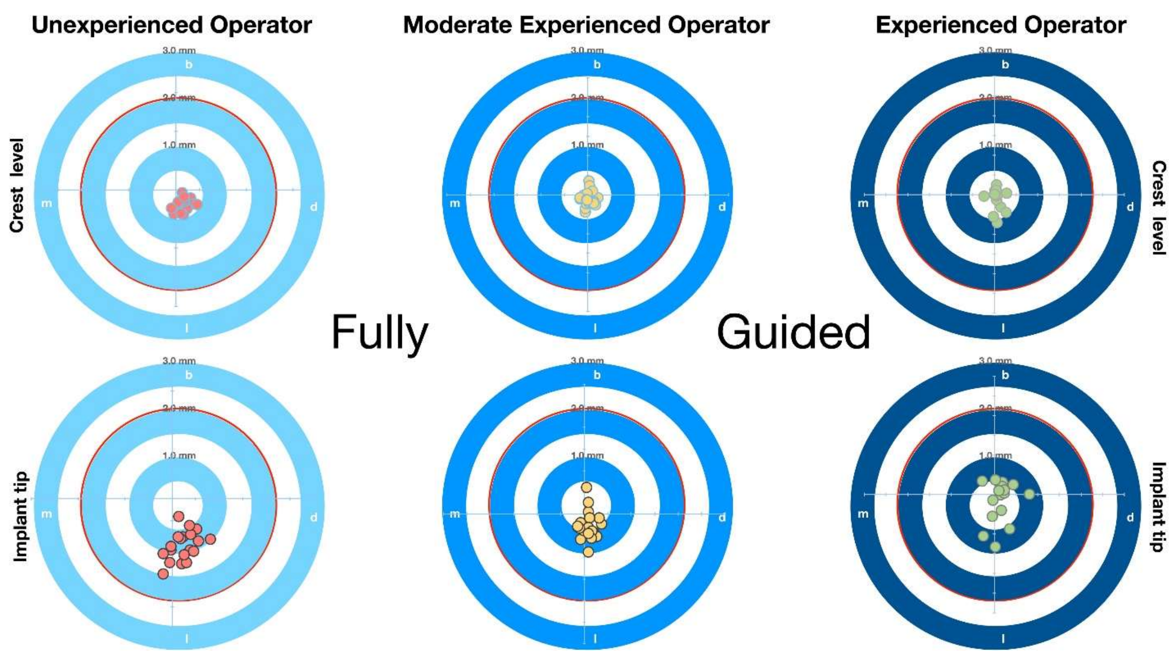


Figure 11. Bull's eye diagrams of the linear deviation including the fully guided implants placed by all three operators of differing levels of experience.

Due to the reproducibility of this in vitro study's design, intra-operator reliability can be determined. Statistically, this is completed by calculating Cronbach's Alpha. The resulting values for Cronbach's Alpha ranges from 0 to 1, with the closer the value is the greater the internal consistency or reliability. The ranges include 0.00-0.69 as poor, 0.70-0.79 as fair, 0.80-0.89 as Good, and 0.90-0.99 as excellent. As seen in Table 10, the lowest value is associated with the 3D deviation at the crest (0.854). Even though this value was the lowest, the intra-operator reliability is still considered good. The values ranged up to 0.982, for the deviation at the apex in the apico-coronal direction, is an excellent reliability score. Overall, in the hands of a moderately experience or experienced operator, the fully guided surgical protocol is very reliable treatment modality.

The methods used in this study are not without inherent limitations. Inaccuracies have been investigated regarding the imaging techniques, the fabrication of the surgical guide, and analysis of implant of the implant. The imaging used for this study includes the CBCT used to for planning and model and surgical guide fabrication. CBCTs have been shown by several studies to have a varying range of inaccuracies. Baumgaertel, et. al. in 2009, published a skull study evaluating the accuracy of linear measurements on tha CBCT in comparison to the caliper measurements using the skull.[29] The results of the study show the measurements on the CBCT were highly reliable, but slightly underestimated the anatomic truth. The only time the CBCT measurements were significantly different from the caliper measurements were when the measurements were compounded on top of each other. In 2014, Gaia, et. al. completed another skull study evaluating the accuracy and reliability of linear measurements using CBCT.[30] The results showed a range of -0.01 to 1.85mm, with high inter-examiner correlation coefficients. Due to this measurement discrepancy, the authors recommended sparing use the specific software in planning for Le Fort I osteotomy. Finally, in 2018, Fokas, et. al. published a systematic review of the accuracy of linear measurements on CBCT images.[31] A total of twenty-two studies were included and the results showed the use of cross-sectional images of the CBCT produced highly reliable and accurate measurements, with most studies showing less than 1mm differences between the CBCT and physical measurements. The studies, however, ranged from overestimating to underestimating the measurement in comparison to the gold-standard measurements. Due to the deviation, the authors recommended leaving a 2mm safety margin between the planned surgery and any vital anatomic considerations.

For this study, any inaccuracy in the CBCT was minimized due to the use of only one image for the planning, surgical guide fabrication, and analysis. Inaccuracy in the CBCT would have played a role if the analysis of the implant placed would have been completed via a “post-op” CBCT, however, this studying used a surface scan to complete this analysis. The laboratory scanner used is a 3Shape E3 (3Shape A/S, Copenhagen, Denmark), has an accuracy of 10 µm. For reference, the 3Shape TRIOS intraoral scanner has been shown to have trueness of 16.9 µm and in the in vitro study, the intraoral scans were tested in comparison to the 3Shape E3 laboratory scanner.[32] The inaccuracy due to CBCT, however, should be something that is considered when CBCT is used for clinical applications.

The fabrication or stereolithographic printing of the surgical guide and mandibular replicas is another source of inherent error. In 2013, Cassetta, et. al. have published an article investigating the inherent error of stereolithographic printing of surgical guides.[33] When looking at angulation deviation, the mean intrinsic error was 2.57^{o}, which was significantly influenced by clinical variables, including the use of fixation screws and support using the palate in the upper arch. In 2012, the Stumpel published a case series discussing deformation of the stereolithographically produced surgical guides.[34] Discussion about the ISO values, or the threshold used to by the computer to build the virtual model from the CBCT, plays an important part in the accuracy of the surgical guide produced. If the ISO values are set too high, the resulting surgical guide will shrink in size, and if the ISO is set too low, the surgical guide will be larger in size. Since each system is different, the ISO value needs to be individualized for each set up and one universal setting is not applicable. For this study, again the surgical guide and replica was fabricated using the same CBCT and planning, removing variation from multiple scans.

When looking at the accuracy of the Form 2 (FormLabs Inc. Somerville, MA, USA), the stereolithographic printer used for this study, Msallem, et. al. published a study in 2020, comparing it to two other types of 3D printers. Each printer printed 50 replica mandibles and Form 2 printer produced a mean trueness of 0.23mm, with a range of -1.91-1.69mm. This discrepancy alone could produce a majority of the deviation seen in the outcomes of this study. However, since the same surgical guide was used for all three operators, this deviation is the same for all three. There is potential that the discrepancy in the printed components could have allowed for fitment variability, allowing for the operators to manipulate the surgical guide slightly and create these discrepancies.

Chapter 6
Conclusion

Within the limitations of this study, the results of this study show fully guided surgical protocol for implant place is a highly accurate, precise, and reliable modality. The operator's experience does play a role in influencing the outcome of guided surgery. However, it appears there is a learning curve that allows a moderately experienced provider to perform similarly to an experienced operator. In the end, more operators, with different levels of experience should be used in this same study design to help describe influence of operator experience on the accuracy of fully guided implant placement.

Chapter 7
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