

**GUIDED SURGERY AND IMMEDIATE LOADING.
A DIGITAL APPROACH**

Ali Tahmaseb

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The logo for ACTA, consisting of the letters 'ACTA' in a bold, blue, sans-serif font.

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A DIGITAL APPROACH**

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Everything should be as simple as it is but not simpler.
Albert Einstein

*In memory of my father and my best friend Parviz and
dedicated to my family.*

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Parts of the research reported in this thesis have been published earlier or are submitted for publication.

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Chapter 3

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Chapter 4

Tahmaseb A, De Clerck R, Wismeijer D. Computer-guided implant placement: 3D planning software, fixed intraoral reference points, and CAD/CAM technology. A case report. *Int J Oral Maxillofac Implants*. 2009 May-Jun;24(3):541-6.

Chapter 5

Tahmaseb A, Mercelis P, De Clerck R, Wismeijer D. Optical Scan analysis to detect minor misfit on implant supported superstructures. *Int J Oral Maxillofac Implants*. Accepted for publication.

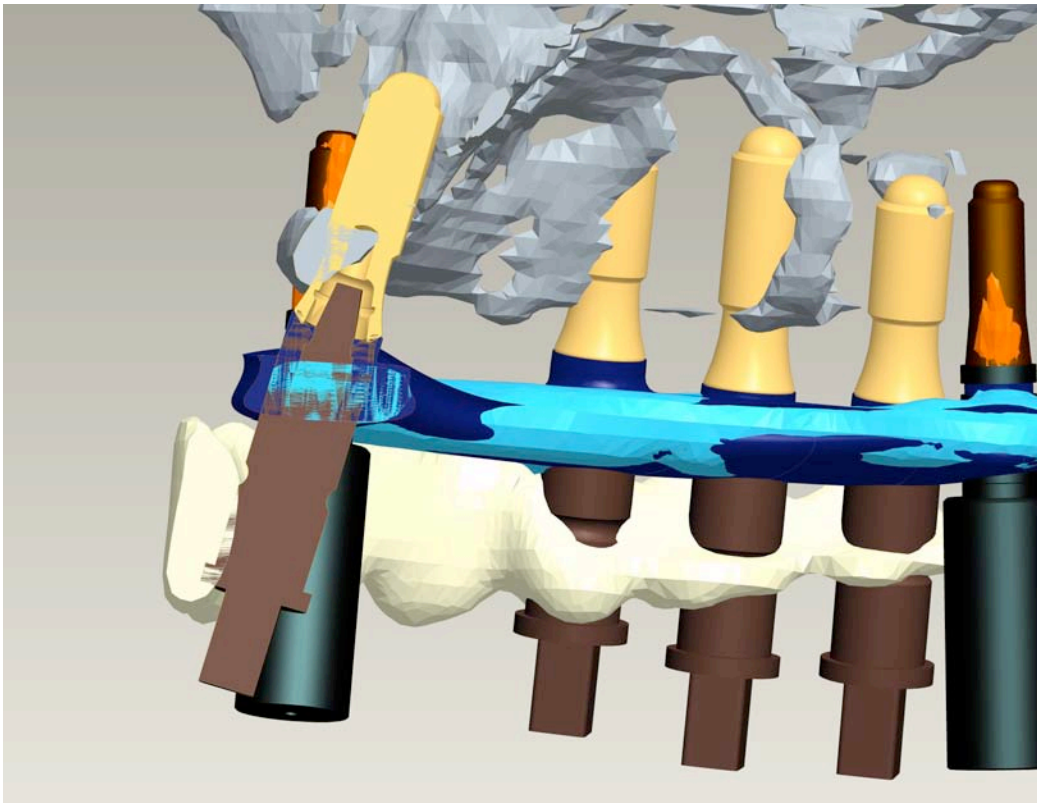
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Chapter 7

Tahmaseb A, De Clerck R, Aartman I, Wismeijer D. Digital protocol for reference-based guided surgery and immediate loading: A prospective clinical study. Submitted to *Int J Oral Maxillofac Implants*.

CHAPTER 1



General Introduction

When looking at computed tomography, implant planning software and guided implant surgery it can be concluded that the digital era has merged into implant dentistry. Computer-aided design (CAD) technique is being integrated into patient treatment planning, and computer-assisted manufacturing (CAM) is becoming more and more popular. Different concepts and technologies have been widely introduced into the scientific literature in an attempt to achieve perfect safety and precision of implant treatments. The ITI consensus paper on guided surgery¹ distinguished two general concepts in image-guided surgery:

- **Computer-guided (static) surgery:** use of a static surgical template that reproduces the virtual implant position directly from CT data and does not allow intra-operative modification of the position of the implant.
- **Computer-navigated (dynamic) surgery:** use of a surgical navigation system that directly reproduces the virtual implant position from the CT data and allows for intra-operative implant position changes. Dynamic or surgical navigation concepts are not yet widely accepted in daily practice because the technology is very sophisticated and expensive, which limits its possible use to specialised hospital situations.

This study focused on static-guided surgery. The introduction of cone beam (CB) CT has made these concepts available to general private offices. Several terms that describe the basis of the techniques used in guided surgery are defined in the Glossary of Oral and Maxillofacial Implants (GOMI)² as follows:

- **Radiographic template:** Acrylic resin guide used by the surgeon to direct the placement of an implant into its proper position. It uses information from 2D panoramic radiographs and 3D CT or digital volume tomography (DVT) scans to achieve optimal implant body placement within the available bone and to preserve vital structures.
- **Image guidance:** General technique of using pre-operative diagnostic imaging with computer-based planning tools to facilitate surgical and restorative plans and procedures.
- **Imaging guide:** Scan to determine bone volume, inclination, and shape of the alveolar process, and bone height and width used at a surgical site.
- **Surgical navigation:** Computer-aided, intra-operative navigation of surgical instruments at the operation site using real-time matching to the patient's anatomy. During surgical navigation, deviations from the preoperative plan can be immediately observed on the monitor.

- **Computer-aided navigation:** Intra-operative navigation computer systems provide the surgeon with current positions of the instruments and the operation site on a 3D reconstructed image of the patient that is displayed on a monitor in the operating room. This system aims to transfer pre-operative planning on radiographs or CT scans of the patient in real time and independent of the position of the patient's head.
- **Surgical template (surgical guide):** Laboratory-fabricated guide based on ideal prosthetic positioning of implants used during surgery.
- **Stereolithographic guide:** Surgical guides that assist placement of implants *in vivo* in the same location and direction as those in a planned simulation. Stereolithography (3D layering and 3D printing) is a technique that is used to create solid plastic 3D objects from CAD drawings by selectively solidifying an ultraviolet-sensitive liquid resin (photopolymer) using a laser beam.
- **Immediate loading:** Application of a functional or non-functional load to an implant at the time of or shortly after surgical placement, generally loaded within 48 h of implant placement.
- **CAD/CAM:** Acronym for computer-aided design/computer-assisted manufacturing.

All existing approaches in guided surgery follow a similar (semi) digital workflow: The digital CT (also including cone beam CT [CBCT]) images of patients wearing a prosthetic setup can be converted into a virtual 3D model of the treatment area using planning software. This provides the practitioner with a realistic view of the patient's bony anatomy, thus permitting virtual execution of the surgery in an ideal, prosthetically driven manner. For this reason, and to create some references to transfer the prosthetic information to the CT images, the so-called double-scanning technique was introduced. The denture or the prosthesis replica is prepared before scanning. At least 5 small (\varnothing 1 mm) gutta-percha balls were inserted in the prosthetic surface to act as radiopaque markers that are randomly spread over the prosthesis. The CT protocol consists of 2 scans. First, the patient, wearing the index and the prosthesis, was scanned with the occlusal plane parallel to the axial slices. Immediately after the scanning, a second CT scan of the prosthesis itself was performed using the same CT scanner settings. The two resulting sets of axial CT slices were fused on the basis of the radiopaque gutta-percha markers. This double-scan procedure attempted to accurately image the

prosthesis and facilitate easy fusing of the prosthesis CT scan to the patient CT scan³. Different approaches have been introduced to transfer this planned digital information to the clinical situation. Mechanical positioning devices or drilling machines convert the radiographic template to a surgical template by executing a computer transformation algorithm,⁴⁻⁶ using a plaster cast (analogue, not digital) of the treated jaw. In other approaches, stereolithography or rapid prototyping is used to fabricate a surgical guide.^{7,8} These computer-designed surgical guides in combination with CAD software and CAM technology were also used to create a superstructure prior to the actual implant surgery. To make this possible, a plaster model that included the planned implants was prepared using the surgical guide. An optical scan device (e.g. Procera, Nobel Biocare Sweden) digitalised this information again to allow CAD software design and CAM of the superstructure. These surgical guides that were produced using these techniques were then positioned on the mucosa, bony structure, or dentition depending on their design to guide the osteotomy and implant placement in the pre-planned positions. In the case of procedures in which a superstructure was fabricated, the patients were also prosthetically restored either immediately or shortly after surgery. These surgical guidance approaches have been subject to different clinical and *in vitro* studies. On the basis of 2 clinically advanced cases, Sarment *et al.*^{9,10} introduced *in vitro* the use of stereolithography to produce a radiographic template that not only allows the precise translation of the treatment plan directly to the surgical field but also offers many significant benefits over traditional procedures, such as surgical guidance for implant insertion, flapless and non-invasive implant surgery, and a decreased risk of damaging vital anatomic structures like the mental nerve and the maxillary sinus. In a clinical study conducted in 2005,^{11,12} 6 stereolithographic surgical guides were used in 4 patients and a total of 21 implants were placed. After surgery, a new CT scan was taken and the software was used to fuse the planned and placed implant images for comparison of the locations and axes. On average, the following distance differences were measured between the planned and placed positions: 1.45 ± 1.42 (SE) mm at the implant shoulder and 2.99 ± 1.77 mm at the implant apex. In all patients, a greater distance between the planned and placed positions was measured at the implant apex than at the implant neck. As a result, we concluded that, in addition to the suggestion that computer-aided rapid prototyping of surgical guides may be useful in implant placement, stereolithographic fabricated surgical guides require improvement to provide better stability of the guide during the surgery,

especially in cases of unilateral bone-, mucosa-, and non-tooth-supported guides. As mentioned before, considering the idea that the use of pre-operative planning and guided surgery could reliably predetermine the position of dental implants, some companies introduced pre-fabrication of prosthetic devices followed by immediate loading of dental implants at the time of surgical placement using CAD/CAM technology.

Several definitions for variations on immediate loading are referred to in the Glossary of Oral and Maxillofacial Implants. Terms used to describe types of immediate loading include: immediate functional loading, immediate non-functional loading, immediate provisionalization and immediate restoration. The basic differences between the terms relate to whether the implant-supported restorations are placed in full occlusal contact with the opposing dentition or if they are left short of contact on the day of implant placement. Despite the reduction in stability that occurs during normal healing, implant mobility does not usually increase to a level that would cause implant failure. Similarly, there is few clinical¹³⁻²² and some scientific²³⁻²⁵ evidence suggesting that with few exceptions^{26,27} successful osseointegration can be achieved with an immediate implant loading protocol.

Van Steenberghe *et al.*³ showed in a prospective multicenter clinical study that, based on 3D implant planning software for CT scan data, customised surgical templates and final dental prostheses could be designed to ensure high precision transfer of the implant treatment planning to the operative field and an immediate rigid splinting of the installed implants. Twenty-seven consecutive patients with edentulous maxillae were treated according to the Teeth-in-an-Hour concept (Nobel Biocare AB, Göteborg, Sweden), which includes a CT scan-derived customised surgical template for flapless surgery and a pre-fabricated prosthetic superstructure. All patients received their final prosthetic restoration immediately after implant placement, that is, both the surgery and the prosthesis insertion were completed within approximately one hour. In the 24 patients followed for 1 year, all prostheses and individual implants were recorded as stable. On the basis of models derived from 3D oral implant planning software, they concluded that the pre-fabrication of surgical templates used in flapless surgery as well as dental prostheses in an immediate loading procedure is a reliable treatment option. However, not every group reported such positive results. Komiyama *et al.*²⁸ evaluated the outcome of immediately loaded implants installed in edentulous jaws following computer-assisted virtual treatment planning combined with flapless surgery. Twenty-nine edentulous patients were treated using the Nobel Guide protocol for surgical planning, fixture installation, and immediate loading of a pre-fabricated

fixed implant prosthesis. They recorded that 19 of 176 fixtures placed in 29 patients who were followed for up to 44 months were lost 2–18 months after installation resulting in a survival rate of 89%. They lost 5 implant-supported superstructures during the follow-up period (90% maxilla, 70% mandible). They also reported surgical or technical complications in 42% of the treated cases. Misfit of the abutment bridge occurred in 5 cases, resulting in fixture disconnection from the bridge (misfit) in 2 patients and unloaded healing. Fixture losses resulted in removal of the superstructure in three patients, who then had to accept removable dentures. Extensive occlusion adjustments were made in 10% of the immediately connecting bridges. They concluded that the patient's post-operative discomfort such as swelling and pain was almost negligible. However, compared to conventional protocols, the occurrences of surgical and technical complications were significantly higher. During the ITI Consensus Meeting in 2008, our group from ACTA together with the University of Zurich presented a systematic literature review to assess the accuracy and clinical performance of computer technology applications in surgical implant dentistry.¹ Electronic and manual literature searches were conducted to collect information about the accuracy and clinical performance of computer-assisted implant systems. Meta-regression analysis was performed to summarise the accuracy studies. Failure/complication rates were analysed using random-effects Poisson regression models to obtain summary estimates of 12-month proportions. Twenty-nine different image guidance systems were included. From 2,827 articles, 13 clinical and 19 accuracy studies were included in this systematic review. Meta-analysis of the accuracy (19 clinical and preclinical studies) revealed a total mean error of 0.74 mm (max, 4.5 mm) at the entry point in the bone and 0.85 mm at the apex (max, 7.1 mm). For the five included clinical studies (totalling 506 implants) using computer-assisted implant dentistry, the mean failure rate was 3.36% (0–8.45%) after an observation period of at least 12 months. Intra-operative complications were reported in 4.6% of the treated cases, such as limited interocclusal distances to perform guided implant placement, limited primary implant stability, or the need for additional grafting procedures. It was concluded from this systematic literature search that several different computer-assisted guided implant systems are available today in clinical practice. Future long-term clinical data are necessary to identify clinical indications and to justify additional radiation doses, efforts, and costs associated with computer-assisted implant surgery. Till date, there is no evidence to suggest that computer-assisted surgery is superior to conventional procedures in terms of safety, outcomes, morbidity, or efficiency. The question '**What went wrong and how it can be fixed?**' is the basis for the research reported in this thesis. We categorised the possible errors causing the inaccuracy in the digital implant planning and treatment into 2 categories:

- (1) Errors that occurred during the pre-operative planning process
- (2) Errors that occurred during surgery

Thus, the first idea was to establish stable references by inserting specially developed mini-implants before the treatment was enhanced. These mini-implants would remain during the complete procedure as fixed reference points. In this way, the prosthetic guide could be inserted in a reliable and reproducible manner during the CT imaging as a future surgical template when screwed onto the mini-implants. Since all systems described in the literature were CT-based, the primary error probably occurred right at the beginning of the workflow²⁹. compared the accuracy of CBCT and multi-slice CT (MSCT) for linear jaw bone measurements. An *ex vivo* formalin-fixed human maxilla was imaged with both CBCT and MSCT. The MSCT images were reconstructed using different reconstruction filters to optimise bone visualisation. Before scanning, triplets of small gutta-percha markers were glued onto the soft tissues overlying the top of the maxillary bone and on both sides of the alveolar ridge to define a set of reproducible linear measurements in 11 planes. Image measurements were performed by 2 observers. The gold standard was determined by 3 observers who took physical measurements with a caliper. They concluded that both CBCT and MSCT yield sub-millimeter accuracy for linear measurements on an *ex vivo* specimen. Hassan *et al.*³⁰ investigated the influence of patient scanning position in an *in vitro* study. The influence of the position of the patient's head in the scanner on linear measurement accuracy was assessed on 3D surface-rendered images generated from CBCT by comparing 2D slices and 2D lateral and postero-anterior cephalometric projections. Eight dry human skulls were scanned twice using a CBCT in an ideal and a rotated position and the resulting datasets were used to create 3D surface-rendered images, 2D CT slices, and 2D lateral and panoramic projections. Ten linear distances were defined for cephalometric measurements. The physical and radiographic measurements were repeated twice by 3 independent observers and were compared using repeated measures analysis of variance. Radiographic measurements were also compared between the ideal and the rotated scan positions. The radiographic measurements of the 3D images were closer to the physical measurements than the 2D slices and projection images. No statistically significant differences were found between the ideal and the rotated scan measurements for the 3D images and the 2D CT slices. A statistically significant difference ($P < 0.001$) was observed between the ideal and rotated scan positions for the 2D projection images. The findings indicate that measurements based on 3D CBCT surface images are accurate and that small variations in the patient's head position do not influence measurement accuracy. However, as measuring of a certain distance or a line seems to be quite accurate on CT or CBCT images even when the patient positioning in the scan

devices is not optimal, the so-called artefacts caused by metals like mini-implants used in our study can result in measurement inaccuracy. For this reason, the fiducial markers (what we called the screw complex) were designed to not only to screw the CT template on the mini-implants but also to contribute to the determination of the position of the mini-implants. Birkfellner *et al.*³¹ reported the use of fiducial markers in image-guided implant dentistry. In addition to the accuracy of the tracking system based on fiducial markers, the precision of localising a specific position on 3D pre-operative imagery is governed by the registration algorithm that conveys the coordinate system of the pre-operative CT scan to the actual patient position. Two different point-to-point registration algorithms were compared for their suitability for this application. The accuracy was determined separately for the localisation error of the position measurement hardware and the error as reported by the registration algorithm. The investigators found that a registration algorithm based on the use of 3 fiducial markers is the superior approach for point-to-point matching in terms of mathematical stability. In a more recent study, Widdmann *et al.*³² investigated *in vitro* registration and targeting accuracy for surgical navigation in the edentulous jaw based on 3 fixed intra-oral reference points. For evaluation of the registration accuracy, the fiducial registration error was recorded and application accuracy was evaluated by the fusion of postsurgical CT scans of the drilled dental stone casts with the pre-surgical planning computed tomogram. They concluded that 3 fixed intraoral reference points successfully support a registration mouthpiece and provide *in vitro* registration and targeting accuracy that is comparable to tooth-supported registration templates or bone marker registration. Another cause of inaccuracy might be the multiple data transfers that occur between the patient and the computer during the procedure. The scanned image data (DICOM) needs to be imported into the CAD/CAM environment in order to fabricate the surgical guide following stereolithographical principles. Some procedures (e.g. Nobel Guide) use a fabricated computed drill guide to drill the future implants in a cast made after taking an impression of the jaw to be treated. This cast is subjected to an optical scanning procedure (e.g. Procera) to fabricate a CAD/CAM superstructure. These multiple data transfers could accumulate minor errors that might result in inaccuracy. The surgical procedure and the osteotomy protocol can also influence the final correct 3D position of the inserted implant, which might differ from the planned position. The drill precision and the correct pre-planned 3D position of the implants were considered crucial to achieve accuracy in our study. For this reason, a new drill design and drilling sequence was introduced in our study, as was a tool to physically control the depth during implant insertion. This tool was evaluated in both *in vitro* and in a clinical trial. It is the purpose of this thesis to address various issues related to computer-guided

surgery, CAD/CAM technology, and immediate loading. The following questions were addressed in this thesis: How precise is the digital approach in guided surgery and immediate loading? How reliable is this technique in clinical situations? How can the precision of superstructures be analysed? How reliable and reproducible are these measuring techniques? Is it possible to use this protocol for all clinical situations?

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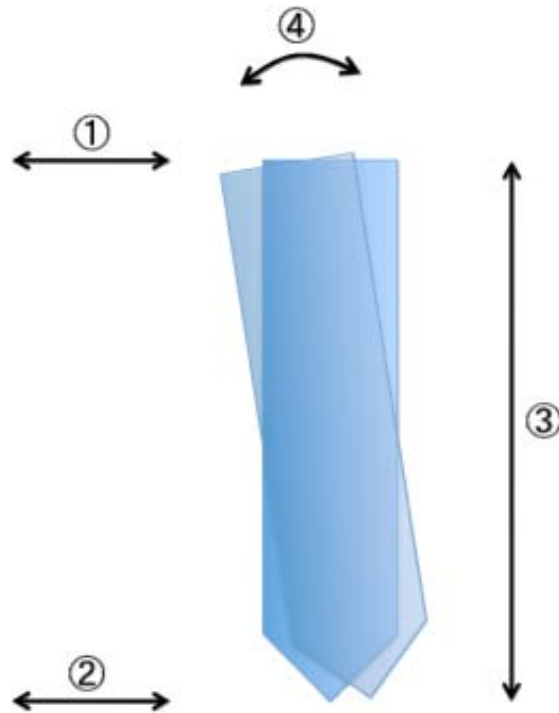
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CHAPTER 2



Computer Technology Applications in Surgical Implant Dentistry: A Systematic Review

Ronald E. Jung, David Schneider, Jeffrey Ganeles, Daniel
Wismeijer, Marcel Zwahlen, Christoph H. F. Hämmerle,
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Abstract:

Purpose: To assess the literature on accuracy and clinical performance of computer technology applications in surgical implant dentistry. **Materials and Methods:** Electronic and manual literature searches were conducted to collect information about (1) the accuracy and (2) clinical performance of computer-assisted implant systems. Meta-regression analysis was performed for summarizing the accuracy studies. Failure/complication rates were analyzed using random-effects Poisson regression models to obtain summary estimates of 12-month proportions. **Results:** Twenty-nine different image guidance systems were included. From 2,827 articles, 13 clinical and 19 accuracy studies were included in this systematic review. The meta-analysis of the accuracy (19 clinical and preclinical studies) revealed a total mean error of 0.74 mm (maximum of 4.5 mm) at the entry point in the bone and 0.85 mm at the apex (maximum of 7.1 mm). For the 5 included clinical studies (total of 506 implants) using computer-assisted implant dentistry, the mean failure rate was 3.36% (0% to 8.45%) after an observation period of at least 12 months. In 4.6% of the treated cases, intraoperative complications were reported; these included limited interocclusal distances to perform guided implant placement, limited primary implant stability, or need for additional grafting procedures. **Conclusions:** Differing levels and quantity of evidence were available for computer-assisted implant placement, revealing high implant survival rates after only 12 months of observation in different indications and a reasonable level of accuracy. However, future long-term clinical data are necessary to identify clinical indications and to justify additional radiation doses, effort, and costs associated with computer-assisted implant surgery.

Introduction:

Osseointegration of dental implants is today considered to be highly predictable.¹⁻² Even in patients with bone atrophy and in locations previously considered unsuitable for implants, implant placement has been made possible through bone regeneration techniques. The predictability of these techniques has allowed placement of implants according to the prosthetic requirements.

Conventional dental panoramic tomography and periapical radiography are often performed with the patient wearing a radiographic template simulating the preoperative prosthetic design. However, these imaging techniques do not provide complete three-dimensional (3D) information of the patient's anatomy. In addition, conventional surgical templates have been fabricated on the diagnostic cast that will direct the bone entry point and angulations of the drill, but they neither reference the underlying anatomical structures nor provide exact 3D guidance.³⁻⁴

To overcome these limitations in dental implantology, current research has been dedicated to developing techniques that can provide optimal 3D implant positioning with respect to both prosthetic and anatomical parameters. The introduction of computed tomography (CT), 3D implant planning software, and CAD/CAM (computer-aided design/computer-assisted manufacturing) technology has undoubtedly been important achievements in this field. The digital CT (also including cone beam CT, or CBCT) images derived in this way can be converted into a virtual 3D model of the treatment area. This provides the practitioner with a realistic view of the patient's bony anatomy, thus permitting a virtual execution of the surgery in an ideal and precise prosthetically driven manner.

Different approaches have been introduced to transfer this planned digital information to the clinical situation. Mechanical positioning devices or drilling machines convert the radiographic template to a surgical template by executing a computer transformation algorithm.⁵⁻⁶ Other approaches include CAD/CAM technology to generate stereolithographic templates or bur tracking to allow for intraoperative real-time tracking of the drills according to the planned trajectory. The so-called navigation systems visualize the actual position of the surgical instrument in the surgical area on the reconstructed 3D image data of the patient on a screen "chairside" (see Appendix for definitions).

The use of these computer-assisted technologies is often restricted to the surgical aspects of implant treatment. Prosthetic treatment still has to be carried out following conventional protocols. However, the link to transfer prosthetic information to the patient is of great importance, and exact reference points are required to position the implants in such a way that prefabricated prosthetics have a precise fit.⁷

Today, a growing body of literature on the topic of computer-assisted implant dentistry is available. Authors report about different guided techniques, about the accuracy of the position of the implants compared to the virtual digital planning, and about clinical and patient-centered outcomes. As many of these techniques are already available in clinical practice or are on the way to becoming established as routine clinical treatment options, it is of great importance to analyze the currently available systems. This will allow discussion of the possibilities and limitations of computer-assisted implant dentistry in clinical applications. Hence, the aim of this systematic review was to systematically assess the literature regarding the accuracy and the clinical performance of computer technology applications in surgical implant dentistry.

Materials and Methods

An electronic literature search of the PubMed data- base was performed with the intention of collecting relevant information about (1) the accuracy and (2) the clinical performance of computer-assisted implant systems. The search included articles published from 1966 up to December 2007 in the dental literature. The search was limited to studies in English, German, Italian, or French, using the terms dental, implant, implants, implantation, implantology, compute*, guid*, and navigat*, and was performed by two independent reviewers. Every search was complemented by manual searches of the reference lists of all selected full-text articles. Additionally, full-text copies of review articles published between January 2004 and December 2007 were obtained.

Inclusion Criteria

The applied inclusion criteria were different for the studies focusing on accuracy and for the studies focusing on clinical outcomes. For the accuracy studies, clinical, preclinical, and ex vivo studies were included. The primary outcome of the experiments had to be accuracy of computer-assisted implant dentistry. Only studies providing exact information about the amount and direction of implant or instrument deviation were included.

For the clinical studies at least five patients had to be included. A follow-up period was not defined for evaluation of intraoperative complications or unexpected events during operation. However, for the evaluation of implant and prosthetic survival and complication rates, the minimum follow-up time was set at 12 months. The reported treatment outcomes had to include at least one of the following parameters: clinical, radiographic, or patient-centered outcomes of computer-assisted implant dentistry in humans.

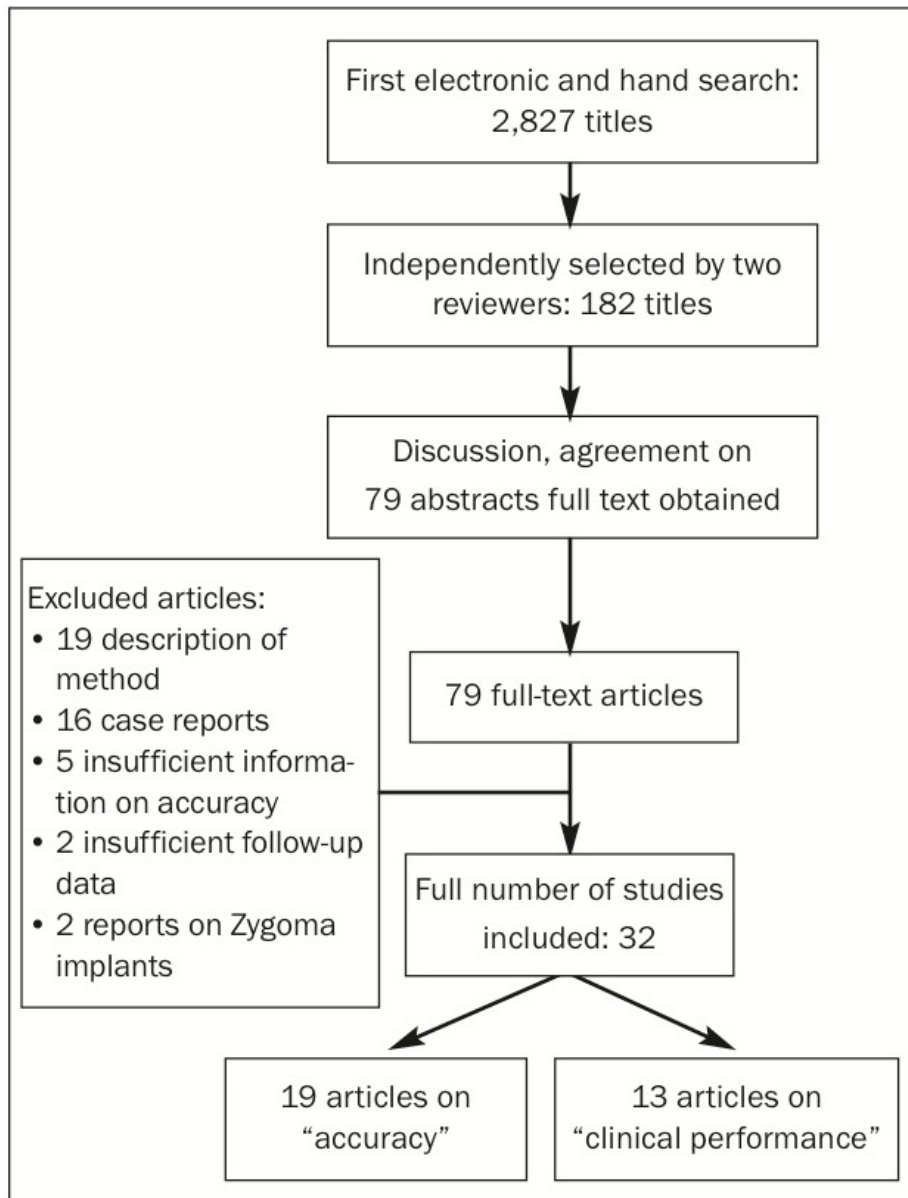


Figure 1: Literature search and selection of articles.

Exclusion Criteria

Studies not meeting all inclusion criteria were excluded from the review. Case reports with fewer than five patients were not included for the analysis of accuracy or for clinical studies. Studies with zygoma implants, pterygoid implants, or mini-implants for orthodontic purposes were excluded. Publications were also excluded if the study exclusively reported on the radiographic planning.

Table 1 Distribution and Number of Specimens (Humans, Cadavers, or Models) According to Location and Dentition

Specimens	Maxilla				Mandible				Edentulous		Part edent	
	Total	Edent	Part edent	Dentition unknown	Total	Edent	Part edent	Unknown	Total	Unknown	Part edent	Unknown
Model	112	46	20	26	56	29	11	16	30	1	31	10
Cadaver	6	1		1	3			3				2
Human	33				29	21		8	41	20		4
Total	151	47	20	27	88	50	11	27	71	21	31	16

Edent = edentulous; Part edent = partially edentulous.

Data Extraction

Two reviewers independently extracted the data using data extraction tables. Any disagreements were resolved by discussion. Data were only included in the analysis if there was agreement between the two reviewers.

Statistical Analysis

The statistical analysis comprised two parts: (1) a summary of the evidence from the accuracy studies and (2) a summary of the outcomes reported from the clinical studies. For summarizing the accuracy studies, methods appropriate for meta-analysis of the mean values observed in groups of a given size were used. The ideal information for this would be to have the mean and its standard error and then to perform inverse variance weighted fixed or random effects meta-analysis. The standard error (SE) can be derived from the observed standard deviation (SD) of the accuracy values using the formula: $SE = SD/\sqrt{n}$, where n is the number of observations in the study. Therefore, when the mean or the standard deviation was not reported in the original article, it was imputed using the available information according to the formulae given in Table 3 of the research methods article by Hozo and colleagues.⁸ Heterogeneity between studies was assessed with the I² statistic as a measure of the proportion of total variation in estimates that is due to heterogeneity,⁹ where I² values of 25%, 50%, and 75% are considered as cutoff points for low, moderate, and high degrees of

heterogeneity. Meta- regression analyses were done to perform formal statistical tests of the differences in mean accuracy according to the groupings of the studies.¹⁰

For summarizing the outcomes reported from the clinical studies, methods described in detail in a systematic review of fixed partial dentures were used.¹ Briefly, for each report the event rate was calculated by dividing the number of events (failures or intraoperative complications) in the numerator by the total exposure time in the denominator. Total exposure time was approximated by multiplying the number of implants by the mean follow-up time reported in the studies. For further analysis, the total number of events was considered to conform to a Poisson distribution for a given sum of exposure time, and Poisson regression with a logarithmic link function and total exposure time per study as an offset variable were used. To assess heterogeneity of the study-specific event rates, the Spearman goodness-of-fit statistics and associated P value were calculated. If the goodness-of-fit P value was below .05, indicating heterogeneity random-effects Poisson regression (with g-distributed random effects) was used to obtain a summary estimate of the event rates.

Summary estimates and 95% confidence intervals (95% CI) and P values from meta-regression or Poisson regression for assessing differences in outcomes between groups of studies are reported. All analyses were done using Stata (Stata Corp.) version 10.

Results

After initial identification of a total of 2,827 titles, the exclusion of irrelevant studies was performed by two independent reviewers, who reduced the number of titles to 182. After review of these manuscripts' abstracts, 85 publications were selected for full-text evaluation. Thirteen clinical and 19 accuracy studies were ultimately used for this review (Fig 1).

Accuracy Studies

Literature. Nineteen articles from the systematic review, published from 2001 to 2007, provided useful information about accuracy in computer-assisted implant dentistry. Twelve research groups from seven countries were involved.

Material. Eleven in vitro studies were performed on models, mostly made of acrylic. Of the remaining eight studies, four reported the use of human cadavers and four were available as clinical studies with a total of 45 patients. In 16 of these patients, implants were placed in an edentulous mandible, in 20 cases in edentulous jaws without further specification, and in the remaining cases the location was not reported (Tables 1 and 2).

Table 2 Extracted Data on Accuracy

Study	Year	System	Principle	Study design	Positioning Sites method (n)	Error entry (mm)			Error apex SD (mm)			Error angle (degrees)			Error height (mm)			
						Mean	SD	Max	Mean	SD	Max	Mean	SD	Max	Mean	SD	Max	
1 Di Giacomo et al ²⁴	2005	SimPlant	Guide	Human	Implant	21	1.45	1.42	4.50	2.99	1.77	7.10	7.25	2.67	12.20	-	-	-
2 Sarment et al ²⁶	2003	SimPlant	Guide	Model	Bore	50	1.50	0.70	1.80	2.10	0.97	3.70	8.00	4.50	8.70	-	-	-
			Guide	Model	Bore	50	0.90	0.50	1.20	1.00	0.60	1.60	4.50	2.00	5.40	-	-	-
3 Van Assche et al ²⁷	2007	Nobel	Guide	Cadaver	Implant	12	1.10	0.70	2.30	1.20	0.70	2.40	1.80	0.80	4.00	-	-	-
4 van Steenberghe et al ²⁸	2002	Nobel	Guide	Cadaver	Implant	16	0.80	0.30	-	0.90	0.30	-	1.80	1.00	-	-	-	1.10
5 Kusumoto et al ¹¹	2006	PHANTOM	Navigation	Model	Bore	6	0.12	0.06	-	-	-	-	-	-	-	-	-	-
			Navigation	Model	Bore	6	0.20	0.18	-	-	-	-	-	-	-	-	-	-
6 Chiu et al ¹²	2006	Igi, DenX	Navigation	Model	Bore	80	0.43	0.56	2.23	-	-	-	4.00	3.50	13.60	0.37	0.28	1.04
7 Kramer et al ²⁵	2005	Igi, DenX	Navigation	Model	Implant	40	-	-	0.30	-	-	-	-	-	4.00	-	-	0.30
8 Brief et al ²⁹	2001	Igi, DenX	Navigation	Model	Bore	38	0.50	-	1.10	0.60	-	1.10	-	-	-	0.20	-	0.70
			Navigation	Model	Bore	38	0.30	-	0.90	0.30	-	1.00	-	-	-	0.20	-	0.70
			Navigation	Model	Bore	8	0.30	-	0.60	0.20	-	0.30	-	-	-	0.20	-	0.50
			Navigation	Model	Bore	8	0.20	-	0.50	0.60	-	1.20	-	-	-	0.20	-	0.50
9 Widmann et al ⁵	2005	Treon	Navigation	Model	Bore	112	0.42	0.26	1.00	-	-	-	-	-	-	0.25	0.12	0.60
10 Widmann et al ³⁰	2007	Treon	Guide	Model	Bore	56	-	-	-	0.50	0.30	1.20	-	-	-	-	-	-
			Guide	Model	Bore	56	-	-	-	0.60	0.30	1.40	-	-	-	-	-	-
			Navigation	Model	Bore	56	-	-	-	0.40	0.30	1.00	-	-	-	-	-	-
11 Wittwer et al ³¹	2006	Treon	Navigation	Human	Implant	80	1.20	0.80	3.40	0.80	0.60	2.00	-	-	-	-	-	-
12 Gaggi et al ⁴	2002	SNM	Navigation	Model	Bore	60	0.20	-	-	-	-	-	-	-	-	0.11	0.22	0.60
			Navigation	Model	Implant	60	0.20	-	-	-	-	-	-	-	-	0.25	0.26	0.90
13 Gaggi et al ¹³	2001	SNM	Navigation	Model	Bore	100	-	-	-	-	-	-	-	-	-	0.14	0.05	0.23
14 Wanschitz et al ³²	2002	VISIT	Navigation	Cadaver	Implant	20	0.55	0.31	1.50	1.44	0.79	3.50	-	-	-	-	-	-
			Navigation	Cadaver	Implant	20	0.49	0.38	1.40	1.36	0.70	3.20	-	-	-	-	-	-
15 Wanschitz et al ³³	2002	VISIT	Navigation	Cadaver	Implant	15	0.58	0.40	1.40	0.79	0.71	3.10	3.55	2.07	10.40	-	-	-
			Navigation	Cadaver	Implant	15	0.57	0.49	1.80	0.77	0.63	2.90	-	-	-	-	-	-
16 Wagner et al ³⁴	2003	VISIT	Navigation	Human	Implant	32	1.00	0.50	2.60	1.30	0.90	3.50	6.40	-	17.40	-	-	-
			Navigation	Human	Implant	32	0.80	0.30	2.10	1.10	0.90	3.40	-	-	-	-	-	-
17 Hoffmann et al ¹⁵	2005	Vector Vision	Navigation	Model	Bore	240	0.95	0.25	-	-	-	-	1.35	0.42	-	0.97	0.34	-
18 Brief et al ¹⁶	2005	Robodent	Navigation	Model	Bore	15	0.35	0.17	0.75	0.47	0.18	0.72	2.12	0.78	3.64	0.32	0.21	0.71
			Navigation	Model	Bore	15	0.65	0.58	2.37	0.68	0.31	1.22	4.21	4.76	20.43	0.61	0.36	1.43
19 Wittwer et al ¹⁷	2007	VISIT	Navigation	Human	Implant	32	1.00	0.50	2.00	0.60	0.20	0.90	-	-	-	-	-	-
			Navigation	Human	Implant	32	0.70	0.30	1.20	0.70	0.30	1.00	-	-	-	-	-	-
			Navigation	Human	Implant	32	1.00	0.50	2.40	0.80	0.60	2.00	-	-	-	-	-	-
			Navigation	Human	Implant	32	1.20	0.80	3.40	0.70	0.50	1.60	-	-	-	-	-	-

Table 3 Systems Used in Studies Reporting on Accuracy	
System	No. of studies
Dynamic	
IGI, DenX	5
VISIT	4
Treon	4
SMN, Zeiss	2
Vector Vision	1
Robodent	1
PHANToM	1
Static	
SimPlant	2
Nobel Biocare	2

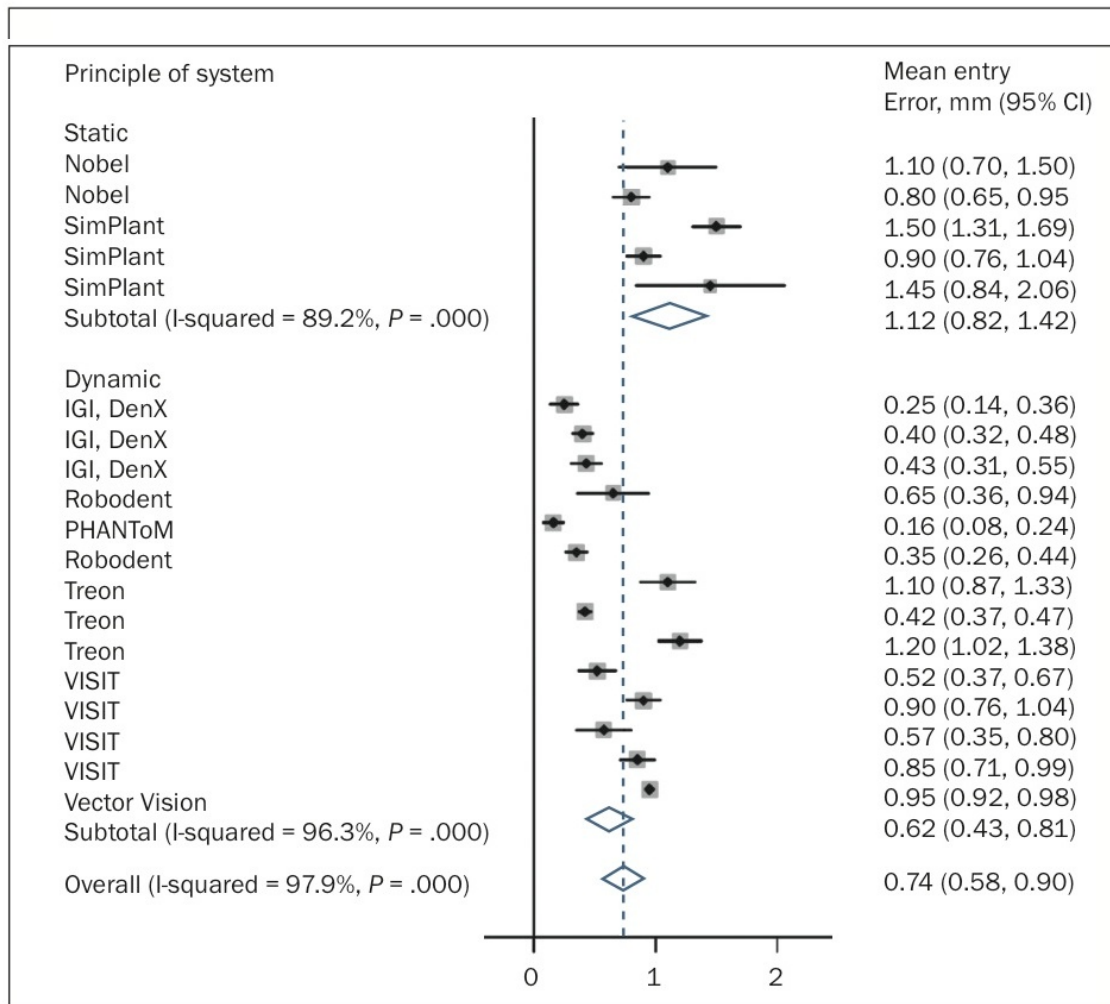


Figure 2: Mean deviation at entry point, stratified by principle of system (static vs. dynamic).

Table 4 Distribution and Number of Evaluated Sites in Terms of Accuracy		
	No. of sites	No. of studies
Navigation	1,041	14
Guide	261	5
Model	1,042	10
Cadaver	63	4
Human	197	5
Drill	942	10
Implant	360	9

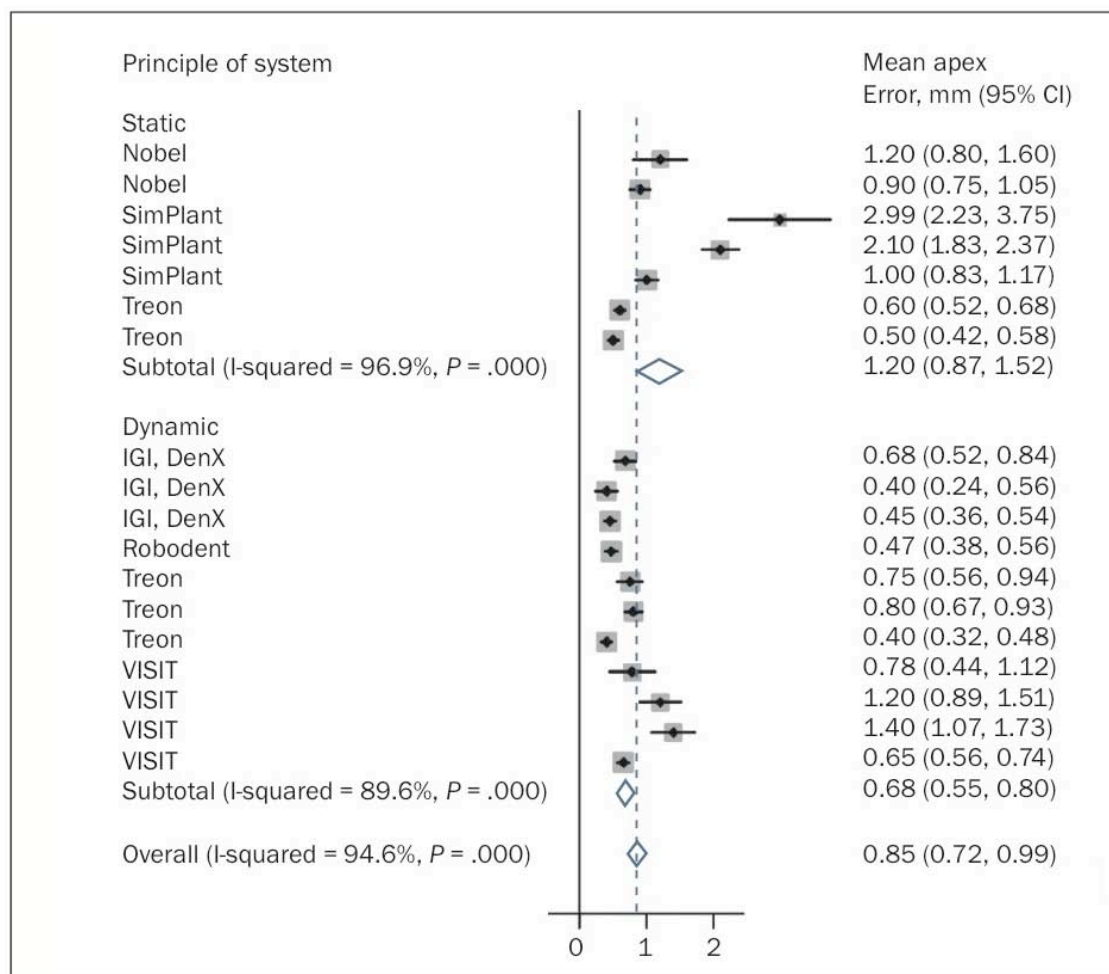


Figure 3: Mean deviation at apex, stratified by principle of system (static vs dynamic).

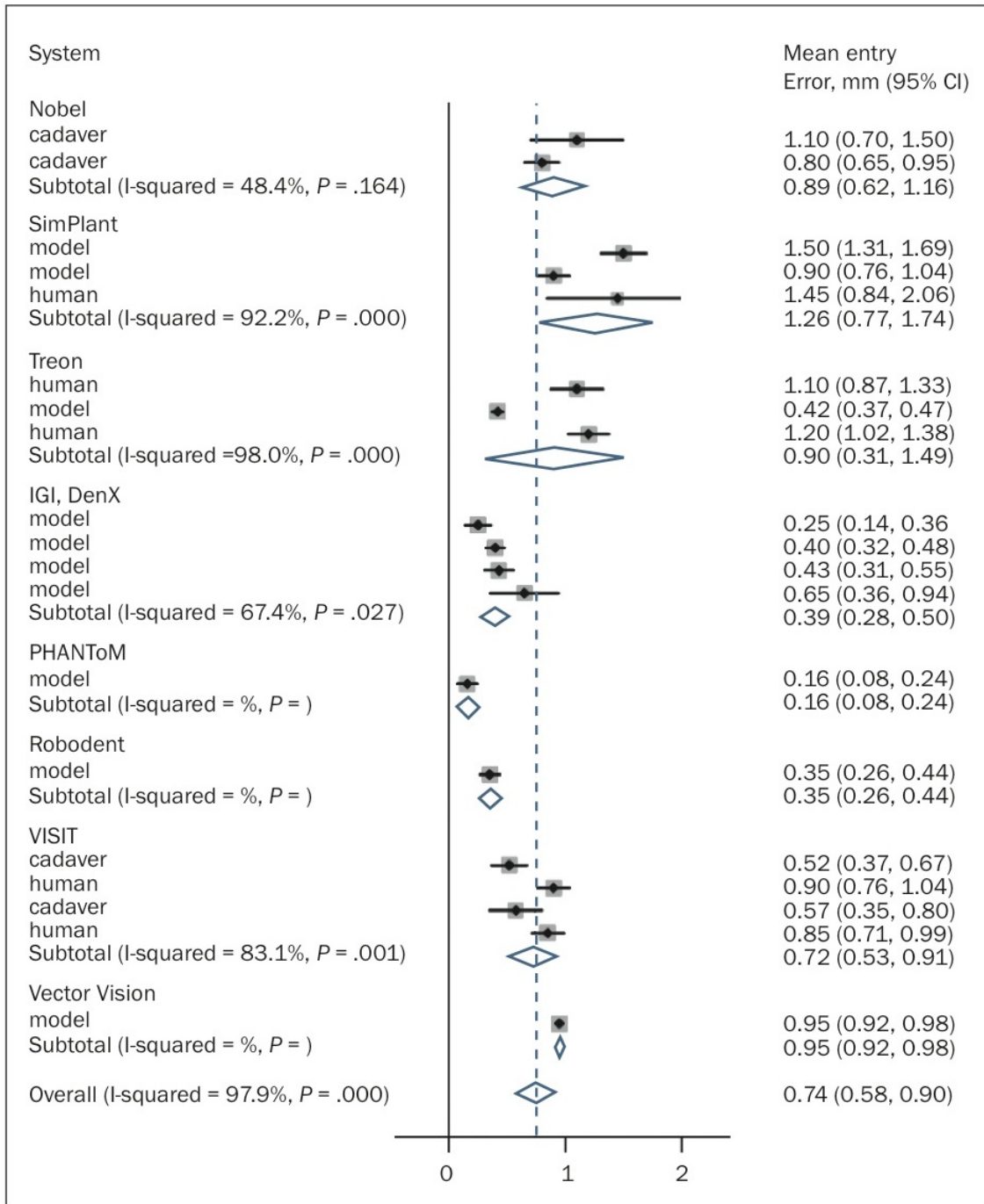


Figure 4: Mean deviation at entry point, stratified by system

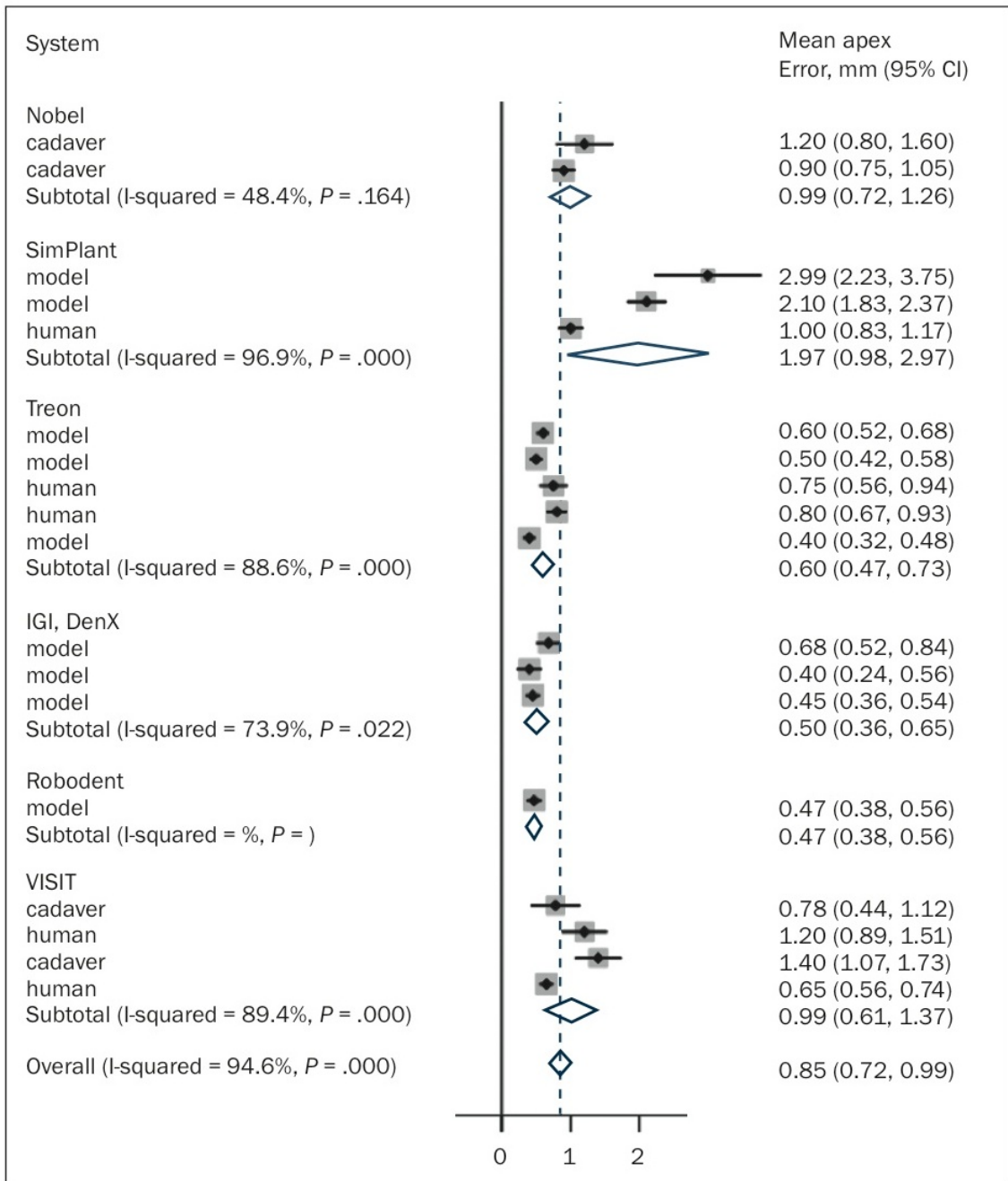


Figure 5: Mean deviation at apex, stratified by system.

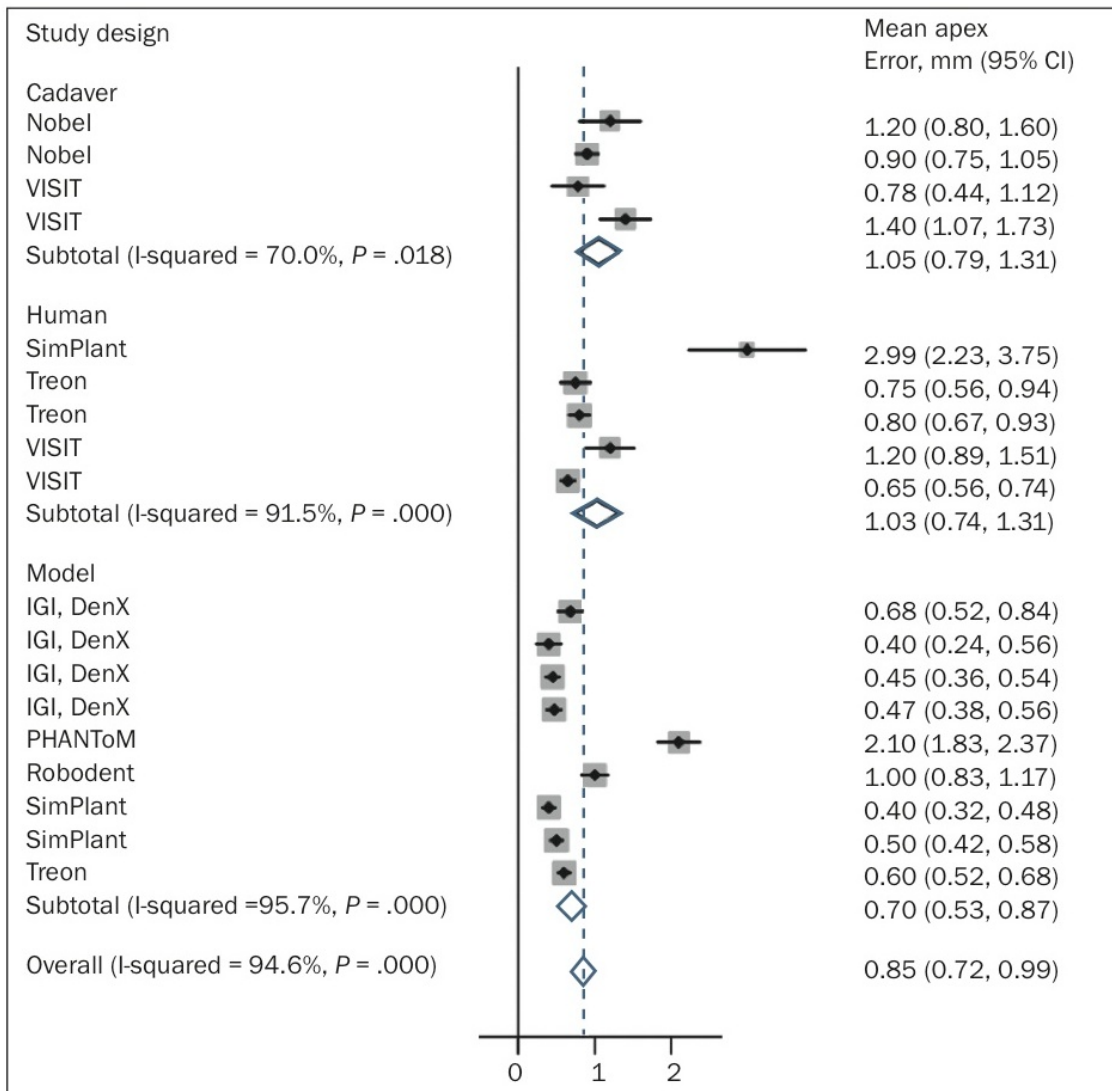


Figure 6: Mean deviation at entry point, stratified by study design (cadaver, human, model).

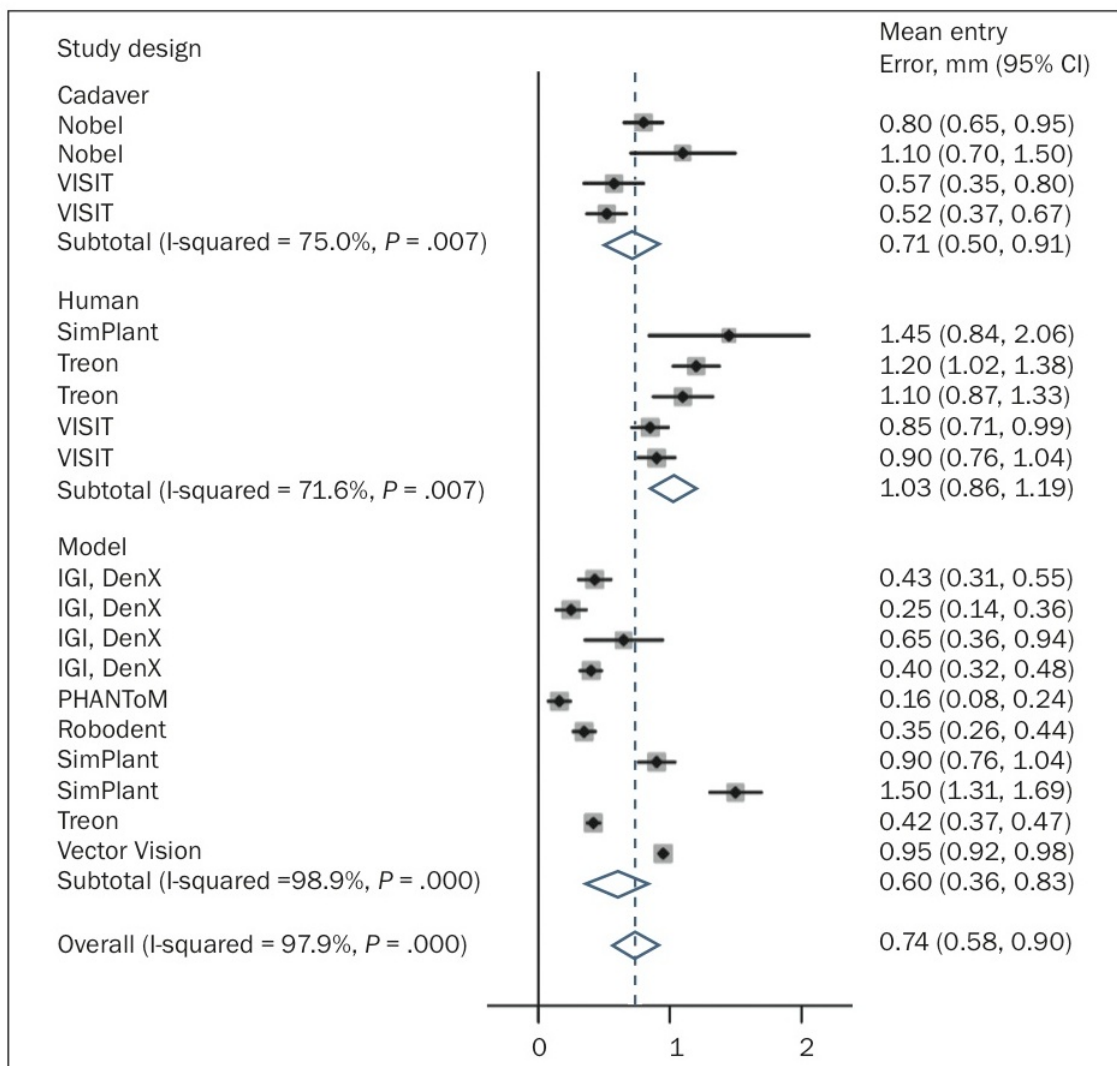


Figure 7: Mean deviation at apex, stratified by study design (human, cadaver, model).

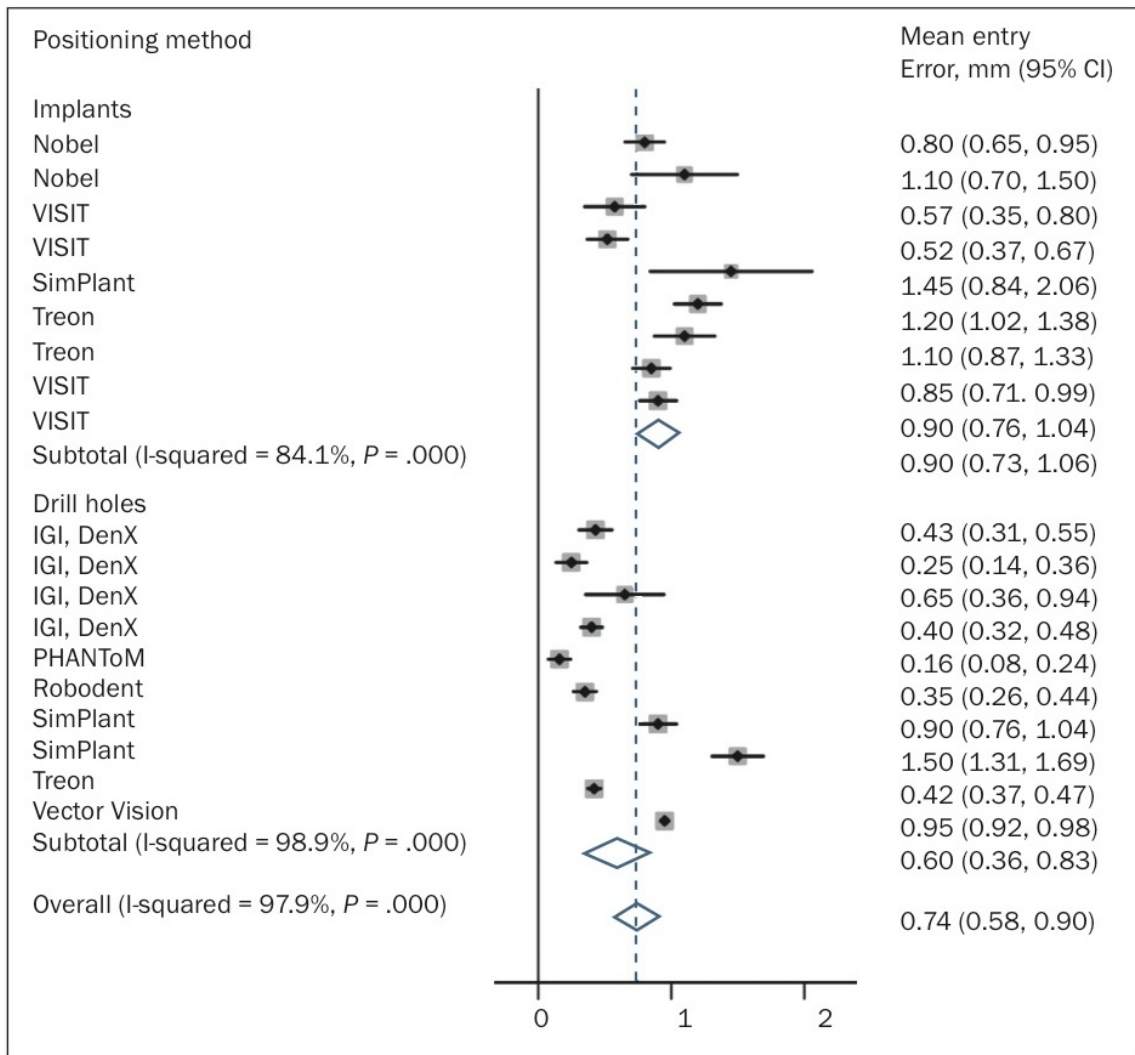


Figure 8: Mean deviation at entry point, stratified by positioning method (drill-holes vs. implants).

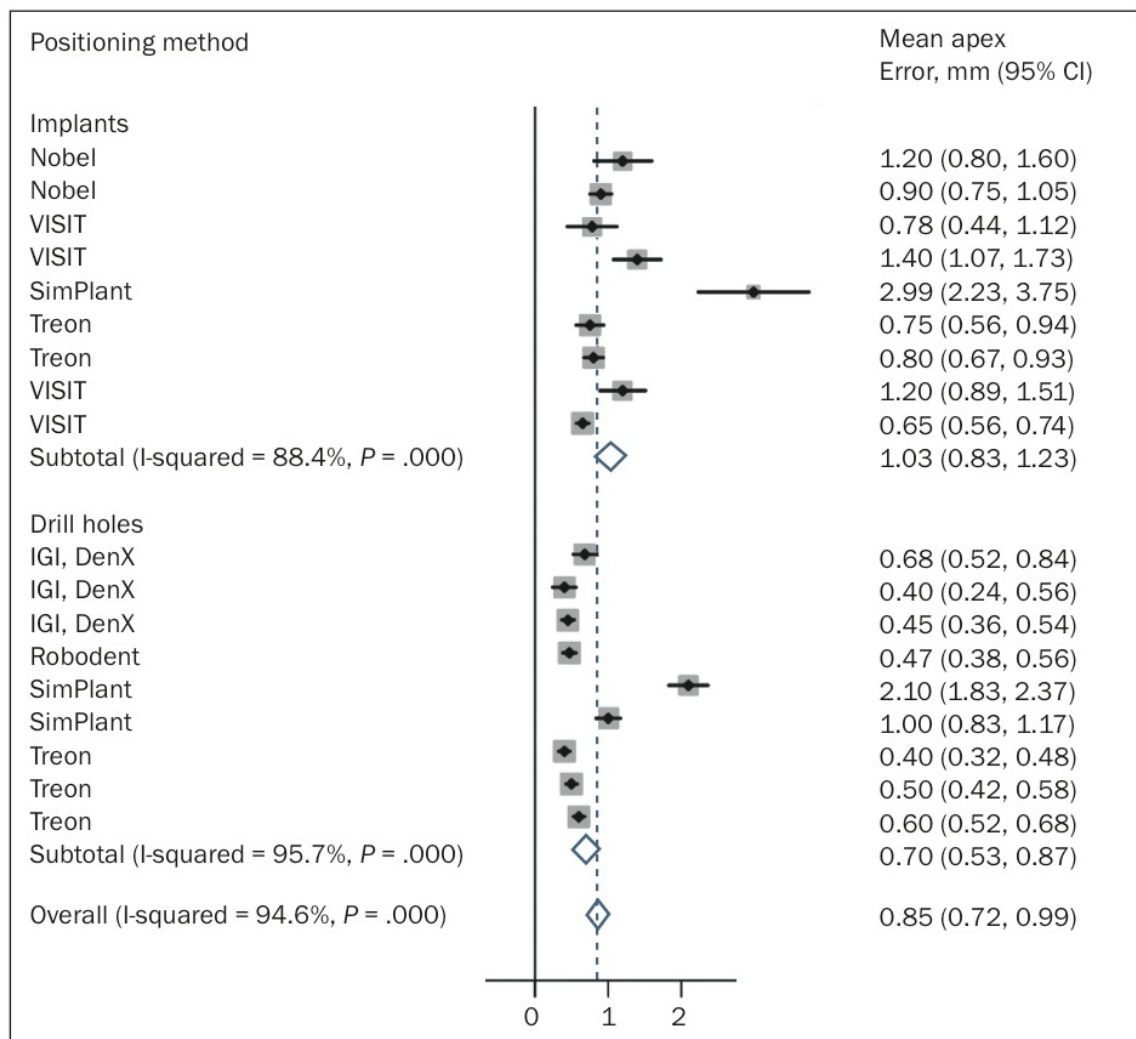


Figure 9: Mean deviation at apex, stratified by positioning method (drill-holes vs. implants).

Table 5 Clinical Studies

Study	Year	Study design	No. of patients	No. of implants after dropout	Age range (y)	Mean age (y)	Follow-up period (mo)	System	Dynamic			Implant			No. of						
									intraop nav	Single tooth	Part edent	Comp edent	Max Mand	Implant type	Flapless rest	Imm complications	intraop failures	No. of implant failures	No. of prosthetic failures		
1	Siesseger et al ³⁵	2001	Prospective	5	18	NR	NR	0	Vector Vision 2	1	0	1	1	0	Frialit 2	0	0	7	NR	NR	
2	Mischkowski et al ²²	2006	Prospective	142	501	NR	NR	6	Med3D	0	1	1	1	1	NR	NR	0	0	8 (1.31%)	NR	
		Prospective	21	78	NR	NR	6	coDiagnostiX	0	1	1	1	1	NR	NR	0	0	0	NR		
		Prospective	5	32	NR	NR	6	SimPlant	0	1	1	1	1	NR	NR	0	0	0	NR		
		Prospective	20	71	NR	NR	6	Robodent	1	1	1	1	1	NR	NR	0	0	4 (2.96%)	NR		
		Prospective	18	64	NR	NR	6	Vector Vision 2	1	1	1	1	1	NR	NR	0	0	0	NR		
3	Wittwer et al ³¹	2006	Prospective	20	78	53-75	61.4	4	Stealth Station	1	0	0	1	0	Ankylos	1	0	2	2	NR	
4	Wittwer et al ³⁶	2007	Prospective	25	88	55-77	62.1	24	Stealth Station	1	0	0	1	0	1	Ankylos	1	1	4	2	0
		2007	RCT	16	64	56-77	63.4	0	Stealth Station	1	0	0	1	0	1	Ankylos	1	1	0	0	0
6	Wittwer et al ³⁷	2007	Prospective	20	80	56-77	64.3	0	VISIT	1	0	0	1	0	1	Ankylos	1	1	2	0	NR
		2006	RCT	60	152	19-82	50	0.25	CADimplant	0	0	1	1	1	NR	NR	1	NR	NR	NR	
8	van Steenberghe et al ³⁸	2005	Prospective	27	164	34-89	63	12	NobelGuide	0	0	0	1	1	0	Nobel Biocare	1	1	0	0	0
		2004	Prospective	10	NR	NR	NR	12	CADimplant	0	0	0	1	1	NR	NR	1	1	NR	0	0
10	Fortin et al ⁴⁰	2003	Prospective	30	95	18-70	44	0	CADimplant	0	0	1	1	1	NR	NR	0	0	14	NR	NR
		2007	Prospective	102	250	22-58	40.4	0	coDiagnostiX	0	1	1	1	1	NR	NR	1	0	13	0	NR
12	Sanna et al ²¹	2007	Prospective	30	183	38-74	56	26.4	NobelGuide	0	0	0	1	1	0	Nobel Biocare	1	1	NR	9 (4.9%)	NR
13	Vrielinck et al ²⁰	2003	Prospective	29	71	37-71	56.4	14	SurgtGuide, Materialise	0	0	0	1	1	0	Nobel Biocare	0	0	0	6	0
		Total		580	1,243	56.1	7.7		5	6	9	17	3	4	0	9	6	6	42		

nav = navigation; Part edent = partially edentulous; Comp edent = completely edentulous; Max = maxilla; Mand = mandible; Imm rest = immediate restoration; NR = not reported.

Table 6 Systems Used in Studies Reporting on Clinical Outcome

System	No. of studies	No. of patients	No. of implants
Dynamic			
VISIT	2	28	122
Treon	3	53	198
Vector Vision	2	23	82
Robodent	1	20	71
Static			
SimPlant	1	5	32
SurgiGuide	1	29	71
Nobel Guide	2	57	347
coDiagnostiX	2	123	325
CADImplant	3	100	247
Med3D	1	142	501

Table 7 Implant Failures, Follow-up Period and Annual Failure Rates

Study	Year	Principle	No. of patients	No. of implants after dropout	No. of failures	% failures	Follow-up period (mo)	Failure rate (events per 100 y)
Wittwer et al ³⁶	2007	Navigation	25	88	2	2.27%	24	1.1
van Steenberghe et al ³⁸	2005	Guide	27	164	0	0.00%	12	0
Fortin et al ³⁹	2004	Guide	10	NR	0	0.00%	12	0
Sanna et al ²¹	2007	Guide	30	183	9	4.92%	26.4	2.2
Vrielinck et al ²⁰	2003	Guide	29	71	6	8.45%	14	7.2
Total			121	506	17	3.36%		
Summary rate (95% CI)								2.4 (0.8-7.6)

NR = not reported.

Systems. Nine different computer-assisted implantation systems were tested (Table 3). The majority of the systems were “dynamic” systems, based on intra-operative feedback produced by recording the position of the handpiece with infrared cameras (six systems) or by haptic feedback (one system, PHANToM¹¹). These navigational systems were used in 19 studies at 1,041 implant sites (Tables 2 and 4). Two of the nine systems used drill guides, based on the computer-assisted implant planning; 261 implant sites were drilled or implanted with the assistance of a drill guide.

Drillings/Implants/Positions and Their Evaluation. A total of 1,302 positions were evaluated (Tables 2 and 4); 360 of the positions were measured on implants, with 100 of

Table 8 Currently Available Systems in Computer-Assisted Implant Dentistry

Application	Website	Company	Virtual implant planning	Guide	Drill guide production	Notes
Surgical guides (static)						
3D-Doctor	www.ablesw.com	Able Software, USA	yes	Models	CDD	
Biodental Models	www.biomodel.com	BioMedical Modeling, USA	yes	Models	RP	
Implant3D	www.implant3d.com	Media Lab, Italy	yes	Models	RP	Create stereolithographic model
CyrтинаGuide	www.cyrтина.nl	Oratio, Netherlands	yes	Surgical guide	RP	
DentalSlice	www.bioparts.com.br	BioParts, Brazil	yes	Surgical guide	RP	
EasyGuide	www.keystonedental.com	Keystone Dental, USA	yes	Surgical guide	CDD	
GPI S		GPI Technology, Germany	Simplant/IVS	Surgical guide	CDD	
ILS	www.tactile-tech.com	Tactile Technologies, Israel	yes	Surgical guide	Custom drilling tubes	Under development
ILUMA DigiGuide	www.imtec.com	IMTEC, USA	yes	Surgical guide	RP	Specific for MDI implants
Impla 3D	www.sdginnovations.com	Schutz Dental Group	yes	Surgical guide	CDD	
InVivoDental	www.anatmage.com	Anatmage, USA	yes	Surgical guide	CDD	Under development
AnatoModel	www.anatmage.com	Anatmage, USA	yes	Surgical guide	CDD	See EasyGuide
Implant 3D	www.med3d.de	Med3D, Switzerland	yes	Surgical guide	CDD	
Implant Master	www.ident-surgical.com	I-Dent Imaging, USA	yes	Surgical guide	RP	
Scan2Guide	www.ident-surgical.com	I-Dent Imaging, USA	yes	Surgical guide	RP	"Light" version of Implant Master
Ondemand3D Implant	www.cybermed.co.kr	Cybermed, Korea	yes	Surgical guide		
Oralim Oral Implant Planning System	www.medicim.com	Medicim, Belgium	yes	Surgical guide	RP	Marketed by Nobel Biocare
NobelGuide (Medicim Oralim)	www.nobelguide.com	Nobel Biocare, USA	yes	Surgical guide	CDD	Specific for Nobel Biocare implants
Simplant Master	www.materialise.com	Materialise Dental, Belgium	yes	Surgical guide	RP	
Simplant Planner	www.materialise.com	Materialise Dental, Belgium	yes	Surgical guide	RP	
Simplant Pro	www.materialise.com	Materialise Dental, Belgium	yes	Surgical guide	RP	
VIP	www.implantlogic.com	Implant Logic Systems, USA	yes	Surgical guide	CDD	Marketed by BioHorizons
Navigation systems (dynamic)						
VoNavix	www.codagnostix.de	IVS Solutions, Germany	yes	Navigation	None	
Mona-Dent	www.imt-web.de	IMT, Germany	yes	Navigation	None	
NaviBase, NaviDoc & NaviPad	www.robodent.com	Robodent, Germany	yes	Navigation	None	
Treon (medical)	www.medtronicnavigation.com	Medtronic Navigation, USA	yes	Navigation	None	Not commercially available
IGI	www.image-navigation.com	Image Navigation, Israel	yes	Navigation	None	Formerly DenX, Inc
VISIT		University of Vienna, Austria		Navigation	None	not commercially available

RP = rapid prototyping; CDD = computer-driven drilling.

these placed in models, 63 in human cadavers, and 197 in humans. The remaining 942 positions were assessed on drill holes made in models. In the majority of the studies (14 studies) a CT scan was performed to assess the accuracy, whereas only in three studies was the position of the drill holes or implants directly measured in models.¹²⁻¹⁴

Calculation of the error by registration of the handpiece or 3D probe position after drilling and by coordinate measurements was used in two studies.¹⁵⁻¹⁶

To assess the accuracy of the implant systems, the following parameters were selected:

- Deviation error in a horizontal direction at the entry point of the drill or implant
- Deviation error in a horizontal direction at the apex of the drill or implant
- Deviation in height (vertical direction)
- Deviation of the axis of the drill or implant

For the first two parameters, the extracted data allowed a statistical analysis (Table 2). Regarding the latter two parameters, data were insufficient for a meta-analysis.

(a and b) Error at Entry Point and Apex (Figs 2 to 9).

The overall mean error at the entry point was 0.74 (95% CI: 0.58 to 0.90) mm with a maximum of 4.5 mm, while the mean error at the apex was 0.85 (95% CI: 0.72 to 0.99) mm with a maximum of 7.1 mm.

With systems using surgical guides, the mean error was 1.12 (95% CI: 0.82 to 1.42) mm (max 4.5 mm) at the entry point and 1.2 (95% CI: 0.87 to 1.52) mm (max 7.1 mm) at the apex. For dynamic intraoperative navigation (14 studies) the mean error was 0.62 (95% CI: 0.43 to 0.81) mm (max 3.4 mm) at the entry point and 0.68 (95% CI: 0.55 to 0.80) mm (max 3.5 mm) at the apex. The dynamic systems showed a statistically significantly higher mean precision by 0.5 mm ($P = .0058$) at the entry point and by 0.52 mm ($P = .0354$) at the apex.

Implants positioned in humans showed a higher mean deviation at entry point and apex compared to implants or drills in cadaver studies ($\Delta_{\text{entry}} = 0.32$ mm, $P = .0497$; $\Delta_{\text{apex}} = 0.02$ mm, $P = .8546$) and studies on models ($\Delta_{\text{entry}} = 0.43$ mm, $P = .0015$; $\Delta_{\text{apex}} = 0.33$ mm, $P = .1245$).

The mean error was significantly higher in studies in which the position of implants was measured, compared to studies in which the position of drill holes was assessed ($\Delta_{\text{entry}} = 0.3$ mm, $P = .0103$; $\Delta_{\text{apex}} = 0.33$ mm, $P = .0578$).

(c) Error in Height (Table 2). The mean error in height was reported in seven studies, all of which were performed on models using a dynamic implant system. Only one of these seven studies used implants¹⁴; all others used drill holes for the evaluation of the system accuracy. The median error in height was 0.23 mm, with a maximum of 1.43 mm.

(d) Error in Angulation (Table 2). Information about the deviation in angulations was found in nine studies. The median error in angulation was 4.0 degrees, with a maximum of 20.43 degrees.

Clinical Studies

Literature. Thirteen human studies identified by systematic review and published from 2001 to 2007 provided information about clinical, radiographic, or patient-centered outcomes in computer-assisted implant dentistry. Only two studies were randomized controlled clinical studies^{17,18} whereas the remaining 11 studies were prospective studies.

Material. A total of 580 patients with 1,243 implants were treated with computer-assisted implant dentistry and have been included in this review. The mean age was 56.1 years, with a range from 18 to 89 years. The mean follow-up period was 7.7 (0 to 26.4) months. The

majority of the studies reported on edentulous patients in the maxilla and mandible. However, there were also studies treating single-tooth gaps and partially edentulous patients.

In 6 of the 13 included studies an immediate restoration of the implants was performed. In addition, all of these implants were inserted using a flapless procedure (Table 5).

Systems. The included studies reported about 10 different dynamic and static systems (Table 6). In all except one study,¹⁹ in which a cone beam technique was used for preoperative planning, a CT scan was performed for that purpose.

Treatment Outcomes. The majority of the studies described intraoperative complications and reliability of the implant placement after computer-assisted implant planning. Other studies have looked at the assessment of pain, the operating room time, and marginal bone remodeling. Due to the short mean observation time, it was difficult to assess implant survival or success rates. However, 5 of the 13 studies reported an observation period of at least 12 months (Table 7). These studies have been included in the statistical analysis.

The mean annual implant failure rate for all 5 studies was 3.36%, ranging from 0% to 8.45%. In immediately restored cases the failure rate was significantly lower ($P = .0018$) by a factor of 5. A delayed restoration protocol was used in only one study with 29 patients and 71 implants.²⁰

Ten of 13 studies reported on intraoperative complications, including interocclusal distances that were too limited to perform guided implant placement, limited primary stability of the inserted implants, or the need for additional grafting procedures (see Table 5). Intraoperative complications or unexpected events were observed in 4.6% (95% CI: 1.2% to 16.5%) of the implant placements. Dynamic systems showed a 2.2 times higher incidence of complications, although this ratio was not significant ($P = .5282$). In flapless procedures, the rate ratio for complications was 0.15 (95% CI: 0.03 to 0.88, $P = .035$), 7 times lower compared to procedures with an open flap. In edentulous patients, the rate ratio for complications was 0.23 (95% CI: 0.02 to 2.6, $P = .237$), 4 to 5 times lower than in partially edentulous patients.

One randomized clinical trial compared pain experience after implant placement with either an open flap or a flapless surgical procedure.¹⁸ The results showed a significant difference in pain measurements, with higher scores on the visual analog scale with the open-flap surgery. Very limited data are available regarding prosthetic complication rates.

Discussion

This review systematically assessed the literature regarding accuracy and clinical performance of computer-assisted implant dentistry. In the dental literature, 28 different

image guidance systems are described (Appendix, Table 8). Based on five included clinical studies with a total of 506 implants using computer-assisted implant dentistry, it was demonstrated that the mean annual failure rate was 3.36% (0% to 8.45%) after an observation period of at least 12 months. As assessed by 19 clinical and preclinical studies, the accuracy at the entry point revealed a mean error of 0.74 mm, with a maximum of 4.5 mm, while at the apex the mean error was 0.85 mm, with a maximum of 7.1 mm.

Clinical Outcomes

It is important to distinguish between clinical studies reporting about dynamic navigation systems and about static template-based guidance systems. The majority of clinical studies have investigated the template-based guidance systems. The overall mean survival rate of 96.6% after 1 year is considered to be rather high. However, it is difficult to compare with other systematic reviews reporting implant survival rates ranging from 95.4% (implant-supported fixed partial dentures) to 96.8% (single-tooth implants) after 5 years, due to the lack of long-term data for the guided implant placements.^{1,2} Only one study is available with an observation period of more than 2 years, and this reveals an implant survival rate of 95.1% using a template-based guidance system and a prefabricated fixed prosthesis that was immediately loaded.²¹ To evaluate a new operation technique, it is important to know not just the implant survival rate but also the practicality of the method in clinical practice. In 4.6% of the cases, intraoperative complications or unexpected events were reported, including (1) interocclusal distances that were too limited to perform guided implant placement, (2) limited primary stability of the inserted implants, or (3) the need for additional grafting procedures. Since they are not always reported and there is no consistent definition of a complication or an unexpected event, the data must be interpreted with caution. In addition, the rate for intraoperative complications and unexpected events was six times lower in flapless procedures. It might be possible that due to the lack of visual access, the complication rate in terms of implant malpositioning and the need for additional grafting procedures might be underestimated. However, this finding is only based on very limited data and should be further evaluated in future study designs.

It is clearly beyond the intent or scope of this review to judge the benefits or merits of navigation versus template-based guidance systems. Only one included study performed a comparison of the two. It was reported that the static approach has a clear advantage due to the uncomplicated intraoperative handling of the surgical templates and the less expensive equipment. Additionally, the process can be planned by the surgeon and/or coworkers, or in cooperation with the company, which is responsible for the fabrication of the templates. In

contrast, with the dynamic system the time spent on presurgical setup and intraoperative application can be considered significantly longer, partly due to the navigation device. High purchase and maintenance costs of the systems have to be taken into consideration.²² In general, today there seems to be a trend toward the static template-based guidance systems in dental implantology.

A consensus workshop organized by the European Association of Osseointegration raised several questions, including which clinical indication would potentially benefit from computer-assisted implant dentistry.²³ The present systematic review included studies reporting about edentulous, partially edentulous, and single-tooth replacement cases. The majority of the included studies reported about edentulous cases. The reason may be the better cost-benefit ratio and the better acceptance of additional radiographic examinations (CT scans) in patients with completely edentulous ridges compared to single-tooth replacements. However, in the future, reductions in radiation doses through improved radiographic techniques (i.e. cone beam technique) and greater accuracy might increase the number of indications for computer- assisted implant placement.

Accuracy

Computer-assisted implant dentistry has often been recommended for flapless procedures and for implant placements in situations with a limited amount of bone or proximity to critical anatomical structures. Hence, it is of utmost importance to know the accuracy of the dynamic and static systems available for implant dentistry. In this systematic review, the accuracy in computer-assisted implant dentistry was assessed by including various methods of evaluation (mostly CT, but also direct measurements of sectioned models or registration of the handpiece position), and by including preclinical and clinical models. In general, the accuracy was better in studies with models and cadavers than in studies with humans. This can be explained by better access, better visual control of the axis of the osteotomy, no movement of the patient, and any saliva or blood in the preclinical models. There was no significant difference between cadavers and models; therefore, the influence of the material (bone versus acrylic) might be negligible for testing the accuracy in a preclinical model. However, it is recommended that the accuracy be assessed in clinical situations. This recommendation is supported by the results of this review, in which the highest number of deviations were revealed in human studies compared to preclinical models (see Table 7). In addition, it is more important to report the maximum deviation, which is crucial to prevent damage of anatomical structures, than to report the mean deviation.

One included study using a static template-based system reported a maximum deviation of 4.5 mm at the entry point.²⁴ This is by far the highest value for deviation reported in all

studies in the present review. The authors proposed that this difference might result from movements of the surgical guide during implant preparation. They suggested further improvements to provide better stability of the template during surgery when unilateral bone-supported and non-tooth-supported templates are used.²⁴

In the present systematic review, the overall mean error at the entry point was 0.74 mm. To interpret this value it is important to know the accuracy of manual implant preparation. Two preclinical studies performed on acrylic models compared the accuracy of two dynamic navigated systems with conventional implant preparation.¹⁶⁻²⁵ In one study, the reported maximum error at the entry point ranged from 0.8 to 1 mm for the conventional insertion and was 0.6 mm for the navigated insertion.²⁵ The other study reported a mean error at the entry point of 1.35 mm for manual implantation and 0.35 to 0.65 mm (RoboDent and IGI DenX Systems) for dynamic navigated implant placement. These values are in accordance with the mean error at the entry point in preclinical models revealing a difference of 0.6 mm in the present review. Both studies demonstrated a statistically significantly higher accuracy for the navigated systems compared to the manual implant placement.¹⁶⁻²⁵ However, this comparison was only performed on dynamic navigated systems, and no data for static template-based systems are available. This is even more important because the dynamic systems in the present systematic review provided greater accuracy than the static systems. This difference might be explained by the fact that static template-based systems were more often used clinically rather than in preclinical models, which have provided better accuracy.

Because of different study designs (human versus cadaver or model, drill holes versus implants, different evaluation methods), it is not possible to identify one system as superior or inferior to others.

A series of errors during the entire diagnostic and operative procedure might contribute to an accumulation of minor errors, leading to larger deviations of the implant position. The reproducibility of the template position during radiographic data acquisition and during implantation is a delicate issue, especially in edentulous patients.

In addition, it is important to realize that computer-assisted implant surgery is a new field of research that is undergoing rapid development and improvements in clinical handling properties and accuracy. Hence, the systems used today in clinical practice might demonstrate greater accuracy and might have solved some of the above-mentioned problems encountered with earlier versions, but these data are not yet available in the dental literature. This rapid advancement in computer technology should be considered when evaluating older reports of various systems, since those that were tested may not bear much similarity to current offerings.

Conclusion

It is concluded from this systematic literature search that a large number of different computer-assisted guided implant systems are available today in clinical practice. Differing levels and quantity of evidence were noted to be available, revealing a high mean implant survival rate of 96.6% after only 12 months of observation in different clinical indications. In addition, the mean percentage of intraoperative complications and unexpected events was 4.6%. The accuracy of these systems depends on all cumulative and interactive errors involved, from data-set acquisition to the surgical procedure. The meta-analysis of all preclinical and clinical studies revealed a total mean error of 0.74 mm at the entry point and 0.85 mm at the apex. Future long-term clinical data are necessary to identify clinical indications and to justify additional radiation doses, efforts, and costs associated with computer-assisted implant surgery. There is not yet evidence to suggest that computer-assisted surgery is superior to conventional procedures in terms of safety, outcomes, morbidity, or efficiency.

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Appendix

Review of Systems for Computer-Assisted Implant Dentistry

From information derived from review of the literature, combined with Internet searches and additional commercial sources, a compilation of computer based products for implant surgery was created. It is important to clarify and distinguish the types of systems based on very specific definitions published in the Glossary of Oral and Maxillofacial Implants (GOMI; Chicago: Quintessence, 2007).

- **Computer-aided design/Computer-assisted manufacture (CAD/CAM):** Computer technology used to design and manufacture various components.
- **Image guidance:** General technique of using pre-operative diagnostic imaging with computer-based planning tools to facilitate surgical and restorative plans and procedures.
- **Imaging guide:** Scan to determine bone volume, inclination and shape of the alveolar process, and bone height and width, which is used at a surgical site.
- **Surgical navigation:** Computer-aided intraoperative navigation of surgical instruments and operation site, using real-time matching to the patients' anatomy. During surgical navigation, deviations from a preoperative plan can be immediately observed on the monitor.
- **Computer-aided navigation:** Computer systems for intraoperative navigation, which provide the surgeon with current positions of the instruments and operation site on a three-dimensional reconstructed image of the patient that is displayed on a monitor in the operating room. The system aims to transfer preoperative planning on radiographs or computed tomography scans of the patient, in real-time, and independent of the position of the patient's head.
- **Surgical template:** Laboratory-fabricated guide based on ideal prosthetic positioning of implants used during surgery. Also called surgical guide.
- **Three-dimensional guidance system for implant placement:** A computed tomography (CT) scan is performed to provide image data for a three-dimensional guidance construct for implant placement. A guide is a structure or marking that directs the motion or positioning of something, thus in implant dentistry this term should not be used as a synonym for surgical implant guide. A radiographic guide is rather used as a positioning device in intra- oral radiography.

For the purpose of this consensus review, some GOMI definitions were clarified:

- **Computer-guided (static) surgery:** Use of a static surgical template that reproduces virtual implant position directly from computerized tomographic data and does not allow intraoperative modification of implant position.

- **Computer-navigated (dynamic) surgery:** Use of a surgical navigation system that reproduces virtual implant position directly from computerized tomographic data and allows intraoperative changes in implant position.

All systems incorporate planning of implant positions on a computer, using various software tools. These plans are then converted into surgical guides or used in other positioning systems in a variety of methods. In general, these implant positioning devices can be categorized into “static” and “dynamic” systems. “Static” systems are those that communicate predetermined sites using “surgical templates” or implant guides in the operating field. Therefore, “static systems” and “template-based systems” are synonymous. Alterations to implant position or deviations from the prefabricated template can be accomplished “free-hand”.

Dynamic systems communicate the selected implant positions to the operative field with visual imaging tools on a computer monitor, rather than intra-oral guides. The dynamic systems include “surgical navigation” and “computer-aided navigation” technologies. With these, the surgeon may alter the surgical procedure and implant position in real time using the anatomical information available from the preoperative plan and CT scan. Since the surgeon can see an avatar of the drill in a three-dimensional relationship to the patient’s previously scanned anatomy during surgery, modifications can be accomplished with significantly more information. In essence, the navigation system provides a virtual surgical guide or template that may be altered when conditions indicate.

Table 8 is a compilation of currently available image guidance systems and those that appear to be in development or have some scientific publications available for review. The commercially available systems have been divided into two categories. The first section represents 22 software systems that are available for radiographic diagnosis and also generally provide for fabrication of surgical guides. The systems fall into the category of “three-dimensional guidance systems for implant placement,” permitting implant planning from patient CT or CBCT scans. These products offer computer-based diagnostic and planning tools that permit enhancement, manipulation, and analysis of a patient’s digital scan. Planning information can remain stored on a computer in digital files for visual review or can be sent to a manufacturing facility to create three-dimensional models of the stored images. Most systems generate information to fabricate a surgical guide once appropriate surgical planning has been completed. This manufacturing process, generically called CAD/CAM, uses either rapid prototyping technologies such as 3D printing and stereolithography or “computer-driven drilling (CDD)” to create anatomical models.⁴¹

For surgical planning, implant avatars are positioned into the scanned images using software to simulate surgical placement. Once a satisfactory plan is approved and saved, CAD/CAM technology is used to produce a customized surgical template or guide. Depending on the manufacturer, guides can be indexed to available surrounding teeth, mucosal contours, or bony contours. Some manufacturers additionally offer prosthesis fabrication, combining the digital information with dental prosthetics.

Advantages of these systems may include general familiarity with the use of surgical guides based on long-established procedures. A high degree of precision may be obtained, particularly when guides incorporate graduated dimensions of drilling sleeves to guide increasing diameters of drills. Some systems provide two-dimensional (mesiodistal and bucco-lingual) guidance, while others also incorporate depth control. The precision of the surgical templates depends on the accuracy of the scan and the fit of the device during use. Some manufacturers require casts of the patients' arches or teeth to insure accurate fit, while others create the guides from the scanned images and contours. Difficulties can arise when patients have poor edentulous ridge form or loose teeth, or extractions are anticipated, since anatomical landmarks required for surgical guide stabilization could move or change. Several strategies to overcome these problems have been devised. As previously noted, some manufacturers fabricate provisional or final restorations from the digital plans, but there are too few long-term data to permit considering this a routine or accepted procedure.

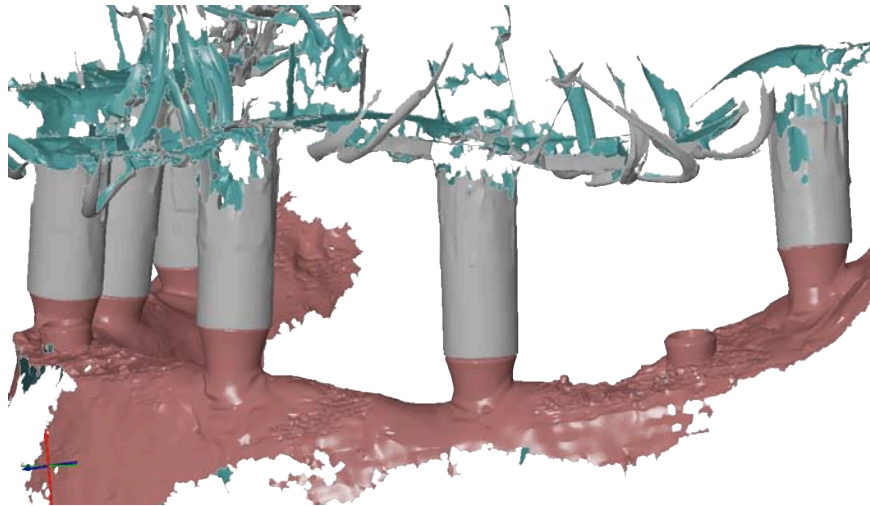
The final group of devices includes six surgical navigation systems, four of which are commercially available. Surgical navigation systems require that sensors be attached to both the patient and the surgical handpiece. These sensors transmit three-dimensional positional information to a camera or detector that allows the computer to instantaneously calculate and display the virtual position of the instruments relative to the stored image of the patient's anatomy.

An analogous technology is the global positioning system used for personal transportation, which similarly uses a satellite to track an individual's movements against a previously stored map. During surgery, the surgeon typically watches the computer monitor in addition to, or instead of, the surgical site to monitor positional accuracy. In medicine, this is similar to endoscopic or laparoscopic procedures, where the surgical sites are obscured, requiring viewing on a monitor.

An advantage of navigation systems is that the surgical plan can be altered or modified while retaining the "virtual vision" of the technology. The surgeon can either move the virtual implant on the plan or ignore the plan completely and use the navigation system to contemporaneously visualize the patient's anatomy. This permits the surgeon to steer around

obstacles, defects, or conditions that were not apparent on the presurgical scan. Similar technology has been safely and effectively used in other branches of medicine, including neurosurgery, spinal surgery, and cardiac surgery. In addition to the stability problems noted for surgical guides, complications and difficulties can arise with navigation if the sensors are not precisely and firmly attached to the patient or handpiece. To date, restorations have not been CAD/CAM produced from planning files of the navigation systems. It is possible to do a sham procedure on dental casts, so that a dental laboratory could prefabricate restorations for immediate-loading procedures prior to implant placement. As with restorations planned from computer-generated surgical guides, this technique has not been adequately investigated.

CHAPTER 3



Parameters of Passive Fit Using a New Technique to Mill Implant-Supported Superstructures: An In Vitro Study of a Novel Three-Dimensional Force Measurement-Misfit

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Abstract

Purpose: The objectives of this study are to describe, in vitro, a novel technique to measure the misfit of digitally designed and manufactured implant-supported frameworks according to a new concept based on computer-guided surgery in combination with previously placed mini-implants. Also, the digitally created framework and an impression-based milled structure were compared using strain gauge measurements. **Materials and Methods:** Acrylic resin and plaster models were prepared to represent the edentulous mandible. After insertion of three mini-implants in the acrylic resin model, a cone-beam computed tomographic scan was performed. The data were imported to planning software, where six implants were virtually inserted. A drill guide and titanium framework were designed and milled using a fully digital computer-aided design/computer-assisted machining protocol. Six implants were inserted using the drill guide attached to the mini-implants. After an impression was made of the acrylic resin model with six implants, the second model (plaster model) was prepared. A second milled titanium structure was fabricated following optical scanning of the acrylic resin model. Strain gauge measurements were done on both structures attached to both models. To validate the results, a high-accuracy industrial optical scanning system was used to capture all connection geometry and the measurements were compared. **Results:** The accuracy of the digital superstructures was 19, 22, and 10 μm with standard deviations (SD) of 19.2 (17.9), 21.5 (28.3), and 10.3 (10.1) μm for the x-, y-, and z-axes, respectively. For the impression-based superstructure the measured misfit was 11, 20, and 17 μm , with SD 11.8 (10.5), 19.7 (11.7), and 16.7 (8.2) μm for the x-, y-, and z-axes, respectively. **Conclusion:** The misfit of the digitally designed and produced superstructure on the digitally planned and inserted implants was clinically insignificant.

Introduction

Accurate fit of dental prostheses is thought to be critical to the long-term success of the supporting structures whether those structures be teeth, mucosa, or implants. The introduction of computer-aided design/computer-assisted machining (CAD/CAM) technology in dentistry has resulted in more accurate milling of prosthetic frameworks, resulting in greater precision of dental restorations and implant supported prostheses in particular.¹ Jemt *et al.* demonstrated the precision of CAD/CAM-milled frameworks for implant treatment and concluded that the precision of fit of the first CAD/CAM-milled prostheses was comparable to that of conventional cast frameworks.² Thus, CAD/CAM technology has been described as a method that reduces error and thereby improves the fit of prostheses. Karl *et al* found, through strain gauge analysis of fit, that restorations fabricated using optical impressions demonstrated a level of fit that is at least as accurate as that of conventional fixed dental prostheses.³

However, the evaluation of an absolute passive fit of superstructures is not possible using conventional clinical and laboratory procedures, as clinical fit evaluation methods often do not detect inaccuracies that are below the level of visual acuity or the measurement capacity of the testing equipment. In a randomized clinical trial, Ortorp and Jemt demonstrated acceptable clinical performance after 1 year with CAD/CAM-milled titanium frameworks supported by implants in edentulous arches. Similar clinical and radiographic performance was observed with CAD/CAM and conventional cast frameworks. In their research they demonstrated improvement of the accuracy and precision of fit with CAM frames over conventional wax casting techniques.^{4,5} Nevertheless, these techniques are based on scanning procedures of a cast that was produced after conventional impression taking.

The other important development in the field of implant dentistry is undoubtedly the introduction of surgery guided by computed tomography (CT). Multiple studies have demonstrated the value of CT for diagnosis, planning, and guided placement of dental implants.^{6,7} Commercial software packages have been developed to allow the use of CT scanning to improve visualization of edentulous arches. Implants may be planned virtually using these images while considering both anatomic and prosthetic factors. Imaging technology allows design and fabrication of the prosthetic framework prior to implant placement.

Endosseous implants may be placed as fiducial markers to ensure reliable orientation of imaging data obtained from CT scans. The complete digital protocol based on the fixed

intraoral references described in the present report makes it possible to position the drill guide in a reproducible position. The design and fabrication of both the drill guide and the superstructure are based on CT scan images. The primary purpose of the present study is to analyze a technique to examine the misfit of milled superstructures made according to this novel, fully digital technique. The secondary goal is to compare this kind of structure with impression/scan-based milled superstructures.

Materials and Methods

Test Model and Surgical Protocol

Two models, an acrylic resin cast (model 1) and a plaster-derived cast (model 2) fabricated using an impression of the acrylic resin cast, were used to analyze and compare the fit of a digitally created implant-supported framework (S1) and an impression-based milled framework (S2).

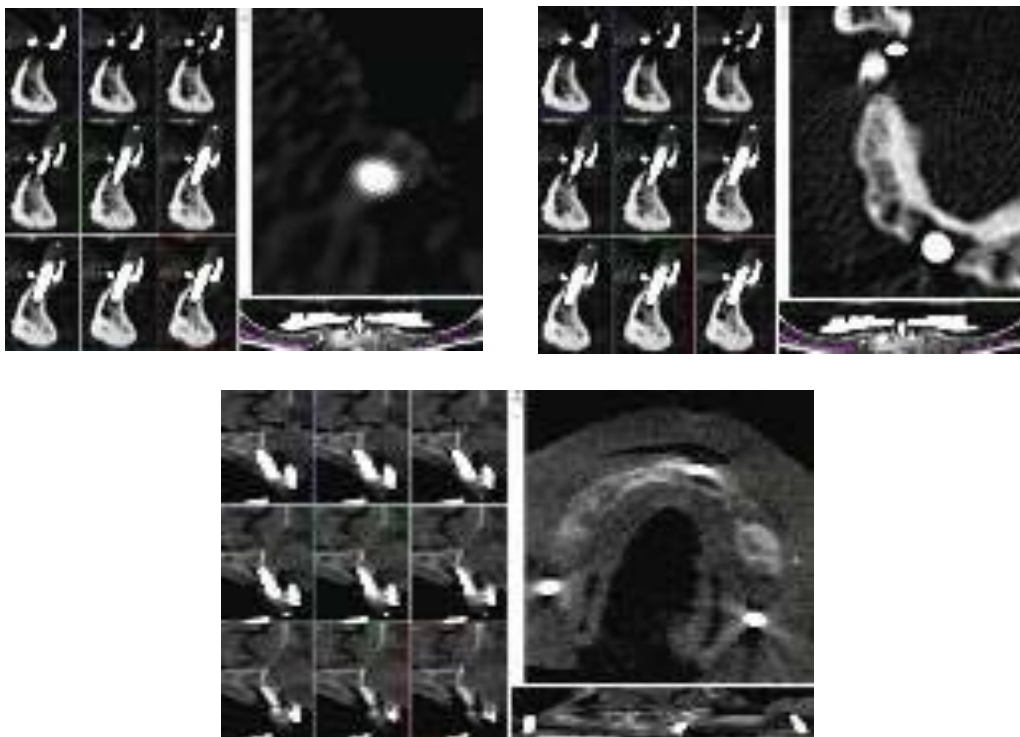
The acrylic resin model of an edentulous mandible (designated the treatment cast) was used as the test model. Mini-implants (6 mm long, 3 mm diameter; Straumann) were inserted in the retromolar area bilaterally and in the mandibular midline to establish a tripod distribution (Fig 1).⁸



Figure 1: Model 1: Radiopaque acrylic resin model of edentulous mandible with three mini-implants in place.



Figures 2a and 2b: Screw complex principle: The acrylic resin top and gutta-percha marker are used to prevent errors induced by metal distortion.



Figures 2c to 2e: (Left) A cross-section through the gutta-percha marker; the marker is always circle-shaped (arrow). (Middle and right) Cross-sections through a mini-implant. Depending on the angle of the cross section, these can have different geometric shapes (arrows).



Figure 2f: (Left) Determination of mini-implant axes and positions on the computer.

A CT scan (Veraviewepox, Morita Corporation) was made with a specially designed screw complex attached to the mini-implants (Fig 2a) to determine the position of the mini-implants on the CT images. The screw complex consists of a cylinder with a defined length and a radiopaque gutta-percha marker point placed on the top. The radiopaque gutta-percha point is spherical and 1 mm in diameter (Figs 2a and 2b).

The CT data were processed to generate multiple cross-sections and three-dimensional (3D) images using the planning software (Figs 2c to 2e). A virtual 3D model was then created (Fig. 2f). Six implants (Straumann), 4.1 mm in diameter and 12 mm in length, were virtually inserted in the planning software. The planning data were exported to the CAD software program, where the surgical templates and the frameworks were designed using the same data as the planning software. The designed structures were then transferred back into the planning software, where the fit was virtually checked. The surgical guide and the superstructure were designed using the same data used during planning.

After the plan and design of S1 were approved, the data were sent to the milling company (ES Tooling). A simultaneous five-axis milling device was used to fabricate the surgical templates (peek composite) and the titanium framework. The surgical template was then connected to the mini-implants using gold screws (Straumann), then transferred back into the

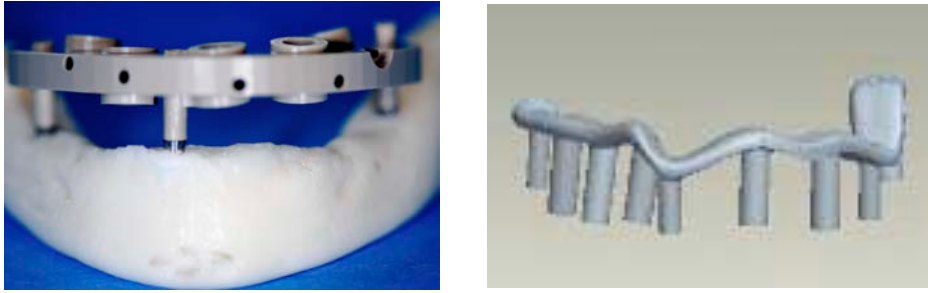


Figure 3: Drill guide connected to the mini-implants. (Right) Framework with extended implant connections.

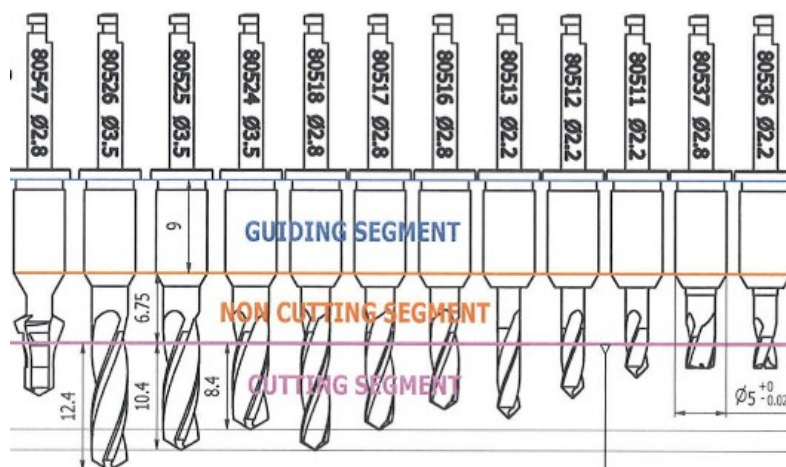


Figure 4: Guiding segments of drills with the same diameter. The cutting segments differ in length and diameter. The 9-mm guiding segment ensures effective guidance during surgery.

planning software where the fit was virtually checked. The surgical guide and the superstructure were designed using the same data used during planning (Fig. 3). The internal connection of the mini-implant and tripod distribution in the edentulous mandible ensured stability of the drilling guide. The drilling sequence involves three different drill diameters. Drilling begins with a flat-headed drill (< 2 mm), which flattens the entry point. Subsequent drills increase by 2 mm in length per step. In this way, heat and undesired movements are prevented during the osteotomy preparation. The guiding segment of all the drills has the same diameter, which fits in the drilling guide in a precise manner. The stop on each drill dictates, together with the drill guide, the depth of the osteotomy (Fig. 4). The drilling sequence was executed for every implant through the surgical guide (Fig. 5). Then the implants were inserted using the specified implant driver (Straumann). Figure 6 provides a

systematic overview of the digital protocol used, from the three-implant model to the CAM milling process.

To ensure precise vertical positioning of the predetermined implant locations, the implant driver is provided with a fixing part in the form of a ring-shaped recess that extends over the surface of the drill's cylindrical body (Figs 7a to 7d). The ring-shaped recess forms a notch that extends over the entire perimeter of the implant driver. The blocking element, the so-called precision pin, is a stick with a preferably round, pointed far end. The cross section of this stick is selected such that it can be pushed into the mentioned recess. To determine whether the implant has reached the desired vertical position in the template, the aforementioned blocking element is placed into the implant guide via the recess, which is situated in the surgical template (Figs 7a to 7d). When inserting the implant, a small amount of pressure is exerted on the precision pin, according to its longitudinal direction, such that the latter pushes against the cylindrical body of the implant driver. Once the desired vertical position of the implant has been reached, the fixing part (implant driver) with its ring-shaped recess will be situated opposite the recess in the drill guide, as a result of which the blocking element, under the influence of the pressure exerted on it, will move into the recess (Fig 7e).

This procedure was repeated for every implant in the test model. After the placement of the last implant, the surgical template was removed by unscrewing the connection screws. This surgical procedure has been described in a case report published by the authors.⁸

To compare the digitally designed superstructure achieved using the digital planning protocol to that created using a traditional protocol, an impression was made from the test site and the inserted implants. The derived cast was scanned with an optical scanner (ES Tooling) and a similar superstructure was milled (S2).

Measurement Technique and Devices

Each frame was measured by a three-dimensional tension-measurement method utilizing strain gauges. The length of each cylinder (connection posts from the superstructure to the implants) was 12 mm to allow placement of the strain gauges. A total of four strain gauges was attached along the long axis of each cylinder of both superstructures at 90-degree angles to each other (Fig 8). The axes of the different cylinders are all oriented in the same direction to make the calculation of the total measured misfit possible. This misfit-induced tension is measured in all axes by electrical circuits called the Wheatstone bridge. This is used to measure an unknown electrical resistance by balancing two legs of a circuit, one leg of which

includes the unknown component (Fig 9). In the test model, the changes in resistance in the strain gauges are a result of force-induced stretch or shrinkage (plus or minus). The misfit and tension in all three axes are measured using four strain gauges connected by three Wheatstone bridges.

Relationship Between Signals and Forces

Signals delivered by the Wheatstone bridges were measured in volt and converted into Newton. The relationship was determined with a force inducer in each dimension (x-, y-, and z-axes) for each cylinder on the superstructure. A force inducer is an instrument by which one can produce a known force. A known amount of force delivered by means of the force inducer can be expressed in volts measured by strain gauges and the Wheatstone bridges. In this way it is possible to determine the relationship between the signal of the Wheatstone bridges and the force (Volt/Newton), which is necessary to calculate the forces after the connection of the superstructure.

Resilience Constants of Cylinders and Implants

The cylinders and the implants in the acrylic resin model (model 1) react as springs when they undergo misfit-induced forces after connection to the superstructure, whereas on the plaster model (model 2), a resilience constant of zero is assumed because of the model's rigidity. Thus the determination of a resilient constant in the acrylic resin model is necessary to calculate the force-induced misfit. For this analysis, both a movement transducer and a force inducer are needed. With the use of a force inducer, a known force can be induced into one of the axes (directions) and at the same time determine the related displacement of the implants by the displacement transducer. The outcome is the resilient constant (force/displacement), which is determined in all directions and for each axis of the cylinders of the superstructures.

Processing the Signals

Measurements to compare the frames S1 and S2 were performed nine times consecutively on the plaster model (model 2) produced after making an impression of model 1. The reason is that it can be assumed that after the first measurement of S1 on model 1, the implants move toward the structure as a result of the misfit-induced tension between the superstructure and the implants. This movement would not occur if the frameworks were torqued on the rigid plaster model (model 2). This makes it possible to perform measurements comparing both structures in the same condition in a reproducible and reliable manner. The superstructure S1

Measurement no.	Implant 1	Implant 2	Implant 3	Implant 4	Implant 5	Implant 6
1	53.90732789	54.85435261	71.16881339	28.33725463	65.42935121	69.70652767
2	65.62773804	47.67598976	67.33498348	20.85665361	52.32590181	82.46817568
3	51.28352562	46.07602413	60.04165221	20.46948949	45.43126677	79.93122043
4	55.22680509	39.45883931	54.30469593	21.49418526	46.66904756	86.37129153
5	47.77028365	39.9374511	61.81423784	21.21320344	46.7653718	85.02940668
6	50.3189825	35.35533906	59.28743543	18.89444363	44.15880433	91.20307012
7	53.79591063	37.70941527	59.16924877	22.29349681	46.23851209	85.63877626
8	46.56178691	39.23009049	60.10823571	23.02172887	46.23851209	83.57631243
9	43.94314509	40.5092582	60.2245797	21.77154106	48.71344784	82.96384755
Average/implant	52.04838949	42.31186221	61.49487583	22.03911076	49.10780172	82.98762537
Total average	51.66494423					

Measurement no.	Implant 1	Implant 2	Implant 3	Implant 4	Implant 5	Implant 6
1	21.21320344	29.59729717	63.85922016	52.02883816	30.23243292	30.5450487
2	16.03121954	41.34005322	56.36488268	67.12674579	29.68164416	34.11744422
3	15.16575089	33.55592347	57.94825278	63.65532185	26.30589288	30.6757233
4	15.65247584	33.2565783	59.97499479	63.07931515	21.1896201	31.20897307
5	16.43167673	36.35931793	68.38859554	61.56297589	21.84032967	29.63106478
6	15.8113883	34.07345007	64.75337829	59.97499479	14.86606875	23.34523506
7	13.45362405	33.67491648	61.56297589	61.22907806	16.64331698	22.75961335
8	7.549834435	32.58834147	50.06995107	40.22437072	6.164414003	12.08304597
9	13.19090596	34.0147027	64.84597135	58.21511831	16.43167673	21.40093456
Average/implant	14.94445324	34.27339787	60.86313584	58.56630652	20.3728218	26.19634256
Overall average	35.86940964					

was attached to model 1. The misfit-induced tensions at each implant were recorded and processed, with consideration of the resilient constant and signal/force relationship. Thereafter, both S1 and S2 were attached respectively to model 2. The misfit-induced tensions at each implant were recorded and processed with consideration only of the signal/force relationship. All signals were processed in a data acquisition software program that was specially designed for this purpose and based on Labview software (Tables 1 and 2).

Optical Scan Analysis to Validate Findings

The misfit between the acrylic resin CT model (model 1) and the milled structures S1 and S2 as well as the misfit between the cast (model 2) and the milled structures were also analyzed using 3D optical measurements (LayerWise). A high-accuracy industrial optical scanning system was used to capture all connection geometries.^{9,10} Fringe pattern projection was applied in combination with dual-camera vision to reconstruct the 3D geometry.

Shape measurement based on digital fringe projection is a technique for non-contact shape measurement. The optical scanning method using fringe projection employs a projector and two cameras. The projector generates a line pattern of different grey values. Points in the transition region are observed by the two cameras simultaneously, after which the 3D coordinates of these points can be calculated. By moving the line pattern, points at different

Table 3 Measurements of Milled Structure (S1) (In μm) Immediately After Implant Placement			
Implant	x-axis	y-axis	z-axis
Implant 1	41	-32	43
Implant 2	5	31	45
Implant 3	-57	31	-14
Implant 4	-69	-16	-54
Implant 5	-15	16	55
Implant 6	16	-9	5
Mean	33.8	22.5	36.0
SD	25.8	10.0	21.3
Sqrt (total misfit)	55		

Table 4 One of Ten Consecutive Measurements of Both Structures Fixed on Model 2 (Plaster Model)				
Measurement	x-axis	y-axis	z-axis	Average
Misfit on SS1				
Implant 1	0	0	30	30.0
Implant 2	-50	-17	6	53.15
Implant 3	27	2	8	27.73
Implant 4	-20	-16	-3	25.78
Implant 5	6	-17	-4	18.46
Implant 6	-12	77	11	78.70
Average misfit				38.97
Misfit on SS2				
Implant 1	-9	12	8	23.43
Implant 2	26	-16	15	34.01
Implant 3	1	-18	12	28.44
Implant 4	-24	-31	-30	49.36
Implant 5	6	-5	-23	24.28
Implant 6	5	36	12	38.27
Average misfit				32.96
Mean (SD) SS 1	19.2 (17.9)	21.5 (28.3)	10.3 (10.1)	
Mean (SD) SS2	11.8 (10.5)	19.7 (11.7)	16.7 (8.2)	
Sqrt (total misfit)	31		29	



Figures 5a to 5c: Surgical procedure and implant insertion.

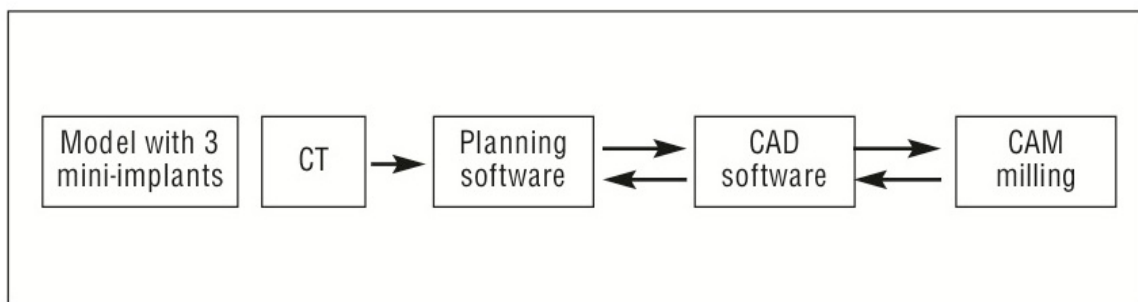
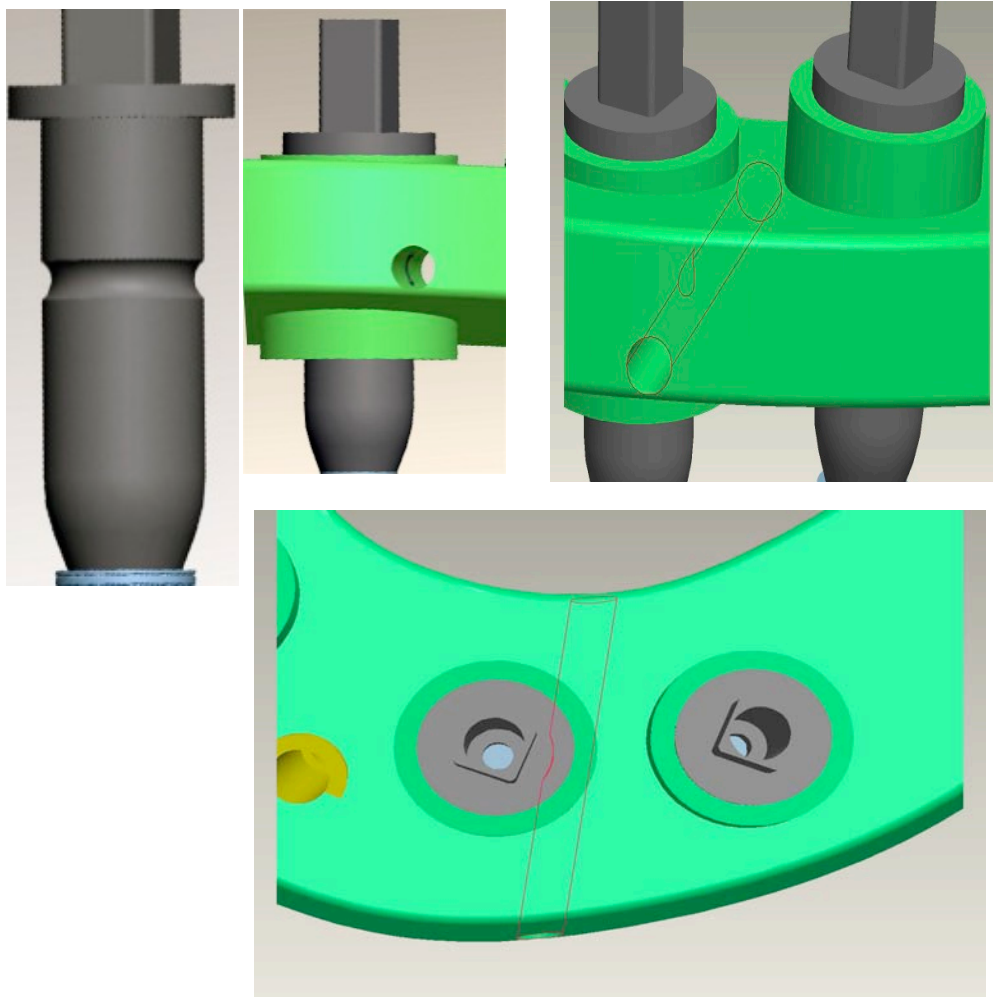


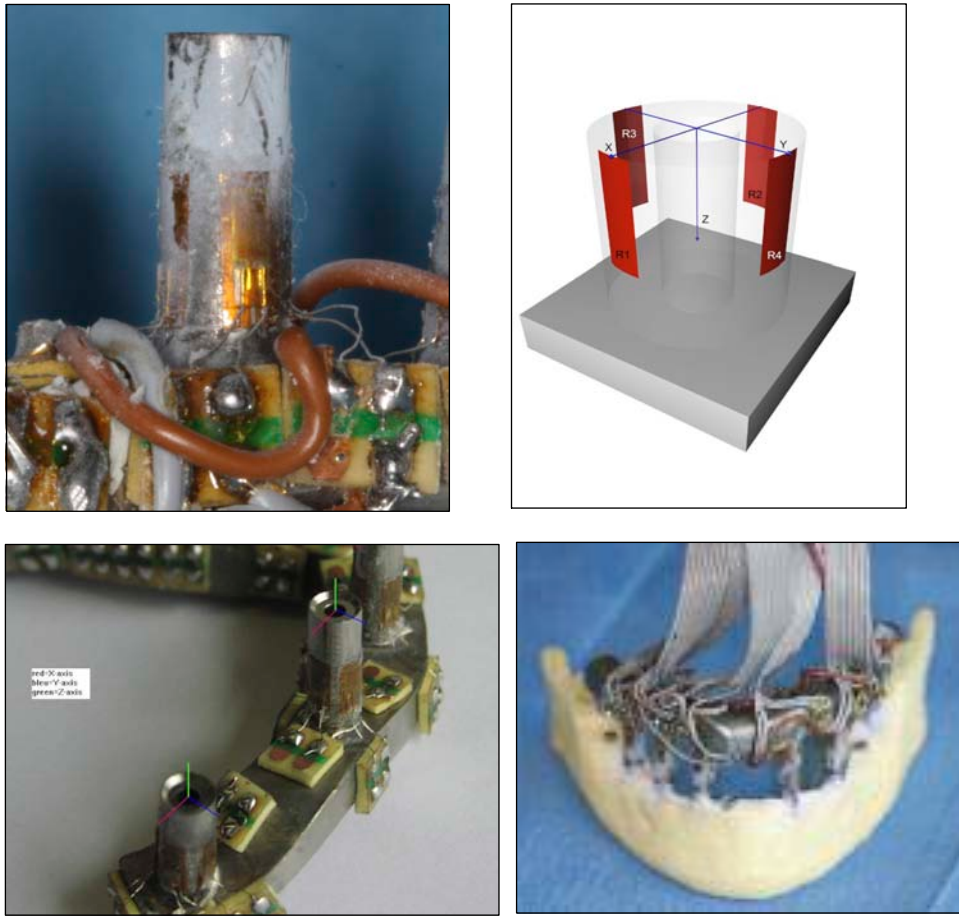
Figure 6: Systematic overview of the different stages of the implant placement and superstructure creation protocol.



Figures 7a to 7d: Recess on the implant driver and surgical guide.



Figure 7e: Precision pin concept for control of implant depth.



Figures 8a to 8d: The test model setup. Four strain gauges per implant connection on each superstructure make it possible to analyze fit in all three dimensions.

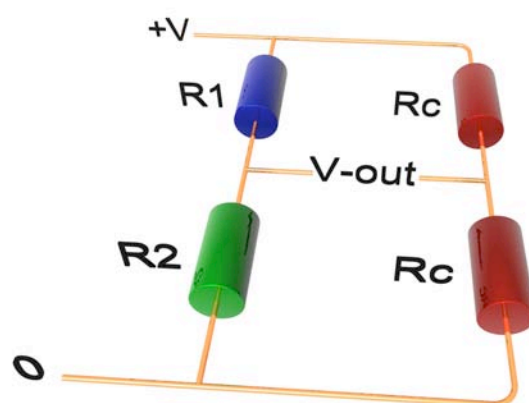
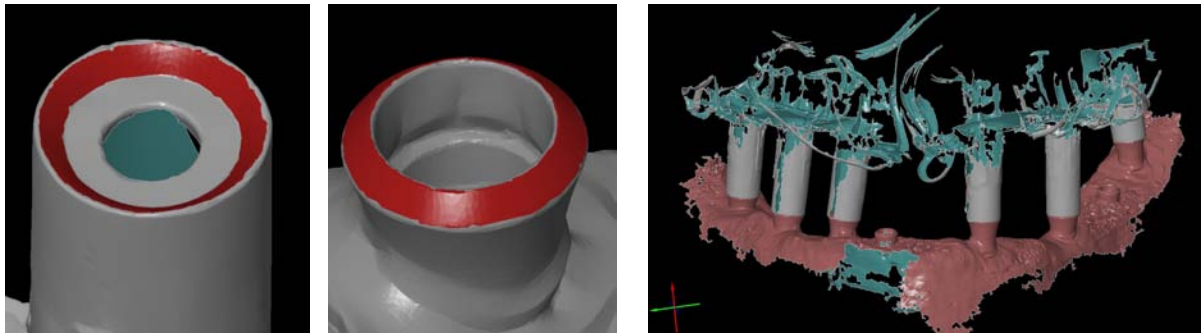


Figure 9: The Wheatstone bridge principle.



Figures 10a to 10c: An example of the optical fitting method using least square fitting of the conical connection faces. (Left) Conical interface on milled structure. (Center) Conical face on the CT model. (Right) Spatial fit of the CT model scan with the milled structure.



Figure 10d: Negative distances as a result of intersecting models.

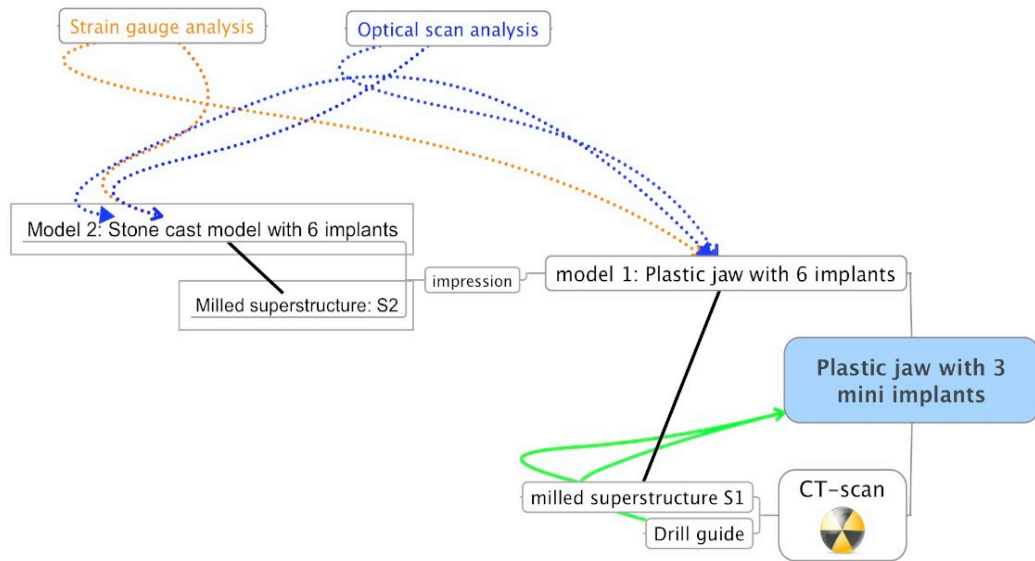


Figure 11: Schematic outline of the different measurement procedures. Blue line demonstrates the optical scan analysis. Please note that compression between the both superstructures has been made additionally to the individual measurements.

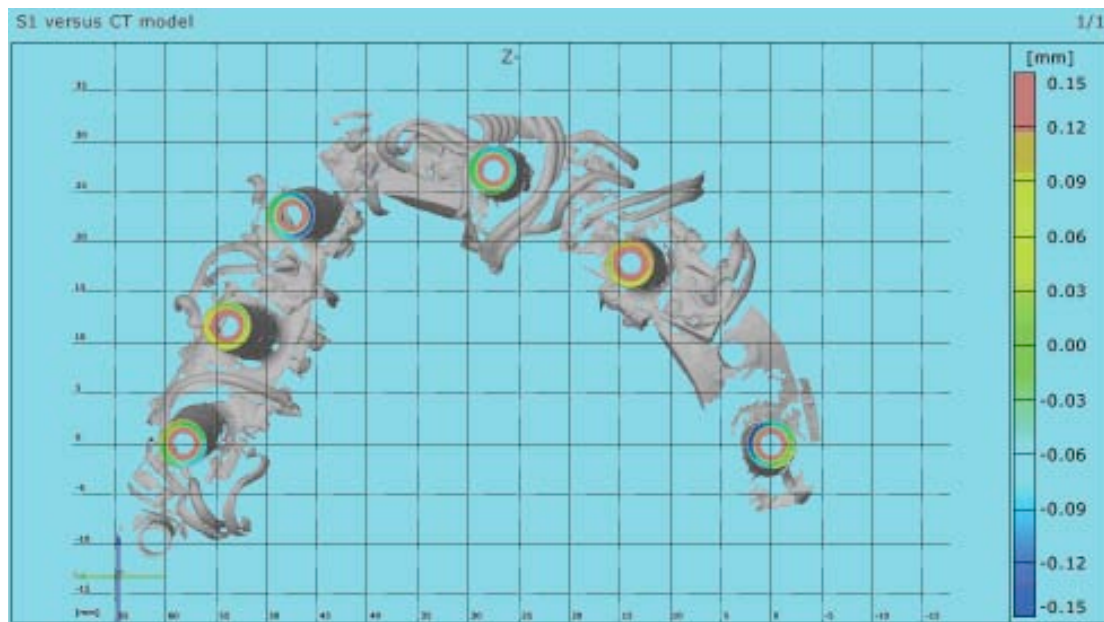


Figure 12: Misfit of S1 versus model 2 using best-fit algorithm surface fitting.

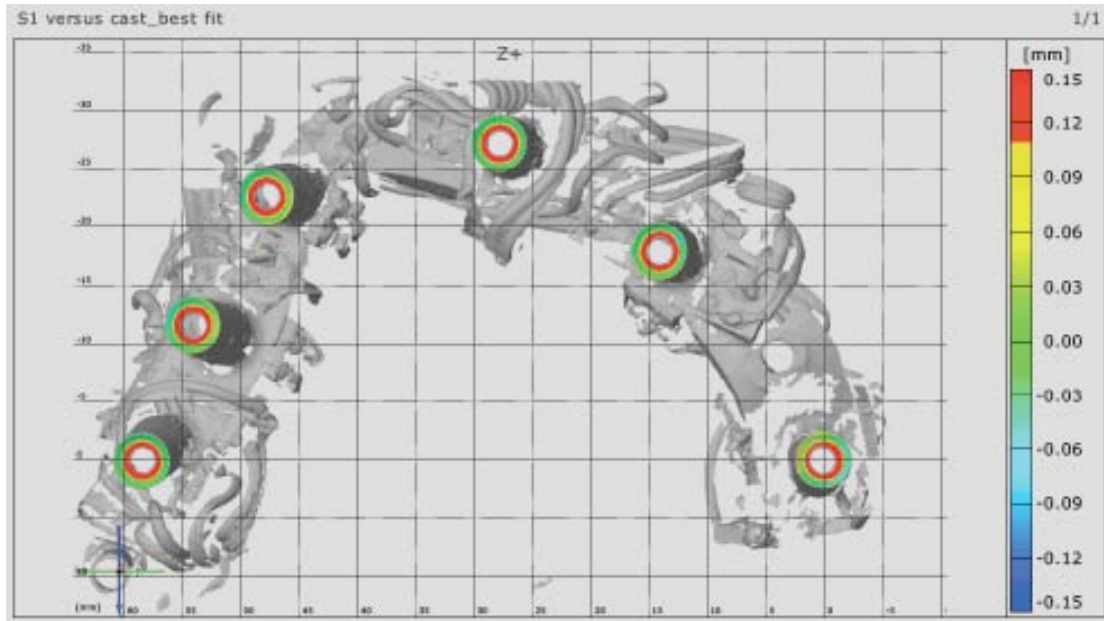


Figure 13: Misfit of S2 versus model 1 using best-fit algorithm surface fitting.

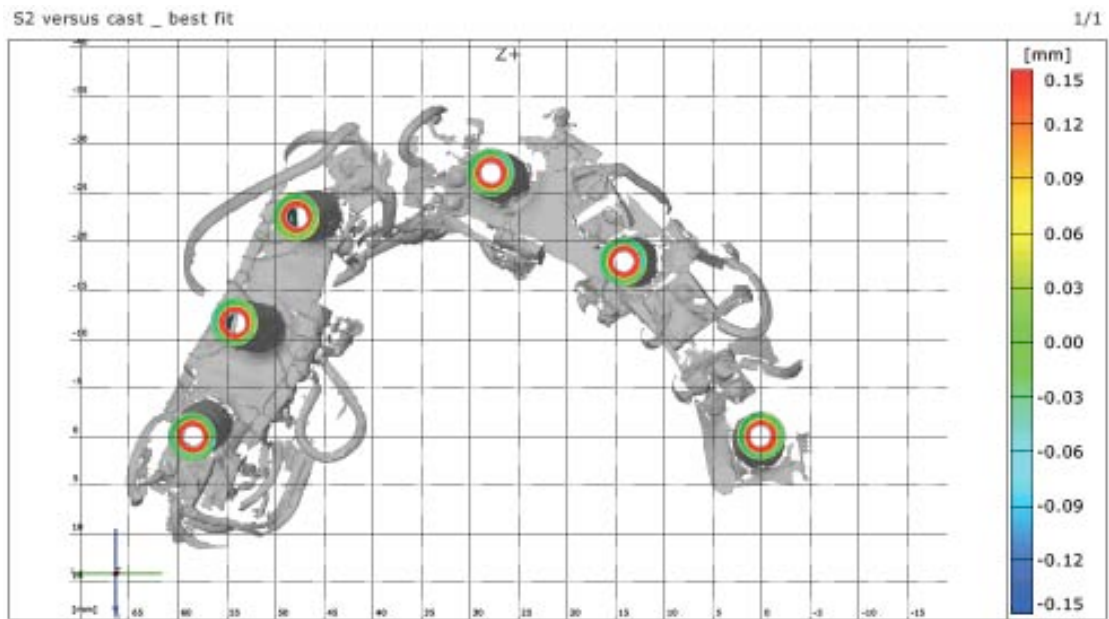


Figure 14: Misfit of S2 versus model 2 using best-fit algorithm surface fitting.

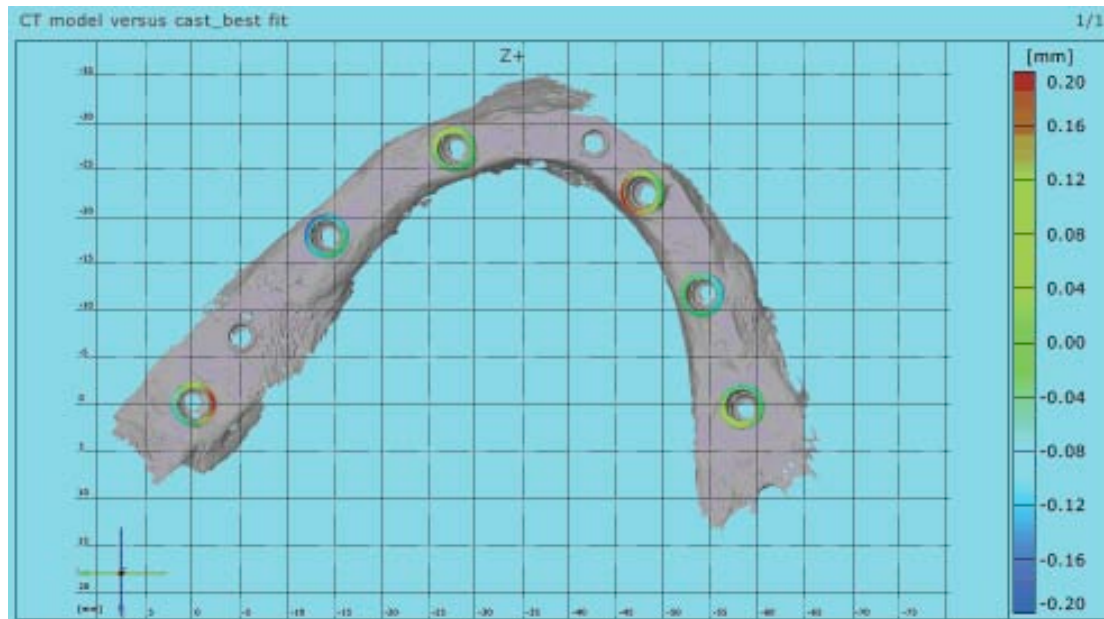


Figure 15: Comparison of the CT-created model 1 with the cast model 2.

locations can be measured very accurately. Using a small measurement volume, a measurement accuracy of about 8 μm can be achieved.¹¹ The calculation method uses the actual measured conical surfaces (the bevel on the shoulder of the Straumann implant) of the implant replicas and the milled connections to position the optical scans next to each other, again using a best-fit algorithm method (Figs 10a to 10c). A titanium oxide layer was applied to the surface prior to scanning. An airbrush system was used instead of a standard scanning spray, because this method allows spraying a layer of titanium oxide with a thickness below 5 μm , whereas regular sprays may have a thickness of more than 100 μm . A best-fit algorithm was preferred in this case, because it corresponds better to the actual clinical situation than a fitting method based on the fixing of individual points or axis directions. The latter would lead to different results, depending on which implant centre point and axis is fixed and which is not. The best-fit method corresponds to the case where all implant screws are torqued simultaneously on the implants. The deviations found after the best-fit algorithm relate to the deviations that the implants will need to handle while the structures are being torqued. With this method, the geometric misfit of the conical connection is then determined by calculating the minimum distance between the CT model (or cast) and the milled structure (S1 or S2). It should be noted that this calculation method does not correspond with the actual clinical situation, since negative distances can be calculated because of optical models intersecting each other (Fig 10d). However, this method does give a good prediction of the displacements occurring at the connection level when the structures are torqued onto the model.

Finally, model 1 and model 2 as well as the milled structures S1 and S2 were compared directly with each other using the same optical fitting method (Figs 11 to 15).

Statistical Analyses

Statistical analysis was performed using paired t tests as well as Wilcoxon signed rank tests, with significance established at $P < .05$. A schematic outline of the different measurement procedures is shown in Fig 16.

Results

The maximum measured misfit observed during the first strain gauge measurements on the milled structure S1 (fully digital design and fabrication) was 57 μm . The average misfit (SDs) in the x-, y-, and z-axes was 33.8 (25.8), 22.5 (10.0), and 36.0 (21.3) μm , respectively. The total misfit calculated according to the Pythagorean theorem and Cartesian coordinates^{12–14} was 55 μm (Table 3).

$$d = \sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2}$$

The next recordings were done on the rigid plaster model (model 2) based on the assumption that the implants might undergo some micro movement in model 1 caused by forces induced when the superstructure was attached and torqued down for the first time. Each superstructure was connected to model 2 and torqued to 35 N/m. The misfit-induced tensions on each implant were recorded and converted into displacement values.

The recorded misfit for S1 was 19.2 (17.9), 21.5 (28.3), and 10.3 (10.1) μm for x-, y-, and z-axes, respectively. For S2 the measured misfit was 11.8 (10.5), 19.7 (11.7), and 16.7 (8.2) μm for the x-, y-, and z-axes, respectively. The total misfits calculated following the Pythagorean theorem and Cartesian coordinates were 31 and 29 μm for S1 and S2, respectively (Tables 1 and 4).

The optical measurements using the analytic fitting elements resulted in an average misfit of superstructure number 1 with plastic model 1 of 60, 21, and 58 μm in the x-, y-, and z-axes, respectively. Using the cast model 2, the average misfit for superstructure number 1 is 60, 30, and 9 μm for x-, y-, and z-axes, whereas for superstructure number 2, the average misfit is 65, 49, and 14 μm , respectively. Using model 2, the reproducibility of the measurements was assessed by intraclass correlation coefficients (ICC). The ICC was 0.993 for the S1 group (average measure; 95% confidence interval: 0.979 to 0.999) and 0.995 for the S2 group (average measure; 95% confidence interval: 0.986 to 0.999). The measurements were

averaged and these averaged measurements were compared between the two groups by an independent sample t test. This test indicated that there was no statistically significant difference between the S1 group and the S2 group ($t = 1.39$, $df = 10$; $P = .195$).

Discussion

Different adjustments to the CT scan images and the digital data were made during the explained protocol before their processing in the planning software.

1. The mini-implants are inserted prior to the actual implant insertion, at the beginning of the procedure. They remain in place during the procedure and are used again to place the drill guide during the surgery. They are removed after the insertion of the last implant. The gutta-percha markers on the screw complex are used to determine the exact positions of the mini-implants on the CT images. This information is crucial for subsequent implant planning and superstructure design using a CAD system. However, the exact position of these titanium screw structures is difficult to define on the reconstructed images because of CT-specific image artefacts. The artefacts include scatter radiation, the limited dynamic range of the x-ray area detectors, the truncated view artefacts, and beam hardening.¹⁵⁻¹⁸ These artefacts have a significant influence on image quality.¹⁹ The geometric accuracy of cone-beam CT is well established, with no significant discrepancies from physical (gold standard) measurements, and its accuracy is in the submillimeter range.^{19,20} However, while cone-beam CT systems are inherently geometrically accurate, locating the exact positions of mini-implants remains challenging because of observer variability and image artefacts. A screw complex is designed to compensate for the resulting measurement error. A ball-shaped radiopaque gutta-percha point of 1 mm is positioned on top of the screw complex. As such, the gutta-percha marker is always visible on one of the cross sections on the CT scans. The reconstructed image cross sections through the metallic ball are circular, regardless of slice orientation (Fig 2b). This facilitates exact determination of the centre of the radiopaque marker in all situations. This marker represents the first and most anterior point of the measurement line. The second point of the measurement line is determined on a cross section through the apex of the mini-implant. The cross sections of the mini-implants can be elliptic or circular, depending on their angulations relative to the positioning of the patient in the scanner or the angulations of the mini-implants. It is hence more difficult to determine the centre of these geometric shapes. Therefore, the second point on the measurement line is invariably less accurate. This results in small deviations of the mini-implants' axes. To minimize this deviation and determine the positions of the mini-implants more accurately, the screw complex extends the length of the

mini-implants from 4 to 6 mm to 25 to 27 mm. Those two points define the axis of each mini-implant, as the known length of the complex plus the mini-implant determines the exact position. In clinical cases the screw complex has an additional function, apart from compensating for the mentioned errors of the CT scan namely, to stabilize the CT template.

2. The other contribution to the precision of implant placement is the so-called precision pin. The precision pin gives the implant driver extra precision, positioning the implant in the correct vertical dimension that was determined during the computerized planning, thereby decreasing possible misfit.

3. Use of the same data for planning, surgery, and designing of the surgical guide and the super structure allows the clinician to eliminate errors that may occur when the data have to be translated or scanned.

The strain gauge measurements on S1 were performed on both an acrylic resin model (test/model 1) and a plaster model (control/model 2), while the measurements on S2 were done only on the plaster model (control). Because of the elasticity of model 1, the implants probably were subjected to some movement because of the forces related to stress-induced misfit. This could explain the small (submillimetric) differences in outcome between these two measurements (see Tables 3 and 4).

Because of its fast speed, flexibility, low cost, and potentially high accuracy, shape measurement based on digital fringe projection has proven to have great promise for 3D shape measurement, especially for applications that require acquisition of dense point clouds.¹²⁻¹⁴ The optical measurement results are presented in Figs 12 to 15. In all the images, it appears as though the centre circle exhibits a large misfit. However, this is not a misfit; since this plane is not a fitting one, a gap is designed between this plane and the implant top faces. The superstructure is not designed to fit on this space but only to sit on the bevel of the implant.

It can be seen that the misfit of the bevel connection faces of S1 and S2 on model 1 is larger than that on model 2. This was also found using the strain gauge test method. From Fig 16 it is clear that model 1 exhibits large deviations from model 2. This is probably a result of movement of the implants in model 1 after several torquing cycles.

Both the milled superstructures S1 and S2 exhibited an average misfit of around 40 μm on the bevelled faces (Figs 12 and 14) when compared with model 2 (Figs 13 and 15).

Conclusions

The misfit of a digitally designed and produced superstructure on digitally planned and inserted implants mimicked that found using impression-based approaches. The errors were clinically insignificant.

Acknowledgments

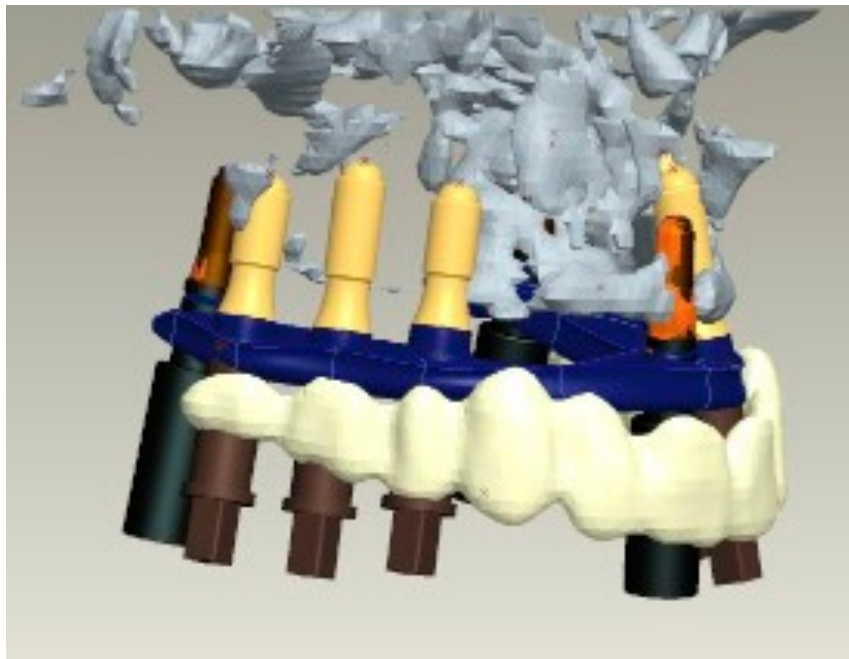
I would like to thank Dr Steven Eckert, Editor-in-Chief, and Prof Dr M. Naeije, University of Amsterdam, for their tremendous support. Also I would like to thank Dr I.H.A. Aartman, ACTA, and Dr Rene Willi, Mr Matteo Taormina, and Mr Wim van Dam, Straumann Company, for their help and technical assistance.

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CHAPTER 4



Computer-Guided Implant Placement: 3D Planning Software, Fixed Intraoral Reference Points, and CAD/CAM Technology. A Case Report.

Ali Tahmaseb, Renaat De Clerck, Daniel Wismeijer

Abstract

The aim of this article is to explain the use of a computer-aided 3-dimensional planning protocol in combination with previously placed mini-implants and computer-aided design/computer-assisted manufacture (CAD/CAM) technology to restore a completely edentulous patient. Mini-implants were used to establish a setup for computerized tomographic imaging and a surgical template. The software and its 3-dimensional simulation allowed the authors to plan ideal implant placement, digitally integrating the future prosthetic and anatomic situations to design the definitive superstructure. The CAD/CAM superstructure is produced digitally with a precise fit and occlusion and good esthetics and is placed immediately after surgery.

Introduction

The introduction of computer-aided design/computer-assisted manufacture (CAD/CAM) technology and computer planning based on images obtained using computerized tomography (CT) has been an important development in implant dentistry.¹ These images can be converted to a virtual three-dimensional (3D) model of the treated jaws. This virtual 3D model gives the surgeon a realistic view of the anatomic bony morphology of the patient, allowing the surgeon to virtually execute the surgery in an ideal and precise manner.

This method, in addition to stereolithography, has been used to develop a new generation of precise surgical templates. Stereolithography is a technology that can produce physical models by selectively solidifying an ultraviolet-sensitive liquid acrylic resin using a laser beam, accurately reproducing, for instance, actual maxillary and mandibular anatomic dimensions. With these models, it is possible to fabricate surgical guides that can be used in vivo to place implants in the same sites and directions as in a planned computer simulation.¹

With the planning software, the practitioner determines the implant position according to both the ideal position dictated by the definitive prosthesis and the available bone volume. The surgical template then dictates the actual implant positions at the surgical sites. The template can be used not only in critical anatomic situations but also to place the implant in an ideal position in the bone because it eliminates possible manual placement errors and matches planning to prosthetic requirements in a precise manner.²⁻⁷

With this case report the authors describe a modified concept in guided surgery based on the use of CT scan images and computer processing to create a digital and non-stereolithographic milled surgical guide using mini-implants as references to transfer the information from the computer to the patient. This 3D imaging protocol using templates attached to diagnostic transfer (mini-) implants enabled the authors to digitally plan the treatment of a patient and to design and fabricate a surgical guide and eventually the definitive superstructure, to be placed at the time of surgery.

Case Report

A 65-year-old completely edentulous male patient with moderate resorption (Cawood VI) caused by the long-term absence of his teeth was referred to a consulting session at the Oral Implantology Clinic at the University of Amsterdam, ACTA (Fig 1). Clinical and medical examinations confirmed his good health. Problems with his removable prostheses included lack of comfort and stability, inability to function and chew normally, and, most important, the psychologic impact and uncertainty about the idea of having removable dentures in the

mouth. With this information, the panoramic radiograph, the articulator with the study models, and clinical observations, the authors advised treatment with fixed implant- retained restorations in both the mandible and the maxilla.



Figure 1: Panoramic image of an edentulous patient with moderate resorption of both arches.

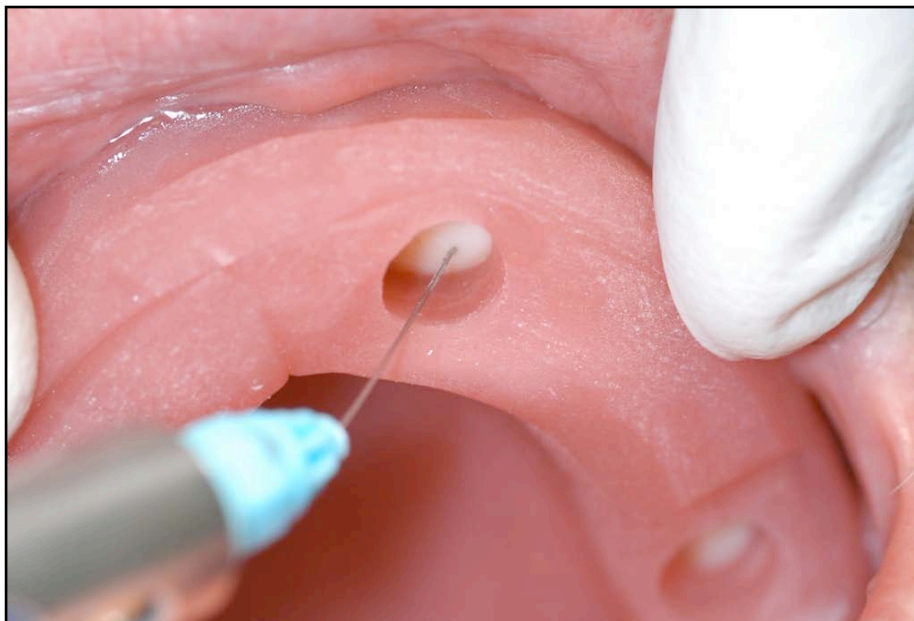
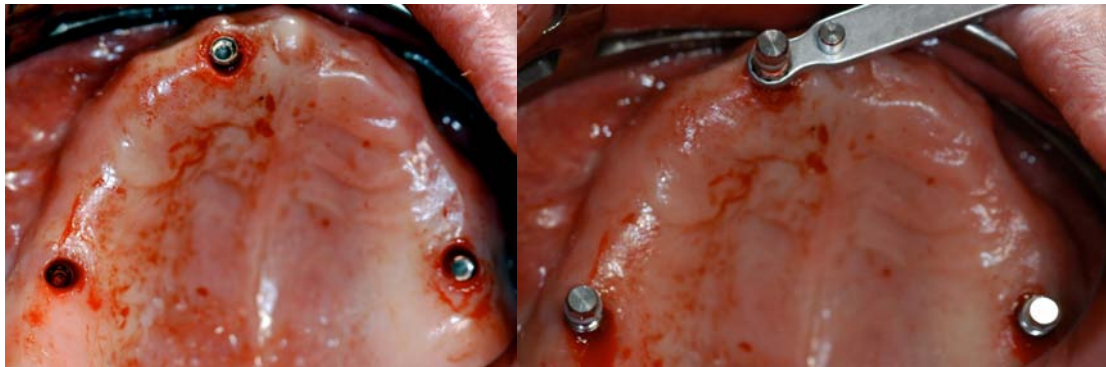


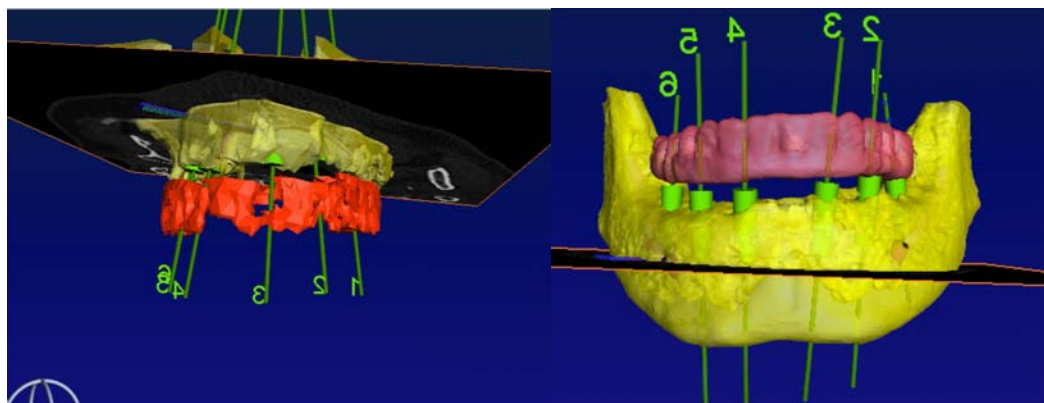
Figure 2: Planned positions of the mini-implants take the positions of the definitive implants into consideration.



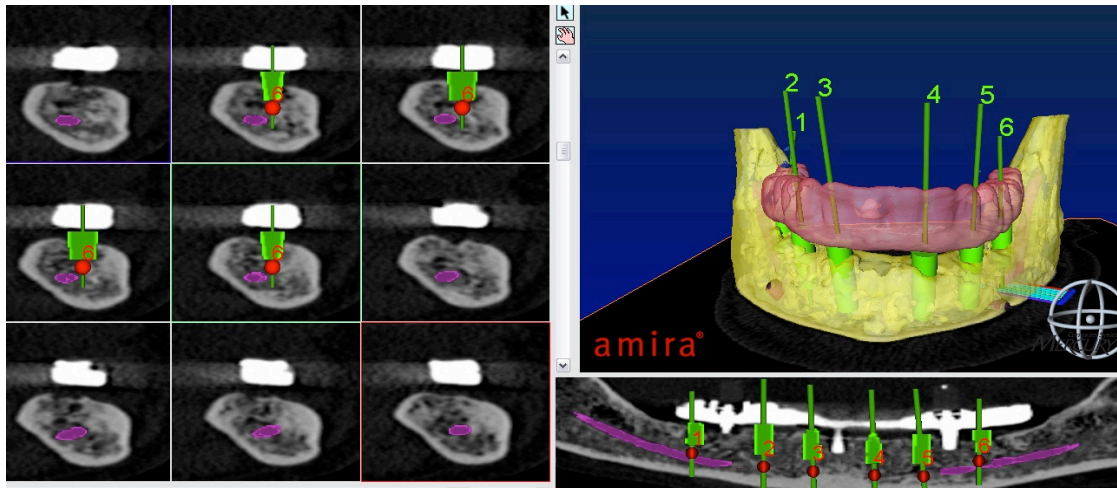
Figures 3a and 3b: Insertion of the mini-implants following a flapless procedure 3 weeks prior to placement of the definitive implants.



Figure 4: The master stone cast with the positions of the mini-implants indicated



Figures 6a and 6b: Three-dimensional simulations of maxillary and mandibular restorations



Figures 7a and 7b: The planning software shows a 3D model of the bony structure of the mandible and the design of the future restoration.

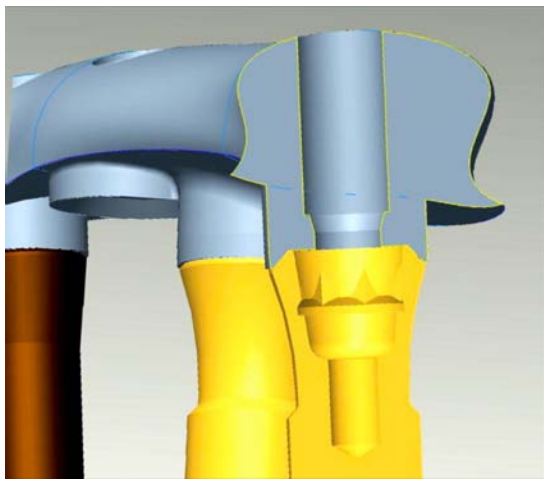


Figure 8a: The designed framework

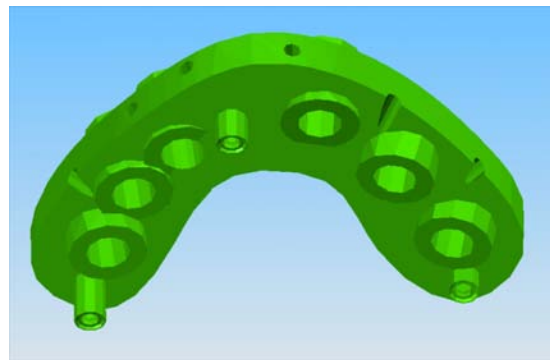


Figure 8b: The surgical template

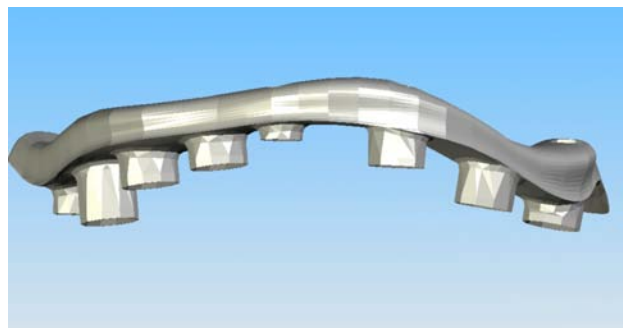


Figure 8c Superstructure design in CAD

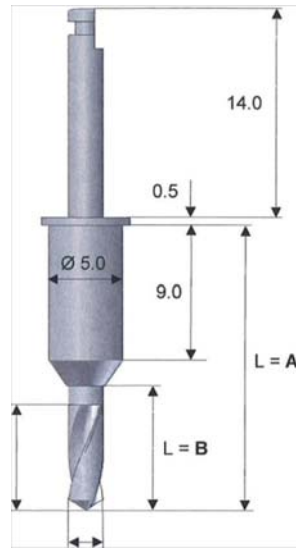
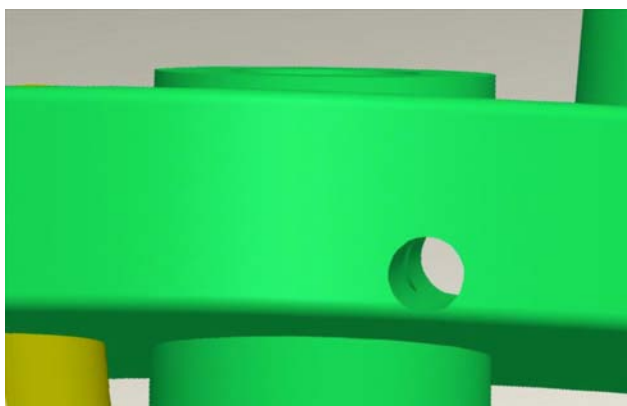
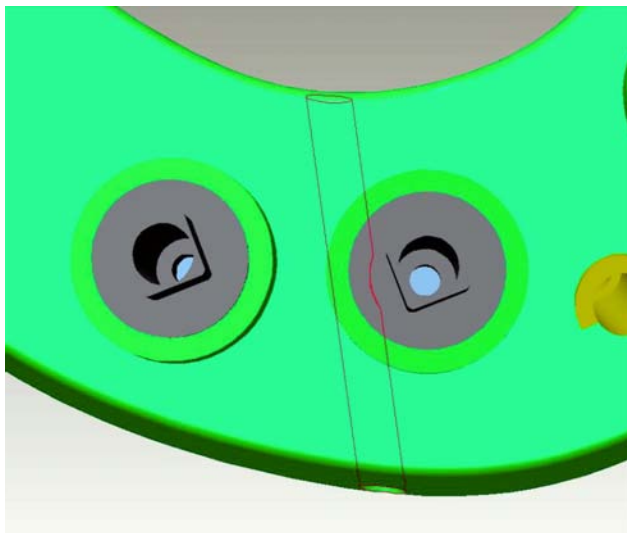
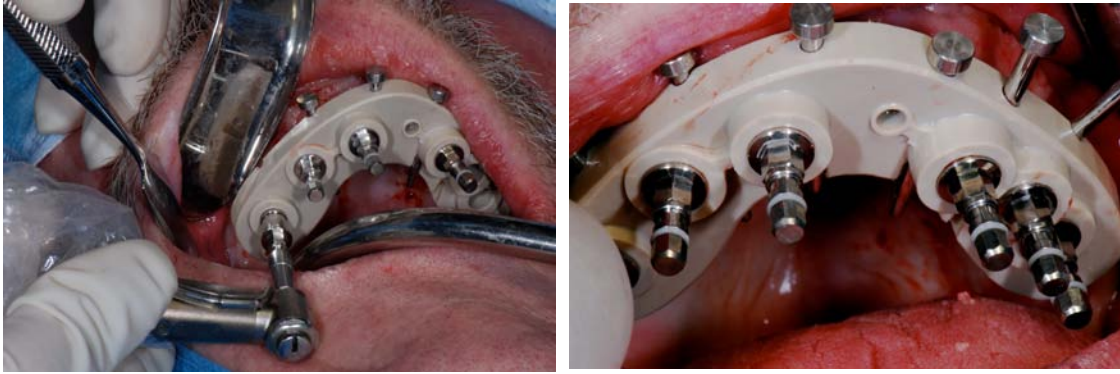


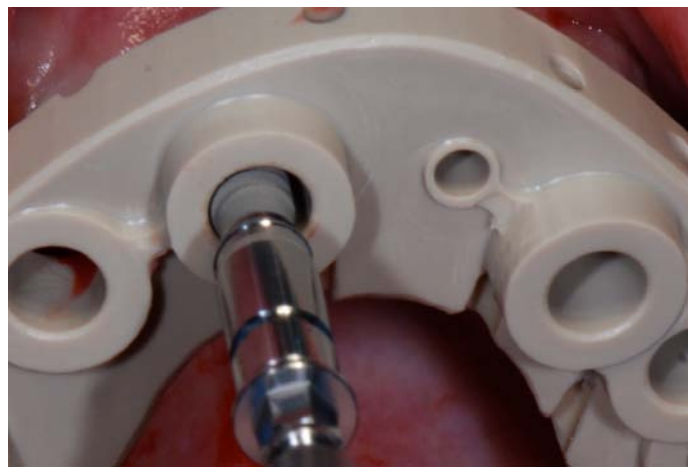
Figure 9: Drill design. *A* = total length. *B* = the length of the cutting segment



Figures 10a to 10d: Precision pin concept



Figures 11a and 11b: Surgery employing the position pin principle



Figures 11c: Insertion of implant through the surgical guide



Figures 12a and 12b: Final prosthetic restoration, in place immediately after surgery

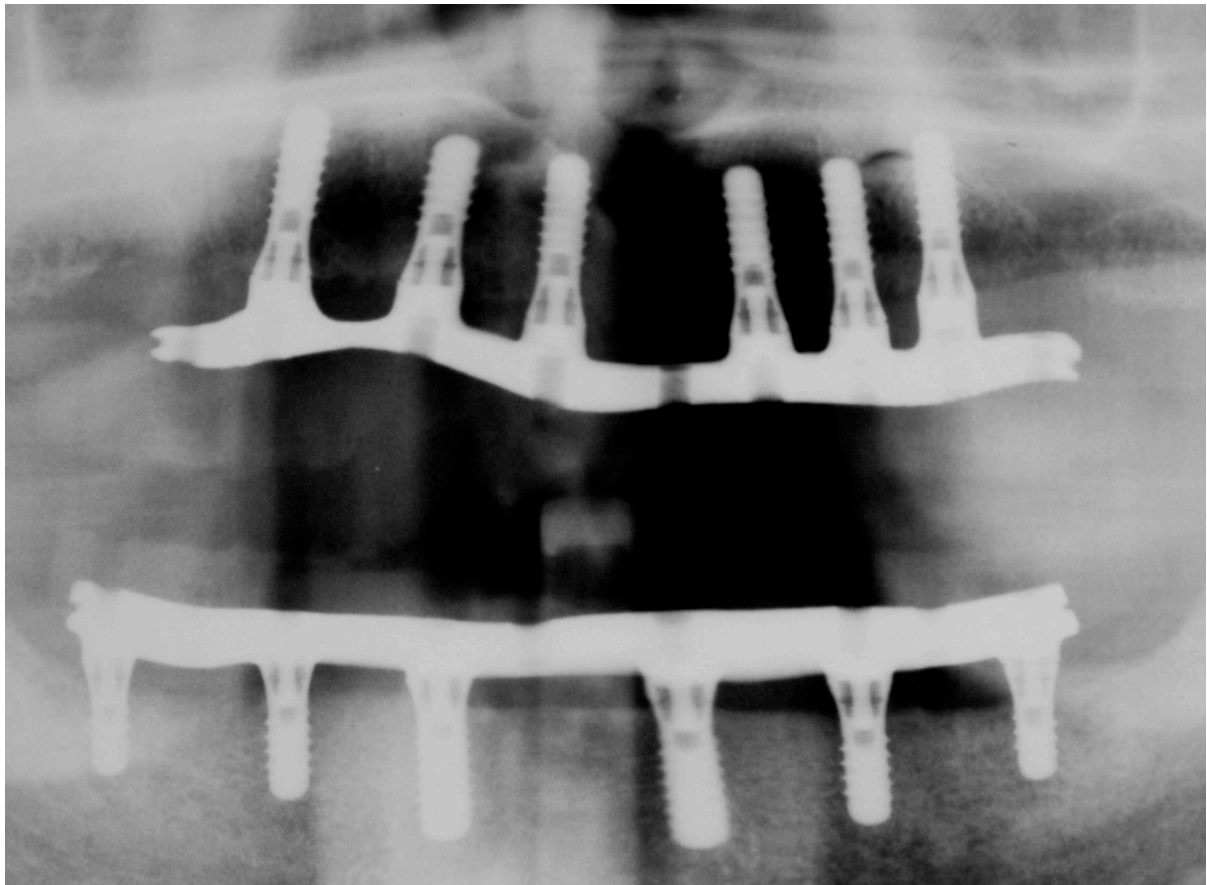


Figure 13: Post-insertion radiography

Six reference implants (three in each arch, 3 mm wide and 4 to 6 mm long; Straumann, Basel, Switzerland) were inserted transgingivally according to a flapless procedure 3 weeks prior to definitive implant surgery (Figs 2 and 3). The triangular distribution of the mini-implants, which were placed in positions that would not interfere with the future definitive implants, would ensure the stability of the CT setup and the future surgical template. The mini-implants were placed in the midline and tuberosities in the maxilla and in the midline and the retromolar regions in the mandible. These positions were set on the study model that was made during the patient's first visit. Impressions were made immediately after insertion of the mini-implants using impression copings and a polyether impression material. A master cast (stone) was fabricated using the mini-implant analogues (Fig 4).

The prosthetic procedures were undertaken in the following phases:

1. Maxillo-mandibular relationship record
2. Intraoral occlusal registration
3. Wax trial denture: esthetic and functional evaluation

4. Copying the ideal setup using a silicon wraparound

The CT setup was delivered using an acrylic resin that contained barium sulfate (Vivotac/Orthotak, Ivoclar Vivadent, Schaan, Liechtenstein). This diagnostic CT setup represents the future definitive restoration. The fixed CT template allowed for accurate evaluation of esthetics, function, and occlusion. The CT template was then screwed onto the mini-implants during the CT recordings using a specially designed screw complex (Fig 5). The screw complex is used not only to stabilize the CT template but also to compensate for CT error. CT images are prone to metal-induced image distortion and errors within 0.5 to 1 mm.⁸⁻⁹ The screw complex has a determined and known dimension with radiopaque gutta percha marked on the top. This can be visualized on the CT images, allowing the clinicians to calibrate and adjust for errors and compensate for the distortion caused by the mini-implants during scanning. Before the CT scan was initiated, the template was connected to the mini-implants using the screw complex. The CT data were processed to create multiple cross-sectional and 3D images with the planning software (exe-plan software, Brussels, Belgium) (Figs 6a and 6b).

Twelve implants (six in each arch; Standard implants, Straumann, Basel, Switzerland) were virtually inserted, considering the available bone, the future definitive restoration, and the underlying anatomic structures. The planning data were exported to the CAD software program, where the surgical templates and the frameworks of the future superstructure were designed using the same data as the planning software (Figs 6 and 7). The designed structures were imported back to the planning software program, where the fit was checked virtually (Figs 7 and 8). The use of the same data for planning, surgery, and designing the surgical guide and the superstructure prevents errors that could occur when the data have to be translated or scanned.

After the planning and the design of the structure were approved, the data were sent to a milling company (ES Tooling, Beringen, Belgium). A simultaneous five-axis milling device fabricated the surgical templates (PEEK composite, ES Tooling) and the titanium frameworks. The dental lab (Van de Bijl TTL, Tilburg, The Netherlands) processed the titanium frameworks to the definitive restorations using the same master stone casts that were created at the beginning of treatment.

Treatment Day

The patient was locally anesthetized first in the maxilla using lidocaine (Alphacaine SP, Oral Hygiene Center, Zeist, The Netherlands). The surgical template was then connected to the mini-implants using gold screws (Straumann, Basel, Switzerland). The drilling guide was

extremely stable because of the good internal connection of the mini-implants, which is similar to the connection of the Straumann Standard implants, and their triangular distribution.

The drilling sequence was executed for each implant starting with the punch and ending with the last drill through the template. Then the implants were inserted using the specified implant driver (Straumann) (Fig 9). The drilling sequence includes three different drill diameters, while the length increases by 2 mm per drill. In this way extreme movements are prevented during the osteotomy. The guiding segment of all the drills has the same diameter, which fits in the drilling guide in a very precise manner. The stop on each drill dictates the depth of the osteotomy (Figs 10a to 10c).

The other important improvement contributing to the higher precision of the implant placement is the so-called precision pin. This pin locks the insertion device when the implants are positioned exactly at the depth that had been determined during the planning phase (Fig 10).

The procedure was repeated for each implant in the maxilla (Figs 11a to 11c). After the placement of the last implant, the surgical template was removed by unscrewing the gold screws. The same procedure was then executed in the mandible.

Immediately after insertion of the implants, the definitive restorations were screwed directly at the implant level without interlocking any abutments (Figs 12a and 12b). The mini-implants were removed by reverse torquing. The fit was evaluated by panoramic radiography (Fig 13) and the occlusion was checked. Minor occlusal adjustments were carried out.

Evaluation and Follow-up

The patient was seen 2 weeks, 6 months, and 1 year after treatment. At 2 weeks, the patient reported no postoperative pain or discomfort and satisfactory esthetics and comfort. He was able to eat and chew. The occlusal screw access points were covered with composite. At 6 months, high satisfaction and an absence of discomfort continued. There was some minor chipping of the acrylic resin in the mandible. At 1 year, the superstructures were disconnected, and Ostell and probing depth measurements were executed. Implant stability quotients ranged between 70 and 80. The acrylic resin chipping were restored and the structures were reinserted.

Acknowledgments

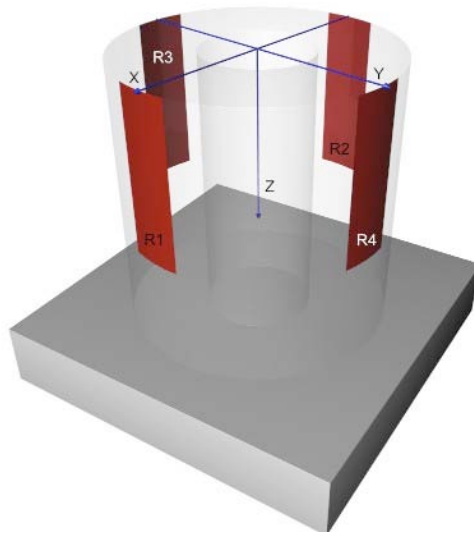
We would like to thank Prof. Dr P.F. Van der Stelt and Prof. Dr M. Naeije of University of Amsterdam, ACTA, for their cooperation in this study. We also thank Dr R. Herzog, Dr R.

Donath, Mr W. Van Dam, and Dr A. Haverhals of the Straumann Company; Mr E. Schildermans, ES Tooling; and Mr C. Verschuren, TTL Van der Bijl; for their technical support.

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CHAPTER 5



Optical Scan analysis to detect minor misfit on implant supported superstructures

Ali Tahmaseb, Peter Mercelis, Renaat De Clerck,
Daniel Wismeijer

Abstract

Purpose: Despite novel and more precise fabrication methods, absolute passive fit of implant-supported superstructures has yet to be consistently achieved. In the past, several laboratory techniques have been described to analyze the fit. The purpose of this article is to assess two methods of fit evaluation with a control and an intentionally misfit prosthesis.

Material and methods: In this in vitro study two comparable implant supported superstructures, Control and Test Misfit, were fabricated after scanning a test model in which four implants, 2 on each side, were inserted. One of the superstructures, the test superstructure, Test Misfit was fabricated with a known minor misfit on one of the inserted implants by manipulating the coordinates on the scanned files. The other superstructure was fabricated as accurately as possible without manipulating any scanned information. Both superstructures were evaluated using optical scanning and strain gauge measurement by an investigator who was blinded to the designed misfit.

Results: Optical scanning demonstrated an accuracy of 10 μms for the control frame while the misfit frame demonstrated greater discrepancies in the planned misfit connection (connection # 2 misfit of 29 μm) and on the other connections (#1 of 4 μm , #3 of 5 μm and #4 of 4 μm) to a lesser extent. The strain gauge measurement showed a higher mean deviation of 26.2 μm (SD=5.9) in Test Misfit comparing with 15.3 μm (SD=4.3), measured on Control.

Conclusion: The optical scan analysis detected the test superstructure and the manipulated implant. The strain gauge measurements confirmed these findings, indicating both methods of assessing inaccuracy to be effective. The optical scan analysis may be used as a simplified and clinically applicable method to detect minor misfits in implant-supported superstructures.

Introduction

Although the precision of screw-retained frameworks has often been subject of discussion no consensus has been achieved in the relationship between the misfit and biological impact of such misfit. There are contradictory findings when reviewing the early literature in this regard.¹⁻⁷

Since the development of new technologies (e.g. milled titanium frameworks) to fabricate the implant supported frameworks, the precision of fit has improved dramatically when compared with traditional lost wax cast frameworks.⁸⁻⁹ Passive fit of superstructures may not be achieved using conventional clinical and laboratory procedures. In addition, clinical fit-evaluation methods often do not detect discrepancies that are smaller than those seen with the naked eye. To address this concern, more sensitive strain-gauge techniques have been developed to provide objective assessment of fit.¹⁰⁻¹¹

Accuracy of component fit may be evaluated through visual or microscopic inspection, tactile assessment or displacement when single screws are tightened.¹²⁻¹⁴ All of these techniques are somewhat objective. Strain gauge assessment may provide more objective analysis however this approach is more difficult and may not lend itself to routine quality control. Optical scanning methodology may provide a satisfactory assessment method that could be used in a quality control system. The aim of this study was to analyze the precision of the optical scan method compared to the strain gauge analysis and their ability to detect microscopic misfits in milled titanium frameworks.

Material and Methods

A test model with four inserted implants (Straumann Standard implant), 4.1 mm in diameter and 12 mm in length, was prepared. The model was scanned using an optical scanner (ATOS II SO by GOM GmbH, Braunschweig, Germany) to calculate the implant positions using high precision scan adaptors that are mounted on the implants. Two similar superstructures were designed using dedicated software (DentWise- LayerWise). The Control superstructure (Control) was designed according to the measured implant positions, as calculated from the optical measurements, to obtain the best possible fit on the inserted implants. The second superstructure, Test Misfit, was designed with a known but minor misfit on one of the inserted implants. This was done by altering the coordinates of implant 2 by an arbitrary value of +/- 55 μm in X, Y and Z direction, while keeping the coordinates of all other implants the same as in the control frame (Figs 1a&b). Both superstructures were manufactured using combined Selective Laser Melting (SLM) / CNC technology (DentWise-

LayerWise NV, Leuven, Belgium) in a Ti6Al4V alloy. This alloyed titanium powder was used as the base material for the Selective Laser Melting process. In a second stage, a CNC controlled process is applied based on the same three-dimensional CAD model to accurately finish the implant connections to the necessary tolerance (less than 20 μm misfit).

Both structures analyzed in this study were designed following a direct scanning of the test model and were virtually designed using CAD software. This technology is based on a three-dimensional CAD model of the implant superstructure. The CAD model is virtually sliced in a series of successive, two-dimensional layers with a limited thickness (typically 20 to 40 μm), which allows accurate reconstruction of the complex anatomical geometries of the dental prostheses. Moreover, the method of manufacturing allows integration of the complex features in the design of the dental superstructures, like surface retention and sealing edges. This is different from the other CNC-milled protocols described in the literature where an impression of the implants is taken and a master cast is fabricated. Dental laboratories develop a wax or resin pattern, which is then scanned and the gained STL files are used to CNC-mill the frameworks.¹⁵⁻¹⁶

The implant connections on both superstructures were numbered as illustrated in figure 1b. Since strain gauge analysis would be performed on both superstructures; a rigid design was used with long implant connections to allow for the attachment of the respective strain gauges (Fig 1c). Both structures were sent to the measuring lab. The lab technician was not aware of their level of the precision so as to execute a blind test protocol.

The implant connections of produced structures, Control & Test Misfit, were measured with an industrial optical scanner (ATOS II SO by GOM GmbH, Braunschweig, Germany). To ensure the best possible measurement accuracy, a dedicated airbrush system was used to spray the implant connection, resulting in a spray thickness of less than 2 μm . Next, the conical fitting planes of the produced implant connection were used to perform a least-squared positioning of the measured mesh with conical fitting planes of the Straumann implant connections of the correct CAD model (Control).

Finally, to evaluate the accuracy of a produced superstructure with respect to the dental model, the misfit calculation was also performed based on a direct optical measurement of the implant replicas on the model. First, an overall best-fit technique was applied using all four implants. However, in cases where the misfit is caused primarily by inaccuracies in a single implant (with all other implant connections perfectly positioned and produced) this method is not very accurate. This is caused by the fact that a single implant connection misfit will also induce stresses on the other implants due to the least squares fitting algorithm. Therefore, a novel technique was applied, called the method of successive exclusion,

whereby a number of successive least-square fits are calculated, each time by excluding one of the implant connections. By comparing the different calculations, the implant connection exhibiting the largest misfit can be determined, and the exclusion of this implant connection will result in very low surface deviation on all other implants.

Strain Gauge Measurements

Both superstructures were then prepared for the strain gauge measurements. Each frame was measured by a three-dimensional, tension-measurement method utilizing strain gauges. The length of the cylinders (connection posts from the superstructure to the implants) was 12 mm to allow for placement of the strain gauges. To measure the misfit-induced stress (force) in all three axes (x, y and z), a total of 4 Strain gauges were attached along the long axes of each cylinder of both superstructures in a 90° deviation to each other (Figs 2a&b). To attach the strain gauge elements in a standard and reproducible manner a device was developed that could attach 4 strain gauge elements simultaneously.

A key was developed to reproduce the position of the strain gauges on a same manner on both frames. The key gave a start position of 360°, the contour of cylinder. This contour was then divided on the key into 4 equal positions at 0, 90, 180 and 270 degrees.

To attach the strain elements at the same height, a plastic tube was developed containing 4 windows, equally divided, which was shifted over the cylinders. The cylinder together with the plastic tube was sandblasted to mark all four positions. A transitional device was developed to glue he should probably mention the material that was used to create the adhesive bond between materials the strain elements simultaneously at the same height by shifting it over the cylinders. Shrink-wraps were used to maintain pressure on the strain elements during the gluing process to insure an effective attachment. The wires on the elements were then connected to the cables of the measuring device (Figs 3a-c).

Using this standardized method, the respectively inner distance between the strain elements were equal in the test frames, and the axes of the different cylinders were all oriented in the same direction, making the calculation of the total measured misfit possible. The misfit-induced tension was measured in all axes by electrical circuits called Wheatstone bridges. These were used to measure the unknown electrical resistance by balancing two legs of a bridge circuit, one leg of which includes the unknown component. In the test model resistance changes in the strain gauges are a result of the force-induced stretch or shrinkage (plus or minus). The misfit and tension in the all three axes were measured using 4 strain gauges connected by 3 Wheatstone Bridges. Combining the different strain gauges by Wheatstone Bridges makes it possible to measure in a three-dimensional fashion (three axes

x, y and z) as illustrated in figures 2a&b.

Electric current (signal)/forces relation

Signals delivered by the Wheatstone Bridges were measured in volt units, which must be converted into Newton force units. These forces could then be used to determine amount of misfit. The relationship was determined using a force inducer in each direction (x, y and z) for each cylinder of the superstructure. A force inducer is an instrument by which one can produce a known force. A known amount of force delivered by means of the force inducer can be expressed in volts measured by strain gauges and the Wheatstone bridges. In this way it was possible to determine the relationship between the signal of the Wheatstone Bridges and the forces (volt/Newton), which was necessary to calculate the forces after the connection of the superstructure. This procedure was repeated for each implant and as illustrated in table 1 the data is slightly different for each cylinder. This could be explained by the fact that although all the strain gauges were attached using a standard protocol, it was not possible to attach each gauge with the same precision.

Resilience-constant of cylinders and implants

The cylinders and the implants in the plaster model react as springs when they undergo misfit-induced forces after connection to the superstructure. Thus the determination of a resilient constant in the plaster jaw was necessary to calculate the tension caused by force-induced misfit. Moreover, this tension had to be converted to the level of misfit. For this analysis, both a movement transducer and a force inducer were needed. With the use of a force-inducer, a known force can be induced into one of the axes and at the same time determine the relative displacement of the implants by the displacement transducer. The resilient-constant (force/displacement) was determined in every direction and for each axis of the cylinders (framework), implants and also cylinders connected to implants as one entity (table 1).

Processing the signals

The measurements to compare the Control and Test Misfit structures were consecutively performed in three sessions of five times each on the test model. Both Control and Test Misfit were tightened respectively to the test model using a torque wrench (Straumann, Basel Switzerland) applying 25N/cm on its scale. The misfit-induced tensions between the implants and the superstructure were recorded for each implant and processed considering signal/force relationship and the resilient constant (table 3). All the signals were processed in a data

acquisition software program, based on Labview® software and designed especially for this purpose.

Callibration (Volt/Newton)	X	Y	Z
Cylinder 1	0.024	0.026	0.0043
Cylinder 2	0.024	0.025	0.0043
Cylinder 3	0.027	0.024	0.0045
Cylinder 4	0.028	0.028	0.0045
Cylinder 5	0.03	0.027	0.0041
Cylinder 6	0.023	0.021	0.0041

Table 1: Calibration, Electric current/Force relation

MOBILITY (μ/N)	X	Y	Z
CYLINDER (Framework)	0.8	0.8	0.3
IMPLANT	0.5	0.5	0.1
IMPLANT+CYLINDER	1.3	1.3	0.4

Table 2: Resilient Constant

	Misfit values in mm (four points along the conical interface were measured)			
	implant1	implant2	implant3	implant4
Exclusion of implant 1	-0,019	0,005	0,015	-0,018
	0,010	-0,011	-0,009	-0,012
	0,022	-0,012	-0,012	-0,013
	0,027	-0,014	-0,005	-0,004
Mean absolute misfit	0,020	0,011	0,010	0,012
Exclusion of implant 2	-0,002	0,038	-0,006	-0,005
	-0,003	-0,037	0,008	0,006
	0,006	-0,020	-0,004	0,002
	0,004	0,021	-0,002	0,001
Mean absolute misfit	0,004	0,029	0,005	0,004
Exclusion of implant 3	-0,017	0,008	0,028	-0,023
	0,020	-0,019	-0,014	-0,021
	0,021	-0,021	0,029	0,002
	-0,011	-0,017	0,026	0,007
Mean absolute misfit	0,017	0,016	0,024	0,013
Exclusion of implant 3	0,009	0,008	-0,017	-0,031
	-0,012	-0,021	-0,007	-0,021
	0,019	-0,012	0,020	0,018
	-0,016	-0,005	-0,015	-0,031
Mean absolute misfit	0,014	0,012	0,015	0,025

Table 3: calculated misfit on the conical implant interface, resulting from the method of successive exclusion. Exclusion of implant 2 results in the highest level of misfit.

Results

The optical measurements of the control frame indicate that the overall accuracy of the used production methodology is less than 10 μm (Fig 4A).

The overall misfit of Test Misfit was calculated using all four implant connections. Table 3 indicates that the exclusion of the second implant results in a large mean misfit value on this implant (29 μm), while the mean misfit on all other implants is below 5 μm . Exclusion of the first, third or fourth implant, on the other hand, does not result in very low misfit values on all other implants.

The other connections exhibited microscopic misfits as well, 4, 5 and 4 μm in respectively implant 1, 3 and 4. Table 3 presents the misfit calculations using the successive exclusion method.

The same conclusion regarding the misfit was obtained when comparing the optical scans of both superstructures Control and Test Misfit (Fig 4c). By comparing the calculated surface deviation contours, it was concluded that a clear misfit on the second implant caused the inaccuracy of Test Misfit.

Similar results were found with the strain gauge measurements (tables 4&5) although the measured values are slightly higher than when measured using optical scans.

The average, mean- and standard deviations of misfit of the three sessions was calculated and was compared between Control and Test Misfit with the four implants as units of measurements. Test Misfit showed a higher mean deviation of 26.2 μm (SD=5.9) written out as 26.2 $\mu\text{m} \pm 5.9$ comparing with 15.3 μm (SD=4.3) 15.3 $\mu\text{m} \pm 4.3$, measured on Control. The independent sample t-test showed that the Test Misfit showed a significant higher misfit compared to the Control ($t=-3.00$, $df=6$, $p=0.024$).

Discussion

In this study, both methods of measurement succeeded in detecting a known misfit, with a small difference in the measured misfit between the two techniques. The measured values by the optical scan more accurately match the planned misfit created at the prosthetic fabrication stage. Still, considering the very limited amount of misfit, these differences are not likely to be of clinical significance. Further comparative testing should be performed to confirm the accuracy of both techniques and the preference for one or the other relative to truth.

SS1			
	Session 1	Session 2	Session 3
som Sqr impl 1	15.9	25.3	22.9
som Sqr impl 2	12.5	17.4	12.8
som Sqr impl 3	14.4	11.2	8,1
som Sqr impl 4	13.5	14.8	14,7
Average misfit	14.07	17.17	14.64
SS2			
	Session 1	Session 2	Session 3
Som Sqr impl 1	28.2	15.3	19.7
som Sqr impl 2	29.7	36.1	33.5
som Sqr impl 3	16.2	25.3	23.3
som Sqr impl 4	27.3	33.2	26.8
Average misfit	25.35	27.48	25.82

Table 4: The strain measurements on SS1 and SS2

Group Statistics				
ss	N	Mean	Std. Deviation	Std. Error Mean
1,00	4	15,2917	4,29784	2,14892
2,00	4	26,2167	5,87452	2,93726

Table 5: The statistical numbers after measuring the misfit in both frameworks

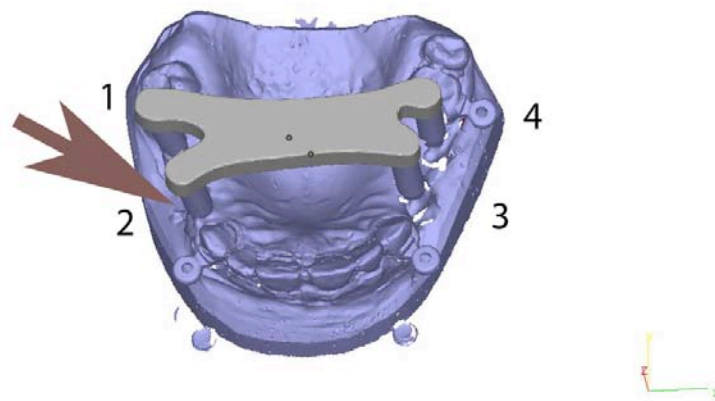


Figure 1: Arrow shows the right anterior implant with alteration on the SS2.

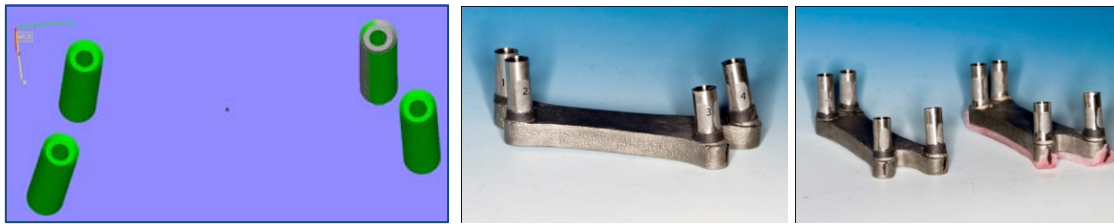


Figure 1b: Gray area on implant 2 indicates the inputted misfit.

Middle below:

Numbered implant-connections:

Implant 1: right side posterior.

Implant 2: right side anterior (implant with alteration on the SS2).

Implant 3: left side anterior.

Implant 4: left side posterior.

2 identical superstructures, one of which with a known misfit.

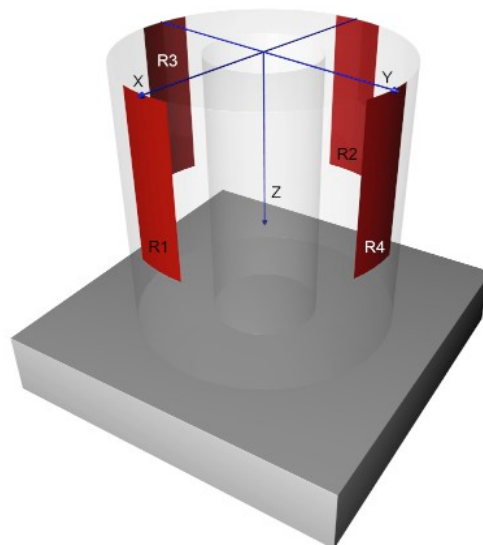


Figure 2: Schematic illustration of strain gauges and their relation to all axes

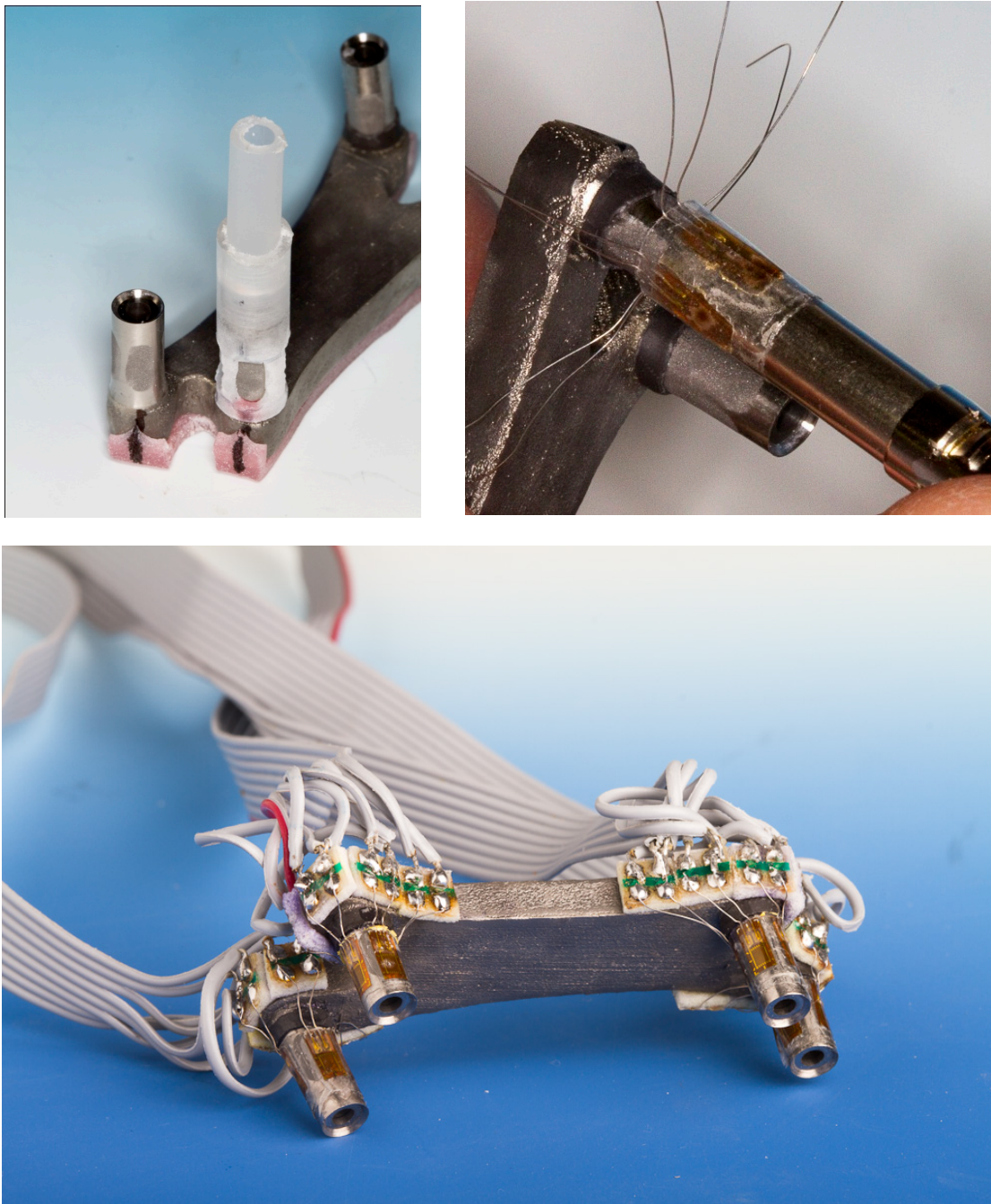


Figure 3: Device to attach the strain elements on the frameworks and the prepared framework

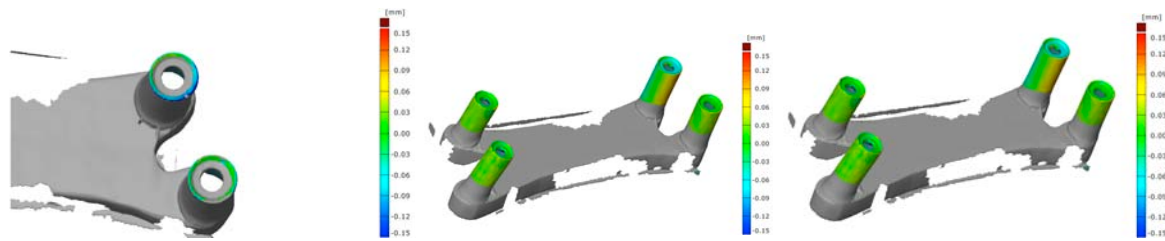


Figure 4:

A) Accuracy of produced superstructure SS1 versus the CAD model. Green color indicates a precision below 10 µm on the scale.

B) Deviation plot of SS2 versus the measured model using all four implant connections in the least-squares calculation. Implant 2, upper, shows a deviation, blue color (30-50 µm) on the scale.

C) Comparison of SS1 versus SS2 clearly indicating a misfit on implant 2 in both X, Y and Z directions of about 50 to 60 µm.

Given the simplicity of the optical scan it may be suggested as an instrument used by dental laboratories to evaluate the accuracy of fabricated frameworks.

In the optical scan analysis in this study, a method of successive exclusion was used to determine the inaccurate implant since misfit of milled frameworks are often caused by artifacts on one or more of the engaging implants like marker misplacement causing the micrometric.

Implant 2 from Test Misfit showed the highest level of misfit when comparing the surface deviation values of the three connectors that were used in the least-square fitting. When the second implant was excluded, the surface deviations on the three remaining implants became very small ($< 10 \mu\text{m}$), meaning that the three implants that were used in this case were fitted accurately and only the excluded implant (implant 2) caused the misfit of the superstructure. Moreover, in this case the misfit on the excluded implant was the largest. When the distance between the conical faces under 45° is compared, it is logical that the retrieved surface deviation values are slightly smaller than the coordinate translation of $55 \mu\text{m}$ that was introduced on the second implant of Test Misfit.

Structure Test Misfit was then measured using the same optical equipment. The obtained mesh was then fitted in a similar way with the CAD design of the correct superstructure model, Control. By doing so, the misfit that was artificially induced on the second implant

connector of Test Misfit became clearly visible. Moreover, the magnitude and the direction of the misfit in X, Y and Z directions were deduced from the surface deviation plot.

Due to the limited number of subjects in this study, there is a need for farther investigation to compare the 2 described technologies, using actual clinical frameworks that were fabricated using CAD/CAM and/or lost wax techniques.

The measurements are assumed to be accurate and since there is a slight difference between the two techniques, it is impossible to tell which one is the more accurate. Although this study identified the created error within 10 μ , still the measurement failed to identify fit exactly. Thus, more investigation is required to fine tune and improve the technique.

Conclusion

An in vitro comparison of 2 methods of fit and analysis was performed. The methods consisted of an optical measurement and a strain gauge assessment. Both clearly identified a known missed fit that was created through a CAD/CAM frame fabrication method. Given the simplicity of the optical method it may have benefit as a quality control measure in the dental laboratory.

Both measurements were capable of detecting microscopic misfits. Even an induced minor misfit could be detected. Based on the limitations of this in vitro study, it can be concluded that optical scan analysis could be effectively used to evaluate passive fit on implant-supported superstructures. Also the results indicate that the method of successive exclusion is capable of determining which of the implants is causing the misfit.

The strain gauge measurements supported these findings.

By comparing these two techniques it may be concluded that optical scan analysis and its associated methods are more precise, less complicated and less time consuming than the strain gauge measurements. Although optical scan analyses and strain measurements can detect a single inaccurate implant connection on an implant superstructure, misfit of this single implant will also induce stresses in all other implants.

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I would like to thank Mr. Hans van Capelle master dental technician, ACTA, Amsterdam and Layerwise, Leuven, Belgium for their tremendous technical support. Also I would like to thank Ir. J.J van der Weijden, Department of Oral Function, ACTA, Amsterdam, for his work on the strain gauge measurements and Dr. I. Aartman, Department of Social Dentistry and

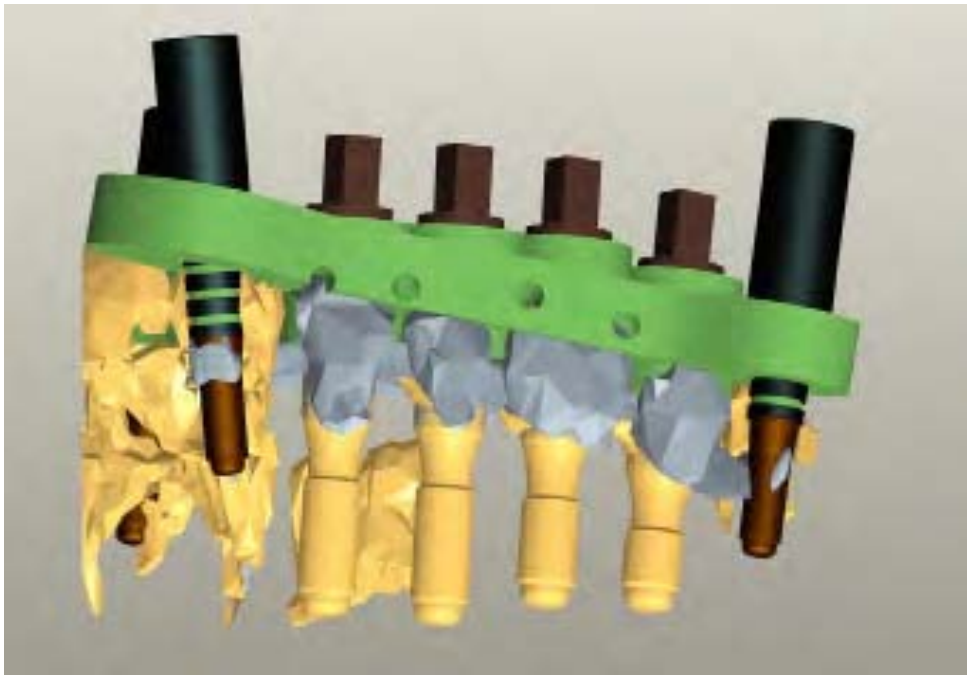
Behavioral Science, ACTA, Amsterdam for her work on Statistics. Last but not least I would like to thank Dr Steve Eckert for his effort to lead us to the right direction.

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CHAPTER 6



Reference-Based Digital Concept to Restore Partially Edentulous Patients Following an Immediate Loading Protocol: A Pilot Study

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Daniel Wismeijer

Abstract

Purpose: To describe the use of a computer-aided three-dimensional planning protocol in combination with previously placed reference elements and computer-aided design/computer assisted manufacture (CAD/CAM) technology to restore the partially edentulous patient.

Materials and Methods: Mini-implants and/or reference brackets were inserted or positioned in specified locations in a test cast and in two patients prior to imaging to act as definitive fiducial markers. This served as a fixed base to better define a setup for the fabrication of a surgical template used during computed tomographic imaging. A simulated partially edentulous maxilla was used for the study, and two partially edentulous patients participated. With the CT images, a CAD/CAM superstructure was created prior to surgery and inserted immediately after surgery. Fit of the prosthesis was assessed using three-dimensional tension measurements with strain gauges. **Results:** Mean misfit for all implants in the x-, y-, and z-axes was 26.6, 24.8, and 10.4 μm , respectively. The total misfit calculated according to the Pythagorean theorem was 42.6 μm . **Conclusions:** Based upon this pilot study in two patients and an in vitro analysis, it appears that the use of reproducible fiducial markers consisting of mini-implants and reference brackets results in the fabrication of an acceptably accurately fitting definitive prosthesis prior to implant placement.

Introduction

Early treatment protocols with osseointegrated implants used an undisturbed healing period to allow bone to heal around the endosseous implant.¹

The initial protocol gradually evolved to one in which implants could be placed and loaded immediately if the implants were rigidly splinted, thereby reducing implant movement to less than 100 μm .²⁻⁴

The use of computed tomography (CT) allows three-dimensional reconstruction of the jaws using stereolithographic techniques.⁵⁻¹¹ These models result in excellent graphic representations, but the absolute accuracy of the models has been described as suspect.¹² Early generations of prostheses fabricated upon such models exhibited errors of such magnitude that definitive prostheses could not be made using traditional implant components. Prostheses could be fabricated only through the use of special abutments that allowed a small (up to 0.7 mm) compensatory movement. Concerns with the compensating abutments led to adoption of techniques that relied upon provisional prostheses connected to implants through the use of auto polymerizing resin. Ultimately, these prostheses would require replacement with definitive prostheses after osseointegration had occurred. Through the use of definitive fiducial markers, it is thought that virtual implant placement and prosthetic design might be accomplished with a level of precision that would allow fabrication of a definitive prosthesis that would be placed on the day of implant placement. With such a prosthesis, the cost of care and treatment time would be reduced. This pilot study presents a novel technique to accomplish this treatment approach.

Materials and Methods

This pilot study was divided into an in vitro phase and a clinical phase, which involved the treatment of two patients. The in vitro phase of the study, a cast of a partially edentulous arch with a unilateral posterior partially edentulous space in the right maxilla was used. A test cast (model A) was fabricated (Ludo Beckers) using methacrylate resin containing barium sulfate to provide radiodensity (Fig 1a). This cast was used to evaluate the precision of the cast using a strain gauge analysis. It represented a partially edentulous arch with teeth present in the maxillary canine and left premolar regions. Simultaneously, two patients were treated with the same treatment protocol (Figs 1b through 1f). Both patients signed an informed consent document.

A mini-implant (Straumann) was inserted in the maxillary right tuberosity region to serve as the first reference point in test model A. Two custom-made brackets connected to a prosthetic table similar to that of the mini-implant were attached to the two canines in test model A (Figs 2a and 2b). Both patients underwent similar procedures in which impressions of the arches were made with polyether impression material (Impregum, ESPE). Alginate impressions were made of the opposing arches and soft tissue casts were fabricated. After the bite registration procedure, a wax-up of the intended prosthetic rehabilitation was produced. After approval of the wax-up, CT setups were delivered using an acrylic resin containing barium sulfate (Vivotac/orthotak, Ivoclar Vivadent). These diagnostic CT setups represented the anticipated definitive prosthesis. Three reference brackets per arch were attached to the casts of both patients using dental wax. Because these patients presented with tooth-bound edentulous spaces, no mini-implants were used, but reference brackets were used as reference points to ensure the stability of the surgical guide. Three screw complexes (used for the CT scan calibration) were connected to the screw connection of the brackets. An acrylic resin key was then fabricated on the cast and connected carefully to the brackets and the barium sulfate (prosthetic wax-up) teeth (Figs 2c through 2e). A cone beam CT scan (Veraviewepox, Morita) was used to scan the test model and the patients, with the specially designed screw complex attached to the mini-implants and the brackets. The screw complex determined the position of the mini-implants on the CT images.¹³⁻¹⁴ The screw complex consisted of a cylinder with a defined length and a radiopaque gutta-percha marker point placed on the top. The radiopaque gutta-percha points were 1-mm-diameter spheres and could be visualized on the CT scan images without artifacts.

The CT data were processed to create multiple cross sections and three-dimensional images using planning software (Exe-plan software, R. De Clerck) (Fig 3). In test model A, four Straumann Standard implants (two in each quadrant) were virtually inserted.

In both patients, two implants with different thread designs (Straumann and MIS) were virtually inserted with consideration of the available bone, the planned definitive restoration, and the underlying anatomical structures. The difference in implant thread geometry can be helpful to achieve primary stability in different types of bone. These kinds of implants can be swapped during the operation depending on the bone quality without affecting the outcome of the prefabricated framework, since they have identical prosthetic systems. The planning data were exported into a computer-aided design (CAD) software program, where the surgical template and the framework of the future superstructure were designed (Fig 4) using the same data set as the planning software. The design data were imported into the planning software, where the fit was virtually checked.

After the planning and design were approved, the data were sent to a milling company (ES Tooling). A simultaneous five-axis milling device fabricated the surgical templates in pink composite and the titanium frameworks for test model A and the two patients (Fig 5). For both patients, titanium frameworks were sent to the dental laboratory (Corpix, Kasterlee, Belgium) to be finalized with veneered porcelain (Fig 6).

On the day of surgery, the transfer keys were placed on the remaining dentition of the selected patients and the brackets were attached using light curing composite on the determined teeth. The surgical template was then connected to the mini-implant and the brackets in test model A and to the brackets in both patients using gold screws (Straumann) (Fig 7).

The internal connection of the mini-implant and the brackets and tripod distribution in the edentulous arch ensured stability of the surgical guide.

Preparation of the implant sockets was performed using a sequence of drills. The drilling sequence involves three groups of different drill diameters: 2.2, 2.8, and 3.5 mm (Fig 8a). The first drill sequence (2.2 mm) starts with a flat-headed drill, which flattens the entry point. The following drills increase by 2 mm in length per step, up to the last drill (7 mm in length). In this way, heat and undesired tilting are prevented during the osteotomy. The second drill sequence (2.8 mm) is similar to the first one; it begins with a flat drill and ends with the last drill, which is 10 mm long. The final drill sequence (3.5 mm) determines the length of the inserted implants, starting with 10 mm and ending with 12 mm (Fig 8a). The guiding segment of all the drills has the same diameter, which fits in the surgical guide in a precise manner. The stop on each drill dictates, together with the surgical guide, the depth of the osteotomy.

Every implant was inserted through the surgical guide following site preparation (Figs 8b and 8c). The exact vertical positions of the implants were achieved using the drill stops on the surgical guide and the precision pins (Fig 9). After all planned implants had been inserted, the surgical guide was removed (and in the patients, the brackets were removed) (Fig 10) and the definitive restorations were screwed directly onto the implants without incorporating any abutments (Fig 11). The implant positions and the fit of the superstructure were evaluated in the patients by means of panoramic radiographs (Fig 12) and the occlusion was checked. Minor occlusal adjustments were made as necessary.

Postoperative visits were conducted 1 week, 3 weeks, 3 months, 6 months, and 1 year after implant placement. Radiographs (panoramic and/or periapical) were obtained immediately after surgery and 3 months, 6 months, and 1 year postsurgically (Fig 13).

Probing depths and Bleeding Index were recorded 6 months after surgery. The fit of the superstructure on test model A was measured by a three-dimensional tension measurement

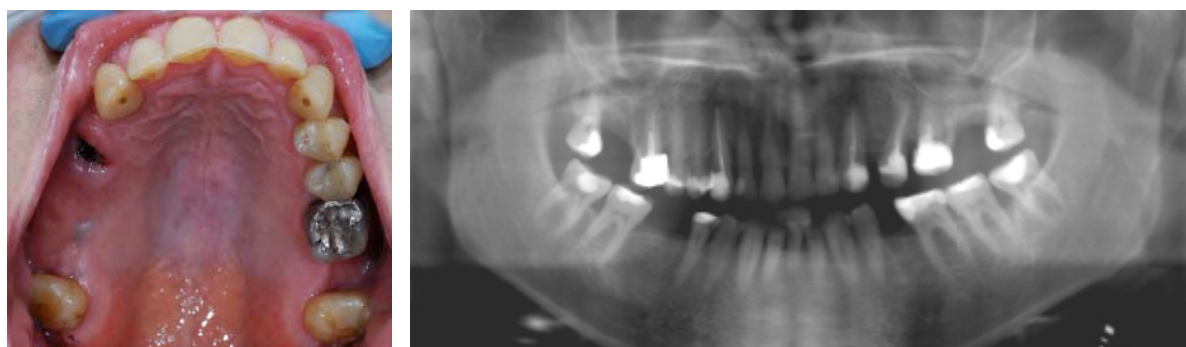
method using strain gauges. The length of each cylinder (connection posts from the superstructure to the implants) was 12 mm to allow for placement of the strain gauges. Four strain gauges were attached along the long axis of each cylinder of the superstructure at 90-degree angulations from each other (Fig 14). The axes of the different cylinders were oriented in the same direction, so that it was possible to calculate the total measured misfit. This misfit-induced tension is measured for all axes by an electrical circuit called a Wheatstone bridge. This is used to measure an unknown electrical resistance by balancing two legs of a bridge circuit, one leg of which includes the unknown component. In the test model, the changes in resistance in the strain gauges are a result of force induced stretch or shrinkage (plus or minus). The misfit and tension in all three axes were measured using the four strain gauges connected by Wheatstone bridges.

The measurements were consecutively performed five times on the test model to which the superstructure was attached. The misfit-induced tensions on each implant were recorded and processed, considering the resilient constant and signal/force relationship.

All the signals were processed in a data acquisition software program specially designed for this purpose and based on Labview software. This measurement technique was described previously.^{13,14}



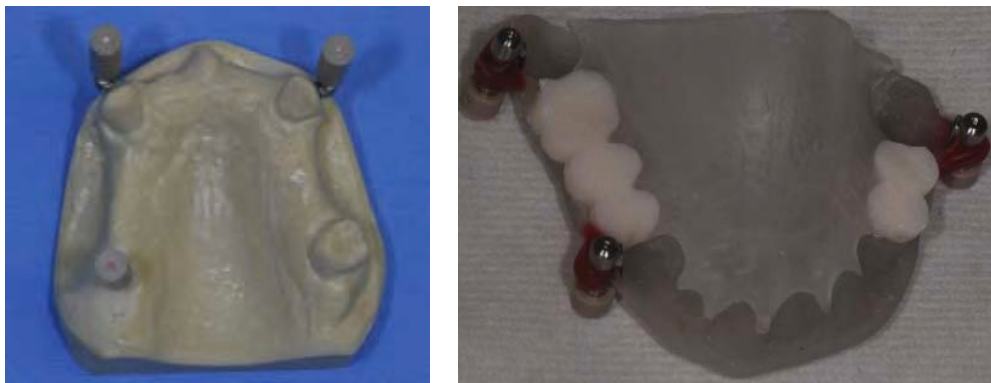
Figure 1a: Test model A: partially edentulous cast of the maxilla



Figures 1b and 1c: Patient with partial edentulous maxilla



Figures 1d to 1f: Patient with partially edentulous maxilla and mandible



Figures 2a and 2b: Reference elements: one mini-implant and two brackets were attached to test model A. Calibration flags, as part of the screw complex, fixing the scan denture with dentition (made out of barium resin) to the mini implants or reference brackets. Gutta percha markers are situated on the plastic flags indicating the position of the mini implants and reference brackets on the CT images.



Figures 2c to 2e: Cast of a treated patient with brackets attached to the selected teeth. The acrylic resin transfer key is used to transfer the reference elements from the cast to the patient.

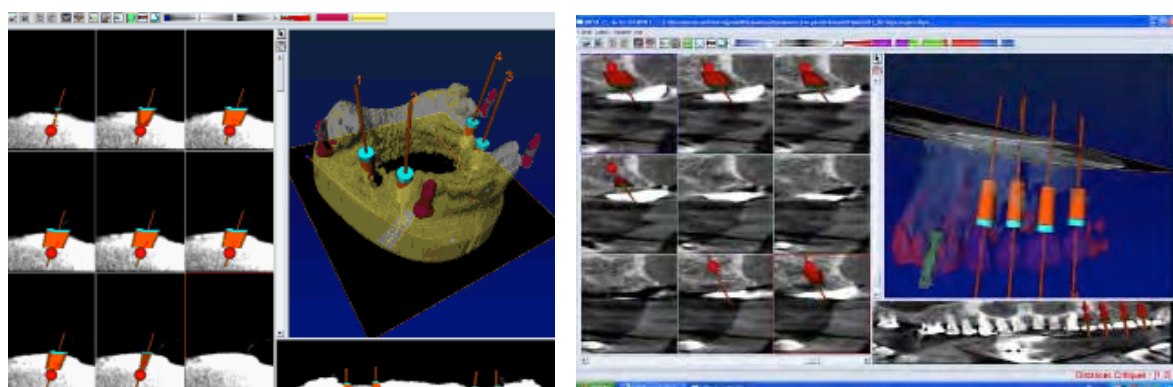


Figure 3: Planning and CAD/CAM phase. The CT images were imported into the planning software and the implants were virtually inserted.

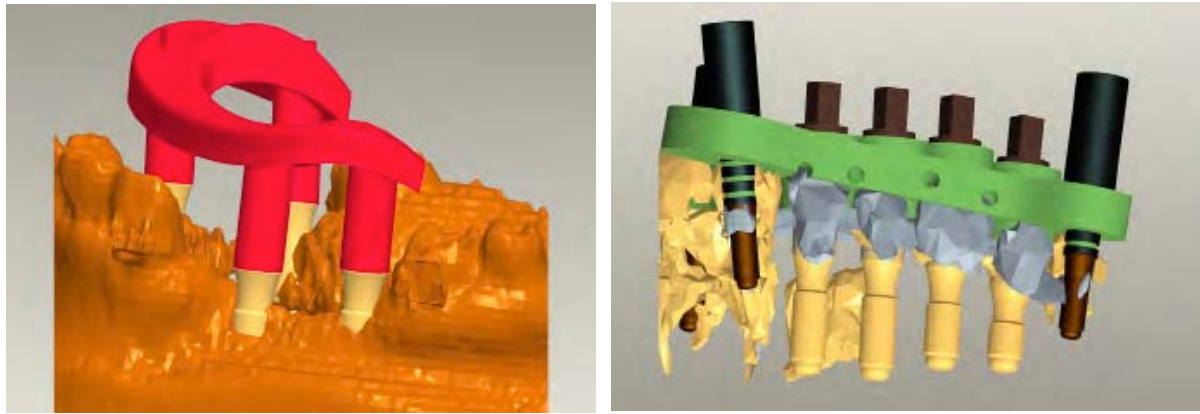


Figure 4: The data were exported from the planning software and imported into the CAD software, where the framework and the surgical guide are designed.



Figure 5: The frameworks and the surgical guide are milled. Two implant replicas are inserted into the master cast using the surgical guide. The framework is further processed and finished.



Figure 6: The screw-retained finished porcelain-fused-to-metal restorations are ready before implant insertion. The superstructure is connected directly to the implants without the use of any abutments.



Figure 7a: Brackets are connected to the reference teeth in the same position as on the diagnostic cast using the transfer key.

Figure 7b: The surgical guide is connected to the reference elements.

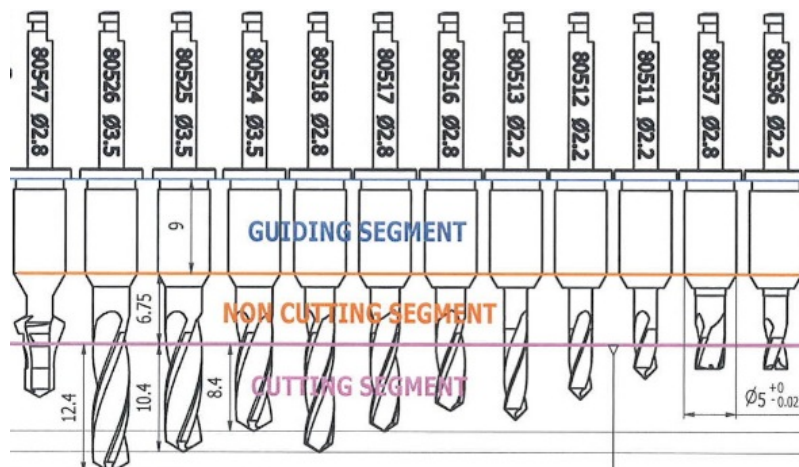


Figure 8a: The drilling sequence. Each drill has an identical guiding segment, whereas the cutting segments differ in length and diameter.



Figures 8b and 8c: The osteotomies are guided using drills with stops to achieve the planned positions.



Figure 9: The guided osteotomy and guided implant insertion. The precision pin helps ensure the correct (predetermined) vertical position of the implants.



Figure 10a: The implants have been inserted through the surgical guide on the test model, and the guide has been removed.

Figure 10b: Implants have been placed in a minimally invasive flapless approach.

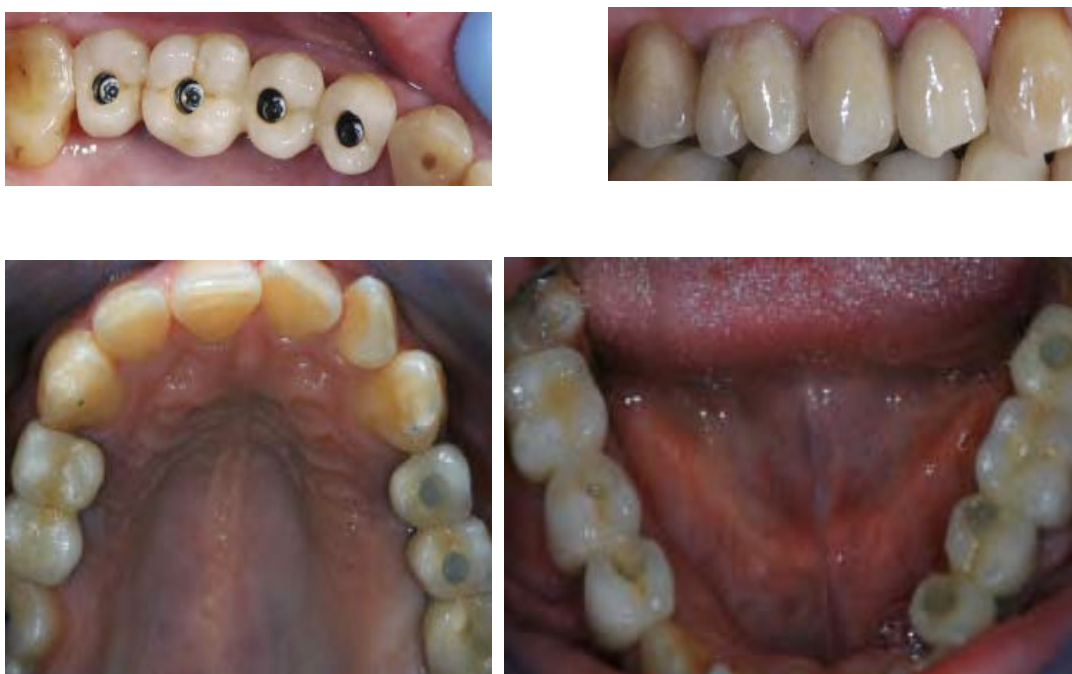


Figure 11: Superstructures in place on the implant level (no abutments) immediately after implant insertion.

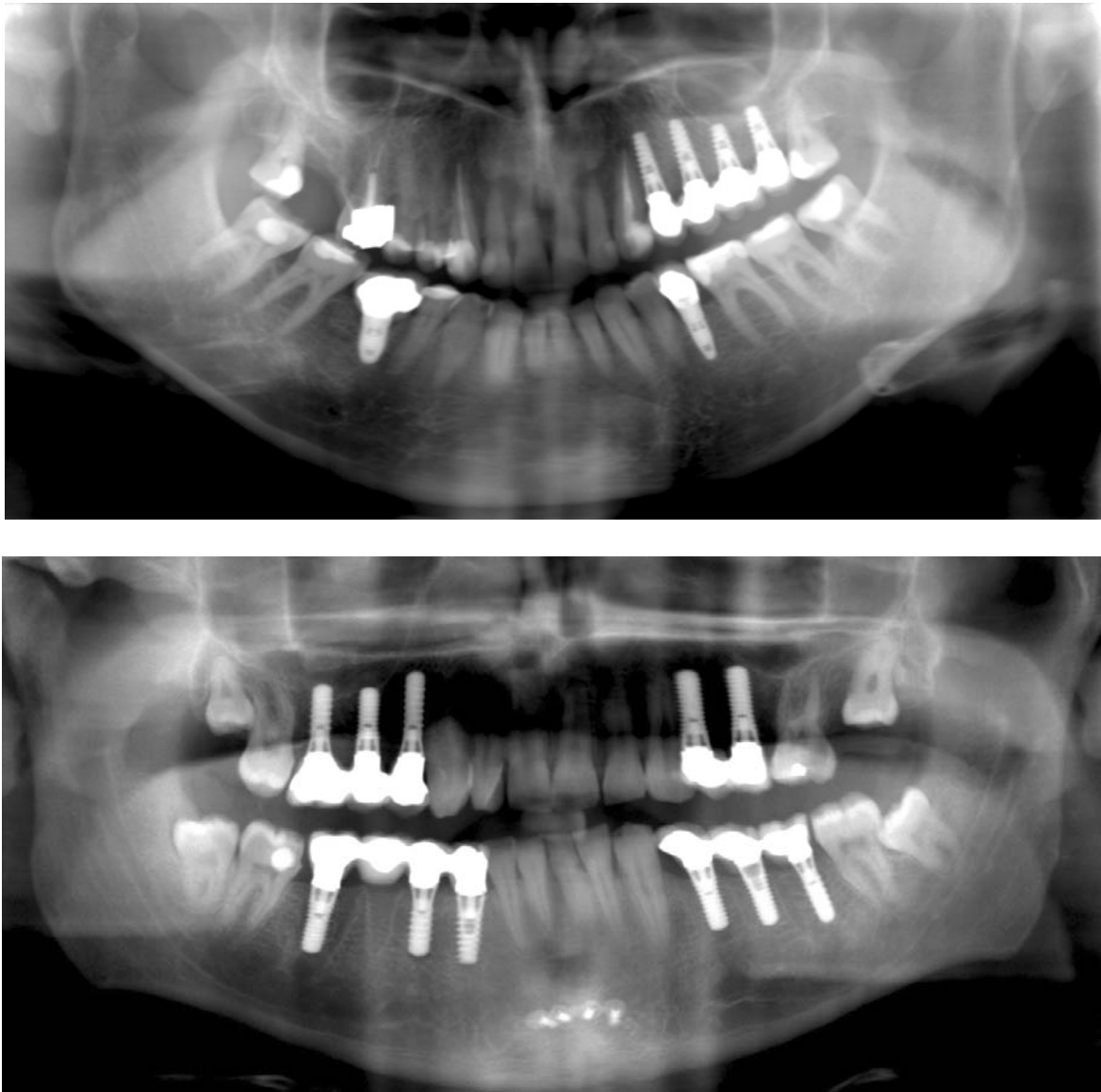


Figure 12: Postoperative radiographs of patients

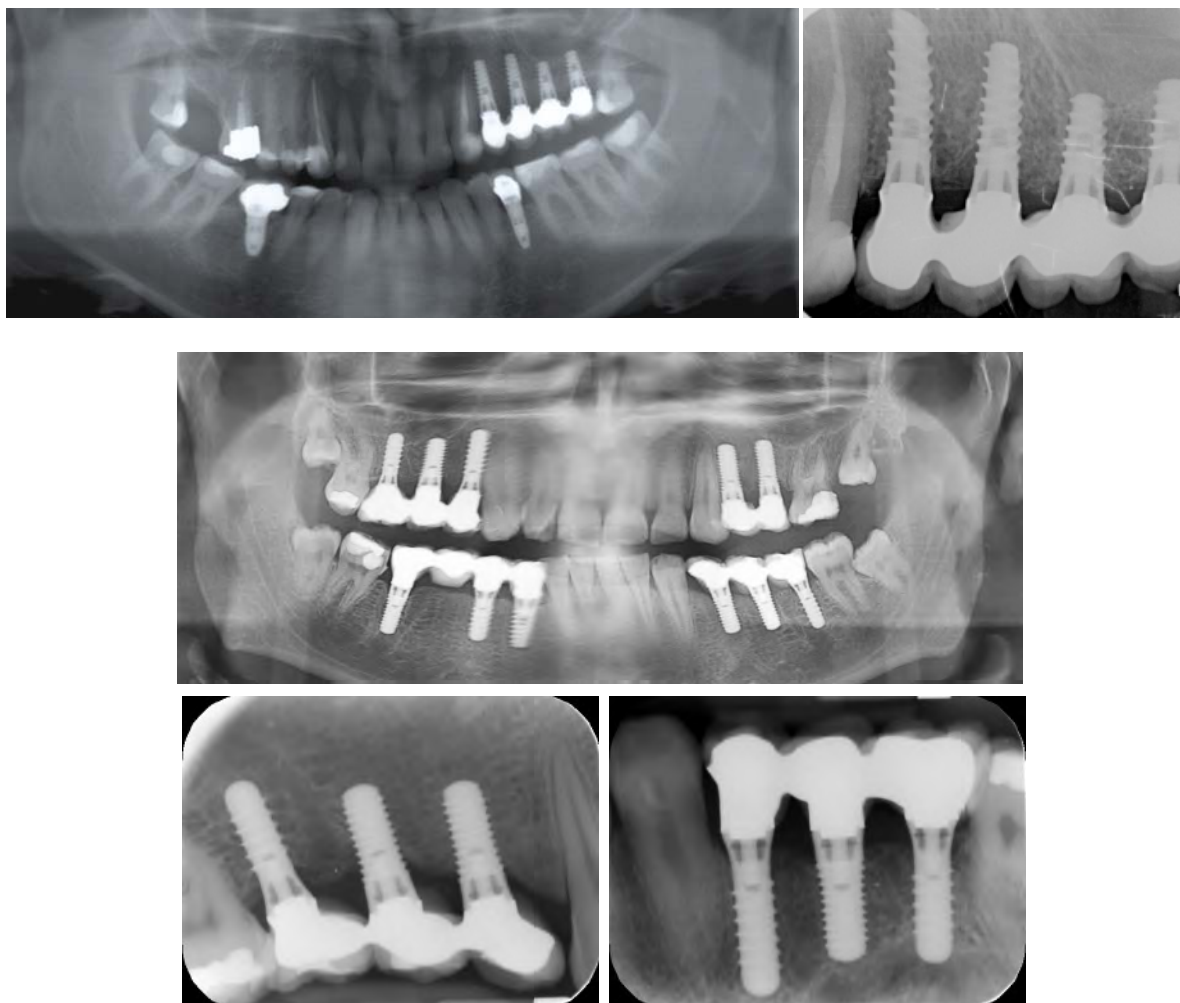


Figure 13: One-year postoperative radiographs

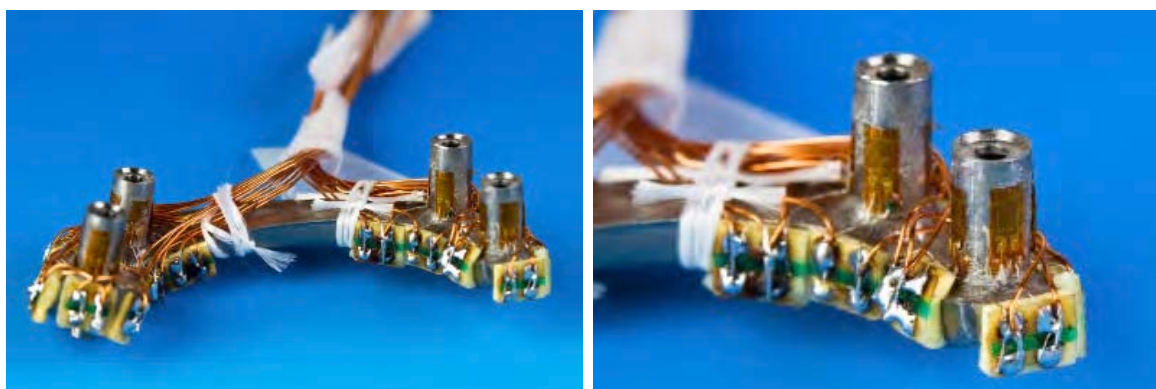


Figure 14: Strain gauges are attached to the framework to measure the misfit.

Table 1 Results of In Vitro Measurements				
Implants	Misfit (μm)			RMS (μm)
	x-axis	y-axis	z-axis	
Implant 1	24.4 \pm 3.6	16.4 \pm 2.4	8.7 \pm 1.8	30.6
Implant 2	29.7 \pm 3.7	60.5 \pm 6.7	10.8 \pm 1.9	68.3
Implant 3	45.9 \pm 6.9	4.5 \pm 1.9	6.2 \pm 0.8	46.6
Implant 4	6.6 \pm 1.7	17.9 \pm 1.6	16 \pm 2.6	24.6
Total average	26.6	24.8	10.4	
Total misfit			42.6	

Table 2 Implant and Clinical Data for Treated Patients								
	Left				Right			
	2nd M	1st M	2nd PM	1st PM	Canine	1st PM	2nd PM	1st M
Implant data								
Patient 1 (max)	MIS, 4.1 \times 8 mm	MIS, 4.1 \times 8 mm	MIS, 4.1 \times 11.5 mm	MIS, 4.1 \times 11.5 mm				
Patient 2 (max)			TE 4.1 \times 12 mm	TE 4.1 \times 12 mm		S 4.1 \times 12 mm	TE 4.1 \times 10 mm	S 4.1 \times 10 mm
Patient 2 (mand)		S 4.1 \times 10	TE 4.1 \times 10 mm	TE 4.1 \times 10 mm	MIS 4.1 \times 10 mm	TE 4.1 \times 10 mm		TE 4.1 \times 10 mm
Probing depth (mm) (M, D, B, P)								
Pt 1	2, 2, 3, 2	2, 2, 2, 2	2, 3, 2, 2	2, 3, 3, 3				
Pt 2 (max)			2, 3, 2, 3	3, 3, 3, 3		2, 2, 2, 2	2, 2, 2, 2	3, 2, 3, 2
Pt 2 (mand)		2, 2, 2, 2	2, 3, 2, 2	2, 2, 2, 2				
Bleeding Index								
Pt 1 (max)	0, 0, 0, 1	0, 1, 0, 1	0, 0, 0, 0	0, 0, 0, 0				
Pt 2 (max)			0, 0, 0, 1	1, 0, 1, 1		0, 0, 0, 0	0, 0, 0, 0	0, 1, 0, 0
Pt 2 (mand)		0, 0, 0, 0	0, 1, 0, 0	0, 0, 0, 0	2, 2, 2, 2	2, 2, 2, 2		2, 3, 2, 2

S = Straumann; TE = Straumann Tapered Effect Implants; MIS = MIS Implant Technologies; M = mesial; D = distal; B = buccal; P = palatal. Probing depths and Bleeding Index were measured 6 months postoperatively.

Results

The average misfit values for all implants measured in the in vitro model in the x-, y-, and z-axes were 26.6, 24.8, and 10.4 μm , respectively. The total misfit calculated according to the Pythagorean theorem^{15–17} was 42.6 μm (Table 1).

This treatment modality was tested in two patients (56 and 26 years old, respectively). There were no intraoperative complications during the surgery, and the screw-retained superstructures were inserted directly on the implants. The postoperative radiographs showed satisfactory fit. At the 1-year evaluation, all implants were successful with satisfactory esthetic results.

The prefabricated screw-type porcelain-fused-to-metal restorations were successful and performed well, with esthetically acceptable results. Clinical examinations did not show any unusual or unfavorable results (Table 2).

Discussion

Various adjustments to the CT scan images and the digital data were made during the described protocol before they were incorporated into the planning software. The mini implants and brackets (reference points) are placed prior to the actual implant insertion, at the beginning of the procedure. The gutta-percha markers on the screw complex are used to determine the exact positions of the mini-implants on the CT images. This information is crucial for subsequent implant planning and superstructure design using a CAD system. However, the exact positions of these titanium screws or metal brackets are difficult to define on the reconstructed images because of CT-specific image artifacts. The artifacts include scatter radiation, the limited dynamic range of the x-ray area detectors, the truncated view artifacts, and beam hardening.⁵⁻⁷

These artifacts have a significant influence on image quality.⁸ The geometric accuracy of cone beam CT has been well established; it shows no significant discrepancies from physical (gold standard) measurements.⁹ The accuracy of cone beam CT has been established in the submillimeter range. However, whereas cone beam CT systems are inherently geometrically accurate, locating the exact positions of reference points (brackets or mini-implants) remains challenging as a result of observer variability and image artifacts. A screw complex is designed to compensate for the resulting measurement error. A ball-shaped radiopaque gutta-percha point of 1 mm is positioned on top of the screw complex. As such, the gutta-percha marker is always visible on one of the cross sections on the CT scans.

The reconstructed image cross-sections through the metallic ball are circular, irrespective of slice orientation. This facilitates determination of the exact center of the radiopaque marker in all situations.

The other contribution to the precision of implant placement in this procedure is the so-called precision pin. The precision pin positions the implant driver exactly, allowing the implants to be placed in the correct vertical dimension that was calculated during computerized planning and decreasing possible misfit. The exact description of the precision pin was described in a previous publication.¹⁴

Conclusion

Within the limitations of this pilot study, which included an in vitro analysis and the treatment of two patients, it can be concluded that this reference-based digital procedure, in

which a superstructure is fabricated on the basis of calibrated computed tomographic images only, can result in a high level of precision. With the level of accuracy reached, a definitive fixed prosthesis could be fabricated in different clinical cases prior to implant placement. All implants survived, with pleasing esthetic and clinical outcomes.

Acknowledgments

We would like to thank Ing. Ko van der Weijden, ACTA, The Netherlands; Dr Alon Schifter and Mr H. van Elst, MIS, The Netherlands; and Dr Rene Willi, Straumann, Switzerland; for their co-operation in this study and Corpix Dental Lab for their technical support.

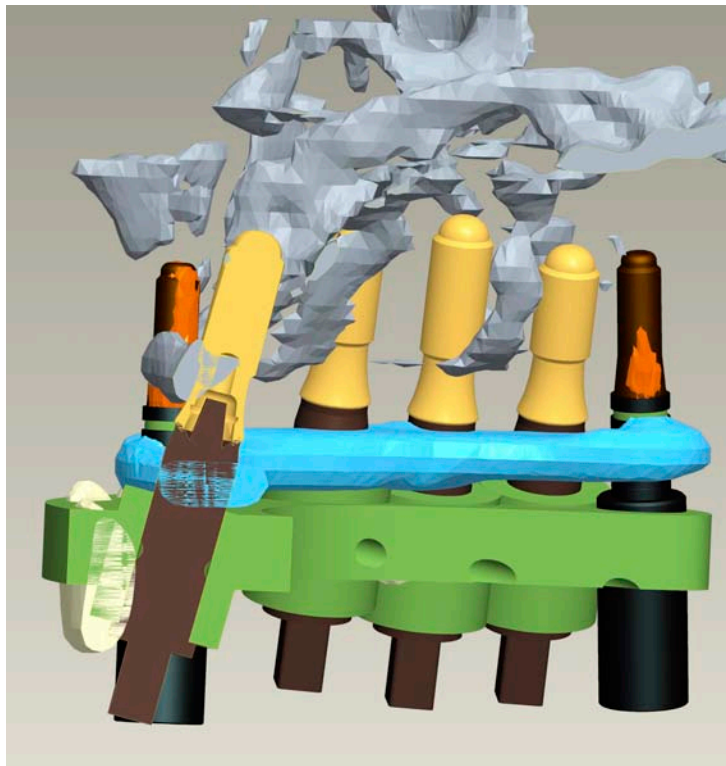
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CHAPTER 7



Digital protocol for reference-based guided surgery and immediate loading: A prospective clinical study.

Ali Tahmaseb, Renaat De Clerck, Daniel Wismeijer

Abstract

Aim: The purpose of this study was to evaluate the performance of a computer-aided three-dimensional planning protocol in combination with previously inserted reference mini-implants and CAD/CAM technology to restore completely edentulous patients. The study evaluated implant and superstructure survival in a prospective clinical trial. **Materials and Methods:** The plan protocol called for treatment of 35 patients who were edentulous in either jaw. Mini-implants were used to establish a platform for computerized tomography and the fixation of the surgical template. The planning software based on 3D simulation was used to plan ideal implant placement, digitally integrating the future prosthetic and anatomic situations to design the final superstructure. **Results:** A total of 34 patients, 20 with edentulous maxillae, 10 with edentulous mandibles and 5 patients with edentulism in both arches, were treated. All patients received definitive prostheses on the day of surgery. The majority of patients treated in maxilla underwent a sinus graft procedure to achieve sufficient bone to place implants. A total of 40 final superstructures were inserted and immediately loaded. Of the 240 inserted implants 229 survived (95.4%), with 146 (93.6% survival) and 83 (98.8% survival) implants in the maxillary and mandibular jaws, respectively. Of the 11 implants that failed in the maxilla, 10 occurred in the patients with augmented sinus. All the final restorations demonstrated clinically acceptable fit. **Conclusions:** When using implant and superstructure survival, reference based guided surgery seems to be a reliable treatment option for treatment of edentulous patients. The CAD/CAM superstructure, inserted and loaded immediately after guided implant insertion, demonstrated acceptable fit to the underlying implants.

Introduction

Computerized tomography (CT)-guided dental implant surgery is a treatment modality that may offer several advantages for both patients and clinicians. Specifically, the introduction of cone beam CT (CBCT) provides an affordable method for the application of computerized tomography to the dental environment. With this technology, three-dimensional imaging of the jaws is possible. The data derived from these images allows the simulation of a virtual patient.¹⁻⁵ This virtual information could also be used in computer-aided design and computer-aided manufacturing (CAD/CAM) to create a surgical guide that directs flapless implant placement according to a predetermined planning protocol that was established with the ultimate prosthetic design as the treatment objective. For example, using a limited patient population suggested that even flapless implant placement is useful when it is based on accurate and reliable 3D CT imaging data and dedicated implant-planning software.⁶ The information obtained from the predetermined implant location could be used to prefabricate the dental prosthesis and achieve immediate loading of dental implants. Also the new technologies on the surface modification of the dental implants suggest predictable outcome in early or immediate loading procedures.⁷

The literature describes two main fabrication modalities of the drill guides used in these systems: rapid prototyping (stereolithography) and model-based drill guide. Rapid prototyping or stereolithography is a technique in which a 3D image of the jaw and the planned implants are used to create a drill guide, slice by slice from bottom to top, in a vessel of liquid polymer that hardens when struck by a computer-driven laser beam.⁸⁻¹¹ Model-based drill guides are fabricated by using an acrylic part that fits on the cast recorded from the patient. The computer matches the scan images and the cast according to different types of references and a computer-driven device drills the implant positions in the acrylic part according the implant-planning protocol.^{12,13}

Although the reports on these techniques emphasize high implant survival rates, a systematic review¹⁴ questioned the precision and reliability of the commercially available techniques. In essence, the technique provides a reliable approach for implant survival however the

adaptation of the prefabricated prosthesis is not sufficiently accurate to allow this to be a definitive prosthesis.

In the present study the results of a new technique used to increase the precision of guided surgery are reported. The aim of this study is to evaluate the use of a computer-aided three-dimensional planning protocol in combination with previously inserted reference mini-implants and CAD/CAM technology to restore completely edentulous patients in a prospective clinical trial.

Material and Methods

This was a prospective study designed to evaluate the performance of implants placed in immediate function to support full arch fixed restorations that were fabricated prior to surgery using CAD/CAM technology. The ethical committee of VU University (Amsterdam, Netherlands) approved the study. All patients were informed about the treatment protocol and its risks and provided written informed consent.

Inclusion criteria

- Patients referred to a university-based dental clinic for implant placement between April 2006 and May 2007 were selected to participate in this study if they met inclusion and exclusion criteria (tables 1). In general the inclusion criteria demanded patients that were not growing, had sufficient bone for implant placement and were generally healthy. Exclusion criteria consisted of systemic disease, localized mucosal lesions, radiation therapy, para-functional activity, and inadequate bone quantity or quality.
- Patients referred to a university-based dental clinic (University of Amsterdam, ACTA, Department of Implantology and Fixed Prosthesis) for implants between April 2006 and May 2007 were selected according to the following criteria:
 - Individuals of either gender, older than 25 years, with full craniofacial growth;
 - Dentate patients with failing maxillary and/or mandibular teeth;
 - Sufficient osseous structure to place 4–8 dental implants with a minimum length of 13 mm at the time of surgery;
 - Negative pregnancy test for women of childbearing age;
 - At least a 3-month period between extraction or loss of teeth at the implant site and the date of surgery;

- patients willing to provide written informed consent and willing to comply with the study requirements.

The patients were selected after clinical and radiographic (panoramicevaluation. The existing dentures were also evaluated and shortcomings were detected and noted. Alginate impressions of both jaws were made and stone casts (Model 1) as well as impression trays for the use of open impression copings were fabricated in the dental laboratory.

Exclusion criteria	
Systemic exclusion criteria	Local exclusion criteria
<ul style="list-style-type: none"> • Conditions requiring chronic routine prophylactic use of antibiotics (e.g. rheumatic heart disease, bacterial endocarditic, cardiac valvular anomalies, prosthetic joint replacements); • Conditions requiring prolonged use of steroids; • History of leucocyte dysfunction and deficiencies; • History of bleeding disorders; • History of neoplastic disease requiring the use of radiation or chemotherapy; • History of renal failure; • History of metabolic bone disorders; • History of uncontrolled endocrine disorders; • Physical handicaps that would interfere with the ability to perform adequate oral hygiene; • Use of any investigational drug or device within the 30-day period immediately before implant surgery (study day 0); • Alcoholism or drug abuse; • Conditions or circumstances, in the opinion of the investigator, that would prevent complete participation or interfere with analysis of the results, such as history of non-compliance and unreliability. 	<ul style="list-style-type: none"> • Mucosal diseases; • History of local irradiation therapy; • Presence of osseous lesions; • Severe smoking (>10 cigarettes/day); • Unhealed extraction sites (<4 months after extraction of teeth); • Bone surgery at the implant site(s) (bone grafts, guided tissue regeneration techniques for bone enhancement) before implant placement, unless performed more than 6 months before implant placement; • Surgical sites requiring bone grafting at the time of surgery; • Visible bruxism or clenching habits; • Persistent intra-oral infection; • Lack of primary stability of 2 (or more) implants at the time of surgery (the patient must be withdrawn and treated accordingly); • Inadequate oral hygiene or lack of motivation for adequate home care.

Table 1: *Exclusion criteria*

Preparation phase

Reference implants were inserted at predetermined locations, which were chosen on the cast (model 1). Three reference implants of 3-mm diameter and 4–6 mm length (Straumann, Basel, Switzerland) were inserted. These implants were designed on the basis of the existing architecture of Straumann Standard Implants (soft Tissue Implants, Straumann, Basel, Switzerland). The implant was placed using a pilot drill even when soft bone was encountered. These implants were inserted in a triangular pattern at least three weeks prior to the final implant surgery (Fig. 1) at positions chosen to avoid interference with the anticipated locations of the prosthesis supporting implants: the maxillary reference Implants were thereby inserted in the midline and bilateral tuberosities, and the mandibular implants were inserted in the midline and bilateral dorsal regions. The reference mini implants were inserted under local anaesthesia after performing a minor flap for secure insertion.

Impressions of the reference Implants were recorded immediately after insertion by using the open impression trays and polyether impression material (Impregum, 3M ESPE, Seefeld, Germany). Specially designed impression copings (Straumann, Basel, Switzerland) were used. A master stone-cast (Model 2) was fabricated by using mini-implant analogues (Straumann, Basel, Switzerland), as illustrated in Figure 1. If patients required a sinus graft, the patients underwent the sinus graft procedure and the reference Implants were simultaneously inserted and left submerged for healing over a period of 6 months. The impressions were recorded after uncovering the reference mini-implants in the second-stage surgery. Thereafter, the patients of all groups were treated according to the conventional prosthetic procedure, followed by bite registration and fabrication of a wax-up (Fig. 2).

After approval of the wax-up, function, aesthetic and phonetics, a plaster matrix was prepared to duplicate the final wax-up. A CT template was fabricated by using barium sulphate-containing resin (Vivotac/Orthotak, Ivoclar Vivadent, Schaan, Liechtenstein) for CT scanning (Fig. 2). This template formed the basis for manufacturing the final dental superstructure and permitted full diagnostic evaluation of aesthetics, function, and occlusion.

The CT template was affixed to the reference Implants with a specially designed screw complex before imaging (Fig. 3). The screw complex not only stabilized the CT template but



Figure 1: Insertion of RMI, 3 per jaw. An impression has been taken and stone cast 1 has been fabricated.

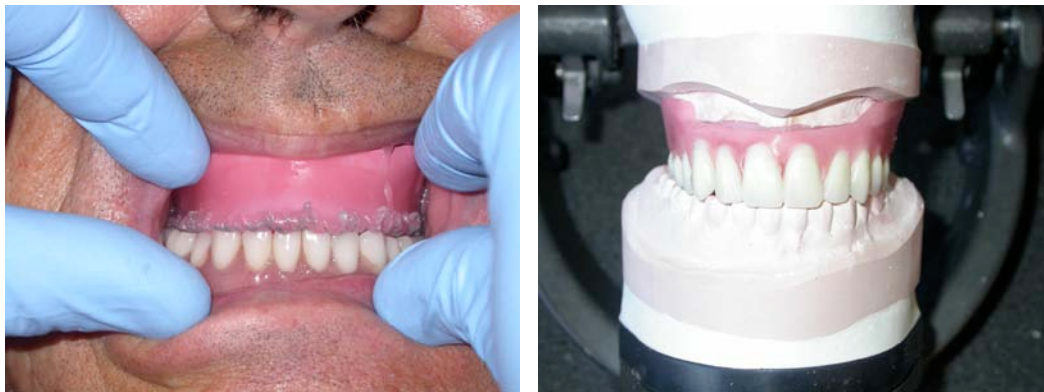


Figure 2: The prosthetic preparation. Bite registration and wax-up.



Figure 3: Left, Plaster key (PK) to duplicate the final wax up. Right, the affixed to Reference implants barium sulphate CT-template together with the screw complex.

also compensated for scanning error. A sphere-shaped radiopaque-percha point of 1 mm was positioned on the top of the screw complex. As such, the gutta-percha marker was always visible on cross-sections (range, 0.5–1 mm) on CT images without any distortion.

CBCT device Morita, Japan) was used to scan the jaw and fixed CT template were recorded to enable pre-operative implant planning. The CT data were processed to generate multiple cross-sections and 3D images by using the planning software (Exeplan, Brussels, Belgium) as illustrated in Figure 4. The implant positions were planned according to the bone anatomy

and future prosthetic situation and were represented by the barium sulphate-enhanced image of the diagnostic template affixed to the reference Implants.

After approval of the plan, the data were exported to the CAD program. The surgical template and framework of the future dental superstructure were designed by using the same digital data. In the design software, the imported CT data and planned implants were represented as dots denoting the apex and top of the implants, and thus, their orientation, and length. The design of the template and titanium bar of the future superstructure was simplified by the clarity of the barium sulphate-enhanced image of the diagnostic template. The design software permitted cross sectioning in different segments of the diagnostic template, which facilitated delineation of the titanium bar that accords with the available volume of the future prosthesis. The design data were then imported back into the planning to virtually check the fit of the planned implants. In this way, errors in design within the virtual environment were eliminated before fabrication. Figure 5 illustrates the CAD phase.

After the plan and design of the dental superstructure were approved, the data were sent to a milling company (Es-Healthcare, Beringen, Belgium). A simultaneous 5-axis milling device was used for fabrication of the surgical template and titanium frameworks. The frameworks were then sent to a dental laboratory (Van de Bijl TTL, Tilburg, The Netherlands; Ceulemans Dental Laboratory, Kessel, Belgium; Kint-de Jong, Harlem, The Netherlands, Kies Tandtechniek, Amsterdam, The Netherlands) to prepare the full dental prosthesis (Fig. 6) by using Model 2 and the Plaster Key.

Surgical phase

The patients received local anaesthesia. The surgical template was then connected to the mini-implants with a narrow-neck occlusal screw (Straumann, Basel, Switzerland). Stability of the drilling guide was established. An open structure drill guide was used to ensure visualization of the operative site. Further, additional, external, cooling was utilized the osteotomy as required (Fig. 7).

The guiding segment of each drill was of standard diameter and the stop dictated the depth of osteotomy, which was pre-determined during the computer-aided planning stage.

No additional instruments were used adjust the diameter of each drill (Fig. 8). During the drilling sequence, drills of three different diameters (2.2 mm in three lengths as the pilot drill; 2.8 and 3.2 mm for 3.3 and 4.1 mm length implants, respectively) were used (Fig. 9).

The pre-planned implants (Straumann Standard Implants, Soft Tissue Implant, which were pre-packed with special for this study designed implant mount, Basel, Switzerland) of 4.1- or 3.3-mm diameter and 8, 10, or 12 mm length were then inserted by using an implant mount (Straumann, Basel, Switzerland) modified with a stop and the guiding segment fitting the drill guide (Fig. 9). These implants were specially pre-packed including the modified guided implant mount. The Precision pin concept was used to determine the correct vertical position of the implants as planned on the computer software. To determine whether the implant reached the desired vertical position in the template, the Precision pin concept was used. The precision pin is placed in the implant guide via the groove, which is situated in the surgical template. When inserting the implant, a small amount of force is exerted on it, moves into the groove and blocks deeper insertion of the implant (Fig. 10). The procedure was repeated for each Implant in the treated jaw (Fig. 11).

After placing the last implant, the surgical template was removed by unscrewing the connections to the Reference implants and implants (Fig. 12). The reference Implants were removed by reverse torquing. Immediately thereafter, the dental superstructure was connected to the implants without using abutments (Fig. 13) and torqued with 30 Ncm using Straumann Torque wrench (Straumann, Basel, Switzerland). The schematic view of the complete procedure is shown in Figure 14. The passive fit was evaluated clinically and by panoramic radiography after tightening the connection screws (Fig. 15). The occlusion was checked and minor corrections were made. Any other complications than minor occlusal adjustments were considered as prosthetic complication and were registered.

The patients received post-surgical medication (ibuprofen, 600 mg) and were asked to rinse thrice a day for at least seven days with chlorhexidine solution. Patients were also asked to be cautious and avoid extreme chewing activity.

Follow-up

Patients returned for follow-up at one week, 2 months, 6 months and 12 months following surgery. They were assessed using clinical and radiographic (panoramic X-rays) means (figs. 15-16). In addition resonance frequency was assessed using an Osstell device (Osstell A.B, Gothenburg, Sweden). The occlusal screws were checked and torqued again (30 Ncm) when it was necessary.

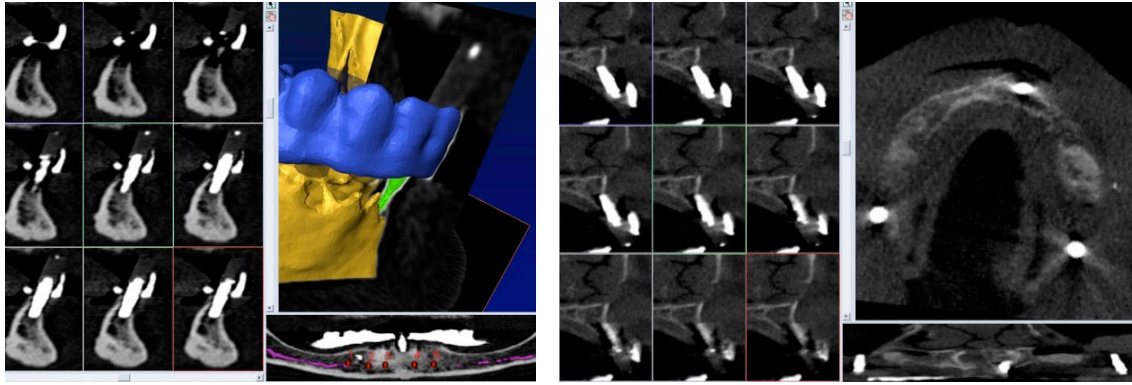


Figure 4: the determination of the reference points on the CT using implant placement-planning software.



Figure 5: CAD stage:

Upper left: The dots, digital coordinates, which represent the most coronal and the most apical points of the planned implants.

Upper middle: CAD image of the planned implants and prosthetic setup

Upper right: CAD image of the designed drill guide

Lower left: STL file of a designed framework

Lower middle: Designed framework in situ

Lower left: A cross section through all structures

Radiographic analysis

The pre- and post-surgical panoramic x-rays were analysed by three different individuals. Any implants with possible bone loss were recorded as the demarcation line between the rough and polished surface of Implants was considered as initial bone level. Any bone loss below this level was registered.

Statistical analysis

The per-patient proportion and jaw-wise proportion of failed implants were calculated. These proportions were compared across groups using a Kruskal–Wallis test, Mann–Whitney U-tests and a χ^2 –test.

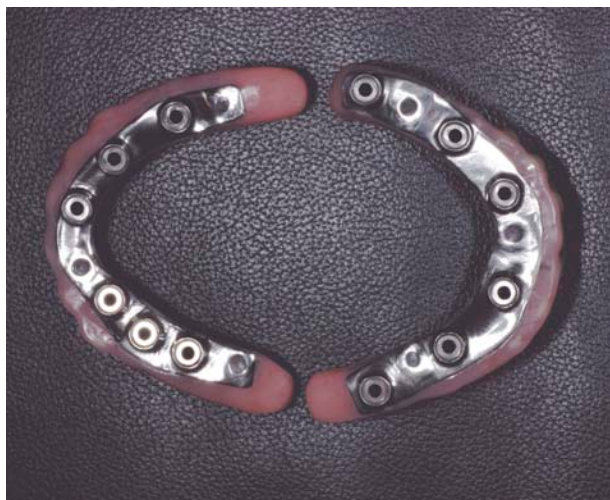


Figure 6: *The finished superstructure*



Figure 7: *Left: The drill guide affixed to the reference mini implants (RMI) in a stable fashion. Middle and right: The open drill guide provides a good vision and accessibility of the operation site.*

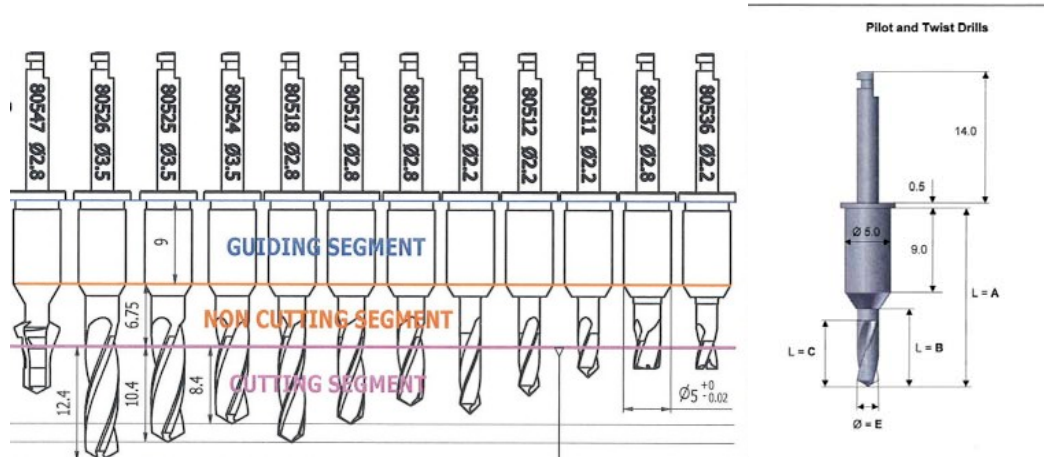


Figure 8: Left: Schematic view of the drill sequence, Right: The guided drills: The guiding segment of 9mm has an identical diameter in all drills.

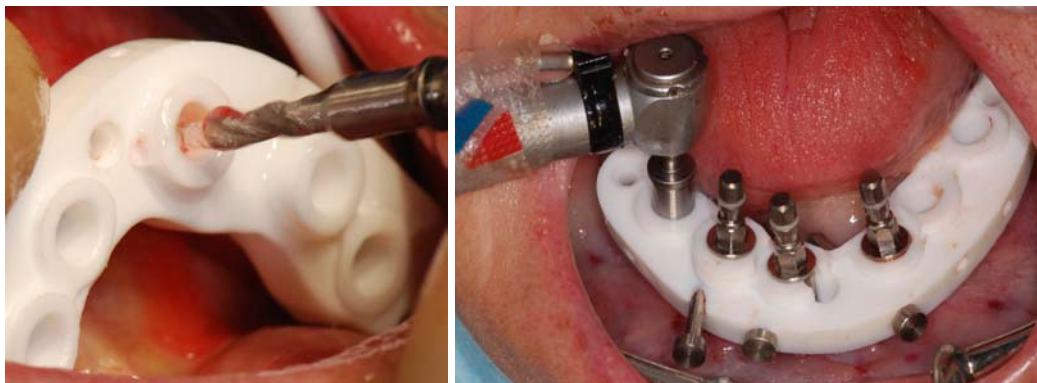


Figure 9: Guided osteotomy

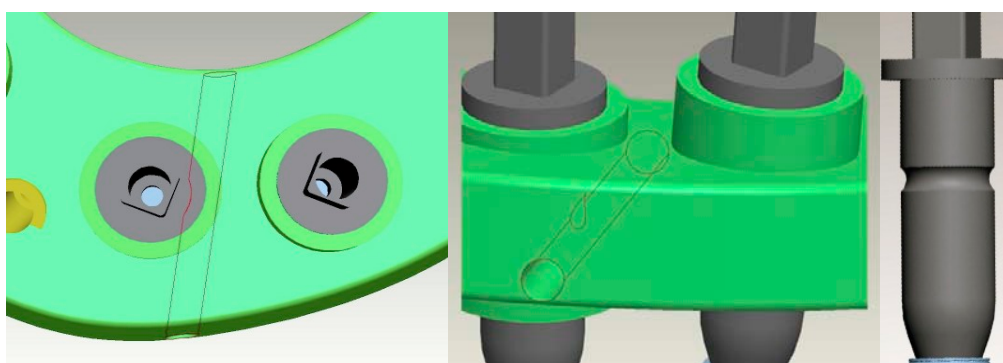


Figure 10: The schematic illustration of the precision pin concept, from left to right:

- Groove situated on the drill guide
- Corresponding recess on the implant-mount.

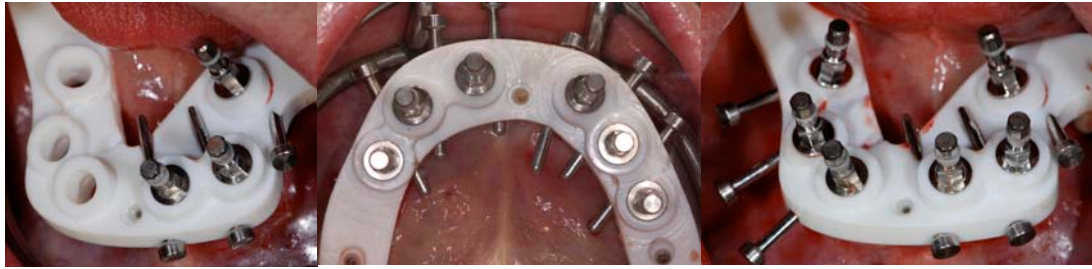


Figure 11: Guided implant placement with vertical control using the precision pin concept



Figure 12: Clinical view after removal of the drill guide



Figure 13: The superstructures were connected immediately after the surgery.

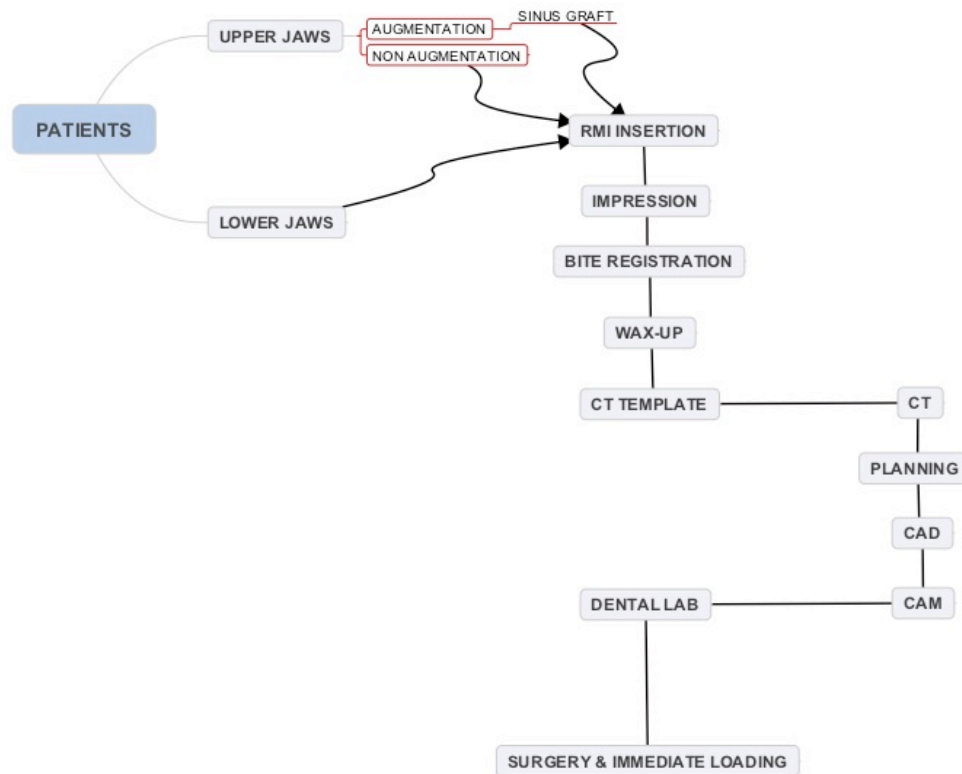


Figure 14: Schematic view of the procedure

Results

Thirty-four patients (17 men and 18 women) with 40 edentulous jaws were treated and completed the study.

The patients were divided into different groups according to the treated jaw and the amount of residual bone volume (table 2):

Group Edentulous Mandible: 10 Patients with adequate amount of bone volume in the edentulous mandibular arch to insert implants

Group Edentulous Maxilla: 5 Patients with adequate bone volume in the edentulous maxilla to insert implants

Group Edentulous Augmented Maxilla: 10 Patients with insufficient bone volume in the posterior maxilla who required sinus graft augmentation as a pre-implant treatment 6 months prior to the implant surgery.

Group both jaws: 5 patients with adequate bone volume in both jaws to insert implants.

In total, 240 implants (84 in 15 mandibles and 156 in 20 maxillas) were inserted. All the patients completed at least one year of evaluation (12–36 months). Sixty implants were inserted in five patients (**Group both jaws**) with combined, upper and lower, jaws.

In general, 229 of the 240 inserted implants survived (95.4%), with 146 (93.6%) and 83 (98.8%) implants in the maxillary and mandibular jaws, respectively. When looking at the individual groups, 1 (out of 60) implant failed in **Group Edentulous Mandible (98.4% survival rate)**, 1 (out of 30) implant failed in **Group Edentulous Maxilla (96.7 survival rate)**, 9 (out of 90) implants failed in **Group Edentulous Augmented Maxilla (90% survival rate)** and finally none (out of 60) implants failed in **Group both jaws (100% survival rate)**. Four implants in one patient were failed 6 months post surgical; this patient was considered to have a cluster failure Was this in the augmentation group? It would pride be best to describe this was in, my assumption is that it would be in the augmentation and if this is the case it might be nice to point that out. The remaining failures were limited to one failed implant per patient. Most of the failures were diagnosed and removed during the last appointment, at twelve months post-operatively. Figure 17 shows the result on the implant level.

All surgical procedures were performed with a flapless protocol. However, in one case, a mini-flap was raised to correct an extensive knife-edge ridge diagnosed during the treatment-planning phase.

One patient reported some post-operative pain, which lasted for three days. The other patients experienced no pain to minor pain limited to the surgery day .

All the metal frames (n=40) were produced in the first production run, avoiding the need to remake the individual frameworks before the surgery and showed a clinically passive fit at the time of surgery. No adjustments of the metal-to-implant fit were needed. 39 (out of 40) finished superstructures (97.5%) showed satisfactory occlusion and no major adjustments were necessary.

The frameworks were placed and torqued with 30 Ncm using Straumann torque wrench immediately after the implant insertion. During the first recall appointment, one week post-op, all occlusal screws were checked and it was found that in almost all patients some minor screw loosening was occurred, although these findings were not recorded during the following recall appointments.

One patient (both maxillary and mandibular jaws treated in one surgery) experienced

occlusion failure. Although the framework fitted well on the implants, the occlusion differed from that established during the preparation phase. The occlusion of the prosthesis in the mandible was corrected extensively for the new FDP to function. The mandibular superstructure was adjusted with new teeth arranged appropriately six months post-operatively.

Patient with the cluster failure, (from Group Edentulous Augmented Maxilla) the superstructure was obviously lost as well. In this case, patient was retreated following the conventional implant approach and restored according to delayed protocol.

In two cases where an implant was lost, the superstructures were adjusted in cooperation with the dental laboratory. The respective implant connection was cut, filled with acrylic, and re-attached onto the remaining implants. However, in one case of implant failure in the mandible, the lost implant was replaced three months later. The original drilling guide was used during the implant surgery and the same superstructure was re-attached with a passive fit.

The radiographic analysis 229 remaining implants showed bone lost on two implants, both in posterior augmented maxilla, up to second implant threads. 15 implants were not measurable due to the quality of the panoramic images. Resonance frequency analysis (RFA) was recorded during the last appointment and showed that the ISQ (Implant Stability Quotient) of the remaining implants was above 65.

A Kruskal–Wallis test indicated that there was no statistically significant difference among the patients with only maxillary implants, only mandibular implants and implants in both jaws with respect to the mean proportion of failed implants ($p = 0.308$). Further, no significant difference was found between the patients with maxillary implants and those with mandibular ones (Mann–Whitney U-test, $p = 0.298$).

A Mann–Whitney U-test showed no statistically significant difference in the proportion of failed implants in the maxillary jaw ($p = 0.313$) between the patients with and without bone augmentation. In addition, smoking did not influence the results ($p = 0.424$ for the maxillary jaw and $p = 0.546$ for the total proportion of failed implants).

The total number of failed implants in the maxillary jaw was significantly different between the patients with and without bone augmentation ($\chi^2 = 4.57$, $df = 1$, $p = 0.033$): a relatively higher number of implants failed in the patients with bone augmentation. However, when this

analysis was repeated without including the patient with the cluster failure, no difference was noted ($\chi^2 = 1.90$, $df = 1$, $p = 0.169$). There was no statistically significant difference between the patients with and without bone augmentation having at least one failed implant ($\chi^2 = 1.04$, $df = 1$, $p = 0.307$).

Groups	Patients	Implants	Failed implants
Group Edentulous Mandible	10	60	1
Group Edentulous Maxilla	5	30	1
Group Edentulous Augmented Maxilla	15	90	9
Group both jaws	5	60	0

Table 2 Study groups and patient distribution

Next, 120 Reference implants were inserted in the maxillary and mandibular jaws (75 and 45 Reference implants, respectively). Fourteen Reference implants (8 maxillary [9.4%] and 6 mandibular [13.3%]) were lost prematurely. All the premature loss of Reference implants occurred before the CT-scan procedure and during the prosthetic phase. One patient lost two Reference implants and needed re-treatment by repeating the procedure to insert Reference implants. In fifteen patients of Group B, the insertion of Reference implants and sinus graft

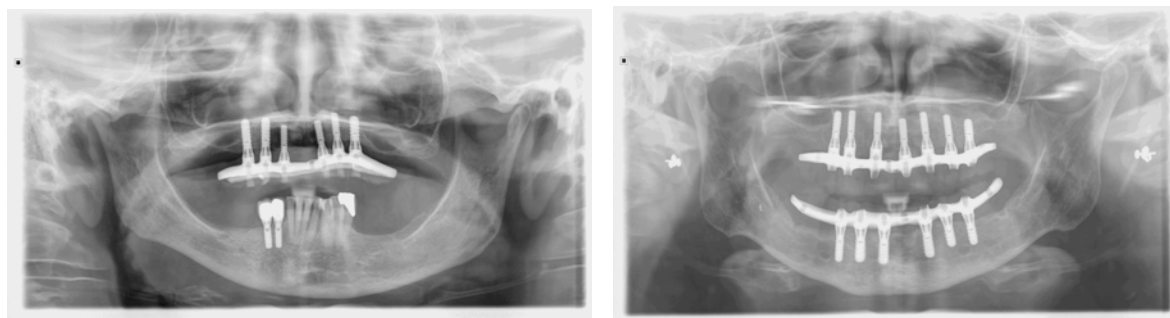


Figure 15: Post-op panoramic X-rays

procedure were performed at the same time; only three of these Reference implants (6.6%) were lost and were replaced (Fig. 17). There was no statistically significant difference in the success or failure of the mini-implants between the maxillary and the mandibular jaws ($\chi^2 = 0.194$, $df = 1$, $p = 0.660$) or between the augmented and the non-augmented maxillary jaws ($\chi^2 = 1.889$, $df = 1$, $p = 0.169$). When this analysis was repeated at the patient level, there was no difference in the survival or failure of the mini-implants among the maxillary, mandibular,

and both jaws ($\chi^2 = 1.377$, $df = 2$, $p = 0.502$) and between the augmented and the non-augmented maxillary jaws ($\chi^2 = 2.482$, $df = 1$, $p = 0.115$).

Discussion

The present clinical trial demonstrates the possibility to digitally design and fabricate surgical guides and superstructure and their reliability to integrate this technique in immediate loading of dental implants in fully edentulous patients. In this protocol, Reference implants were inserted before the actual implant insertion at the beginning of the procedure; they remained during the procedure and were used to place the drill guide during the surgery. They were removed after the insertion of the last implant and removal of the drill guide. Thus, unlike in the other concepts of guided surgery, there are clear references from the beginning of the procedure to the end of the treatment period. However, the insertion procedure of these mini implants is an extra, minor surgery for the patients.

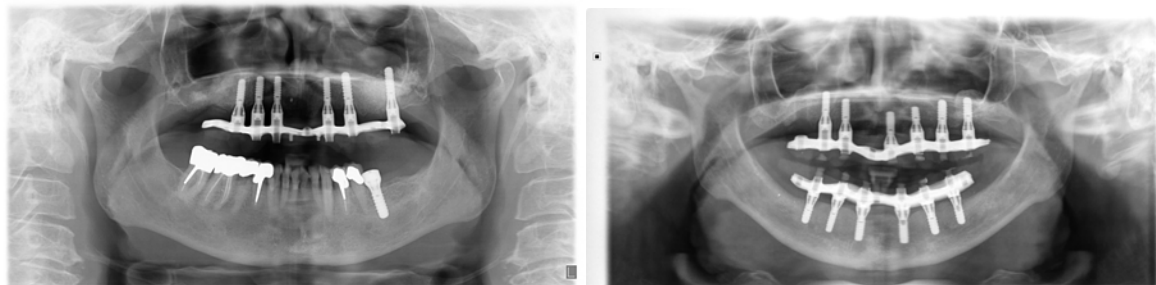


Figure 16: 12 months post-op panoramic x-rays:
-Panoramic, patient: Fully integrated implants,
-Panoramic, patient: one failed implant, upper right most posterior.

A total of 13 patients lost 14 Reference implants prematurely, before the CT scan- and thus final procedure; these failures may be attributed to their design, which is similar to that of Straumann standard implants. Straumann standard implants have a passive, not self-tapping, feature; thus, a drill is required to insert these implants. Most of the patients treated during this study had a compromised bone condition because of edentulousness for many years. The compromised bone condition and use of the drill might have caused poor primary stability of some of these Reference implants, leading to their premature loss. A self-tapping implant (an

implant that cuts its own path into bone) feature would be a better and more reliable choice. because of edentulousness for many years. The premature lost of Reference implants resulted in compromised reference situation. Although there was only slightly occlusion inaccuracies occurred when one RMI was lost, the loss of multiple Reference implants resulted (in one patient) in extended treatment time where the Reference implants were reinserted.

The exact position of titanium Reference implants is difficult to define on reconstructed images because of CT-specific image artefacts, including scatter radiation, limited dynamic range of the x-ray area detectors, truncated-view artefacts and beam hardening.^{1,3} These

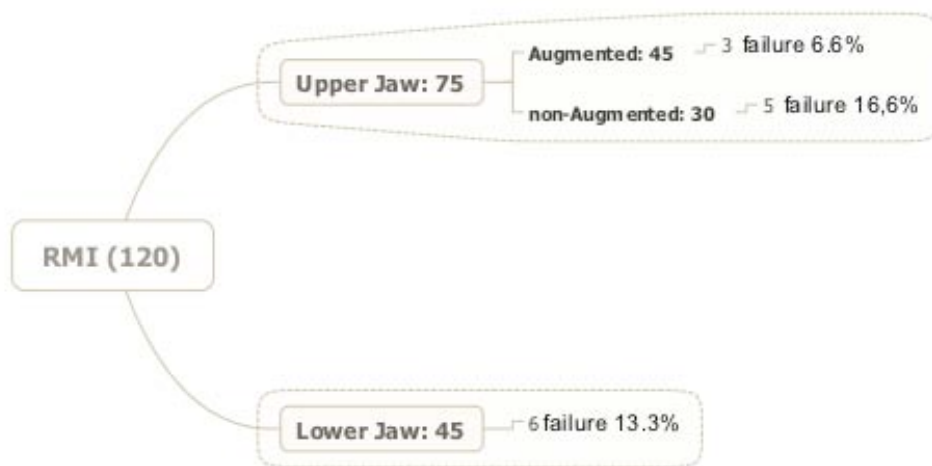


Figure 17: Reference Implants (RMI) distribution and results

artefacts have a significant influence on the image quality (5). Also CT images introduce a transfer error of 0.6 mm (standard deviation of 0.4 mm) in the maxilla and 0.3 mm (standard deviation of 0.4 mm) in the mandible.^{2,15} The positions of the screws were defined, and visualized, in CT images by means of a gutta-percha marker (Fig. 5). A ball-shaped radio-opaque gutta-percha point of 1 mm was positioned on the top of the screw complex. As such, the gutta-percha marker was always visible on cross-sections (range, 0.5–1 mm) on CT images without any distortion. (Fig. 18). This information on the measurements is crucial for the subsequent implant planning and superstructure design in a CAD system.

Further to minimize the errors during the surgery, the osteotomy procedure was modified. The guiding segment of each drill was of the same diameter, which fit the drilling guide in a precise manner. The stop on each drill dictated the depth of osteotomy, as pre-determined during the computer-aided planning of the case. Consequently, no additional instruments

were required to adjust the diameter of each drill, minimizing errors during treatment. During the drilling sequence, drills of three different diameters were used. Each drill was used to bore through about +/- 2 mm length of bone. This strategy avoids extreme movements during the osteotomy, which can occur even during complete guided surgery using full-length drills, and ensures continuous guidance of the drills. The same principles were used when inserting the implants. The implant mount had the same guiding segment as the drills, which fits into the drill guide. The stop on the mount determined the implant depth, which was additionally controlled by using the precision pin. The precision pin gives the implant driver extra precision to position the implant in the correct vertical dimension determined during the computerized planning, decreasing the possibility of misfit. Also by utilizing the same data for planning, surgery, and designing of the surgical guide and superstructure, we excluded transition error, which may occur when the data has to be translated or scanned.

Furthermore, nine of eleven implant failures occurred in the patients with sinus graft augmentation before implant insertion. Although the sinus grafts were allowed to heal for at least six months, the implants were loaded immediately after insertion. In these cases, therefore, a delayed protocol should be applied. The overall survival rate, 95.4%, is in the range of previously reported numbers published in ITI Consensus meeting in 2008 ¹⁶. Further research on the loading protocol is required to draw any final conclusions. The patient with the cluster failure received a new treatment where a conventional implant-retained over-denture was implemented.

In the current study, all the patients were restored according to an immediate loading protocol. The frameworks were placed and torqued with 30 Ncm using Straumann torque wrench immediately after the implant insertion. During the first recall appointment, one week post-op, all occlusal screws were checked and it was found that in almost all patients some minor screw loosening was occurred, although these findings were not recorded during the following recall appointments. This might emphasise that the immediate loaded implants had moved towards the framework during the early post-loading period, due to tension induced by limited amount of misfit in implant/framework interface. Duyck et al. reported similar findings in their animal study that prosthesis misfit led to topographically adaptation of immediately loaded implants to the prosthesis, thereby minimizing the existing misfit.¹⁷ Still there are more studies required to determine the clinically acceptable maximum misfit, as well as the misfit induced micro-movement of dental implants.

Also the lack of an exact information of the condition of the soft tissue around the planned implants during the computer planning phase can affect the long term success of the placed implants.¹⁸⁻²⁰ More innovation and research in this field may improve the guided procedure. Accuracy of component fit may be evaluated through visual or microscopic inspection, tactile assessment or displacement when single screws are tightened²¹⁻²³ and Strain gauge assessments may provide more objective analysis however this approach is more difficult and may not lend itself to routine quality control. Unfortunately all these techniques could be used in laboratory environment and not in clinical situation. Post-surgical radiographs taken in this study might indicate the passive fit but it is not a scientifically objective method. Still, it is a fact that an objective fit evaluation in case of patient treated in this study, following a fully digital approach where no master model has been fabricated, might be extremely difficult. The implant/bone contact analysis was not one of the objectives in this study. For this reason no standardized peri-apical radiographs were taken. However, panoramic radiographs were taken on, 6 and 12 months of post-op evaluation, to monitor any unexpected complication. The panoramic radiographs have been previously described in literature to evaluate the implant/bone contact in atrophic jaws.²⁴

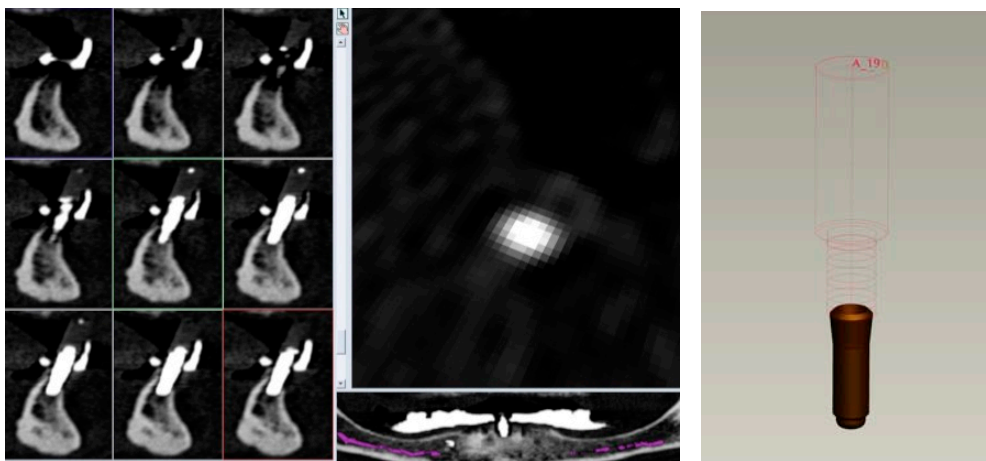


Figure 18: Right, Clearly visible Gutta Percha point on the CT cross-section.
Left, the exported data of the entire screw complex image.

Conclusions

On the basis of the results, high survival rate of inserted implants and superstructures, in limited number of treated patients, it is concluded that immediate loading of dental implants after reference-based guided surgery is a successful surgical and prosthetic treatment option for fully edentulous patients. Despite that the evidence is weak for a difference between augmentation- and non-augmentation cases, it is proposed to apply the loading protocol with caution in patients with augmentation. The findings emphasise the importance of communication and collaboration between all the involved parties.

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Summary And Future Perspectives

Despite the rising popularity of guided surgery and immediate loading, profound scientific evidence is lacking to support this approach in dental implant treatment.

Nevertheless, the possible advantages of guided surgery protocols such as flapless and minimally invasive surgery, protection of vital anatomical structures, and immediate restoration have been extensively highlighted as marketing tools in the dental implant industry. The introduction of **Cone Beam CT (CBCT)** scanning and the increasing availability of this technique to dental offices have made the digitalisation of implant dentistry more and more accessible.

Different companies have developed software packages and technologies to deliver a digital approach to treating patients using dental implants. These software packages for guided surgery are similar and are based on comparable technology. However, the manners in which the drill guides are fabricated differ.

Stereolithography, rapid prototyping, and a model-based approach using computer algorithms are among the most commonly applied technologies.

On the other hand, our systematic review showed that, despite the different levels of research quality for computer-assisted implant placement, an evaluation of the evidence suggesting that computer-assisted surgery is superior to conventional procedures in terms of safety, implant precision, morbidity, and efficiency has yet to be performed.

Some studies have demonstrated that the maximum observed deviations from computer-aided planned implant positions exceeded what one might call clinically acceptable levels. Thus, future long-term clinical data are necessary to evaluate its clinical success and to justify the additional CBCT-associated radiation doses, effort, and costs associated with computer-assisted implant surgery (**Chapter 1**).

Why are there large deviations from the planned implant position? What are the possible causes of the deviations and how can we improve this technique's precision?

Various hypotheses have been put into consideration to address this question:

- In the treatment of edentulous jaws, lack of stable references might result in inaccuracy due to resilience of the oral mucosa and lack of stability of the scan prosthesis and the drilling template. CT image distortion and errors might cause errors in the planning software.
- Failure to control and stabilise the surgical procedure and implant placement might lead to differences between planned and placed implants.

In an *in vitro* study (Chapter 3), we demonstrated that insertion of mini-implants as references prior to the actual implant insertion could create a permanent reference base throughout the entire treatment procedure.

Calibration flags, what we refer to as screw complexes, that act as fiducial markers were also developed to assist clinicians with identifying the reference mini-implants on the CT images. An improved drilling sequence with a specifically developed drill design and an instrument to physically control the implant depth were introduced in an attempt to improve guided implant surgery precision (**Chapter 2**).

To analyse the procedure precision, 2 different approaches were followed:

- Optical scan analysis
- Strain gauge analysis

Both an acrylic resin and plaster models were prepared to mimic the edentulous mandible. After 3 mini-implants were inserted in the acrylic resin model, a CBCT scan was performed. Data comprising 6 implants were imported into the planning software. A drill guide and a titanium framework were designed in the same virtual environment and then milled using a fully digital computer-aided design/computer-assisted machining protocol, providing a completely digital approach. Six implants were inserted into the acrylic test model using the drill guide screwed onto the mini-implants. After an impression was made of the acrylic resin model with the 6 implants, a second model (plaster model) was prepared. A second milled titanium structure was fabricated following optical scanning of the acrylic resin model (traditional optical scanning approach). Strain gauge measurements were done on both structures when attached to both models. To validate the results, a high-accuracy industrial optical scanning system was used to capture the connection geometry, and the measurements were compared.

The accuracy and standard deviations (SD) of the superstructures made after the complete digital approach were 19.2 (17.9), 21.5 (28.3), and 10.3 (10.1) μm for the x-, y-, and z-axes, respectively.

The accuracy (SD) of the impression-based superstructure using strain gauges and measured misfits was 11.8 (10.5), 19.7 (11.7), and 16.7 (8.2) μm for the x-, y-, and z-axes, respectively. We concluded that the misfit of the digitally designed and produced superstructure on the digitally planned and inserted implants compared to the analogue impression technique was clinically insignificant (**Chapter 2**).

A new study was designed to validate these findings. Two comparable implant-supported superstructures, a Control and a Test Misfit, were fabricated in an *in vitro* study after scanning a test model in which 4 implants, 2 on each side, were inserted. In the test superstructure, the Test Misfit was fabricated with a known minor misfit on one of the inserted implants by manipulation of the coordinates in the scanned files. The other superstructure was fabricated as accurately as possible without manipulation of the scanned information. Both superstructures were evaluated using optical scanning and strain gauge measurement by an investigator who was blinded to the designed misfit.

The optical scan analysis detected the test superstructure and the manipulated implant position. The strain gauge measurements confirmed these findings, indicating that both methods of assessing inaccuracy were effective. The optical scan analysis may be used as a simplified and clinically applicable method to detect minor misfits in implant-supported superstructures (**Chapter 4**).

In the next stage, we tested whether this novel approach could be clinically applied. Before starting a clinical trial, a completely edentulous patient agreed to undergo treatment with this novel approach in a pilot study. The patient was subjected to the same criteria imposed by the medical and ethical committees, as it was demanded for our clinical trial.

Mini implants were used to establish a setup for CT imaging, acting as fiducial markers and fixators for the surgical template. The 3D software simulation allowed for planning of ideal implant placement by digitally integrating the future prosthetic and anatomic situations to design the definitive superstructure. The computer-aided design/computer-assisted manufacture (CAD/CAM) superstructure that was digitally produced with precise fit and occlusion and good aesthetics was placed immediately after surgery (**Chapter 3**).

Following this pilot study, a clinical trial was designed to see if we could get similar results in a larger patient cohort. Thirty-five patients, 20 with edentulous upper jaws, 10 with edentulous lower jaws, and 5 with edentulous upper and lower jaws, were treated. Patients whose upper jaws were treated had to undergo a sinus graft procedure to ensure the presence of sufficient bone for the implants. Mini-implants were used to establish the CT setup and the surgical template fixation. The planning 3D simulation software was used to plan the ideal implant placement and integrate the future prosthetic and anatomic situations to design the final superstructure.

A total of 240 final superstructures were inserted and immediately loaded; 229 (95.4%), 146 (93.6%) in the maxillary jaw and 83 (98.8%) in the mandibular jaw, survived. Ten of the 11 implants lost in the upper jaw occurred in patients with an augmented sinus. All of the final

restorations fit sufficiently. Having evaluated implant and superstructure success, we concluded that reference-based guided surgery seems to be a reliable treatment option for the treatment of edentulous patients. The CAD/CAM superstructure, inserted and loaded immediately after guided implant insertion, was produced digitally with a precise fit and with the most acceptable occlusion and aesthetics (**Chapter 6**).

A pilot study was designed to describe the use of a 3D CAD planning protocol in combination with previously placed reference elements and CAD/CAM technology to restore the partially edentulous patient. Mini-implants and/or reference brackets were inserted or positioned in specified locations in a test cast in 2 patients prior to CBCT imaging to act as definitive fiducial markers. This served as a fixed base to define a setup for the fabrication of a surgical template used during the imaging process. A simulated partially edentulous maxilla was used for the study in addition to the 2 partially edentulous patients. After the CT images were imported into the design software, a CAD/CAM superstructure was created prior to surgery. The framework fit was assessed on the simulated acrylic model using 3D tension measurements with strain gauges. We found that the mean misfit for all implants in the x-, y-, and z-axes was 26.6, 24.8, and 10.4 μm , respectively. The total misfit calculated according to the Pythagorean theorem was 42.6 μm (**Chapter 5**). The implants inserted into the 2 patients were clinically observed for 6–12 months. All implants survived due to the frameworks that were inserted, and were loaded immediately after the implant surgery.

On the basis of the results of this pilot study in 2 patients and an *in vitro* analysis, it appears that the use of reproducible fiducial markers consisting of mini-implants and reference brackets results in the fabrication of an accurately fitting final prosthesis prior to implant placement. These results are in line with those found in cases of edentulous patients when treated following our novel digital protocol in the previous study.

In conclusion, we believe that these techniques can possibly compensate for some shortcomings in the previous approaches described in the literature. Even so, more studies are needed to analyse its success in the hands of other clinicians. More research is necessary to test the accuracy and the influence of different individual innovations introduced into this specific guided surgery protocol.

Samenvatting en Conclusies

Geleide Chirurgie en Immediate belasting. Een Digitale Benadering

Ondanks de stijgende populariteit van geleide chirurgie (guided surgery) en onmiddellijk belasten (immediate loading) van orale implantaten is er nog een gebrek aan grondig wetenschappelijk onderzoek om deze benadering te ondersteunen. Tot nu toe worden de mogelijke voordelen van protocollen gebaseerd op geleide chirurgie zoals “flapless surgery”, minimaal invasieve chirurgie, bescherming van vitale anatomische structuren en “immediate loading” uitvoerig gebruikt als marketinginstrumenten in de dentale industrie. Door invoering van Cone Beam CT (CBCT) scanning en de toenemende beschikbaarheid van deze techniek voor tandartspraktijken is de digitalisatie van de orale implantologie meer toegankelijk geworden.

Verscheidene firma's hebben softwarepakketten en technologie ontwikkeld om een digitale planning ter ondersteuning van de behandeling met orale implantaten mogelijk te maken. Deze softwarepakketten zijn gebaseerd op vergelijkbare technologieën, maar de manier waarop uiteindelijk, computergestuurd, een chirurgische boormal wordt geproduceerd is verschillend. Rapid prototyping en model-based benaderingen gecombineerd met computeralgoritmes zijn de meest gebruikte toepassingen.

Anderzijds laten de resultaten van onze systematische review zien dat er nog steeds geen onderzoek is uitgevoerd dat kan aantonen dat computergeleide chirurgie superieur is aan conventionele procedures als gekeken wordt naar veiligheid, precisie van de implantatie, morbiditeit en efficiëntie.

Sommige studies hebben aangetoond dat de maximaal geregistreerde afwijkingen van de computergeplande en vervolgens -geleide klinisch geëvalueerde posities van implantaten groter is dan wat men klinisch aanvaardbaar acht. Daarom zijn aanvullende klinische studies nodig om deze behandelmethode te evalueren. Tevens zal de hogere stralingsdosis, die gepaard gaat met CBCT, moeten worden verantwoord, evenals de extra inspanningen en de kosten die voortvloeien uit de computergeleide implantatiechirurgie (Hoofdstuk 2).

Waarom zijn er zulke grote afwijkingen tussen de geplande en klinisch gerealiseerde implantaatposities? Wat zijn de mogelijke oorzaken van deze afwijkingen en hoe kunnen we de nauwkeurigheid van deze techniek verbeteren?

Verschillende hypothesen zijn in overweging genomen om een antwoord te vinden op deze vragen:

- Bij de behandeling van tandeloze kaken kan een gebrek aan stabiele referentie- en retentiepunten leiden tot onnauwkeurigheden die onder andere te wijten zijn aan de elasticiteit van het mondslijmvlies. Dit kan onvoldoende stabiliteit van de scanprothese en de boormal tot gevolg hebben..
- Beeldvervorming van de CT en daarvan afgeleide onnauwkeurigheden kunnen afwijkingen in de planningsoftware tot gevolg hebben.
- Onnauwkeurigheden zowel bij het stabiliseren van de referentieplaat als bij het plaatsen van de implantaten kunnen ook leiden tot verschillen tussen de geplande en de klinisch gerealiseerde implantaatposities.

In een *in-vitro*-studie (Hoofdstuk 3) hebben we aangetoond dat het aanbrengen van mini-implantaten als ijkpunten voorafgaand aan de eigenlijke behandelprocedure, als een permanente referentiebasis zouden kunnen dienen gedurende de gehele behandelprocedure.

Om de clinici te helpen bij de identificatie van deze referentie-implantaten op de CT- beelden werden schaalverdelingpunten ontwikkeld (schroevencomplex) die fungeren als vaste markers.

Een verbeterde geleiding met een specifiek ontwikkeld boorontwerp en een instrument om de diepte van de implantaatpositie fysisch af te stellen werden aangewend in een poging om de precisie van geleide implantatiechirurgie te verhogen (Hoofdstuk 3).

Om de nauwkeurigheid van de procedure te bepalen, hebben we twee verschillende benaderingen toegepast:

- een optische scananalyse;
- een analyse met behulp van *strain gauges* (rekstrookjes).

Een kunststofmodel (testmodel) werd gefabriceerd om de tandeloze kaak na te bootsen. Nadat drie mini-implantaten in het testmodel waren aangebracht, werd een CBCT scan gemaakt. Zes implantaten werden vervolgens virtueel (in de planningsoftware) in de kaak geplaatst. Een boormal en een frame van titanium werden in dezelfde virtuele omgeving ontworpen en vervolgens gefreesd (CAD/CAM), zodat een volledig digitale benadering werd verwezenlijkt. Zes implantaten werden in het acryl testmodel geplaatst door middel van de

boormal die was vastgeschroefd aan de mini-implantaten. Nadat een afdruk was gemaakt van het testmodel met zes implantaten, werd een gipsmodel gecreëerd. Een tweede suprastructuur van titanium werd gefabriceerd na een optische scanning van het gipsmodel (traditionele optische scanningmethode). Vervolgens werden *strain gauge* metingen uitgevoerd op de beide structuren die werden vastgeschroefd aan het testmodel. Met het oog op het valideren van de resultaten werden er metingen uitgevoerd door het gebruik van een optisch scannersysteem met hoge precisie.

De pasvorm van de structuur (SD), gefabriceerd volgens de volledig digitale benadering was respectievelijk 19,2 micron (17,9), 21,5 micron (28,3) en 10,3 micron (10,1) voor de x-, y- en z-as. De pasvorm (SD) van de op een afdruk gebaseerde suprastructuur met gebruikmaking van “*strain gauges*” en daarmee gecalculerde misfit was respectievelijk 11,8 micron (10,5), 19,7 micron (11,7) en 16,7 micron (8,2), voor de x-, y- en z-as. We kwamen tot de conclusie dat de digitaal ontworpen en vervaardigde suprastructuur op de digitaal geplande en geplaatste implantaten vergeleken met de analoge afdrucktechniek klinisch nauwelijks verschilden en de verschillen niet significant waren (Hoofdstuk 3).

Om deze bevindingen te valideren werd een nieuw onderzoek opgezet. Twee vergelijkbare door implantaten gesteunde suprastructuren, de controle- en de testsuprastructuren, werden gefabriceerd in een *in-vitro*-studie na een scan van het testmodel, waarin vier implantaten, twee aan iedere zijde, waren aangebracht. In de testsuprastructuur werd een onnauwkeurigheid aangebracht door manipulatie van de coördinaten in de scandata op een van de geplaatste implantaten. De andere suprastructuur, de controlesuprastructuur, werd zo nauwkeurig mogelijk vervaardigd zonder de gescande informatie te manipuleren. Beide suprastructuren werden vervolgens geëvalueerd door middel van optische scanning en *strain gauge* metingen door een onderzoeker, die niet van de ontworpen onnauwkeurigheid op de hoogte was.

De analyse met de optische scan detecteerde de testsuprastructuur en de gemanipuleerde implantaatpositie. Deze bevindingen werden bevestigd door de metingen met *strain gauge*, wat kan aantonen dat beide methodes bruikbaar zijn om de onnauwkeurigheid vast te stellen. De optische scananalyse zou mogelijk gebruikt kunnen worden als een vereenvoudigde en klinisch toepasbare methode om geringe onnauwkeurigheden op te sporen in implantaatgesteunde suprastructuren (Hoofdstuk 4).

In een volgende fase hebben we onderzocht of deze nieuwe methode klinisch toegepast zou kunnen worden. Voor de aanvang van een clinical trial werd, in een pilot study, een volledig

tandloze patiënt behandeld met deze nieuwe methode. De patiënt werd onderworpen aan de criteria zoals die opgelegd zijn door medische en ethische commissies voor klinische studies. De mini-implantaten fungeerden als vaste markers en bevestigingspunten voor zowel de CT setup als de chirurgische boormal. De planningssoftware met 3D-simulatie maakte een ideale implantaatpositie mogelijk door de toekomstige prothese en de anatomische omgeving digitaal te integreren en hiermee rekening houdend, de definitieve suprastructuur te ontwerpen. De CAD/CAM suprastructuur werd onmiddellijk na de geleide chirurgische ingreep geplaatst. Alle implantaten en beide suprastructuren overleefden na een observatieperiode van 12 maanden (Hoofdstuk 3).

Na deze pilot study werd een clinical trial ontworpen om na te gaan of we vergelijkbare resultaten bij een grotere patiëntengroep konden bereiken. Vijfendertig patiënten werden behandeld: 20 met tandeloze bovenkaak, 10 met tandeloze onderkaak en 5 met een tandeloze boven- en onderkaak. De meeste patiënten (10) van wie de bovenkaak werd behandeld moest een sinusaugmentatie ondergaan om ervoor te zorgen dat er voldoende bot aanwezig was om implantaten te kunnen plaatsen. Mini-implantaten werden geplaatst ten behoeve van het positioneren en stabiliseren van de CT set-up tijdens de CT-opname en de fixatie van de chirurgische boormal. De 3D simulatiesoftware werd gebruikt om de ideale plaats van de implantaten te kunnen plannen, rekening houdend met de nieuwe prothese en de anatomische beperkingen. In totaal werden 240 implantaten aangebracht en onmiddellijk belast. Na een observatieperiode van minimaal 12 (12-36) maanden na het plaatsen van implantaten, overleefden 229 (95,4%), waarvan 146 (93,6%) in de bovenkaak en 83 (98,9%) in de onderkaak. Tien van de elf implantaten die verloren gingen in de bovenkaak werden geplaatst bij patiënten met een geaugmenteerde sinus.

Op basis van de resultaten van deze trial concludeerden we dat op referenties gebaseerde en geleide chirurgie een betrouwbare behandeloptie blijkt te zijn om volledig tandeloze patiënten te kunnen behandelen (Hoofdstuk 6).

Een pilot study werd ontworpen om het gebruik van deze 3D planningsprotocol in combinatie met vooraf geplaatste referentiepunten te beschrijven, met het doel gedeeltelijk tandeloze patiënten te gaan behandelen. Bij twee patiënten en een testmodel met een gedeeltelijk tandeloze bovenkaak werden mini-implantaten en/of referentiesteunelementen (speciale brackets) op gespecificeerde plaatsen geplaatst voorafgaand aan de CBCT beeldvorming. Deze dienden, tijdens het beeldvormingsproces, als een vaste basis om de prothetische setup te fixeren en tijdens de chirurgie om de chirurgische boormal te stabiliseren. De 3D simulatie- software werd gebruikt om de ideale plaats van de implantaten te kunnen plannen, rekening houdend met de nieuwe prothese en de anatomische beperkingen. Nadat de CT-

beelden en de coördinaten van implantaatposities in de CAD software werden ingevoerd, werden, vóór de chirurgische ingreep, een chirurgische boormal als ook de suprastructuur gefreesd (CAD/CAM). De pasvorm van het frame werd op het gesimuleerde kunststofmodel bepaald met behulp van 3D spanningsmetingen door middel van “*strain gauges*”.

We constateerden dat de gemiddelde afwijking in de pasvorm voor alle implantaten op de x-, y- en z-assen respectievelijk 26,6 micron, 24,8 micron en 10,4 micron was. De totale misfit, berekend volgens de pythagoriaanse theorie bedroeg 42,6 micron (Hoofdstuk 5). De implantaten die bij de twee patiënten werden aangebracht, werden onmiddellijk belast met digital (CAD/CAM) gefabriceerde frames. De patiënten werden voor een periode van 6-12 maanden gevolgd. Alle implantaten bleven stabiel.

Het blijkt uit de resultaten van deze pilot study, dat het gebruik van reproduceerbare vaste markers, bestaande uit mini-implantaten en/of referentiebrackets de fabricatie van een nauwkeurig passende, definitieve prothese, voorafgaand aan de eigenlijke implantaatplaatsing, mogelijk maakt. Deze resultaten zijn in overeenstemming met de uitkomsten van de evaluatie van de volledig tandeloze patiënten (Hoofdstuk 5).

Tot slot, dit proefschrift laat zien dat het technisch mogelijk is om bepaalde tekortkomingen in de tot nu toe gebruikte protocollen bij geleide chirurgie te compenseren om de precisie van het behandelconcept te verbeteren. Meer onderzoek is vereist om de nauwkeurigheid en de invloed te testen van de verschillende afzonderlijke vernieuwingen die in het hier beschreven concept in geleide chirurgie werden voorgesteld.

List of Abbreviations:

2D	2-Dimensional
3D	3-Dimensional
CAD/CAM	Computer Aided Design/ Computer Aided Manufacture
CBCT	Cone Beam Computer Tomography
CDD	Computer Driven Drilling
CNC	Computer Numerical Control
CT	Computer Tomography
ICC	Interclass Correlation Coefficient
MSCT	Multi Slice Computer Tomography
RFA	Resonance Frequency Analysis
SD	Standard Deviation
SE	Standard Error
STL	Stereolithography

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