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ACCURACY OF VIRTUALLY PLANNED AND CAD/CAM-GUIDED DENTAL IMPLANT SURGERY

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To
My parents, Gerd and Kjell-Erik
My sister Annica and her family
My grandmother Kalina
My family, Johanna & Linnéa

"A man should look for what is, and not for what he thinks should be."
Albert Einstein

"Fast is fine, but accuracy is everything"
Wyatt Earp

ABSTRACT

The treatment with dental implants was introduced in the 1960s as an aid for patients who were missing teeth.
Recently CAD/CAM guided surgical concepts have been launched on the market as a solution for treating single, partial or completely edentulous patients with dental implants. The mucosa based surgical templates is one of the fairly new dental implant systems on the market for treating patients. With this new technique it is crucial to thoroughly evaluate the accuracy, in order to avoid damaging sensitive anatomical structures of patients. Another factor of importance to consider, is the possibility to connect the bridge immediately onto the CAD/CAM guided placed implants. Companies could also benefit from more knowledge about accuracy in order to, i.e., further improve the instructions and the hardware to further enhance the security and usability of the systems.

The general aim of this project was to evaluate the accuracy between virtually planned and actually placed dental implants using a surgical guide. Study I and III aimed to compare the deviation between the position of virtually planned implants and the position of implants placed with a CAD/CAM-guided surgical template in the mandible and maxilla. The aim of Study II was to perform virtual variation simulations on virtually planned implant placements and to compare them with corresponding results from actual surgeries, performed on human cadavers in Study I.
In Study IV the aim was to evaluate the deviation between the results obtained from five different surgeons, from CAD/CAM guided implant surgery on plastic jaw models.

Completely edentulous human cadavers, patients and plastic maxilla jaw models were included in Study I, III and IV. Study II utilized 3D STL files obtained from Study I.

Study I and III, demonstrated a statistical significant difference between the virtually planned implant positions and the clinically placed implant positions after surgery. Study I demonstrated a statistically significant difference between mandibles and maxillae for the outcome variables, hex, apex and depth measurements, with smaller deviations for the maxilla.

In Study III it was found that the patients moved during the preoperative and postoperative CBCT scans. When combining the movement factor between the virtually planned implants and actually placed implants positions, a statistical significant difference was observed for the hex and apex. If the movement factor was included, a statistical significant difference was found between the maxilla and mandible for the outcome variable angle.

In Study II, the implant distributions were neither static nor normally distributed. Thus, within the limitations of this study, the definitive geometrical variations of the implants were not static, as they depend on the individual anatomy of the jaws and the ability to place the CAD/CAM-guided surgical template in the proper position. The Mann-Whitney U test showed that the definitive implant distributions in this study could not be assumed to be normally distributed.

In Study IV a statistically significant difference was observed between all five surgeons for the outcome variables, apex, depth and angle. A statistically significant difference

was also found between the virtually planned implant positions and the actually placed implant positions for the outcome variables, apex, hex and depth.

The mean value was smallest for the plastic jaw model study and largest for the human cadaver study, for the outcome variables, apex, hex and angle. For the depth, the smallest mean value was present in the patient study and largest in the plastic model study. However, the human cadaver study and patient study presented a larger range in deviation.

Further studies have to be performed to evaluate the contributing factors of all steps involved in CAD/CAM guided surgery. In order to further improve knowledge about guided surgery accuracy, it is important to perform accuracy studies on conventional surgery in order to compare the results and, thus, provide a more secure treatment to the patients. In other words, the most important goal is to provide the most secure treatment available for the patients.

Keywords: dental implant, computer-guided surgery, CAD/CAM-guided surgery, surgical template, flapless surgery, virtual planning, CT, CBCT, stereolithography, accuracy

LIST OF PUBLICATIONS

I. Pettersson A, Kero T, Gillot L, Cannas B, Fäldt J, Söderberg R, Näsström K
Accuracy of CAD/CAM-guided surgical template implant surgery on human cadavers: Part I. Journal of Prosthetic Dentistry 2010; Vol.103, Issue 6:326-394

II. Kero T, Pettersson A, Fäldt J, Andersson M, Gillot L, Cannas B, Näsström K, Söderberg R
Virtual variation simulation of CAD/CAM template-guided surgeries performed on human cadavers: Part II. Journal of Prosthetic Dentistry 2010; Vol 104, Issue 1:48-55

III. Pettersson A, Komiyama A, Hultin M, Näsström K, Klinge B
Accuracy of virtually planned and template guided implant surgery on edentate patients. Clinical Implant Dentistry and Related Research 2010; Research, no. doi: 10.1111/j.1708-8208.2010.00285.x

IV. Pettersson A, Kero T, Fäldt J, Söderberg R, Karin Näsström
Accuracy of virtually planned and CAD/CAM guided implant surgery on plastic models. Clinical Implant Dentistry and Related Research; Submitted

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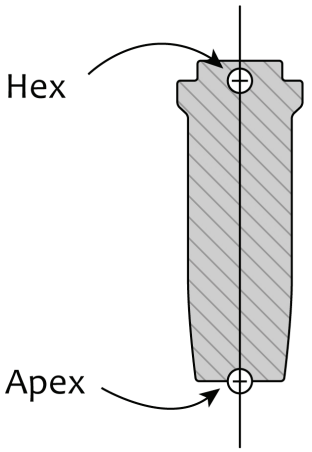
LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
Apex	Tip of implant
CAD/CAM	Computer Aided Design/Computer Aided Manufacturing
CBCT	Cone Beam Computed Tomography
CI	Confidence Interval
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
Fig	Figure
Hex	Center of implants prosthetic connection
Min/Max	Minimum/Maximum
mm	Millimeter
SD	Standard Deviation
SLA	Stereolitography Apparatus
STL	Stereolitography
2D	Two Dimensional
3D	Three Dimensional



The figure illustrates the measurement position of the hex and apex.

1 INTRODUCTION

Restorative dentistry has a long history. Solutions for replacing teeth with prostheses made of gold wire; ox bone or wood has been found in Egypt.[1] The Mayan used inlays of jade and turquoise and even replaced lower incisor teeth with shell. During early times, missing teeth replacement was either made from i.e ivory, teeth, bone and even missing teeth from dead persons. Due to the invention of porcelain, the previous teeth transplantation disappeared.[1] In the beginning feldspar was used in bridges. From the 1950s, glass ceramics was introduced, followed by glass-infiltrated ceramics during 1980s and more recently aluminum oxide, zirconia and other composites has been introduced in dental restorations.[2]

Patients who are partially or fully edentulous live with a serious handicap. Some of them may feel embarrassed in social circumstances, other might have limitations such as difficulties to speak or eat certain things. One patient treated by the Brånemark group, with dental implants in the end of 1960s described the following "*I felt free as never before. And how I ate! Food which I could not chew for twenty years went down like a dream.*".[3]

A patient who undergoes an implant treatment may have several considerations before the surgical event will take place.

When performing an implant treatment of a patient there are important factors to take into consideration. The clinician needs to confirm whether there is enough bone in order to place implants and determine the suitable length and dimension that shall be used. When performing the implant surgery, the clinician needs to ensure whether there are any sensitive anatomical structures in the area. The clinician needs to take into consideration an optimal prosthetic outcome for the connection between the implant and the prosthetic solution. All the factors involved before surgery at the planning stage is normally to utilize information that is conventionally retrieved.

The goal is long-term successful result with the implant in place and the prosthetic solution to be comfortable and function aesthetically as well as for speech and eating.

The innovation and development of dental implant treatment has contributed to predictable results in rehabilitation of patients for the last 40 years. Applying the

original protocol for treatment of fully edentulous and partial cases, successful clinical success rates have been reported.[4-9] The protocols for implant treatment has undergone a development and progress resulting in further improvements, thus allowing dental implants to be used in more challenging treatment situations.

1.1.1 Osseointegration

Oral rehabilitation by aid of osseointegrated titanium implants is one of the most innovative concepts in dental treatment of today. The original protocol for implant treatment was described by Brånemark and co-workers 1969.[4] The protocol described a 2-stage surgical procedure (the implants manufactured in pure titanium including a turned surface), followed by a healing period, and then the abutment was connected to the implant (Fig. 1).

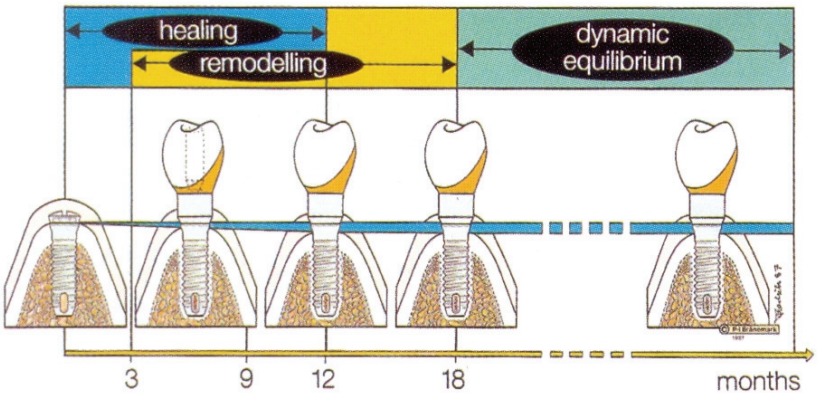


Fig. 1 *"The dynamic relation between the fixture and the jaw bone can be distinguished over time as three partially overlapping periods. During the healing phase new bone is formed close to the immobilized, resting fixture. When the anchoring element is exposed to masticatory forces, the newly formed bone remodels according to the magnitude, direction, and frequency of the applied load. After about 18 months a steady state is achieved, which means a balance is established between the forces acting on the fixture and the remodelling capacities of the anchoring bone."*[10]
Copyright P-I Brånemark

In 1977, the Brånemark group published their experience of 235 edentulous upper (128) and lower (107) jaws and thereby introduced the osseointegration concept. The word osseointegration was coined and could be defined as *"...direct anchorage of an implant by the formation of bony tissue at the bone implant interface as observed at the light microscopic level"*.[11] High predictability applying this treatment concept has been demonstrated in several long-term studies (5-15 years) for edentulous as well as for partially dentate patients.[5, 6, 12-15] Therefore, the implant methodology is based on a scientific platform regarding implant stability and demonstrates predictable long-term clinical success.

Over the years, there has been a re-evaluation of the traditional 2-stage surgical protocol. Schroeder et al.[16-18] demonstrated that it is possible and predictable to acquire proper osseointegration also when applying a 1-stage surgical technique, i.e. the implant pillar is piercing the mucosa and exposed in the oral cavity directly following placement. However, the implants are still subjected to a healing period, similar to that used for the original 2-stage protocol, before being exposed to functional load via a supra-construction. Clinical studies using the 1-stage surgical protocol have reported on successful results when treating edentulous jaws as well as when treating partial dentate jaws.[19-25]

1.1.2 Bone healing process

Observations regarding bone and marrow tissue regeneration have indicated a potential for controlled bone healing in jawbone following careful surgical procedures (Fig. 2).[26]

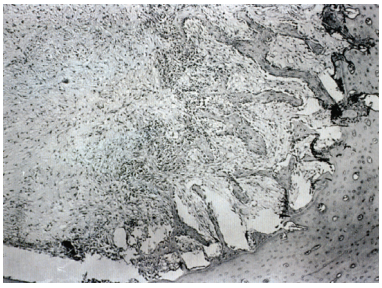


Fig. 2 *"Endosteal bone regeneration in response to ablation of marrow tissue."*[10]
Copyright P-I Brånemark

Furthermore, experimental studies in mice have clearly demonstrated that predictable and long-term integration can be established between a titanium surface and regenerated bone and marrow.[27] Experimental studies regarding *de novo* bone formation at the implant-bone interface have been performed and the authors concluded that *"osseointegration represents a dynamic process both during its establishment and maintenance……with a delicate interplay between resorption…..and bone formation areas during the establishment phase. During the maintenance phase, osseointegration is secured through continuous remodelling and adaptation to function"*[28] (Fig. 3 and 4 A-B).

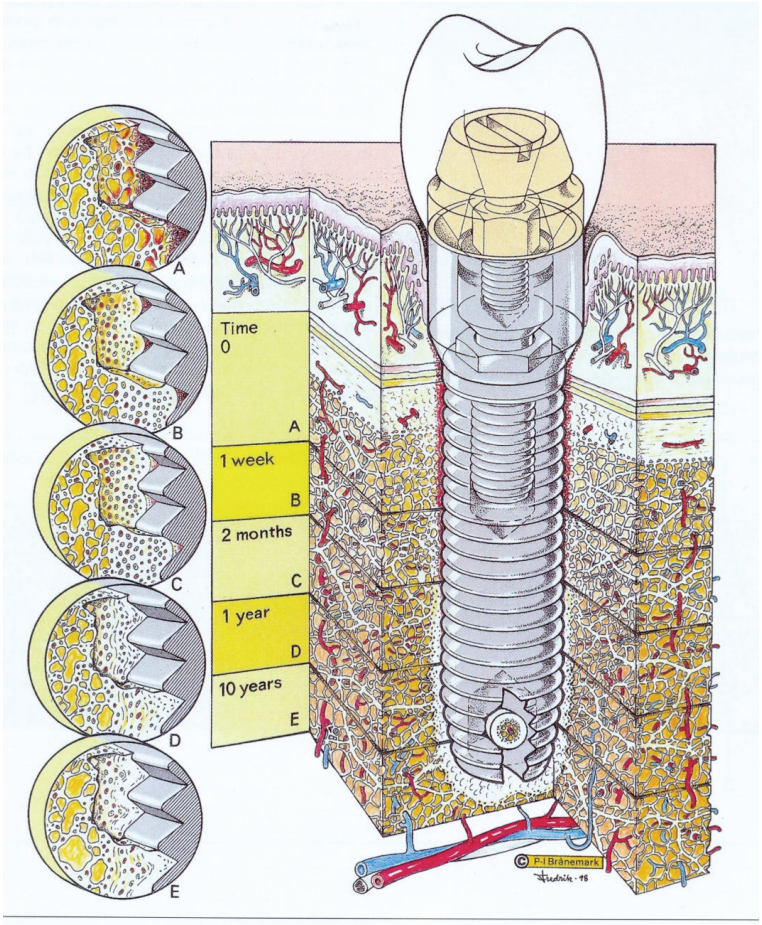


Fig. 3 *"Physiologic evolution of the biology of the interface over time."*[10] Copyright P-I Brånemark

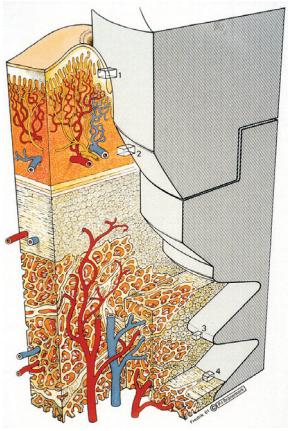


Fig. 4a *"Three-dimensional diagram of the tissue titanium interrelationship showing in overall view of the intact interfacial zone around the osseointegrated fixture."*[10]

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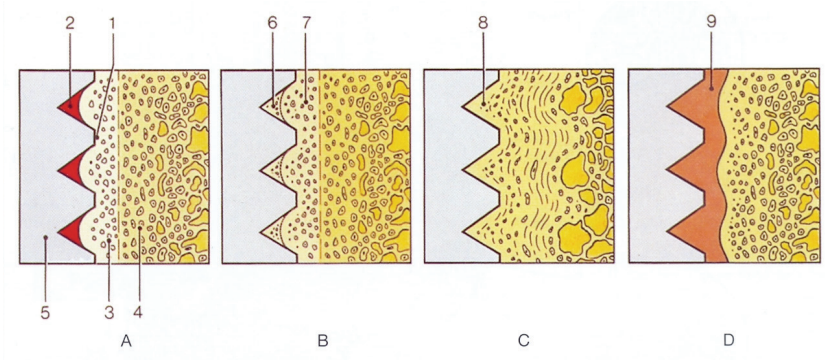

Fig. 4b *"Diagrammatic representation of the biology of osseointegration. A, The threaded bone site cannot be made perfectly congruent to the fixture. The object of making a threaded socket in bone is to provide immobilization immediately after placement and during the initial healing period. The diagram is based on relative dimensions of fixture site. (1) Contact between fixture and bone (immobilization); (2) hematoma in closed cavity, bordered by fixture and bone; (3) bone damaged by unavoidable thermal and mechanical trauma; (4) original undamaged bone; (5) fixture. B, During the unloaded healing period, the hematoma is transformed into new bone through calcus formation. (6) Damaged bone, which also heals, undergoes revascularization, demineralization, and remineralization (7). C, After the initial healing period, vital bone tissue is in close contact with the fixture surface without any other intermediate tissue. Border zone bone (8) remodels in response to the masticatory load applied. D, In unsuccessful cases nonmineralized connective tissue (9), constituting a kind of pseudoarthrosis, forms in the border zone at the fixture. This development can be initiated by excessive preparation trauma, infection, loading too early in the healing period before adequate mineralization and organization of hard tissue has taken place, or supraliminal loading at any time, even many years after*

integration has been established. Once lost osseointegration cannot be reconstituted. Connective tissue can become organized to a certain degree but is not a proper anchoring tissue because of its inadequate mechanical and biologic capacities, resulting in creation of a locus minoris resistentiae."[10] Copyright P-I Brånemark

1.1.3 Loading of implants

When to load dental implants is still a topic of controversy and confusion. However, some proposals were defined at the Implant World Congress consensus meeting in Barcelona 2002.[29] The following terminology was proposed:

Implant Loading

Occlusal Loading: The crown/bridge is in contact with opposing dentition in centric occlusion.

Non-occlusal Loading: The crown/bridge is not in contact in centric occlusion with opposing dentition in natural jaw positions.

Timing of Implant Loading

Delayed Loading: The prosthesis is attached at a second procedure after a conventional healing period of 3-6 months.

Early Loading: The prosthesis is attached at a second procedure, earlier than the conventional healing period of 3-6 months; time of loading should be stated in days/weeks.

Immediate Loading: The prosthesis is attached to the implants the same day the implants are placed.

The clinical outcome of applying the **Early Loading** protocol has been reported to be similar to the traditional 2- and 1-stage protocol, i.e. the implants are allowed to "rest" during the healing period either in a submerged position or piercing the mucosa and exposed in the oral cavity (Fig. 5).[30-32]

Immediate Loading of implants involves a 1-stage surgical installation procedure. An immediately connected implant-supported fixed prostheses (ISFP) is most commonly used for loading of implants. The ISFP will deliver the load to the implants more controlled than when the implants are loaded via a removable prosthesis. Szmukler-Moncler et al.[33] have concluded that one important prerequisite for successful implant

osseointegration is the degree of micromotion, i.e the motion at the bone/implant interface. A micromotion amounting to maximum 50 um will allow for proper osseointegration also when using turned surfaces. However, a somewhat rough implant surface can accept a higher micromotion threshold (up to 100-150 um) at the bone/implant interface. In other words, implants installed according to the 1-stage surgical procedure have to be loaded via an ISFP in order control the load and not to increase the risk for implant failures. One reason for this statement could be that the ISFP will connect all the implants rigidly to each other and thus limit the degree of micromotion.[33]

The use of the Immediate Loading protocol is to day increasing. Experimental and clinical studies on immediate loaded implants have histologically demonstrated a bone-to-implant healing pattern comparable to that of conventionally loaded ones.[34-37] Furthermore, the clinical outcome of immediately loaded implants has been proven to function at a most acceptable level.[38-49]

During the last decade different systems (computer-guided virtual treatment planning) have been used to optimize the position and to facilitate the placement of dental implants (e.g. NobelGuide – Nobel Biocare AB, Sweden; Navigator – Biomet3i, USA; Facilitate – AstraTech AB, Sweden, Simplant – Materialise Dental NV, Belgium). Such a treatment approach has also been applied for immediate loading of the implants (NobelGuide – Nobel Biocare). The patients will thus be supplied with a provisional or final ISFP within an hour following implant installation ("Teeth-in-an-Hour"; i.e. (digitally planned, immediately loaded implants with prefabricated prostheses).[50-54]

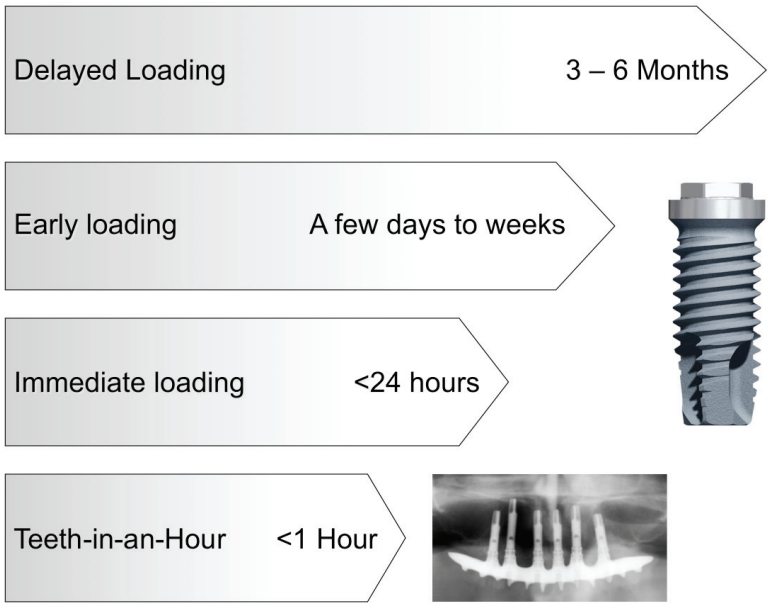

Fig. 5. Time schedule regarding delivery of the prosthetic solution after surgery. Delayed loading, early loading and immediate loading,[29] Teeth-in-an-Hour.[55]

1.1.4 Mental navigation

Van Steenberghe et al.[56] has previously described the wording *mental navigation*, which means that the surgeon has access to the planned position of the implant on a computer monitor during the surgery, where the clinician manually has to transfer the virtually planned implant position to the actual position in the patient during surgery. The conventional placements of implants are demanding for the performing clinician. It relies on a very god spatial ability to transfer a large amount of information from different sources into a reliable three-dimensional (3D) model that can be mentally navigated in. Since the overall workflow picture is compiled in the brain of the surgeon, the accuracy is limited to the individual capability. This could result in a limited plan utilizing e.g. intraoral, panoramic, Computed Tomography (CT) or Cone Beam Computed Tomography (CBCT) radiographic information. The information is collected and evaluated before the actual surgery starts. The clinician does not know the bone anatomy until the mucoperiostal flap is raised. During surgery, when the surgeons get further visual information, decisions can be altered from the initial plan, in order to adjust the selection of the final position of the implant, as well as the length and dimension of the implant.

1.1.5 Imaging technology

During the last two decades, a revolution has taken place in retrieving digital information about geometry from different structures in human objects. Data from CT/CBCT examinations can serve as measurement data for building a model of structures, which can be used in advance of surgery to determine the most optimal position for the placed implants, with considerations to the anatomy of the patient (Fig. 6).

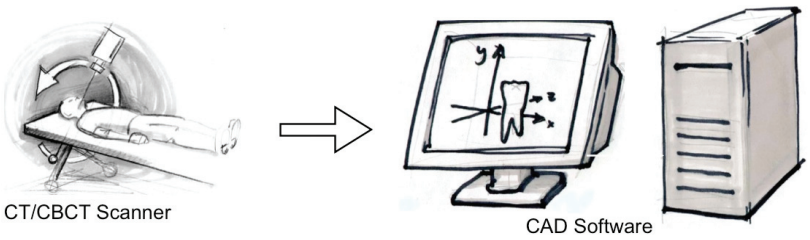

Fig. 6. Import measurement data from scan of patient to virtual environment.

The CT technology is commonly used within the medical field to examine patients. The data obtained from CT scanners are collected in slices generated through an X-ray source that rotates around the patient. The two-dimensional (2D) cross sectional images can be stacked together creating a 3D volume. The thickness of the slices can be determined and selected in advance of the scanning procedure.
When the patient is scanned, the data is exported to a format called DICOM (Digital Imaging and Communications in Medicine). The DICOM data contains a series of sequential, CT "slices" for each individual patient. Each "slice" contains a 2D array of small 3D volume elements or "voxels." These slices can visualize the internal structure of a patient across a 3D volume. Each "voxel" in a CT slice has a corresponding "grey value," which is a measurement of the density of the tissue and is quantified in Hounsfield units. For example, air has a Hounsfield value of -1000, water has a value of 0, and cortical bone has a Hounsfield value of around 1000 or more. Negative Hounsfield unit values, such as air, are typically shaded black in CT data, while higher positive Hounsfield unit values, such as bone, are shaded white, with intermediate gray values for tissues with intermediate density (e.g. gums, tendons, etc.). The grey value and voxels contains information that can identify anatomical structures and be

contoured using segmentation algorithms to create a 3D structure in software. As an example, segmentation can be used to isolate bone tissue from other tissues by labeling all voxels above a particular Hounsfield unit threshold value as bone. As a result of this segmentation step, a 3D segmentation classified as “bone” is created. After the segmentation step is performed and a 3D model of the object is created, the data can be exported in a file format to be used in a Computer Aided Design (CAD) environment. The CT is considered to represent the patient anatomy geometrically accurate.[57]
CT scanners are still expensive and mostly used at hospitals with a limited access for referring dentists.
The introduction of CBCT has introduced a new type of scanner with a lower price to the dental field. It also has contributed to a lower dosage when examining patients compared to a CT scanner.[58, 59] The CBCT technology was introduced in the 1990’s in the maxillofacial field.[60, 61] In a CBCT scanner, the X-ray beam contains the shape of a cone. The volume of interest (VOI) is scanned during the rotation of the tube around the patient with a detector on a fix axis. The patient is positioned on a bench, laying down or sitting in a chair without movement during the scanning procedure. The NewTom 9000 was one of the first available CBCT scanners on the market (QR s.r.l, Verona, Italy.) with a possibility to scan an area of 13 centimeters in a diameter and 13 cm in height. The scan time of the NewTom 9000 averages to a mean of 72 seconds. The raw data of the examination of the patient can be exported from the software in the computer connected to the NewTom9000 in DICOM format. The accuracy of the NewTom 9000 has been evaluated as appropriate to be used for image-guided surgeries.[57, 62]

1.1.6 CAD/CAM dental history

Software programs developed for industrial design work has undergone a tremendous development. The first generations of CAD programs were able to handle normal drawing in 2D. The general development within computers, especially computer graphic and the fast decrease of price of computers has led to an almost explosive development in medical imaging. Representation in 3D calculations from CT-data, which just a few years ago required advanced workstations and very expensive programs, can now be done with common personal computers.

Another general development is the possibility to transfer 3D models generated in computers to the real world with aid of Computer Aided Manufacturing (CAM).
A pioneer in CAD/CAM within dentistry was François Duret, creating a visionary system, with the possibility to produce copings in resin material.[63]
The oldest commercially available method to transfer a dental model into a computer was to calculate tooth position from the surface of a 3D model in 2D CAD software and use the information to guide a numerical controlled machine (milling machine). The method was developed by Dr. Matts Andersson during the beginning of the 1980's to be able to introduce titanium crowns as a biocompatible material for restorations of teeth.[64] The first step was to copy the patient's individual anatomy of the preparation from a cast in a copy milling machine and later use a spark erosion method. The development progressed to include ceramic crowns in alumina oxide with a press technique combined with a milling process.

1.1.7 CAD/CAM

Development of imaging technology and CAD has made it possible to transfer measurement data from a CT/CBCT scan, into a full virtual 3D model of e.g. a patient. The anatomy of the patient obtained from the scan can be positioned within a coordinate system in e.g. virtual planning software. Objects such as virtual implants and abutments can be positioned in regards to the anatomy of the patient in such software, and then exported to CAD software. More and more sophisticated software programs have been developed where different operations can be achieved, such as adding and removing objects in the CAD environment. One example is boolean[65] operations, where support structures and objects such as cylinders or other tools can be e.g. subtracted or added in 3D from or to the models, either whether it is the patient's anatomy or the virtual surgical template in advance of production.
Parallel with the development of creating 3D models in the CAD environment and software development, there has also been a rapid development building physical models from the digital data CAM. One is a numerical controlled machine for milling the shape obtained from the digital 3D model. Another CAM technology is rapid prototyping, where 3D models can be produced, either with a 3D printer or with other means such as SLA (Stereo Lithographic Apparatus). The investigated system within this project is utilizing a surgical template which is ultimately produced by means of rapid prototyping with SLA technique. SLA is a method where the CAD computer

sends information to a CAM production unit, where a bath with resin, such as epoxy is present. A UV laser light is used to cure and solidify the pattern in slices using data from the 3D digital file. Each layer is solidified from the 3D model, which is positioned on an elevator platform that descends by a single layer thickness. As the elevator platform descends, the next layer is cured and eventually a 3D model is created from the digital file.[66, 67]

The possibility to build accurate models of a structure in the human body together with the possibility to produce devices from digital data, makes it possible to transfer a virtual planning made in the computer to the patient.[55, 66-68] When the 3D model is manufactured, such as a surgical template, other physical components can be added as well, e.g., steel sleeves to be used for guiding the drills and implants during surgery.[55]

1.1.8 CAD/CAM-guided implant surgery – the investigated system

Lately, there has been a development of 3-dimensional (3-D) planning programs to aid surgeons in accurate placement of implants in regards to anatomic and prosthetic needs. The 3D planning programs has made it possible to mimic the anatomy of the patient's jawbone and prosthesis in 3D software. The investigated system, NobelGuide, with the ability to virtually plan implants and perform guided surgery has been developed based on 3D CAD/CAM technology.

During the development phase, a cadaver study was performed in order to evaluate the accuracy in the end of 1990´s, which then was published in 2002.[68] Furthermore, a multicentre study started in 2001 with three surgical teams from Leuven, Zurich and Luleå in order to evaluate the guided surgery concept. The results were presented in a paper 2005.[55] The investigated system has been evaluated in several clinical reports and studies.[50-55, 69, 70]

Since flapless guided surgery was introduced in 2005, further demands have increased in order to achieve a more accurate plan before surgery.[55]

1.1.8.1 Summary of steps involved in the investigated system – NobelGuide

Several steps are involved in the process of creating a custom surgical template. Firstly, a radiographic guide is created. Secondly, CT scans of the patient and the radiographic guide are taken. Thirdly, the CT scan data is segmented, matched and saved as 3D models in a file. Then the virtual planning software is used to plan coordinates for guide sleeves, implants and anchor pins, to be used during the implant placement procedure. Finally, a surgical template with holes and stainless steel drill sleeves for surgical planning is manufactured and used during surgery (Fig. 7).

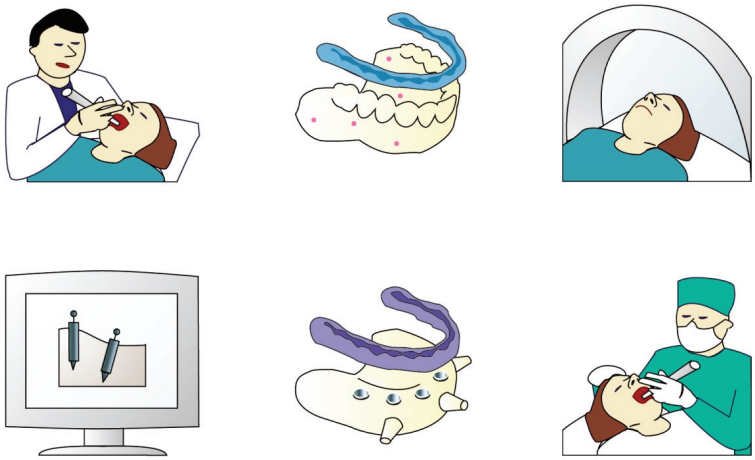

Fig. 7. Overview of the surgical procedure. From left to right: patient examination; radiographic guide and index; CT/CBCT scan; virtual planning; surgical template and index; and clinical procedures. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

Today there are CAD/CAM guided systems available for treating edentulous patients.[55, 71, 72] Each patient has a unique anatomy. In order to proceed with a safe and accurate implant treatment it is utmost important to evaluate the accuracy of CAD/CAM-guided surgery.

1.1.9 Guided surgery accuracy – different systems

Schneider et al.[73] reviewed published articles regarding accuracy of implants placed with a surgical template, reported until 2009. Five different systems were reviewed, Simplant, SurgiGuide, NobelGuide, Stent CAD and Med3D. The accuracy studies had been performed with bone, teeth, model and mucosa supported surgical templates. Seven out of eight studies relied on rapid prototyping while one of them was utilizing a dental laboratory. The article by Schneider et al.[73] included four cadaver studies, three human studies and one model study. The number of implants evaluated in the studies varied from 12 to 50 implants. For all studies, the mean accuracy for the entry point was reported to be 1.07 mm (95% CI: 0.76-1.22 mm), (maximum error of 4.7 mm), for the apex 1.63 mm (95% CI: 1.26-2mm), (maximum error of 7.1 mm), and 5.26 degrees for the angulation (95% CI: 3.94-6.58 degrees) (maximum error of 21 degrees). The authors concluded that they did not find any statistical significant difference between the cadaver, human and model study for the horizontal deviation at the entry point nor apex.[73] They did neither find any statistically significant difference regarding the study design or kind of template support. The authors states that there is limited information to compare the differences between mucosa supported templates compared to other techniques as there were only one mucosa based accuracy study available (Ozan et al 2009).[71, 73] In the study by Ozan and co-workers[71], they found that tooth supported SLA surgical guides showed a more accurate result compared to bone or mucosa supported SLA surgical guides. In the review article by Schneider et al.[73], the authors pointed out the difficulty that the directional deviation is reported inconsistent among the studies evaluated.

Other difficulties for comparison are the different types of matching and measurement techniques used in some of the published accuracy studies, different implant systems, as well as different guided surgical systems and type of surgical guides.[72, 74-81]

In a review article, Vercruyssen et al.[82], it was stated "*Deviations may reflect the sum of all errors, occurring from imaging to transformation to hardware, such as the drill guide, to the improper positioning of the latter during surgery. Thus all errors, although seldom, may add to each other*.".[82] There are several steps included in the CAD/CAM guided surgical systems, from examining the patient to the surgical event. The errors can occur at different steps, such as when creating the radiographic guide, the settings used during the CT scan of the patient, the positioning of the radiographic

guide or the surgical template in the patients mouth during the CT scan of the patient or surgery.

1.1.10 Computer assisted surgery

Developments within implant therapy, such as 3D implant planning in combination with the possibility of manufacturing of a surgical template, have been presented recently.

In order to establish appropriate definitions, it was decided to discuss which terms to be used for applications of computer technology in implant surgery, at a consensus meeting in 2009.[83] Two types of definitions were stated:

- *"Computer-guided (static) surgery: The use of a static surgical template that reproduces the virtual implant position directly from computerized tomographic data and does now allow for intraoperative modification of the implant position."*
- *Computer-navigated (dynamic) surgery: The use of a surgical navigation system that reproduces the virtual implant position directly from computerized tomographic data and allows for intraoperative changes in implant position."*[83]

The studies performed within this thesis have been performed with computer-guided (static) surgery, which is equivalent to CAD/CAM-guided dental implant surgery.

In a computer-assisted accuracy review study by Jung et al.[84], in total 19 accuracy studies were included. Seven of the accuracy studies were performed with computer-guided (static) surgery and 12 with computer-navigated (dynamic) surgery. Eleven studies were performed on models, four on human cadavers and the last four as clinical studies with totally 45 patients included. For all implants, the mean value at the entry point (hex) was 0.74 (95% CI:0.58-0.90) mm (max 4.5 mm), for the apex 0.85 (95% CI:0.72-0.99) mm (max 7.1) mm. For systems using surgical guides (static), the mean value for the entry point (hex) was 1.12 (95% CI:0.82-1.42) mm (max 4.5 mm) and for the apex 1.2 (95% CI:0.87-1.52) mm (max 7.1 mm). For the navigation systems (dynamic) the mean value for the entry point (hex) was 0.62 (95% CI:0.43-0.81) mm (max 3.4 mm) and for the apex 0.68 (95% CI:0.55-0.80) mm (max 3.5 mm). *"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.".[84] The implants positioned in humans presented a higher deviation for the entry point and apex when comparing to cadaver studies where they had used implants or drills as comparison. The authors also stated that the mean deviation was significantly higher in studies where the implant position was measured compared to studies where the drill holes position was measured.

CAD/CAM-guided template surgery combines traditional surgical skills with new techniques to place implants.[85-88] In other words, the rehabilitation is prepared and planned with the assistance of both physical and virtual models.[86, 89] Then the implants can be placed with a CAD/CAM-guided surgical template.[90-92]

The accuracy studies within this project are performed with (static) templates.

1.1.11 Virtual variation simulation

The variation simulation software was initially introduced to evaluate variation within mass production, with focus on the aerospace and automotive industries.[93-97]

The complete manufacturing and mounting processes are mapped, and the tolerances are then used in the virtual simulation software to adjust parameters and enhance the tolerances during the production process. The same method and software have been used to map the total rehabilitation and manufacturing process of the NobelGuide CAD/CAM template for guided surgery, and the definitive implant placements were predicted by using the Monte Carlo iteration method. The Monte Carlo method is often used when simulating physical and mathematical systems. It is a method for iteratively analyzing a deterministic model by randomly generating numbers for all input parameters according to predefined distributions.[98] Then distributions for the output parameters (critical product dimensions) can be generated. The virtual variation simulation method captures non-linearities and allows any type of distribution of input parameter variation and graphical visualization of results. Earlier studies within virtual variation simulation have shown the most sensitive parameter to be the surgery, which contributed to the eventual deviations.[98] Geometric variation in critical product dimensions and features results from a number of different sources. Size and for

variations in the geometry of the individual parts originate from the manufacturing process used, which varies over time. The positioning method used within variation simulation is an orthogonal 3-2-1 system, a common method for assembling parts. The system contains locating points which lock the object to control all degrees of freedom regarding movement around each locating point, previously described by Kero et al. 2007.[98]

2 AIMS

2.1 GENERAL AIM

The general aim of this project was to evaluate the accuracy between virtually planned and actually placed dental implants using a surgical guide.

2.2 SPECIFIC AIMS OF STUDIES

2.2.1 Study I:

To compare the deviation between the position of virtually planned implants and the position of implants placed with a CAD/CAM-guided surgical template in the mandible and the maxilla in human cadavers.

2.2.2 Study II:

To perform virtual variation simulations on virtually planned implant placements and to compare them with corresponding results from actual surgeries performed on human cadavers in a previous study.

2.2.3 Study III:

To verify if any variation exists between virtually planned implants' position using a computer, compared with the subsequently clinically placed implants with the aid of a surgical template in the mandible and the maxilla.

2.2.4 Study IV:

To evaluate the deviation between the results obtained from five different surgeons, from CAD/CAM guided implant surgery on plastic models.

3 MATERIAL AND METHODS

3.1 MATERIAL & INCLUSION CRITERIA

3.1.1 Study I:

Seventeen completely edentulous human cadavers were included, 10 maxillae and 7 mandibles. The experimental material should be representative of the clinical situation; thus, each jaw was intact and completely edentulous with a sufficient bone volume in order to place implants. Brånemark Groovy RP implants, in total 145 implants, were planned in the software program and placed with the aid of a CAD/CAM-guided surgical template.

3.1.2 Study II:

Seventeen computer-aided plans obtained as CAD files from Study I was used for the virtual variation simulation of surgeries. In total 17 virtual CAD files of human cadaver jaws and 145 virtually planned implants were used. For each virtual planned CAD file obtained from Study I, 10,000 virtual variation simulation surgeries were performed, resulting in 1,450,000 implant placements in the simulation software.

3.1.3 Study III:

A total number of 25 edentate jaws were treated with the aid of a surgical template. In total, 139 Brånemark System ® MkIII TiUnte RP (Regular Platform) implants were inserted and evaluated. Fifty implants were inserted in the mandible and 89 in the maxilla.

- In advance of surgery the patients were examined to ensure a sufficient amount of bone, to be able to place at least five implants in the maxilla and four implants in the mandible.
- The minimum length of implants was 10 mm for placement in the bone.
- The patient had to fulfill health requirements for implant placement
- The patients had to be able to open the mouth at least 50 mm in the anterior part between the alveolar crests.

3.1.4 Study IV:

In total, 25 duplicate plastic maxilla jaw models, produced in spongious plastic material, were operated using a surgical template. The models had sufficient room for placing at least six implants in each jaw model, which originally was intended for surgical training. Five surgeons participated in the study, and each surgeon received five jaw models and six implants to place in each plastic jaw model. In total 150 Brånemark System ® MK III Groovy RP ∅3.75x13 mm implants were placed.

3.2 ETHICAL CONSIDERATIONS:

In Study I & II the use of human-derived materials was approved by the Laboratory of Anatomy Department, University Paris Descartes, according to the regulations in France.

Study III was approved by the Ethics committee at the Karolinska University Hospital, Huddinge Sweden (Dnr: 278/03), and the Swedish Radiation Safety Authority. All the patients were informed of the study protocol and signed an informed consent form.

3.3 METHODS

In Study I, III and IV the subjects underwent implant surgery using NobelGuide surgical templates.

In Study II, the virtually planned 3D reconstructions from software were exported as CAD files obtained from Study I, and virtual surgeries were performed in virtual variation simulation software.

The clinical procedure for NobelGuide and matching and calculation is summarized in Fig. 8.

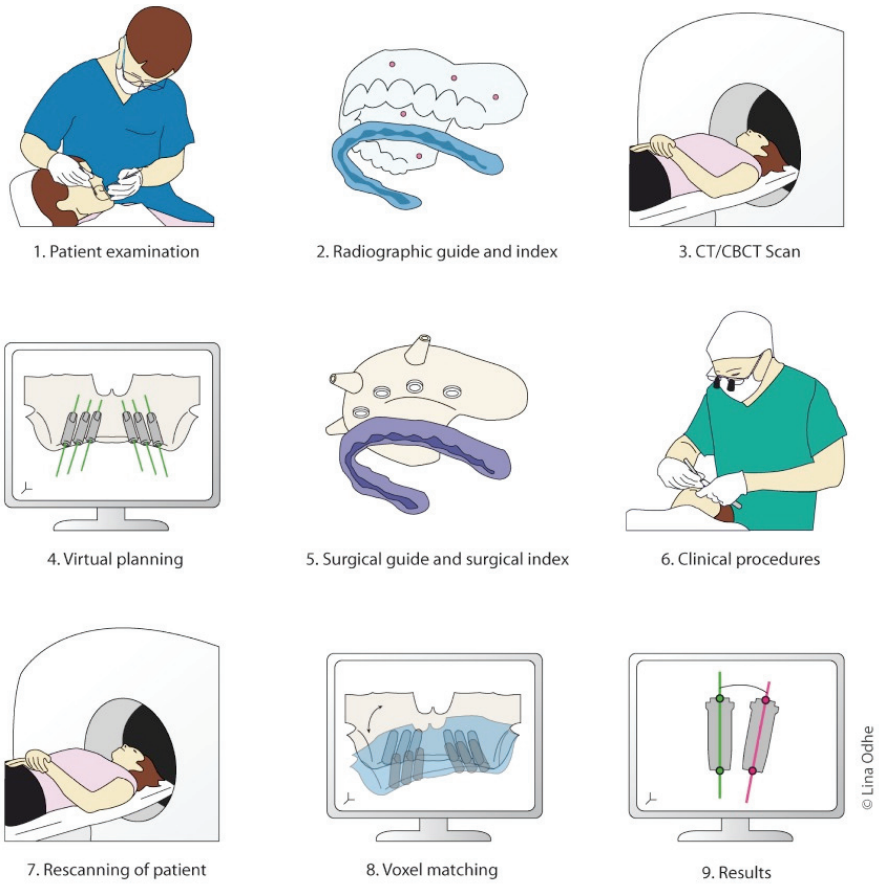

Fig. 8. Illustration of the different steps during the surgical procedure.

3.3.1 Brief description: NobelGuide protocol, matching & calculation

3.3.1.1 Creation of the Radiographic guide & index

First a radiographic guide was custom created for each patient. The dental technician or prosthodontist ensured that the radiographic guide properly was adjusted to the patient's anatomy. The radiographic guide included six to nine inserted radio-opaque markers in gutta-percha with a diameter of 1-1.5 mm and a depth of 0.5 mm. Then a radiographic index was created in the patient's mouth, by the clinician in order to register the correct position between the patient's upper and lower jaw (Fig. 9).

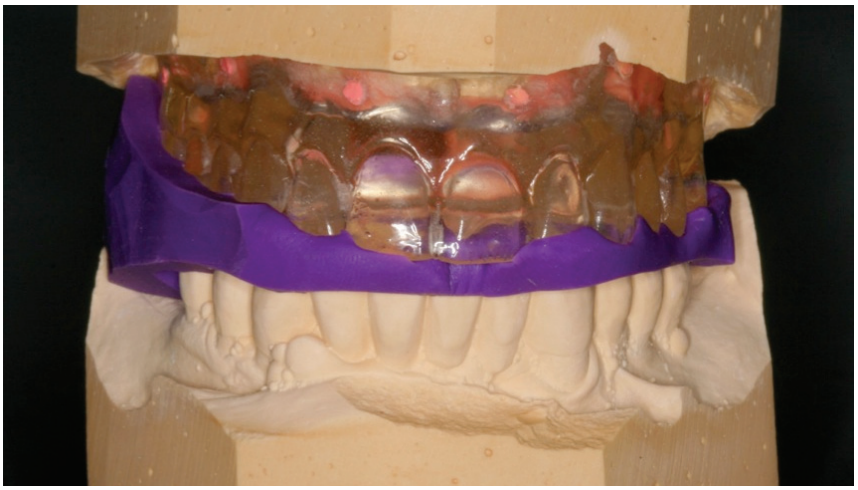

Fig. 9. Radiographic guide mounted and registered in articulator with radiographic index in position.

3.3.1.2 CT/CBCT scans

After the radiographic guide was created, CT scans of the patient/subject and the radiographic guide were performed. First, the patient was scanned wearing a radiographic guide and the radiographic index. For this scan, the radiographic guide was first positioned in the mouth of the patient. The radiographic index was then positioned in the patient's mouth, thereafter the patient occluded into the pre-registered position.

In the second scan, the radiographic guide was scanned separately. The material used for the radiographic guide was based on non radio-opaque acrylic. The original CT scans of the patient and the radiographic guide were exported on a CD by the

radiologist, in a file format referred to as DICOM (Digital Imaging and Communications in Medicine).

3.3.1.3 CT conversion

After the CT scans of the patient and radiographic guide were complete, the resulting CT DICOM data were transferred into the NobelGuide software, and the CT conversion software could convert the data into 3D reconstructions.
The DICOM files were converted into a file format, which included CT grey value data of the patient's jawbone and 3D reconstructions of the radiographic guide and jawbone. The DICOM data was converted in the CT-Converter software into a segmented 3D model of the bone and radiographic guide, which were matched together in the software utilizing the gutta-percha, radio-opaque markers present in the radiographic guide.

3.3.1.4 Virtual planning and CAD

During planning, the clinician could specify coordinates and locations of the implants and anchor pins in order to plan a surgical template to be used during surgery. This was carried out using the Procera Software Planning Program – Surgical software module in the NobelGuide software.
Using these reconstructions, the clinician could determine the position of the drill sleeves in advance by specifying coordinates for the implants in the planning software. The clinician also considered how to plan the location of horizontal anchor pins, which are anchoring the surgical template during the surgical session. During planning, the clinician specified coordinates for the location and depth of these anchor pins (Fig. 10).

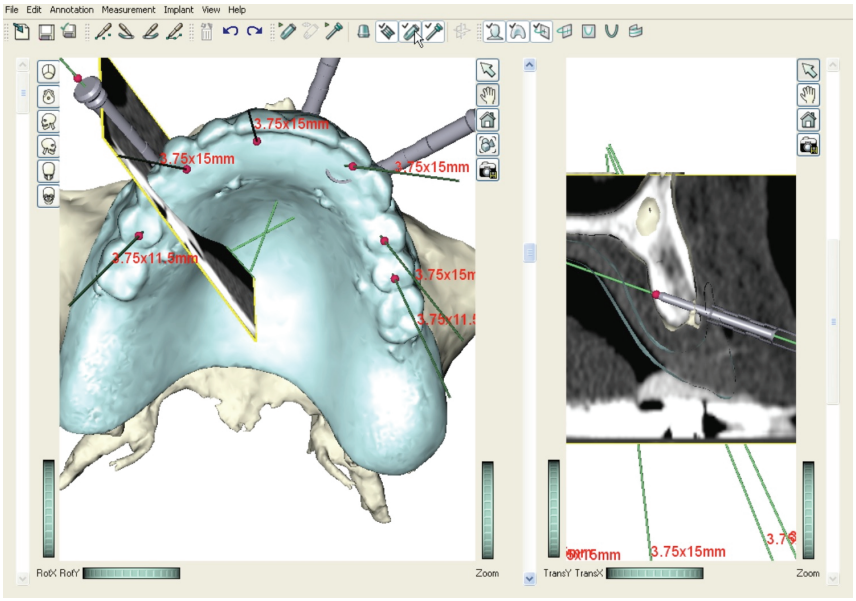

Fig. 10. Virtual planning performed in software to specify the positions for the implants, anchor pins and sleeves in advance of surgery.

When the clinician had completed the virtual planning by specifying the coordinates of the implants and anchor pins, the information was saved.
The planned coordinates were then exported together with the product information to the Procera CADDesign software. A 3D object was generated and visualized as a surgical template after planning has been completed (Fig. 11).
During the ordering process in the NobelGuide software, the clinician could order the surgical template and necessary tools for the surgery.

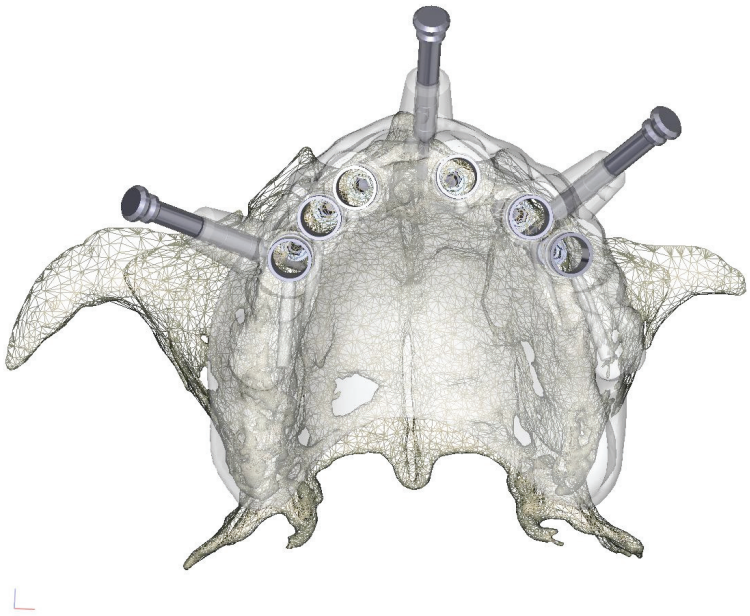

Fig. 11. Virtual CAD surgical template visualized in CAD software with implants, sleeves, anchor pins and jawbone.

3.3.1.5 Surgical Template and surgical index

During the production stage, a 3D object of the surgical template was ultimately produced (Fig. 12). The surgical template included sleeves to provide the guiding function to the clinician for the use of drills and placement of implants during surgery. A surgical index was created in the articulator, which filled the space between the surgical template and the plaster model of the opposing jaw (Fig. 13).

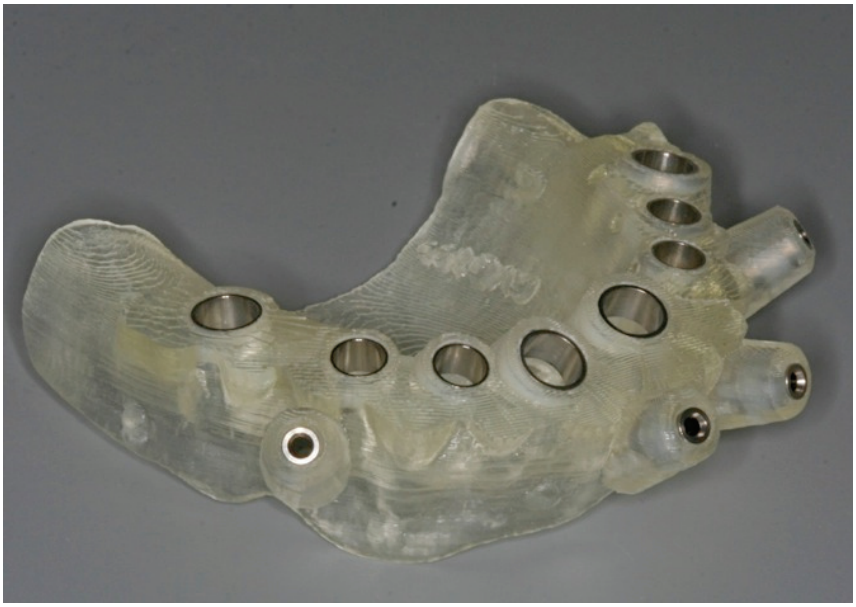

Fig. 12. NobelGuide, CAM produced surgical template.

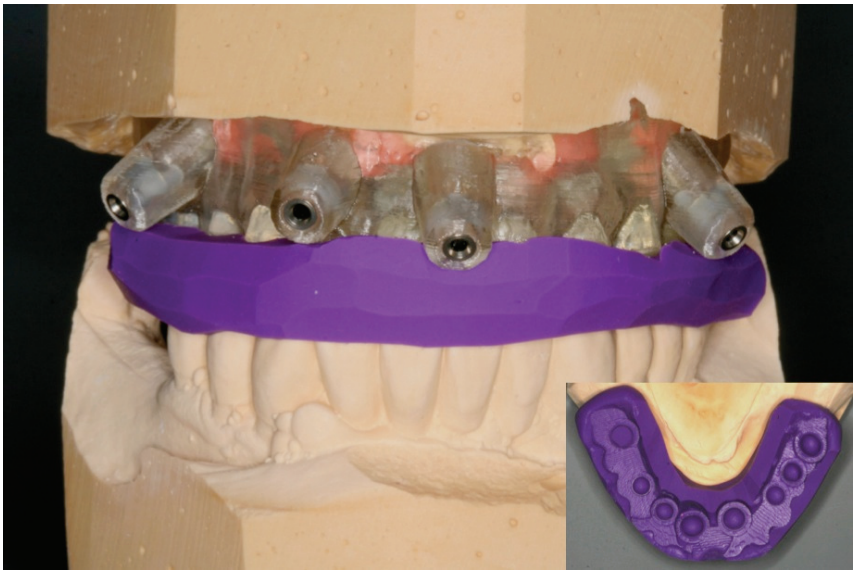

Fig. 13. Surgical index is created to register position between the opposing jaw and surgical template. Small picture shows the side of the surgical index corresponding to surgical template.

3.3.1.6 Surgery

Using the surgical template and the surgical index, the surgical session could be performed, and dental implants placed in their predetermined positions. To carry out this surgery, the surgical template was placed onto the patient's residual ridge. The surgical index was attached to the surgical template, and the patient occluded.
In order to keep the registered position of the surgical template, anchor pins were added through drill sleeves that had a pre-determined position from the planning software. The anchor pins were used to prevent movement of the template during surgery, and help to secure the template onto the residual ridge. Then the surgical index was removed.
Once the template had been secured against the patient's jaw, implant surgery could begin. Using the drill sleeves as a reference, holes were drilled through the drill sleeves, passing the soft tissue, to a predefined position in the jaw bone according to the treatment plan of the sleeves, thus enabling the installation of the dental implants (Fig. 14).

Fig. 14. Surgical template in position, secured with anchor pins. The most posterior implant is placed through the metal sleeve, with aid of the implant mount that has guiding capabilities.

Once installed, these implants could support an artificial prosthesis, such as a bridge, to replace the patient's missing teeth. Several authors have described the treatment procedure in detail.[50, 51, 55, 69, 70]

3.3.1.7 Matching and calculation

The postoperative CT scan was matched against the preoperative CT scan using a 3D voxel-based matching method, previously described by Maes et al.[99]. The postoperative data were registered and aligned to the preoperative data with help of calculation of mutual information between the corresponding voxels in the two datasets and into one coordinate system. The voxel-based software searched for the corresponding gray values between the 2 data sets and aligned them. Then, the implants from the postoperative scan were segmented from the data set and the position and orientation of the clinically placed implants position were compared with the virtually planned position of the implants. Linear and angular deviations between the actually placed and virtually planned implants position were analyzed in 3D. The apex refers to the tip of the implant and the hex refers to the center of the prosthetic connection of the implant (Fig. 15). The shortest distance in 3D between the virtually planned and actual implant position was measured at the center of the apex and the center of the hex of each implant (Fig. 16). The angular deviation between the main axes of the planned and actual implant positions was calculated as well as the depth deviation in the software program (Fig. 16).

The matching and calculation was performed in three-dimension by a software, developed at the Katholic University of Leuven, Belgium.[99] For Study III and IV, updated software were used (NobelGuide Validation 2.0.0.4, Nobel Biocare AB, Gothenburg, Sweden).

The results were then exported to an Excel sheet containing the pre- and postoperative implants position coordinates, as well as the deviation results for each virtually planned implant and actually placed implant, from each case. During the export, a file was saved containing the preoperative virtual planned implants position and postoperative implants position (Fig. 17).

The voxel matching and calculation of the deviation has been previously described by several authors.[68, 77, 99-101] The results were collected together in an Excel sheet and provided to a statistician.

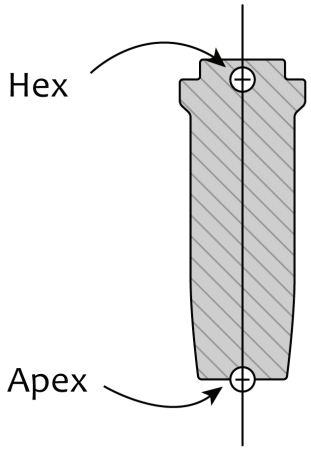

Fig. 15. The figure illustrates the measurement position of the hex and apex.

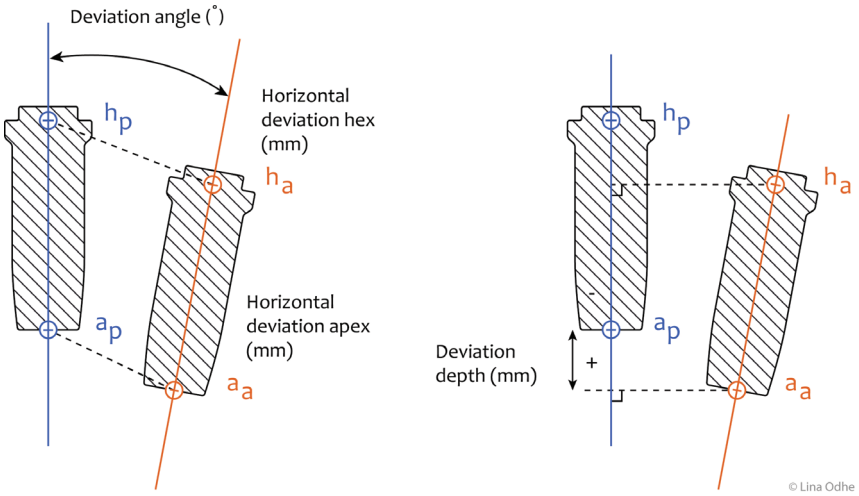

Fig. 16. (Left) deviation calculation of the hex, apex and the angle. (Right) deviation calculation of the depth. Both represents calculation between virtually planned implant and implant placed after surgery. (hp=hex planned, ap=apex planned, ha=hex actual, aa=apex actual)

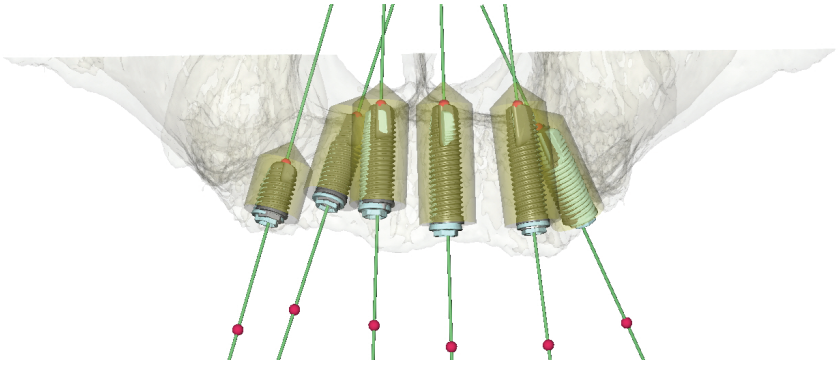

Fig. 17. Preoperative virtually planned implants and postoperative implants position results, after matching procedure, visualized in software (Blue implants=actually placed implants after surgery, grey implants=virtually planned implants) (translucent, yellow security zone is attached to virtual implant).

3.3.2 Study I

3.3.2.1 Operators

The study was performed in collaboration with the University of Paris Descartes at the anatomy department. Two different experienced prosthodontists performed the surgeries by means of NobelGuide.

3.3.2.2 Preparation of radiographic guide

First, a radiographic guide was fabricated by a dental technician that recorded the soft tissue and the future occlusal scheme containing 6-10 gutta-percha spherical markers. Second, a radiographic index was produced in advance of the CT scan.

3.3.2.3 CT scan

All subjects were scanned with a CT scanner (SOMATOM Sensation 10; Siemens AG, Erlangen, Germany). The radiographic guide was positioned onto the edentulous residual ridge together with the radiographic index. Rubber bands were used in order to fixate the jaws. The CT scans were performed using a 0-degree gantry tilt, 120kV, 80 mAs, a slice width of 0.75 mm, and a reconstruction increment of 0.5mm. A second CT

scan was performed of the radiographic guide alone using the same settings as in the first scan. The data was exported electronically.

3.3.2.4 Segmentation and matching

The DICOM files obtained from the radiologist were loaded into the software's CT scan file converter application and the files for the bone and prosthesis were segmented to 3D models and matched together by means of the gutta-percha markers found in software. A single file was created containing a 3D file of the matched bone and radiographic guide.

3.3.2.5 Virtual planning

The virtual plan of each case was performed in order to maximize the number of implants in the study to be compared in each jaw by the two clinicians. The virtual plan was exported to the Procera CAD design software (Procera Software Clinical Design Premium, version 1.5; Nobel Biocare AB). A virtual surgical template was created by means of rapid prototyping and necessary drills, implants and surgical relevant components to be needed were ordered.

3.3.2.6 Surgery

All implants were placed in the cadaver jaws with a CAD/CAM-guided surgical template according to the treatment plan. The placement of the surgical template onto the residual ridge was done using visual guidance. The surgical template that is produced in a transparent material was used to visualize the contact between the soft tissue with the intaglio surface of the surgical template, and manual pressure was used while positioning the anchor pins. The drilling sequence and implant placement simulated the actual clinical situation. Template abutments were used according to the treatment protocol in order to secure the position of the surgical template. Standard components were used during the surgical procedure.
Immediately after surgery, a CT scan of each jaw was performed with the same settings used for the preoperative scans. For further details see 3.3.1.6.

3.3.2.7 Matching and calculation

The matching and calculation was performed by a PhD student at the Section for Image and Functional Odontology, Department of Medicine, Karolinska Institute, Huddinge, Sweden. For further details see 3.3.1.7.

3.3.2.8 Statistics

Statistical calculations were performed using statistical software (SAS Enterprise 4; SAS Institute, Inc, Cary, NC) Calculations were further reproduced using a second statistical program (Statistica 7.0; StatSoft, Inc, Tulsa, Okla) to verify results. The deviation for the apex, hex, translation deviation[102] and angle deviation were log (e) transformed to have approximately normal distributed data for use in the statistical analyses. To test for deviation equal to zero, a 1-sample t test was used. Deviations were summarized using median, minimum, maximum, mean and standard deviation and the corresponding 95% confidence interval. Differences between the mandible and maxilla were tested using the 2-sample t test. All tests were 2-sided, and P=<.05 was considered as statistically significant.

3.3.3 Study II

3.3.3.1 Operators

A PhD student conducted all virtual surgeries in software at the Department of Product and Production Development, Chalmers University of Technology.

3.3.3.2 Collecting of data

All virtual plans performed in Study I was exported as CAD files in stereolitography (STL) format. The included 3D objects as STL files for each case included 3D models of the jaw bone, virtual surgical template, implants, sleeves for implants, sleeves for anchor pins.

3.3.3.3 Virtual variation simulation surgeries

The data from the 17 cadaver surgeries from Study I were simulated with virtual variation simulation software (RD&T; RD&T Technology AB) developed at the University of Chalmers in Gothenburg. One hundred and forty-five implant placements

were performed with the aid of virtual variation simulation software. Each surgery was simulated 10.000 times; therefore, 170.000 surgeries and 1.450.000 implant placements were analyzed. The virtual variation simulation was performed by simulating actual surgery. Critical measures were defined at the apex of each implant in the bone and at the center of the hex, which later connected to the fixed complete denture. The simulation used in the study included calculations of expected deviations in critical dimensions as well as visualizations of virtual bone, surgical CAD/CAM template guides, anchor pins and implants. The final deviation is a sum of all errors that is included during all steps during the treatment procedure (Fig. 18).

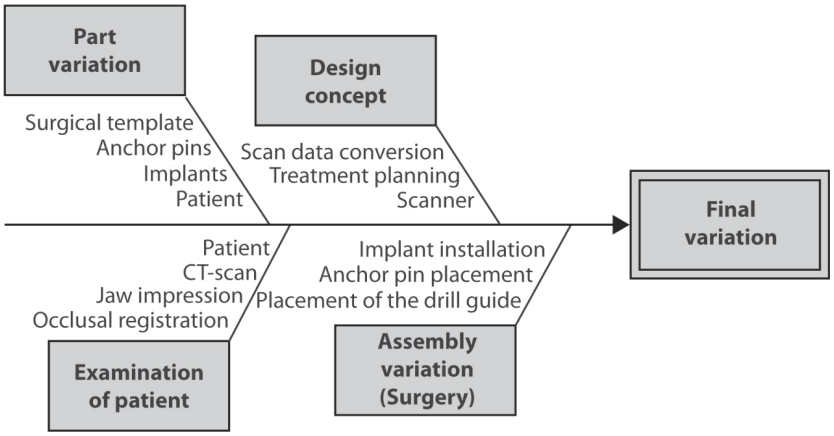

Fig. 18. Cause and effect diagram for medical treatments based on mass customization for CAD/CAM template-guided surgeries. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

For this variation simulation, 10.000 Monte Carlo iterations were used to stabilize the results to the second decimal place, corresponding to 10.000 surgeries. Furthermore, the analysis used a virtual assembly model with all mating conditions defined together with distributions on all inputs. Here, the 3-2-1 positioning method was used for the virtual simulation. The parts were mounted with the aid of an orthogonal 3-2-1 system (locating scheme) (Fig. 19).

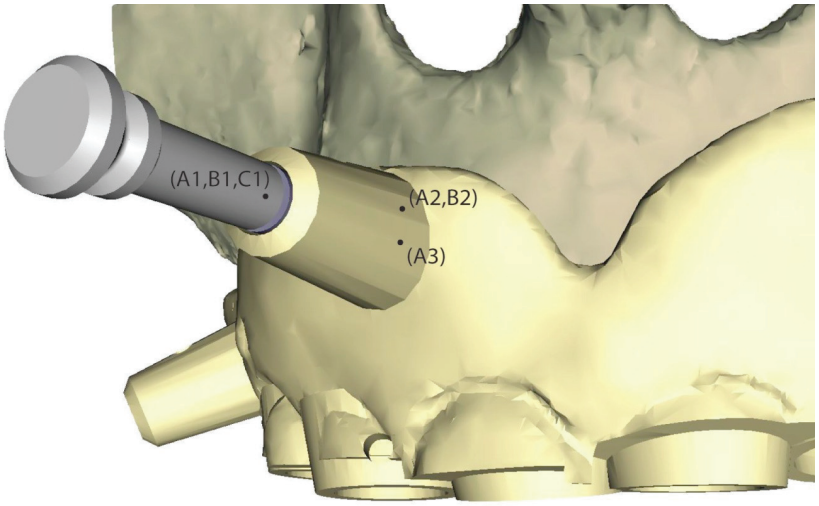

Fig. 19. Schematic figure of assembly method, orthogonal 3-2-1 system. Local 3-2-1 is anchor pin, which is assembled into anchor pin sleeve, corresponding to Target 3-2-1. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

Three primary locating points, A1, A2 and A3, control 3 degrees of freedom and lock the object to a plane, translation in the z axis, rotation around the x axis, and rotation around the y axis. The 2 secondary locating points, B1 and B2, control 2 degrees of freedom, locking the object to a line and translation in the x axis and rotation around the z axis. The last, tertiary locating point, C1, controls 1 degree of freedom and translation in the y axis.[98] Finally, the variation contributors from the manufacturing as well as the assembly processes are applied in the location points.

The virtual variation simulation method captures non-linearitites, and allows any type of distribution of input parameter variation and graphical visualization of results. For these simulations, only data for the maximum range and mean were collected for the specified critical dimensions and graphical visualization.

For the virtual variation simulation, the surgery was conducted according to the following method: (1) the surgical CAD/CAM template guide was positioned on the jaw; (2) the surgical CAD/CAM template guide was fixed on the jaw with anchor pins; and (3) the first implants were placed. The CAD/CAM template guide abutments were attached to the first placed implants to minimize the vertical and horizontal movement of the surgical template. In the model, a vertical tolerance was added at the template abutments, while the horizontal movement was embedded at the anchoring pins. The

remaining implants were placed, and (4) the virtual variation simulation was performed.

3.3.3.4 Statistics

A Mann-Whitney U test was performed on 3 levels: (1) total (all patients), (2) jaw level (maxilla and mandible), and (3) patient level. The nonparametric Mann-Whitney U test was used for assessing whether 2 independent samples of observations came from the same distribution or not. The deviation results from the implants that were actually placed (145 implant placements) from the cadaver surgeries were compared to the deviation results from the simulations (1.450.000 implant placements).

3.3.3.5 Comparison of results

To verify the theoretical variation simulation model, the results from the virtual variation simulations were compared with the results from CAD/CAM template-guided surgery performed on human cadavers in Study I. A measurement for each implant deviation was obtained from the virtual variation simulation results and compared to the virtual planning from the previous study before the actual surgery. The results were summarized and presented as mean of the range and mean of the mean for each simulated surgery, and compared with the results from the actual surgeries for each subject, which were presented as the maximum deviation as well as the median.

3.3.4 Study III

3.3.4.1 Operators

One clinician from the Division of Periodontology, Department of Medicine, Karolinska Institute, performed all surgical treatments of patients with NobelGuide. The matching and calculation of the data was performed by a PhD student at the Section for Image and Functional Odontology, Department of Medicine.

3.3.4.2 Preparation of radiographic guide

The patient´s prosthesis was examined regarding occlusion, alignment of teeth and the fitting to the mucosa. The denture or replica was made in acrylic resin with non radio-opaque properties. At least six spherical gutta-percha markers with a diameter of 1-1.5 mm were placed into the optimized radiographic guide used for matching in software

before planning. A radiographic index was created in the patient´s mouth, in order to register the correct occlusion.

3.3.4.3 CBCT scan

The patients were referred to the Division of Image and Functional Odontology for a CBCT scan (NewTom QR-DVT 9000; QR s.r.l., Verona, Italy). The protocol used followed generic instructions for CBCT scanners in the Procera ®. The scan settings used were between 4 and 6 mAs and 110 Kv with 0.3 mm in voxel size. First the patient was scanned according to the double scan protocol, wearing the radiographic guide and radiographic index to obtain correct occlusion during the scan. After the patient was scanned, the radiographic guide was scanned alone, utilizing the same settings as for the first scan. The data of the axial reconstructed slices was exported in DICOM format, on a cd (Compact Disc). The reconstruction slice thickness was 0.3 mm.

3.3.4.4 Segmentation and matching of the DICOM data

The DICOM files obtained were used in order to segment the bone and radiographic guide into 3D models in software (Procera Software version 1.5 build 75; Nobel Biocare AB). The data of the patient and radiographic guide were then matched together in software by locating the radio-opaque markers from the two scans. A file was saved and opened in the virtual planning software.

3.3.4.5 Virtual planning

Two clinicians from the Division of Periodontology, Department of Medicine, Karolinska Institute, performed all virtual plannings. During the virtual planning of each patient, the clinician specified the locations of the implants, abutments, sleeves and anchor pins. The virtual planning was saved, approved and exported to the Procera ® CAD software and a virtual surgical template was created. An order was sent from the CAD software to the production facility to produce a surgical template, and components needed for surgery were ordered.

3.3.4.6 Surgical template, implant supported bridge and surgical index

The surgical template was manufactured with rapid prototyping and contained guide sleeves for each implant site as well as for the anchor pins according to the virtually planned position. The surgical template was sent to a dental technician. The technician mounted inserted guided cylinders with pins in the implant sleeves positioned in the surgical template and connected implant replicas to each site. Then a soft tissue substitute was inserted towards the mucosal side of the surgical template and around the guided cylinders. Plaster was then added onto the soft tissue material and cured. The finished master model containing implant replicas and a soft tissue substitute and was mounted in an articulator together with the plaster model of the patients opposing jaw, the radiographic guide or duplicate denture. The models were positioned according to the registered occlusion in the articulator using the radiographic index previously created. The radiographic guide or duplicate denture was removed and the surgical template positioned on the master model containing implant replicas in the articulator. The space that was present was filled with index material that recorded the relation between the surgical template and the opposing jaw in the articulator, and a surgical index was created. The technician then created an implant bridge frame in acrylic onto the master model containing implant replicas mounted in the articulator. The plaster model with the implant replicas in position together with the frame was sent to the Procera production facility. A measurement machine registered the implant replicas position and the frame was scanned and sent to CAD/CAM software in production. A titanium framework was milled and sent back to the dental technician.
The dental technician received and finished the individually produced titanium framework. A surgical index to record the relationship between the surgical template and the opposing occlusal surfaces, was created by the dental technician.

3.3.4.7 Surgery and prosthesis connection

All implants were inserted without elevating any mucoperiostal flaps and according to the protocol of NobelGuide (Nobel Biocare AB, Sweden). The patient was instructed to bite on the surgical index with a similar pressure to that used during the preoperative CBCT scan. A twist drill with a diameter of 1.5 mm was used to drill to a predefined stop and anchor pins (Guided Anchor Pin 1.5 mm; Nobel Biocare AB, Sweden) were positioned into the sleeves. The surgical index was removed when all anchor pins were placed. A counterbore (Guided Start Drill/Counterbore; Nobel Biocare AB, Sweden)

was used to remove soft tissue and bone according to the planned position. The drilling protocol for the implant placement included twist drills with diameters of 2.0, 2.8, 3.0 and 3.2 mm, respectively (Guided Twist Drill; Nobel Biocare AB, Sweden). The first implant was connected to an implant mount (Guided Implant Mount; Nobel Biocare AB, Sweden) using guiding capabilities, when engaging the sleeve in the surgical template. A template abutment (Guided Template Abutment; Nobel Biocare AB, Sweden) was connected to the first placed implants platform and secured into the sleeve of the surgical template. A second implant was inserted and the template was fixed according the same procedure. All remaining implants were then inserted in series. On some occasions, a screw tap was used, depending on bone quality and clinical judgment. A prefabricated prosthesis, including specially designed expandable abutments, was connected onto the implants immediately after implant placement in all cases but one. For further details see 3.3.1.6.

3.3.4.8 Postoperative CBCT scan

One year or more after surgery, the patients underwent a second CBCT scan. The suprastructure including abutments were removed prior to the scan to avoid artifacts from the metal. Plastic impression copings were temporarily attached to the individual implant to prevent collapse of the soft tissue and minimize the artifact during the scan. The equipment and settings used for the scan was the same as for the preoperative scan.

3.3.4.9 Voxel matching and measurements

The matching and calculation was performed by a PhD student at the Section for Image and Functional Odontology, Department of Medicine, Karolinska Institute, Huddinge, Sweden. For further details see 3.3.1.7.

3.3.4.10 Statistics

All analyses were done in STATISTICA 7.0 (Statsoft Inc., Tulsa OK, USA). The data variation was not normally distributed; therefore, in order to attain approximately normally distributed data, the outcome variables, apex, hex and angle, except depth were e-log transformed. In these three variables (apex, hex and angle), mean deviation at implant level was presented as the geometric mean while mean of depth deviation was presented as arithmetic mean. Subsequently, parametric tests were used. Statistical

analyses were performed using the t-test for the positional difference between virtually planned implants and inserted implants in the following outcome variables; apex, hex, angle, and depth. The analysis of variance (ANOVA) was used when fixed factors, such as mandible and maxilla, prelaunch and launched components, and movement of the jaw in the preoperative and postoperative CBCT scans were included. All tests were two sided and $p < .05$ was considered as statistically significant. All data were presented using descriptive statistics, for example, number of observations, mean, standard deviation (SD), median, minimum and maximum. The outcome variables that were e-log transformed and further analyzed using the ANOVA model were presented with the corresponding 95% confidence interval (95% CI). The estimates of the mean and the 95% CI were back transformed.

3.3.5 Study IV

3.3.5.1 Operators

The insertion of the implants by aid of surgical templates, was performed by five experienced implant surgeons. The matching and calculation procedure was performed by a PhD student at the Section for Image and Functional Odontology, Department of Medicine, Karolinska Institute, Huddinge, Sweden.

3.3.5.2 Presurgical preparation

A master impression was performed on one of the plastic jaw models (Xantalgin select fast set: Heraeus Kulzer GmbH, Germany). A working cast was created by a dental technician. Then individual impression trays were created for each plastic jaw model (Magma Tray, M-tec Dental AB, Malmo, Sweden). The space between the individual tray and plastic jaw model was 3 mm with four small support structures controlling the distance when taking the impression. Two of the support structures were positioned at the front and two at the back of the tray in order to obtain an even positioning during the impression procedure. Adhesive was used before the impression was performed (Universal Adhesive for siloxane impression materials, Heraeus Kulzer GmbH, Germany). During the performed impression, a silicon impression material was used (Honigum Mixtar Heavy, DMG Chemisch-Pharmazeutische Fabrik GmbH, Germany). The impression work was supervised by a prosthodontist with more than 15 years of experience. Excessive impression material was removed to reduce undercuts. A dental

drill was used to create cavities and 14 glass and ceramic spherical markers with a diameter of <2 mm were positioned in the cavities (Spherical ceramic markers, SKF AB, Sweden; Glasmarkers 2mm, Aporis NV, Belgium).[103] Cyan acrylate was used to fixate the position of each marker (Sekunden-kleber, Renfert, GmbH, Germany).

3.3.5.3 CT scan

First the plastic jaw was scanned together with the individual impression tray in position (Lightspeed VCT XT, General Electric, United Kingdom). Then the impression tray was scanned alone. The settings used during the CT scans were 120 kV, auto mAs (74 mAs for each scan), 0-degree gantry tilt, the slice thickness during the scan was 0.625 mm. The slice increment during the reconstruction was 0.312 mm. The data was exported in DICOM format to a CD.

3.3.5.4 Conversion of DICOM data and virtual planning

The DICOM files were loaded into software (Procera Software, Version 2.2, Nobel Biocare AB, Sweden) and the plastic jaw model along with the radiographic guide (individual impression tray) were segmented into 3D models. The radiographic guide was matched together with the jaw model, searching for the corresponding radio-opaque markers. The data was saved and opened in virtual planning software. One operator performed all virtual plannings. As all plastic jaw models were alike, six implants (Brånemark System MK III Groovy RP ∅3.75x13 mm, Nobel Biocare AB, Sweden) and three anchor pins (Guided Anchor Pin, ∅1.5 mm; Nobel Biocare AB, Sweden) were planned in each model as individual cases. After the virtual plan was ready, the file was saved, approved and imported in the CAD software. All necessary clinical components along with the surgical template were ordered in software.

3.3.5.5 Adjustment of surgical template

When the rapid prototyped SLA surgical template arrived from production, the trained dental technician controlled and removed any present undercuts in the surgical template.

3.3.5.6 Surgery

Two pilot cases were performed in order to determine the drilling sequence and surgical protocol. The drilling sequence defined after the two pilot cases included a 2.0 mm drill and 2.8 mm drill due to the fragile and spongious plastic material in the jaw models. The two pilot cases were not included in the study.

During surgery one assistant participated to aid the surgeon. First the assistant held down the surgical template on top of the plastic jaw model adding pressure with one finger in the anterior part of the model and two fingers on each of the posterior parts of the model. No surgical index could be used due to inability of occlusion. Then the surgeon used a twist drill 1.5 mm (Guided Twist Drill 1.5 mm; Nobel Biocare AB, Sweden) to drill into the sleeve for the anchor pins. When the anchor pins were placed in position, the assistant removed the pressure of holding down the surgical template in position. A countersink was used in the second last posterior implant position in order to remove any excessive plastic material according to the treatment plan (Guided Start Drill/Counterbore; Nobel Biocare AB). Drills with a diameter of 2.0 and 2.8 mm respectively (Guided Twist Drill; Nobel Biocare AB) were used for the first site, second last to the posterior position of all planned implants. Then an implant mount was connected to the implant (Guided Implant Mount; Nobel Biocare AB) and the first implant was placed in the first site. A template abutment (Guided Template Abutment; Nobel Biocare AB, Sweden) replaced the implant mount and, thus secured the surgical template to the placed implant. Thereafter, the second implant was inserted in the same manner as described for the first one. The remaining implants were then placed in series.

Immediately after surgery, a CT scan of each model was performed with the same settings used for the preoperative scans. For further details see 3.3.1.6.

3.3.5.7 Matching and measurements

The matching and calculation was performed by a PhD student at the Section for Image and Functional Odontology, Department of Medicine, Karolinska Institute, Huddinge, Sweden. For further details see 3.3.1.7.

3.3.5.8 Statistics

All data were presented using descriptive statistics, i.e. number of observations, mean, median, minimum, maximum and standard deviation. The variables deviation at apex, hex, and angular deviation were skewed distributed and log(e) transformed, and also presented using the geometric mean.

Statistical analysis was done using STATISTICA v 9.0, Statsoft Inc, Tulsa,US.. To test the hypothesis that the deviation in various outcomes was equal to zero, the Student's t-test was used. To test for differences between surgeons, the ANOVA (Analysis of Variance) was used with surgeon as a fix factor in the model. Post hoc comparisons between pairs of surgeons were done using the Scheffé test. All tests were two-sided and $P<0.05$ was regarded as statistical significant.

4 RESULTS

A voxel-based matching method was used in order to superimpose the preoperative and postoperative CT scan data. The implants that were actually placed were compared to the virtually planned position of the implants. The results were exported from the software to an Excel sheet. The voxel-based method and calculations were applied in Study I, Study III and Study IV. In Study II a virtual variation simulation technique was used in order to perform virtual surgeries and achieve results. All results from all studies were sent to the same statistician for calculations.

4.1 STUDY I:

The differences between the mandible and maxilla were statistically significant for apex, hex, and depth deviation, with smaller deviations for the maxilla (Table I).

	Mandible						Maxilla						
		Range			95% CI	95% CI		Range			95% CI	95% CI	
Variable	Mean	Min	Max	SD	LL	UL	Mean	Min	Max	SD	LL	UL	*P*
Depth	0.48	−0.07	1.46	0.52	0.36	0.61	0.1	−0.03	1.61	0.60	0.03	0.24	<.001
Apex	1.24	0.13	3.63	0.58	1.08	1.43	0.96	0.12	2.43	0.50	0.86	1.08	.01
Hex	1.05	0.41	3.13	0.47	0.94	1.18	0.83	0.07	2.78	0.57	0.73	0.94	.01
Angle	2.46	0.26	7.44	0.67	2.09	2.9	2.02	0.08	5.38	0.66	1.74	2.34	.08
Translation	0.49	0.01	2.87	1.12	0.37	0.64	0.45	0.00	2.24	1.07	0.35	0.57	.63

Table I. Summary statistics for tests between mandible and maxilla. Numbers of implants: 67 for mandible and 78 for maxilla. Deviations in millimeters. Note: Negative value for depth deviation indicates that the implant did not reach planned position. Positive value indicates that implant was placed deeper than planned position. LL stands for lower level, UL stands for upper level. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

The differences between the virtually planned implants and the actual positions of the implants were statistically significant for all 5 outcome variables: apex, hex, depth, translation deviation, and angle.

The mean value for all 145 implants placed comparing the deviation between the virtually planned implants position and the actually placed implants position was 1.25 mm (SD 0.68) and corresponding 95% CI of 1.13;1.36 for the apex, 1.06 mm (SD 0.58) and corresponding 95% CI of 0.97;1.16 for the hex, 0.28 mm (SD 0.59) and corresponding 95% CI of 0.18;0.38 for the depth, 0.71 mm (SD 0.59) and corresponding 95% CI of 0.61;0.81 for the translation deviation and 2.64 degrees (SD

1.42) and corresponding 95% CI of 2.41;2.87 for the angle. The median for all 145 implants placed comparing the deviation between the virtually planned implants position and the actually placed implants position was 1.12 mm for the apex, 0.93 mm for the hex, 0.39 mm for the depth, 0.56 mm for the translation deviation and 2.48 degrees for the angle deviation.

4.2 STUDY II:

The results from the 17 virtual variation simulations and the Mann-Whitney U test were summarized for each treatment (Table 2).

Subject		Simulation (mm)				Surgery (mm)				Mann-Whitney U Test	
		Deviation Apex		Deviation Hex		Deviation Apex		Deviation Hex		Apex	Hex
	Number of Implants	Mean Range	Mean Mean	Mean Range	Mean Mean	Maximum	Median	Maximum	Median	*P*	
1Mand	9	4.76	1.37	1.98	0.60	1.85	1.17	0.93	0.69	.14	.23
2Mand	9	4.48	1.28	1.98	0.59	1.72	0.96	1.04	0.95	.05	.23
3Mand	11	4.80	1.51	1.74	0.51	3.63	3.14	3.13	2.46	.07	.001
4Mand	11	4.50	1.20	1.78	0.51	3.27	1.60	1.82	1.36	.34	.001
5Mand	8	4.68	1.35	1.78	0.53	2.34	1.47	1.35	1.18	.52	.001
6Mand	11	4.52	1.27	1.78	0.53	2.21	1.16	1.34	0.91	.30	.001
7Mand	8	4.70	1.35	1.76	0.53	1.32	0.87	1.37	1.06	.001	.001
8Max	8	4.30	1.25	1.98	0.85	1.50	1.17	1.32	0.91	.25	.001
9Max	6	4.22	1.24	1.66	0.66	0.80	0.51	0.88	0.54	.01	.87
10Max	8	4.82	1.20	1.72	0.63	1.70	1.13	1.11	0.85	.40	.01
11Max	8	4.56	1.29	1.74	0.53	1.37	1.02	0.80	0.66	.03	.40
12Max	10	4.20	1.20	1.72	0.52	1.30	1.00	0.96	0.57	.11	.55
13Max	8	4.76	1.34	2.04	0.58	2.43	1.00	2.78	1.78	.40	.001
14Max	8	4.02	1.16	1.76	0.53	0.97	0.67	0.94	0.86	.001	.01
15Max	6	5.86	1.20	1.66	0.52	2.25	1.26	1.81	0.95	.87	.001
16Max	9	4.68	1.38	1.94	0.59	2.15	1.38	1.75	1.46	.89	.001
17Max	7	4.12	1.25	1.72	0.53	1.44	1.30	1.19	0.79	.95	0.65

Table 2. Summary of simulation and surgery results reported in millimetres, from simulation of template-guided human cadaver surgeries and corresponding results from template-guided surgeries performed on human cadavers. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

The results were summarized and presented as average mean of the range and average mean of the mean for each simulated patient. The compared cadaver surgery results were summarized and presented as maximum deviation from the theoretical planning

for each patient, and the median for the implant positions. The Mann-Whitney U test *P* value was derived for each compared surgery/simulation (Table 2).

The average mean of the mean results for the virtual variation simulation on the maxilla was 1.26 mm at the apex and 0.59 mm at the hex; the average mean of the range was 4.55 mm at the apex and 1.79 mm at the hex. The average mean of the mean results for the simulation on the mandible was 1.29 mm at the apex and 0.54 mm at the hex, while the average mean of the range was 4.63 mm at the apex and 1.83 mm at the hex. The average of the median was 1.04 mm (mean: 0.96 mm) at the apex and 0.94 mm (mean: 0.83 mm) at the hex for the deviation of the actually placed implants in the maxillae in human cadavers. The average of the maximum was 1.59 mm at the apex and 1.35 mm at the hex. For the mandible, the average of the median was 1.48 mm (mean: 1.24 mm) at the apex and 1.23 mm (mean: 1.05 mm) at the hex. The average of the maximum was 2.33 mm at the apex and 1.57 mm at the hex. The Mann-Whitney U test, on the patient level, is presented in Table I. Comparing the implant distributions between the simulations and the surgeries with the Mann-Whitney U test resulted in significant differences at the hex ($P<.001$) and at the apex ($P<.001$). A virtual variation simulation of specimen 17Max was visualized by using color coding (Fig. 20). In the posterior quadrant of the mouth, the color was red (1.5-mm variation), which indicated larger variation than the blue color (0.5-mm variation). The possible implant positions for 1 planned implant, after 10,000 iterations, is illustrated for specimen 17Max as deviation compared to the virtually planned implant (Fig. 21).

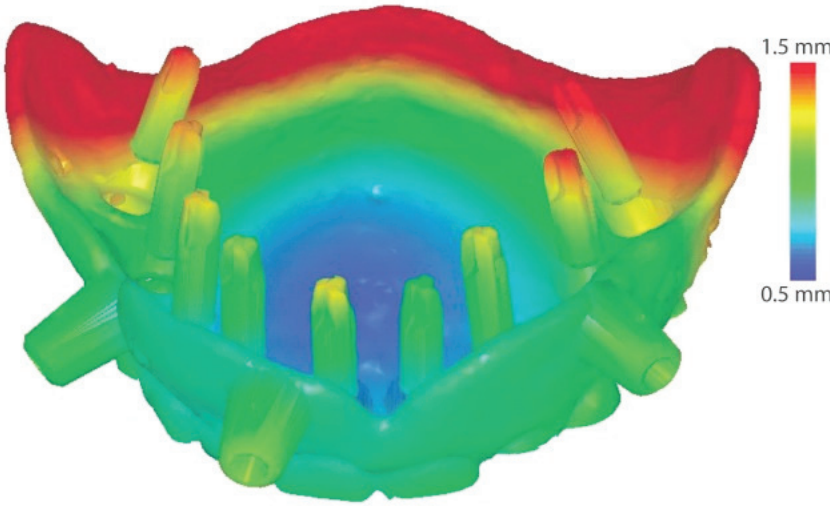

Fig. 20. Virtual variation simulation conducted on 1 planning of cadaver 17Max with 9 implants and surgical template. Right posterior implant has largest variation. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

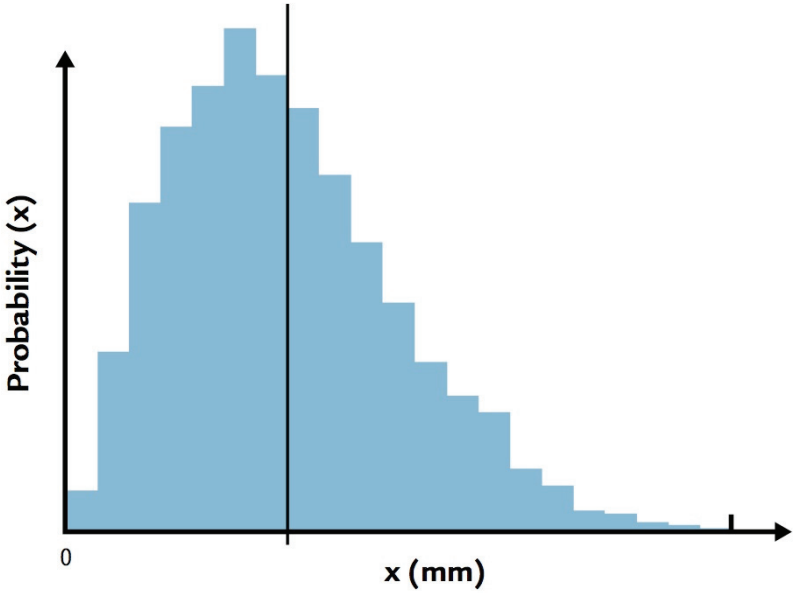

Fig. 21. One implant placement simulated 10.000 times, from cadaver 17Max; mean: 1.19 mm, and range: 4.21 mm. "Reproduced with permission by the Editorial Council of *The Journal of Prosthetic Dentistry*."

4.3 STUDY III:

A statistical significant difference was observed between mandible and maxilla comparing the virtually planned and actually place implants. However, when all four variables were taken into consideration, no statistically significant difference was observed when comparing the results from the maxilla and mandible, despite the deviation being slightly larger in the maxilla than in the mandible for angulation. Mean differences between planned and inserted implants were significantly different in all four outcome variables: depth, apex, hex and angle ($P<.05$).

Mean value for apex was 1.09 mm (range: 0.24-3.62), and corresponding 95 % CI of 1.001;1.18. Mean value for hex was 0.80 mm (range: 0.10-2.68), 95 % CI of 0.72; 0.89, for angle 2.26 degrees (range:0.24-11.74), 95 % CI of 2.01; 2.53 and for depth -0.15 mm (range:-2.33-2.05) (SD=0.76) with 95 % CI of -0.27; -0.02, respectively. In the maxilla, mean value for apex was 1.05 mm (range:0.25-2.63), 0.80 mm (range: 0.10-2.68) for hex, 2.31 degrees (range: 0.24-6.96) for angle and -0.06 mm (range:-1.65-2.05) for depth. Mean value in the mandible was 1.15 mm (range: 0.24-3.62) for apex, 0.80 mm (range: 0.16-2.45) for hex, 2.16 degrees (range: 0.27-11.74) for angle and -0.29 mm (range: -2.33-0.94) for depth.

During the matching procedure, it was apparent that in some cases the segmented implants from the postoperative scan were not cylindrical in shape. Therefore, one radiologist reviewed all the CT images and found double contours, implying that the patient had moved during the scans. Movements were found both in some of the preoperative and postoperative CT data. As the “movement” factor was not originally considered as a variable for inclusion, additional calculations were performed in order to be used as a factor for exploratory analyses. The numbers of implant classified as “movement” are presented in Table 3.

The mean e-log apex and mean e-log hex results showed statistically significant differences between the presence and absence of movement during the pre- and post-operative CT scans (Fig. 22). In addition, differences in the mean e-log angle between the presence and absence of movement during post-operative CT scans were also statistically detected. However, no differences in depth were statistically demonstrated.

	Post-op scan Movement	Post-op scan Non-movement
Pre-op scan Movement	15	6
Pre-op scan Non-movement	28	90

Table 3. Movement during the preoperative and postoperative scanning (n=number of implants included)

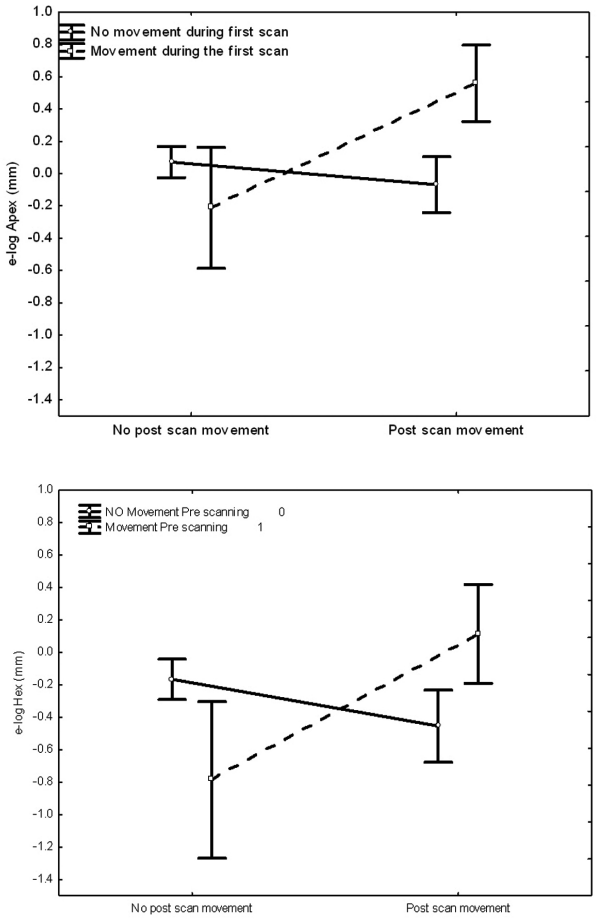

Fig. 22. Mean e-log apex (upper) and mean e-log hex (lower) differences between presence and absence of movement during preoperative and postoperative scans.

If the “movement” factor was included in the analysis, the angular deviation indicated a difference between the maxilla and the mandible of 3.1 degrees in the maxilla and 2.4 degrees in the mandible, albeit, no statistically significant differences were observed between the maxilla and the mandible, on any other occasion.
Deviation of implants without any movement (90 implants in 16 patients) and implants with movement at both during the pre-operative and the post-operative CT scan (15 implants in 3 patients) is presented in Table 4.

Deviation	No. of implants	Mean	Min	Max
Hex	90	0.85	0.20	2.68
Apex	90	1.07	0.24	2.63
Angle	90	2.00	0.24	6.96
Depth	90	-0.09	0.01*	2.05*

Table 4 a. Deviations of implants without any movement (90 implants)

Deviation	No. of implants	Mean	Min	Max
Hex	15	1.12	0.16	2.45
Apex	15	1.75	0.69	3.62
Angle	15	4.27	1.97	11.74
Depth	15	-0.57	0.03*	2.33*

Table 4 b. Deviation of the implants with movement both during pre- and postoperative CT scan. * Minimum and maximum in depth are presented using distance from base line

Significant differences were observed in the mean depth when comparing pre- and post-launched components. Implants inserted using pre-launch components were 0.25 mm deeper than those inserted using post-launched components.

4.4 STUDY IV:

There was a statistically significant difference between all surgeons for the apex, depth and angle ($P<.05$). Furthermore, no statistical significant difference was observed for the hex between the surgeons.
The difference between the actually placed implants compared to the virtually planned implants demonstrated a statistically significant difference for three out of the four outcome variables, the apex, hex and depth ($P<.05$), no statistically significant difference was observed for the angle. For all implants, the mean value for the apex was 0.73 mm (range: 0.27-1.46 mm) with a median of 0.73 mm and a CI of 0.70; 0.77, for the hex 0.59 mm (range 0.27-1.19 mm) with a median of 0.60 mm and a CI of 0.56;

0.61, for the angle 1.14 degrees (range 0.06-4.39) with a median of 1.27 degrees and a CI of 1.00; 1.30, for the depth -0.51 mm (range -1.17-0.12), a median of -0.52 mm and a CI of -0.54; -0.48.

A summary of the results for each surgeon is presented in Table 5. A comparison between the statistically significant difference (P<.05) between surgeons for the outcome variables, apex, hex, angle and depth are presented in Table 6.

	Deviation Apex						Deviation Hex					
Surgeon	Mean	Median	95 % LL	95 % UL	Min	Max	Mean	Median	95 % LL	95 % UL	Min	Max
1	0.69	0.68	0.62	0.77	0.32	1.14	0.53	0.54	0.50	0.57	0.33	0.73
2	0.72	0.71	0.64	0.83	0.26	1.46	0.64	0.65	0.57	0.72	0.27	1.19
3	0.69	0.69	0.63	0.76	0.39	1.10	0.58	0.58	0.53	0.63	0.33	0.82
4	0.69	0.74	0.61	0.79	0.28	1.19	0.62	0.63	0.56	0.69	0.30	0.94
5	0.89	0.89	0.81	0.98	0.51	1.33	0.57	0.59	0.52	0.63	0.32	0.84
	Deviation Angle						Deviation Depth					
Surgeon	Mean	Median	95 % LL	95 % UL	Min	Max	Mean	Median	95 % LL	95 % UL	Min	Max
1	1.57	1.66	1.27	1.96	0.32	3.73	-0.49	-0.52	-0.52	-0.45	-0.71	-0.28
2	0.86	0.98	0.59	1.25	0.05	3.73	-0.63	-0.60	-0.71	-0.55	-1.16	-0.22
3	0.95	1.12	0.70	1.30	0.15	2.63	-0.48	-0.49	-0.56	-0.39	-0.78	0.12
4	0.89	1.12	0.65	1.21	0.08	3.56	-0.53	-0.52	-0.59	-0.48	-0.84	-0.27
5	1.67	1.95	1.36	2.04	0.84	4.39	-0.42	-0.42	-0.47	-0.37	-0.65	0.00

Table 5. Deviations in mm for apex, hex and depth. Angle deviation in degrees. Min and max deviations for depth are represented as the distance from the virtually planned baseline of the apex (implant tip).

P<0.05	Apex					Hex					Angle					Depth				
Surgeons	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
1		0.98	1.00	1.00	.01		0.11	0.85	0.26	0.88		0.06	0.18	0.09	1.00		.01	1.00	0.89	0.69
2	0.98		0.99	0.99	0.15	0.11		0.63	0.99	0.58	0.06		0.99	1.00	.01	.01		.01	0.31	.01
3	1.00	0.99		1.00	.01	0.85	0.63		0.87	1.00	0.18	0.99		1.00	0.1	1.00	.01		0.81	0.79
4	1.00	0.99	1.00		.01	0.26	0.99	0.87		0.83	0.09	1.00	1.00		.01	0.89	0.31	0.81		0.16
5	.01	0.15	.01	.01		0.88	0.58	1.00	0.82		1.00	.01	0.1	.01		0.69	.01	0.79	0.16	

Table 6. Sheffé test for comparison between pairs of surgeons. P<0.05 regarded as statistically significant.

5 DISCUSSION

CAD/CAM guided surgical systems have recently been introduced as an aid in implant dentistry. However, a limited number of studies have been presented evaluating the accuracy between virtually planned and surgically placed implants utilizing NobelGuide.

When performing an accuracy study, comparing the virtually planned position of the implants to the actual position of the implants placed after surgery, there are a lot of possible contributing factors to the final deviation. Different types of CT or CBCT scanners could be one reason, the surgeons per se could be another one. Other factors of importance for the final accuracy outcome are e.g. the surgeons ability to follow the protocol, left or right handed surgeons, patient selection, length of implants, position of placement in the mouth of the patient, preparation of the radiographic guide for an optimal fit, selection of threshold while segmenting the virtual surgical template, and variable biting force of patient during CT/CBCT scan or during surgery.
In the studies defined within this project some factors were therefore chosen in order to try to limit the contributing factors in order to try to learn more about guided surgery accuracy.

5.1 STUDY I:

In the first study, when using human cadavers, the initial idea was that the material should be more controllable compared to a clinical situation. It was decided to limit the factors of inclusion to implants placed as close to a normal clinical situation as possible, to perform a comparison between the virtually planned implants and the actually placed implants position. The implant length and the position of the implants, (anterior versus posterior position), were excluded as inclusion factors, but are possible to investigate from the material collected, and will be carried out in future studies.
When the treatment started, we found that it was difficult to position the radiographic guides of the subjects properly during the CT scans due to the inability to occlude in accordance with the protocol. Therefore it was decided to use rubber bands to keep the radiographic guide and index in position. This means that the radiographic guide and index might have been placed in a non-optimal position.[100] When reviewing the data we found that a space was present in 12 out of 17 cadaver jaws between the mucosa

and the radiographic guide. This fact was recorded as a black area between the mucosa and the radiographic guide (Fig. 23).

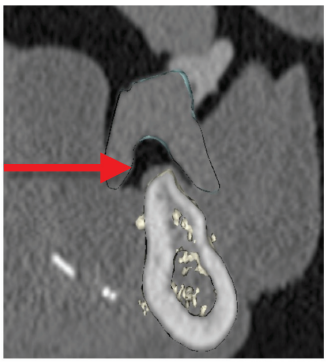

Fig. 23. The black area demonstrates a space (see red arrow) between the radiographic guide and the mucosa that was found in CT data in 12 out of 17 cadaver jaws.

A mal-positioning of the radiographic guide is possible to detect in advance of surgery. It is more difficult to detect a mal-positioned surgical template; the position of the surgical template is never registered at the postoperative CT scan. During surgery in Study I, the surgeons had to try to find the most optimal position of the surgical template due to the inability of occlusion from the subjects, which excluded the possibility of using the surgical index. Another possible contributing factor to the final accuracy result might have been that the specimens were frozen and thawed up to four times. This could have resulted in dehydration and a change in size and shape of the soft tissue.[100]

The objective in Study I was to compare the deviation between the positions of virtually planned implants and the positions of implants placed with a CAD/CAM-guided surgical template in the mandible and the maxilla in human cadavers. The research hypothesis was that there would be no difference in accuracy between the virtually planned implant positions and the actual positions of the implants placed in the mandible and maxilla with a CAD/CAM-guided surgical template.

When the statistical calculations were performed it was obvious that the difference between the mandible and maxilla were statistically significant for the apex, hex and depth. One explanation for the variation could be that the surgical template in the mandible is less stable, as it covers a smaller area compared to the maxilla. The difference between the virtually planned implants and the actual positions of the

implants were statistically significant for all 5-outcome variables: apex, hex, depth, translation deviation and angle. Even though the results were statistically significant, it was not clear whether the results are clinically significant or not.[100] When comparing the results in Study I to other published accuracy studies this study demonstrates similar or better results.[73] In comparison with other accuracy studies performed on human cadavers using NobelGuide, more implants were included in the present study (Fig. 24).[68, 77, 100] The mean value for the apex, hex and angle was smaller in the study by van Steenberghe et al.[68] compared to the study by van Assche et al. [77] and Study I[100] (Fig. 25-Fig. 27). The mean deviation was largest in the study by van Assche et al.[77] for the variables, hex and apex. For the angle the largest mean deviation was presented in Study I[100] (Fig. 25-Fig. 27).

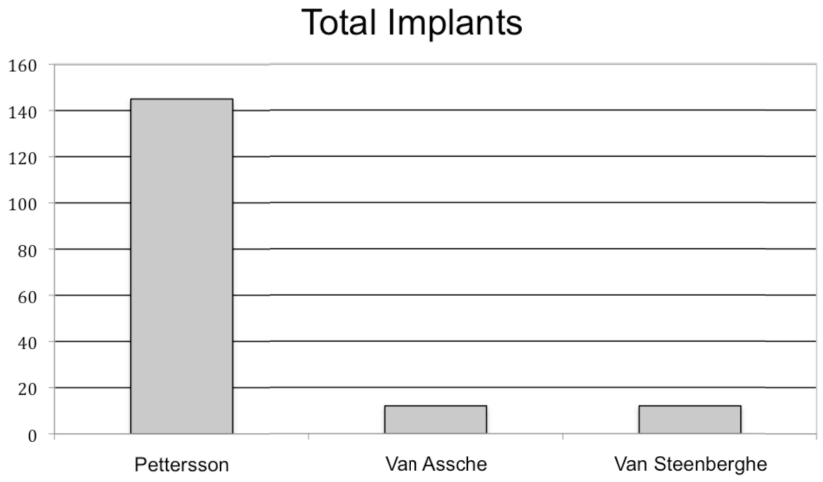

Fig. 24.Total number of implants included in three different accuracy studies performed on human cadavers with NobelGuide.

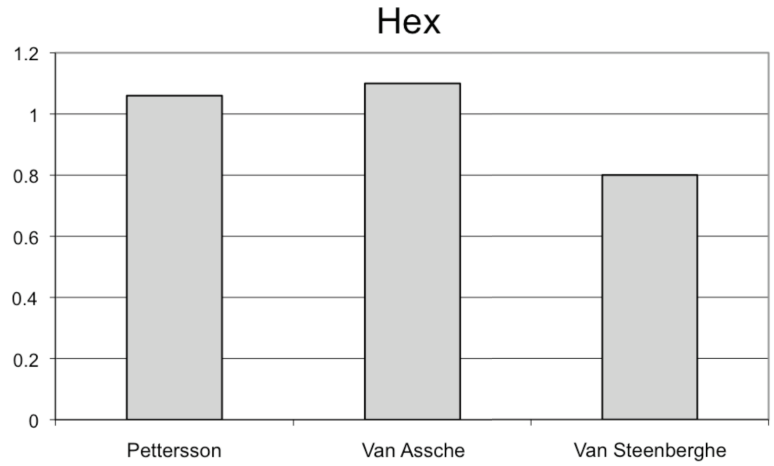

Fig. 25. Mean values of the results for the hex in three different accuracy studies performed on human cadavers with NobelGuide. Measurements in mm.

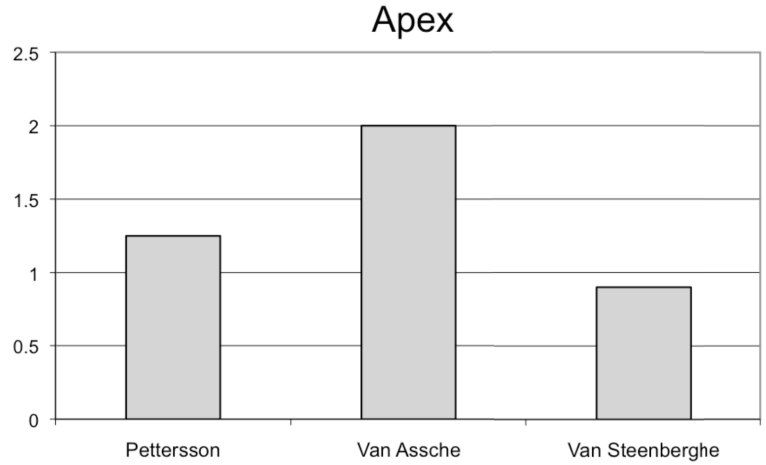

Fig. 26. Mean values of the results for the apex in three different accuracy studies performed on human cadavers with NobelGuide. Measurements in millimetres.

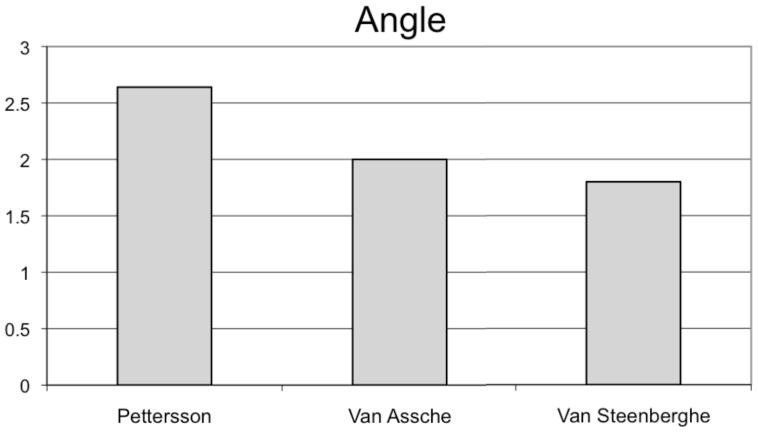

Fig. 27. Mean values of the results for the angle in three different accuracy studies performed on human cadavers with NobelGuide. Measurements in degrees.

Depth measurements were not available in the two other studies and therefore not compared. The study by van Assche et al.[77] used formalin-fixed human cadavers with tooth supported surgical templates. The study by van Steenberghe et al.[68] used human cadavers but did not specify whether they were formalin-fixed or not. In the study by van Assche et al.[77], teeth supported surgical templates were used while in the study by van Steenberghe et al.[68], bone supported surgical templates were used and in Study I[100] mucosa based surgical templates were used. The study by van Steenberghe et al.[68] was performed before the NobelGuide system was launched on the market and therefore utilized development components that differed from the launched components. The difference between the pre-launch and post-launch components could have resulted in different accuracy results between the studies. The van Assche et al. study[77] and Study I[100] used launched components of NobelGuide.

However, the three studies referred to above used bone supported, teeth supported as well as mucosa supported surgical templates, which could have affected the final different accuracy result. The amount of implants included in the three studies varied from 12 to 145, which as well could have affected the final accuracy result. The type of CT scanner used was not specified in the study by van Steenberghe et al.[68], while in the study by van Assche et al.[77], a 3D Accuitomo FDP® cone-beam CT was used (J. Morita, Kyoto, Japan) with a scanning volume of 60x60 mm was used and Study I[100], used a CT scanner, Siemens SOMATOM Sensation 10 (Siemens AG, Erlangen,

Germany). The usage of different CT/CBCT scanners could have affected the accuracy result.

5.2 STUDY II:

The focus and objective of this study was verification of a new technological method using virtual variation simulation, with the purpose of predicting the definitive deviation results of CAD/CAM template-guided surgeries. Since each treatment is unique, it requires a flexible system, and due to the flexibility within the system and the individual anatomy of the jaw, the outcome will be unique. Consequently, this results in difficulties in predicting the definitive implant positions during virtual planning. Virtual variation simulation can be used to help clinicians to predict the deviation result before the actual surgery in the field of medical and dental rehabilitation. The statistical result demonstrated that the data from the surgeries could not be assumed to be normally distributed; consequently, the research hypothesis was accepted. As a starting point when analyzing a phenomenon or as in this situation, a surgical treatment method, with little or limited knowledge, it is reasonable to assume that the implant distributions are normally distributed and test that assumption. Therefore, the results are of interest to clinicians and to the developers of such technology.

The median from the cadaver surgery implant positions is close to the simulated mean, which indicates that the result from the surgery is close to the most probable outcome (Fig. 21). Furthermore, if the maximum deviation from the surgery is located close to the range from the simulations, the implant position is found at an area of low probability. From Table 2, it can be seen that the majority of the results are within a relatively homogenous distribution; however, there are outlier specimens such as 3Mand and 13Max. When reviewing the deviation results from the actual surgeries, the specimen 3Mand is an outlier, as the medians for both the apex and hex are outside the simulated range. For specimen 3Mand, the median also appears close to the maximum of the results from the surgery and outside the mean for the simulations (Table 2). An explanation for these outlier results could be that the radiographic guide or surgical CAD/CAM template guide could have been placed in a non-favorable position during the CT scan or during surgery. Specimen 13Max was likely rotated, as the deviation at the apex was relatively large and the median was rather small.

From a statistical point of view it is important to consider that, the comparison was performed between an investigation in which the results were based on one surgery per

specimen,[100] and, for the simulations in this study[104], 10,000 surgeries per specimen. The nonparametric Mann-Whitney U test was selected since it provides the opportunity to assess whether 2 independent samples of observations come from the same distribution. In this study, it was found that the implant distributions could not be assumed to be normally distributed (Fig. 21).

Generally, it can be seen that the variation is greater for longer implants, and the implants close to the anchoring system show less variation compared to the implants at the posterior area of the template. It can also be seen that the deviation of the template placement increases with the distance from the anchoring system (Fig. 20). The magnitude of the deviation can be analyzed with the help of virtual variation simulation on complex and individual geometries.

There were some limitations to accomplishing the guided surgeries on the previously frozen cadavers, including (1) radiographic guide positioning, (2) surgical guide positioning, and (3) number and location of implants[100]. The radiographic guide was placed in a position, which was assumed to be optimal without occlusion. The radiographic guides were fixed in position with rubber bands. The surgical guide was placed with visual guidance. According to the clinical protocol, the patient assists during the positioning of the surgical guide by occluding the CAD/CAM template guide into position with the use of an occlusal index. The same procedure is performed with the patient occluding with the radiographic guide and index during the CT scan of the patient. The implant planning was performed in an experimental manner, placing as many implants as possible in the available bone.[100] These limitations may contribute to a deviation larger than that obtained if the same surgeries were performed in a clinical study involving patients. It is also noted that the results from the simulation were based on initial tolerance allocation and analysis, and the virtual variation simulation model was not in any way adjusted to harmonize with the clinical results.

The knowledge of robust design theories and the enabling of virtual variation simulations offer new possibilities for geometrical optimization to enhance rehabilitation and establish robust treatment methods that minimize geometrical variation. Future studies should focus on virtual variation simulation of CAD/CAM template-guided surgeries on actual patients, as well as jaw models, to gain more knowledge. It is important to emphasize that the results from each surgery only represent a single outcome of the deviation, whereas each simulation corresponds to 10,000 surgeries. The actual surgery could resulted in different deviation results if performed several times on the same subject and site. Size and form variations in the

geometry of individual parts originate from the manufacturing process used, which will vary over time.[98] The results from the virtual variation simulations indicate that the definitive variation depends on the relation between the final structure and the mounting of each surgical CAD/CAM template guide. This knowledge is helpful during the planning of the surgery and can be used to increase patient safety. The results from the virtual variation simulation may in the future give information about the tolerances obtained after surgery at the virtual planning stage. Therefore, the treating clinician may select which prosthetic solution that would be most optimal in advance of surgery.

The simulation technique presented in this study[104] could be used in product development to reduce deviation and enhance robustness in the system. This can be accomplished by evaluating the proposed treatment method before physical models and manufacturing procedures are established. Virtual variation simulations could be used in the future as methods for verifying surgeries before actual surgery to increase patient safety, prosthetic planning and improvements of the surgical system

5.3 STUDY III:

The virtually planned implant positions compared to the actually placed implant positions demonstrated a statistically significant difference in all four outcome variables: depth, apex, hex and angle, and therefore the hypothesis was rejected. In the study pre-and postlaunched components were used. A statistical significant difference was shown between the pre- and postlaunched components. The difference shown was that the deviation was 0.25 mm deeper for the implants inserted with the postlaunched components. The question is whether this has any clinical relevance or not. No statistically significant difference was observed between the maxilla and the mandible.[101] During the matching procedure it was found that some of the implants were not cylindrical in shape. Therefore a radiologist reviewed the preoperative CT scan and the postoperative CT scan of the patients. Of all 139 placed implants, 90 implants were placed in patients who did not move during the preoperative and postoperative scan. When comparing the results, statistical significance was found when combining the movement of the preoperative and the postoperative scan with the results of the deviation at the level of the hex and apex of the implants. The movement factor included in the statistical analysis showed significant difference between the maxilla and mandible (3.1 and 2.4 degrees respectively). However, this statistically

significant difference may not prove to be clinically relevant. When comparing the results of all implants between the mandible and the maxilla, no statistically significant difference was observed. This was unexpected as the radiographic guide and the surgical template covers a larger portion of the palate in the maxilla, whereas in the mandible it only covers the alveolar crest. Only when combining the movement factor, a statistically significant difference was observed between the mandible and maxilla for the variable angulation.[101] However, the movement error might have introduced a false center position for the axis, which could have resulted in incorrect measurement data affecting the overall results. When comparing Study III[101] to other studies[73] performed with different guided surgical systems it is apparent that a larger amount of implants have been included (Fig. 28). Schneider et al.[73] compared the results from five different human accuracy studies with different guided surgical systems in a review article. The results of Study III[101] are well in line with the limits of previous studies[73]. Study III[101], using mucosa based surgical templates (NobelGuide), presented the smallest deviation for the hex, compared to the other human accuracy studies presented in the Schneider et al.[73] review article (Fig. 29). The largest deviation occurred in the study by Vrielinck et al.[73] for the hex, with a bone supported surgical template (SurgiGuide, Materialise) (Fig.29).[101] When comparing the results of the apex, a teeth supported surgical template (Stent CAD) provided the smallest deviation, whereas the largest deviation was presented from a study by Vrielinck et al., using bone supported surgical templates (SurgiGuide, Materialise) (Fig.30).[73, 101] When comparing the angular deviation, Study III[101] presented the smallest deviation, the largest deviation occurred in the study by Vrielinck et al.[73] with bone supported surgical templates (SurgiGuide, Materialise) (Fig. 31). It is difficult to pinpoint a certain factor why the results differ, when comparing the studies presented by Schneider et al.[73] to the present one[101]. *"After comparison of the data on deviation the hypothesis that a template supported by bone, teeth or implants provides superior accuracy than a mucosa-supported template, cannot be confirmed."*.[73] The authors also stated that limited data was available for comparison as few studies were published presented on mucosa supported surgical templates. Only the study by Ozan et al.[71] was available for comparison while preparing the review article.[73]

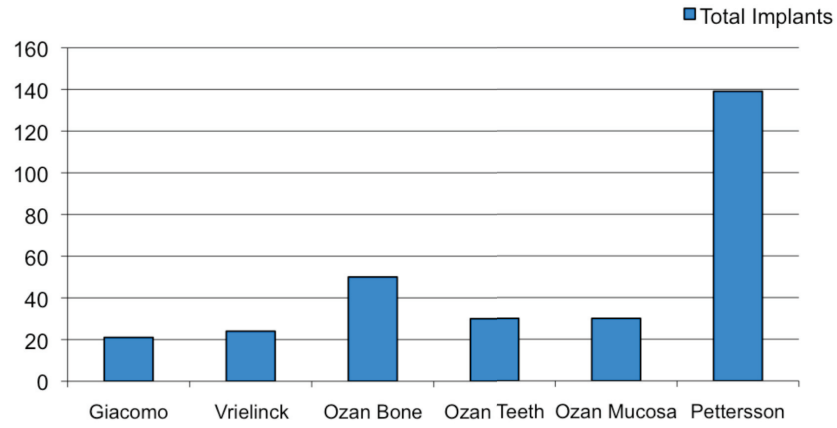

Fig. 28. Total number of implants included in each of the different accuracy studies performed on patients with surgical guides.

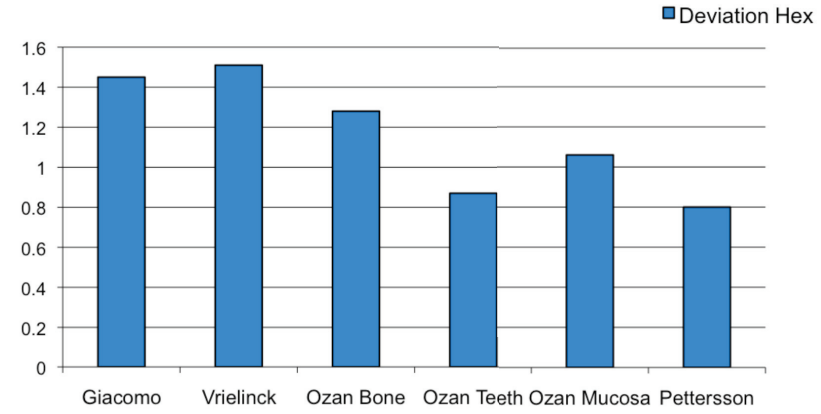

Fig. 29. Mean values of the results for the hex in six different guided surgery accuracy studies performed on patients. Measurements in mm.

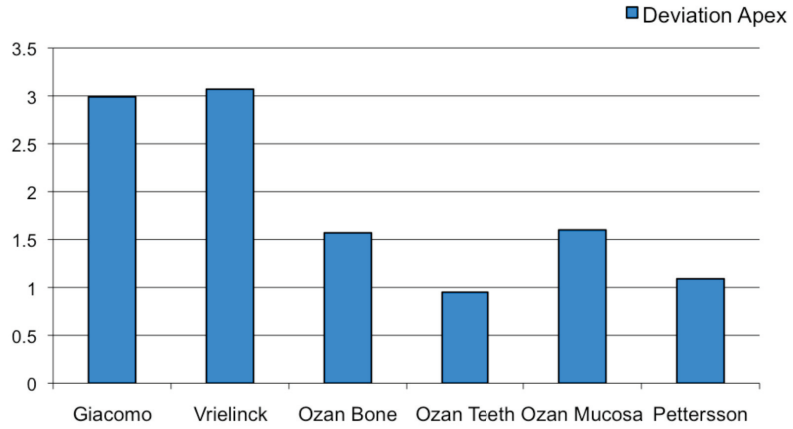

Fig. 30. Mean values of the results for the apex in six different guided surgery accuracy studies performed on patients. Measurements in mm.

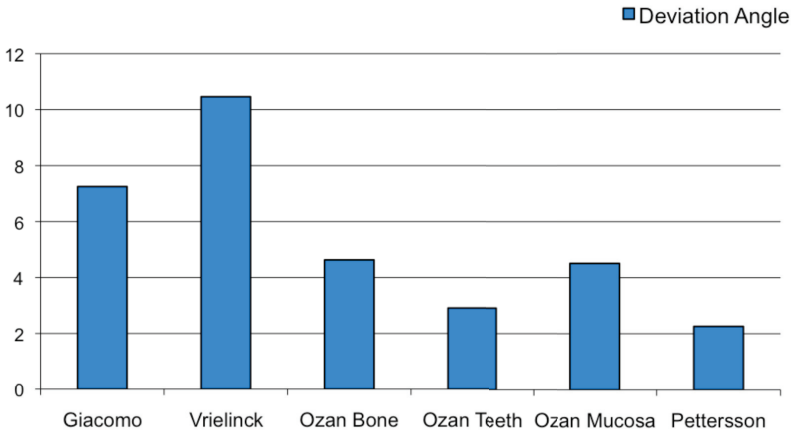

Fig. 31. Mean values of the results for the angle in six different guided surgery accuracy studies performed on patients. Measurements in degrees.

5.4 STUDY IV:

The previous studies included factors that affected the final accuracy result, such as no possibility to use index or movement by patients. In order to limit the possible influencing factors that could affect the final accuracy, it was decided to perform a study on plastic maxilla jaw models, with the objective to evaluate whether the deviation differed between surgeons. Some examples of factors that could influence the accuracy result in patient studies, might be: access to the site in the patients mouth, thickness of the soft tissue, movable soft tissue, different lengths of implants, few surgeons involved, different clinicians, creating the radiographic guide etc. In a model study, obstacles as mentioned above, could be removed as possible factors for affecting the final accuracy result. One possible limiting factor for the model study might be that the index system could not be used.

The difference between the actually placed implants compared to the virtually planned implants demonstrated a statistically significant difference for three out of four outcome variables, the apex, hex and depth ($P<.05$), no statistically significant difference was observed for the angle. There was a statistically significant difference between all surgeons for the apex, depth and angle ($P<.05$). Furthermore, no statistical significant difference was observed for the hex between the surgeons.[105]

As the surgery on the plastic models was performed on a working bench with full visible access to the placement of the implants, allowing the surgeons to trying to center the implants as good as possible could have contributed to that there was no significant difference for the variable of the hex. Another possible explanation for the result of the hex could be that the implant mount in connection with the sleeve, guides the hex part (equivalent to the prosthetic connection) of the implant more accurate, as the distance to the guide sleeve is shorter compared to the apex.
All steps before the actual surgery were controlled by one trained dental technician, one trained radiology assistant and one trained prosthodontist. One assistant/operator performed the virtual plans, ordered the surgical templates and assisted during surgery[105]. Instead of using a radiographic guide produced in acrylic, a decision was made to use an individual impression tray in order to reduce the steps involved in the CAD/CAM guided protocol, and thus also reduce some of the factors that might contribute to the final accuracy results of deviation. In the present study an impression

based radiographic guide was used.[105] The total amount of included implants evaluated was largest for Study IV (model) and the smallest amount of implants included was in Study III (patient) (Fig. 32).[100, 101, 105]

When comparing Study IV[105] (model) to Study I[100] (human cadaver) and Study III[101] (patient), the results in Study IV[105] presented smaller deviations for the apex, hex and angle (Fig. 33-Fig. 35). Study I[100] was performed on human cadavers, which presented the largest deviation. One explanation could be that the index system could not be used, according to the protocol, during the CT scan of the subjects, using rubber bands to keep the radiographic guide in position, which could have resulted in a non optimal position according to the "normal" registered position during the possibility of occlusion. In Study I[100], the surgical template as well had to be placed with visual guidance without the surgical index and the soft tissue was frozen and thawed up to four times which could have resulted in dehydration of the soft tissue and a possible change in size and shape. However, the index system could be used in Study III[101], which presented a smaller deviation for the apex, hex, depth and angle, compared to Study I[100]. In Study III[101], the patients underwent a CBCT scan with a scanning time of 72 seconds, which resulted in movement of the patients both at the first and the second scan. The study showed a statistically significant difference between the patients who did move during the preoperative and postoperative scans compared to the patients who did not move; with a smaller deviation for the non-moving group.

Another important factor was that in the patient study only one clinician performed the surgeries. This could have affected the final results compared to if another surgeon would have been involved. For all studies all involved clinicians contribute in different ways to the final accuracy as people are more or less experienced, are using different materials and methods to accomplish their daily work and therefore could affect the final accuracy result in different ways.

When comparing the depth results from the different studies, the patient study and the human cadaver study presents a smaller mean error but also a larger deviation for the range compared to this study.[100, 101, 105] The range for the depth was -0.03-1.61 mm for the human cadaver study, the range for the depth in the patient study was -2.33-2.05 mm and for the plastic model study -1.17-0.12 mm.[100, 101, 105] Therefore, the largest deviation for the depth range occurred in the patient study while the smallest range was shown in the plastic model study.[100, 101, 105] One factor that could provide a smaller mean error and a larger deviation for the range could be the flexibility of the mucosa.

The soft tissue should be more forgiving compared to hard plastic. Another contributing factor could be that soft tissue might introduce different types of errors depending of the thickness and if it is movable, which could have resulted in a larger deviation for the range. The difference between the human cadaver study and the patient study could be that the soft tissue of the cadavers might have had a different flexibility, size and shape compared to the live tissue on patients. Other factors that could have contributed to the difference might be the selection of cases.

An accuracy study performed on artificial edentulous mandibles made by epoxy has previously been published.[106] Five surgeons drilled five sites in one jaw, each with the aid of a stereolithographic guide (test side). The other side was performed with a standard surgical guide that was modified from the scannographic template (control side). The mean value for the test side, were 0.9 mm for the entrance (hex) and 1.0 mm for the apex.[106]

The mean value in Study IV[105] was 0.59 mm for the hex and 0.73 mm for the apex. This study used NobelGuide with impression based radiographic guides, performed on 25 duplicate plastic jaws of a maxilla, with a total number of 150 implants.[105] The above mentioned model study by Sarment et al.[106], reported on five epoxy mandible jaws and with a total of 25 drilled sites. Some factors that might have contributed to the different results could be the different systems used, type of test-jaw and impression based templates used in this study, compared to scannographic templates used in the previous study. The Sarment et al. study[106] compared the position of the surgically drilled site, compared to the virtually planned implant position. However, the present study[105] compared the actually placed implants position to the virtually planned implants position. However, an even larger deviation might have been presented in the study by Sarment et al.[106] if implants would have been placed and compared as in the present study[105]. In a review article by Jung et al.[84], the authors stated: *"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"*.
The authors also found that the deviation was larger for implants placed in human studies compared to cadaver studies and studies on models. *"This can be explained by better access, better visual control of the axis of the osteotomy, no movement of the patient, and no saliva or blood in the preclinical models"*.[84] The mean values does not correspond to that statement within this project as the human cadaver study presents the

largest mean values for the majority of the variables, while the model study presents the smallest deviations for the majority of variables.[100, 101, 105] Most likely the larger deviation of the mean deviation that occurred in the human cadaver study was due to the inability of using the index system, according to the protocol, during the CT scan and during surgery. *"One of the factors considered to be crucial for precision is the reproducibility and stability of the template position during the CT scan and the implant placement".*[73]

In Study III[101], it was found that movements of the patients occurred during the preoperative and postoperative CBCT scans, and thus leading to a statistic significant difference compared to the non-moving patients. When comparing with the results obtained within this project, the human cadaver study presented the largest mean error for the outcome variables, hex, apex and angle, between all three studies, except for the mean error for depth (Fig. 33-Fig. 36).[100, 101, 105] However, no statistical calculation has been performed within this project, to test whether there are any statistical significant differences or not. This should be performed in a future study.

One important question is how accurate CAD/CAM guided surgery is compared to conventional surgery with free hand placement of implants. Therefore, it is important to learn more about the deviations that could occur when placing implants conventionally compared to the results of implants placed with a CAD/CAM guided surgical template in a future study.

The variation simulation software could in the future be used as a tool for clinicians to perform virtual surgeries in advance of the actual surgery takes place. Today, a yellow security zone of 1.5 mm built into the software in order to visually inform the clinician during planning of their case in the computer. With the virtual variation simulation software, it could be possible to use it as a tool in the future to in advance of surgery get individual warning zones depending on how the clinician has performed the virtual plan of the case. Information and suggestions could also be implemented to help the clinician to get instructions on how to alter their virtual plan of their case in order to reduce the deviation of the implants. The information from the virtual variation software could also be used in advance of surgery to determine the final accuracy in order to select the most appropriate prosthetic solution for the patient case depending on the accuracy obtained. In Fig. 20 it can be seen that the posterior part of the surgical

template and implants placed posteriorly had a larger deviation compared to the anterior part. One possible instruction to clinicians in the future could be in such case, change the planned position of the anchor pins, or add more anchor pins, in order to reduce the deviation in the posterior part.
The variation simulation software could also be used to improve the hardware for the manufacturer of the system. One example could be to increase the length of the sleeve in the anterior part of the surgical template compared to the length of the sleeve used today. This could create better accuracy in the anterior part, which would be beneficial i.e. due to esthetic reasons. However, in order to proceed to evaluate the future wishing of using the variation simulation software as a tool for such things, it is important to continue to perform accuracy studies. A future study of the virtual variation simulation should be performed on patient data, data from the model study as well as a study on partially dentate patients to learn more and adjust the parameters in the software in order to correspond to the clinical reality. Then a tool could be possible to implement for a safer treatment of patients, optimized prosthetics, and to improve hardware as well as clearer instructions to clinicians. The studies within this project[100, 101, 104, 105] are just a minor part in order to accomplish improvements and learn more.

It is utmost important to learn more about CAD/CAM guided surgery accuracy in order for clinicians to learn more about the deviations that might occur during guided surgery in order to avoid damaging sensitive anatomical structures, achieve an optimal result for the final prosthetic reconstruction as well for producers of guided surgical systems to further improve the accuracy in the future.

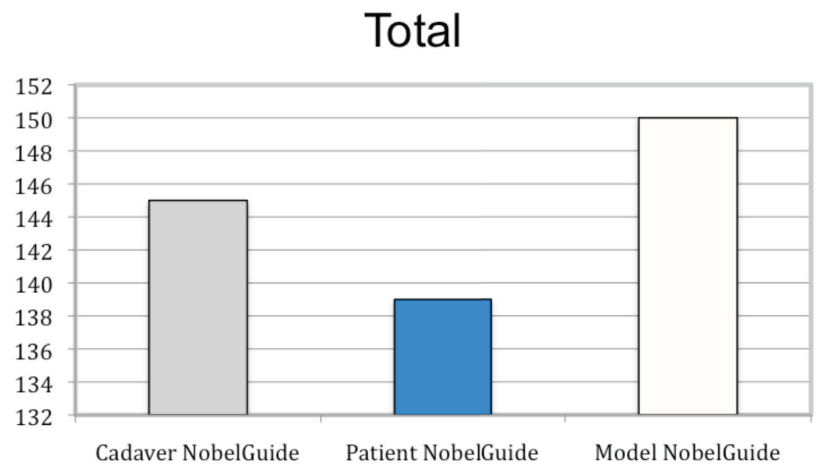

Fig. 32. Total number of implants included in each study within this project.

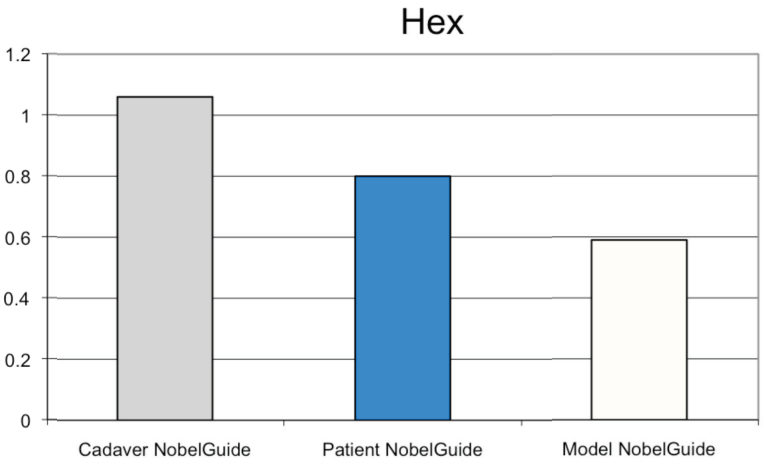

Fig. 33. Mean values of the results for the hex in the three different guided surgery accuracy studies within this project. Measurements in mm.

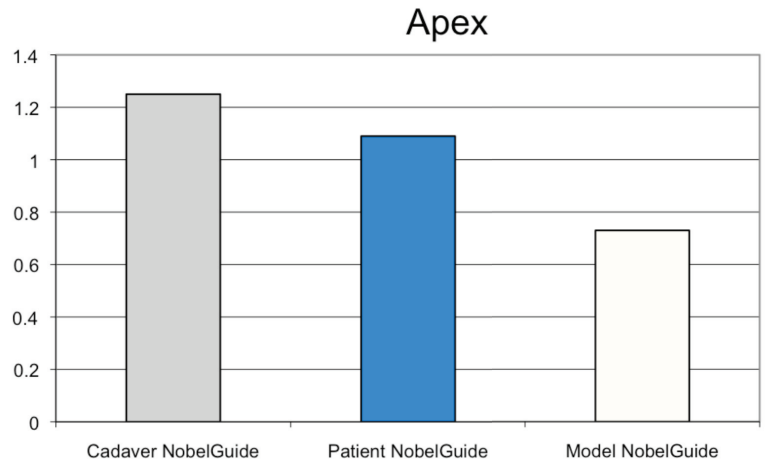

Fig. 34. Mean values of the results for the apex in the three different guided surgery accuracy studies within this project. Measurements in mm.

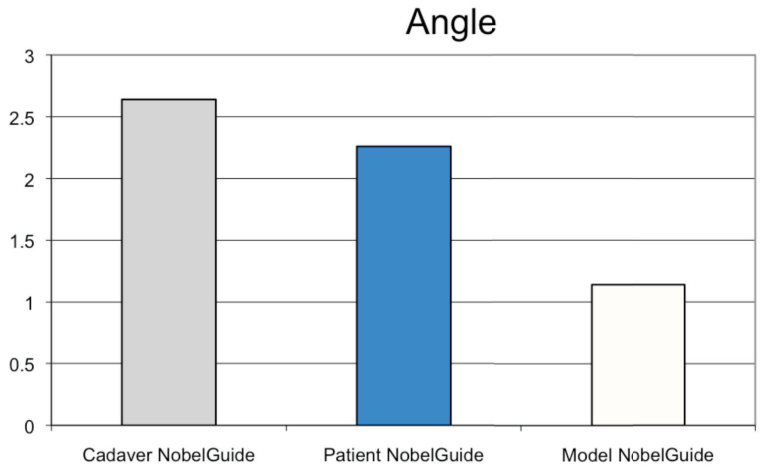

Fig. 35. Mean values of the results for the angle in the three different guided surgery accuracy studies within this project. Measurements in degrees.

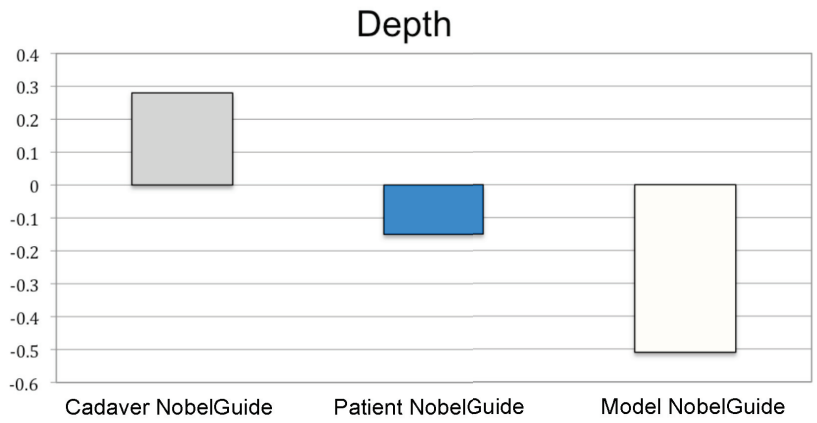

Fig. 36. Mean values of the results for the depth in the three different guided surgery accuracy studies within this project. Measurements in mm. Negative value indicates that the implant did not reach the planned position. Positive value indicates that implant was placed deeper than planned position.

6 MAIN FINDINGS

- The results demonstrated a statistically significant difference between mandibles and maxillae for the hex, apex and depth measurements in the variation between the virtually planned implant positions and the positions of the implants placed after surgery with a CAD/CAM-guided surgical template.
  A statistically significant difference was observed between the virtually planned implants and the actual positions of the implants for all 5 outcome variables: apex, hex, depth, translation deviation and angle.

- The implant distributions were neither static nor normally distributed. Thus, within the limitations of this study, the definitive geometrical variations of the implants were not static, as they depend on the individual anatomy of the jaws and the ability to place the CAD/CAM-guided surgical template in the proper position.
  The Mann-Whitney U test showed that the definitive implant distributions in this study could not be assumed to be normally distributed.

- The results demonstrated statistically significant differences between the virtually planned implants position and the final position of implants placed clinically.
  A statistical significant difference was observed when combining the movement of preoperative and postoperative scan for the outcome variables hex and apex.
  No statistically significant difference was observed between the maxilla and the mandible.
  If the movement factor was included, a statistical significant difference between the maxilla and mandible was found for the outcome variable, angle.

- There was a statistically significant difference between all five surgeons for the outcome variables, apex, depth and angle.
  A statistically significant difference between the actually placed implants position compared to the virtually planned implants position was observed for three out of four outcome variables, the apex, hex and depth.

7 CONCLUDING REMARKS

The treatment of patients with implants has demonstrated successful long-term results. Some of the focus has been to reduce the treatment time as well as loading times of the implants. Recently several guided surgical systems have been available on the market as an option for patient treatment. As there are several sensitive anatomical structures that could harm the patients if damaged during surgery, it is important to secure a safe treatment protocol for the patients, and to learn more about the accuracy of guided surgery. Other important factors are whether the prosthetic solution will fit the planned position and whether the accuracy will allow for delivery of the bridge. As flapless surgery now is available in guided surgery, it is important to proceed with studies investigating whether the guided surgery provides less discomfort and trauma compared to conventional surgery. If guided flapless surgery will show less postoperative trauma, a solution might be available for more sensitive patients. Less trauma could also mean a reduced healing time and thus patients might go back to work faster in comparison to traditional flap surgery.

There are many steps involved in CAD/CAM guided surgery. Some of them must be taken care of before the treatment of the patient, and this could affect the final accuracy result.

In order to continue the investigations of the accuracy in CAD/CAM guided surgery, more studies should be performed in the future, such as comparing the deviation for the implant length, anterior vs. posterior placement of implants. The collected data should then be used to perform variation simulation surgeries, in order to enhance the parameters of the software to correspond to real life deviations. When the variation simulation software has been improved for clinical purposes, it could be used as a tool for surgeons. Hardware could be improved in order to deliver a more predictable accuracy result, depending on the prosthetic solution to be used. The security zone around the implants could be enhanced to fit the individual anatomy of the patients.

In advance of surgery, the specific virtual planning, performed by the surgeon can be validated in software with the virtual variation simulation tool. This could further secure the treatments of patients, and thus provide an optimal prosthetic outcome.

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