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A Study of the Accuracy of Static Guided Implant Surgery for Fully Edentulous Patients - Comparison of Pre-Planned Implant versus Actual Implant Positions

A Thesis

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by

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ABSTRACT

Aim & Hypothesis

Understanding of the maximum discrepancy of template guided surgical systems is extremely pertinent. Catastrophic failure of implants can occur as a result of these 3D deviations at time of implant placement. The aims of this study were to assess the positional 3-D deviations between the implant analogs in the casts generated from the Nobel Biocare CAD/CAM surgical templates, and the implant analogs in the post-surgical casts. The hypothesis is that there are differences between the 3-D positions of virtually planned implants and the actual implant positions for fully edentulous patients.

Materials & Methods

Study population

The current study included the records of patients that were treated for the implant-prosthetic treatment of fully edentulous arches. The stone casts were generated from 8 fully edentulous patients (12 edentulous arches) that underwent computer-planned and template-guided implant placement according to Nobel Guide concept (Nobel Biocare AB, Gothenburg, Sweden). In total, 59 implants (NobelReplace® Conical Connection) were inserted in 12 jaws (seven maxillae, five mandibles). Four patients were treated both in the maxilla and in the mandible.

Group One (I): Full-arch open tray splinted implant impressions were completed using polyether based impression material (Impregum, 3M ESPE, St Paul, MN, USA). The post-surgical stone cast was fabricated with low expansion (0.06%) type IV die stone (New FujiRock® IMP GC Corp, Tokyo, Japan).

Group Two (II): Surgical templates were used for fabricating master stone casts.

Superimposition and Accuracy Measurements: The stone casts were scanned for digitalization with an extra-oral scanner (Activity 880 scanner; Smart Optics, Bochum, Germany). The scan bodies (NobelProcera® Position Locator Conical Connection) were first placed in the group I casts, and digitization completed, followed the group II casts. The stereolithography(STL) files were saved. The STL dataset overlap and matching were executed by 3D inspection and metrology software (Geomagic® Control™) for all casts of both groups. The 3D inspection software calculated positional deviation as the Root Mean Square Error (RMSE). A mixed-effects model was used in order to account for the lack of independence between observation from the same subject.

Results

Based on the RMSE values from both arches, one subject was considered an outlier for which the values were 691.52 μ m and 670.92 μ m for the maxilla and mandible respectively. The mean age of the subjects when excluding the outlier was 65.8 years (64.6 years with outlier) with a standard deviation (SD) of 7.7 (7.5 with outlier) and median of 66.5 (64 with outlier). The mean and median of the RMSE values obtained after the superimposition of the group I casts over the group II cast were 163.30 μ m and 145.25 μ m, respectively, excluding

the arches from the outlying subject. The mean (SD) of the RMSE values for the maxillary arch, not including the outlier, was 165.51 (70.02) μm . Corresponding numbers for the mandibular arch were 161.83 (79.23) μm . The difference between arches was not statistically significant, whether excluding ($P = 0.947$) or including ($P = 0.541$) the outlier.

Conclusion

Within the limitations of this study, the following conclusions may be drawn:

1. There were measurable 3-D deviations between the implant analogs in the casts generated from the Nobel Biocare CAD/CAM surgical templates and the implant analogs in the post-surgical casts created with splinted full-arch open tray implant impressions.
2. No statistically significant differences were found in the positional 3-D deviations between the implant analogs in the maxillary and mandibular casts.

DEDICATION

I dedicate my thesis work to my loving family and friends.

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μ : Micron.....	39
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**A Study of Accuracy of the Static Guided Implant Surgery for Fully Edentulous
Patients - Comparison of Pre-Planned Implant versus Actual Implant Positions**

Introduction

Through research and clinical experience over the past four decades, dental implants have been proven to be a scientifically efficient way of treating the completely as well as the partially edentulous patient.¹ According to Papaspyridakos et al.'s systematic review assessing studies ranging over a 15-years' time span (1997 to 2012), implant survival in the edentulous mandible ranged from 98.42% to 96.86% for five and ten-years follow-up, respectively, with the use of rough surface implants.¹ On the other hand, smooth surface implants showed a survival rate of 98.93% and 97.88% for five and ten years respectively.¹ Five hundred and one patients and 2,827 implants were included in the review.¹ The implant surface, the number of implants and their distribution did not affect implant survival.¹ Moreover, the veneering material, prosthesis type, design, or loading protocol had no statistically significant effect on implant survival.¹ The authors concluded that the utilization of implants for the treatment of the edentulous mandible yields a survival rate of over 96% over a ten-years period.¹ Therefore, the prosthesis may not affect the survival of the implants.¹

Dental implants have proven to be a reliable solution for the edentulous maxilla as well.² Lambert et al.'s systematic review assessed the implant survival over a 15-year period, taking into consideration implant surface, bone grafting procedures, and prosthodontic factors in connection with the prosthesis design, materials, implant number, and distribution.² Regarding the prosthesis design, this was further divided into complete fixed conventional prosthesis and complete fixed hybrid prosthesis. Data of a total of 1,320 patients and 8,376

implants were analyzed for a period of one, three, five, ten, and 15 years.² The analysis demonstrated a decrease in survival over time, with the rough surface implants having higher survival rate compared to the smooth (machined) implants.² Additionally, less peri-implant bone loss was presented throughout the study's term, which would seem to indicate that rough surface implants are a more favorable choice when rehabilitating the edentulous maxilla.² Prosthodontically, data of 1,024 patients were analyzed, resulting in 98.2% survival after one year, and 92.1% after ten years.² Veneering material, design, and number of prostheses did not result in a statistically significant influence within the 15-year period.² The number of implants supporting a prosthesis did not have any effect on implant survival, though six or more implants consistently had higher survival rates in all the articles reviewing scenarios with less than six implants.² Prostheses retained by implants distributed anteriorly to the mental foramina resulted in a statistically significant lower survival rates compared to implants with a wider anterior-posterior spread.² It was also noted by the authors that smooth (machined) implants placed in native bone resulted in superior survival rates compared to implants placed in grafted areas.² However, the studies using rough surface implants seemed to have comparable results for native versus grafted sites.² The authors suggested that further investigation into the matter is necessary.²

Several prosthetic choices are available for the fixed implant rehabilitation of the edentulous jaw. One of the first options to be adopted was the metal-resin hybrid prosthesis.³ The purpose of placing inter-foraminal implants was the availability and superior density of inter-foraminal bone combined with the frequently encountered advanced resorption in the posterior mandible.³ In Gallucci et al.'s study, 45 edentulous patients were rehabilitated with a hybrid prosthesis out of which 41 were metal-resin hybrid, and a five years follow-up

period was established.³ Inter-foraminal implant placement was performed for all cases.³ The implant survival rate was 100%, whereas the prosthesis survival rate was found to be 95.5% because two prostheses had to be remade after framework fracture.³ Four more prostheses were deemed unsuccessful due to more than four complications within the same prosthesis.³ Most complications were technical (54/79) in nature, such as screw loosening or fracture as well as the fracture of the resin base or teeth.³ These findings reflect the limitations of this type of reconstruction.³ Similar complications were also found in Friberg et al.'s study, who observed that the fracture of the resin veneering was most common cause.⁴

A second material option, by many considered the gold standard for fixed implant prosthesis, is porcelain-fused-to-metal (PFM).⁵ Not many longitudinal studies that have been conducted for this type of prosthesis.⁶ Amongst these, the study by Teigen et al. analyzed a pool of 198 patients who had received implant supported PFM restorations, of which 67 were full arch implant supported.⁷ Amongst the restorations with 2 to 3 cantilever teeth, there was no statistically significant difference when compared to prostheses containing only one or no cantilever units when measuring the time of the first necessary repair.⁷ Likewise, there was no significant difference when comparing the framework alloys, whether cobalt-chromium or type 3 gold.⁷ Implant survival resulted was between 90% to 95% after a 15-year period.⁷ Almost half of the patients (42%) did not have to undergo any kind of repair or intervention, whether technical or biological, whereas the rest experienced at least one complication.⁷

An alternative material to the traditional all-ceramic systems for fixed dental prostheses (FDP) fabrication is represented by the use of high-strength metal-oxide ceramics. These have been developed to try and solve some of the mechanical issues experienced in all-ceramic FDPs, such as significant porcelain veneering fracture rates.⁸ Yttria-stabilized

zirconium dioxide (Y-TZP) presents several benefits, such as esthetic superiority due to color, high level of biocompatibility as well as low levels of plaque adhesion, even more so than high-gold cast alloys.⁸ Additionally, reducing the risk of marginal bone loss, its long-term stability, lack of discoloration of the mucosa, high flexural strength and fracture toughness compared with conventional PFMs are mentioned as advantages for Porcelain-fused-to-zirconia (PFZ) prostheses.⁸ Nonetheless, there seems to be a lack of substantial evidence in the scientific literature to support its use due to a lack of long-term studies as well as studies regarding implant supported zirconia prostheses.⁸ A systematic review by Sailer et al. found no statistically significant difference in the survival rate between single unit or short span PFM restorations to PFZ restorations when tooth-borne.⁸ To the contrary, Pjetursson et al.'s systematic review comparing tooth-borne to implant supported PFZ FDPs found that complications are more common with the latter.⁹ Pozzi et al. reported a 100% survival rate of both implants and 26 prostheses in a retrospective study with follow-up between three and five years of patients who had received cross-arch screw-retained implant-supported PFZ prostheses.¹⁰ Prosthetically, three FDPs experienced veneer fractures, specifically for five units out of 348, resulting in an 89% success rate per FDP, and 99% per unit.¹⁰ No other type of complications occurred such as framework fracture, screw loosening or fracture.¹⁰ Accordingly, all patients were content with the delivered restorations both aesthetically as well as functionally.¹⁰ Concerning the restorations' design and implant type, distribution, number, and time of placement, the only factor that showed to be statistically significant was the implant to abutment connection type.¹⁰ External connection implants were the only ones to experience veneering fractures, while none were found in the internal connection type implants.¹⁰ Amongst the limitations of PFZ prostheses is the bonding

between the core zirconia frame and the veneering ceramic.¹⁰ The veneering is over ten times weaker than the zirconia core, which increases the risk of chipping under tensile forces.¹⁰ The bond between the two is mostly influenced by the difference in coefficient of thermal expansions, volumetric shrinkage, the methods used for the finishing of the zirconia, specifically the framework abrasion, as well as the wetting properties of the veneer.¹⁰

The high survival rate in the short-term period is also confirmed by a study by Papaspyridakos et al. In this study 16 arches restored with complete-arch PFZ prostheses were analyzed over a four-year period.¹¹ The survival rate was found to be 100%, with no prosthesis needing replacement or receiving a low satisfaction score by the patient.¹¹ Five of the restorations presented chipping of the zirconia veneering, resulting in a 31.25% chipping rate over the entire study sample.¹¹ Only one of the patients experienced an extensive fracture, which occurred before delivery of the occlusal guard.¹¹ Three risk factors were established, these being the absence of an occlusal guard, parafunctional activities as well as the presence of a complete fixed implant reconstruction in the opposing arch.¹¹ No other technical or biologic complications such as screw loosening or gingival recession were encountered.¹¹ Both studies highlight the fact that the main complication found with implant PFZ prostheses restoring fully edentulous arches is the chipping of the zirconia veneer layer, which on the other hand seems to have a minimal effect on the survival of the prosthesis on the implants.¹¹

An innovative material choice for the prosthetic rehabilitation of the edentulous jaw is monolithic zirconia. Its monolithic nature lessens the chance of fracture and chipping, increases its structural properties, and facilitates its fabrication.¹² According to Abdulmajeed et al.'s systematic review, out of 141 full arch implant supported monolithic zirconia

prosthesis, a 96.8% survival rate was achieved.¹² Complications included veneer fracture and framework fractures, both complications not unique to its monolithic nature.¹² Other complications, such as phonetic, masticatory, and abutment related issues, were not found to be present among the monolithic prostheses analyzed.¹² The possible advantages of monolithic zirconia are seen in its reduced wear, improved aesthetics, and inferior biofilm accumulation.¹² However, these aspects were not backed by the evidence provided by the studies analyzed in this systematic review.¹² The paper highlighted the current lack of sufficient long-term follow-ups as well as convincing evidence regarding this prosthetic choice, which warrant further investigation.¹² Nonetheless, with the necessary precautions, one can affirm that complete-arch implant-supported monolithic zirconia fixed dental prosthesis offer a short-term success rate, with a few relatively low risks for complications such as chipping and framework fracture.¹² No information was provided regarding antagonist teeth, soft tissues, osseous or implant complications.¹² The aid of CAD/CAM technology for the fabrication of such prostheses using modern materials is promising in the treatment of the completely edentulous patient, for so-called ideal situations and with cautious optimism.¹² Further studies will have to be performed to better understand the long term survival and complication risks of this prosthetic choice.¹²

When it comes to implant placement, multiple options are available regarding the timing and mode of insertion. For instance, guided surgery can be a great aid for the avoidance of complications in each mode of placement. According to the 3rd ITI Consensus Conference, there are four types of placement relative to the time after tooth extraction.¹³ Type 1 indicates implant insertion within the alveolus at the time of tooth removal.¹³ Type 2 suggests implant insertion after completion of soft tissue healing, i.e. between 6-8 weeks post-extraction, but

before any substantial bone has started filling the alveolus.¹³ Type 3 stands for implant placement after a significant amount of bone has filled the alveolus, and Type 4 refers to implant insertion in a completely healed alveolus.¹³ Regarding implant survival, all four types share a similarly high rate.¹³ Choosing the type of placement is a decision which regards the benefits and risks each type offers.¹³ Type 1 provides the advantage of a reduced number of surgeries while simultaneously being favorable to bone grafting at the time of implant placement.¹³ Furthermore, it offers the possibility, when indicated, of delivering a provisional restoration, and therefore avoiding the need for a removable provisional prosthesis.¹³ The limitations include the difficulty of achieving primary implant stability.¹³ Also, an optimal prosthetically-driven implant positioning is more challenging to accomplish.¹³ Additionally, the risk of soft tissue recession is increased.¹³ Type 2 being an early placement 6-8 weeks after tooth extraction offers the advantage of an augmented soft tissue availability, which facilitates suturing and flap closure, as well as a predictable esthetic result.¹³ Furthermore, pathology present in the tooth site has time to resolve before the implant is placed.¹³ The disadvantages include a higher number of surgical procedures and the still greater risk of not achieving primary implant stability due to the bone formation still being at its primary stages.¹³

Type 3, on the other hand, increases the chances of achieving good primary stability due to the further development of bone healing.¹³ Moreover, with the soft tissue completely healed this permits a suitable primary closure of the surgical area.¹³ The disadvantage of this type is the fact that the alveolar bone will have undergone remodeling due to the extended time after extraction which might increase the amount of bone grafting needed at the implant placement.¹³ In the type 4 scenario, the amount of bone remodeling and resorption will be the

highest, increasing the chance of an insufficient bone quantity for the implant placement.¹³ Through the precise implant placement provided by guided surgery,¹⁴ tackling each one of these four different implant placement stages can be facilitated after a thorough and careful planning, thus reducing the risk of early complications.

Amongst the goals of dental treatment, the reduction of the time spent by the patient in the dental chair as well as the simplification of the dental procedures is an increasingly important objective, both to boost the patient's acceptance of the dental treatment as well as their satisfaction with the treatment process without sacrificing the treatment's long term success.¹⁵ In pursuance of doing so, different loading protocols have been developed with the objective of trying to reduce the time to loading of implants as much as possible. There are altogether three types of protocols which have reached a consensus in the scientific literature: conventional loading, early loading, and immediate loading. Conventional loading consists of connecting the prosthesis after a minimum period of 2 months of healing after implant placement.^{16,17} Early loading refers to connecting the prosthesis to the implant within a period of 1 week to 2 months after implant placement.^{16,17} Lastly, immediate loading consists of connecting the prosthesis to the implants within the first seven days of implant placement.^{16,17} A meta-analysis by Papaspyridakos et al. assessed the implant survival rates resulting from different loading protocols within the studied edentulous patient population that received a fixed prosthesis.¹⁸ A total of 2,695 patients, 2,757 edentulous arches, and 13,653 implants were analyzed.¹⁸ Implant survival was considered after one year from placement.¹⁸ For the maxillary arches, conventional loading resulted in a 99.6% survival rate, early loading led to a 99.3% survival rate, whereas immediate loading resulted in a 99.2% survival rate.¹⁸ For the mandibular arches, conventional loading exhibits a 99.7% survival

rate, whereas for early loading it was 98.5%, and for immediate loading a 99.3%.¹⁸ The authors conclusion was that the survival rate is not affected by the protocol providing the fixed prosthesis supported by multiple implants as there was no statistically significant difference between the three different loading protocols.¹⁸

The installation of dental implants with a prosthodontically-driven approach has been a subject of interest to dental clinicians for several years.¹⁹⁻²¹ Implant treatment has experienced considerable changes, keeping up with the rapid development of computer technology.¹⁹⁻²¹ One of the novel treatment concepts is computer-planned and template-guided implant surgery.¹⁹⁻²¹ This treatment concept has been developed with the aid of three-dimensional (3D) computed tomography (CT) and computer-aided design/ computer-aided manufacturing (CAD/CAM) technology.¹⁹⁻²¹ Guided surgery has the benefits of prosthodontically-driven implant placement minimizing angulations and postoperative complications, as well as reducing surgery time.²¹ Virtual planning of the implant surgery should be used as an adjunct to proper diagnosis and treatment planning, whether or not it is going to be used for a guided surgery.²¹ It is the clinician's responsibility to decide on the final positions following a prosthodontically-driven approach and on the need for bone grafting procedures using digital technology to accurately plan. Digital technology also facilitates better patient information related to the planned procedure.²¹

The workflow for guided surgery for the edentulous patient begins with the construction of a radiolucent radiographic template²² by duplicating a well fabricated complete denture.²⁰ A minimum of six fiducial markers is positioned at different levels in respect to the occlusal plane.²³ The CT scan is completed with dual scan protocol of the radiographic template and a

radiolucent interocclusal index is used as a reference for the reproducible seating of the radiographic template.²³

A virtual planning software allows clinicians to place implants in the virtual 3D Digital Imaging and Communication in Medicine (DICOM) file that is reconstructed from CBCT data, for prosthetically-driven planning.^{19,20,24-28} The aforementioned enables clinicians to make the implant treatment plan in consideration of anatomical structures and visualizing prosthetic restorations.^{19,20,24-28} The planning is then transferred into a stereolithographic surgical template, which makes it possible to insert implants in a pre-planned position with or without raising a flap,^{19,20,24-28} which has been shown to provide the same success rates as in flap surgeries.²⁹ Therefore providing a minimally invasive and reduced surgical procedure, which consequently diminishes the postoperative pain and swelling.³⁰ Furthermore, it is possible to fabricate a screw-retained fixed prosthesis to be delivered at the time of implant placement, therefore loading the implants on the day of surgery and providing the patient with an immediate fixed temporary prosthesis.³¹ The guided surgical technique, therefore, provides the patient with all of the benefits of implant dentistry, while reducing the amount of treatment and clinical time to a minimum.³¹

Tahmaseb et al. carried out a systematic review of a total of 14 implant survival studies.²¹ Concerning the survival rate, there was no statistically significant difference between freehand surgery concerning guided surgery.²¹ Implants placed through the static guided implant approach were a total of 1941, with an average failure rate of 2.7% over a one year period.²¹ The high implant survival rates reported in the previous review were confirmed in Balshi et al.'s study, in which 23 edentulous arches were restored via Nobel Biocare's guided protocol and resulted in a 97.6% survival rate, with four implants out of a total of 168 failing

over a period of three years follow-up.³¹ On the other hand, the prosthetic survival rate was 100%, as none of the failed implants was vital to the prosthesis survival, and no additional surgery was necessary.³¹

The use of surgical guides has been developed, intending to aid the clinician during the implant placement to achieve the ideal prosthetically driven implant placement which is the prime benefit of the guided surgery. The aforementioned entails several advantages, starting with improved esthetics due to the possibility of designing an optimal prosthesis for every individual case, including cleansability by the patient simultaneously. Additionally, the use of the cone-beam computerized tomography in conjunction with virtual planning software permits a greater safety of the implant placement regarding important anatomical features, such as the inferior alveolar nerve or the maxillary sinus.

There have been two approaches for the guided implant placement, a static and dynamic one.²¹ The dynamic approach guides the clinician through visual imaging on a computer screen, allowing the operator to perform changes to the plan at the time of implant placement.²¹ This procedure is rarely used in clinical practice due to its significantly high cost.²¹ The static approach utilizes a prefabricated guide based on a previously made virtual plan, which is stably seated in the patient's mouth and does not permit changes in implant positioning.²¹ A systematic review by Jung et al. resulted in a more precise positioning with the static approach in comparison to the dynamic one.³² Precision is furthermore improved through the intimate fit of the radiographic template throughout the scanning stage.³³ Tahmaseb et al. carried out a systematic review of a total of 24 accuracy studies and 14 implant survival studies.²¹ Regarding the precision of implant positioning using the static method, out of a total of 1530 implants, a mean of 1.12mm discrepancy in the entry point

from the planned position in contrast to the final implant position resulted.²¹ The highest difference was 4.5mm.²¹ As far as the mean discrepancy related to the apical position an average of 1.39mm was reported, and a 7.1mm discrepancy as the highest.²¹ A total of 1465 implants were analyzed.²¹ Lastly, the implant angulation was analyzed for a total of 1854 implants, and a mean of 3.89 degrees and a maximum of 21.16 degrees resulted.²¹ A statistically significant difference was obtained when comparing the accuracy of freehand in comparison to guided surgery, in favor of the guided approach.²¹ Whereas no statistically significant difference was found for mandibular in contrast to maxillary arch or dentate concerning an edentulous arch regarding the accuracy of placement, a 98.8% success rate concerning the final implant position in comparison to the digitally planned implant position was achieved.³¹

To avoid injudicious exposure of CBCT radiation on the patient and eliminate research error from patient movement,¹⁹ a new technique will be applied by comparing two stone casts, first fabricated from the stereolithographic surgical template and the second fabricated from the fixture level impression after the osseointegration of implants.¹⁹ Also through the whole planning of computer-guided surgery, all the presurgical and surgical procedures can lead to inconsistencies.^{19,20} Thus, there is a need for more studies assessing the 3-D accuracy of the guided surgery.

A recent systematic review by Tahmaseb et al. examined in-depth the accuracy of guided surgery but with a drawback of pooling the data from both partially edentulous and fully edentulous patients.²¹ Of the above mentioned 24 accuracy studies, nine examined exclusively edentulous arches, seven only partially edentulous patients, and the remaining eight had mixed data from both partially edentulous and fully edentulous patients.²¹

Thus, in light of the very little current evidence in the literature, there is a definitive need for more studies exclusively assessing the 3-D accuracy of the guided surgery for fully edentulous patients.²¹ Furthermore, with the domination of guided surgery in the market, there are ongoing improvements in the knowledge and protocol of the guided surgery, making it imperative to know the current status of the accuracy currently.²¹ In this study, we focus our attention to fully edentulous patients as the percentage of older patients is constantly on the rise as life expectancy increases.³⁴ Hence the incidence of the fully edentulous patient is growing as well with the need for simplifying fixed implant rehabilitation for this population.³⁴

Aim and Hypothesis

Aim 1

To assess the positional 3-D deviations between the implant analogs in the casts generated from Nobel Biocare CAD/CAM surgical templates and the implant analogs placed in the respective post-surgical casts.

Aim 2

To assess the positional 3-D deviations between the implant analogs in the maxillary and mandibular casts generated from Nobel Biocare CAD/CAM surgical templates and the implant analogs in the post-surgical casts.

Hypothesis 1

There are differences between the 3-D positions of virtually planned and actual implant positions in edentulous arches.

Hypothesis 2

The expected differences are smaller for the maxillary compared to the mandibular arch.

Materials and Methods

Study Population

The current in study included the records of patients that were treated by the student co-investigator in the Division of Postgraduate Prosthodontics at Tufts University School of Dental Medicine, between July 1st, 2014 and June 14, 2017, for fixed implant prostheses. AxiUm records of 40 patients were reviewed to identify appropriate cases for the inclusion in the study. All arches that underwent computer-planned and template-guided implant placement following the Nobel Guide concept (Nobel Biocare AB, Gothenburg, Sweden) were included.

The stone casts were generated during the implant-prosthodontic treatment of 8 fully edentulous patients (12 edentulous arches) that underwent computer-planned and template-guided implant placement according to Nobel Guide concept (Nobel Biocare AB, Gothenburg, Sweden). Informed consent was obtained from all participants prior to treatment, and the indication of CAD/CAM-guided and prosthodontically-planned implant placement was confirmed. In total, 59 implants (NobelReplace® Conical Connection) were inserted in 12 jaws (seven maxillae, five mandibles). Four patients were treated both in the maxilla and in the mandible.

All the surgeries were done by postgraduate prosthodontics residents and supervised by two experienced and calibrated supervisors. The final prosthodontic rehabilitation was completed by postgraduate prosthodontics residents and supervised by the same two experienced and calibrated faculty at the Division of Postgraduate Prosthodontics, Tufts University School of Dental Medicine, Boston, USA.

Chart Review

From the patient axiUm charts the following information was collected: patient's age, gender, the total number of implants, implant site and arch in treatment.

Treatment Sequence and Study Protocol

All the patients had normal health condition recommended for conventional implant surgery at the Division of Postgraduate Prosthodontics. Adequate bone quantity was mandatory to allow for the placement of a minimum of 4 dental implants to allow for an implant-supported fixed prosthesis or an overdenture. Also, for surgical tooling and instrumentation, a minimum mouth opening of 50mm was compulsory.

Before implant treatment, the patient's complete denture prosthesis was gauged for the fitting surface, occlusion and teeth arrangement. If the prosthesis was deemed not optimal, it was modified or remade before utilization as a radiographic CBCT template with the dual scan technique. A minimum of six fiducial radiopaque gutta-percha spheroids (diameter: 1–1.5 mm, depth: 0.5 mm) was positioned on the radiographic template. An occlusal index (Blu-Mousse®, Parkell inc., Edgewood, NY) was made intra-orally for the registration of occlusion and stabilization of the radiographic template while the CBCT scan was performed.

CBCT Scan and Surgical Planning

CBCT was used to examine all patients (i-CAT® FLX Cone Beam 3D system). The first scan, was of the patient along with radiographic template positioned and stabilized by occlusal index. For the second scan, the same settings were used to scan the radiographic

template alone. The data obtained were used to generate 3D reconstructions using NobelClinician® software (Nobel Biocare AB), and the two scans were paired with the help of the fiducial markers.

The virtual planning was sent to the manufacturer (Nobel Biocare AB), where a customized stereolithographic surgical guide incorporating guided sleeves and anchor pin sleeves was constructed (Fig. 3).

Surgery

The implants were placed with the aid of the surgical guide in compliance with Nobel Guide™ protocol. The surgical template was stabilized during surgery, by a surgical index made intra-orally that logged the association between the surgical guide and the opposing arch. After implant placement, the patients underwent follow-up examinations at one day, one week, one, three, and four months. Afterward, the patients underwent the clinical procedure for the delivery of definitive prosthesis supervised by the two experienced and calibrated supervisors.

Group One (I)

Four months after the surgery, full-arch open tray splinted implant impressions were completed. Urethane dimethacrylate-based visible light-cured resin (Triad gel; Dentsply Inc, York, PA) was utilized to bind the implant-level impression posts together. The diameter and form of the binding material was homogenized by the use of the same brand of disposable drinking straws, to manufacture triad gel rods (Fig. 4). The Triad gel rods were sectioned and

attached to the impression posts with a minimum quantity of Triad (Fig. 5). Impressions were made using Polyether (Impregum, 3M ESPE, St Paul, MN, USA).

Impressions were taken with plastic stock trays and windows were made to enable access to the guide pins. A layer of paraffin wax was used to close stock tray windows, followed by applying tray adhesive which was adequately dried. Based on manufacturer's instruction, the operator's hand stabilized the tray for the time required for impression material polymerization. The post-surgical stone cast were fabricated with low expansion (0.06%) type IV die stone (New FujiRock® IMP GC Corp, Tokyo, Japan) and the soft-tissue material (Coltène® Gi-Mask) after attaching implant analogs to the impression posts (Fig. 6).

Group Two (II)

Surgical templates were used for fabricating master stone casts with low expansion (0.06%) type IV die stone (New FujiRock® IMP GC Corp, Tokyo, Japan). For the production of pre-surgical stone casts, implant analogs were mounted on to guided cylinders passing through the guide sleeves using the guided cylinder pins (Fig. 7). A small syringe was utilized to inject soft-tissue material (Coltène® Gi-Mask) (Fig. 8) around the guide cylinders, over which the stone was poured after Gi-Mask polymerization (Fig. 9). All the surgical template casts were fabricated three weeks prior to the surgery.

Stone Cast Digitization Procedures

The stone casts made as the standard of care for groups one and two were stored at 70 degrees Fahrenheit for one week, after which the cast was scanned for digitalization with the extra-oral scanner (Activity 880 scanner; Smart Optics, Bochum, Germany) (Fig. 10). The 3D conversion widget of the scanner allows recording 3D implant position. The 3D digital model of the cast was constructed from the multiple images captured by the white light camera of the scanner.

The extra-oral scanner was calibrated as per manufacture's recommendation before the stone cast digitization procedure. For the scanning procedure scan bodies (NobelProcera® Position Locator Conical Connection) were first placed in the group I casts and digitization completed (Fig. 11). Following this step, the scan bodies were transferred to the group virtually planned implant position casts for scanning and subsequent digitization (Fig. 12).

To nullify the effect of scan bodies, they were arranged in corresponding implant analog position in cast 1 to cast 12 of both groups. All casts were digitized by the technician blinded to the group of casts. The Stereolithography(STL) files were saved.

STL Superimposition Procedures

The STL dataset overlap and matching were executed by 3D inspection and metrology software (Geomagic® Control™) for all casts of both groups after the STL files from group II were segmented to only maintain scanbodies (Fig. 13). The 3D inspection software calculated positional deviation as the root mean square error (RMSE) by means of best fit alignment (Fig. 14).

All study data remained confidential to the fullest extent of the law. Upon IRB approval, the student co-investigator accessed the axiUm records for patients. Patients who qualified were assigned a unique identification number to allow coding of the extracted data for analysis. There was no link between identifiable information and the collected data. All electronic data was kept on the “Tufts Box,” a HIPAA compliant secure file storage application. The data was accessed only by the study team using their Tufts credentials and passwords.

The casts that were part of the existing patient records were only accessed by the study team. The casts were labelled with the same unique identifier to link to the data from the axiUm charts. The casts were stored in a locked cabinet assigned to research materials accessible to the principal investigator.

Convenience Sample

All the casts of the patients of the student co-investigator that underwent the treatment with computer-planned and template-guided implant placement mentioned above between July 1st, 2014 and March 31st, 2017 were included in the sample.

Statistical Analysis

For continuous variables, several descriptive statistics (means/standard deviations/medians/inter-quartile ranges/minima/maxima) were calculated; for categorical variables, counts/percentages were calculated.

To compare the mean global deviation between maxillary and mandibular implants a mixed-effects model was used in order to account for the lack of independence between observations from the same subject.

The analysis was conducted twice: once excluding two high outliers, and once including these outliers. The data were log transformed in the case in which outliers were included, due to lack of normality in that case. The level of significance was set at $\alpha = .05$. The statistical software package R (Version 3.3.1) was used in the analysis.

Results

A total of 8 subjects with 12 arches with five maxillary (41.7%) and seven (58.3%) mandibular arches were enrolled in this study. Among the subjects, 7 (87.5%) were male, and 1 (12.5%) was female (Table 1). Of all 59 implants placed with the stereolithographic surgical templates, the seven male subjects received 47 implants; the female subject received 12 implants. The 59 implants were distributed between maxilla and mandible in a number of 25 and 34, respectively (Table 2). One male subject, who contributed both maxillary and mandibular arches to the study, was considered an outlier based on his RMSE values acquired from 3D inspection and metrology software (Geomagic® Control™). The RMSE values for the above mentioned were 691.52 μm and 670.92 μm for the maxilla and mandible respectively.

The mean age of the subjects when excluding the outlier was 65.8 years (64.6 years with outlier) with a standard deviation (SD) of 7.7 (7.5) with outlier and median of 66.5 (64 with outlier). Also obtained were the interquartile range of 11 (12 with outlier) and a minimum and maximum of 51 and 72 years (51 and 74 years with outlier), respectively.

The mean and median of the RMSE values obtained after the superimposition of the pre-treatment casts over the post-treatment casts were 163.30 μm and 145.25 μm , respectively, for the analysis done excluding the arches from the outlying subject. The same analysis resulted in an SD of 71.59 μm and an interquartile range of 143.66 μm along with minimum and maximum values of 65.79 μm and 266.91 μm , respectively. See Figure 1 for a boxplot of all RMSE data (excluding the outlier).

The mean (SD) of the RMSE values for the maxillary arch, not including the outlier, was 165.51 (70.02) μm . Corresponding numbers for the mandibular arch were 161.83 (79.23)

μm . Medians were 151.34 μm and 138.23 μm , and interquartile ranges were 126.55 μm and 152.28 μm , for the maxilla and mandible, respectively. Also, the minimum values were 96.36 μm and 65.79 μm and maximum values were 263.01 μm and 266.91 μm for the maxilla and mandible, respectively. See Figure 2 for side-by-side boxplots of the RMSE data by the arch (excluding the outlier). The difference between arches was not statistically significant, whether excluding ($P = 0.947$) or including ($P = 0.541$) the outlier.

Discussion

The increasing demand for implant dentistry coupled with an ever-growing elderly population has resulted in an increased demand for full arch edentulous fixed rehabilitations. In the interest of achieving the most accurate and prosthetically driven outcome, the use of guide templates appears to be an increasingly fundamental tool in this constant pursuit of excellence. The objective of this study was therefore to analyze the reliability of a mainstream static guided surgical protocol, specifically the Nobel Biocare system, by comparing the software implant planned position to the final post-surgical implant position and thus assessing whether the guide template is a reliable tool when trying to transport the digital planning into the post-surgical intraoral implant position. A secondary aim was to compare the amount of difference in the planned position versus the final implant position between the maxillary and mandibular arch, to assess whether the anatomical differences of the respective arches are an associated factor in the precision and reliability of the guide templates.

In this study, there were quantifiable differences between the 3-D positions of virtually planned implants and the actual implant positions for fully edentulous patients. Additionally, the difference between the maxillary and mandibular arches was not statistically significant.

Geomagic software was utilized for the superimposition of the casts from the group I and II to make a comparison. Best-fit match algorithm was used by the software for the overlapping of the STL files from both groups and calculation of the positional 3-D deviations values, which were reported as RMSE in micrometers. RMSE was used to communicate positional 3-D deviations difference to counter the elimination of negative and positive deviation values to each other. However, utilization of RMSE has a flaw as it fails to report the discrepancy

on x, y and z axis separately and provides no information about the pattern of implant displacements.

As shown in the results, the mean RMSE between the pre-surgical and the actual implant position was 163.30 μ m. The difference in mean RMSE between the maxillary arches in contrast to the mandibular arches, which was 165.51 μ m (SD, 70.02 μ m) and 161.83 μ m (SD, 79.23 μ m) respectively, was not statistically significant. Due to the relatively modest RMSE values observed, this would seem to indicate that the guide templates are in fact reliable tools for the positioning of dental implants. Additionally, their reliability seems to be confirmed for both the maxillary as well as the mandibular arches. The findings of this study are in disagreement with past studies on the accuracy of implant position in guided surgery, which have found larger discrepancy values in the implant positions.

Petterson et al. analyzed the three-dimensional inaccuracies of the implant planned position compared to the final position of a total of 145 implants placed in edentulous cadavers in both the maxilla and the mandible using the Nobel Guide system.³³ A postoperative CT scan found that the mean entry error was 1.06mm, the average apex error was 1.25mm, the average depth error was 0.28mm, and the average translation deviation was 0.71mm.³³ In the following study in 2012, Petterson et al. completed a similar study but this time on live edentulous patients, comparing the positions of 139 implants once again in both the maxilla and the mandible using the Nobel Guide system and a postoperative CBCT scan.²⁰ It was found that the mean entry error was 0.8mm, the average apex error was 1.09mm, and the mean depth error was -0.15mm.²⁰ Lastly, Di Giacomo et al. analyzed 60 implants placed on 12 edentulous patients in both the maxillary and mandibular arches with a postoperative CBCT scan.³⁵ Those above resulted in a mean coronal deviation of 1.35mm, a mean apical

deviation of 1.79mm, and a statistically significant difference between the virtually planned implant position and the post-surgical implant position achieved in the patient's mouth.³⁵ Despite using similar surgical guide systems, relying on both the mucosa plus pins for seating and stabilization of the templates, all three studies found a higher discrepancy in the implant position in comparison to the present study, which only found a 0.163mm generalized error when pooling the results of both the mandibular and maxillary arches.

On the other hand, Arisan et al.'s study, which analyzed eleven patients for a total of 108 implants, which were later compared to their digitally planned positions with a postoperative CT or CBCT scan, found a mean apical discrepancy of 0.80mm, and a mean hex error of 0.75mm for the CT group.³⁶ For the CBCT group, the apical discrepancy was 0.87mm, while the hex error 0.81mm.³⁶ The statistical analysis found no statistically significant difference in the planned versus post-surgical implant position.³⁶ The above-mentioned is following the present study, which found a measurable difference between the planned and the placed implants.

When analyzing the maxillary arch alone, van Steenberghe et al., who conducted a very early study on the subject in 2002 using the Nobel system, a comparison of the accuracy of the implant position was made through a post-op CBCT scan.²⁶ The study used a bone supported guide on edentulous patients, found that the mean entry error was 0.8mm whereas the mean apical error was 0.9mm.^{25,26} In D'Haese et al.'s study, which compared the position of 78 maxillary implants in 13 edentulous patients through a post-op CT scan, an average error of 0.91mm was found in the entrance point, which was not found to be statistically significant, while an average of 1.13mm was discovered in the apical point, which to the contrary was found to be statistically significant.³⁷ Both these studies, are in agreement with the results of

the present study, which similarly found measurable difference in the position of the virtually planned implant position and the position of the placed implants. Conversely, these findings are in contrast with the errors produced in the studies by Petterson et al. and Di Giacomo et al.^{20,33,35} Petterson et al.'s study on cadavers yielded an average error of 0.83mm at the hex, and 0.96mm at the apex, both being statistically significant.³³ Petterson et al.'s study on live patients found a mean discrepancy at the hex of 0.80mm, and 1.05mm at the apex. Once again, the inaccuracy was statistically significant.²⁰ Lastly, Di Giacomo et al. found a statistically significant coronal divergence of 1.51mm and a statistically significant apical divergence of 1.86mm.³⁵

In the present study, the analysis of the maxillary to mandibular implants positions yielded no significant difference. The above-mentioned is in accord with Tahmaseb et al.'s in vitro study, in which the discrepancy between implant positions was analyzed by the use of strain gauges on both milled structures and rigid plaster models.³⁸ On the x, y, and z axes, the mean misfit was 33.8 μ m, 22.5 μ m, and 36 μ m respectively and the total misfit was 55 μ m.³⁸ The minimal misfit values were possible by the in vitro nature of the study, which offers a much more controlled environment, and therefore a lesser chance for error. In Viegas et al.'s in vitro study, a total of 11 identical edentulous mandible models and 22 implants were used to perform simulated guided surgery using post-op CBCT scans for implant position verification.³⁹ The implants placed on the right side of the mandibular models showed a mean coronal, central, and apical error of 0.30mm, 0.31mm, and 0.37mm respectively.³⁹ The implants placed on the left side of the mandibular models showed a coronal, central, and apical error of 0.37mm, 0.39mm, and 0.41mm respectively. Again, the in vitro nature of this study might have had some influence on the small error values. When analyzing the

mandibular results of the two Pettersson et al. studies and the Di Giacomo et al. study, we find once again higher error values.^{19,33,35} Pettersson et al.'s cadaver study showed an average error of 1.05mm at the hex and 1.24mm at the apex.³³ Pettersson et al.'s study on live subjects resulted in an average error of 0.80mm at the hex and 1.15mm at the apex, while Di Giacomo et al.'s study found a mean error of 1.51mm at the implant neck, and a mean error of 1.86mm at the apex.^{20,35} Once again, these results are in discord with the present study's results.

Finally, the significance of the mean error between the maxillary arches and the mandibular arches was analyzed. Petterson et al.'s cadaver study found that there was a statistically significant difference between the two arches, with an increased error discovered in the mandible.³³ The authors suggested that a possible explanation for this might be the lesser surface area offered by the mandibular arch in comparison to the maxilla, which might hinder the stability of the surgical guide and therefore the accuracy of the implant positions.³³ The authors added that though the intra-arch, as well as the inter-arch implant positions, were found to have statistically significant discrepancies, it is not clear whether these findings are clinically significant for a prosthetically driven implant rehabilitation.³³ In Di Giacomo et al.'s study, the mean angular deviations between the maxillae and mandibles showed a significant difference, but not the lateral deviations in the implant positions.³⁵ To the contrary, Pettersson et al.'s live patients study did not find a statistically significant difference when comparing the maxillae to the mandibles, which is in agreement with the present study.²⁰

All of the previous comparisons were made with studies that comprised exclusively of edentulous patients or models. If one considers studies on partially edentulous patients or

both fully edentulous and partially edentulous, it becomes noticeable that the vast majority of studies on the accuracy of implant position with the use of a surgical template are in disaccord with the present study.⁴⁰⁻⁵¹

The current study has a major advantage over other in vitro studies as the sample is derived from actual human patients for the assessment of the accuracy of the computer-planned, and template-guided implant placement systems, i.e., simulating real-time clinical scenario making it more relevant for the clinician. Additionally, unlike in previous studies where the data was pooled together for partially dentate and fully edentulous patients, the current study exclusively analyses fully edentulous arches.

The most popular technique to quantify the accuracy of guided implant placement in regards, to pre-operative planning and actual implant placement is the voxel-based registration method.²⁰ This method merges the preoperative DICOM with the postoperative DICOM file and so requires a new CBCT scan after implant placement or implant osseointegration.²⁰ The fusion of the postoperative second CBCT scan data and the preoperative scan data of first CBCT is performed in compliance to the maximization of the gray values of the voxels in the DICOM image.^{20,52} The limitation of this method is the additional radiation exposure of the patient for a second CBCT scan.¹⁹ Additionally, a study concludes, that during CBCT scanning the patient movement affects the accuracy of fusion (superimposition) of the DICOM files.¹⁹ The same study compared the 3-D precision of pre-planned and actual implant positions by scanning the casts.¹⁹ The postoperative casts had been generated by full-arch open tray non-splinted impressions.¹⁹ This is a major limitation of the aforementioned study since it has been well documented in the literature that full-arch splinted implant impressions are superior compared with non-splinted ones.¹

Another limitation of the same study is the use of an older scanner as a measuring device (Zeiss Prismo 5 Vast, Carl Zeiss, Oberkochen, Germany).¹⁹ The measurement repeatability of the measuring device is <12 microns, which was improved upon in the current study by the use of a newer scanner (Activity 880 scanner; Smart Optics, Bochum, Germany) with a measurement repeatability <10 microns.¹⁹

The limitations of the current study includes the small sample size which should be considered in future research, especially to explore the influence of different anatomy that of the maxilla and mandible on the accuracy the computer-planned, and template-guided implant placement systems. Furthermore, a more advanced software should in utilized to calculated the inaccuracies separately on x, y and z axis considering RMSE value provides no information about the pattern of implant displacements. Lastly, only one system of computer-planning and template-guided implant placement systems was examined.

The findings from this study improve the fundamental knowledge of planning and installation techniques of dental implants, to enhance patient treatment as well as provide a sounder comprehension of the inaccuracies that may happen during guided surgeries. However, the reported positional 3-D inaccuracy cannot be used to quantify the amount and clinical relevance of the misfit of the fixed full arch one piece implant prosthesis.

In future studies, the computer-planned, and template-guided implant placement systems should be accessed in conjugation with variations between surgeons as well as for the errors and limitations of the surgical system. Further studies are also warranted to determine the accuracy of CAD/ CAM-guided surgery in comparison to the conventional freehand installation of implants as well as different factors affecting virtual planning and guided surgery.³³

Conclusion

Within the limitations of this study, the following conclusions may be drawn:

1. There were measurable 3-D deviations between the implant analogs in the casts generated from the Nobel Biocare CAD/CAM surgical templates and the implant analogs in the post-surgical casts created with splinted full-arch open tray implant impressions.
2. No statistically significant differences were found in the positional 3-D deviations between the implant analogs in the maxillary and mandibular casts.

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APPENDICES

Appendix A: Tables

Appendix B: Figures

Appendix A: Tables

Table 1: Patient Gender Distribution

Patient Gender Distribution		
Patient Gender	Sample Size	Sample Distribution %
Male	7	87.5
Female	1	12.5

Table 2: Descriptive statistics of 3-D Deviation (μm) for the dental casts

Arch Distributions (All values are excluding the outlier except for the p-value of 0.541)						
Arch Type	Arches (%)	Implants Count	RMSE Mean (SD) μm	Median (μm)	Inter Quartile Range (μm)	P-Value
Maxilla	4 (40)	20	165.51 (± 70.02)	151.34	126.55	0.541 *
Mandible	6 (60)	28	161.83 (± 79.23)	138.23	152.28	

* With Outlier

** Without Outlier

Appendix B: Figures

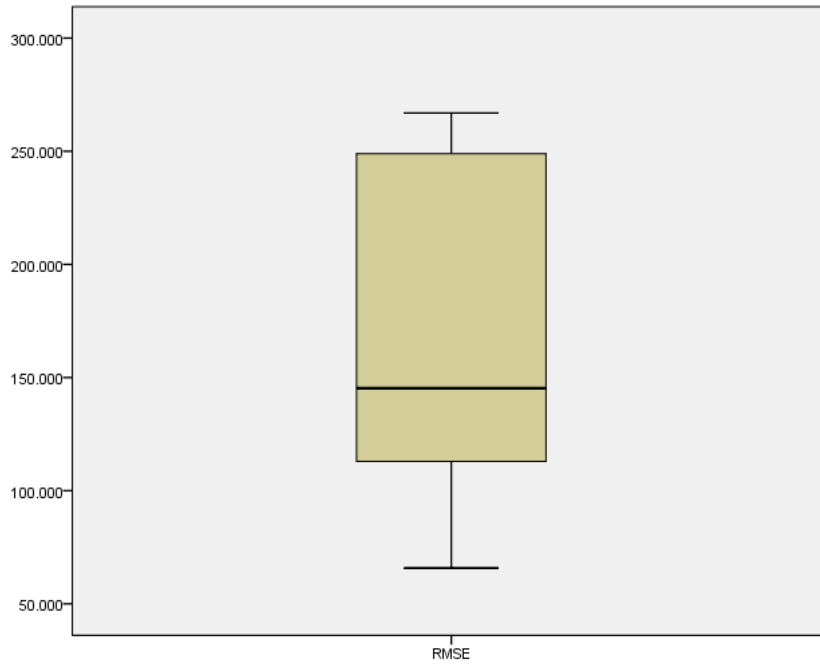


Figure 1: Boxplot showing the RMSE distribution (μm) excluding the outliers

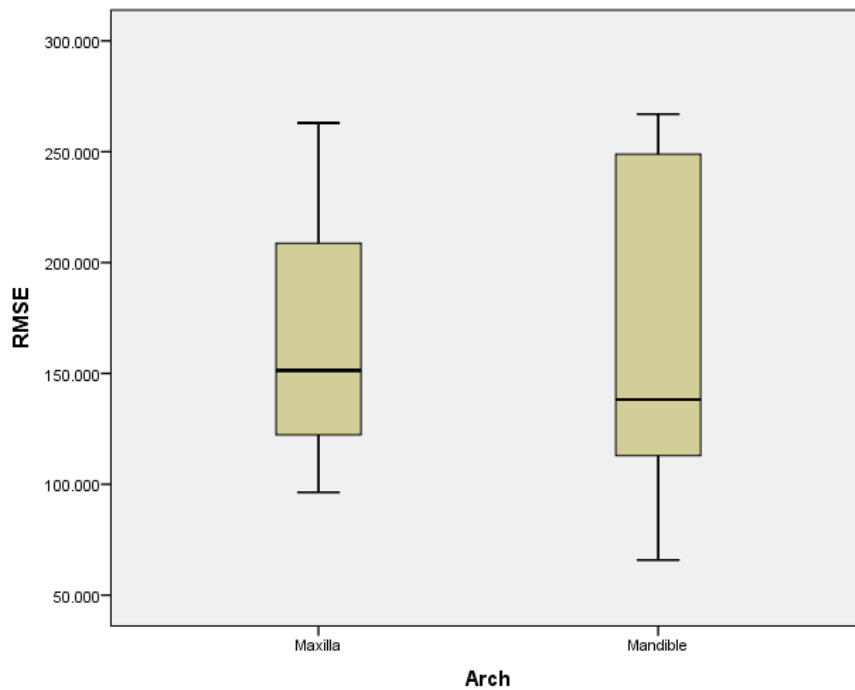


Figure 2: Side by side boxplots of the two arches (RMSE distribution in μm)



Figure 3: Stereolithographic surgical guide incorporating guided sleeves and anchor pin sleeves

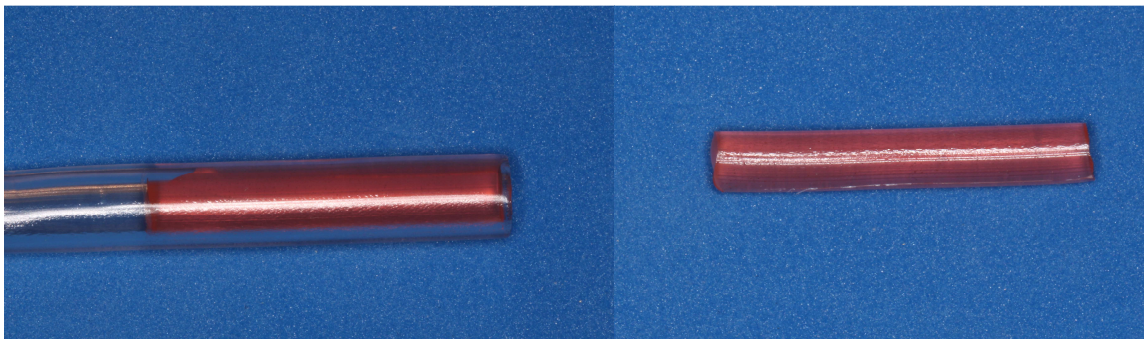


Figure 4: Triad gel stick fabrication in Straw for full-arch open tray splinted implant impression



Figure 5: Full-arch open tray impressions coping



Figure 6: Post-surgical master cast fabricated with low expansion (0.06%) type IV die stone (New FujiRock® IMP GC Corp, Tokyo, Japan)



Figure 7: Stereolithographic surgical guide with implant analogs mounted on to guided cylinders



Figure 8: Soft-tissue material (Coltène® Gi-Mask) injected around the guide cylinders, over which the stone was poured after Gi-Mask polymerization

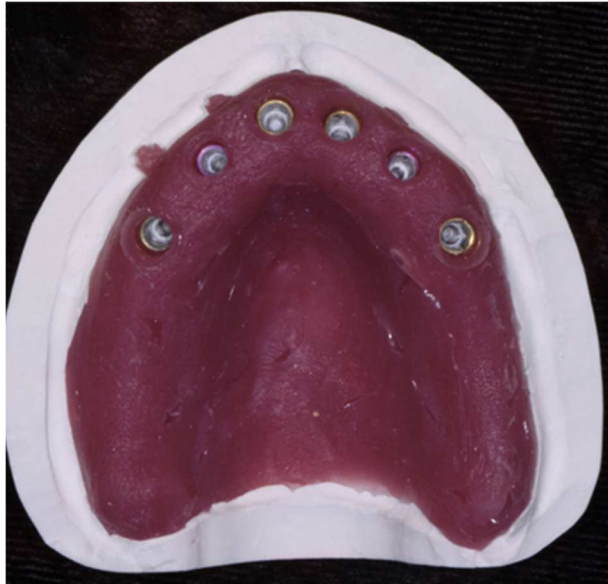


Figure 9: Pre-surgical master cast fabricated with low expansion (0.06%) type IV die stone (New FujiRock® IMP GC Corp, Tokyo, Japan)



Figure 10: Laboratory Dental Scanner (Activity 880 scanner; Smart Optics, Bochum, Germany)

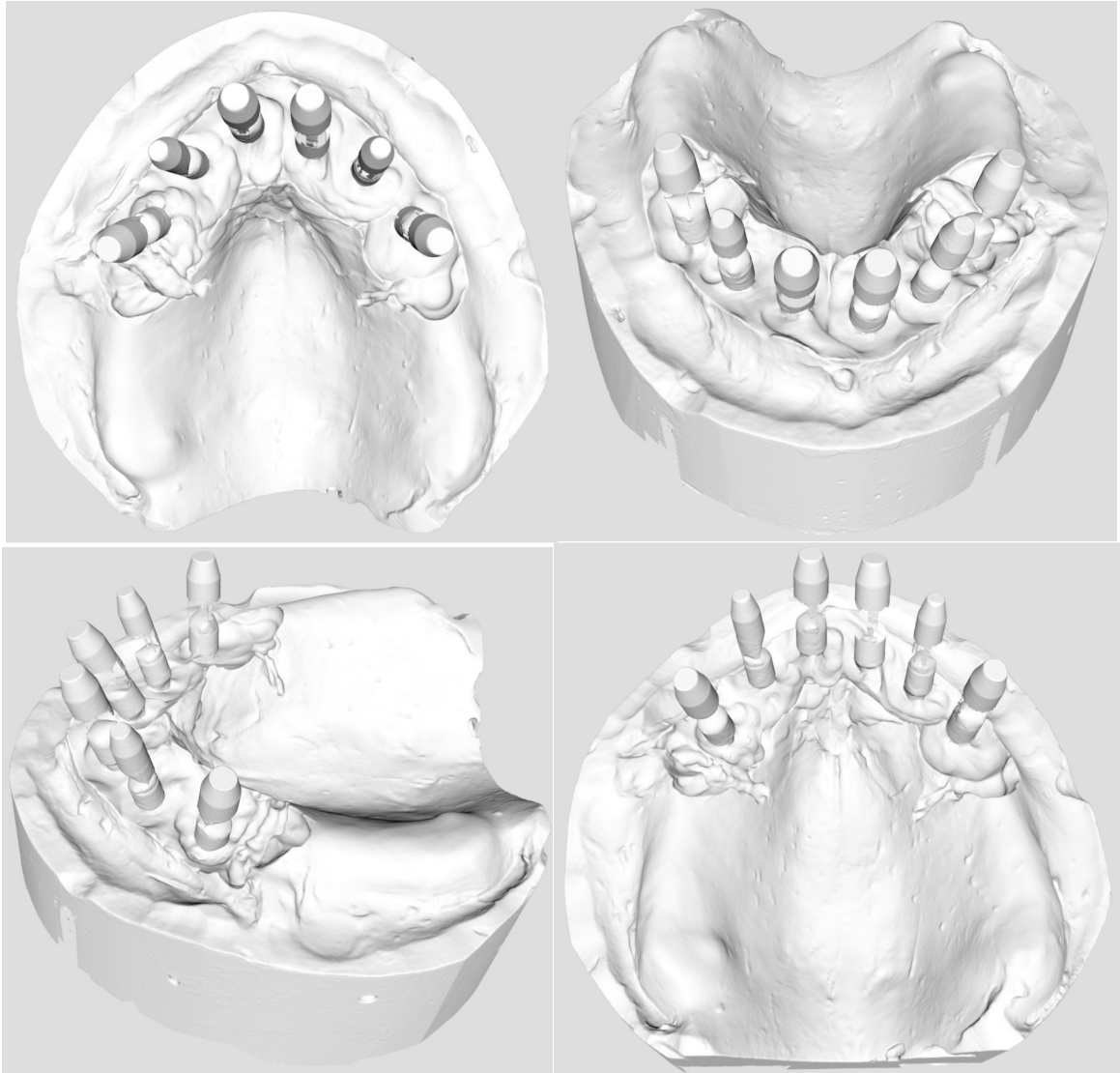


Figure 11: Group I casts and digitization into Stereolithography (STL) files

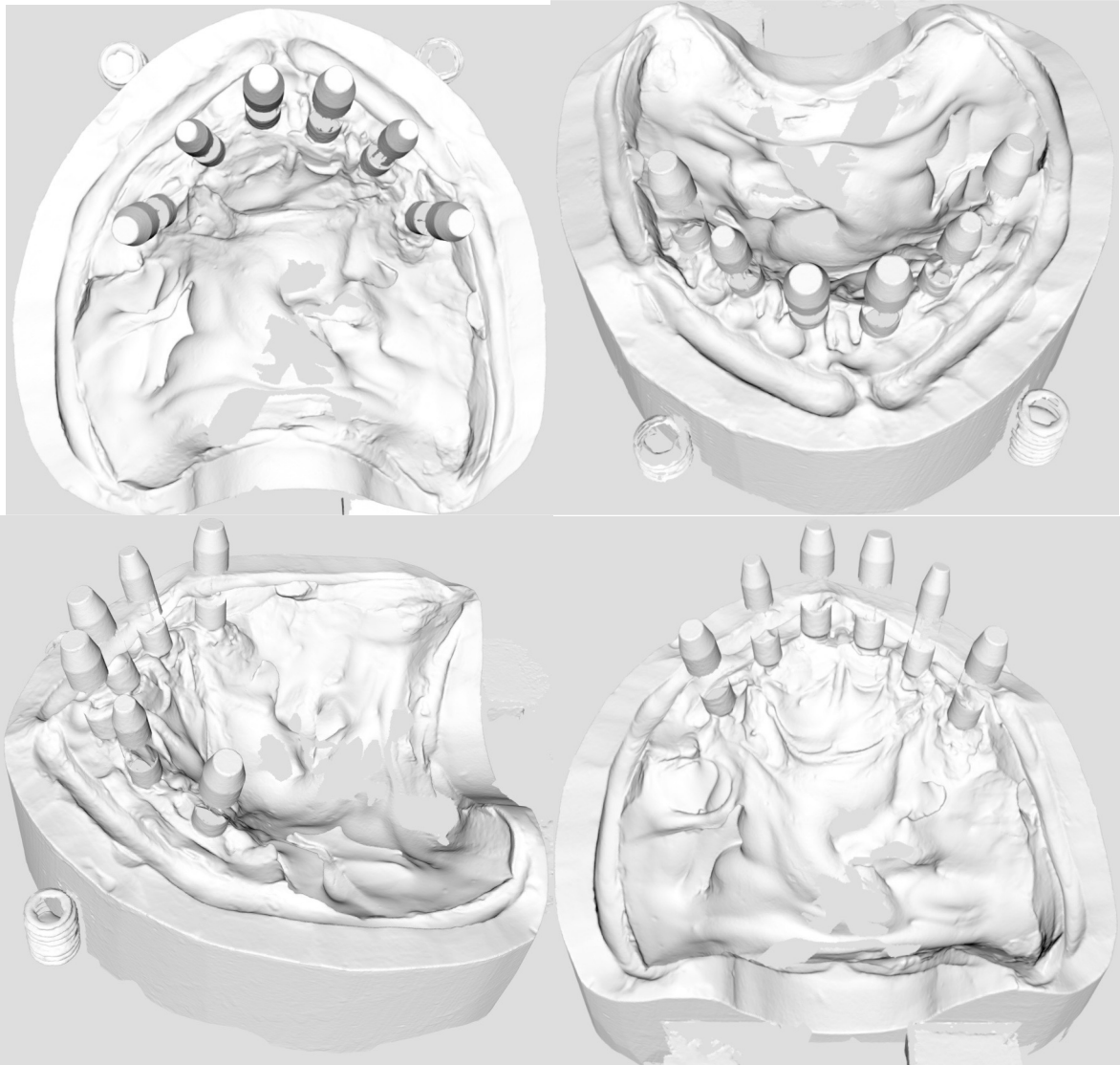


Figure 12: Group II casts and digitization into Stereolithography (STL) files

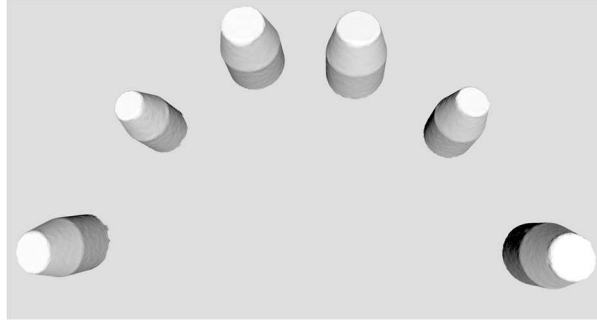


Figure 13: Segmented scan bodies of group II cast

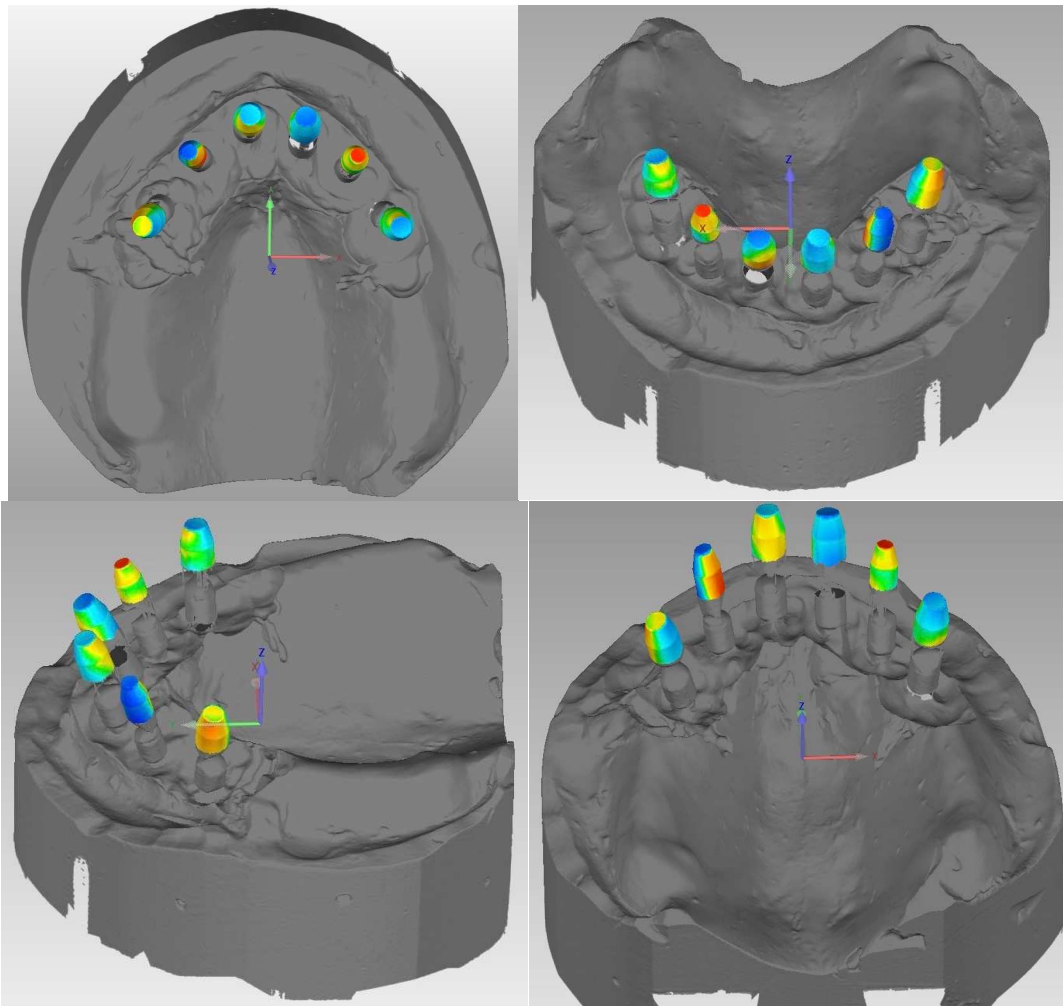


Figure 14: RMSE calculated by 3D inspection software (Geomagic® Control™) for all casts of both groups.

